IEC 60601-1-8

Edition 2.2 2020-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006-10+AMD1:2012-11+AMD2:2020-07 CSV(en)

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IEC 60601-1-8:2006-10+AMD1:2012-11+AMD2:2020-07 CSV(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

FOREWORD

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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-1-8 edition 2.2 contains the second edition (2006-10) [documents 62A/519/CDV and 62A/537A/RVC], its amendment 1 (2012-11) [documents 62A/824/FDIS and 62A/837/RVD] and its amendment 2 (2020-07) [documents 62A/1392/FDIS and 62A/1407/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendments 1 and 2. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 60601-1-8 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC 3: Lung ventilators and related devices of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as double logo standard.

IEC 60601-1-8 constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

This edition of IEC 60601-1-8 was revised to structurally align it with the 2005 edition of IEC 60601-1 and to implement the decision of IEC Subcommittee 62 A that the clause numbering structure of collateral standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in IEC 60601-1:2005.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type. In addition, in Annex A text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes Subclauses 6.1, 6.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.3.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 60601 series, under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

INTRODUCTION

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are increasingly used in medical practice. ALARM SIGNALS are frequently used to indicate unsatisfactory physiological PATIENT states, unsatisfactory functional states of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM or to warn the OPERATOR of HAZARDS to the PATIENT or OPERATOR due to the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM. INFORMATION SIGNALS convey information that is independent of an ALARM CONDITION.

Surveys of healthcare personnel have indicated significant discontent with ALARM SIGNALS. Problems include difficulty in identifying the ~~source~~ origin of an ALARM SIGNAL, loud and distracting ALARM SIGNALS, and the high incidence of FALSE POSITIVE or NEGATIVE ALARM CONDITIONS [16] [1]. Surveys of MANUFACTURERS of medical monitors demonstrated a wide variety of DEFAULT ALARM PRESETS. The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS. See also bibliography.

Safety of PATIENTS depends on the ability of the OPERATOR to correctly discern the characteristics of ALARM SIGNALS. USABILITY is an important element in the design of ALARM SIGNALS that are readily discernible without being unnecessarily distracting or disturbing. This approach is intended to rationalize the current situation, to reduce confusion by limiting proliferation of ALARM SIGNALS and their control states, and to minimize distraction for other people. This collateral standard was developed with contributions from clinicians, engineers and applied psychologists.

The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for particular standards.

The effectiveness of any ALARM SYSTEM depends critically on its implementation by the RESPONSIBLE ORGANIZATION. It is important that the RESPONSIBLE ORGANIZATION configure the ALARM SYSTEM so that an OPERATOR is not able to compromise it.

INTRODUCTION to Amendment 1

The second edition of IEC 60601-1-8 was published in 2006. Since its publication, an issue has been identified with respect to pulse and burst testing. In addition, issues have been raised by IEC/62D/MT 22, *Electromedical diagnostic and patient monitoring equipment*, during implementation of alarm system requirements in particular standards within their scope of work.

At the Brussels meeting, IEC/SC 62A accepted a proposal, based on ISO/TC 121/SC 3 Resolution Orebro 6, to develop the 1st amendment to IEC 60601-1-8:2006 to address the issues identified above. IEC/SC 62A – ISO/TC 121/SC 3 Joint Working Group 2, *Alarms*, was reactivated as a maintenance team to develop this amendment.

1) Figures in brackets refer to the bibliography.

INTRODUCTION to Amendment 2

The second edition of IEC 60601-1-8 was published in 2006 and amended in 2012. Since the publication of IEC 60601-1-8:2006+A1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the third edition of IEC 60601-1-8, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 20 items were presented to the National Committees present. All 20 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the third edition of IEC 60601-1-8.

The "short list" of issues was documented in the design specification for Amendment 2. As IEC 60601-1-8 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 2. JWG 2 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-8:2006, the style in force at the time of publication of IEC 60601-1-8 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

1 * Scope, object and related standards

1.1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard specifies requirements for ALARM SYSTEMS and ALARM SIGNALS in ME EQUIPMENT and ME SYSTEMS.

It also provides guidance for the application of ALARM SYSTEMS.

1.2 Object

The object of this collateral standard is to specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements and tests for ALARM SYSTEMS in ME EQUIPMENT and ME SYSTEMS and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent ALARM SIGNALS and consistent control states and their marking for all ALARM SYSTEMS.

This collateral standard does not specify:

– whether any particular ME EQUIPMENT or ME SYSTEM is required to be provided with ALARM SYSTEMS;

– the particular circumstances which initiate an ALARM CONDITION;

– the allocation of priorities to a particular ALARM CONDITION; or

– the means of generating ALARM SIGNALS.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone ~~(latest edition~~ including any amendments~~)~~;

– "this collateral standard" designates IEC 60601-1-8 alone, including any amendments;

– "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following ~~referenced~~ documents, in whole or in part, are normatively referenced in this document and are indispensable for ~~the~~ its application ~~of this document~~. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60417, *Graphical symbols for use on equipment*. Available from: <http://www.graphical-symbols.info/equipment>

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

~~IEC 60601-1-2:---[2], *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests*~~

~~IEC 60601-1-6:---[3], *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*~~

~~IEC 60651:1979[4], *Sound level meters*~~
~~Amendment 1 (1993)~~
~~Amendment 2 (2000)~~

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

~~IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*~~

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
Amendment 1:2020

ISO 3744:~~1994~~2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering method ~~in~~ for an essentially free field over a reflecting plane*

ISO 7000~~:1989~~, *Graphical symbols for use on equipment ~~– Index and synopsis~~*. Available from: <http://www.graphical-symbols.info/equipment>

~~2) A second edition of IEC 60601-1-2 exists, published in 2004 under the title *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests*. A third edition under the title given above is currently to be published. References to IEC 60601-1-2 in this standard refer to the new edition.~~

~~3) A first edition of IEC 60601-1-6 exists, published in 2004 under the title *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral Standard: Usability*. A second edition under the title given above is currently to be published. References to IEC 60601-1-6 in this standard refer to the new edition.~~

~~4) IEC 60651:1979 has been withdrawn and replaced by IEC 61672-1:2002 and IEC 61672-2:2003. Future editions of this publication will be amended to take this fact into account.~~

3 Terms and definitions

~~For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012 and IEC 62366:2007, IEC 60601-1-2:---[5], IEC 60601-1-6:---[6], and the following definitions apply.~~

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012+A2:2020, IEC 62366-1:2015+A1:2020, and the following definitions apply.

NOTE 1 The term "electrical equipment" is used to mean ME EQUIPMENT or other electrical equipment. This standard also uses the term "equipment" to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

NOTE 2 An index of defined terms is found beginning on page 131.

3.1
*** ALARM CONDITION**
state of the ALARM SYSTEM when it has determined that a potential or actual ~~HAZARD~~ HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.

3.2
*** ALARM CONDITION DELAY**
time from the occurrence of a triggering event either in the PATIENT, for PHYSIOLOGICAL ALARM CONDITIONS, or in the equipment, for TECHNICAL ALARM CONDITIONS, to when the ALARM SYSTEM determines that an ALARM CONDITION exists

3.3
*** ALARM LIMIT**
threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

3.4
ALARM OFF
state of indefinite duration in which an ALARM SYSTEM or part of an ALARM SYSTEM does not generate ALARM SIGNALS

3.5
*** ALARM PAUSED**
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate ALARM SIGNALS

3.6
ALARM PRESET
set of stored configuration parameters, including selection of algorithms and initial values for use by algorithms, which affect or modify the performance of the ALARM SYSTEM

3.7
ALARM RESET
OPERATOR action that causes the cessation of an ALARM SIGNAL for which no associated ALARM CONDITION currently exists

3.8
ALARM SETTINGS
ALARM SYSTEM configuration, including but not limited to:

~~5) To be published. See footnote 2.~~

~~6) To be published. See footnote 3.~~

– ALARM LIMITS;

– the characteristics of any ALARM SIGNAL inactivation states; and

– the values of variables or parameters that determine the function of the ALARM SYSTEM

NOTE Some algorithmically-determined ALARM SETTINGS can require time to be determined or re-determined.

3.9
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

3.10
*** ALARM SIGNAL GENERATION DELAY**
time from the onset of an ALARM CONDITION to the generation of its ALARM SIGNAL(S)

3.11
ALARM SYSTEM
parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

3.12
AUDIO OFF
state of indefinite duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

3.13
AUDIO PAUSED
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

3.14
BURST
group of PULSES with a distinctive rhythm or pattern

3.15
DE-ESCALATION
PROCESS by which an ALARM SYSTEM decreases the priority of an ALARM CONDITION or decreases the sense of urgency of an ALARM SIGNAL

3.16
DEFAULT ALARM PRESET
ALARM PRESET that can be activated by the ALARM SYSTEM without OPERATOR action

NOTE MANUFACTURER- or RESPONSIBLE ORGANIZATION-configured ALARM PRESETS are possible types of DEFAULT ALARM PRESETS.

3.17
*** DISTRIBUTED ALARM SYSTEM**
DAS
ALARM SYSTEM that involves more than one item of equipment of a ME SYSTEM intended for delivery of ALARM CONDITIONS with technical confirmation

NOTE 1 The parts of a DISTRIBUTED ALARM SYSTEM can be widely separated in distance.

NOTE 2 A DISTRIBUTED ALARM SYSTEM is intended to notify OPERATORS of the existence of an ALARM CONDITION.

NOTE 3 For the purposes of this document, technical confirmation means that each element of a DISTRIBUTED ALARM SYSTEM confirms or guarantees the successful delivery of the ALARM CONDITION to the next element or appropriate TECHNICAL ALARM CONDITIONS are created as described in 6.11.2.2.1.

3.18
ESCALATION
PROCESS by which an ALARM SYSTEM increases the priority of an ALARM CONDITION or increases the sense of urgency of an ALARM SIGNAL

3.19
FALL TIME
t_f
interval over which the PULSE amplitude decreases from 90 % to 10 % of its maximum (see Figure 1)

3.20
FALSE NEGATIVE ALARM CONDITION
absence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE An ALARM CONDITION can be rejected or missed because of spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the ~~equipment~~ ALARM SYSTEM itself.

3.21
FALSE POSITIVE ALARM CONDITION
presence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE A FALSE POSITIVE ALARM CONDITION can be caused by spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the ALARM SYSTEM itself.

3.22
HIGH PRIORITY
indicating that immediate OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Immediate implies the interruption of current workflow is expected [59], [60].

3.23
*** INFORMATION SIGNAL**
any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO_2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

NOTE An ADVISORY is a type of INFORMATION SIGNAL.

3.24
*** INTELLIGENT ALARM SYSTEM**
ALARM SYSTEM that makes logical decisions based on monitored information without OPERATOR intervention

EXAMPLE 1 An ALARM SYSTEM that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 An ALARM SYSTEM that suppresses an ALARM CONDITION when a related ALARM CONDITION of higher priority has recently generated an ALARM SIGNAL.

3.25
INTERBURST INTERVAL
t_b
period of time between the end of the last PULSE of a BURST and the start of the first PULSE of the next BURST of the same ALARM SIGNAL (see Figure 1 and Figure G.1)

NOTE For the purposes of this document, when an AUDITORY ICON is used, the INTERBURST INTERVAL begins at the end of the AUDITORY ICON.

3.26
LATCHING ALARM SIGNAL
ALARM SIGNAL that continues to be generated after its triggering event no longer exists until stopped by deliberate OPERATOR action

3.27
LOW PRIORITY
indicating that OPERATOR awareness is required and future action might be needed

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Awareness implies the planning of future workflow is expected [59], [60].

3.28
MEDIUM PRIORITY
indicating that prompt OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Prompt implies the re-planning of current workflow is expected [59], [60].

3.29
NON-LATCHING ALARM SIGNAL
ALARM SIGNAL that automatically stops being generated when its associated triggering event no longer exists

3.30
OPERATOR'S POSITION
intended position of the OPERATOR with respect to the ALARM SIGNAL generating part of the ALARM SYSTEM

NOTE A DISTRIBUTED ALARM SYSTEM can have multiple OPERATOR'S POSITIONS.

3.31
PHYSIOLOGICAL ALARM CONDITION
ALARM CONDITION arising from a monitored PATIENT-related variable

EXAMPLE 1 High exhaled anesthetic agent concentration.

EXAMPLE 2 Low exhaled tidal volume.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

3.32
PULSE
brief continuous sound having a specific spectral content

3.33
PULSE FREQUENCY
f_o
fundamental frequency (first harmonic) of a PULSE

3.34
*** REMINDER SIGNAL**
periodic signal that reminds the OPERATOR that the ALARM SYSTEM is in an ALARM SIGNAL-inactivation state

3.35
RISE TIME
t_r
interval over which the PULSE increases from 10% to 90% of its maximum amplitude (see Figure 1)

3.36
TECHNICAL ALARM CONDITION
ALARM CONDITION arising from a monitored equipment-related or ALARM SYSTEM-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

3.37
*** ACKNOWLEDGED**
state of an ALARM SYSTEM initiated by OPERATOR action, where the auditory ALARM SIGNAL associated with a currently active ALARM CONDITION is inactivated until the ALARM CONDITION no longer exists or until a predetermined time interval has elapsed

NOTE ACKNOWLEDGED only affects ALARM SIGNALS that are active at the time of the OPERATOR action.

3.38
*** ADVISORY**
ADVISORY SIGNAL
INFORMATION SIGNAL notifying the OPERATOR of a condition of the PATIENT or ME EQUIPMENT providing contextual awareness that is intended to improve the clinical workflow or understanding of the PATIENT condition, the awareness not being intended as a means of RISK CONTROL

NOTE 1 A notification that a lab result is available, where the lab result requires immediate clinical action is not an ADVISORY. It is an ALARM CONDITION.

NOTE 2 A signal associated with an ADVISORY, which is an INFORMATION SIGNAL, is required by this document to be designed so that an OPERATOR does not confuse it with an ALARM SIGNAL. See 6.3.2.2.2 and 6.3.3.2.

EXAMPLE 1 A notification that it is time to draw the next blood sample.

EXAMPLE 2 A battery status notification that replacement will be needed in a day.

EXAMPLE 3 A notification that it is time to bathe the PATIENT.

EXAMPLE 4 A notification that a lab result is available, where the lab results are normal.

3.39
*** ALARM FATIGUE**
situation wherein the presence of frequent ALARM SIGNALS desensitizes an OPERATOR to an ALARM SIGNAL

NOTE 1 A desensitized OPERATOR can fail to perceive, recognize or act on an ALARM SIGNAL.

NOTE 2 The response of a desensitized OPERATOR can be inadequate, delayed or non-existent.

NOTE 3 ALARM FLOOD can cause ALARM FATIGUE.

3.40
ALARM FLOOD
situation wherein OPERATORS receive more ALARM SIGNALS in a time period than they can manage appropriately

NOTE See [56], [57].

3.41
*** ALERT**
synonym for the combination of PHYSIOLOGICAL ALARM CONDITIONS, TECHNICAL ALARM CONDITIONS and ADVISORIES

[SOURCE: ISO/IEEE 11073-10201:2020 [76], 3.3, modified – Replaced "alarms" with "ALARM CONDITIONS", "equipment-user advisory signals" with "ADVISORIES" and deleted "patient related".]

3.42
AUDITORY ICON
sound that creates a strong semantic link to the category it represents

NOTE 1 An AUDITORY ICON is typically a real-world sound or mimics a real-world sound.

NOTE 2 An AUDITORY ICON can aid in locating the COMMUNICATOR and the SOURCE type.

3.43
AUDITORY POINTER
sound that attracts attention, denotes the priority and aids in localization of the COMMUNICATOR

3.44
*** CLINICALLY ACTIONABLE**
type of ALARM CONDITION for which a panel of experts would agree that OPERATOR action is necessary to prevent HARM within the timeframe implied by the priority communicated by the ALARM SYSTEM

NOTE 1 An OPERATOR action can include assessment of a PATIENT or the changing of ALARM LIMITS when they are inappropriately set for the state of the PATIENT.

NOTE 2 A LOW PRIORITY ALARM CONDITION, which requires action within the timeframe of a MEDIUM PRIORITY or HIGH PRIORITY timeframe, is considered CLINICALLY ACTIONABLE. A HIGH PRIORITY ALARM CONDITION, which requires action within the timeframe of a LOW PRIORITY or MEDIUM PRIORITY timeframe, is considered CLINICALLY NONACTIONABLE. In both cases, the ALARM CONDITION priority was improperly assigned.

NOTE 3 A FALSE POSITIVE ALARM CONDITION is never considered CLINICALLY ACTIONABLE even though an unrelated OPERATOR action might be required to prevent a future FALSE POSITIVE ALARM CONDITION.

NOTE 4 A CLINICALLY ACTIONABLE ALARM CONDITION is generally considered useful by the OPERATOR.

3.45
*** CLINICALLY NONACTIONABLE**
type of ALARM CONDITION for which a panel of experts would agree that OPERATOR action is not expected within a timeframe equal to or shorter than the timeframe implied by its priority

NOTE 1 A LOW PRIORITY ALARM CONDITION, which requires action within the timeframe of a MEDIUM PRIORITY or HIGH PRIORITY timeframe, is considered CLINICALLY ACTIONABLE. A HIGH PRIORITY ALARM CONDITION, which requires action within the timeframe of a LOW PRIORITY or MEDIUM PRIORITY timeframe, is considered CLINICALLY NONACTIONABLE. In both cases, the ALARM CONDITION priority was improperly assigned.

NOTE 2 CLINICALLY NONACTIONABLE ALARM CONDITIONS are considered detrimental to OPERATOR performance and PATIENT safety.

NOTE 3 ALARM SIGNALS for an ALARM CONDITION of which the OPERATOR is already aware are considered CLINICALLY NONACTIONABLE.

3.46
COMMUNICATOR
COM
ANNUNCIATOR
function of the ALARM SYSTEM that generates ALARM SIGNALS to notify an OPERATOR (e.g. to the presence of an ALARM CONDITION)

NOTE 1 A COMMUNICATOR can receive an OPERATOR response.

NOTE 2 An OPERATOR response is not limited to direct OPERATOR action.

NOTE 3 See Figure 2.

3.47
DISTRIBUTED ALARM SYSTEM WITH OPERATOR CONFIRMATION
CDAS
DISTRIBUTED ALARM SYSTEM that includes the capability to receive an OPERATOR response

3.48
*** DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS**
DIS
system that involves more than one item of equipment in a ME SYSTEM intended to provide information about ALARM CONDITIONS but does not guarantee delivery of that information

NOTE 1 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended to notify OPERATORS of the existence of an ALARM CONDITION as a RISK CONTROL measure. A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is intended to provide information about an ALARM CONDITION while the OPERATOR is aware of the existence of the ALARM CONDITION by an ALARM SYSTEM.

NOTE 2 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended for confirmed delivery of ALARM CONDITIONS.

3.49
INTEGRATOR
INT
ALARM MANAGER
function of the ALARM SYSTEM that distributes ALARM CONDITIONS, combines ALARM CONDITIONS from SOURCES or handles the communication between those SOURCES and COMMUNICATORS

NOTE 1 An INTEGRATOR can direct or redirect an ALARM CONDITION to another COMMUNICATOR and hence OPERATOR.

NOTE 2 An INTEGRATOR can send the acceptance of responsibility from a COMMUNICATOR to a SOURCE.

NOTE 3 See Figure 2.

3.50
*** NUISANCE ALARM SIGNAL**
ALARM SIGNAL for which a panel of experts would agree that the HARM associated with the ALARM SIGNAL is greater than the benefit associated with action resulting from the ALARM SIGNAL

NOTE 1 A NUISANCE ALARM SIGNAL contributes to ALARM FATIGUE.

NOTE 2 A NUISANCE ALARM SIGNAL can arise from a FALSE POSITIVE ALARM CONDITION.

NOTE 3 A NUISANCE ALARM SIGNAL can arise from a CLINICALLY NONACTIONABLE ALARM CONDITION.

NOTE 4 A NUISANCE ALARM SIGNAL can cause an inappropriate OPERATOR action.

EXAMPLE Causing the OPERATOR to set ALARM LIMITS to inappropriate settings.

NOTE 5 An ALARM SIGNAL that unnecessarily irritates or startles the PATIENT or OPERATOR can be a NUISANCE ALARM SIGNAL.

3.51
REDIRECTION
means by which an INTEGRATOR provides a response hierarchy for directing an ALARM CONDITION to a COMMUNICATOR or transfers an ALARM CONDITION to another COMMUNICATOR

NOTE See Figure 2.

3.52
RESPONSIBILITY ACCEPTED
state created by an OPERATOR response accepting ownership for addressing an ALARM CONDITION

NOTE 1 A RESPONSIBILITY ACCEPTED can be used to initiate an ALARM SIGNAL inactivation state.

NOTE 2 See Figure 2.

3.53
RESPONSIBILITY REJECTED
state created by an OPERATOR response rejecting ownership for addressing an ALARM CONDITION

NOTE 1 A RESPONSIBILITY REJECTED can be used to initiate an ESCALATION or REDIRECTION.

NOTE 2 See Figure 2.

3.54
RESPONSIBILITY UNDEFINED
state, automatically initiated when neither a RESPONSIBILITY ACCEPTED nor RESPONSIBILITY REJECTED is received within a specified period, which indicates that an OPERATOR is not responding

NOTE 1 RESPONSIBILITY UNDEFINED is not used as an indication that the COMMUNICATOR and INTEGRATOR cannot communicate.

NOTE 2 See Figure 2.

3.55
SOURCE
SRC
function that has the capability to initiate an ALARM CONDITION

NOTE 1 The SOURCE transfers the ALARM CONDITION to the INTEGRATOR.

NOTE 2 See Figure 2.

3.56
TRUE NEGATIVE ALARM CONDITION
absence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

3.57
TRUE POSITIVE ALARM CONDITION
presence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

4 General requirements

If the MANUFACTURER chooses as a means of RISK CONTROL to have the ME EQUIPMENT or ME SYSTEM notify the OPERATOR that a HAZARDOUS SITUATION can exist, then the ME EQUIPMENT or ME SYSTEM shall include an ALARM SYSTEM complying with this collateral standard for that purpose. See also 12.3 of the general standard.

The RISK ASSESSMENT shall also consider HAZARDS to PATIENTS, OPERATORS, and other persons arising from the ALARM SYSTEM (see 6.8.3).

5 ME EQUIPMENT identification marking and documents

NOTE Additional requirements for the marking on controls and instruments are specified in this collateral standard, together with the technical requirements, giving rise to requirements on markings. These requirements are also listed in Annex B.

5.1 Indicator lights and controls

In addition to the requirements for colours of indicator lights and their meanings in 7.8.1 of the general standard, the requirements of 6.3.2.2 apply.

NOTE Dot matrix or other alphanumeric displays are not considered to be an alarm indicator light unless those displays are used to simulate an alarm indicator lights (see 6.3.2.2).

5.2 ACCOMPANYING DOCUMENTS

NOTE Additional requirements on ACCOMPANYING DOCUMENTS are specified in this collateral standard, together with the technical requirements, giving rise to requirements on ACCOMPANYING DOCUMENTS. These requirements are also listed in Table B.2.

5.2.1 Instructions for use

The instructions for use shall:

- * provide an overview of the ALARM SYSTEM, including a listing and description of every possible ALARM CONDITION and, as appropriate for the intended OPERATOR, a summary of how it is determined;
- indicate any delay inherent in the determination of an ALARM CONDITION;
- disclose the OPERATOR'S POSITION; and
- * include how and when to verify the functionality of the ALARM SYSTEM.

As applicable, the instructions for use shall caution against setting ALARM LIMITS to extreme values that can render the ALARM SYSTEM useless.

NOTE Additional requirements on instructions for use are specified in this collateral standard, together with the technical requirements, giving rise to requirements on instructions for use. These requirements are also listed in Table B.3.

Compliance is checked by inspection of the instructions for use.

5.2.2 Technical description

NOTE Additional requirements on technical description are specified in this collateral standard, together with the technical requirements, giving rise to requirements on technical description. These requirements are also listed in Table B.4.

6 ALARM SYSTEMS

6.1 ALARM CONDITION

6.1.1 * General

If ALARM CONDITIONS are grouped into PHYSIOLOGICAL ALARM CONDITIONS, TECHNICAL ALARM CONDITIONS or other ALARM CONDITION groups by the MANUFACTURER, this shall be disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use.

6.1.2 * ~~ALARM CONDITION priority~~ Determination of ALARM CONDITIONS and assignment of priority

~~ALARM CONDITIONS shall be assigned to one or more of the following priorities: HIGH PRIORITY, MEDIUM PRIORITY, or LOW PRIORITY. Unless a particular ALARM CONDITION priority is specified in a relevant particular standard, the assignment of priorities is part of the RISK MANAGEMENT PROCESS and shall be based on Table 1. The priority of each ALARM CONDITION shall be disclosed in the instructions for use. Priorities may be identified in groups.~~

For each HAZARDOUS SITUATION where the MANUFACTURER has chosen to use an ALARM SYSTEM as a means of RISK CONTROL, the MANUFACTURER shall assign an ALARM CONDITION and its priority using Table 1.

For HAZARDOUS SITUATIONS where the onset of potential HARM is delayed and the potential result of a failure to respond is discomfort or minor reversible injury, the MANUFACTURER may determine that no ALARM CONDITION is required. In such cases, the MANUFACTURER may implement an INFORMATION SIGNAL.

NOTE Not all LOW PRIORITY ALARM CONDITIONS require prompt notification of the OPERATOR. On this basis an auditory ALARM SIGNAL or repeating auditory ALARM SIGNAL can be omitted, when appropriate, since the OPERATOR is expected to check the ME EQUIPMENT at intervals. In the event that the OPERATOR does not check the ME EQUIPMENT in a timely fashion, the ALARM CONDITION should escalate from LOW PRIORITY to MEDIUM PRIORITY or HIGH PRIORITY, and can additionally increase the sound pressure level of the related auditory ALARM SIGNALS, as appropriate.

The priority of each ALARM CONDITION shall be disclosed in the instructions for use. Priorities may be identified in groups.

Compliance is checked by inspection of the instructions for use and RISK MANAGEMENT FILE.

Table 1 – Determination of ALARM CONDITION and assignment of priorities

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY [e]	HIGH PRIORITY	MEDIUM PRIORITY
Reversible injury	HIGH PRIORITY	MEDIUM PRIORITY	LOW PRIORITY
Minor injury or discomfort	MEDIUM PRIORITY	LOW PRIORITY	LOW PRIORITY or no ALARM SIGNAL
An INFORMATION SIGNAL may also be used to indicate the potential for delayed minor injury or discomfort.			

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under “prompt”.

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY ALARM CONDITION [e]	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION
Reversible injury	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION
Discomfort or reversible minor injury	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION, no ALARM CONDITION or INFORMATION SIGNAL

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under “prompt”.

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

6.2 * Disclosures for INTELLIGENT ALARM SYSTEM

If an INTELLIGENT ALARM SYSTEM is provided, the instructions for use shall include, as applicable, an overview of how the ALARM SYSTEM:

a) determines an ALARM CONDITION on the basis of time, weightings, multiple variables, or other advanced processing (including, but not limited to, algorithms, neural networks, fuzzy logic, etc.);

b) generates ALARM SIGNALS for two or more ALARM CONDITIONS of equal priority (including, but not limited to, internal ranking, effect on generation of ALARM SIGNALS);

c) changes the previously-assigned priority or relative prioritization of a particular ALARM CONDITION (e.g., ESCALATION or DE-ESCALATION);

d) changes the ALARM SIGNAL GENERATION DELAY or ALARM CONDITION DELAY; and

e) changes the characteristics of the generated ALARM SIGNALS (for example, volume, pitch, tempo, urgency, AUDITORY ICON category).

Compliance is checked by inspection of the instructions for use.

6.3 Generation of ALARM SIGNALS

6.3.1 General

Each ALARM CONDITION shall cause the generation of visual ALARM SIGNALS by a COMMUNICATOR as specified in this collateral standard. If deemed necessary by RISK ASSESSMENT regarding the environment in which the ALARM SYSTEM is intended to be used, additional ALARM SIGNALS shall be generated. These additional ALARM SIGNALS may be auditory, verbal, vibratory or produced by other means.

EXAMPLE ALARM SYSTEMS with HIGH or MEDIUM PRIORITY ALARM CONDITIONS that are intended not to be continuously attended by an OPERATOR in NORMAL USE should generate additional auditory ALARM SIGNALS.

Compliance is checked by inspection of the ALARM SYSTEM.

6.3.2 * Visual alarm signals

6.3.2.1 General

ALARM SYSTEMS shall generate visual ALARM SIGNALS to indicate the presence of ALARM CONDITIONS, their priority and each specific ALARM CONDITION.

6.3.2.2 * Characteristics of visual ALARM SIGNALS

6.3.2.2.1 * 4 m (distant) visual ALARM SIGNALS

If a visual indicator is necessary for the OPERATOR to identify the equipment or part of the equipment that requires OPERATOR response or awareness, at least one visual ALARM SIGNAL shall be provided that:

a) indicates the priority of the highest priority ALARM CONDITION; and

b) can be perceived correctly at a distance of 4 m from the ALARM SYSTEM.

If an alarm indicator light or graphical simulation of an indicator light is used for these purposes, it shall comply with the colour and flashing requirements given in Table 2. ~~Alternatively, this indication may be generated by some other type of visual display or device.~~

ALARM SYSTEMS that do not contain HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITIONS are exempt from this requirement if their visual indication cannot be confused with a HIGH PRIORITY or MEDIUM PRIORITY alarm indicator light complying with Table 2.

NOTE 1 This visual indicator is necessary for ALARM SYSTEMS that are intended to be located in the proximity of other ALARM SYSTEMS.

NOTE 2 This visual indicator is not necessary for ALARM SYSTEMS that are worn, e.g., a paging receiver.

NOTE 3 An indicator light can be simulated, e.g. by a graphical display.

Table 2 – Characteristics of alarm indicator lights

Alarm category	Indicator colour	Flashing frequency	Duty cycle
HIGH PRIORITY	Red	1,4 Hz to 2,8 Hz	20 % to 60 % on
MEDIUM PRIORITY	Yellow	0,4 Hz to 0,8 Hz	20 % to 60 % on
LOW PRIORITY	Cyan or yellow	Constant (on)	100 % on

6.3.2.2.2 1 m (OPERATOR'S POSITION) visual ALARM SIGNALS and INFORMATION SIGNALS

At least one visual ALARM SIGNAL that identifies the specific ALARM CONDITION and its priority shall be provided. This signal shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION. This visual indication may be text placed beside an indicator light or text on a display. The presence ofan ALARM CONDITION may be visually indicated (marked) with symbol IEC 60417-5307 (2002-10) (see Symbol 1 of Table C.1). The priority may be indicated by adding one, two or three optional elements, (e.g., **!** for LOW PRIORITY, **!!** for MEDIUM PRIORITY, and **!!!** for HIGH PRIORITY).

NOTE ~~4~~ 1 Factors affecting the legibility of a visual indication include the nature and characteristics of the visual indication itself, ambient lighting in the intended environment of use, and viewing angle and distance.

NOTE ~~5~~ 2 The use of text that flashes on and off is discouraged because it is often difficult to read. Flashing text that alternates between normal and reverse video or another colour is acceptable.

NOTE ~~6~~ 3 Multiple-purpose computer-generated graphic displays should be designed in accordance with modern human interface design principles. Attention is drawn to ~~IEC 60601-1-6~~ IEC 62366-1.

NOTE ~~7~~ 4 The identification of the ALARM CONDITION is intended to convey information necessary for PATIENT safety and safe use of the equipment.

If multiple ALARM CONDITIONS occur at the same time, each individual ALARM CONDITION shall be visually indicated, either automatically or by OPERATOR action, unless an INTELLIGENT ALARM SYSTEM is provided that prevents a lower internal rank ALARM CONDITION from generating ALARM SIGNALS when a higher internal rank ALARM CONDITION is generating or has recently generated ALARM SIGNALS (see 6.2).

Visual INFORMATION SIGNALS, if provided, shall be correctly perceived as different from HIGH PRIORITY or MEDIUM PRIORITY visual ALARM SIGNALS at a distance of 1 m from the ALARM SYSTEM or from the OPERATOR'S POSITION.

NOTE 5 It is recognized that visual INFORMATION SIGNALS and visual ALARM SIGNALS can sometimes contain identical or similar information. When they are intended to convey different meanings, care needs to be taken to ensure that visual ALARM SIGNALS cannot be confused with visual INFORMATION SIGNALS.

Compliance is checked by inspection of the visual ALARM SIGNAL under the following conditions:

– *the OPERATOR has a visual acuity of 0 on the logMAR* [17] *scale or 6-6 (20/20) vision (corrected if necessary),*

– *the viewpoint is at the OPERATOR'S POSITION or at any point within the base of a cone subtended by an angle of 30° to the axis horizontal to or normal to the centre of the plane of display of the monitoring display or visual indication, and*

– *the ambient illuminance in the range* [21] *of 100 lx to 1 500 lx.*

6.3.3 * Auditory ALARM SIGNALS

6.3.3.1 * Characteristics of auditory ALARM SIGNALS

~~An ALARM SYSTEM provided with auditory ALARM SIGNALS shall have at least one set of ALARM SIGNALS that:~~

~~a) is priority encoded and meets the requirements of Table 3 and Table 4; or~~

~~a) is generated by means of different technology (e.g., voice synthesizing of verbal ALARM SIGNALS) and is VALIDATED (e.g., by clinical or simulated clinical USABILITY testing).~~

If a COMMUNICATOR of an ALARM SYSTEM is provided with auditory ALARM SIGNALS:

a) all auditory ALARM SIGNALS shall be priority encoded;

b) of HIGH PRIORITY, the HIGH PRIORITY auditory ALARM SIGNALS of that COMMUNICATOR shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;

c) of MEDIUM PRIORITY, the MEDIUM PRIORITY auditory ALARM SIGNALS of that COMMUNICATOR shall convey a higher level of urgency than the LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;

d) the COMMUNICATOR shall have at least one set of ALARM SIGNALS that:

1) complies with Annex G; or

i) * A COMMUNICATOR with means to provide more than one set of auditory ALARM SIGNALS should be equipped with at least one set of auditory ALARM SIGNALS that complies with Annex G.

2) * is generated by means of different technology (e.g. voice synthesizing of verbal ALARM SIGNALS) and is VALIDATED (e.g. by clinical or simulated clinical USABILITY testing); or

3) * meets the requirements of Table 3 and Table 4.

Table 3 – * Characteristics of the BURST of auditory ALARM SIGNALS

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL[d]
Number of PULSES in BURST [a, e]	10	3	1 or 2
PULSE spacing (t_s) (see Figure 1)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>15 s or no repeat
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB

Where: x shall be a value between 50 ms and 125 ms,

y shall be a value between 125 ms and 250 ms,

the variation of t_d, x and y within a BURST shall ~~be~~ not exceed ± ~~5~~ 20 %, and

MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.

The INTERBURST INTERVAL (t_b) for HIGH PRIORITY auditory ALARM SIGNALS shall not be greater than the INTERBURST INTERVAL for MEDIUM PRIORITY auditory ALARM SIGNALS which shall not be greater than the INTERBURST INTERVAL for LOW PRIORITY auditory ALARM SIGNALS.

[a] See also Table 4 for characteristics of the PULSE.

[b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT.

[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the ~~source~~ origin of the ALARM CONDITION.

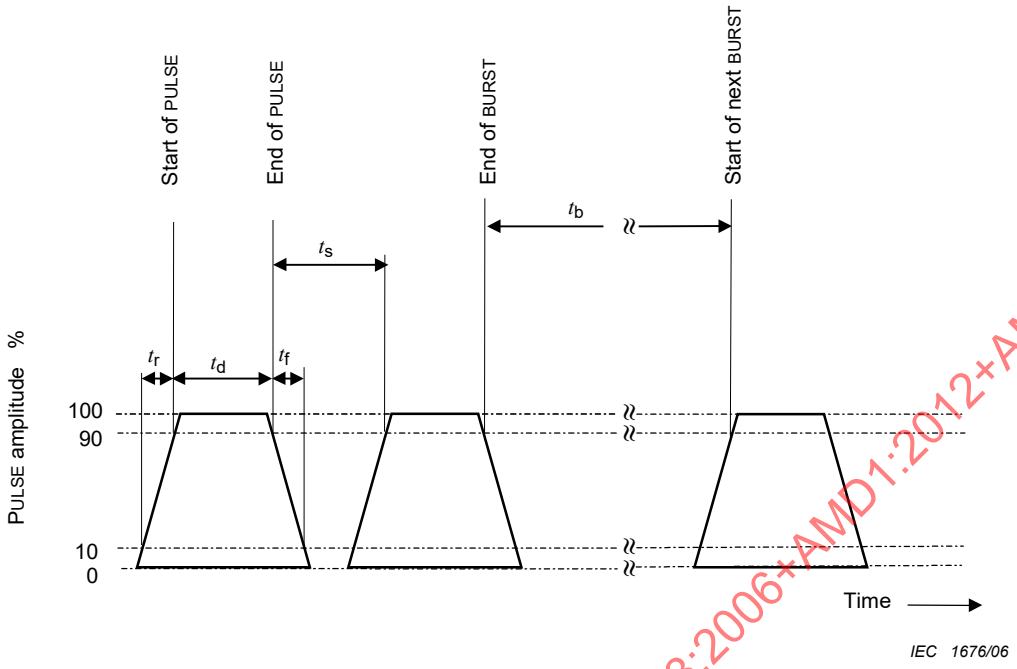
[d] The generation of the auditory component of a LOW PRIORITY ALARM CONDITION is optional.

[e] Unless inactivated by the OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.

Table 4 – * Characteristics of the PULSE of auditory ALARM SIGNALS

~~Characteristic~~	~~Value~~
~~PULSE FREQUENCY (f_o)~~	~~150 Hz to 1 000 Hz~~
~~Number of harmonic components in the range 300 Hz to 4 000 Hz~~	~~Minimum of 4~~
~~Effective PULSE duration (t_d)~~ ~~HIGH PRIORITY~~ ~~MEDIUM and LOW PRIORITY~~	 ~~75 ms to 200 ms~~ ~~125 ms to 250 ms~~
~~RISE TIME (t_r)~~	~~10 % – 20 % of t_d~~
~~FALL TIME[a] (t_f)~~	~~$t_f \leq t_o - t_r$~~
~~NOTE The relative sound pressure level of the harmonic components should be within 15 dB above or below amplitude at the PULSE FREQUENCY.~~	
~~[a] Prevents overlap of PULSES.~~	

Characteristic	Value
Frequency component in the range of 150 Hz to 1 000 Hz	At least one that is among the four frequency components with the largest sound pressure level
Number of peaks in the frequency range of 150 Hz to 4 000Hz	At least four peaks in the frequency domain
Effective PULSE duration (t_d) (see Figure 1) HIGH PRIORITY MEDIUM and LOW PRIORITY	 75 ms to 200 ms 125 ms to 250 ms
RISE TIME (t_r) (see Figure 1)	[a]
FALL TIME (t_f) (see Figure 1)	[b]
Within the frequency range of 150 Hz to 4 000 Hz, the relative sound pressure levels of the four frequency components with the largest sound pressure levels should be within 15 dB of each other. NOTE Care is needed to ensure that the MEDIUM PRIORITY ALARM SIGNAL cannot be confused with the audible emergency evacuation signal specified in ISO 8201:2017 [30]. [a] The RISE TIME should not be so short as to create mechanical speaker noise. [b] The FALL TIME should be short enough to ensure that the PULSES do not overlap.	



NOTE 1 Figure 1 is intended to show the designation of temporal characteristics and does not illustrate any individual auditory ALARM SIGNAL.

NOTE 2 See Figure G.1 and Figure G.2 for additional information.

Figure 1 – Illustration of temporal characteristics of auditory ALARM SIGNALS

If the ALARM SYSTEM is additionally provided with other sets of auditory ALARM SIGNALS, the following shall apply:

~~c) auditory ALARM SIGNALS shall be priority encoded;~~

~~d) HIGH PRIORITY auditory ALARM SIGNALS of a particular set of ALARM SIGNALS shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY ALARM SIGNALS and INFORMATION SIGNALS of that ALARM SIGNAL set;~~

~~e) MEDIUM PRIORITY auditory ALARM SIGNALS of a particular set of ALARM SIGNALS shall convey a higher level of urgency than the LOW PRIORITY ALARM SIGNALS and INFORMATION SIGNALS of that ALARM SIGNAL set;~~

~~f~~e) the other auditory ALARM SIGNALS shall be VALIDATED, e.g., by clinical or simulated clinical USABILITY testing;

~~g~~f) means shall be provided to store a set of auditory ALARM SIGNALS in the DEFAULT ALARM PRESET; and

~~h~~g) means may be provided to store a set of auditory ALARM SIGNALS in any ALARM PRESET.

NOTE 1 See also Annex D.

NOTE 2 Attention is drawn to ~~IEC 60601-1-6~~ IEC 62366-1.

~~Any melody shall preclude the possibility of confusion with the auditory ALARM SIGNALS of Table 3, Table 4 and Annex F, unless their meaning is the same. If any of the melodies of Annex F is used to meet the requirements of Table 3 and Table 4, its meanings shall be as specified in Annex F.~~

When a TECHNICAL ALARM CONDITION that precludes the generation of the usual ALARM SIGNALS occurs, e.g. power or ALARM SYSTEM failure, the ALARM SYSTEM may generate an auditory ALARM SIGNAL that does not comply with the above requirements.

If selection of auditory ALARM SIGNAL sets is provided, means shall be provided for the RESPONSIBLE ORGANIZATION to prevent the OPERATOR from unauthorized access to changing the auditory ALARM SIGNAL set in use (see 6.7).

Compliance is checked by inspection and functional testing of the ALARM SYSTEM and inspection of any relevant VALIDATION documentation. Measure the drive signal of the audio transducer utilizing an oscilloscope or other suitable instrument to cover the frequencies and the RISE and FALL TIMES of the waveform. Confirm the values of x, y, t_b, t_s, t_f and t_d in Table 3 and Table 4. When the sound files of Annex G are utilized, only testing of t_b is required and testing of the acoustic signal is permitted.

Amongst the required frequency components with the largest sound pressure levels, acoustically confirm the presence of at least one frequency component in range of 150 Hz to 1 000 Hz and at least the required components in the range of 150 Hz to 4 000 Hz in the auditory ALARM SIGNAL at 1 m or the intended OPERATOR's POSITION. Only the AUDITORY POINTERS need be tested when evaluating the ALARM SIGNALS of Annex G.

6.3.3.2 * Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

The auditory HIGH PRIORITY and MEDIUM PRIORITY ALARM SIGNAL sound pressure level range and measurement radius~~, as~~ measured in accordance with the method of this subclause, shall be disclosed in the ~~instructions for use~~ ACCOMPANYING DOCUMENTS.

~~The sound pressure level of MEDIUM PRIORITY ALARM SIGNALS shall not exceed that of HIGH PRIORITY ALARM SIGNALS. If provided, the sound pressure level of LOW PRIORITY ALARM SIGNALS shall not exceed that of MEDIUM PRIORITY ALARM SIGNALS.~~

If auditory INFORMATION SIGNALS are provided, they shall be distinguishable from those of auditory ALARM SIGNALS and their characteristics shall be disclosed in the instructions for use.

NOTE Unless the sound pressure level of INFORMATION SIGNALS is independently adjustable, it should not exceed that of LOW PRIORITY ALARM SIGNALS.

Compliance is checked by inspection of the instructions for use and with the following test:

~~– Place a microphone of a sound level meter complying with the requirements for a type 1 instrument as specified in IEC 60651 at the position of maximum sound pressure level in the horizontal plane passing through the geometric centre of the front of the part of the equipment that contains the auditory ALARM SIGNAL generating device at a radius of 1 m or at the OPERATOR'S POSITION. Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter. The indicated sound pressure level when measuring BURSTS is corrected in accordance with Clause 7 of IEC 60651:2001 or a test PULSE of continuous duration is used for purposes of the measurement. Take measurements in a free field over a reflecting plane as specified in ISO 3744. The A-weighted background level of extraneous noise, including any INFORMATION SIGNALS, is to be at least 10 dB below that measured during the test.~~

~~– Simulate a HIGH PRIORITY ALARM CONDITION.~~

~~– Measure the sound pressure level.~~

~~– Repeat above with MEDIUM and LOW PRIORITY ALARM CONDITIONS.~~

~~– Confirm that the HIGH PRIORITY ALARM SIGNAL sound pressure level ≥ MEDIUM PRIORITY ALARM SIGNAL sound pressure level ≥ LOW PRIORITY ALARM SIGNAL sound pressure level.~~

a) Set the ALARM SIGNAL sound pressure level (volume level) to its maximum setting.

b) If the ALARM SYSTEM is provided with a HIGH PRIORITY ALARM CONDITION, simulate a HIGH PRIORITY ALARM CONDITION.

c) Place the equipment containing the COMMUNICATOR on the floor and use a microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the sound pressure levels at least at positions 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10, as specified in Figure B.1 and Table B.1 of ISO 3744:2010, in a hemisphere with a radius of 1 m from the geometric centre of the COMMUNICATOR. For a large COMMUNICATOR, where d_O, as calculated in Figure 1 a) of ISO 3744:2010, is greater than 0,5 m, utilize a radius such that the distance from the surface of the COMMUNICATOR to the hemisphere is at least 0,5 m everywhere, extended to the next higher value in the series 1,5 m, 2 m, 2,5 m, 3 m, 3,5 m, 4 m.

d) Measure the maximum time-weighted sound pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{AFmax}).

e) For ALARM SIGNALS utilizing AUDITORY POINTERS complying with Annex G, confirm that the drive signal of the audio transducer utilizing an oscilloscope or other suitable instrument is not clipped.

f) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.

g) If the ALARM SYSTEM is provided with a MEDIUM PRIORITY ALARM CONDITION, simulate a MEDIUM PRIORITY ALARM CONDITION and repeat c) to f).

h) If the ALARM SYSTEM is provided with a LOW PRIORITY ALARM CONDITION, simulate a LOW PRIORITY ALARM CONDITION and repeat c) to f).

i) Set the ALARM SIGNAL sound pressure level (volume level) to its minimum setting.

j) Repeat b) to h).

k) Confirm that the criteria for background noise, including any INFORMATION SIGNALS, specified in 4.2 of ISO 3744:2010 are fulfilled.

l) Confirm that the measured sound pressure level range is in compliance with the values indicated in the ACCOMPANYING DOCUMENTS.

6.3.3.3 * OPERATOR-adjustable sound pressure level

If an ALARM SYSTEM is provided with a HIGH PRIORITY ALARM CONDITION and an OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level, the instructions for use shall include a warning to the effect that auditory alarm signal sound pressure levels that are less than ambient levels can impede OPERATOR recognition of ALARM CONDITIONS and the ALARM SYSTEM shall:

a) provide a restricted means for the RESPONSIBLE ORGANIZATION to configure the minimum OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level (see 6.7); or

b) provide a visual indication that the current sound pressure level might be inaudible when the auditory ALARM SIGNAL sound pressure level is below a threshold that is configured:

   – by a means restricted to the RESPONSIBLE ORGANIZATION (see 6.7); or

   – by the MANUFACTURER.

   This condition may be visually indicated (marked) with symbol IEC 60417-5576 (2002-11) (see Symbol 5 of Table C.1). If this symbol is used as that visual indication, an INFORMATION SIGNAL or other additional visual indication may be provided to distinguish this state from AUDIO OFF.

An ALARM SYSTEM may be equipped with a dynamically algorithm-adjusted minimum auditory ALARM SIGNAL sound pressure level. If equipped, the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7) to enable and disable the algorithm-adjusted minimum auditory ALARM SIGNAL sound pressure level. If equipped, the instructions for use shall describe the algorithm and the minimum and maximum levels.

EXAMPLE 1 An algorithm that sets the minimum auditory ALARM SIGNAL sound pressure level in response to current ambient sound pressure levels, time of day, evidence of OPERATOR attendance or other variables.

EXAMPLE 2 An algorithm that escalates unresolved active auditory ALARM SIGNALS by increasing their sound pressure level over time.

Compliance is checked by inspection.

6.3.4 * Characteristics of verbal ALARM SIGNALS

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with verbal ALARM SIGNALS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

6.4 * Disclosure of delays

6.4.1 * ALARM SYSTEM delays

If the sum of the maximum ALARM CONDITION DELAY plus the maximum ALARM SIGNAL GENERATION DELAY is greater than 10 s, then the statistics of each distribution or statistics of the distribution of the sum shall be disclosed in the instructions for use.

If the sum of the mean ALARM CONDITION DELAY plus the mean ALARM SIGNAL GENERATION DELAY is greater than 5 s, then each delay or their sum shall be disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use.

6.4.2 * Delays to or from a DISTRIBUTED ~~ALARM SYSTEM~~ INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) or a DISTRIBUTED ALARM SYSTEM (DAS)

~~If an ALARM SYSTEM is provided with a means to send or receive ALARM CONDITIONS in a DISTRIBUTED ALARM SYSTEM:~~

~~a) the delay time from the onset of the ALARM CONDITION to the point that the representation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART shall be disclosed in the instructions for use; and~~

~~b) the maximum remote ALARM SIGNAL GENERATION DELAY or the time to determine the generation of the TECHNICAL ALARM CONDITION (see 6.11.2.2 item 6.11.2.2.1 b)) shall be disclosed in the instructions for use.~~

~~For a DISTRIBUTED ALARM SYSTEM, the ALARM SIGNAL GENERATION DELAY may be measured and reported, as applicable:~~

~~c) from the onset of the ALARM CONDITION;~~

~~d) from the time of the local ALARM SIGNAL generation;~~

~~e) to or from the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART;~~

~~f) to or from the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART; or~~

~~g) to the time of the remote ALARM SIGNAL generation.~~

~~*Compliance is checked by functional testing and inspection of the instructions for use.*~~

If an ALARM SYSTEM is provided with a means to send or receive ALARM CONDITIONS in a DIS or DAS:

a) the delay time from the onset of the ALARM CONDITION to the point that the representation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART shall be disclosed in the instructions for use; and

b) the maximum ALARM SIGNAL GENERATION DELAY of the COMMUNICATOR, including the method used to determine the maximum ALARM SIGNAL GENERATION DELAY, or the time to determine the generation of the TECHNICAL ALARM CONDITION (see 6.11.2.2.1 b)) shall be disclosed in the instructions for use.

The following methods may be used to determine the ALARM SIGNAL GENERATION DELAY contribution for each component of a DIS or DAS, as applicable:

c) from:

1) the onset of the ALARM CONDITION;

2) the time of the ALARM SIGNAL generation at the SOURCE;

3) the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART of the SOURCE or INTEGRATOR; or

4) the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART of the INTEGRATOR or COMMUNICATOR;

d) to:

1) the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART of the SOURCE or INTEGRATOR;

2) the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART of the INTEGRATOR or COMMUNICATOR; or

3) the time of the ALARM SIGNAL generation at the COMMUNICATOR.

Compliance is checked by functional testing under maximum load conditions of NORMAL USE and inspection of the instructions for use.

6.5 ALARM PRESETS

6.5.1 * General requirements

Any ALARM PRESET that uses mechanical adjustment is exempt from the requirements of 6.5.

Example 1 A switch that indicates the value of a set point.

An ALARM SYSTEM is exempt from the requirements of 6.5 if in NORMAL USE it:

a) can only retain current ALARM SETTINGS, and

b) does not otherwise provide ALARM PRESETS, and

c) displays each adjustable ALARM SETTINGS continuously.

EXAMPLE 2 A simple monitor that always initializes with the previous ALARM LIMIT and that limit is continuously displayed.

ALARM PRESETS shall include the ALARM LIMIT used to trigger each ALARM CONDITION and its priority, or they shall be determined from information available to the ALARM SYSTEM concerning the current PATIENT. ALARM PRESETS may include other parameters that affect or modify performance of the ALARM SYSTEM.

EXAMPLE 3 An ALARM LIMIT calculated from entered data, e.g. PATIENT weight and gender.

EXAMPLE 4 An ALARM LIMIT calculated from current physiological status of the PATIENT, e.g. 1,2 times the current heart rate.

The instructions for use shall contain a warning statement to the effect that a HAZARD can exist if different ALARM PRESETS are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.

Compliance is checked by inspection of the ALARM SYSTEM and the instructions for use.

6.5.2 MANUFACTURER-configured ALARM PRESETS

An ALARM SYSTEM shall be provided with at least one MANUFACTURER-configured ALARM PRESET.

The ALARM LIMITS and a summary of any algorithms used in any MANUFACTURER-configured ALARM PRESETS shall be disclosed in the instructions for use.

Compliance is checked by inspection of the ALARM SYSTEM and the instructions for use.

6.5.3 * RESPONSIBLE ORGANIZATION- and OPERATOR-configured ALARM PRESETS

6.5.3.1 ALARM SYSTEMS with one ALARM PRESET

If the ALARM SYSTEM can store only one ALARM PRESET:

a) means shall be provided to prevent the OPERATOR from saving changes to this ALARM PRESET. Saving changes to this ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7); and

b) means shall be provided to the RESPONSIBLE ORGANIZATION to restore the ALARM PRESET to its MANUFACTURER-configured state.

Compliance is checked by inspection.

6.5.3.2 ALARM SYSTEMS with more than one ALARM PRESET

If the ALARM SYSTEM provides means to store or activate one or more RESPONSIBLE ORGANIZATION-configured or OPERATOR-configured ALARM PRESETS in addition to any MANUFACTURER-configured ALARM PRESETS:

a) means shall be provided for the OPERATOR to choose between the available ALARM PRESETS;

b) means shall be provided for the OPERATOR to readily identify which ALARM PRESET is in use;

c) the instructions for use shall contain a warning statement to the effect that the OPERATOR should check that the current ALARM PRESET is appropriate prior to use on each PATIENT;

d) the means for configuration and storage of ALARM PRESETS shall be disclosed in the ACCOMPANYING DOCUMENTS;

e) means shall be provided to prevent the OPERATOR from saving changes to any RESPONSIBLE ORGANIZATION-configured or MANUFACTURER-configured ALARM PRESET. Saving changes to any RESPONSIBLE ORGANIZATION-configured or MANUFACTURER-configured ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7);

f) means shall be provided to prevent an individual OPERATOR from saving changes to ALARM PRESETS that were stored by any other OPERATOR (see 6.7); and

g) the ALARM SYSTEM may store the current ALARM SETTINGS for later recall.

EXAMPLE Temporary storage can permit a return to ALARM SETTINGS that were in use prior to choosing an ALARM PRESET.

Compliance is checked by inspection.

6.5.4 DEFAULT ALARM PRESET

6.5.4.1 General requirements

If the DEFAULT ALARM PRESET can be set to values that differ from the MANUFACTURER-configured values:

a) means shall be provided to prevent any OPERATOR from storing changes to the DEFAULT ALARM PRESET. Storing changes to the DEFAULT ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7); and

b) means shall be provided to the RESPONSIBLE ORGANIZATION to restore the DEFAULT ALARM PRESET to its MANUFACTURER-configured values.

Compliance is checked by inspection.

6.5.4.2 * Selection of DEFAULT ALARM PRESET

Whenever:

a) the OPERATOR switches the ALARM SYSTEM on after an interval specified by the MANUFACTURER as being longer than might be considered unintentional; or

b) the ALARM SYSTEM is enabled; or

c) the OPERATOR indicates to the ALARM SYSTEM, preferably through an "admit new PATIENT" function, that a different PATIENT has been connected to the ALARM SYSTEM; or

d) power is restored to the ALARM SYSTEM after it has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) beyond the time that it automatically restores the ALARM SETTINGS (see 6.5.5);

then:

e) the DEFAULT ALARM PRESET shall be automatically selected; or

f) means shall be provided for the OPERATOR to select an ALARM PRESET; or

g) means may be provided for the OPERATOR to select the retained ALARM SETTINGS from the previous use.

NOTE Care is needed to ensure that the OPERATOR is aware of which previously retained ALARM SETTINGS are being restored when the OPERATOR selects the retained ALARM SETTINGS.

The MANUFACTURER shall disclose in the instructions for use an estimate of the duration of the power interruption after which the ALARM SYSTEM is unable to restore the ALARM SETTINGS and the subsequent behaviour of the ALARM SYSTEM.

Compliance is checked by observing the equipment's ALARM SETTINGS, then temporarily disconnecting the power ~~source~~ for a period exceeding that indicated in the instructions for use and then inspecting the state of the ALARM SETTINGS. The mains switch, if provided, shall remain in the 'on' position during this test. Inspect the ALARM SETTINGS and compare them to the appropriate behaviour.

6.5.5 * Interruptions of less than or equal to 30 s

When power is lost for less than or equal to 30 s, the ALARM SETTINGS prior to the power loss shall be restored automatically. This behaviour shall be described in the instructions for use.

NOTE Power refers to external SUPPLY MAINS, any INTERNAL ELECTRICAL POWER SOURCE exchangeable in NORMAL USE, or external batteries.

Compliance is checked by observing the ALARM SYSTEM'S operating mode and ALARM LIMIT(S), then temporarily disconnecting the power ~~source~~ for 30 s – 3 s + 0 s. Then after power is restored, compare the ALARM SETTINGS with those preceding the disconnection. The mains switch, if provided, shall remain in the "on" position during this test.

6.6 ALARM LIMIT

6.6.1 General requirements

An ALARM LIMIT may be non-adjustable, a simple OPERATOR-adjustable setpoint or an algorithmically determined criterion.

Compliance is checked by inspection.

6.6.2 * Adjustable ALARM LIMIT

6.6.2.1 Indication of OPERATOR-adjustable ALARM LIMIT

If an OPERATOR-adjustable ALARM LIMIT is provided, the ALARM LIMIT shall be indicated continuously or by OPERATOR action. The means of control to display the ALARM LIMITS may be

visually indicated (marked) with symbol IEC 60417-5649 (2002-10) (see symbol 10 of Table C.1), IEC 60417-5650 (2002-10) (see symbol 11 of Table C.1) or IEC 60417-5651 (2002-10) (see symbol 12 of Table C.1), as appropriate.

Compliance is checked by inspection.

6.6.2.2 * Indication of automatically set ALARM LIMIT

An ALARM LIMIT may be automatically set, with or without OPERATOR action, to ranges or percentages above or below:

a) the value of a monitored variable at a point in time; or

b) recent values of a monitored variable; or

c) a current control setting.

If such an automatically set ALARM LIMIT is provided, its value shall be indicated continuously or by OPERATOR action, unless:

d) this ALARM LIMIT is obvious from the associated control setting and the behaviour is described in the instructions for use; or

e) the ALARM LIMIT is determined by an INTELLIGENT ALARM SYSTEM (see 6.2).

Compliance is checked by functional testing and inspection of the instructions for use.

6.6.2.3 * ALARM SYSTEM operation during adjustment of ALARM LIMIT or ALARM PRESET

During adjustment of any ALARM LIMIT or OPERATOR-adjustable ALARM PRESET, the ALARM SYSTEM shall continue to operate normally.

Compliance is checked by functional testing.

6.7 * ALARM SYSTEM security

Means of restricting access to changing or to the storage of changes shall be described in the technical description (see 6.3.3.1, 6.3.3.3, 6.5.3.1, 6.5.3.2, 6.5.4.1, 6.8.2 b) and c), 6.8.3 b), 6.8.5, 6.10, 6.11.2.2.1 and 6.12.3):

EXAMPLE 1 Access controlled by a tool.

EXAMPLE 2 Access controlled by RESPONSIBLE ORGANIZATION password and a technical description that is separate from the instructions for use.

EXAMPLE 3 Access controlled by individual OPERATOR password.

NOTE 1 For a password to be considered secure, the owner of the password needs to be capable of changing the password.

EXAMPLE 4 Access controlled by voice recognition.

EXAMPLE 5 Access controlled by fingerprints.

NOTE 2 Multiple means of restriction can be needed, e.g., one for the RESPONSIBLE ORGANIZATION and one for each OPERATOR.

Compliance is checked by inspection of the technical documentation.

6.8 * ALARM SIGNAL inactivation states

6.8.1 * General

Means shall be provided for the OPERATOR to inactivate the auditory, or the visual and auditory, generation of ALARM SIGNALS. Means may be provided to inactivate the generation of other ALARM SIGNALS. Inactivation may apply to an individual ALARM CONDITION, to a group of ALARM CONDITIONS, to the entire ALARM SYSTEM or to any part of a DISTRIBUTED ALARM SYSTEM. The inactivation of the generation of ALARM SIGNALS may be indefinite (i.e., ALARM OFF, AUDIO

OFF) or indeterminate (indefinite ACKNOWLEDGED) or timed (i.e., ALARM PAUSED, AUDIO PAUSED or timed ACKNOWLEDGED). ~~Flashing visual ALARM SIGNALS specified in 6.3.2.2 may be inactivated by AUDIO PAUSED or AUDIO OFF.~~

Means shall be provided for the OPERATOR to determine the ALARM CONDITIONS for which ALARM SIGNALS are inactivated.

NOTE 1 A group can be predetermined or not.

EXAMPLE 1 All ventilation ALARM CONDITIONS.

EXAMPLE 2 ~~The ALARM SIGNALS of all currently active ALARM CONDITIONS.~~ An ALARM SYSTEM that has not received valid data since it was enabled (e.g. after power-up or before a PATIENT has been connected).

NOTE 2 Additional requirements regarding global ALARM OFF or AUDIO OFF are found in 6.8.3.

If ALARM SIGNAL inactivation applies to an individual ALARM CONDITION or a group of ALARM CONDITIONS, the generation of ALARM SIGNALS from other ALARM CONDITIONS shall be unaffected.

During the ALARM OFF or ALARM PAUSED ALARM SIGNAL inactivation states, the ALARM SYSTEM may discontinue the processing of signals used to generate the inactivated ALARM CONDITIONS.

NOTE 3 If the ALARM SYSTEM discontinues the processing of a signal used to generate an ALARM CONDITION, the ALARM SYSTEM log cannot log that ALARM CONDITION.

AUDIO PAUSED or AUDIO OFF shall not inactivate the 1 m visual ALARM SIGNALS specified in 6.3.2.2.2.

AUDIO PAUSED or AUDIO OFF may inactivate some or all of the 4 m visual ALARM SIGNALS specified in 6.3.2.2.1 or may cause DE-ESCALATION of the ALARM CONDITION priority.

NOTE 4 An INTELLIGENT ALARM SYSTEM can use the OPERATOR'S activation of AUDIO PAUSED or AUDIO OFF to cause DE-ESCALATION or to re-evaluate the need for an ALARM CONDITION.

ACKNOWLEDGED, if provided, shall inactivate the auditory ALARM SIGNALS of currently active ALARM CONDITIONS and shall not affect the ALARM SIGNALS of inactive ALARM CONDITIONS. ACKNOWLEDGED shall terminate automatically, ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists. See also 6.8.4.

A timed ACKNOWLEDGED shall terminate after a defined duration. An indefinite ACKNOWLEDGED shall not terminate after a defined duration.

ACKNOWLEDGED shall not inactivate the 1 m visual ALARM SIGNALS specified in 6.3.2.2.2.

ACKNOWLEDGED may inactivate some or all of the 4 m visual ALARM SIGNALS specified in 6.3.2.2.1.

ACKNOWLEDGED may cause the DE-ESCALATION of the ALARM CONDITION priority, including DE-ESCALATION of the ALARM SIGNALS of a LOW PRIORITY ALARM CONDITION into an INFORMATION SIGNAL.

Compliance is checked by inspection and functional testing.

6.8.2 * REMINDER SIGNALS

The ALARM SYSTEM may be provided with a REMINDER SIGNAL. If an ALARM SYSTEM is provided with a REMINDER SIGNAL:

a) the nature of the REMINDER SIGNAL and the intervals between REMINDER SIGNALS shall be disclosed in the instructions for use;

b) the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7):

- to enable and disable the REMINDER SIGNAL; and
- to configure the maximum REMINDER SIGNAL interval, if adjustment is provided.

c) the ALARM SYSTEM may include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7):

- to permit designated (see 6.7) OPERATORS to enable and disable the REMINDER SIGNAL;
- to permit any OPERATOR to enable and disable the REMINDER SIGNAL.

Compliance is checked by inspection.

6.8.3 * Global indefinite ALARM SIGNAL inactivation states

If deemed acceptable by RISK ASSESSMENT with regard to the intended environment of use of the ALARM SYSTEM, a global ALARM OFF or AUDIO OFF may be provided. If an ALARM SYSTEM is provided with a global ALARM OFF or AUDIO OFF, the ALARM SYSTEM shall be provided with:

a) a REMINDER SIGNAL; and

b) means to configure (enable or disable) any global ALARM OFF or AUDIO OFF. Such means shall be restricted to the RESPONSIBLE ORGANIZATION and shall prevent the clinical OPERATOR from changing the configuration in NORMAL USE (see 6.7).

NOTE 1 ~~A global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state affects all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM with multiple PHYSIOLOGICAL ALARM CONDITIONS.~~ For the purposes of this standard, a global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state can affect all ALARM CONDITIONS or all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM.

NOTE 2 See also 6.8.2 for requirements for REMINDER SIGNALS.

Compliance is checked by inspection.

6.8.4 * Termination of inactivation of ALARM SIGNALS

Means shall be provided for the OPERATOR to terminate any ALARM SIGNAL inactivation state.

An ALARM SIGNAL inactivation state may terminate automatically, ~~when the ALARM CONDITION that was generating an ALARM SIGNAL when this state was entered, ceases~~ ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists.

EXAMPLE 1 A non-latching PHYSIOLOGICAL ALARM CONDITION automatically terminates when the monitored parameter returns within its ALARM LIMITS.

EXAMPLE 2 When an ALARM CONDITION has been ACKNOWLEDGED, the resulting state automatically terminates when the underlying ALARM CONDITION no longer exists.

When an ALARM SIGNAL inactivation state is terminated, ~~the ALARM SIGNALS of any current ALARM CONDITION shall cause the re-generation of ALARM SIGNALS~~ the ALARM SYSTEM shall re-evaluate the need for ALARM CONDITIONS and generate ALARM SIGNALS if appropriate.

Compliance is checked by functional testing.

6.8.5 * Indication and access

The ALARM SIGNAL inactivation states AUDIO PAUSED, ALARM PAUSED, AUDIO OFF, ALARM OFF and ACKNOWLEDGED shall be visually indicated (marked) with the appropriate symbol referenced in Table 5. This indication shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION.

The means of control used to enter one of the ALARM SIGNAL inactivation states may be marked with a symbol referenced in Table 5. If a symbol that is referenced in Table 5 is used, it shall initiate the associated ALARM SIGNAL inactivation state.

The duration of AUDIO PAUSED, ALARM PAUSED or a timed ACKNOWLEDGED, if provided, shall be disclosed in the instructions for use.

If the AUDIO PAUSED, ALARM PAUSED or a timed ACKNOWLEDGED interval is OPERATOR adjustable, means to adjust the maximum interval shall only be provided to the RESPONSIBLE ORGANIZATION (see 6.7) and means may be provided for the OPERATOR to adjust the interval up to the maximum interval.

Compliance is checked by inspection.

Table 5 – ALARM SIGNAL inactivation states

~~State~~	~~Duration~~	~~Visual indication (marking) of state (mandatory) (row of symbol in Table C.1)~~	~~Marking of controls (optional)~~	
			~~(row of symbol in Table C.1)~~	~~(row of marking in Table C.2)~~
~~AUDIO PAUSED~~	~~Time limited~~	~~6~~	~~6~~	~~1~~
~~ALARM PAUSED~~	~~Time limited~~	~~4 or (4 and 6)~~	~~4~~	~~2~~
~~AUDIO OFF~~	~~Indefinite~~	~~5~~	~~5~~	~~3~~
~~ALARM OFF~~	~~Indefinite~~	~~3 or (3 and 5)~~	~~3~~	~~4~~

ALARM SIGNAL inactivation state	**Usual termination event**	**Visual indication (marking) of state (mandatory) (row of symbol in Table C.1)**	**Marking of controls (optional)**	
			(row of symbol in Table C.1)	**(row of marking in Table C.2)**
AUDIO PAUSED	Time interval elapsed	6	6	1
ALARM PAUSED	Time interval elapsed	4 or (4 and 6)	4	2
AUDIO OFF	OPERATOR action	5	5	3
ALARM OFF	OPERATOR action	3 or (3 and 5)	3	4
Indefinite ACKNOWLEDGED	ALARM CONDITION no longer exists	5 or 8 or 14	7 or 13 or 8 or 14	6
Timed ACKNOWLEDGED	ALARM CONDITION no longer exists or time interval elapsed	6 or 9 or 15	7 or 13 or 9 or 15	7

6.9 * ALARM RESET

The means of ALARM RESET may be marked with symbol IEC 60417-5309 (DB-2002-10) (see symbol 2 of Table C.1) or marking 5 of Table C.2.

Compliance is checked by inspection.

6.10 * NON-LATCHING and LATCHING ALARM SIGNALS

A NON-LATCHING ALARM SIGNAL shall automatically cease being generated when its triggering event no longer exists. A LATCHING ALARM SIGNAL shall continue to be generated after its triggering event no longer exists. An ALARM SYSTEM may consist of a mixture of LATCHING ALARM SIGNALS and NON-LATCHING ALARM SIGNALS.

NOTE 1 An INTELLIGENT ALARM SYSTEM can decrease the priority of a LATCHING ALARM SIGNAL.

In the case of an ALARM CONDITION of short duration, a MEDIUM PRIORITY auditory ALARM SIGNAL shall complete at least one full BURST and a HIGH PRIORITY auditory ALARM SIGNAL shall complete one half of one full BURST, unless inactivated by the OPERATOR.

NOTE 2 If the ALARM CONDITION clears quickly, the OPERATOR might be unable to discover what event triggered the ALARM CONDITION. Alternatives include:

– a visual ALARM SIGNAL that indicates the specific ALARM CONDITION and which continues to be generated for a limited period of time (e.g., 30 s) after the ALARM CONDITION has cleared;
– an ALARM CONDITION log that the OPERATOR can view, print, or record;
– an ALARM CONDITION trend that the OPERATOR can view, print, or record.

Auditory ALARM SIGNALS shall cease being generated when:

a) an OPERATOR has initiated the AUDIO PAUSED, AUDIO OFF, ACKNOWLEDGED, ALARM PAUSED or ALARM OFF state; or
b) an OPERATOR has ALARM RESET the ALARM CONDITION.

Means shall be provided to prevent the OPERATORS from selecting between LATCHING and NON-LATCHING ALARM SIGNALS. The selection between LATCHING and NON-LATCHING ALARM SIGNALS shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7).

Compliance is checked by functional testing.

6.11 * DISTRIBUTED ALARM SYSTEMS and DISTRIBUTED INFORMATION SYSTEMS ABOUT ALARM CONDITIONS

~~**6.11.1 * Existence of DISTRIBUTED ALARM SYSTEM**~~

~~The details necessary for the safe use of a DISTRIBUTED ALARM SYSTEM shall be disclosed in the technical description. A DISTRIBUTED ALARM SYSTEM is a permitted form of an ALARM SYSTEM.~~

~~An ALARM SYSTEM is permitted to send or receive data, including the indication of INFORMATION SIGNALS and ALARM CONDITIONS, to or from other parts of a DISTRIBUTED ALARM SYSTEM. A DISTRIBUTED ALARM SYSTEM is permitted to be located outside of the PATIENT ENVIRONMENT. Part(s) of a DISTRIBUTED ALARM SYSTEM are permitted to be located outside of the PATIENT ENVIRONMENT. Data are permitted to be transmitted between different parts of a DISTRIBUTED ALARM SYSTEM by wire, by telemetry or by other means.~~

~~EXAMPLE 1 A central station.~~

~~EXAMPLE 2 An electronic record-keeping device.~~

~~EXAMPLE 3 Remote viewing from home or office.~~

~~EXAMPLE 4 Bed-to-bed viewing of ALARM CONDITIONS (e.g. one nurse for two beds).~~

~~EXAMPLE 5 Transmission of ALARM CONDITIONS to pagers, cell-phones, hand-held computers, etc.~~

Compliance is checked by inspection of the technical description.

6.11.2 Requirements for DISTRIBUTED ALARM SYSTEM communication of ALARM CONDITIONS

6.11.2.1 Source and identification of ALARM CONDITIONS

In a DISTRIBUTED ALARM SYSTEM, means shall be provided to identify the source of the remote ALARM CONDITION at every site of ALARM SIGNAL generation.

NOTE ALARM SIGNALS that indicate urgency of the response required, categorization of the cause of the ALARM CONDITION and identification of PATIENT, equipment or PATIENT'S location should also be generated by the DISTRIBUTED ALARM SYSTEM.

Compliance is checked by inspection.

6.11.2.2 * Failure of remote communication of ALARM CONDITIONS

6.11.2.2.1 * DISTRIBUTED ALARM SYSTEM intended for confirmed delivery of ALARM CONDITIONS

A DISTRIBUTED ALARM SYSTEM intended for confirmed delivery of ALARM CONDITIONS shall be so designed that a communications failure or failure in any remote part of the DISTRIBUTED ALARM SYSTEM:

a) shall not adversely affect any part of the DISTRIBUTED ALARM SYSTEM other than the loss of the distributed functionality; and

b) shall:

1) initiate a TECHNICAL ALARM CONDITION in the affected source ME EQUIPMENT; and

NOTE 1 The ALARM SYSTEM should provide means for the OPERATOR to inactivate the auditory ALARM SIGNALS of this TECHNICAL ALARM CONDITION.

2) initiate a TECHNICAL ALARM CONDITION for any affected remote parts of the DISTRIBUTED ALARM SYSTEM that can generate ALARM SIGNALS.

NOTE 2 MANUFACTURERS should take care in the design of ME EQUIPMENT to ensure that it reverts to a safe mode of operation, which can include ESCALATION of the volume of auditory ALARM SIGNALS or utilization of a redundant communication pathway.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.2.2 * DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS

A DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS shall be so designed that a communications failure or failure in any remote part of the DISTRIBUTED ALARM SYSTEM:

a) shall not adversely affect any part of the DISTRIBUTED ALARM SYSTEM other than the loss of the distributed functionality; and

b) any remote part of a DISTRIBUTED ALARM SYSTEM that cannot comply with 6.11.2.2.1 shall be marked with a warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS.

EXAMPLE A one-way paging system requires such a warning.

NOTE Inability to successfully send or receive ALARM CONDITIONS or INFORMATION SIGNALS is considered a failure.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.2.3 * ME EQUIPMENT with a global AUDIO OFF in a DISTRIBUTED ALARM SYSTEM

If there is a communications failure between the ME EQUIPMENT with a global AUDIO OFF and the DISTRIBUTED ALARM SYSTEM intended for OPERATOR notification and confirmed delivery of

~~ALARM CONDITIONS, the affected source ME EQUIPMENT shall terminate the global AUDIO OFF state, if active.~~

~~If the OPERATOR subsequently activates AUDIO OFF or a global AUDIO OFF in the source ME EQUIPMENT, continuing failure of the link need not cause additional auditory ALARM SIGNALS.~~

~~*Compliance is checked by functional testing and inspection of the ALARM SYSTEM.*~~

~~6.11.2.3 * Remote ALARM SYSTEM controls~~

~~A DISTRIBUTED ALARM SYSTEM may provide remote OPERATOR access to some or all ALARM SYSTEM controls. If provided:~~

~~a) the ALARM SYSTEM shall provide a means for the RESPONSIBLE ORGANIZATION to restrict remote OPERATOR access to the available remote controls; and~~

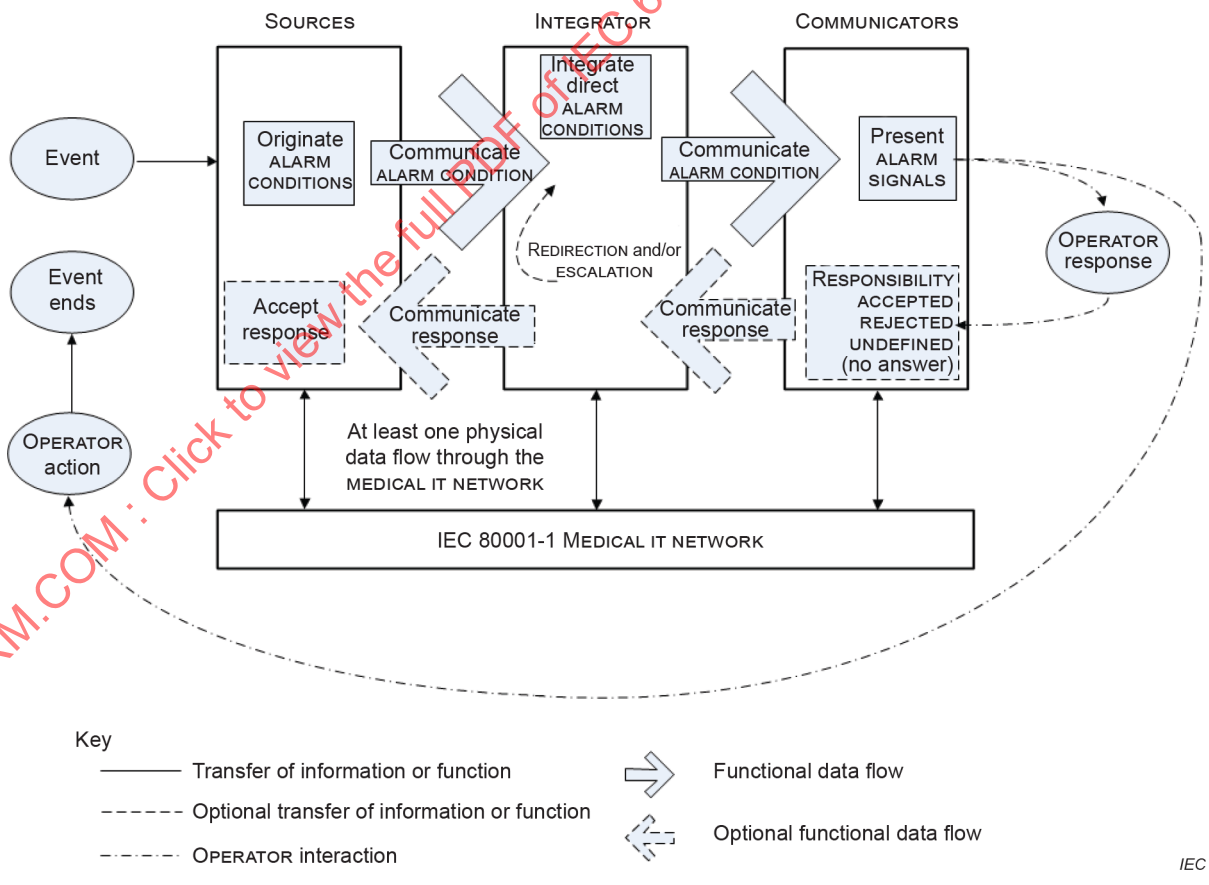
~~b) such means shall be restricted to the RESPONSIBLE ORGANIZATION, preventing the clinical OPERATOR from changing the configuration (see 6.7).~~

~~*Compliance is checked by functional testing and inspection of the ALARM SYSTEM.*~~

6.11.1 * Existence of a DIS or DAS

The details necessary for the safe use of a DIS or a DAS shall be disclosed in the technical description. A DIS or a DAS is a permitted form of an ALARM SYSTEM. Figure 2 illustrates the functions of a DISTRIBUTED ALARM SYSTEM utilizing a MEDICAL IT NETWORK.

NOTE Additional information is found in IEC 80001-2-5 [31].



NOTE This is a functional diagram and does not imply that these functions are in separate components. It is possible for functionality to be provided in one or more components.

Figure 2 – Functions of a DISTRIBUTED ALARM SYSTEM utilizing a MEDICAL IT NETWORK

An ALARM SYSTEM is permitted to send or receive data, including the indication of INFORMATION SIGNALS and ALARM CONDITIONS, to or from other parts of a DIS or a DAS. A DIS or a DAS is permitted to be located outside of the PATIENT ENVIRONMENT. Part(s) of a DIS or a DAS are permitted to be located outside of the PATIENT ENVIRONMENT. Data are permitted to be transmitted between different parts of a DIS or a DAS by wire, by telemetry or by other means.

EXAMPLE 1 A central station.

EXAMPLE 2 An electronic record-keeping device.

EXAMPLE 3 Remote viewing from home or office.

EXAMPLE 4 Bed-to-bed viewing of ALARM CONDITIONS (e.g. one nurse for two beds).

EXAMPLE 5 Transmission of ALARM CONDITIONS to pagers, cell phones, hand-held computers, etc.

Compliance is checked by inspection of the technical description.

6.11.2 Requirements for communication of ALARM CONDITIONS

6.11.2.1 SOURCE and identification of ALARM CONDITIONS

In a DAS or DIS, means shall be provided to identify the SOURCE of the ALARM CONDITION at every COMMUNICATOR that generates ALARM SIGNALS for that ALARM CONDITION.

ALARM SIGNALS that indicate the urgency of the response required, categorization of the cause of the ALARM CONDITION and identification of the PATIENT, equipment or PATIENT's location should also be generated by the DISTRIBUTED ALARM SYSTEM.

Compliance is checked by inspection.

6.11.2.2 * Failure of remote communication of ALARM CONDITIONS

6.11.2.2.1 * DAS or CDAS

A DAS or CDAS shall be so designed that a communications failure or failure in any remote component of the DAS or CDAS:

a) shall not adversely affect any part of the DAS or CDAS other than the loss of the distributed functionality; and

b) shall initiate a TECHNICAL ALARM CONDITION for all relevant COMMUNICATORS of the DAS or CDAS.

1) The ALARM SYSTEM should provide a means for the OPERATOR to inactivate any auditory ALARM SIGNALS of this TECHNICAL ALARM CONDITION.

MANUFACTURERS should take care in the design of ME EQUIPMENT to ensure that it reverts to a safe mode of operation, which can include ESCALATION of the volume of auditory ALARM SIGNALS or utilization of a redundant communication pathway.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.2.2 * DIS

A DIS shall be so designed that a communications failure or failure in any remote component of the DIS:

a) shall not adversely affect any part of the DIS other than the loss of the distributed functionality; and

b) any remote COMMUNICATOR of a DIS that cannot comply with 6.11.2.2.1 shall be marked with a warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS.

EXAMPLE A one-way paging system requires such a warning.

NOTE Inability to successfully send or receive ALARM CONDITIONS or INFORMATION SIGNALS is considered a failure.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.2.3 * SOURCE with a global AUDIO OFF in a DISTRIBUTED ALARM SYSTEM

If there is a communications failure between a SOURCE with a global AUDIO OFF and the DISTRIBUTED ALARM SYSTEM, the affected SOURCE shall terminate the global AUDIO OFF state, if active.

If the OPERATOR subsequently activates AUDIO OFF or a global AUDIO OFF in the SOURCE, continuing failure of the link need not cause additional auditory ALARM SIGNALS.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.3 * Remote ALARM SYSTEM controls

A DAS or CDAS may provide remote OPERATOR access to some or all ALARM SYSTEM controls. If provided:

a) the ALARM SYSTEM shall provide a means for the RESPONSIBLE ORGANIZATION to restrict remote OPERATOR access to the available remote controls; and

b) such means shall be restricted to the RESPONSIBLE ORGANIZATION, preventing the clinical OPERATOR from changing the configuration (see 6.7).

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.4 * CDAS

In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION shall have means to create the OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) and transfer them to the INTEGRATOR.

a) In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION and initiates an OPERATOR response (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) shall indicate the OPERATOR response state (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED).

The means of control used to initiate an OPERATOR response or indication of state may be marked with:

b) symbol ISO 7000-6334A (2015-06) (see Symbol 13 of Table C.1) for RESPONSIBILITY ACCEPTED; or

c) symbol ISO 7000-6335A (2015-06) (see Symbol 16 of Table C.1) for RESPONSIBILITY REJECTED.

Means shall be provided for the OPERATOR to terminate RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED while the related ALARM CONDITION is active. Initiating RESPONSIBILITY REJECTED may be used to terminate RESPONSIBILITY ACCEPTED. Initiating RESPONSIBILITY ACCEPTED may be used to terminate RESPONSIBILITY REJECTED.

In a CDAS, RESPONSIBILITY ACCEPTED may initiate an ALARM SIGNAL inactivation state.

NOTE RESPONSIBILITY ACCEPTED is a different function than an ALARM SIGNAL inactivation state.

In a CDAS, the INTEGRATOR shall have means to accept OPERATOR responses from the COMMUNICATOR.

In a CDAS, the SOURCE may receive OPERATOR responses from the INTEGRATOR.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.12 * ALARM ~~CONDITION~~ SYSTEM logging

~~If an ALARM SYSTEM is provided with an ALARM SYSTEM log:~~

~~a) the ALARM SYSTEM shall log the occurrence and identity of HIGH PRIORITY ALARM CONDITIONS and;~~

~~– the date and time, or~~

~~– the elapsed time since the occurrence of the ALARM CONDITION, or~~

~~– the elapsed time from the start of use of the ME EQUIPMENT;~~

~~b) the instructions for use shall indicate whether the log is maintained when the ALARM SYSTEM is powered down and whether or not the time of powering down is captured in the log;~~

~~c) the instructions for use shall indicate what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration;~~

~~d) the instructions for use shall indicate what happens to the contents of the log as it reaches capacity; and~~

~~EXAMPLE 1 The ALARM SYSTEM generates a TECHNICAL ALARM CONDITION when the log becomes full.~~

~~EXAMPLE 2 The ALARM SYSTEM discards the oldest data when the log becomes full.~~

~~e) the ALARM SYSTEM should log every ALARM CONDITION, including the date and time of beginning and end as well as the associated ALARM LIMITS, if OPERATOR-adjustable, for that ALARM CONDITION and, where feasible, the data that caused the ALARM CONDITION;~~

~~f) the ALARM SYSTEM should log TECHNICAL ALARM CONDITIONS for servicing and maintenance purposes. This log should not be resettable or editable by OPERATOR action.~~

~~*Compliance is checked by inspection.*~~

6.12.1 General

An ALARM SYSTEM may be equipped with an OPERATOR ALARM SYSTEM log or a RESPONSIBLE ORGANIZATION ALARM SYSTEM log.

An OPERATOR ALARM SYSTEM log is intended to be utilized while the ALARM SYSTEM is being used for a PATIENT. A RESPONSIBLE ORGANIZATION ALARM SYSTEM log is intended to be utilized after PATIENT use has been concluded.

An OPERATOR ALARM SYSTEM log is typically a subset of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log.

6.12.2 * OPERATOR ALARM SYSTEM logging

If an ALARM SYSTEM is provided with an OPERATOR ALARM SYSTEM log:

a) the ALARM SYSTEM should log every ALARM CONDITION, including the date and time of beginning and end as well as the associated ALARM LIMITS for that ALARM CONDITION, if OPERATOR-adjustable and, where feasible, the data that caused the ALARM CONDITION;

EXAMPLE 1 The downstream infusion pressure ALARM CONDITION is logged with start time and date, end time (date stamp), pressure ALARM LIMIT, the pressure value and auditory ALARM SIGNAL volume setting.

b) the ALARM SYSTEM shall log the occurrence and identity of all HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS;

c) for each logged ALARM CONDITION, the ALARM SYSTEM shall log:

– the date and time of the occurrence, or

– the elapsed time since the occurrence of the ALARM CONDITION, or

– the elapsed time of the occurrence from the start of use of the ME EQUIPMENT;

d) the ALARM SYSTEM should log the occurrence and identity of all ALARM SIGNAL inactivation states and, for a CDAS, OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED);

1) for each logged ALARM SIGNAL inactivation state, the ALARM SYSTEM shall log:

– the date and time of the occurrence, or

– the elapsed time since the occurrence of the ALARM CONDITION or ALARM SIGNAL inactivation state, or

– the elapsed time of the occurrence from the start of use of the ME EQUIPMENT;

e) if a means is provided for the OPERATOR to indicate to the ALARM SYSTEM that a different PATIENT has been connected, then that event should be logged in the OPERATOR ALARM SYSTEM log;

f) means may be provided for the logging of changes to the OPERATOR-adjustable ALARM SETTINGS in the OPERATOR ALARM SYSTEM log;

g) means may be provided for the OPERATOR to add explanatory notes or comments to the OPERATOR ALARM SYSTEM log, and if provided:

– means should be provided to record the identity of the annotator and the date and time of the annotation;

h) means shall not be provided for the OPERATOR to edit or delete entries in the OPERATOR ALARM SYSTEM log, unless a new PATIENT is admitted or a RESPONSIBLE ORGANIZATION ALARM SYSTEM log is provided;

i) the log may be provided either within the equipment or remotely through a communications interface; and

j) the instructions for use shall indicate:

1) the means for the OPERATOR to access the OPERATOR ALARM SYSTEM log,

2) whether the log is maintained when the ALARM SYSTEM is powered down and whether or not the time of powering down is captured in the log,

3) what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration,

4) the capacity of the log, and

5) what happens to the contents of the log as it reaches capacity.

EXAMPLE 2 The ALARM SYSTEM discards the oldest data when the log becomes full.

Compliance is checked by inspection.

6.12.3 * RESPONSIBLE ORGANIZATION ALARM SYSTEM logging

If an ALARM SYSTEM is provided with a RESPONSIBLE ORGANIZATION ALARM SYSTEM log:

a) viewing the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7);

b) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall contain all of the information contained in the OPERATOR ALARM SYSTEM log;

c) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall contain the ALARM SETTINGS and each change of those settings;

EXAMPLE 1 The name of the ALARM PRESET in use and any changes made to it.

d) means shall not be provided for the OPERATOR or RESPONSIBLE ORGANIZATION to edit or delete entries in the RESPONSIBLE ORGANIZATION ALARM SYSTEM log;

e) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall be retained when the ALARM SYSTEM is powered down;

f) the instructions for use shall indicate what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration;

g) the instructions for use shall indicate:

1) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log capacity, and

2) what happens to the contents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as it reaches capacity;

EXAMPLE 2 The ALARM SYSTEM discards the oldest data when the log becomes full.

h) the ALARM SYSTEM should log TECHNICAL ALARM CONDITIONS for servicing and maintenance purposes. This log should not be resettable or editable by OPERATOR action; and

i) the log may be provided either within the equipment or remotely through a communications interface.

Compliance is checked by inspection.

6.13 ALARM SYSTEM functions

6.13.1 General

An ALARM SYSTEM shall have at least one:

a) SOURCE;

b) INTEGRATOr; and

c) COMMUNICATOR.

Figure 3 illustrates the functions of an ALARM SYSTEM of ME EQUIPMENT.

Compliance is checked with the tests of 6.3.1.

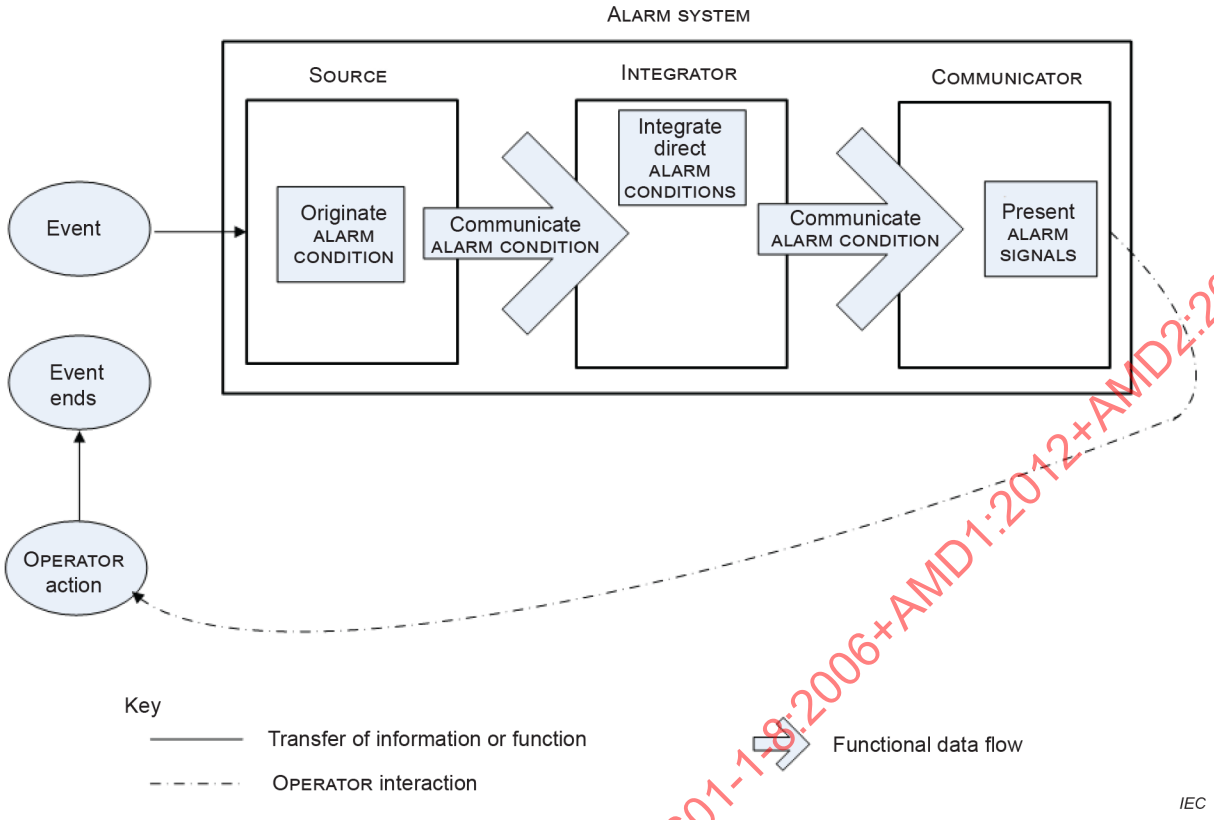


Figure 3 – Functions of an ALARM SYSTEM

6.13.2 SOURCE (SRC)

An ME EQUIPMENT, a DIS or a DAS may have more than one SOURCE.

An ALARM CONDITION shall only originate from a SOURCE.

A SOURCE may receive an indication of RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED or RESPONSIBILITY UNDEFINED originating at a COMMUNICATOR (from an OPERATOR) that was transferred from an INTEGRATOR.

Compliance is checked by inspection.

6.13.3 INTEGRATOR (INT)

An INTEGRATOR shall map SOURCES and their ALARM CONDITIONS to one or more specific COMMUNICATORS.

An INTEGRATOR may receive an indication of RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED or RESPONSIBILITY UNDEFINED originating at a COMMUNICATOR (from an OPERATOR) and may transfer it to a SOURCE.

An INTEGRATOR may provide REDIRECTION to additional or different COMMUNICATORS based on the response or lack of response from COMMUNICATORS. The MANUFACTURER should consider a means for the RESPONSIBLE ORGANIZATION to manage the REDIRECTION to assure an appropriate OPERATOR response.

An INTEGRATOR may:

a) contain a SOURCE that performs the functions of an INTELLIGENT ALARM SYSTEM (see 6.2);

EXAMPLE 1 Removing redundant ALARM CONDITIONS.

EXAMPLE 2 Creating an ALARM CONDITION from multiple inputs.

EXAMPLE 3 Suppressing superfluous ALARM SIGNALS.

b) generate the RESPONSIBILITY UNDEFINED state;

c) generate an ALARM SIGNAL inactivation state.

The ME EQUIPMENT, a DIS or a DAS may have more than one INTEGRATOR.

Compliance is checked by inspection.

6.13.4 COMMUNICATOR (COM)

A COMMUNICATOR receives ALARM CONDITIONS from one or more INTEGRATORS. A COMMUNICATOR may also PROCESS or direct an OPERATOR response (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) to the INTEGRATOR.

An OPERATOR response need not be limited to direct OPERATOR action and can be achieved by other means (e.g. an OPERATOR locator system).

If OPERATOR response is achieved by other means than direct OPERATOR action, the ALARM SYSTEM shall provide means to indicate to the corresponding OPERATOR that RESPONSIBILITY ACCEPTED is active for the affected COMMUNICATOR.

An ME EQUIPMENT, a DIS or a DAS may have more than one COMMUNICATOR.

Annex A
(informative)

General guidance and rationale

A.1 General guidance

A.1.1 Overview

This annex provides a rationale for the important requirements of this collateral standard. Its purpose is to promote effective application of the standard by explaining the reasons for the requirements, providing examples of how they address certain alarm-related HAZARDS and providing additional guidance where appropriate.

From the standpoint of PATIENT safety, ALARM SYSTEMS can be hazardous for PATIENTS or OPERATORS if they fail to effectively warn of potential or actual HAZARDS, cause inappropriate responses, reduce vigilance or interfere with the performance of the OPERATOR, RESPONSIBLE ORGANIZATION, or other persons.

In addition, in this annex text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard.

A.1.2 ALARM SYSTEMS

As part of the RISK MANAGEMENT PROCESS, the MANUFACTURER identifies RISK CONTROL measure(s) that are appropriate for reducing the RISK(S) to an acceptable level.

RISK CONTROL consists of an integrated approach in which the MANUFACTURER uses one or more of the following in the priority order listed.

a) inherent safety by design;

b) protective measures in the equipment;

c) information for safety, e.g., warnings and instructions for use, values of monitored variables.

ALARM SYSTEMS as described in this collateral standard, address b) and c) above by communicating information that requires a response or awareness by the OPERATOR. The following general principles apply.

d) The ALARM SYSTEM should result in a greater probability that the OPERATOR will correctly detect and appropriately respond to the condition that requires their awareness or action than would be the case in the absence of the ALARM SIGNALS.

NOTE 1 Causing too many ALARM SIGNALS from FALSE POSITIVE ALARM CONDITIONS can cause ALARM FATIGUE, which can reduce the effectiveness of an ALARM SYSTEM [73], [74], [75].

NOTE 2 ALARM FLOOD can lead to ALARM FATIGUE, which can reduce the effectiveness of an ALARM SYSTEM [56], [57].

e) ALARM SIGNALS should indicate the onset and continuing presence of an ALARM CONDITION.

f) ALARM CONDITIONS should be prioritized based on the urgency of the required OPERATOR response (or awareness).

g) ALARM SIGNALS should be CLINICALLY ACTIONABLE and help the OPERATOR:

- determine the urgency of the response required;
- locate the room or part of the room where a response or awareness is required;
- locate the specific PATIENT or equipment where a response or awareness is required;

– determine or categorize the cause of the ALARM CONDITION; and

– determine or categorize the nature of the response or awareness that is required.

h) ~~The algorithms that determine ALARM CONDITIONS should be designed to minimize the number of FALSE NEGATIVE and FALSE POSITIVE ALARM CONDITIONS. Both FALSE NEGATIVE and FALSE POSITIVE ALARM CONDITIONS are potentially hazardous. Too many true positive but unhelpful ALARM SIGNALS can result in inappropriate OPERATOR action or reduce vigilance. Algorithms that determine ALARM CONDITIONS should be carefully optimized to provide, on balance, an overall benefit to PATIENT care.~~ The algorithms and ALARM SETTINGS that determine ALARM CONDITIONS should be designed to minimize the number of FALSE NEGATIVE, FALSE POSITIVE and CLINICALLY NONACTIONABLE ALARM CONDITIONS. FALSE NEGATIVE, FALSE POSITIVE and CLINICALLY NONACTIONABLE ALARM CONDITIONS are potentially hazardous. Too many TRUE POSITIVE ALARM CONDITIONS but CLINICALLY NONACTIONABLE ALARM SIGNALS can result in inappropriate OPERATOR action or reduce vigilance. TRUE POSITIVE ALARM CONDITIONS that are CLINICALLY NONACTIONABLE lead to ALARM FATIGUE. Algorithms and ALARM SETTINGS that determine ALARM CONDITIONS should be carefully optimized to provide, on balance, an overall benefit to PATIENT care [55], [58].

i) ALARM SYSTEMS that are continuously attended by an OPERATOR in NORMAL USE should have different characteristics from ALARM SYSTEMS that are unattended by the OPERATOR in NORMAL USE.

j) The design of an ALARM SYSTEM should be based on the TRAINING and skill of the OPERATOR who is intended to use it.

k) The ALARM SYSTEM should reflect the problems and needs of the intended environment of use.

l) ALARM SIGNALS should not be excessively intrusive or degrade the performance of the OPERATOR.

A.1.3 Algorithm quality and performance

ALARM SYSTEM algorithms should aim at approaching 100 % sensitivity and 100 % specificity. [7],[8],[9],[10] ~~*The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS, unhelpful ALARM CONDITIONS, or nuisance ALARM CONDITIONS. Nuisance ALARM CONDITIONS are true positives that are unhelpful because they indicate states that the OPERATOR is already aware of or does not need to know about. [11]*~~ *The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS, CLINICALLY NONACTIONABLE ALARM CONDITIONS or nuisance ALARM CONDITIONS. CLINICALLY NONACTIONABLE ALARM CONDITIONS are TRUE POSITIVE ALARM CONDITIONS that are unhelpful because they indicate states that the OPERATOR is already aware of or does not need to know about [11], [29]. They commonly occur when the ALARM LIMITS have been set inappropriately close to an acceptable value but also occur when multiple redundant ALARM CONDITIONS occur in response to a single underlying problem. Often, ALARM SIGNALS are more confusing than enlightening. Many OPERATORS respond to ALARM SIGNALS by disabling the ALARM SYSTEM or by adjusting an ALARM LIMIT to such an extreme value that the ALARM SYSTEM is effectively disabled. [12]*

Where practical, MANUFACTURERS or writers of particular standards are encouraged to utilize standardized physiological databases to validate the algorithms used to determine ALARM CONDITIONS. Determining and reporting the FALSE POSITIVE, ~~*and*~~ *FALSE NEGATIVE, TRUE POSITIVE and TRUE NEGATIVE ALARM CONDITION accuracy in a standardized format allows OPERATORS and RESPONSIBLE ORGANIZATIONS to understand the performance of equipment.*

EXAMPLE ANSI/AAMI EC57:1998, *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms.[5]*

Other techniques to reduce the number of FALSE POSITIVE and FALSE NEGATIVE ALARM CONDITIONS include:

a) marking the ALARM SYSTEM with symbol ISO 7000-0435 when an algorithm cannot classify or resolve the available data; or

b) using an ALARM CONDITION DELAY to delay the generation ALARM SIGNALS for an ALARM CONDITION to ensure that it remains valid.

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this collateral standard, with clause and subclause numbers parallel to those in the body of the document.

Clause 1 – Scope, object and related standards

This collateral standard provides the general requirements for the implementation of ALARM SYSTEMS in ME EQUIPMENT and ME SYSTEMS to provide information necessary for the safety of PATIENTS, OPERATORS and others involved with PATIENT care. As the urgency of the OPERATOR'S attention is dependent on the cause of the ALARM CONDITION, this collateral standard specifies ALARM CONDITION priorities and their ALARM SIGNAL characteristics so that the OPERATOR can perceive the urgency of the situation and the necessary action independent of the type, brand, etc. of the ME EQUIPMENT that is generating ALARM SIGNALS. [13], [14], [15], [16] In addition, a standardized unambiguous ALARM SYSTEM vocabulary is presented as a means to improve PATIENT safety that will be used in ME EQUIPMENT and ME SYSTEM design and markings as well as in the ACCOMPANYING DOCUMENTS.

Because this standard applies equally to simple INTERNAL ELECTRICAL POWER SOURCE operated or home-care ME EQUIPMENT as well as complex ~~LIFE-SUPPORTING~~ ME EQUIPMENT or ME SYSTEMS that include at least one function intended actively to keep alive or resuscitate a PATIENT, it has not been possible to provide specific requirements for many important issues. Particular standards should provide, as appropriate, more detailed requirements for their equipment category. The nomenclature and basic requirements of this standard should ensure a consistent approach for ALARM SYSTEMS across a wide range of equipment types.

Definition 3.1 – ALARM CONDITION

One consideration was the fact that an ALARM SYSTEM might generate ALARM SIGNALS for an ALARM CONDITION when no valid ALARM CONDITION existed (i.e. a FALSE POSITIVE ALARM CONDITION). A second was the issue that non-numerical values or conditions, or the use of an INTELLIGENT ALARM SYSTEM, might be used to determine the presence of an ALARM CONDITION, yet these factors might not have been included in previous definitions of ALARM LIMIT.

On this basis, the committee defined ALARM CONDITION as: “state of the ALARM SYSTEM when it has determined that a potential or actual HAZARD exists.” This definition recognizes that the ALARM SYSTEM can be correct or incorrect in its determination. It also indicates that this state will cause the ALARM SYSTEM, if it is enabled, to generate ALARM SIGNALS for the ALARM CONDITION to bring about OPERATOR response or awareness.

The committee then defined ALARM LIMIT as: “threshold used by an ALARM SYSTEM to determine an ALARM CONDITION.” The obvious example would be a numerical threshold (such as a threshold for a high heart rate ALARM CONDITION), but some thresholds might be non-numerical. Non-numerical conditions, such as a switch in the incorrect position, failure of the OPERATOR to enter certain data or the failure of the ALARM SYSTEM, can also cause an ALARM CONDITION. Furthermore, an INTELLIGENT ALARM SYSTEM can be used to determine an ALARM CONDITION, using an algorithm rather than a simple threshold value. Such an algorithm may have multiple inputs, perform logic-based or time-dependent averaging, use intelligent artefact filtering or employ other techniques so that the actual threshold changes over time or in response to other circumstances.

Definition 3.2 – ALARM CONDITION DELAY

Filtering in the algorithm that is monitoring for an ALARM CONDITION often causes ALARM CONDITION DELAY. For instance, a heart rate monitor can average the R-R interval for several

heartbeats. An abrupt change in R-R interval will not immediately cause a heart rate ALARM CONDITION because it will take several consecutive heartbeats for the calculated heart rate to exceed the ALARM LIMIT. Similarly, a median filter will cause an ALARM CONDITION DELAY. See also the rationale for Subclause 6.10.

Definition 3.3 – ALARM LIMIT

ALARM LIMIT refers to the criteria that cause the ALARM SYSTEM to generate ALARM SIGNALS. For a simple variable with a single level of urgency, a value selected by the OPERATOR can constitute the ALARM LIMIT. ALARM LIMIT can also refer to algorithmically determined criteria, the exact nature of which the OPERATOR cannot be aware, as well as the criteria structure applicable to a simple ALARM CONDITION variable for which there are multiple urgencies. See also the rationale for Definition 3.1.

Definition 3.5 – ALARM PAUSED

An OPERATOR can use ALARM PAUSED to avoid ~~nuisance~~ generation of NUISANCE ALARM SIGNALS before performing an action that is known to likely cause an ALARM CONDITION.

EXAMPLE 1 Intentional disconnection of a PATIENT breathing circuit to perform suction of the trachea.

EXAMPLE 2 Opening a transducer to air for zero calibration.

Definition 3.10 – ALARM SIGNAL GENERATION DELAY

Operating systems, microprocessor speed, software or network performance can influence the time between the onset of the ALARM CONDITION and generation of ALARM SIGNALS. If the delay is significant, the OPERATOR needs to know not only the mean time but also the distribution of times of the ALARM SIGNAL GENERATION DELAY, since with modern equipment it cannot always be possible to determine the absolute maximum time. If equipment is provided with a DISTRIBUTED ALARM SYSTEM, this duration should be for a typical set-up in its intended area of use. Problems that can be beyond the control of the MANUFACTURER include the speed and throughput of the network components. See also the rationale for Definition 3.2.

Definition 3.17 – DISTRIBUTED ALARM SYSTEM

~~In simple equipment, ALARM CONDITIONS are detected, processed and ALARM SIGNALS are generated within that single piece of equipment. Typical examples would be a stand-alone PATIENT monitor or a stand-alone ventilator.~~

~~In networked equipment, in a system of devices with a central station, or with devices that generate ALARM SIGNALS for caregivers (OPERATORS) at some distance from the PATIENT, more complicated ALARM SYSTEMS are used.~~

~~In a DISTRIBUTED ALARM SYSTEM one of the following takes place in different parts of the ME SYSTEM:~~

~~a) the detection of an ALARM CONDITION;~~

~~b) the processing of an ALARM CONDITION; or~~

~~c) generation of ALARM SIGNALS.~~

~~A DISTRIBUTED ALARM SYSTEM typically comprises at least two devices:~~

~~d) equipment which detects and processes ALARM CONDITIONS and that is generally connected directly to the PATIENT, and~~

~~e) a remote device (part of a ME SYSTEM) that generates ALARM SIGNALS and that may or may not be in the vicinity of the PATIENT.~~

~~Thus in a network of bedside PATIENT monitors, one bedside PATIENT monitor can generate ALARM SIGNALS for ALARM CONDITIONS from a different bedside PATIENT monitor. A central station can generate ALARM SIGNALS for ALARM CONDITIONS from multiple PATIENTS. A two-way~~

~~wireless communication system can generate ALARM SIGNALS for ALARM CONDITIONS to a caregiver in an area far removed from the PATIENT. All these are examples of DISTRIBUTED ALARM SYSTEMS.~~

~~A central station that processes incoming analog or digital signals from multiple PATIENTS and passes ALARM CONDITIONS back to bedside ME EQUIPMENT for generation of ALARM SIGNALS is a DISTRIBUTED ALARM SYSTEM.~~

In simple equipment, the SOURCE, INTEGRATOR and COMMUNICATOR are all within that single piece of equipment. Typical examples would be a stand-alone PATIENT monitor or a stand-alone ventilator.

In networked equipment, in a system with a central station, or with COMMUNICATORS for caregivers (OPERATORS) at some distance from the PATIENT, more complicated ALARM SYSTEMS are used.

In a DISTRIBUTED ALARM SYSTEM, one of the following functions is located in a different part of the ME SYSTEM:

a) the SOURCE;

b) the INTEGRATOR; or

c) the COMMUNICATOR.

A DISTRIBUTED ALARM SYSTEM typically comprises at least two devices:

d) a SOURCE and INTEGRATOR (and likely a COMMUNICATOR) that is generally connected directly to the PATIENT, and

e) a remote COMMUNICATOR (part of an ME SYSTEM) that might or might not be in the vicinity of the PATIENT.

Thus, in a network of bedside PATIENT monitors, one bedside PATIENT monitor can act as a COMMUNICATOR for ALARM CONDITIONS from a different bedside PATIENT monitor. A central station can act as a COMMUNICATOR for ALARM CONDITIONS from multiple PATIENTS. A two-way wireless communication system can act as a COMMUNICATOR for ALARM CONDITIONS to a caregiver in an area far removed from the PATIENT. All these are examples of DISTRIBUTED ALARM SYSTEMS.

A central station that processes incoming signals from multiple PATIENTS and as a SOURCE passes ALARM CONDITIONS back to bedside ME EQUIPMENT to act as a COMMUNICATOR is a DISTRIBUTED ALARM SYSTEM.

Definition 3.23 – INFORMATION SIGNAL

ALARM SIGNALS are only generated because of the presence of ALARM CONDITIONS. In contrast, INFORMATION SIGNALS are those which are generated regardless of whether or not an ALARM CONDITION is present, e.g. the tone of the pulse oximeter, the tone of the electrocardiograph, the waveform of the electrocardiograph, the heart rate numeric. INFORMATION SIGNALS are independent of ALARM CONDITIONS, although INFORMATION SIGNALS can frequently convey information that is "alarming" to the OPERATOR.

EXAMPLE 1 The decreasing tonal frequency of the auditory INFORMATION SIGNAL of some pulse oximeters. The decreased tone is "alarming" to the OPERATOR, but in itself is not an ALARM SIGNAL.

EXAMPLE 2 An electrocardiograph waveform indicating ventricular fibrillation.

EXAMPLE 3 A heart rate of 20 beats per minute.

Definition 3.24 – INTELLIGENT ALARM SYSTEM

An INTELLIGENT ALARM SYSTEM can use one or more variables or patterns of a variable or variables to make decisions that determine the presence or absence of an ALARM CONDITION

and its priority. INTELLIGENT ALARM SYSTEM methodologies can include but are not restricted to analysis of trends, limit comparisons, data redundancy, data fusion, rules, fuzzy logic controllers and neural networks. INTELLIGENT ALARM SYSTEMS are also known as smart ALARM SYSTEMS.

Definition 3.34 – REMINDER SIGNAL (see also ~~AAA.201.8.1~~ the rationale for 6.8.1)

A REMINDER SIGNAL reminds an OPERATOR that an ALARM CONDITION still exists although an ALARM SIGNAL is not being generated because it has been previously ~~acknowledged~~ inactivated by an ALARM SIGNAL inactivation state. Appropriate application of REMINDER SIGNALS should reduce the chance that the ALARM SYSTEM is unintentionally left in an ALARM SIGNAL inactivation state, thereby reducing the incidence of FALSE NEGATIVE ALARM CONDITIONS, without unreasonably increasing the chance that the REMINDER SIGNAL will itself be a nuisance signal.

A REMINDER SIGNAL should be considered when the equipment is expected to have multiple OPERATORS or when the equipment is expected to be unattended by an OPERATOR in NORMAL USE.

There are two possible modes of operation for a REMINDER SIGNAL. In the first mode, the REMINDER SIGNAL signals periodically when the ALARM SYSTEM is in an ALARM SIGNAL inactivation state, whether or not any ALARM CONDITION is present. In the second mode, the REMINDER SIGNAL signals only when the ALARM SYSTEM is in an ALARM SIGNAL inactivation state and an ALARM CONDITION is present.

The second mode provides the advantage of less signal pollution in the healthcare environment. There is a HAZARD with the second mode, however, if the OPERATOR forgets to enable the ~~generation of ALARM SIGNALS~~ COMMUNICATOR at the appropriate time.

An example of this situation is when an intubated and ventilated PATIENT requires suctioning in a critical care unit. In order to perform the suctioning, the ventilator is disconnected from the PATIENT. This would cause several ALARM SIGNALS to be generated. The time to repeatedly suction the PATIENT can take longer than the maximum AUDIO PAUSE interval and the OPERATOR would instead choose the AUDIO OFF state. After the suctioning is finished, the OPERATOR would have no auditory ALARM SIGNAL. In this situation, it might be preferable to have a REMINDER SIGNAL that the ALARM SYSTEM was put into AUDIO OFF state. After suctioning the PATIENT, the OPERATOR would hear the REMINDER SIGNAL and would be reminded to terminate the AUDIO OFF state.

In other settings, however, the second mode might be appropriate.

Depending on the design of the ALARM SYSTEM and the INTENDED USE of the ME EQUIPMENT, REMINDER SIGNALS can be auditory, visual, a combination of both or by another means.

Definition 3.37 – ACKNOWLEDGED

The ALARM SIGNAL inactivation state ACKNOWLEDGED differs significantly from the global AUDIO OFF or AUDIO PAUSE. Therefore using the same indication for either AUDIO OFF or AUDIO PAUSE and for this inactivation state would lead to confusion.

When initiating the state ACKNOWLEDGED, the OPERATOR is explicitly acknowledging the presence of the existing ALARM CONDITIONS while at the same time allowing the ALARM SYSTEM to generate ALARM SIGNALS for all other future ALARM CONDITIONS. Furthermore, the ALARM SYSTEM will self-terminate the ACKNOWLEDGED state for a specific ALARM CONDITION when that ALARM CONDITION is no longer true.

This way the OPERATOR acknowledges the fact that certain ALARM CONDITIONS are present, for which the OPERATOR does not want to receive auditory ALARM SIGNALS any more, but that at

the same time the OPERATOR wishes to be alerted to any new ALARM CONDITION that might arise to draw attention to a potentially new situation.

EXAMPLE 1 A TECHNICAL ALARM CONDITION that cannot be resolved at the moment or that arises from an intended OPERATOR action, but that can be ACKNOWLEDGED without suppressing PHYSIOLOGICAL ALARM CONDITIONS from other causes not affected by the TECHNICAL ALARM CONDITION.

EXAMPLE 2 Certain PHYSIOLOGICAL ALARM CONDITIONS (e.g. arrhythmia) that are known to be present can be ACKNOWLEDGED without suppressing other ALARM CONDITIONS from the same physiological source.

EXAMPLE 3 A PATIENT on home oxygen is being monitored with a portable monitor. When the PATIENT gets up and moves to a different room, the oxygen saturation falls with exercise. This fall in oxygen saturation is anticipated and it is expected to last only as long as the exercise itself, and then to recover to normal level within a few minutes. This ALARM CONDITION could be an appropriate use of indefinite ACKNOWLEDGED.

In contrast AUDIO OFF or AUDIO PAUSE is frequently associated with disabling the generation of auditory ALARM SIGNALS on a global scale for all ALARM CONDITIONS or a predetermined group of ALARM CONDITIONS.

Definition 3.38 – ADVISORY

See the rationale for Definition 3.41.

Definition 3.39 – ALARM FATIGUE

There is no universally accepted definition of ALARM FATIGUE. The term is commonly used to describe one or more related conditions that cause degradation of OPERATOR response to ALARM SIGNALS. The degraded response can be delayed, inadequate, inappropriate or absent. ALARM FATIGUE means a degraded response caused by one or more of the following:

– ALARM FLOOD;
– high number of FALSE POSITIVE ALARM SIGNALS;
– high number of CLINICALLY NONACTIONABLE ALARM SIGNALS, including receiving ALARM SIGNALS from other PATIENTS in the area for whom the OPERATOR is not responsible;
– high number of auditory ALARM SIGNALS that are insufficient for detection, identification, localization or prioritization;
– volume (sound pressure level) of the auditory ALARM SIGNAL (too quiet or too loud);
– ALARM SIGNALS that contain insufficient information to support planning a response to the underlying cause of the ALARM CONDITION (e.g. single ALARM SIGNAL to announce a large number of ALARM CONDITIONS or a visual ALARM SIGNAL that is non-specific); or
– other environmental aspects (i.e. ambient noise, ambient light and glare, level of OPERATOR rest, work area temperature, additional workflow interrupts) that impair the OPERATOR's cognitive abilities.

Given OPERATORS' response to the ALARM SIGNAL is based on the percentage of ALARM CONDITIONS they believe are not false [77], it stands to reason that ALARM SYSTEM design is a key factor to help prevent an OPERATOR from experiencing ALARM FATIGUE, and the resulting potential for HARM.

While it stands to reason that the total rate of ALARM SIGNALS is a contributor to ALARM FATIGUE [73], [74], [75], there exists some controversy to contradict that position [78]. There is available evidence that ALARM FATIGUE can be mitigated through the usage of better ALARM SYSTEMS, algorithms and ALARM SETTINGS, and careful consideration to deployment environment, policy, training, and technology selection [58], [59], [79], [80].

Definition 3.41 – ALERT

The committees received comments requesting that a definition for ALERT be added to the document. It is recognized that the terms ALERT and ALARM CONDITION have been used interchangeably and typically, the MANUFACTURERS of electronic medical record software have

purposefully used the term ALERT instead of ALARM CONDITION so that their products are not construed as being part of the PATIENT monitoring system regardless of whether or not the notification was being used as a RISK CONTROL. Some standards [76] have defined an ALERT as a synonym for both what this document calls an ALARM CONDITION and an ADVISORY. These standards also define an ALERT as a signal while this document considers both an ALARM CONDITION and an ADVISORY to be a state that are communicated by signals.

The committees discussed the fact that an ALARM CONDITION is defined as providing a means of RISK CONTROL relating to HARM while a condition resulting in an ADVISORY does not, but the committees agreed that definitions should be provided to clarify the difference. And, it is noted that this document had not previously used the term ALERT or ADVISORY in any context. Since a direct RISK CONTROL is not an outcome of an ADVISORY notification, the definitions have been carefully worded to ensure that an ADVISORY would not be confused with ALARM CONDITION. ADVISORIES are then a type of INFORMATION SIGNAL that notifies an OPERATOR of conditions that relate to the PATIENT, equipment or workflow, but are not an indicator of potential HARM.

The examples provided are types of ADVISORIES that help the OPERATOR's workflow or raise the OPERATOR's cognitive awareness of a condition of the PATIENT, equipment or system.

EXAMPLE 1 An ADVISORY that the next blood draw is needed in approximately two hours notifies the OPERATOR that workflow includes obtaining a blood sample. This ADVISORY does not provide a RISK CONTROL, but rather is a notification to the OPERATOR that in the near future they should perform that task.

EXAMPLE 2 The battery status indicator shows the amount of battery charge remaining which notifies the OPERATOR of the condition of the ME EQUIPMENT and can notify them of a step in their workflow that will need to be done hours in the future, but they have not yet received an ALARM CONDITION for the state of the battery. A low battery LOW PRIORITY TECHNICAL ALARM CONDITION would be treated differently in that continued use of the ME EQUIPMENT will result in loss of power (and therefore loss of monitoring capability) and there is a RISK of PATIENT HARM.

EXAMPLE 3 Consider the case where a PATIENT has a high INR (International Normalised Ratio, an indication of clotting time). In the order entry system, the notification to the OPERATOR that an additional anticoagulant dose is contraindicated could be an ADVISORY since there are many additional workflow steps prior to the administration of the anticoagulant. The type of OPERATOR notification depends on where the anticoagulant dose administration is in the clinical workflow. If the dose is hours away the notification to the clinical OPERATOR can be an ADVISORY – an INFORMATIONAL SIGNAL. On the other hand, if the clinical OPERATOR is about to administer the dose, a HIGH PRIORITY or at least MEDIUM PRIORITY ALARM CONDITION is appropriate because immediate or prompt action will be needed to prevent the HARM that would likely result from an overdose of anticoagulant.

Definition 3.44 – CLINICALLY ACTIONABLE

It can sometimes be difficult to determine if an event is CLINICALLY ACTIONABLE or not. One specific caregiver (physician, nurse, respiratory therapist, other) can notice an ALARM SIGNAL and make their own decision about whether to take action or not. Other caregivers can or might not agree with the decision of that caregiver. Indeed, reasonable, well-trained, expert caregivers frequently have different opinions about optimal PATIENT care.

For the purposes of this document, a single caregiver does not suffice to determine if an event is CLINICALLY ACTIONABLE or not. Instead, one needs to defer to a hypothetical "panel of experts" (physicians, nurses, respiratory therapists, or others) to make that determination. The hypothetical "panel of experts" is analogous to the concept of state-of-the-art. For the purposes of this document, such a panel is not required to be convened by any group (MANUFACTURER, RESPONSIBLE ORGANIZATION, OPERATOR, etc.) under any circumstances. It should be noted, however, that such panels are commonly convened by RESPONSIBLE ORGANIZATIONS to review situations of potential or actual PATIENT injury. A common example is a Hospital Quality Assurance Committee. In any case, if a majority of a hypothetical "panel of experts" would agree that action should be taken, then the event can be considered CLINICALLY ACTIONABLE. Table A.1 maps ALARM SYSTEM output to perceived OPERATOR action [29].

Table A.1 – ALARM SYSTEM output to perceived OPERATOR action

ALARM SYSTEM output	Resulting OPERATOR perception	Scientific definition	CLINICALLY ACTIONABLE ALARM CONDITION?
ALARM SYSTEM generates an ALARM SIGNAL for a HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITION	ALARM SYSTEM made a mistake	FALSE POSITIVE ALARM CONDITION	No
	ALARM SYSTEM performed correctly but the OPERATOR decides no action is required to prevent HARM.	Irrelevant POSITIVE ALARM CONDITION A valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM, but based on the clinical context, the OPERATOR concludes that no action is required to prevent HARM.	
	ALARM SYSTEM performed correctly and the OPERATOR takes action.	TRUE POSITIVE ALARM CONDITION	Yes
ALARM SYSTEM does not generate an ALARM SIGNAL for a HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITION [a]	ALARM SYSTEM made a mistake	FALSE NEGATIVE ALARM CONDITION	Yes
	ALARM SYSTEM performed correctly but the OPERATOR decides action is required.	Relevant NEGATIVE ALARM CONDITION [b] Absence of an ALARM CONDITION when a valid triggering event has not occurred in the PATIENT, the equipment or the ALARM SYSTEM, but based on the clinical context, the OPERATOR concludes an action is required to prevent HARM.	
	ALARM SYSTEM performed correctly and the OPERATOR takes no action.	TRUE NEGATIVE ALARM CONDITION	No

[a] It could be that the ALARM SYSTEM reports a LOW PRIORITY ALARM CONDITION or no ALARM CONDITION – No action.

[b] It is recognized that a special case of the relevant FALSE NEGATIVE ALARM CONDITION can effectively be caused by an ALARM SIGNAL inactivation state.

Definition 3.45 – CLINICALLY NONACTIONABLE

See the rationale for 3.44.

Definition 3.48 – DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS

A DIS is equivalent to "a DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS" as described in IEC 60601-1-8:2006+A1:2012, 6.11.2.2.2.

Definition 3.50 – NUISANCE ALARM SIGNAL

See the rationale for 3.44.

Subclause 5.2.1 – Instructions for use

[First ~~dash~~ bullet]

OPERATORS have found that in legacy equipment the terminology for the ALARM SIGNAL inactivation states has been ambiguous [18]. This has caused confusion and OPERATOR error when an OPERATOR has accidentally indefinitely inactivated (ALARM OFF, AUDIO OFF) instead of

temporarily inactivating the generation of ALARM SIGNALS (ALARM PAUSED, AUDIO PAUSED) due to terminology confusion and inconsistent markings of controls (mode error).

EXAMPLE Some legacy equipment uses the control marking "silence" for ALARM OFF while other equipment uses the control marking "silence" for ALARM PAUSED.

When providing an overview of the ALARM SYSTEM in the instructions for use, it is highly desirable that MANUFACTURERS use the terminology for the ALARM SIGNAL inactivation states that are used in this collateral standard. Writers of particular standards should also use this terminology.

[Fourth ~~dash~~ bullet]

The instructions for use should provide details of any pre-use checks necessary for safe use. [19] These checks could be automatic or be provided by a pre-use checklist. Most equipment will not be fail-safe against a single functional failure such as loudspeaker failure. A faulty loudspeaker can result in an ALARM CONDITION not being recognized due to the absence of an auditory ALARM SIGNAL. To reduce the probability of a FALSE NEGATIVE ALARM CONDITION, the ALARM SYSTEM should be checked at regular intervals.

Long and difficult pre-use checkouts will be resisted by OPERATORS. [20],[22],[24] Ideally, equipment would have an automated or semi-automated checkout to reduce the burden on the OPERATOR. This checkout could include testing of the ALARM SYSTEM, for instance by testing auditory and visual ALARM SIGNALS and asking the OPERATOR to verify their function.

Alternatively, the checkout might include setting the ALARM LIMITS and deliberately introducing a condition that violates those limits, or other means to deliberately generate an ALARM SIGNAL.

Subclause 6.1.1 – General

It can be difficult to classify some ALARM CONDITIONS as to whether they are a PHYSIOLOGICAL ALARM CONDITION (PATIENT-related) or a TECHNICAL ALARM CONDITION (equipment–related).

Subclause 6.1.2 – ~~ALARM CONDITION priority~~ Determination of ALARM CONDITIONS and assignment of priority

ALARM CONDITIONS should be prioritized based on the urgency of the required OPERATOR response or awareness of the situation that triggered the ALARM CONDITION. Priority is assigned through RISK ANALYSIS, either by the writer(s) of a particular standard or by the MANUFACTURER.

NOTE Some ALARM SYSTEMS have OPERATOR-configured or RESPONSIBLE ORGANIZATION-configured priorities.

MANUFACTURERS assign ALARM CONDITION priorities based on RISK ANALYSIS. This RISK ANALYSIS should primarily consider the severity and rapidity of onset of HARM if the ALARM CONDITION is not corrected. It should also consider other factors such as the sensitivity and specificity of the ALARM CONDITION for the actual event in the PATIENT or the equipment. The level of the priority of ALARM SIGNAL only suggests to the OPERATOR the speed at which the OPERATOR should respond to, or be aware of, an ALARM CONDITION. The actual speed of response or awareness required is ultimately based on the assessment by the OPERATOR.

"Immediate" category problems are those that are likely to cause PATIENT injury or death within seconds to several minutes if uncorrected. Few problems fall into the "immediate" category.

EXAMPLE 1 Asystole

EXAMPLE 2 Ventricular fibrillation

EXAMPLE 3 Failure of a cardiac support device (intra-aortic balloon pump, cardiopulmonary bypass machine)

EXAMPLE 4 Sustained high airway pressure

EXAMPLE 5 Extreme hypoxemia

EXAMPLE 6 Sustained high-energy radiation beam

"Prompt" category problems, on the other hand, do not cause PATIENT injury or death until at least several to many minutes have elapsed.

EXAMPLE 7 Many cardiac arrhythmias

NOTE Most cardiac arrhythmias would be prompt or delayed.

EXAMPLE 8 High or low blood pressure

EXAMPLE 9 Apnea (unless prolonged or associated with extreme hypoxia)

EXAMPLE 10 Mild hypoxemia

EXAMPLE 11 High or low pCO_2

"Delayed" category problems cause PATIENT injury only after many minutes to hours have passed.

EXAMPLE 12 Failure of an infusion pump for maintenance of intravenous fluids

EXAMPLE 13 Failure of an enteral feeding pump

EXAMPLE 14 Failure of a PATIENT weighing system

The choice of priority should be based upon RISK ANALYSIS. In general the lowest priority compatible with the RISK ANALYSIS should be selected. In particular, HIGH PRIORITY ALARM SIGNALS should be reserved for those few ALARM CONDITIONS that truly require immediate response for PATIENT safety—that is, a response within seconds to a couple of minutes. Many types of equipment will not require any HIGH PRIORITY ALARM SIGNALS.

ME EQUIPMENT ALARM SYSTEMS are a protective measure used to minimize risks to PATIENT, personnel, and equipment. In certain therapeutic ME EQUIPMENT, a HAZARDOUS SITUATION could develop so rapidly, and cause injury or damage so rapidly, that OPERATOR response to even a well-designed ALARM SYSTEM would be too slow. In such ME EQUIPMENT, an automatic system of mitigating the HAZARDOUS SITUATION is highly desirable, if not essential. The general standard and many particular standards require such safety mechanisms. It is recognized, however, that no ME EQUIPMENT could have protection against every possible HAZARD, or in the presence of multiple fault conditions.

It should be recognized that, almost without exception, OPERATORS have many additional duties in addition to responding to ALARM SIGNALS. The occurrence of a HIGH PRIORITY ALARM SIGNAL, whether the result of a true positive ALARM CONDITION or a FALSE POSITIVE ALARM CONDITION, generally requires the OPERATOR to immediately stop what he or she is doing and address the cause of the ALARM CONDITION. As an example, the OPERATOR might be in the middle of a sterile procedure on a different PATIENT, and that procedure would be interrupted and delayed by the need to respond to a HIGH PRIORITY ALARM SIGNAL.

A MEDIUM PRIORITY ALARM SIGNAL is also an interruption to the OPERATOR, but it allows a minute or a few minutes for the OPERATOR to finish a brief task before addressing the cause of the ALARM CONDITION, or to find an alternate person who can address the cause.

A LOW PRIORITY ALARM SIGNAL should not interrupt the OPERATOR, but rather the OPERATOR should be able to address the cause of the ALARM CONDITION at a convenient time, for instance, after many minutes, or when he or she next checks the ME EQUIPMENT. Even ME EQUIPMENT that is not continuously attended is checked by the OPERATOR at regular intervals. Events that require interruption of the OPERATOR should not be LOW PRIORITY ALARM CONDITIONS, but rather they should be MEDIUM PRIORITY or even HIGH PRIORITY ALARM CONDITIONS. In addition, if the OPERATOR fails to address a LOW PRIORITY ALARM CONDITION in a timely fashion, the ALARM CONDITION should ESCALATE to a MEDIUM PRIORITY or even a HIGH PRIORITY ALARM CONDITION.

Subclause 6.2 – Disclosures for INTELLIGENT ALARM SYSTEM

Every effort should be made in designing equipment to integrate ALARM SYSTEMS into a coordinated system, minimizing the total number of ALARM SIGNALS to which an OPERATOR

needs to respond. This is important as multiple ALARM CONDITIONS can generate ALARM SIGNALS when one problem occurs.

An INTELLIGENT ALARM SYSTEM need not simultaneously generate ALARM SIGNALS for all active ALARM CONDITIONS. The equivalent safety objective can be achieved by priority ranking and generating ALARM SIGNALS for a subset of the current active ALARM CONDITIONS. When multiple concurrent ALARM CONDITIONS exist, the relative importance of each ALARM CONDITION can be used to internally rank the ALARM CONDITION within a given priority. This internal priority ranking can be used to determine which particular ALARM CONDITION is causing the generation of ALARM SIGNALS or can be used to suppress the generation of ALARM SIGNALS for lower internal priority ALARM CONDITIONS. Multiple ALARM CONDITIONS of the same priority and the same or very similar meaning can also be incorporated into a single message (visual ALARM SIGNAL). These techniques are used to reduce the number of ALARM SIGNALS that an OPERATOR is required to respond to on ALARM SYSTEMS with multiple, related ALARM CONDITIONS. The use of INTELLIGENT ALARM SYSTEMS can be an effective way of reducing the number of ALARM SIGNALS that are generated during transient events, thus reducing the number of ~~nuisance or FALSE POSITIVE or FALSE NEGATIVE ALARM CONDITIONS~~ CLINICALLY NONACTIONABLE ALARM CONDITIONS. The use of INTELLIGENT ALARM SYSTEMS also can be an effective way of reducing the number of FALSE NEGATIVE ALARM CONDITIONS.

To assign an ALARM CONDITION priority, an algorithm of an INTELLIGENT ALARM SYSTEM might consider the magnitude of the deviation of a monitored variable from the ALARM LIMIT, the rate of change of the variable, the duration of the ALARM CONDITION and the presence or absence of any other concurrent ALARM CONDITIONS, redundant ~~sources of~~ information or values of other variables.

After an ALARM CONDITION has generated ALARM SIGNALS, subsequent or persisting ALARM CONDITION(S) can cause the ALARM SYSTEM to change the priority of the ALARM CONDITION or to reassess the initial ALARM CONDITION (and perhaps cancel its ALARM SIGNAL generation) through the use of an INTELLIGENT ALARM SYSTEM algorithm.

INTELLIGENT ALARM SYSTEMS are permitted change characteristics of the ALARM SIGNALS to indicate a change in urgency. These changes can include, but are not limited to, changing the intensity of BURST volume, INTERBURST INTERVAL or PULSE FREQUENCY.

The algorithms of INTELLIGENT ALARM SYSTEMS should be evaluated and validated to ensure that the equipment meets the operational needs of the expected OPERATOR in the expected environment of its INTENDED USE. For methods of evaluation of USABILITY see ~~IEC 60601-1-6~~ IEC 62366-1.

Subclause 6.3.2 – Visual ALARM SIGNALS

Visual ALARM SIGNALS should indicate to the OPERATOR the presence and level of urgency of any ALARM CONDITION, help the OPERATOR to locate the specific PATIENT or equipment where an OPERATOR response or awareness is required, and identify to the OPERATOR the specific ALARM CONDITION.

There are two requirements for visual ALARM SIGNALS:

- *a "distant" requirement that the presence of an ALARM CONDITION and its priority are correctly perceived from a distance of 4 m (far away); and*
- *an "OPERATOR'S POSITION" requirement that the visual ALARM SIGNAL indicating the specific ALARM CONDITION and its priority are legible from at least 1 m or from the OPERATOR'S POSITION.*

It is possible to comply with the requirements of this collateral standard using either a single visual ALARM SIGNAL or with separate "distant" and "OPERATOR'S POSITION" visual ALARM SIGNALS.

The "distant" requirements are only required when they are necessary to allow the OPERATOR to locate the part of the ALARM SYSTEM that is generating ALARM SIGNALS. The ability to identify the priority of visual ALARM SIGNALS from a distance of 4 m allows the OPERATOR to decide which equipment to respond to first when simultaneous ALARM SIGNALS occur in a multi-equipment environment without having first to go to the OPERATOR'S POSITION.

The ability to discriminate between specific ALARM CONDITIONS and their priorities from a distance of 1 m or the OPERATOR'S POSITION aids the OPERATOR in deciding what actions need to be taken. MANUFACTURERS can choose to also make this "OPERATOR'S POSITION" visual ALARM SIGNAL legible from a distance of 4 m.

The committee considered the use of the standard general alarm symbol and urgent alarm symbol (triangle with 1 or 2 and extended to 3 curved lines) to represent LOW, MEDIUM or HIGH PRIORITY ALARM CONDITIONS. Concern was raised that they are too similar and would be impossible to distinguish on many displays at a viewing distance of 1 m to 4 m.

The committee recognized this limitation, and decided that adding optional elements could be used to indicate the priority.

MANUFACTURERS are free to enhance legibility by any of several means. For instance, the symbols could be coloured red or yellow, or placed on a red or yellow background. Additional symbols, letters, or words could be added to these symbols to enhance distinctiveness. One suggestion was to use three identical symbols to indicate HIGH PRIORITY, two identical symbols for MEDIUM PRIORITY and a single symbol for LOW PRIORITY.

Subclause 6.3.2.2.1 – ~~Characteristics~~ 4 m (distant) ~~of~~ visual ALARM SIGNALS

The committee considered using the triangle symbol (IEC 60417-5307) with 1, 2 (IEC 60417-5308) or 3 curved lines to represent the presence of LOW, MEDIUM OR HIGH PRIORITY ALARM CONDITIONS. Some comments suggested that such symbols were too similar and would be impossible to distinguish on many displays, particularly at a viewing distance of 4 m.

The committee recognized this limitation and decided to allow other methods to indicate priority. For instance, the visual ALARM SIGNAL representing a HIGH PRIORITY ALARM CONDITION could be coloured red, or placed on a red background. Additional symbols, letters or words could be added to improve distinctiveness. One suggestion was to use three identical triangles for HIGH PRIORITY ALARM CONDITION, two identical triangles for MEDIUM PRIORITY and a single triangle for LOW PRIORITY.

In Table 2, cyan is added as an option for indicating LOW PRIORITY. Differentiating LOW PRIORITY from MEDIUM PRIORITY by colour is an improvement in USABILITY. Historically, only red, yellow and green coloured lamps were readily available. A much broader range of colours is readily available today. The committee has chosen one of the complementary colours that is readily available.

Subclause 6.3.3 – Auditory ALARM SIGNALS

The primary purpose of auditory ALARM SIGNALS is to get the OPERATOR'S attention. Additionally, they should help the OPERATOR identify:

– the onset or presence of ALARM CONDITIONS;

– the urgency of the required OPERATOR response; and

– the location of the ~~device~~ COMMUNICATOR generating ALARM SIGNALS.

The requirements of this subclause are intended to ensure that auditory ALARM SIGNALS in equipment are able to fulfill this purpose.

Equipment that is continuously attended by the OPERATOR in NORMAL USE has different auditory ALARM SIGNAL requirements from equipment that is unattended by the OPERATOR in NORMAL USE.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List element d), 1) i)]

It is the intent of the committees to make the ALARM SIGNALS of Annex G mandatory at the next amendment or edition of this document. MANUFACTURERS that utilize the ALARM SIGNALS of Annex G should report their experiences to the committees. IEC/62A can be reached at https://www.iec.ch/dyn/www/f?p=103:7:0::::FSP_ORG_ID:1359 [viewed 2020-07-09]. ISO/SC3 can be reached at: https://www.iso.org/committee/52012.html [viewed 2020-07-09].

[List element d), 2)]

A different technology implies something other than electronically generated tones. There are a variety of means for generating auditory ALARM SIGNALS, including buzzers, electronic sound generators and speech synthesizers. At least some of the methods described above can be used to indicate priority regardless of the means of generating the signal.

[List element ~~a~~ d), 3)]

Distinctively different auditory ALARM SIGNALS for HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY are specified in Table 3 and Table 4. For any OPERATOR to identify the onset or presence of ALARM CONDITIONS by means of auditory ALARM SIGNALS, they should be audibly different from other sounds in the PATIENT care area. The HIGH PRIORITY auditory ALARM SIGNAL is designed to be very different from most other sounds (e.g. pagers, telephones, etc.).

The ALARM SIGNALS are priority encoded so that the OPERATOR can readily discern the priority of the associated ALARM CONDITION by auditory means alone.

Mandating the presence of at least one set of auditory ALARM SIGNALS that complies with Annex G, Table 3 and Table 4 or uses alternative technology (i.e., not based on PULSES and BURSTS) such as voice synthesis ensures that the RESPONSIBLE ORGANIZATION always has the option of selecting one recognizable, standard set of auditory ALARM SIGNALS on all ALARM SYSTEMS. Additional sets that comply with Table 3 and Table 4 and ~~Annex F~~ Annex G can be provided without any need for VALIDATION. Additional sets that do not comply with Table 3 and Table 4 can be provided so long as they are priority encoded and are appropriately validated. The RESPONSIBLE ORGANIZATION can configure any one of these as the DEFAULT ALARM PRESET.

Table 3 and Table 4 indicate the difference in priority primarily by the number of PULSES in a BURST and their rhythm. A HIGH PRIORITY BURST comprises 10 PULSES, repeating two identical groups of 5 PULSES with a pause between each group. A MEDIUM PRIORITY BURST comprises 3 PULSES and LOW PRIORITY BURSTS can contain one or two PULSES. Other factors can be used to provide additional priority or relative urgency information. Examples include inter-PULSE interval, inter-BURST interval, PULSE width and other PULSE characteristics. Higher priority auditory ALARM SIGNALS should use faster BURSTS with shorter PULSES that are repeated more frequently than lower priority ALARM SIGNALS.

Auditory ALARM SIGNALS that comply with this standard should sound almost identical to auditory ALARM SIGNALS that comply with ISO 9703-2.

Mandating auditory ALARM SIGNALS in Table 3 and Table 4 or Annex G ensures that the RESPONSIBLE ORGANIZATION always has the option of selecting recognizable, standard auditory ALARM SIGNALS for an ALARM SYSTEM.

Urgency of the required OPERATOR response is indicated by the different BURST patterns, BURST speeds, PULSE widths, repetition rates and relative volumes that are specified for LOW,

MEDIUM and HIGH PRIORITY ALARM SIGNALS in Table 3 and Table 4. Annex D indicates factors that affect the perceived urgency of a BURST. MANUFACTURERS can find this helpful when choosing values that comply with Table 3 and Table 4 and are appropriate for the relative degree of urgency of OPERATOR response to a particular ALARM CONDITION. ESCALATION of ALARM CONDITION urgency within a priority ranking can be indicated to the OPERATOR by similar means.

~~*Auditory ALARM SIGNALS that comply with Table 3 and Table 4 are not required to incorporate melodies. However, if melodies are used, their meanings are required to be as specified in Annex F or be designed so as to preclude the possibility of confusion with Annex F. Annex F therefore attempts to standardize pitch pattern (melody) for the majority of ALARM SIGNALS complying with Table 3 and Table 4.*~~

~~*Often (as has already been stated), many ALARM SYSTEMS generate ALARM SIGNALS in one PATIENT care area. [23] Even if the pitch of all PULSES in a BURST is the same, many OPERATORS can learn to recognize differences in tone, overall pitch, and repetition rate. If the pitch of individual PULSES is varied in such a way as to create simple standard "melodies", the average person can learn to recognize approximately six to eight melodies and to associate them with categories of equipment.*~~

~~*If melodies are restricted in number and are reliably associated with defined equipment categories, OPERATORS are likely to "learn" what a particular melody means and to use this information to help them locate the source of an ALARM CONDITION. If unrestrained proliferation of melodies were to occur, a potentially large number of different melodies would likely be presented to the OPERATOR. This would generate such confusion as to render them useless and potentially hazardous. On the other hand, if all equipment of a given type made exactly the same sound, it might be difficult to identify the source of the ALARM SIGNAL by auditory means in situations where many similar items of equipment are present in one location.*~~

~~The committee was of the opinion that the RISK ANALYSIS favoured some degree of regulation of melodies for ME EQUIPMENT. The challenge was to choose an appropriate degree of regulation without being excessively design restrictive.~~

~~The melodies of Annex F were derived by a musically trained subgroup of the experts from the committee. Each melody was chosen to be distinctively different from the others. The assignment of particular melodies to categories was deliberate and based upon a psychoacoustic association between the melody and the category. For more information, see the rationale to Annex F.~~

~~*MANUFACTURERS intending to use melodies are encouraged to select the most appropriate melody from those in Annex F on the basis of the primary function of their equipment. If they intend to use some other melody, it should not be easily confused with any other melody of Annex F unless the meaning (category) is the same. Note that the defining characteristic of a melody is the relative difference in pitch between successive PULSES in a BURST. Absolute pitch variation is acceptable.*~~

~~*Multi-function equipment can either use one melody that indicates the primary function of the equipment or can apply a different melody to each functional sub-system of the equipment. A specific melody that indicates equipment failure or power down can additionally be used on any equipment in addition to the melody indicating the primary function of the equipment.*~~

~~**[List element b d), second dash)]**~~

~~*A different technology implies something other than electronically generated tones. There are a variety of means for generating auditory ALARM SIGNALS, including buzzers, electronic sound generators and speech synthesizers. At least some of the methods described above can be used to indicate priority regardless of the means of generating the signal.*~~

Often (as has already been stated), many ALARM SYSTEMS generate ALARM SIGNALS in one PATIENT care area [23]. Even if the pitch of all PULSES in a BURST is the same, many OPERATORS can learn to recognize differences in tone, overall pitch, and repetition rate. If the pitch of individual PULSES is varied in such a way as to create simple standard "melodies", the average person can learn to recognize approximately six to eight melodies and to associate them with categories of equipment.

Multifunctional equipment can either use one ALARM SIGNAL that indicates the primary function of the equipment or can apply a different ALARM SIGNAL to each functional sub-system of the equipment. A specific ALARM SIGNAL that indicates equipment failure or power down can additionally be used on any equipment in addition to the ALARM SIGNAL indicating the primary function of the equipment.

Table 3 – Characteristics of the BURST of auditory ALARM SIGNALS
Table 4 – Characteristics of the PULSE of auditory ALARM SIGNALS

Table 3 and Table 4 are based on the requirements for auditory ALARM SIGNALS that were found in ISO 9703-2 [26]. These distinctive patterns or rhythms have been used for more than a decade and have been well accepted clinically. Table 3 and Table 4 are slightly different from the equivalent tables in ISO 9703-2. The modifications were intended to simplify interpretation and increase flexibility rather than introduce significant change. Auditory ALARM SIGNALS that complied with ISO 9703-2 should also comply with this collateral standard.

~~Spatial localization of an auditory ALARM SIGNAL is useful because it helps the OPERATOR to identify the source of the ALARM CONDITION promptly. Ensuring that four or more audible higher-frequency harmonics are present in an auditory ALARM SIGNAL enhances spatial localization. Spatial localization is poor at low frequencies, so the lower acceptable limit for fundamental frequency is set at 150 Hz. Hearing impairment from noise exposure or age usually impairs perception of higher frequencies, so that to ensure that all harmonics are audible, the upper limit for fundamental frequency is set at 1 000 Hz.~~

Spatial localization of an auditory ALARM SIGNAL is useful because it helps the OPERATOR to identify the origin of the ALARM SIGNAL promptly. Ensuring that at least four different frequency components are audible, the upper limit for them is set to 4 000 Hz. In addition, for one frequency component of them, the upper limit is set to 1 000 Hz, which makes it audible in distant areas (e.g. outside of an open door). *An even better approach is to create multiple notes at the same time (i.e. a chord), with each note having several harmonics. The more audible peaks in the frequency domain within the indicated band, the better the localization.*

Selection of the INTERBURST INTERVAL requires RISK ANALYSIS and careful consideration. Shorter INTERBURST INTERVALS can result in noise pollution and impair communication among OPERATORS or other personnel who are trying to address the problem, and are inappropriate for equipment that is intended to be continuously attended by the OPERATOR in NORMAL USE. On the other hand, longer INTERBURST INTERVALS can negatively affect the ability of the OPERATOR to identify, in a timely manner, ~~the source of the ALARM CONDITION~~ the origin of the ALARM SIGNAL. This is particularly true for equipment intended to be unattended by the OPERATOR in NORMAL USE. MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application.

The main differences between ISO 9703-2 and this collateral standard and the reasons for the current requirements, are described below:

a) The new PULSE spacing intervals are defined differently from ISO 9703-2 and provide greater design flexibility. PULSE spacing is now defined as the time from the end of one PULSE to the start of the next. As a result there is no possibility of overlap, which could occur in ISO 9703-2. The actual values permit all auditory ALARM SIGNALS complying with ISO 9703-2 except for HIGH PRIORITY ALARM SIGNALS in which the PULSES almost overlap. For obvious reasons, very few MANUFACTURERS actually did this. The committee

considered that PULSES should have reasonable gaps between them, and that near-overlapping of PULSES should not be permitted.

b) In ISO 9703-2, the intended rhythm could not be achieved if each PULSE spacing was the same. The redrafted Table 3 addresses this problem. To ensure that the distinctive pattern is achieved, yet provide some flexibility in overall timing, this standard requires all INTERBURST INTERVALS within a BURST to have the same duration. A tolerance of ±5 % seemed appropriate.

c) The time between the two five-PULSE groups that comprise a HIGH PRIORITY ALARM SIGNAL (time between 5th and 6th PULSES) is now defined as the time from the end of the last PULSE in the first group to the start of the first PULSE in the next. The equivalent requirement in ISO 9703-2 was defined as the time from the start of the first group to the start of the next. In practice, this time could be unacceptably short. Therefore, few MANUFACTURERS actually complied with this ISO 9703-2 requirement. Instead, they chose the interpretation that is now used in this collateral standard. The intent of the pause was that the first group of PULSES would attract the OPERATOR'S attention, and the second group would emphasize the importance of the ALARM CONDITION and aid in identifying ~~the source of the ALARM CONDITION~~ the origin of the ALARM SIGNAL once the OPERATOR'S attention had been gained.

d) A greater range of INTERBURST INTERVALS is permitted. The existing requirement in ISO 9703-2 is not suitable for ALARM SYSTEMS that are unattended by the OPERATOR in NORMAL USE. Selection of the most appropriate INTERBURST INTERVAL requires RISK ANALYSIS and careful consideration of the clinical requirement for the ALARM CONDITION in its intended environment of use. Short INTERBURST INTERVALS can result in noise pollution and impair communication among OPERATORS or other personnel who are trying to address the problem, and are inappropriate for ALARM SYSTEMS that are always attended by the OPERATOR in NORMAL USE. On the other hand, long INTERBURST INTERVALS can negatively affect the ability of the OPERATOR to promptly identify ~~the source of the ALARM CONDITION~~ the origin of the ALARM SIGNAL. MANUFACTURERS and writers of particular standards are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Factors to consider include:

– whether the ALARM SYSTEM is intended to be always attended by the OPERATOR in NORMAL USE. In this case a longer INTERBURST INTERVAL is appropriate;

  EXAMPLE Anesthesia machines.

– the kind of equipment involved;

  EXAMPLE An enteral feeding pump should have a longer INTERBURST INTERVAL than a critical care ventilator.

– whether the ALARM SYSTEM is connected to a ~~remote~~ DISTRIBUTED ALARM SYSTEM, e.g. a central monitoring system. An ALARM SYSTEM that is not so connected (standalone equipment) should consider a shorter INTERBURST INTERVAL, in order to facilitate identification;

  the presence and effectiveness of additional or alternative notification systems (secondary visual ALARM SIGNALS, vibratory ALARM SIGNALS, ALARM SIGNAL lights in hallways, alarm paging systems, etc). Effective alternative ~~generation of ALARM SIGNALS~~ COMMUNICATORS will permit longer INTERBURST INTERVALS.

e) HIGH PRIORITY auditory ALARM SIGNAL PULSES should be “faster” than MEDIUM PRIORITY auditory ALARM SIGNAL PULSES to ensure that they are perceived as being more urgent. Hence, the requirement that the effective PULSE duration for HIGH PRIORITY ALARM SIGNALS is less than that for MEDIUM PRIORITY.

f) The LOW PRIORITY auditory ALARM SIGNAL is optional, but if present can comprise one or two PULSES. It should be relatively unobtrusive and perceived as less urgent than a MEDIUM PRIORITY ALARM SIGNAL.

g) Pitch is now permitted to rise and fall during a BURST. ISO 9703-2 required that changes in pitch proceed in one direction only. The committee considered this to be without safety advantage and excessively design restrictive.

h) ~~The ISO 9703-2 requirement for the presence of four harmonics has been slightly modified. Reflections and standing waves from pure sine wave auditory signals can make it very difficult to find where they are coming from. Ensuring that four or more audible~~

~~harmonics are present in an auditory ALARM SIGNAL enhances spatial localization. These harmonics should be neither so soft as to be inaudible nor so loud as to be excessively dominant. Because tight control of harmonic content can be extremely difficult in simple systems, a value of plus or minus 15 dB (relative sound pressure level) was chosen as a reasonably achievable goal. Decibels were used to express the ratio between the sound pressure level of the fundamental and the sound pressure level of the harmonics because they are commonly used to describe relative sound pressure levels. The choice of harmonic content is very flexible and permits sounds of very different tonal quality to be created.~~ The ISO 9703-2 requirement for the presence of four harmonics has been slightly modified. Reflections and standing waves from pure sine wave auditory ALARM SIGNALS can make it very difficult to determine where they are coming from. Ensuring that four or more audible frequencies are present in an auditory ALARM SIGNAL enhances spatial localization. These frequencies should be neither so soft as to be inaudible nor so loud as to be excessively dominant. Because tight control of frequency can be extremely difficult in simple systems, a value of plus or minus 15 dB (relative sound pressure level) was chosen as a reasonably achievable goal. Decibels were used to express the ratio between the sound pressure levels of the frequencies because they are commonly used to describe relative sound pressure levels. The choice of frequency content is very flexible and permits sounds of very different tonal quality to be created. *Using chords instead of single notes is another means to increase the frequency content of the sound and thereby improving localizability.*

i) FALL TIME for PULSES is now less restrictive. It can be any duration that does not overlap the next PULSE. In contrast, ISO 9703-2 sounds were required to have the same FALL TIME as RISE TIME. The committee found this to be excessively design restrictive. MANUFACTURERS are now permitted to create sounds with more distinctive envelopes (e.g. bell-like decays or reverberation effects).

~~– RISE TIME for PULSES is specified as 10 % to 20 % of PULSE duration. There is no significant change from ISO 9703-2. More rapid RISE TIME can be intrusive and startling, but can express greater urgency.~~

– The RISE TIME of a PULSE influences both the perceived urgency and the intrusiveness of the auditory ALARM SIGNAL. More rapid RISE TIMES provide psychoacoustic cues of greater urgency and better reflect the intent of HIGH PRIORITY auditory ALARM SIGNALS, but they can be intrusive and startling. In contrast, slower RISE TIMES are generally perceived as being less urgent, and can be more appropriate for lower priority auditory ALARM SIGNALS or INFORMATION SIGNALS.

With amendment 1, RISE TIME for PULSES is specified as 10 % to 40 % of PULSE duration with a recommendation that they should not be less than 10 ms. This is a relaxation from ISO 9703-2 and previous versions of this standard. Very short RISE TIMES can cause mechanical distortion arising from the speaker (typically a "thump", "click" or "pop"). Previously the shortest possible RISE TIME was 7,5 ms. This was only possible with a combination of the shortest possible PULSE duration of 75 ms and the shortest possible RISE TIME of 10 %, so this is not a big change. Second, the maximum permitted RISE TIME, which had been 20 % of the PULSE duration, has been doubled to 40%, permitting even less intrusive or startling auditory ALARM SIGNALS than previously permitted. This can be advantageous for lower priority ALARM SIGNALS or INFORMATION SIGNALS.

– There is no change in the PULSE frequency requirement. Spatial localization is poor at low frequencies, so the lower limit for fundamental frequency is set at 150 Hz. Hearing impairment from noise exposure or age usually impairs perception of higher frequencies, so that to ensure that all harmonics are audible, the upper limit for fundamental frequency is set at 1 000 Hz. MANUFACTURERS can choose any frequency they like from within this range. Higher pitch is associated with greater urgency. [11]

– The difference in amplitude between any two PULSES in a BURST should not exceed 10 dB. Again, this refers to a relative sound pressure level ratio (i.e., not an absolute volume difference in dBA). This requirement is unchanged from ISO 9703-2. It is easier to make all PULSES the same amplitude, but if the amplitude of the early PULSES in a BURST is a little less than subsequent PULSES, it can be less startling.

The MEDIUM PRIORITY auditory ALARM SIGNAL can be better differentiated from the auditory emergency evacuation signal as specified in ISO 8201:2017 [30] if the three tones use different pitches or if the PULSE pacing and PULSE duration are short. Annex G ALARM SIGNALS are designed to be clearly distinct from the emergency evacuation signal.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List elements a) to c) ~~to~~ and f)]

The MANUFACTURER can provide more than one set of auditory ALARM SIGNALS. VALIDATION by USABILITY testing is not required if each set complies with Table 3 and Table 4 (or ~~Annex F~~ Annex G). If additional non-standard auditory ALARM SIGNAL sets (i.e., those that do not comply with Table 3 and Table 4 or ~~Annex F~~ Annex G) are provided, they require clinical VALIDATION to ensure that they provide at least an equivalent degree of safety as the standard sounds. Permission to provide non-standard sounds is intended to allow a RESPONSIBLE ORGANIZATION to continue to use non-standard but "historically validated" sound sets that have been successfully used for significant periods of time in their PATIENT care areas, and to ensure that this collateral standard is not excessively design restrictive. For example, the RESPONSIBLE ORGANIZATION might prefer some ventilators in their ICU to make one ALARM SIGNAL sound and ventilators of another type to make a different sound. Finally, this flexible approach should ensure that this collateral standard is not excessively design restrictive and that future development of improved auditory ALARM SIGNALS is not hindered.

When choosing an auditory ALARM SIGNAL set, a RESPONSIBLE ORGANIZATION should check that other devices in the PATIENT care area (e.g., pagers, mobile phones) do not generate sounds that could be confused with the medical auditory ALARM SIGNALS of that set unless their meaning is the same.

Every effort should be made in designing equipment to integrate ALARM SYSTEMS into a coordinated system, minimizing the total number of ALARM SIGNALS to which an OPERATOR needs to respond. This is important as multiple ALARM CONDITIONS can generate ALARM SIGNALS when one problem occurs.

Sounds from non-medical devices, such as pagers and telephones can resemble medical ALARM SYSTEM auditory ALARM SIGNALS. Care needs to be taken when designing auditory ALARM SIGNALS that the spectral content and amplitude of the ALARM SIGNALS facilitate the localization and identification of the ~~source~~ origin of the ALARM SIGNAL, taking into account the usual environmental conditions in which the equipment is intended to be used. (See also Annex D.)

NOTE 1 When auditory ALARM SIGNALS are provided, this collateral standard requires that one set of auditory ALARM SIGNALS be encoded to convey the level of urgency of OPERATOR response required. In addition, other sets of auditory ALARM SIGNALS have been devised based on categorization of the nature of the response or awareness and the level of urgency of response required. [18]

A USABILITY test differs significantly from a clinical trial, but is equally important in producing usable, safe equipment. This test spotlights the OPERATOR interface and reactions of the OPERATOR to it. A USABILITY test can take up to a week per use model, depending on the number of OPERATORS involved. Such tests can be conducted in an office-like setting, away from the medical practice environment. This eliminates interference that would occur in the actual-use environment. While USABILITY test formats vary, typically one individual at a time performs self-exploration as well as directed tasks with the equipment. Test administrators can provide special prompts and feedback as required to add realism. As the OPERATOR performs tasks with the equipment, researchers observe and record results. The PROCESS gives the OPERATOR time to concentrate on using the equipment. An OPERATOR can spend weeks learning to use the equipment. Whether they encounter operating difficulties or causes for dissatisfaction over this time depends largely on how much they use the equipment and which tasks they perform. A USABILITY test compresses the initial use experience into a shorter time frame, usually 1 h to 4 h.

In hunting for USABILITY problems, researchers ask OPERATORS to talk their way through each task, describing what they are thinking, decisions they are contemplating, irritants, advantages, and so on. Sometimes USABILITY problems surface immediately, such as when an OPERATOR tries to turn on the equipment and cannot find the power switch. In such a case the OPERATOR can say:

> *Now, I'll turn the power on. I am looking at the front panel but nothing jumps out at me. I see a switch labelled "standby," but I don't think that turns it on. You probably press that button to save power without turning it off. I'm reaching around the back for a switch, but I don't feel anything. I would expect to find a switch right here [OPERATOR points to lower right side of control panel]. This green light probably illuminates when you turn the power on. Oh, I see [OPERATOR presses the light]. This light is the switch. You press it in to turn the power on. That wasn't obvious to me.*

USABILITY test protocols should include frequent USE SCENARIOS and critical USE SCENARIOS. The effect of stress on how an OPERATOR uses the equipment can be studied by introducing time limits, removing equipment labelling, or the OPERATOR'S manual, and introducing equipment failures. Researchers can create a worst-case scenario and see how OPERATORS react. Test outcomes can be compared across several OPERATORS. MANUFACTURERS performing such tests commonly find that researchers collect a large set of USABILITY problems that may have escaped detection during a clinical trial, since such trials do not explicitly address USABILITY. [25]

NOTE 2 Attention is drawn to ~~IEC 60601-1-6~~ IEC 62366-1.

[List element g)]

When an ALARM SYSTEM is provided with more than one auditory ALARM SIGNAL set, the MANUFACTURER is required to select one set for the DEFAULT ALARM PRESET. The committee chose to require this because it can be hazardous when ALARM SYSTEMS have inconsistent or unknown sounds following resets and power failures.

The RESPONSIBLE ORGANIZATION should be able to change that selection and choose their desired auditory ALARM SIGNAL set for the DEFAULT ALARM PRESET, e.g., RESPONSIBLE ORGANIZATIONS need to be able select the auditory ALARM SIGNAL set that is familiar to their OPERATORS or to differentiate between different types of equipment.

[List element h)]

An ALARM PRESET can store any configuration parameters that affect the performance of the ALARM SYSTEM. One such configuration parameter can be the selection between auditory ALARM SIGNAL sets. A particular set can then become active when a particular ALARM PRESET is loaded. RESPONSIBLE ORGANIZATIONS may find this capability helpful when defining ALARM PRESETS for equipment that is used in a variety of PATIENT care areas. If OPERATORS can store ALARM PRESETS they can find this capability helpful to quickly configure ALARM SYSTEMS with the auditory ALARM SIGNALS that they are most familiar with.

[Signals in case of failure]

There are some failures, such as a power failure of the ALARM SYSTEM, which make it impossible for the ALARM SYSTEM to perform its intended function. In these cases, other means, such as a simple battery-backed tone generator, can be used to generate an ALARM SIGNAL to indicate such a TECHNICAL ALARM CONDITION. It would be best, if possible, for the ALARM SYSTEM to generate an auditory ALARM SIGNAL that complies with Table 3 and Table 4 and the "equipment or supply failure ~~or power down~~" ~~melody~~ ALARM SIGNAL from ~~Annex F~~ Annex G, but it is recognized that this can be impractical and that a non-standard auditory ALARM SIGNAL can be acceptable for this purpose.

A power or ALARM SYSTEM failure auditory ALARM SIGNAL should be generated for at least 120 s. This is particularly important for life-supporting equipment or life-sustaining equipment

where the loss of function without immediate OPERATOR action can lead to a HAZARDOUS SITUATION for the PATIENT. Such a signal should also be considered for vital signs monitors to ensure that the OPERATORS are aware of the malfunction and can alter their clinical practice appropriately.

Allowing the OPERATOR to select LATCHING versus NON-LATCHING ALARM SIGNALS other than those determined to be appropriate by the RESPONSIBLE ORGANIZATION, can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for Subclause 6.7.

[Compliance test for timing]

In the past, there have been different test methods used for the verification of the timing of the AUDITORY POINTER. There are four different methods under use that have given different results. They are:

– analyzing of the timing of the sound file (e.g. .wav);
– analyzing of the electrical signal (e.g. loudspeaker input, sound chip output);
– analyzing of the acoustical time signal (sound pressure vs. time); and
– analyzing of the acoustical signal using sound pressure level vs. time analysis.

These different methods create non-comparable measurement results and have caused discussions between test labs, MANUFACTURERS and authorities having jurisdiction. The acoustic methods for determining timing are not very reproducible. For these reasons, the committees made the decision that the acoustical methods are inappropriate and that standardizing on measuring the drive signal of the audio transducer would give the most consistent results. Furthermore, when the wave files of Annex G are used, no testing is needed as those files are known to have appropriate timing.

Subclause 6.3.3.2 – Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

For the OPERATOR to identify the onset or presence of ALARM CONDITIONS by means of auditory ALARM SIGNALS, those signals need to be audible above the background noise level and different from other sounds.

High background noise levels can mask or conceal the presence of auditory ALARM SIGNALS to such an extent that the OPERATOR can fail to hear them. Conversely, an auditory ALARM SIGNAL can be excessively intrusive or startling if its level is very high in relation to the background noise level. The OPERATOR might then seek to inappropriately disable or deactivate the ALARM SYSTEM.

In any PATIENT care environments where the background noise level is known and constant, a fixed auditory ALARM SIGNAL volume can be reasonable. The volume level of such a fixed auditory ALARM SIGNAL should exceed the background noise level to such an extent that it will be reliably detected but not to such an extent that it would be excessively startling or intrusive. Clinical experience has shown that values between 45 dB and 85 dB can be reliably detected without being too intrusive in most situations.

In many PATIENT care environments the background noise level is not constant. In operating rooms the background noise can vary from 50 dBA to 85 dBA. Additionally, one type of equipment can be used in several different kinds of PATIENT care environments; for example a ventilator that can be used in the home, in the intensive care area or for PATIENT transport.

Given the wide range of possible background noise levels in all possible PATIENT care environments, the committee did not consider it appropriate to specify any absolute volume level or range of levels for auditory ALARM SIGNALS. Designers of ALARM SYSTEMS should therefore be aware of the typical background noise level (and how variable it can be) in the

intended environments of use. ALARM SYSTEMS that are to be used when background noise levels are variable should be provided with means for manual adjustment of the auditory ALARM SIGNAL level or should automatically adjust the auditory ALARM SIGNAL level so that the perceived loudness remains the same despite changes in background noise levels.

Because louder sounds are generally perceived to be more urgent, lower priority auditory ALARM SIGNALS should not be louder than higher priority ALARM SIGNALS. If higher priority auditory ALARM SIGNALS are much louder than lower priority signals, they can be startling or intrusive. A reasonable compromise is for HIGH PRIORITY auditory ALARM SIGNALS to be approximately +6 dB louder than MEDIUM PRIORITY auditory ALARM SIGNALS, with an acceptable range from equal in volume (0 dB) to a maximum of +12 dB louder. MEDIUM and LOW PRIORITY ALARM SIGNALS should be equal in volume, but if they are different, MEDIUM PRIORITY auditory ALARM SIGNALS should not be more than 6 dB louder than LOW PRIORITY auditory ALARM SIGNALS.

It should be possible to adjust the volume level of auditory INFORMATION SIGNALS (e.g., pulse oximeter "beeps" or the "in-use" indicators on electro-surgical units) and the volume level of auditory ALARM SIGNALS independently, so that both can be set to appropriate levels. If the volume levels of auditory ALARM SIGNALS and auditory INFORMATION SIGNALS are not independently adjustable, then INFORMATION SIGNALS should have no greater volume level than LOW PRIORITY auditory ALARM SIGNALS, and both should have lower volume levels than those of MEDIUM PRIORITY and HIGH PRIORITY auditory ALARM SIGNALS. The auditory INFORMATION SIGNAL should be non-intrusive, non-startling and discontinuous in nature.

The volume (and range of adjustment of volume, if provided) of auditory ALARM SIGNALS in an ALARM SYSTEM are required to be disclosed to the ~~OPERATOR~~ RESPONSIBLE ORGANIZATION so that ~~the OPERATOR~~ they will be able to determine if the volume of the auditory ALARM SIGNALS is appropriate for the intended environment of use.

Subclause 6.3.3.3 – OPERATOR-adjustable sound pressure level

In previous editions of this standard, MANUFACTURERS were permitted to allow OPERATOR-adjustable auditory ALARM SIGNAL sound pressure levels without restriction. This permission has now been restricted for ME EQUIPMENT provided with HIGH PRIORITY ALARM CONDITIONS. The reason is that, in general, MANUFACTURERS cannot anticipate every environment in which their ME EQUIPMENT might be used and a RESPONSIBLE ORGANIZATION needs the ability to control the minimum sound pressure level for ME EQUIPMENT provided with HIGH PRIORITY ALARM CONDITIONS. As an example, an item ME EQUIPMENT might be used in a helicopter, while another unit of the same ME EQUIPMENT might be used in a quiet home environment. The minimum auditory ALARM SIGNALS required are extremely different in these environments.

In the future, it is anticipated that ME EQUIPMENT will incorporate a microphone, both to determine the ambient (background) noise level and to set the auditory ALARM SIGNALS to an appropriate volume, and to verify that the ALARM SIGNALS are actually audible.

Another approach involves the use of auditory ALARM SIGNALS that ESCALATE in volume if they are not responded to within a reasonable period. In other words, if the OPERATOR does not attend to an ALARM SIGNAL within the expected timeframe, the auditory ALARM SIGNALS becomes louder in an attempt to attract the OPERATOR'S attention. In a DISTRIBUTED ALARM SYSTEM, the auditory ALARM SIGNALS can also be presented in additional locations. These approaches are useful not only if the auditory ALARM SIGNALS are too soft to be heard in the present noise environment, but if the OPERATOR does not hear or respond to the auditory ALARM SIGNALS for any reason, including being out of the immediate area, tending to another PATIENT, etc.

Care needs to be exercised with the auditory ALARM SIGNALS of HIGH PRIORITY ALARM CONDITIONS when OPERATOR-adjustable auditory ALARM SIGNAL sound pressure levels are available in the ME EQUIPMENT. Unless the RESPONSIBLE ORGANIZATION can configure the minimum OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level, this standard requires that the ME EQUIPMENT visually indicate that the current sound pressure level might

be inaudible. This is required since selecting a sound pressure level that is less than that which can be readily heard is effectively the AUDIO OFF state or the speaker muted state. As an alternative, this standard permits the RESPONSIBLE ORGANIZATION to select the minimum available sound pressure level to ensure that the ALARM SIGNALS are not inadvertently reduced below audible levels.

Subclause 6.3.4 – Characteristics of verbal ALARM SIGNALS

Verbal ALARM SIGNALS are permissible for HIGH, MEDIUM or LOW PRIORITY ALARM SIGNALS as well as INFORMATION SIGNALS. See also Annex E.

Verbal ALARM SIGNALS should only be considered for an ALARM SYSTEM intended for continuous OPERATOR attendance.

Subclause 6.4 – Disclosure of delays

If an event occurs in the PATIENT or the equipment that should result in the generation of ALARM SIGNALS, the generation should occur promptly. For example, clinicians would expect an ALARM SIGNAL soon after an abrupt fall in heart rate to a value below the lower ALARM LIMIT for heart rate, or once apnea or asystole has occurred. This is usually the case.

However, in some situations, ALARM SIGNAL generation can be delayed to such an extent that the delay can be clinically significant. This collateral standard recognizes that there are two fundamentally different potential causes for these delays.

First, it can take some time for the ALARM SYSTEM to determine that an ALARM CONDITION is present after the occurrence of a valid triggering event in the PATIENT. This delay is defined as the ALARM CONDITION DELAY. It can be due to:

– *artifact rejection algorithms, or*
– *INTELLIGENT ALARM SYSTEMS that include event duration as part of the algorithm, or*
– *aperiodic measurement (e.g., intermittent non-invasive blood pressure monitoring).*

When the ALARM SYSTEM is aperiodically measuring rather than continuously monitoring a variable, there can be a significant delay between the time that an event occurs in the PATIENT and when that event is detected. If the OPERATOR is unaware of this, incorrect treatment decisions can occur. The time between measurements is considered to be part of the ALARM CONDITION DELAY.

In the case of apnea or asystole, the valid triggering event in the PATIENT has not occurred until the absence of respiration or heart rate has existed for a defined period of time. Because this defined period of time is required to pass before the event itself exists, it is not included as part of the ALARM CONDITION DELAY. See also the rationale for Definition 3.2.

Second, the generation of ALARM SIGNALS can lag some time after the ALARM SYSTEM has determined that an ALARM CONDITION exists. This delay is defined in this document as the ALARM SIGNAL GENERATION DELAY. In most ALARM SYSTEMS this delay is usually clinically insignificant, but can be important, for example, when paging systems or networked ~~remote devices~~ COMMUNICATORS are used to generate ALARM SIGNALS. See also the rationale for Subclause 6.10.

A further complication can occur when the ALARM SYSTEM is not continuously monitoring, but is aperiodically measuring the variable that causes an ALARM CONDITION, e.g. a non-invasive blood pressure monitor. There can be a significant delay between when an event occurs in the PATIENT and when that event is detected. If OPERATORS are unaware of this likelihood, incorrect treatment decisions can occur.

In that case, the time between measurements is considered to be part of the ALARM CONDITION DELAY.

Figure A.1 illustrates the components of ALARM SYSTEM delay for a PHYSIOLOGICAL ALARM CONDITION normalized variable.

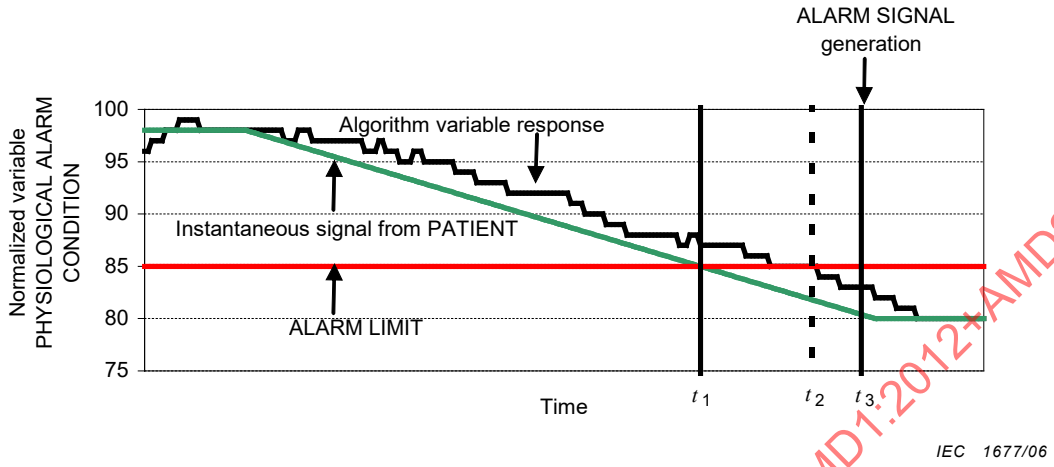


Figure A.1 – Graphical representation of components of ALARM SYSTEM delay

A valid triggering event occurs in the PATIENT at t_1. At t_2 the ALARM SYSTEM determines that an ALARM CONDITION exists.

NOTE In this example, the ALARM LIMIT is less than 85, not less than or equal to 85.

The ALARM CONDITION DELAY is $t_2 - t_1$. This delay is due to the ALARM SYSTEM processing and averaging. The ALARM SIGNAL GENERATION DELAY is $t_3 - t_2$. This delay is attributed to the ALARM SYSTEM strategy and the communication time to the ALARM SYSTEM generating device or DISTRIBUTED ALARM SYSTEM (e.g. PATIENT monitor or central station). At t_3 the ALARM SYSTEM begins to generate ALARM SIGNALS. Thus, the overall ALARM SYSTEM delay time is $t_3 - t_1$.

Subclause 6.4.1 – ALARM SYSTEM delays

The delay times are based on clinical judgement. Delay times shorter than those specified in this collateral standard are considered clinically insignificant.

Subclause 6.4.2 – Delays to or from a DISTRIBUTED ~~ALARM SYSTEM~~ INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) or a DISTRIBUTED ALARM SYSTEM (DAS)

~~DISTRIBUTED ALARM SYSTEMS~~ A DIS or DAS further complicates the consideration of ALARM SYSTEM delays. See also the rationale for Definition 3.2. When an OPERATOR is depending on remote ~~generation of ALARM SIGNALS~~ COMMUNICATOR from a DISTRIBUTED ALARM SYSTEM for treatment decisions, then knowledge about the delays associated with DISTRIBUTED ALARM SYSTEMS is necessary for safety.

~~DISTRIBUTED ALARM SYSTEMS~~ ALARM SIGNALS are being delivered to caregivers (OPERATORS) that are at short, medium or long distances away from the PATIENT. Such DISTRIBUTED ALARM SYSTEMS can include ALARM SYSTEM~~s~~ components made by several different MANUFACTURERS, for example:

- *a PATIENT monitor and a central station network;*
- *a specialized system that connects to the central station network and transmits ALARM CONDITIONS over another network; or*
- *a wireless transmission system that picks up an ALARM CONDITION from the network and transmits it to a wireless ~~ALARM SIGNAL generating device~~ COMMUNICATOR.*

Each component of such a DISTRIBUTED ALARM SYSTEM can add to the ALARM SIGNAL GENERATION DELAY. The MANUFACTURER of each component of a DISTRIBUTED ALARM SYSTEM should disclose its contribution to the ALARM SIGNAL GENERATION DELAY. Depending upon which

ALARM SYSTEM is considered, the contribution to the ALARM SIGNAL GENERATION DELAY can be the time from the:

– *ALARM CONDITION to ~~local generation~~ the of ALARM SIGNALS of the COMMUNICATOR at the SOURCE or to the time that the indication of the ALARM CONDITION leaves a communications interface on the ALARM SYSTEM at the SOURCE; or*

– *receipt of the indication of the ALARM CONDITION by a component to its retransmission ~~of the indication of the ALARM CONDITION~~; or*

– *receipt of the indication of the ALARM CONDITION by a COMMUNICATOR to its ALARM SIGNAL generation.*

Ideally, the maximum time interval added to the original ALARM SIGNAL GENERATION DELAY should be reported as the remote ALARM SIGNAL GENERATION DELAY. It is recognized, though, that some components can have unpredictable, stochastic delays because of the nature of their non-deterministic networks. Still these components should have a "time out" function as described in the following paragraph.

Any component in a DISTRIBUTED ALARM SYSTEM might fail or experience a delay in passing along the indication of the ALARM CONDITION. ALARM SYSTEMS should be designed so that a communication failure (lack of receipt of an acknowledgement signal or failure of a "handshake" or other "time-out" function) results in a TECHNICAL ALARM CONDITION after a finite period. In lieu of the time to pass along the indication of the ALARM CONDITION (that is, the ALARM SYSTEM'S contribution to the ALARM SIGNAL GENERATION DELAY), the MANUFACTURER can disclose the time from detection of the indication of the ALARM CONDITION or receipt of the indication of the ALARM CONDITION to creation of the TECHNICAL ALARM CONDITION. When appropriate, both times (contribution to the ALARM SIGNAL GENERATION DELAY and the time to TECHNICAL ALARM CONDITION) should be disclosed.

It is important for the OPERATOR and the RESPONSIBLE ORGANIZATION to know both of these times for the safety of the PATIENT.

Writers of particular standards should carefully consider whether the maximum remote ALARM SIGNAL GENERATION DELAY or the time to determine the generation of the TECHNICAL ALARM CONDITION needs to be limited for a particular type of ME EQUIPMENT.

Subclause 6.5.1 – General requirements

It is important for OPERATORS to know the how the ALARM SYSTEM will operate when they start to use equipment. As a result, an ALARM SYSTEM is required to have a known priority and ALARM LIMIT for each ALARM CONDITION in every ALARM PRESET.

Subclause 6.5.3 – RESPONSIBLE ORGANIZATION- and OPERATOR-configured ALARM PRESETS

Allowing the OPERATOR to change RESPONSIBLE ORGANIZATION-configured or other OPERATOR-configured ALARM PRESETS can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for Subclause 6.7.

A MANUFACTURER-configured default ALARM LIMIT should be sufficiently wide to minimize unnecessary ALARM CONDITIONS and sufficiently narrow to alert the OPERATOR to a situation that can be dangerous.

Subclause 6.5.4.2 – Selection of DEFAULT ALARM PRESET

The start-up sequence of an ALARM SYSTEM needs careful design to prevent nuisance ALARM SIGNALS. In older ME EQUIPMENT, when it was switched on, any ALARM LIMIT in violation immediately caused an ALARM SIGNAL, even though no PATIENT was connected to the ME EQUIPMENT! Later ME EQUIPMENT, when it was switched on, entered a state of ALARM OFF, or AUDIO OFF, and the state had to be deliberately terminated by OPERATOR action. Additional safety was provided with the introduction of ME EQUIPMENT with automatic enabling of the ALARM SYSTEM when a PATIENT was connected to the ME EQUIPMENT, or when a valid

physiologic signal was first present (for instance, five normal breaths or five heartbeats within a certain time interval), or through an “admit new PATIENT” function which was activated by the OPERATOR.

Another situation is the desire to set up the ME EQUIPMENT, including the ALARM SYSTEM, before the PATIENT is connected. In this instance, it is desirable for the OPERATOR to select the ALARM PRESET, and perhaps to modify values from the ALARM PRESET for the PATIENT planned, without enabling the ALARM SYSTEM. The ALARM SYSTEM would then be enabled, either manually or preferably automatically, when the PATIENT is later connected to the ME EQUIPMENT.

A final situation is when the ALARM SYSTEM, or part of the ALARM SYSTEM, is in separate equipment. For instance, a gas delivery system might incorporate a separate gas monitor with its own ALARM SYSTEM, or an electronic recordkeeper or another equipment might combine the ~~signals~~ ALARM CONDITIONS from several items of ME EQUIPMENT into a single ALARM SYSTEM. In this instance the ~~primary~~ ME EQUIPMENT with the SOURCE and its ALARM SYSTEM might be switched on separately. Another example is a DISTRIBUTED ALARM SYSTEM of a PATIENT monitor with a central station. The ALARM SYSTEM of a central station should not be enabled when no PATIENT is connected! As in the earlier example, it would not be desirable to have the ALARM SYSTEM enabled until the ME EQUIPMENT is in actual clinical use.

When choosing the DEFAULT ALARM PRESET, a RESPONSIBLE ORGANIZATION should check that other devices in the PATIENT care area (e.g., pagers, mobile phones) do not generate sounds that could be confused with the auditory ALARM SIGNALS that are being chosen, unless their meaning is the same.

Subclause 6.5.5 – Interruptions of less than or equal to 30 s

For equipment with ALARM SYSTEMS, interruption of the SUPPLY MAINS for 30 s or less is considered NORMAL CONDITION. 30 s is sufficient time to restore power to the equipment by either plugging it back into SUPPLY MAINS or having the emergency generator initiate operation. Equipment with an OPERATOR-exchangeable INTERNAL ELECTRICAL POWER SOURCE, when they can be quickly replaced, is also expected to maintain its ALARM SETTINGS. The ALARM PRESET is expected to remain unchanged after such interruptions.

Subclause 6.6.2 – Adjustable ALARM LIMIT

Care should be used in the design of an ALARM SYSTEM if an OPERATOR is permitted to set an ALARM LIMIT to extreme values. Such action by the OPERATOR can have the effect of defeating both the auditory and visual ALARM SIGNALS, without providing a visual indication that the ALARM CONDITION is effectively disabled (see the second paragraph of 5.2.1).

Care also needs to be taken that any absolute lower and upper ALARM LIMITS will not be reached by PATIENTS in clinical practice, as this would cause a situation in which an ALARM CONDITION is continuously and erroneously indicated by ALARM SIGNALS.

The provision and use of a pre-use checklist to verify ALARM LIMIT(S) is encouraged.

Subclause 6.6.2.2 – Indication of automatically set ALARM LIMIT

Care should be used in the design of means to automatically set an ALARM LIMIT to help prevent FALSE POSITIVE or NEGATIVE ALARM CONDITIONS. In some cases, a wider or narrower ALARM LIMIT can be required.

Subclause 6.6.2.3 – ALARM SYSTEM operation during adjustment of ALARM LIMIT or ALARM PRESET

It is important for an ALARM SYSTEM to continue to function normally while the OPERATOR adjusts one part of the ALARM SYSTEM. In the past, some equipment has been designed such that all ALARM CONDITIONS were effectively disabled while the ALARM LIMITS for one ALARM

CONDITION were being adjusted. Furthermore in this equipment, once the change had been completed, ALARM CONDITIONS that occurred during the adjustment PROCESS did not generate ALARM SIGNALS.

Subclause 6.7 – ALARM SYSTEM security

The need for and complexity of security for ALARM PRESETS depend on the complexity of the ALARM SYSTEM and the importance of the ALARM SYSTEM to PATIENT or OPERATOR safety. The effectiveness of any security system depends critically on its implementation by the RESPONSIBLE ORGANIZATION. Only the RESPONSIBLE ORGANIZATION can adequately control the security system so that OPERATORS cannot compromise it.

In some legacy equipment, access to configuration of an ALARM PRESET (including DEFAULT ALARM PRESET) has not been restricted. In such instances, OPERATORS have, intentionally or unintentionally, changed an ALARM PRESET (including the DEFAULT ALARM PRESET). PATIENT safety can be compromised when an OPERATOR expects certain ALARM PRESETS on equipment, but the equipment actually has different ALARM PRESETS.

To prevent this problem, MANUFACTURERS need to use care in designing the means to store ALARM PRESETS. Access to configuration of an ALARM PRESET is restricted to authorized persons. There can be more than one level of restriction. For example, OPERATORS should be able to store OPERATOR-configured ALARM PRESETS, but should not be able to store RESPONSIBLE ORGANIZATION-configured ALARM PRESETS. RESPONSIBLE ORGANIZATIONS should be able to store RESPONSIBLE ORGANIZATION-configured ALARM PRESETS. Only MANUFACTURERS should be able to store MANUFACTURER DEFAULT ALARM PRESETS.

In some instances, the password for RESPONSIBLE ORGANIZATION-configured ALARM PRESETS has been printed in the technical description (service manual). These manuals have then been placed where they are accessible to an OPERATOR, and the OPERATOR has learned the password. Such passwords should be made available only to the RESPONSIBLE ORGANIZATION. Both the MANUFACTURER and RESPONSIBLE ORGANIZATION should avoid disclosure of such passwords to an OPERATOR. Therefore, the MANUFACTURER should emphasize the need to maintain password privacy in the technical description (instructions to RESPONSIBLE ORGANIZATIONS).

Similarly, an OPERATOR should not be permitted to change the OPERATOR-configured ALARM PRESETS of other OPERATORS. One solution would be password-protection for each OPERATOR to store his or her own OPERATOR-configured ALARM PRESETS.

Subclause 6.8 – ALARM SIGNAL inactivation states

The committee spent extensive time in discussion of the names of the ALARM SIGNAL inactivation states. In the past, equipment has used a variety of names to describe these inactivation states:

- Silence
- Silence/Reset
- Pre-Silence
- Mute
- Suspend
- Disable
- Inhibit
- Prevent
- Pause
- Off

The situation is problematic because different MANUFACTURERS have used these names to mean different things. “Silence” has been used to mean both a temporary or limited duration (timed) and a permanent (indefinite) state. In addition, some MANUFACTURERS have used these terms and states to apply only to those ALARM CONDITIONS which are generating ALARM SIGNALS, while others have used them to apply to every possible ALARM CONDITION in the ALARM SYSTEM. Also, some MANUFACTURERS used the term “alarms” to mean only the auditory ALARM SIGNALS, while others used it to mean both auditory and visual ALARM SIGNALS. The result has been confusion among OPERATORS about what the various names really mean.

Previous standards used terms such as “Suspend”, “Disable”, and “Inhibit”. These terms had two problems: first, they were not intuitively obvious as to their meaning. Second, they sometimes applied to the auditory ALARM SIGNALS only, and sometimes to both the auditory and visual ALARM SIGNALS. As a result, the confusion continued.

Additional difficulties were encountered in trying to translate these terms into multiple languages.

Early drafts of this collateral standard described multiple ALARM SIGNAL inactivation states, with tables with multiple columns to indicate the effect of each state on ALARM SIGNAL generation and non-generation, present and future ALARM CONDITIONS, recurrent or persisting ALARM CONDITIONS, auditory ALARM SIGNALS, and both near- and far-visible ALARM SIGNALS. There was no consensus on the correct content of the cells of the table and, even if there had been a consensus, OPERATORS would never have remembered the distinction among the multiple various states.

The committee therefore decided to use a small set of names with the same obvious meanings in various languages.

The names selected were:

– AUDIO OFF
– AUDIO PAUSED
– ALARM OFF
– ALARM PAUSED

The use of the distinctive terms “Audio” and “Alarm” should make clear to OPERATORS that “Audio” refers only to the auditory ALARM SIGNAL, while “Alarm” refers to both the auditory and visual ALARM SIGNALS. Similarly, the use of the terms “Off” and “Paused” should be intuitively obvious. Intuitively, one would anticipate that something that is “Off” remains off until it is turned back on again. Something that is “Paused” is expected to start again at a later time. By using a simple two-by-two matrix of “Audio/Alarm” and “Off/Paused,” all the ALARM SIGNAL inactivation states can be reasonably described.

Great simplification also occurred with the decision that these states might apply to a single ALARM CONDITION, a group of ALARM CONDITIONS or the entire ALARM SYSTEM. Thus all the legacy names for the ALARM SIGNAL inactivation states used in legacy ME EQUIPMENT, and in various standards, can be understood in terms of these new names.

MANUFACTURERS are strongly encouraged to use the provided names for the ALARM SIGNAL inactivation states in their equipment and its instructions for use when they have inactivation states as defined in this collateral standard. In this way, OPERATORS will learn to understand the consistent names for consistent functions across all ALARM SYSTEMS.

Subclause 6.8.1 – General

The continuous presence of ALARM SIGNALS can degrade task performance, and impair detection of new ALARM CONDITIONS and the ability to distinguish between existing and new ALARM CONDITIONS. It is important to provide any OPERATOR with deliberate means to initiate

states such as AUDIO PAUSED, ALARM PAUSED, ACKNOWLEDGED, AUDIO OFF and ALARM OFF, by which they can stop the generation of ALARM SIGNALS.

An ALARM SYSTEM is not required to have OPERATOR control functions that initiate all of these states. An ALARM SYSTEM is required to have at least one means to inactivate the generation of ALARM SIGNALS from each COMMUNICATOR.

The presence of unnecessary visual ALARM SIGNALS can clutter the display and degrade the response to new ALARM SIGNALS. The OPERATOR can want to inactivate visual ALARM SIGNALS when some:

– functions of the equipment or system are not in use;

– functions of the equipment or system are not functional;

– monitored variables are generating frequent FALSE POSITIVE ALARM CONDITIONS; or

– monitored variables are known to be in ALARM CONDITION.

In recognition of this, MANUFACTURERS should consider whether the AUDIO PAUSED or AUDIO OFF ALARM SIGNAL inactivation states affect visual ALARM SIGNALS and in particular alarm indicator lights.

The committee wrestled with the behaviour of currently generated ALARM SIGNALS of ALARM CONDITIONS with respect to one, some or all non-currently generated ALARM SIGNALS and other issues. The consensus was that the inactivation could apply to one, a group or to all ALARM CONDITIONS, or (in the case of a DISTRIBUTED ALARM SYSTEM) to part or all of the ALARM SYSTEM. It was further recognized that the definition of a "group" of ALARM SIGNALS need not follow the traditional physiological grouping such as respiratory, cardiac, temperature, and so on. Instead a group could be defined as all currently generated ALARM SIGNALS, all ALARM SIGNALS chosen from a list by the OPERATOR, etc.

In Amendment 1, the committee added a new ALARM SIGNAL inactivation state to clarify which ALARM SIGNALS are and are not affected when the OPERATOR selects an inactivation state. Activation of the new indefinite ACKNOWLEDGED state affects those ALARM CONDITIONS that are currently active and no others. In this state, those ALARM CONDITIONS will be quiet indefinitely, until the ALARM CONDITION is no longer true. It is important for the OPERATOR to understand that this indefinite ACKNOWLEDGED state can last for hours or days, for instance until a variable comes back into range.

As an example, if the pulse oximeter oxygen saturation is 80 %, and the OPERATOR activates the ACKNOWLEDGED feature, then the oxygen saturation can remain at 80 % (or anywhere below the lower limit) for hours or days and the auditory ALARM SIGNALS and the 4 m visual ALARM SIGNALS remain inactivated. Indeed the oxygen saturation could fall further, for instance, to 50 % and these ALARM SIGNALS remain inactive!

While some OPERATORS have used this sort of ACKNOWLEDGED function safely for many years, other OPERATORS have not encountered this function before and might not understand the implications of its use.

The committee therefore believes that PATIENT safety can be enhanced by permitting the MANUFACTURERS to use a "time out" function on top of the ACKNOWLEDGED function. In this timed ACKNOWLEDGED function, the period during which the auditory ALARM SIGNALS and the 4 m visual ALARM SIGNALS are inactive automatically ends after a predetermined time interval, at which time the ALARM SIGNALS become active again. This timed ACKNOWLEDGED should prevent the situation in which the OPERATOR is unaware of the inactive ALARM CONDITIONS.

In any case, it should be made obvious to the OPERATOR which ALARM CONDITIONS are, and are not, in an inactive state such as ACKNOWLEDGED.

Furthermore, MANUFACTURERS might wish to include additional safety features such as safety or extreme ALARM LIMITS. An example of a safety ALARM LIMIT could be an additional HIGH PRIORITY oxygen saturation ALARM CONDITION with an ALARM LIMIT set 10 % below the primary MEDIUM PRIORITY ALARM CONDITION ALARM LIMIT. This allows for ALARM SIGNALS even if the primary "low oxygen saturation" ALARM SIGNALS have been ACKNOWLEDGED. There are other ways that an INTELLIGENT ALARM SYSTEM could contribute to PATIENT safety when the indefinite ACKNOWLEDGED function is used.

Smart enabling of an ALARM SYSTEM is intended to minimise NUISANCE ALARM SIGNALS when the ALARM SYSTEM is enabled. Often monitoring ME EQUIPMENT is powered up, with monitoring cables attached to it, before all cables are attached to the PATIENT. The ALARM SYSTEM should either:

a) automatically be in AUDIO OFF or ALARM OFF, until a valid signal is detected from the monitored parameter; or
b) generate auditory ALARM SIGNALS to alert the OPERATOR to the TECHNICAL ALARM CONDITION that some monitoring components are not connected.

If the ALARM SYSTEM doesn't generate auditory ALARM SIGNALS until a valid signal is detected, the ALARM SYSTEM should, for the relevant monitored parameters:

- *visually indicate AUDIO OFF in association with the affected parameters, and not present an auditory ALARM SIGNAL; and*
- *optionally provide additional visual INFORMATION SIGNALS or REMINDER SIGNALS to assist the OPERATOR; and*

  EXAMPLES 1 Displaying the text "leads off" in the ECG waveform area or "static pressure" in the arterial pressure waveform area.

- *automatically terminate the AUDIO OFF state individually for each parameter when valid data is received, thereby returning the ALARM SYSTEM to its normal monitoring status.*

If the ALARM SYSTEM does generate auditory ALARM SIGNALS while waiting for a valid signal to be detected, the ALARM SYSTEM should:

- *provide a means to inactivate these ALARM SIGNALS, such action resulting in the affected parameters entering the ACKNOWLEDGE state, and*
- *optionally provide additional visual INFORMATION SIGNALS or REMINDER SIGNALS to assist the OPERATOR.*

  EXAMPLES 2 Displaying the text "leads off" in the ECG waveform area or "static pressure" in the arterial pressure waveform area.

  NOTE Since ACKNOWLEDGE automatically terminates individually for each parameter when valid data is received, the ALARM SYSTEM returns to its normal monitoring status as valid signals are detected.

Subclause 6.8.2 – REMINDER SIGNALS

REMINDER SIGNALS are not desirable in all equipment. For example, for operating room monitors that are continuously attended, REMINDER SIGNALS can be annoying, distracting, and disturb other operating room personnel.

ALARM SYSTEMS are required to allow the RESPONSIBLE ORGANIZATION (and only the RESPONSIBLE ORGANIZATION) to determine whether or not REMINDER SIGNALS are appropriate for use. Allowing one OPERATOR to disable REMINDER SIGNALS can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment.

Allowing the OPERATOR to set the duration of a REMINDER SIGNAL interval longer than that determined to be appropriate by the RESPONSIBLE ORGANIZATION can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for 6.7.

Subclause 6.8.3 – Global indefinite ALARM SIGNAL inactivation states

The provision of a global ALARM OFF or AUDIO OFF function requires a careful RISK ANALYSIS. The RISK ANALYSIS needs to weigh the RISK of frequent or constant ALARM SIGNALS (including those from FALSE POSITIVE ALARM CONDITIONS) versus the RISK of an ALARM CONDITION with inadequate or no ALARM SIGNALS being generated. In addition, whether or not the ALARM SYSTEM is intended to be continuously attended by an OPERATOR in NORMAL USE and the presence or absence of a DISTRIBUTED ALARM SYSTEM need to be considered.

If a global ALARM OFF or AUDIO OFF function is provided, MANUFACTURERS are required to provide periodic REMINDER SIGNALS to mitigate the RISK of an OPERATOR forgetting that all auditory ALARM SIGNALS are inactivated.

If a global ALARM OFF or AUDIO OFF function is provided, MANUFACTURERS are required to provide the RESPONSIBLE ORGANIZATION with means to enable or disable the global function. ALARM SYSTEMS are required to allow the RESPONSIBLE ORGANIZATION (and only the RESPONSIBLE ORGANIZATION) to determine whether or not global ALARM SIGNAL inactivation states are appropriate for use.

Subclause 6.8.4 – Termination of inactivation of ALARM SIGNALS

It is important for an OPERATOR to be able to undo an action made in error. PATIENT safety requires this, as human error is inevitable and the ability to mitigate error needs to be provided.

Subclause 6.8.5 – Indication and access

The committee strongly believed that the markings required for ALARM SIGNAL inactivation states needed to be standardized. This is even more important than the standardization of the names of ALARM SIGNAL inactivation states that are standardized to eliminate the confusion of multiple names with different meanings. OPERATOR confusion regarding the status of an ALARM SIGNAL inactivation state is a known HAZARD. The committee has chosen internationally standardized symbols for this marking. Overall, safety will be increased when OPERATORS find consistent marking (symbols) with consistent meaning for the ALARM SIGNAL inactivation states across all equipment.

This collateral standard does not specify how the various ALARM SIGNAL inactivation states are to be invoked. Many approaches currently exist. They include:

– single-function hard keys;
– hard keys that cycle through various states (e.g., AUDIO PAUSED, AUDIO OFF, and all ALARM SIGNALS active);
– soft keys;
– menu selections.

The committee anticipates that ALARM SYSTEMS designed to comply with this collateral standard will continue to use these methods and also might use new methods such as voice recognition.

When a "control" is used to invoke an ALARM SIGNAL inactivation state, this collateral standard permits that it be marked with the appropriate symbol as indicated in Table 5. Certainly, the symbols from Table 5 should only be used for the functions indicated. In the case of a multifunction control, a different marking (symbol or wording) can be used, e.g., a hard key that cycles through ALARM PAUSED, ALARM OFF, and all ALARM SIGNALS active could be marked with IEC 60417-5307(DB:2002-10).

The committee faced a dilemma in the choice of symbols for ALARM CONDITIONS and for ALARM SIGNAL inactivation states. The familiar Bell-X symbol (IEC 60417-5576 (DB:2002-10)) has been used for many years, but some MANUFACTURERS have used it to mean “AUDIO OFF” or “AUDIO PAUSED” while other MANUFACTURERS have used it to mean “ALARM OFF” or "ALARM PAUSED". Thus there is substantial confusion about what the symbol means among clinicians

(OPERATORS). Both what is off (just auditory signals or auditory signals and visual signals), as well as whether this is a permanent loss or a timed loss of ALARM SIGNALS, have been indicated by Bell-X. In either case, however, OPERATORS have recognized that the Bell-X includes the loss of alarm sound.

A HAZARD occurs, however, if an OPERATOR looks for the familiar Bell-X, does not see it, and mistakenly concludes that the auditory ALARM SIGNALS are on. In other words, OPERATORS can not understand that the Triangle-X symbol (IEC 60417-5319 (DB:2002-10)) indicates that part of the ALARM SYSTEM is in the AUDIO OFF or AUDIO PAUSED state. On that basis, the committee decided to permit, or perhaps encourage, the use of the Bell-X as an additional symbol whenever the Triangle-X is used. In that way, OPERATORS would see the familiar Bell-X at any time that a portion of the ALARM SYSTEM is in the AUDIO OFF or AUDIO PAUSED state. Alternatively or additionally, a text message could be added.

Another possible symbol that the committee considered is the Loudspeaker-X (IEC 60417-5436 (DB:2002-10)). This has traditionally been used to mean “sound mute” and it could be interpreted to produce an effect upon both ALARM SIGNALS and INFORMATION SIGNALS. This collateral standard requires that if this symbol is used as an indicator for muting both INFORMATION SIGNALS and ALARM SIGNALS, the appropriate Bell-X is also indicated.

In the event of ALARM PAUSED or AUDIO PAUSED, the X becomes a dashed-X where the dashed-X means limited duration or timed rather than the solid-X that means permanent.

Concern was raised about the amount of dark and light spaces of the dashed-X so that it can be legible on displays of differing resolution. MANUFACTURERS are reminded that icons made from symbol graphics need to be adapted to the display resolution when used.

The use of a countdown timer (which shows the time remaining in ALARM or AUDIO PAUSED state), adjoining the icon, is encouraged. The presence of a countdown timer adds additional distinctiveness to the icon for ALARM PAUSED or AUDIO PAUSED so that they can more easily be distinguished from ALARM OFF or AUDIO OFF.

Allowing the OPERATOR to set duration of an AUDIO PAUSED or ALARM PAUSED interval longer than that determined to be appropriate by the RESPONSIBLE ORGANIZATION can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for 6.7.

Subclause 6.9 – ALARM RESET

The committee received many comments on LATCHING ALARM SIGNALS and ALARM RESET and discussed the topic at length. There were two different philosophies on the operation of the ALARM RESET that the committee considered.

One philosophy holds that ALARM RESET should:

– terminate a LATCHING ALARM SIGNAL and should be the only means of terminating the LATCHING ALARM SIGNAL;

– cause the ALARM SYSTEM to be enabled or re-enabled to respond to future ALARM CONDITIONS;

– terminate any existing AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF state thus re-enabling the ALARM SYSTEM.

In addition, if the OPERATOR wished to enter the state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF, a second, deliberate action should be required. It is believed that this two-step PROCESS should be required at least for the clearing of visual LATCHING ALARM SIGNALS. The concern was that an OPERATOR might cause the removal of visual ALARM SIGNALS before ~~they~~ the OPERATOR had had an opportunity to identify ~~the source of~~ the ALARM CONDITION.

The second philosophy holds that the desired response of an OPERATOR to an auditory ALARM SIGNAL is to cause it to stop. This philosophy holds that activation of the states of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF should serve as the acknowledgement by the OPERATOR of any auditory ALARM SIGNAL, and that a separate ALARM RESET function is unnecessary. This second philosophy thus holds that activation of the functions AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF should terminate the generation of any auditory ALARM SIGNAL, and that the ALARM SIGNAL should not recur at the end of AUDIO PAUSED or ALARM PAUSED unless the ALARM CONDITION is still present. This second philosophy holds that, if the ALARM RESET function is provided, it should terminate the generation of any ALARM SIGNAL, but it should not cause the ALARM SYSTEM to be re-enabled. This philosophy also holds that, if an ALARM RESET function was provided and activated, it should not terminate any existing state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF (for other parts of the ALARM SYSTEM). These states would thus remain as they had been previously.

The first philosophy prefers a single way to accomplish this task. The second philosophy argues for multiple ways to accomplish this task and holds that this is comparable to the “any button answer” function that is found on many cellular telephones. The second philosophy is consistent with the behaviour of most existing equipment.

In summary, the first philosophy holds that the ALARM RESET function should cause the ALARM SYSTEM to be enabled, while the second philosophy holds that the ALARM RESET function should be combined into AUDIO PAUSED, AUDIO OFF, ACKNOWLEDGED, ALARM PAUSED or ALARM OFF.

Thus, the committee faced two incompatible visions of the operation of the ALARM RESET function. It was noted that this collateral standard describes means of activating the states of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED, ALARM OFF or alarms enabled, but that it does not specify what means are required. These states might be entered by separate, specific controls, by a single control that cycles through various states, by voice recognition, etc.

The decision was made to require that an ALARM SYSTEM have a means to perform the ALARM RESET function, but does not specify how this function should be accomplished. This collateral standard thus recognizes that the ALARM RESET function can be accompanied by causing the ALARM SYSTEM to be enabled or re-enabled, or by the opposite concept: by entering the state of AUDIO PAUSED, AUDIO OFF, ACKNOWLEDGED, ALARM PAUSED or ALARM OFF.

Subclause 6.10 – NON-LATCHING and LATCHING ALARM SIGNALS

Auditory ALARM SIGNALS are required to complete a full BURST (or ½ BURST for HIGH PRIORITY ALARM SIGNALS) to help an OPERATOR to identify a transient ALARM CONDITION.

Example 1 A momentary obstruction of a breathing system (the surgeon leans on it).

Example 2 A pair of premature ventricular beats (which only lasts for 2 heartbeats).

Nonetheless, the auditory ALARM SIGNAL should immediately terminate when the OPERATOR activates any of the ALARM SIGNAL inactivation states.

Auditory LATCHING ALARM SIGNALS cause noise pollution and can cause an OPERATOR to invoke the ALARM OFF state. Auditory LATCHING ALARM SIGNALS should be avoided for an ALARM SYSTEM that is intended to be only continuously attended by an OPERATOR in NORMAL USE, if possible. Auditory LATCHING ALARM SIGNALS can be useful in situations where the ALARM SYSTEM is intended to be unattended by an OPERATOR in NORMAL USE and it is desirable to force the OPERATOR to assess the PATIENT or the ALARM SYSTEM. MANUFACTURERS should provide ALARM CONDITION logs (histories) in addition to, or as an alternative to, LATCHING ALARM SIGNALS.

Allowing the OPERATOR to select auditory ALARM SIGNAL sets other than those determined to be appropriate by the RESPONSIBLE ORGANIZATION can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for Subclause 6.7.

Subclause 6.11 – DISTRIBUTED ALARM SYSTEMS and DISTRIBUTED INFORMATION SYSTEMS ABOUT ALARM CONDITIONS

~~*The application of DISTRIBUTED ALARM SYSTEMS is in its infancy. New ideas and new technology are bringing rapid advances and changes in this area. Long-, medium- and short-range two-way wireless communication opens new opportunities and new challenges for DISTRIBUTED ALARM SYSTEMS. At the same time, OPERATORS with different clinical training and new roles for OPERATORS will change the way that OPERATORS respond to ALARM SIGNALS. In many instances, remote OPERATORS can be at a distance from the PATIENT such that they cannot personally respond to a PATIENT or equipment problem.*~~

~~*The committee believed that the field was too immature to write a large number of specific requirements. Perhaps a future edition of this collateral standard will be able to include more specific requirements, when the technology has matured. In the meantime, a MANUFACTURER is left to use good RISK ANALYSIS to be sure that their DISTRIBUTED ALARM SYSTEMS serve their primary purpose: to improve the ability of a qualified OPERATOR to respond in an appropriate and timely manner to every ALARM CONDITION.*~~

~~*Future systems can include transmission of ALARM SIGNALS via wired or wireless local area networks, wired or wireless devices connected to the Internet, commercial landline and cellular telephone networks, commercial one-way or two-way paging systems, and other systems. In all these systems, there can be delays in ALARM CONDITION transmission because of demands on networks and other systems. In every case there will be a delay before the ALARM SYSTEM detects an ALARM CONDITION, a delay before generation of ALARM SIGNALS at the primary ALARM SYSTEM, a delay before the ALARM CONDITION is transmitted to a DISTRIBUTED ALARM SYSTEM, and a delay before the DISTRIBUTED ALARM SYSTEM generates ALARM SIGNALS. Since these delays can vary at times due to factors outside the control of the MANUFACTURER and many of these delays are not deterministic, a statistical analysis will be required to determine the time before the ALARM CONDITION is indicated with ALARM SIGNALS to the appropriate OPERATOR. It may not be possible to guarantee a maximum time.*~~

~~*Any system of transmission of information is subject to failure. In the event of failure of a DISTRIBUTED ALARM SYSTEM or of the link between a primary ALARM SYSTEM and a DISTRIBUTED ALARM SYSTEM, the primary ALARM SYSTEM is required to generate ALARM SIGNALS normally. If the primary ALARM SYSTEM had been placed in the state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED, or ALARM OFF and the system had been relying on a DISTRIBUTED ALARM SYSTEM for attention to ALARM CONDITIONS (e.g. the DISTRIBUTED ALARM SYSTEM is not inactivated), then if the DISTRIBUTED ALARM SYSTEM fails, the primary ALARM SYSTEM should be automatically re-enabled.*~~

~~*EXAMPLE The local ALARM SYSTEM is AUDIO OFF (auditory ALARM SIGNAL volume set to zero) while the DISTRIBUTED ALARM SYSTEM is relied on to notify the OPERATOR. Upon detection of the failure, the local ALARM SYSTEM should return the volume to an audible level.*~~

~~*In addition, the primary ALARM SYSTEM and the DISTRIBUTED ALARM SYSTEM should both generate ALARM SIGNALS to alert the OPERATOR(S) to failure of the DISTRIBUTED ALARM SYSTEM.*~~

~~*Some members of the committee argued that ALARM SIGNALS should always be delivered to the appropriate OPERATOR under SINGLE-FAULT CONDITION, at least for life-supporting equipment. The committee felt it to be impossible to specify requirements and tests for every such situation in this collateral standard.*~~

~~*In any event, as noted above, RISK ANALYSIS should be done in this area. Furthermore, MANUFACTURERS are required to disclose the characteristics, limitations and possible failure modes of their DISTRIBUTED ALARM SYSTEMS.*~~

The use of DISTRIBUTED ALARM SYSTEMS is increasing. New ideas and new technology are bringing rapid advances and changes in this area. Long-, medium- and short-range two-way wireless communication opens new opportunities and new challenges for DISTRIBUTED ALARM SYSTEMS. At the same time, OPERATORS with different clinical training and new roles for OPERATORS will change the way that OPERATORS respond to ALARM SIGNALS. In many

instances, remote OPERATORS can be at a distance from the PATIENT such that they might not be able to respond personally to a PATIENT or equipment problem. DISTRIBUTED ALARM SYSTEMS are enabling significant changes in the clinical workflow.

A MANUFACTURER should use the RISK MANAGEMENT PROCESS to be sure that their DISTRIBUTED ALARM SYSTEMS serve their primary purpose: to improve the ability of the correct, qualified OPERATOR to respond appropriately to a specific ALARM CONDITION, thereby ensuring that every ALARM CONDITION is responded to in a timely manner.

DISTRIBUTED ALARM SYSTEMS can include transmission of ALARM SIGNALS via wired or wireless local area networks, wired or wireless devices connected to the Internet, commercial landline and cellular telephone networks, commercial one-way or two-way paging systems, and other systems. In all these systems, there can be delays in ALARM CONDITION transmission because of demands on networks and other systems. In every case, there will be a delay before the SOURCE detects an ALARM CONDITION, a delay before generation of ALARM SIGNALS at the COMMUNICATOR at the SOURCE, a delay before the ALARM CONDITION is transmitted within the DISTRIBUTED ALARM SYSTEM and a delay before the remote COMMUNICATOR generates ALARM SIGNALS. Since these delays can vary at times due to factors outside the control of the MANUFACTURER and many of these delays are not deterministic, a statistical analysis is required to determine the time before the ALARM CONDITION is indicated with ALARM SIGNALS to the appropriate OPERATOR. It might not be possible to guarantee a maximum time.

Any system of transmission of information is subject to failure. In the event of failure of a component of a DISTRIBUTED ALARM SYSTEM or of the link between the affected SOURCE and a DISTRIBUTED ALARM SYSTEM, any relevant COMMUNICATORS are required to generate TECHNICAL ALARM SIGNALS. If the ALARM SYSTEM of the SOURCE had been placed in the state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF and the system had been relying on a DISTRIBUTED ALARM SYSTEM for the notification to OPERATORS to ALARM CONDITIONS (e.g. the DISTRIBUTED ALARM SYSTEM is not inactivated), then if the DISTRIBUTED ALARM SYSTEM fails, the ALARM SYSTEM of the SOURCE should be automatically re-enabled.

EXAMPLE The ALARM SYSTEM of the SOURCE is AUDIO OFF (auditory ALARM SIGNAL volume set to zero) while the DISTRIBUTED ALARM SYSTEM is relied on to notify the OPERATOR. Upon detection of the failure, the ALARM SYSTEM of the SOURCE should return the volume to an audible level.

Some members of the committee argued that ALARM SIGNALS should always be delivered to the appropriate OPERATOR under SINGLE-FAULT CONDITION, at least for life-supporting equipment. The committee felt it to be impossible to specify requirements and tests for every such situation in this collateral standard.

In any event, as noted above, a RISK MANAGEMENT PROCESS should be used. Furthermore, MANUFACTURERS are required to disclose the characteristics, limitations and possible failure modes of their DISTRIBUTED ALARM SYSTEMS.

Subclause 6.11.1 – Existence of ~~DISTRIBUTED ALARM SYSTEM~~ DIS or DAS

~~DISTRIBUTED ALARM SYSTEM generation of ALARM SIGNALS can be provided by equipment to allow ALARM SIGNAL generation at a distance from the PATIENT. Remote generation of ALARM SIGNALS notifies OPERATORS who are not currently in the PATIENT ENVIRONMENT but who are reasonably expected to be able to respond (or notify and request others to respond) in a timely fashion to the presence of ALARM CONDITIONS.~~

DISTRIBUTED ALARM SYSTEM COMMUNICATORS can be provided by equipment to allow ALARM SIGNAL generation at a distance from the PATIENT. Remote COMMUNICATORS notify OPERATORS who are not currently in the PATIENT ENVIRONMENT but who are reasonably expected to be able to respond (or notify and request others to respond) in a timely fashion to the presence of ALARM CONDITIONS.

Subclause 6.11.2.2 – Failure of remote communication of ALARM CONDITIONS

A DISTRIBUTED ALARM SYSTEM might not receive a message from the ALARM SYSTEM indicating an ALARM CONDITION that was detected by the ALARM SYSTEM. If an OPERATOR is depending on the remote ~~generation of ALARM SIGNALS~~ COMMUNICATOR for treatment decisions, then it is necessary for the ALARM SYSTEM to know when an ALARM CONDITION has been successfully received by the DISTRIBUTED ALARM SYSTEM. When those ALARM CONDITIONS are not successfully received, generating ALARM SIGNALS to indicate a TECHNICAL ALARM CONDITION to warn the OPERATOR of such a fault, is necessary for safety when an ALARM SYSTEM includes a DISTRIBUTED ALARM SYSTEM.

Subclause 6.11.2.2.1 – DAS or CDAS

DISTRIBUTED ALARM SYSTEMS allow ALARM SIGNALS to occur at remote equipment or at a remote location such as a central station. Depending on the use model, the remote equipment can be actively used as a means of notification and control in a DISTRIBUTED ALARM SYSTEM. In such a case, it makes sense to permit control of the inactivation states ALARM PAUSED, AUDIO PAUSED, ALARM OFF, ACKNOWLEDGE or AUDIO OFF (depending on the configuration) remotely. Remote ALARM SIGNAL inactivation controls are required to be configurable by the RESPONSIBLE ORGANIZATION so that the RESPONSIBLE ORGANIZATION can configure the ALARM SYSTEM to be safe for their environment. Control of this feature is restricted to the RESPONSIBLE ORGANIZATION so that ALARM SYSTEM behavior is consistent within a care area, to prevent confusion between and among OPERATORS.

As indicated before, this remote control functionality depends on the use model in a certain environment such as in intensive care units. For this reason, only the RESPONSIBLE ORGANIZATION should have access to the corresponding configuration to prevent the inadvertent inactivation of ALARM SIGNALS that is contrary to the preferred clinical practice. It is important for the RESPONSIBLE ORGANIZATION to communicate the configuration of its ALARM SYSTEM to its staff through appropriate education.

If the ALARM SYSTEM at the SOURCE has lost its link to a DISTRIBUTED ALARM SYSTEM, care is needed so that the ALARM SYSTEM at the SOURCE and the ME SYSTEM revert to a safe mode of operation. In other words, if the DISTRIBUTED ALARM SYSTEM which was being used as the means of OPERATOR notification of ALARM CONDITIONS is now inoperative, then the COMMUNICATOR of the ALARM SYSTEM at the SOURCE is the only COMMUNICATOR that can notify the OPERATOR. In this instance, auditory ALARM SIGNALS that are in an inactivated state (AUDIO OFF, AUDIO PAUSED, ALARM OFF, ALARM PAUSED, ACKNOWLEDGED) only in the ALARM SYSTEM at the SOURCE can need to have those states automatically terminated. Even so, as was discussed above, it is generally not necessary for every ALARM SYSTEM at the SOURCE in the unit to generate auditory ALARM SIGNALS when the link is lost.

In addition, when the link is lost, auditory ALARM SIGNALS at the SOURCE can need to have their volume increased, and they can need ESCALATION or ESCALATION in a different manner than the usual means used when the ALARM CONDITION is unaddressed by the OPERATOR. The RESPONSIBLE ORGANIZATION might need to use an alternate system of alerting OPERATORS (such as an overhead paging system or a beeper paging system).

When designing and configuring DAS and CDAS, careful consideration to the care PROCESS and clinical responsibilities should also consider redundancy in COMMUNICATOR coverage. For example, if the care unit is utilizing a private, in-building wireless phone system as the means to distribute ALARM CONDITIONS, the INTEGRATOR needs to be configured by the SOURCE (PATIENT) and by ALARM CONDITION to deliver the ALARM CONDITION to the appropriate COMMUNICATOR (caregiver). In many cases, these assignments should include redundant COMMUNICATORS (caregivers).

Care is needed in the consideration of where and how the ALARM SIGNALS should be presented according to 6.11.2.3. Consider the example of a 40-bed unit or monitoring station in which the link to one PATIENT is lost. There is no need to present ALARM SIGNALS at all 40 beds, but

only at the "affected" bed(s) – the one with the broken link, and possibly other beds or other locations where the OPERATOR for the PATIENT with the broken link might be located.

Likewise, if the central station itself were to go offline, presentation of a HIGH PRIORITY ALARM SIGNAL at all 40 beds would require OPERATORS to interrupt their activities and address bedside ALARM SIGNALS for all 40 PATIENTS! In such a situation, LOW PRIORITY ALARM CONDITIONS, which might or might not include and auditory ALARM SIGNAL, should be presented at each bedside. In this situation, a different solution should be sought, and the solution might involve procedures for the RESPONSIBLE ORGANIZATION to notify OPERATORS of the problem by overhead paging, beeper paging, personal notification, etc.

As a final example, if several COMMUNICATORS (OPERATOR-carried wireless devices) are used as a part of a DISTRIBUTED ALARM SYSTEM, the failure of one COMMUNICATOR need not generate ALARM SIGNALS at every PATIENT bedside, if the rest of the COMMUNICATORS assigned to a PATIENT can cover the loss of one. This can happen if there are several redundant COMMUNICATORS that are able to inform the relevant OPERATORS, or if the INTEGRATOR is able to provide REDIRECTION of the ALARM CONDITION to an appropriate COMMUNICATOR. If a central station and wireless devices are used as part of a DISTRIBUTED ALARM SYSTEM, perhaps the only "relevant" part of the DISTRIBUTED ALARM SYSTEM is really the central station, or perhaps there are some specific beds that would be affected by the failure. It is doubtful that, for example, all 40 PATIENT bedsides would require presentation of ALARM SIGNALS.

Subclause 6.11.2.2.2 – DIS

~~*With some technologies, it can be impossible for a primary ALARM SYSTEM to know if a DISTRIBUTED ALARM SYSTEM has not received an ALARM CONDITION, or if it has failed. In this case, the MANUFACTURER is required to warn the RESPONSIBLE ORGANIZATION and the OPERATOR by marking the equipment not to rely upon the DISTRIBUTED ALARM SYSTEM for generation of ALARM SIGNALS. A DISTRIBUTED ALARM SYSTEM can be useful, even if it does not work 100 % of the time. Still, MANUFACTURERS and RESPONSIBLE ORGANIZATIONS should take precautions that PATIENT safety is not compromised.*~~

~~*At this time, DISTRIBUTED ALARM SYSTEMS confirmed delivery ("guaranteed delivery") of ALARM CONDITIONS is not present in every DISTRIBUTED ALARM SYSTEM. As an example, a one-way paging system which uses a commercial paging service is an important component of some DISTRIBUTED ALARM SYSTEMS. The ALARM SYSTEM is designed as if the one-way paging system were not present, so that there are always ALARM SIGNALS that will alert the OPERATORS of ALARM CONDITIONS in appropriate locations. But if the paging system is working correctly, pages to devices worn by the OPERATORS allow the OPERATORS to understand the problem more quickly than the rest of the DISTRIBUTED ALARM SYSTEM does. In such a DISTRIBUTED ALARM SYSTEM, the OPERATOR is expected to remain in notification range of the rest of the ALARM SYSTEM and only use the paging device for additional information. Thus the existence of the one-way paging system only decreases OPERATOR response time, and never increases it, compared to the option of deleting the paging system altogether.*~~

~~*It is likely, however, that one-way paging systems will eventually be replaced with two-way paging systems of various sorts.*~~

With a DIS, it is impossible for the ALARM SYSTEM at the SOURCE to know if the COMMUNICATOR has not received an ALARM CONDITION, or if it has failed. In this case, the MANUFACTURER is required to warn the RESPONSIBLE ORGANIZATION and the OPERATOR by marking on the COMMUNICATOR not to rely upon the DISTRIBUTED ALARM SYSTEM for generation of ALARM SIGNALS. A DIS can be useful, even if it does not work 100 % of the time. Still, MANUFACTURERS and RESPONSIBLE ORGANIZATIONS should take precautions so that PATIENT safety is not compromised.

An example of a DIS is a one-way paging system that uses a commercial paging service. The ALARM SYSTEM or DAS is designed as if the one-way paging system were not present, so that there are always COMMUNICATORS providing ALARM SIGNALS that will notify the OPERATORS of ALARM CONDITIONS in appropriate locations. But if the paging system is working correctly,

pages to COMMUNICATORS worn by the OPERATORS allow the OPERATORS to understand the problem more quickly than the DISTRIBUTED ALARM SYSTEM does. In such a system, the OPERATOR is expected to remain in notification range of the rest of the DAS and only use the paging COMMUNICATOR for additional information. Thus the existence of the one-way paging system only decreases OPERATOR response time, and never increases it, compared to the option of deleting the paging system altogether.

Subclause 6.11.2.2.3 – SOURCE with a global AUDIO OFF in a DISTRIBUTED ALARM SYSTEM

The issue of global AUDIO OFF is extremely important, but problematic. As an example, many intensive care units employ a “Night Mode” in which global AUDIO OFF is invoked at every bedside, and auditory ALARM SIGNALS present only at a central station. Such systems are generally used to try to make the bedside ME EQUIPMENT quiet at night, so that the PATIENT can sleep. In this implementation, if the link from a bedside ME EQUIPMENT to the central station is lost, or if the central station is inoperative, ALARM SIGNALS need to be reinstated at the PATIENT’S bedside or there will be no auditory ALARM SIGNALS at all. For this reason the global AUDIO OFF state is required to be terminated when the link is lost.

Care is needed in the design of such systems, however. If the link is down, or if the central station is inoperative, and the PATIENT experiences a cardiac arrest, OPERATORS might still wish to invoke the global AUDIO OFF state at the bedside ME EQUIPMENT. This global AUDIO OFF should be permitted, and indeed the continued non-functioning of the link should not cancel the AUDIO OFF a second time. Further problems can develop, of course, if the link alternates between a functional and non-functional state. PATIENT safety is the key design issue, but PATIENT safety suffers when OPERATORS have to deal with NUISANCE ALARM SIGNALS.

Subclause 6.11.2.3 – Remote ALARM SYSTEM controls

A remote OPERATOR at a central station ("monitor watcher") can respond to ALARM SIGNALS and examine waveforms or check the PATIENT on a video monitor. The remote OPERATOR then notifies other OPERATORS in the event of a CLINICALLY ACTIONABLE ALARM CONDITION, or does not notify other OPERATORS in the event of a FALSE POSITIVE ALARM CONDITION or CLINICALLY NONACTIONABLE ALARM CONDITION. In either case, the remote OPERATOR commonly invokes ACKNOWLEDGED, uses another ALARM SIGNAL inactivation state, adjusts ALARM LIMITS, changes ALARM PRIORITY, or determines which ALARM CONDITIONS need to generate ALARM SIGNALS. The functions permitted to the remote OPERATOR depend upon the configuration of the DISTRIBUTED ALARM SYSTEM and upon the policies of the RESPONSIBLE ORGANIZATION [31]. On this basis it is imperative for the RESPONSIBLE ORGANIZATION to determine what powers are or are not granted to the remote OPERATOR and so configure the DISTRIBUTED ALARM SYSTEM.

Additional issues include the ability of an OPERATOR to control the ALARM SYSTEM from a different bedside ME EQUIPMENT. As an example, a nurse might be assigned two or more different PATIENTS. The nurse might wish to control all ALARM SYSTEM functions for Bedside A while he or she is physically located at bedside B.

In some installations, the capability is provided so that any bedside ME EQUIPMENT anywhere in a hospital can control all the ALARM SETTINGS for any other bedside ME EQUIPMENT located anywhere in the hospital. Thus a person in the Emergency Department might be able to adjust ALARM LIMITS or invoke an ALARM SIGNAL inactivation state on ME EQUIPMENT in the neonatal intensive care unit. Such a design greatly increases the chances of inappropriate remote control of ALARM SETTINGS. One situation would involve error, for example, if the OPERATOR is trying to adjust the ALARM SETTINGS at the local bedside ME EQUIPMENT, but is actually in a menu to adjust remote ALARM SETTINGS. A second situation might involve operation of the ME EQUIPMENT by unauthorized persons.

Such systems should generally be designed to provide remote access to ALARM SETTINGS only in locations where that access is required.

Another design challenge is the complexity of control that is required. In an extreme case, one can imagine that the ability to control remote ALARM SETTINGS could be assigned by the following.

a) *Example*
   - *All PATIENTS within the hospital,*
   - *all PATIENTS on a certain unit,*
   - *all PATIENTS of a certain class (cardiac PATIENTS, neurosurgery PATIENTS, neonatal PATIENTS, PATIENTS of a certain physician, etc.), or*
   - *each individual PATIENT in the hospital would have different privileges about remote control of his/her ME EQUIPMENT.*

b) *Example*
   - *All OPERATORS of a certain kind (physicians, nurses, respiratory therapists, etc.) could have different privileges, or*
   - *each individual OPERATOR by name could have different privileges.*

c) *Example*
   - *Certain functions could be allowed from every location,*
   - *only from locations of a certain kind (at all central stations or at all remote bedsides),*
   - *at restricted locations (the central station of that same unit, or at a bedside within the same unit), or*
   - *at each possible location (at each bedside ME EQUIPMENT and at each central station) individually.*

d) *Example*
   - *ALARM CONDITIONS of different sorts could be controlled in one setting,*
   - *ALARM CONDITIONS from each ME EQUIPMENT could be controlled separately (bedside monitor, infusion pumps, ventilator),*
   - *ALARM CONDITIONS could be controlled by organ system (cardiac, respiratory, etc.),*
   - *ALARM CONDITIONS could be controlled by their priority, or*
   - *every ALARM CONDITION could be individually controlled, including each separate cardiac arrhythmia ALARM CONDITION.*

e) *Example*
   - *Whether the control is allowed could be simply "on" or "off,"*
   - *specific ALARM inactivation states (AUDIO PAUSED, AUDIO OFF, etc.) could be permitted or not permitted, or*
   - *the ability to change ALARM SETTINGS and ALARM LIMITS could be permitted or not permitted.*

It can be seen from these examples that the configuration of the ability of remote OPERATORS to configure the ALARM SYSTEM could be reasonably straightforward, or it could be incredibly complex in a five-dimensional matrix. It is not the intent of this standard to require the lowest level of control within any of the five categories. Instead RISK MANAGEMENT and concern for the ability of OPERATORS and RESPONSIBLE ORGANIZATIONS to understand how the ALARM SYSTEM works should be the driving forces.

Subclause 6.11.2.4 – CDAS

The terms RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED, and RESPONSIBILITY UNDEFINED are new to this document. They are most often applicable to a DISTRIBUTED ALARM SYSTEM for use in an intensive care setting or a hospital ward setting, in which each OPERATOR has a COMMUNICATOR (example: pocket pager or phone) that provides an ALARM CONDITION to a specific OPERATOR. If the DISTRIBUTED ALARM SYSTEM presents an ALARM CONDITION to a specific OPERATOR, then there can be three possibilities:

- the specific OPERATOR accepts responsibility for the ALARM CONDITION, and the state RESPONSIBILITY ACCEPTED becomes true;
- the specific OPERATOR is busy and therefore rejects responsibility, the state RESPONSIBILITY REJECTED becomes true, and the DISTRIBUTED ALARM SYSTEM redirects the ALARM CONDITION to a different COMMUNICATOR, hence OPERATOR;
- the OPERATOR does not respond to the ALARM SIGNAL within the timeframe established by the RESPONSIBLE ORGANIZATION in the INTEGRATOR, the state RESPONSIBILITY UNDEFINED becomes true, and the INTEGRATOR redirects the ALARM CONDITION to a different COMMUNICATOR, hence OPERATOR in this instance also.

A similar configuration might be provided for other DISTRIBUTED ALARM SYSTEMS, for instance, from a bedside monitor to a different bedside monitor, or from a beside monitor to a central station.

Care is needed in the design of a CDAS when there is a non-homogenous set of SOURCES. The logic (REDIRECTION and ESCALATION) behind the processing of RESPONSIBILITY UNDEFINED can become very complex and needs to take into account how each SOURCE responds to the resulting states. These complex systems can inadvertently cause ALARM FLOOD or 'lost' ALARM CONDITIONS (i.e. no assigned COMMUNICATOR).

Such a configuration would not be expected in ME EQUIPMENT without a DISTRIBUTED ALARM SYSTEM. For example, an anaesthesia workstation, for which an OPERATOR is normally present during all PATIENT care, would not be expected to provide these functions.

Subclause 6.12 – ALARM ~~CONDITION~~ SYSTEM logging

The logging of ALARM CONDITIONS can be useful for several reasons:

a) to determine the cause of a transient ALARM CONDITION when NON-LATCHING ALARM SIGNALS are used;

b) to determine the cause of an ALARM CONDITION when the equipment is unattended by an OPERATOR in NORMAL USE;

c) for quality assurance purposes;

d) for the study of critical incidents, similar to the event logging of aircraft "black-boxes";

e) to determine when an ALARM CONDITION occurred.

Life-supporting equipment or life-sustaining equipment as well as vital signs monitors should be equipped with ALARM CONDITION logging. Means should be provided, either within the equipment or remotely through a communications interface, to store a history of ALARM CONDITIONS and their level of priority in an ALARM CONDITION log. The log should also include the value of the variable that caused the ALARM CONDITION as well as the relevant current values of the elements in the ALARM PRESET including the ALARM LIMIT.

If there is a log, ~~all generated ALARM SIGNALS of ALARM CONDITIONS, or all generated ALARM SIGNALS of ALARM CONDITIONS at or above a specified priority,~~ all ALARM CONDITIONS, or all ALARM CONDITIONS at or above a specified priority, should be logged. TECHNICAL ALARM CONDITIONS are as important as PHYSIOLOGICAL ALARM CONDITIONS, since many situations are problematic as to whether the cause of an ALARM CONDITION ~~source~~ is technical or physiological (e.g., low signal strength).

In the ALARM OFF or ALARM PAUSED state, some equipment does not process signals (monitor for ALARM CONDITIONS) at all. In these instances, ALARM CONDITIONS are not determined, and they cannot be logged. Other equipment does process signals during ALARM OFF and/or ALARM PAUSED, and this equipment can log the ALARM CONDITIONS. In every instance of AUDIO OFF or AUDIO PAUSED, however, ALARM CONDITIONS should be logged. In any case, the entry and exit for each ALARM SIGNAL inactivation state (ALARM OFF, ALARM PAUSED, AUDIO OFF and AUDIO PAUSED) should be recorded.

An example will make this last situation clear. Suppose a monitor has a HIGH PRIORITY ALARM SIGNAL for high heart rate. ALARM CONDITIONS for high heart rate should be logged. If the OPERATOR places the high heart rate ALARM CONDITION in the ALARM OFF or AUDIO OFF state, that fact should be recorded in the log. In other words, the ALARM CONDITION log should reflect high heart rate ALARM CONDITIONS and any period of time in which the ALARM SIGNALS for high heart rate ALARM CONDITIONS were not generated or that auditory ALARM SIGNALS ~~where~~ were not generated. Otherwise, the ALARM CONDITION log is meaningless, because review of the log would not reveal if:

f) there were no high heart rate ALARM CONDITIONS during that period, or

g) the ALARM SYSTEM was in an ALARM SIGNAL inactivation state during that period of time.

If the ALARM SYSTEM is provided with a log of ALARM CONDITIONS:

- *the contents of the log can be stored either for a specified period of time or until deleted by RESPONSIBLE ORGANIZATION or OPERATOR action;*
- *the contents of the log should be available for review by the OPERATOR;*
- *short losses of power (less than 30 s) should not cause the loss of the contents of the log.*

The previously stored contents of the log can be deleted when the OPERATOR indicates to the equipment, preferably through an "admit new PATIENT" function, that a different PATIENT has been connected to the equipment.

~~*MANUFACTURERS should consider including a log of TECHNICAL ALARM CONDITIONS that cannot be reset by OPERATOR action for servicing and maintenance purposes.*~~

The ALARM SYSTEM should log the date and time of occurrence and the identity of the OPERATOR who changes the ALARM LIMITS, the ALARM SIGNAL volume and the ALARM SIGNAL inactivation states. As the state of technology advances this capability is expected to become a requirement.

An ALARM SYSTEM log should not be editable by the (clinical) OPERATOR.

ALARM SYSTEM logs are in their infancy. It is essential to know when an ALARM CONDITION occurred, by either knowing the date and time, or the time since ALARM CONDITION itself, or the time that the ME EQUIPMENT was placed into use.

As these ALARM SYSTEM logs continue to develop, date and time stamping will become more and more important. The time synchronization of all ME EQUIPMENT will become even more important in the future. Eventually it is anticipated that a common time server synchronizes the time in all ME EQUIPMENT (and that the time server will allow a smooth transition to and from Daylight Savings Time (summer time) when appropriate).

A significant issue is the use of ALARM SYSTEM logs as a sort of "black box" recorder. In the event of a PATIENT adverse event, it is often desired to review what happened, including the ALARM SETTINGS, the invocation of any ALARM inactivation states, the occurrence of ALARM CONDITIONS, changes in ALARM PRIORITY, the time elapsed before the OPERATOR responded to ALARM SIGNALS (for instance by invoking an ALARM SIGNAL inactivation state), etc. While nearly all logs are incomplete today, it is anticipated that such functions will be needed in the future.

It is also desirable that the events which led to an ALARM CONDITION should be captured. A simple limit violation might record the high ALARM LIMIT setting and the actual reading, such as 120 > 100. Other ALARM CONDITIONS derived from multiple readings or from complex algorithms can be more difficult to record. For instance, it might not be possible to store waveforms recognized by pattern recognition algorithms. In any case, ME EQUIPMENT should log whatever relevant data that they can.

Care is needed to prevent OPERATORS from tampering with this record. In today's ME EQUIPMENT, it is possible that loss of SUPPLY MAINS or the function of admitting a new

PATIENT can cause deletion of the ALARM SYSTEM log, but in the future these logs should be preserved in some way. In any case, it should be made impossible for OPERATORS to edit the log or to deliberately erase it.

In the future, it is anticipated that ME EQUIPMENT should record the identity of OPERATORS who interact with that ME EQUIPMENT, including its ALARM SYSTEM. This identification might take place via passwords, proximity sensors, biometric identification including face recognition, etc.

Additional care is needed in the design of the ALARM SYSTEM log and other data storage capabilities so that the ME EQUIPMENT complies with relevant PATIENT privacy laws.

Subclause 6.12.2 – OPERATOR ALARM SYSTEM logging

An OPERATOR ALARM SYSTEM log can be used for reviewing and analysing events that have occurred for a PATIENT, typically while the PATIENT is still connected to the ME EQUIPMENT, or after they are disconnected from the ME EQUIPMENT, but before being discharged from the ME EQUIPMENT. This OPERATOR ALARM SYSTEM log can be used to identify the state of the ALARM SYSTEM, including the activation/inactivation status, at the time of an ALARM CONDITION.

In general, the OPERATOR ALARM SYSTEM log contains HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS but could also contain LOW PRIORITY ALARM CONDITIONS if the RESPONSIBLE ORGANIZATION finds it necessary. For example, LOW PRIORITY ALARM CONDITIONS could include low battery ALARM CONDITIONS for a telemetry transmitter that can be beneficial to aid in analysis or planning of workflow.

The OPERATOR ALARM SYSTEM log can be useful for:

a) reviewing the ALARM CONDITION history of the PATIENT;

b) reviewing the ALARM SETTINGS used for the PATIENT, including ALARM LIMITS and ALARM INACTIVATION STATES;

c) analysis of ALARM CONDITION events associated with a PATIENT, including date, time, and length of the event; and

d) annotation and rationale for adjustments made to the ME EQUIPMENT ALARM SETTINGS based on the clinical acuity of the PATIENT.

The OPERATOR ALARM SYSTEM log is unique for a PATIENT. That is to say, when a new PATIENT is connected, a new log should be established. This is necessary to prevent PATIENT-to-data-association errors and for proper analysis of events and workflows. The identification of a new PATIENT could, and most likely would, occur when a different PATIENT is admitted. A means could be provided, either automatically or manually, for the OPERATOR to enable identification of a different PATIENT.

The OPERATOR ALARM SYSTEM log can provide a means to enable the OPERATOR to insert notes or comments to the log, which can assist in identification or rationale for ALARM SYSTEM adjustments, including ALARM LIMIT SETTINGS and activation/inactivation states of the ALARM SYSTEM. The identification of the OPERATOR who inserted notes or comments in the log is beneficial in the review of ALARM CONDITION events and clinical workflow for further or more detailed analysis of the history of the state of the PATIENT.

Subclause 6.12.3 – RESPONSIBLE ORGANIZATION ALARM SYSTEM logging

A RESPONSIBLE ORGANIZATION ALARM SYSTEM log can be used for analysing events that occurred in the past, typically after a PATIENT has been disconnected and the ME EQUIPMENT is no longer being used for the PATIENT to whom it was connected during an event. Sometimes this is called a forensic log in that it is used to identify a sequence of conditions, or the state of the ME EQUIPMENT ALARM SYSTEM so the RESPONSIBLE ORGANIZATION can analyse how the event occurred in the first place. The cause can have been due to changing an ALARM SETTING

in which case the RESPONSIBLE ORGANIZATION needs understanding to assist them in determining their ALARM SYSTEM management PROCESSES.

In general, the RESPONSIBLE ORGANIZATION ALARM SYSTEM log should contain all the elements in the OPERATOR ALARM SYSTEM log plus additional information that can be used to analyse all aspects of suspected events. This can be a necessity to understanding all conditions in place during an event.

The RESPONSIBLE ORGANIZATION ALARM SYSTEM log can be useful for:

a) logging of ALARM CONDITIONS, including any ALARM SIGNAL inactivation state;

b) determining the ALARM SETTINGS and any change that was made to ALARM SETTINGS and the time the changes were made;

c) determining when an ALARM CONDITION began and ended (the amount of time an ALARM CONDITION existed); and

d) identifying TECHNICAL ALARM CONDITIONS in addition to PHYSIOLOGICAL ALARM CONDITIONS.

Since the RESPONSIBLE ORGANIZATION ALARM SYSTEM log files are used to determine the configuration of the ME EQUIPMENT during an event, it should not be possible to edit or delete entries in the RESPONSIBLE ORGANIZATION ALARM SYSTEM log. To allow this would create an inaccurate representation of the state of the ME EQUIPMENT and could be misleading.

Because many events are analysed after the fact when the ME EQUIPMENT might have been powered down, or a different PATIENT admitted, the RESPONSIBLE ORGANIZATION ALARM SYSTEM log should retain this data for a sufficient period.

The instructions for use should provide a description of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log so the RESPONSIBLE ORGANIZATION has an understanding of how to retrieve the data and the period for which the data is still available in the log. If the data are maintained on a first in, first out basis, the instructions for use should so state.

~~**Annex F**~~

~~Annex F provides a set of melodies and associated meanings that can be used for equipment-encoded and urgency-encoded auditory ALARM SIGNALS. If a melody from Annex F is used in an auditory ALARM SIGNAL, then the meaning of the melody is required to be consistent with the underlying ALARM CONDITION or equipment category as described in Annex F. The use of melodies other than those defined in Annex F is acceptable if they are constructed and implemented in such a way that they cannot be confused with the melodies from Annex F.~~

~~Table A.1 and Table A.2 indicate the interpretation of the melodies of Annex F.~~

Table A.1 – Reference interpretation of Table F.1

Cause	MEDIUM PRIORITY	HIGH PRIORITY	Mnemonic notes	Examples of type of ALARM SYSTEM
General	c c c	c c c – c c	Fixed pitch	Other ALARM SYSTEMS that do not readily fall into one of the following categories, including but not limited to electrical or non-oxygen gas supply systems, EEG monitors, intracranial pressure monitors, laparoscopic gas insufflation systems, calf compressor systems, etc. Optionally this sound is permitted for the ALARM SYSTEM of any kind of equipment.
Cardiac	c e g	c e g – g C	Trumpet call; Call to arms; Major chord	Anesthesia workstations that include cardiac monitors, multi-parameter monitors which include cardiac monitors, heart rate monitors, invasive or non-invasive blood pressure monitors, cardiac output monitors, peripheral perfusion monitors (plethysmographs), transesophageal echo, fetal heart rate monitors.
Artificial perfusion	c f#c	c f#c – c f#	Artificial sound; Tri-tone	Cardio-pulmonary perfusion pumps ("heart-lung machines") and associated equipment, intra-aortic balloon pumps, renal dialysis systems.
Ventilation	c a f	c a f – a f	Inverted major chord; Rise and fall of the lungs	Anesthesia workstations which include ventilators (but which do not include cardiac monitors); lung ventilators, spirometers, CO_2 monitors, ventilator disconnect (airway pressure) monitors, etc.
Oxygen	C b a	C b a – g f	Slowly falling pitches; Top of a major scale; Falling pitch of an oximeter	Pulse oximeters, transcutaneous / tissue oxygen monitors, oxygen analyzers, oxygen concentrators, oxygen gas supply lines.
Temp / energy delivery	c d e	c d e – f g	Slowly rising pitches; Bottom of a major scale; Related to slow increase in energy or (usually) temperature	Temperature monitors, heated air humidifiers, infant radiant warmers, neonatal incubators, PATIENT heating or cooling systems, blood or fluid warmers; electrocautery, ultrasound, laser, X-ray or MRI systems, nerve stimulators.
Drug or fluid delivery	C d g	C d g – C d	Jazz chord (inverted 9th); Drops of an infusion falling and "splashing" back up	Volumetric infusion pumps, syringe drivers, anesthetic agent delivery systems or analyzers.
Equipment or supply failure	C c c	C c c – C c	Falling or dropping down	Any device when it experiences loss of power or other major failure of the device.

Table A.2 – Reference interpretation of Table F.2

Cause	LOW PRIORITY	Mnemonic, notes
Any	e c	Hostess call or door bell "ding-dong"

Annex G – Auditory ALARM SIGNAL

A sizeable body of evidence that demonstrates that AUDITORY ICONS are easier to learn and recognize than more abstract ALARM SIGNALS and sounds exists. The main reason for this is that AUDITORY ICONS, which are usually everyday sounds, have much stronger links with the events that they are representing than do abstract sounds. For example, once a user knows that a cardiovascular ALARM CONDITION is indicated by a heartbeat, or a sound that has been developed in order to sound like a heartbeat, they are likely to remember this association rapidly and long-term. A second reason for advocating the use of AUDITORY ICONS is that real-world sounds are often harmonically rich and complex, making them easier to localize and making them more resistant to masking than abstract sounds. A third by-product of the use of AUDITORY ICONS is that the selection of specific AUDITORY ICONS for specific functions means that sounds which might occur naturally in a clinical environment might be avoided, thereby preventing confusion.

The general advantages of using AUDITORY ICONS are described in the literature [34] [35] [36] [37] [38].

The committees know more about the performance of these auditory ALARM SIGNALS than probably any auditory ALARM SIGNALS in history, and the data is available in high-quality peer-reviewed publications that are in the public domain. The performance data of these auditory ALARM SIGNALS is embodied in Table H.1. Most of the data for Table H.1 comes from four key papers [36], [66], [67], [68].

The committees know so much about these auditory ALARM SIGNALS that they can extrapolate from the findings to situations where the auditory ALARM SIGNALS might not have been directly tested. There are three points that are important to note.

1) The two main requirements of the new auditory ALARM SIGNALS are that they are audible and recognizable. Almost everything else is a matter of taste and preference. The committees have considerable data to show that both learnability and audibility are high with regard to all of the proposed new auditory ALARM SIGNALS.
2) In terms of these two principles of audibility and recognisability, the key factors that influence people's ability to detect and recognize the sounds are their age and their hearing ability, rather than their clinical role or some other local variable. There can be some cultural factors around suitability and recognisability, but this document permits development in these areas.
3) There are many principles and known scientific observations which allow the committees to predict outcomes of some features (such as audibility), without the need to test the auditory ALARM SIGNALS in all possible environments. Because the proposed auditory ALARM SIGNALS perform so well on so many counts, it would be correct to say that if it is a struggle to hear and recognize these auditory ALARM SIGNALS, then it would be a struggle to hear and recognize any auditory ALARM SIGNALS and therefore a solution other than auditory ALARM SIGNALS (e.g. vibration, stroboscopic lights) would be appropriate under those circumstances.

Auditory ALARM SIGNALS cannot be imbued with magical properties allowing them to work in all possible environments, regardless of how extreme or unusual that environment might be. However, the committees have used what is known about auditory cognition and perception to develop and test these auditory ALARM SIGNALS. They follow best practice and are the best they can be, given what the committees know and can predict from the science.

Clause G.1 a) 2) – General

Adding an AUDITORY ICON to a LOW PRIORITY ALARM SIGNAL unnecessarily increases the audio burden on the OPERATOR. Additionally, given the short nature of the LOW PRIORITY AUDITORY POINTER, its priority could be masked by the AUDITORY ICON.

Clause G.2 – AUDITORY POINTERS

Table G.1 and Table G.2 specify the spectral, amplitude and timing variables for the HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY AUDITORY POINTERS. The three priority levels are differentiated via the application of acoustic parameters, which are known to be important in determining the perceived urgency and the detectability/resistance to masking of the sounds.

The intent of the AUDITORY POINTER is to identify the COMMUNICATOR generating the ALARM SIGNAL and indicate the ALARM CONDITION priority, whereas the intent of the AUDITORY ICON is to identify the category of the ALARM CONDITION as well as to localize the COMMUNICATOR generating the ALARM SIGNAL. The categories are meant to distinguish between types of ME EQUIPMENT (the type of physiological function affected) generating the ALARM CONDITION. The OPERATOR is able to respond to the ALARM CONDITION more quickly by knowing the type of ME EQUIPMENT that generated the ALARM CONDITION. In order to localize the ALARM SIGNAL, it is important that the AUDITORY ICON be in combination with the AUDITORY POINTER. The reference AUDITORY ICONS use pitch, rhythm and auditory streaming to facilitate separation from the AUDITORY POINTER; the ear readily detects both sounds even when heard together. Table G.4 illustrates the characteristics of the AUDITORY ICONS including their metaphors and descriptions.

Urgency

Many acoustic parameters influence the perceived urgency of sound. These include pitch and frequency, amplitude, speed, repetition, harmonic harshness and musical structure, among other factors. These factors can be used to both differentiate between levels of urgency and influence the absolute level of urgency of a sound. The former is easier to achieve than the latter so consideration should be given to how the AUDITORY POINTERS work in the environment for which they have been designed.

Relative urgency: If one ALARM SIGNAL is higher pitched, louder and faster and repeats more often (and more quickly) than another it will likely be judged more urgent. Equally, the reverse is true: ALARM SIGNALS that are lower pitched, softer, slower and repeat more slowly (or not at all) will likely be judged less urgent. However, caution should be used with using loudness to influence urgency as:

a) if ALARM SIGNALS are too loud, they startle; and

b) the loudness of ALARM SIGNALS should be determined by the typical level of ambient noise, which would be the same for all ALARM SIGNALS, regardless of their urgency. See the rationale for Subclause 6.3.3.2; and

c) OPERATORS cannot compare the loudness of two ALARM SIGNALS unless they are presented adjacent to each other. Therefore, loudness can rarely be used effectively to indicate urgency.

Absolute urgency: If an ALARM SIGNAL is designed according to the known principles of urgency, listeners find it possible to triage (at least) ALARM SIGNALS into HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY – although it is impossible to say exactly where the cut-off between categories occurs. If a HIGH PRIORITY ALARM SIGNAL is perceived as being too urgent, it can be made less urgent by applying the known principles of urgency and, if it is not urgent enough, it is possible to do the reverse. Further refinement of urgency can be achieved by manipulating secondary factors such as harmonic structure and harmonic content, for example, see [39], [40], [41], [42], [43] and [44].

Detectability

The requirement that the PULSES of the AUDITORY POINTERS should possess a fundamental frequency between 150 Hz and 1 000 Hz, with at least four frequency peaks below 4 000 Hz, is primarily for detectability, resistance to masking and localizability (though variation in harmonic content can also influence urgency, as indicated above). One of the major reasons for 4 peaks is that pure tones are irritating to listen to, and are more likely to startle an

OPERATOR. In general, the more frequencies (and harmonic peaks) a sound possesses, the more resistant it will be to masking and the more likely it will be localized with some accuracy. This will be true for both AUDITORY POINTERS and AUDITORY ICONS. Frequencies between approximately 800 Hz and 1 600 Hz are not useful for the purposes of localization (but will be useful for resistance to masking) as neither of the two mechanisms the head uses for localization work within this range. In general, the more frequency components a sound possesses, the easier it will be to localize and the more resistant to masking it will be. Software and models that allow the modelling and prediction of masking exist [45] [46] [47] [48] [49] [50].

Most of the audibility issues can be predicted from what is known about the science of detectability. The key to this is the signal-to-noise ratio at which a sound is detectable. The test data shows that the auditory ALARM SIGNALS are detectable at very low signal-to-noise ratios, and this is a consequence of the way the auditory ALARM SIGNALS were designed in the first place [66].

Because the AUDITORY POINTERS (to some extent) and the AUDITORY ICONS (to a larger extent) are complex sounds with many harmonics, they are much more resistant to masking by other sounds than most of the ALARM SIGNALS currently being used. By using many harmonics and ensuring that the auditory ALARM SIGNALS contain some low frequency harmonics, the audibility of the ALARM SIGNALS has been maximised, as the data suggests. Thus, these auditory ALARM SIGNALS are at least as audible as almost any other sound that might be used in the same contexts. This means that their volume can be kept at a reasonable level. There can be some exceptional circumstances where the auditory ALARM SIGNALS might be temporarily masked, but this would be the case for any other auditory ALARM SIGNAL and most other auditory ALARM SIGNALS will be less resistant to masking. The solution to this rare problem is to recommend that auditory ALARM SIGNALS are not made so loud that they are aversive under most other circumstances. In such circumstances, using auditory ALARM SIGNALS might not be appropriate.

Learnability

Early formative testing compared the learnability of Annex F auditory ALARM SIGNALS to new AUDITORY POINTERS as well as the combination of the AUDITORY POINTERS and AUDITORY ICONS. The existing general auditory HIGH PRIORITY ALARM SIGNAL had 65 % accuracy while the new HIGH PRIORITY AUDITORY POINTER had more than 80 % accuracy. The remaining Annex F auditory ALARM SIGNALS had an accuracy that ranged from 25 % to 35 % [36].

Clause G.3 – AUDITORY ICONS

AUDITORY ICONS are presented along with either a HIGH PRIORITY or a MEDIUM PRIORITY AUDITORY POINTER (see Clause G.2), depending on the urgency of the situation being signalled. The reserved AUDITORY ICONS are listed in Table G.3.

An AUDITORY ICON should contain many harmonic components or peaks, and for guidance these should be no less than as indicated in Table G.2. As AUDITORY ICONS are intended to be everyday sounds, it is likely that there will be considerable variation in the amplitude of the spectral peaks so care needs be taken to ensure that an appropriate number of the spectral peaks are within 15 dB of one another.

An advantage of the complex harmonic structure is that the AUDITORY ICONS are easier to localize (to tell the direction from which the sound is coming) than the current auditory ALARM SIGNALS [36] [67].

Table G.4 – Characteristics of the AUDITORY ICON

There are important conceptual issues that need to be considered when using Table G.4 and its information.

The categories in Table G.4 are derived from a "risk-and-response rationale" [51]. Other categories, or subdivisions of categories, can be appropriate for specific environments. The use of more than eight categories is possible with the use of AUDITORY ICONS as they are considerably easier to learn and retain than abstract ALARM SIGNALS and melodies. However, there is always a RISK that as the number of ALARM SIGNALS increases the possibility of masking becomes more likely. Thus, the number of ALARM SIGNALS used in any environment should never be more than the minimum number considered necessary.

However, in a DISTRIBUTED ALARM SYSTEM with multiple SOURCES and multiple COMMUNICATORS, careful consideration is needed to determine the appropriate AUDITORY ICON or AUDITORY ICONS, if any, to use on a COMMUNICATOR.

EXAMPLE 1 A multi-PATIENT central station COMMUNICATOR might not use AUDITORY ICONS, even if some or all of the ALARM SIGNALS are using AUDITORY ICONS at the local COMMUNICATOR of the SOURCE.

EXAMPLE 2 A role-based COMMUNICATOR, such as a mobile app used by the respiratory therapist, where the AUDITORY POINTER and AUDITORY ICON might be used for specific ALARM CONDITIONS, but only the general AUDITORY POINTER for other specific ALARM CONDITIONS.

Generating new or alternative categories is likely to work best if any new categories are developed through the application of an underlying principle or set of principles, rather than being piecemeal. For example, a category might be designated by equipment type, or could represent a subdivision of a basic category. However, if new categories are generated, it is important to be aware of how each new category fits into the ALARM SYSTEM hierarchy or philosophy, and that the mapping of sounds and categories back to the philosophy is recorded and understood at some point in the PROCESS by the MANUFACTURER [52].

The generation of appropriate categories is also likely to lead to greater success if an empirical, user-centred PROCEDURE is used to derive those categories. Two possible methods are reported in the literature [53] [54].

The AUDITORY ICONS have been tested in a number of lab and simulation studies and have been found to perform well in comparison to both the melodies of Annex F and other sounds which themselves are an improvement on the melodies of Annex F [36] [66] [67] [68].

The AUDITORY ICON metaphor has been selected after testing and has been found to be adequate (see Clauses H.1 and H.2).

It is possible for a MANUFACTURER to perform the following.

a) Develop an AUDITORY ICON (sound) for the same category that is different acoustically from the one indicated. As an example, the current temperature sound might be replaced with a different sound, which has a different spectrum – possibly a lower frequency sound, or the introduction of a temporal pattern into the same sound, etc. This does not alter the nature of the metaphor.

b) Develop a new metaphor for one or more categories. For example, the current temperature category might be replaced with another metaphor and AUDITORY ICON (sound) that represents "frying on the stove", which has a different spectrum – possibly a lower frequency sound, or the introduction of a temporal pattern into the same sound, etc. This does not alter the nature of the metaphor as it is also associated with temperature.

Reasons for doing this might include:

- the presence of a complex or unusual noise background (so a new sound or metaphor needs to be developed in order to be heard);
- other sounds in the environment that might be confused with the current sound or metaphor;
- a particular version of the metaphor or a different metaphor is considered to be capable of better performance than the provided sounds.

Annex H provides an evaluation PROCEDURE for a different sound or metaphor for

a) the existing categories; or

b) new categories.

Table A.2 contains examples of ME EQUIPMENT for each category of the SOURCE of the ALARM CONDITION.

Table A.2 – Examples of ME EQUIPMENT for each category of the SOURCE of an ALARM CONDITION

Category	Examples
General	Other ME EQUIPMENT that does not readily fall into one of the following categories including, but not limited to, electrical or non-oxygen gas supply systems, EEG monitors, intracranial pressure monitors, laparoscopic gas insufflation systems, calf compressor systems, bed exit systems, etc. Additionally, this category is permitted for the ALARM SYSTEM of any kind of equipment.
Cardiovascular	Anaesthesia workstations that include cardiac monitors, multi-parameter monitors which include cardiac monitors, heart rate monitors, invasive or non-invasive blood pressure monitors, cardiac output monitors, external pacemakers, peripheral perfusion monitors (plethysmographs), transoesophageal echo, foetal heart rate monitors.
Artificial perfusion	Cardio-pulmonary perfusion pumps ("heart-lung machines") and associated equipment, intra-aortic balloon pumps or left ventricular assist devices, renal dialysis systems, extracorporeal membrane oxygenation systems and continuous veno-venous haemodialysis
Ventilation	Ventilators, ventilatory support equipment, spirometers, CO_2 monitors, ventilator disconnect (airway pressure) monitors, nitric oxide delivery systems, anaesthesia workstations which include ventilators (but which do not include cardiac monitors) and apnoea monitors
Oxygenation	Pulse oximeters, transcutaneous tissue oxygen monitors, oxygen analysers, oxygen concentrators, oxygen gas supply lines
Temperature/energy delivery	Temperature monitors, warming blankets, respiratory heated humidifiers, infant radiant warmers, neonatal incubators, PATIENT heating or cooling systems, blood or fluid warmers; electrocautery, ultrasound systems, diagnostic imaging systems, nerve stimulators and laser systems
Drug or fluid delivery/administration	Volumetric infusion pumps, syringe pumps, enteral delivery systems, anaesthetic agent delivery systems and anaesthetic agent analysers
Equipment or supply failure	Any ME EQUIPMENT when it experiences loss of power or other major failure of the ME EQUIPMENT

Annex B
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

B.1 Marking of controls and instruments

The requirements for marking of controls and instruments are found in 7.4 and in Table C.3 of the general standard. Additional requirements for marking of controls and instruments relating to ALARM SYSTEMS in ME EQUIPMENT and in ME SYSTEMS are found in the subclauses listed in Table B.1.

Table B.1 – Cross-reference of marking

Description	Clause or subclause
ALARM CONDITION, priority	6.3.2.2.1
ALARM CONDITION, visual indication	6.3.2.2.2
ALARM CONDITION, visual indication, multiple	6.3.2.2.2
ALARM LIMIT, automatically adjusted	6.6.2.2
ALARM LIMIT, OPERATOR adjusted	6.6.2.1
ACKNOWLEDGED, means of control	6.8.5 Table 5
ACKNOWLEDGED, state indication	6.8.5 Table 5
ALARM OFF, means of control	6.8.5 Table 5
ALARM OFF, state indication	6.8.5 Table 5
ALARM PAUSED, means of control	6.8.5 Table 5
ALARM PAUSED, visual indication	6.8.5 Table 5
ALARM RESET, means of control	6.9
AUDIO OFF, means of control	6.8.5 Table 5
AUDIO OFF, visual indication	6.8.5 Table 5
AUDIO PAUSED, means of control	6.8.5 Table 5
AUDIO PAUSED, visual indication	6.8.5 Table 5
Failure of remote communication of ALARM CONDITION	6.11.2.2
Display the ALARM LIMITS, means of control	6.6.2.1
Warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS	6.11.2.2.2
NOTE Guidance on using markings to help avoid FALSE POSITIVE and NEGATIVE ALARM CONDITIONS is given in A.1.3.	

B.2 Accompanying documents, General

The requirements for information to be included in the ACCOMPANYING DOCUMENTS are found in 7.9.1 and Table C.4 of the general standard. Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS relating to ALARM SYSTEMS in ME EQUIPMENT and in ME SYSTEMS are found in the subclauses of this standard listed in Table B.2.

Table B.2 – Cross-reference of ACCOMPANYING DOCUMENTS

Description	Clause or subclause
ALARM PRESET, means for configuration and storage	6.5.3.2 d)
Auditory ALARM SIGNAL, sound pressure level range (volume)	6.3.3.2

B.3 ACCOMPANYING DOCUMENTS, Instructions for use

The requirements for information to be included in the instructions for use are found in 7.9.2 and Table C.5 of the general standard. Additional requirements for information to be included in the instructions for use are found in the subclauses of this standard listed in Table B.3.

Table B.3 – Cross-reference of instructions for use

Description	Clause or subclause
ALARM SIGNAL GENERATION DELAY of DISTRIBUTED ALARM SYSTEM, maximum time or time to TECHNICAL ALARM CONDITION	6.4.2 b)
ALARM SIGNAL GENERATION DELAY, mean	6.4.1
ALARM SIGNAL GENERATION DELAY, statistics of distribution	6.4.1
ALARM CONDITION DELAY, mean time	6.4.1
ALARM CONDITION DELAY, statistics of distribution	6.4.1
~~ALARM CONDITION log after power down~~	~~6.12 b)~~
~~ALARM CONDITION log after power failure~~	~~6.12 c)~~
~~ALARM CONDITION log after reaching capacity~~	~~6.12 d)~~
Capacity of the log	6.12.2 j) 4)
Means for the OPERATOR to access the OPERATOR ALARM SYSTEM logALARM CONDITION log after power down	6.12.2 j) 1)
RESPONSIBLE ORGANIZATION ALARM SYSTEM log capacity	6.12.3 g) 1)
What happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power for a finite duration	6.12.2 j) 3)
What happens to the contents of the log as it reaches capacity	6.12.2 j) 5)
What happens to the contents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as it reaches capacity	6.12.3 g) 2)
Whether the log is maintained when the ALARM SYSTEM is powered down and whether or not the time of powering down is captured in the log	6.12.2 j) 2)
ALARM CONDITION, grouping	6.1.1
ALARM CONDITION, priority of each	6.1.2
ALARM or AUDIO PAUSED interval	6.8.5
ALARM PRESET, MANUFACTURER-configured description and ALARM LIMITS	6.5.2
ALARM PRESET, warn OPERATOR to check values	6.5.3.2 c)
~~Auditory ALARM SIGNAL, sound pressure range (volume)~~	~~6.3.3.2~~
Auditory INFORMATION SIGNAL, characteristics	6.3.3.2

Description	Clause or subclause
Behavior of automatically set ALARM LIMIT	6.6.2.2 d)
DISTRIBUTED ALARM SYSTEM, delay from ALARM CONDITION to SIGNAL INPUT/OUTPUT PART	6.4.2 a)
Duration of power loss that causes loss of ALARM SETTINGS	6.5.4.2
For a dynamically algorithm-adjusted minimum auditory ALARM SIGNAL sound pressure level, algorithm and the minimum and maximum levels	6.3.3.3
INTELLIGENT ALARM SYSTEM, ALARM CONDITIONS of the equal priority, internal ranking	6.2 b)
INTELLIGENT ALARM SYSTEM, ALARM SIGNAL generation change algorithms	6.2 e)
INTELLIGENT ALARM SYSTEM, changes in delay times	6.2 d)
INTELLIGENT ALARM SYSTEM, overview of logic decisions	6.2 a)
INTELLIGENT ALARM SYSTEM, priority assignment algorithms	6.2 c)
Behavior of ALARM SETTINGS for power loss for < 30 s	6.5.5
Multiple ALARM PRESETS, warn OPERATOR to check	6.5.1
REMINDER SIGNAL, characteristics	6.8.2
REMINDER SIGNAL, duration of any interval	6.8.2
Sum of ALARM SIGNAL GENERATION DELAY and ALARM CONDITION DELAY mean	6.4.1
Sum of ALARM SIGNAL GENERATION DELAY and ALARM CONDITION DELAY statistics of distribution	6.4.1
Warning, auditory alarm signal sound pressure levels that are less than ambient levels can impede operator recognition of alarm conditions	6.3.3.3

B.4 ACCOMPANYING DOCUMENTS, Technical description

The requirements for general information to be included in the technical description are found in subclause 7.9.3 and in Table C.6 of the general standard. Additional requirements for general information to be included in the technical description are found in the subclauses listed in Table B.4.

Table B.4 – Cross-reference of technical description

Description	Clause or subclause
DISTRIBUTED ALARM SYSTEM, details necessary for safe use	6.11.1

Annex C
(normative)

Symbols on marking

The symbol graphics of Table C.1 required by this collateral standard shall conform to the IEC or ISO reference standard, as indicated. Where appropriate, supplemental titles and descriptions have been added for specific application to ME EQUIPMENT and ME SYSTEMS that contain ALARM SYSTEMS. Table C.2 provides an informative reference to symbol graphic, title and description from the reference standard for these graphical symbols as a quick reference. Table C.2 provides a normative reference to the ALARM SYSTEM description and the reference standard for these graphical symbols. See also Annex B.

Table C.1 – Graphical symbols for ALARM SYSTEMS

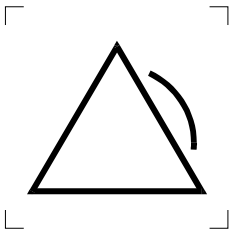
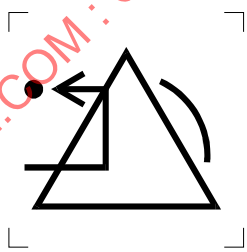
No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
1		IEC 60417-5307 (DB-2002-10)	Alarm, general	To indicate an alarm on a control equipment. *NOTE 1 The type of alarm may be indicated inside the triangle or below the triangle.* *NOTE 2 If there is a need to classify alarm signals and symbol 5308 is used, symbol 5307 should be used for the less urgent condition.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: ALARM CONDITION To indicate an ALARM CONDITION. *NOTE 1 The ALARM CONDITION may be indicated inside, beside or below the triangle.* *NOTE 2 If there is a need to classify ALARM CONDITIONS according to priority, this may be indicated by adding one, two or three optional elements, e.g., ! for LOW PRIORITY, !! for MEDIUM PRIORITY and !!! for HIGH PRIORITY.*
2		IEC 60417-5309 (DB 2002-10)	Alarm system clear	On alarm equipment: To identify the control by means of which the alarm circuit can be reset to its initial state. *NOTE - The type of alarm may be indicated inside the open triangle or below the triangle.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: ALARM RESET To identify the control for ALARM RESET. *NOTE The ALARM CONDITION may be indicated inside, beside, or below the triangle.*

Table C.1 – Graphical symbols for ALARM SYSTEMS (*continued*)

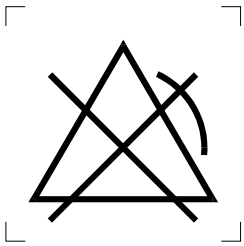
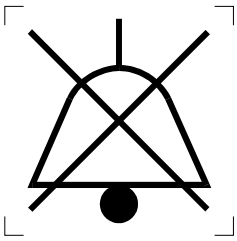
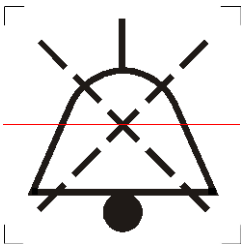
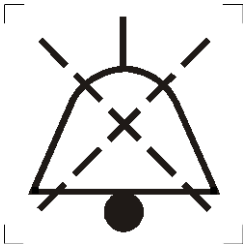
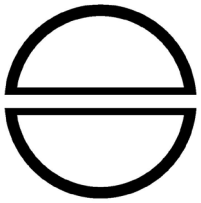
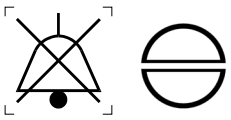
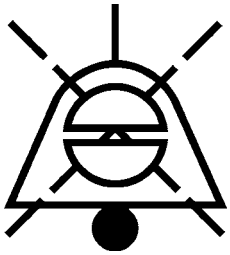
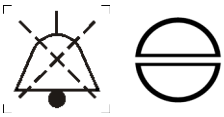
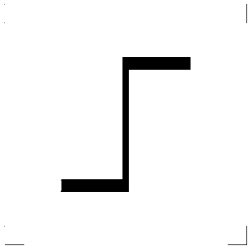
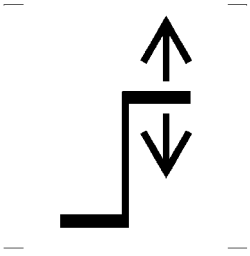
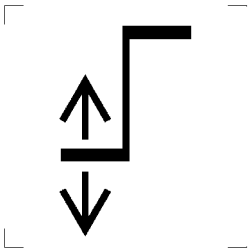
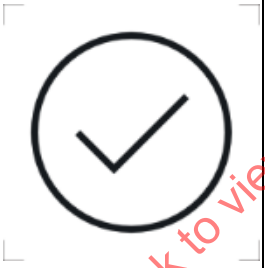
No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
3		IEC 60417-5319 (DB 2002-11)	Alarm inhibit	To identify the alarm inhibit on control equipment. *NOTE 1 The type of alarm may be indicated inside the triangle or below the triangle.* *NOTE 2 The graphical symbol may be used for temporary alarm inhibit by replacing the negation cross with a cross of broken lines.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: When used with a negation cross of solid lines: ALARM OFF To identify the control for ALARM OFF or to indicate that the ALARM SYSTEM is in the ALARM OFF state. *NOTE 1 The ALARM CONDITION may be indicated inside, below, or beside the triangle.* *NOTE 2 As far as there is no danger of confusion, this symbol may also be used to identify equipment that has no ALARM SYSTEM.*
4		IEC 60417-5319 (DB 2002-11) variant of according to Note 2	Alarm inhibit	To identify the alarm inhibit on control equipment. *NOTE 1 The type of alarm may be indicated inside the triangle or below the triangle.* *NOTE 2 The graphical symbol may be used for temporary alarm inhibit by replacing the negation cross with a cross of broken lines.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: When used with a negation cross of broken lines: ALARM PAUSED To identify the control for ALARM PAUSED or to indicate that the ALARM SYSTEM is in the ALARM PAUSED state. *NOTE 1 The ALARM CONDITION may be indicated inside, below, or beside the triangle.* *NOTE 2 A numerical time remaining counter may be placed above, below, or beside the triangle.*

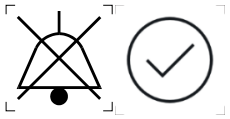
Table C.1 – Graphical symbols for ALARM SYSTEMS (*continued*)

No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
5		IEC 60417-5576 (DB 2002-11)	Bell cancel	To identify the control whereby a bell may be switched off or to indicate the operating status of the bell. *NOTE 1 As far as there is no danger of confusion, this symbol may also be used for "acoustic signal, switched off"* *NOTE 2 The graphical symbol may be used for temporary bell cancel by replacing the negation cross with a cross of broken lines.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: When used with a negation cross of solid lines: AUDIO OFF To identify the control for AUDIO OFF or to indicate that the ALARM SYSTEM is in the AUDIO OFF state. *NOTE The ALARM CONDITION may be indicated inside, below, or beside the bell.*
~~6~~		~~IEC 60417-5576 (DB 2002-11)~~ ~~variant of according to note 2~~	~~Bell cancel~~	~~To identify the control whereby a bell may be switched off or to indicate the operating status of the bell.~~ ~~*NOTE 1 As far as there is no danger of confusion, this symbol may also be used for "acoustic signal, switched off"*~~ ~~*NOTE 2 The graphical symbol may be used for temporary bell cancel by replacing the negation cross with a cross of broken lines.*~~	~~On medical ALARM SYSTEMS this graphical symbol is used as follows:~~ ~~When used with a negation cross of broken lines:~~ ~~AUDIO PAUSED~~ ~~To identify the control for AUDIO PAUSED or to indicate that the ALARM SYSTEM is in the AUDIO PAUSED state.~~ ~~*NOTE 1 The ALARM CONDITION may be indicated inside, below, or beside the bell.*~~ ~~*NOTE 2 A numerical time remaining counter may be placed above, below, or beside the bell.*~~

No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
6		IEC 60417-5576-2 (2012-09)	Bell, cancel temporary	To indicate the operating status of the bell being temporarily cancelled.	On medical ALARM SYSTEMS this graphical symbol is used as follows: When used with a negation cross of broken lines: AUDIO PAUSED To identify the control for AUDIO PAUSED or to indicate that the ALARM SYSTEM is in the AUDIO PAUSED state. *NOTE 1 The ALARM CONDITION may be indicated inside, below or beside the bell.* *NOTE 2 A numerical time remaining counter may be placed above, below or beside the bell.*
7		ISO 7000-1326 (2004-01)	Acknowledge-ment		On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To identify the control for ACKNOWLEDGED.
8	 Or 	IEC 60417-5576-1 (2012-09) Combination of: ISO 7000-1326 (2004-01) and IEC 60417-5576 (2002-11)	Bell, cancel acknowledged; acknowledged	To identify the control whereby a bell may be acknowledged or to indicate that the bell has been acknowledged. The alarm condition may be indicated below or beside the bell.	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To indicate that an ALARM CONDITION is in the ACKNOWLEDGED state for an indefinite period. *NOTE The ALARM CONDITION may be indicated below or beside the bell.*

No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
9	 Or 	IEC 60417-5576-3 (2012-09) Combination of: ISO 7000-1326 (2004-01) and IEC 60417-5576-2 (2012-09)	Bell, cancel temporary acknowledged; temporary acknowledged	To identify the control whereby a bell may be temporarily acknowledged or to indicate that the bell has been temporarily acknowledged. A numerical time remaining counter may be placed above, below, or beside the symbol.	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To indicate that an ALARM CONDITION is in the ACKNOWLEDGED state until a time interval has elapsed. *NOTE 1 The ALARM CONDITION may be indicated below or beside the bell.* *NOTE 2 A numerical time remaining counter may be placed above, below, or beside the bell.*

No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
10		IEC 60417-5649 (2002-10)	Limits, general	To identify the control or the indicator to display and/or set limits, for example, on MEDICAL EQUIPMENT for patient monitoring, to indicate reference to limit values corresponding to a possible critical situation.	On medical ALARM SYSTEMS this graphical symbol is used as follows: ALARM LIMITS To identify the control to display or set ALARM LIMITS.
11		IEC 60417-5650 (2002-10)	Adjustable upper limit	To identify the control or the indicator to display and/or set the upper limit.	On medical ALARM SYSTEMS this graphical symbol is used as follows: Upper ALARM LIMIT To identify the control to display or set upper ALARM LIMIT.
12		IEC 60417-5651 (2002-10)	Adjustable lower limit	To identify the control or the indicator to display and/or set the lower limit.	On medical ALARM SYSTEMS this graphical symbol is used as follows: Lower ALARM LIMIT To identify the control to display or set the lower ALARM LIMIT.
13		ISO 7000-6334A (2015-06)	Selection; affirmative acknowledgement; success; ACK	To identify the control to acknowledge affirmatively and to indicate the status of acknowledgement, or to indicate the successful status.	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED or RESPONSIBILITY ACCEPTED To identify the control for ACKNOWLEDGED or RESPONSIBILITY ACCEPTED or to indicate that the ALARM CONDITION is in the RESPONSIBILITY ACCEPTED state.

No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
14	 Or 	IEC 60417-5576-4 (2019-03) Combination of: ISO 7000-6334A (2015-06) and IEC 60417-5576 (2002-11)	Bell, cancel affirmatively acknowledged; acknowledged Acknowledge-ment Bell cancel	To identify the control whereby a bell cancel may be affirmatively acknowledged for an indefinite period or to indicate that the bell has been affirmatively acknowledged for an indefinite period. *NOTE 1 See also variant IEC 60417-5576-5 as a member of the same group of symbols.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To indicate that an ALARM CONDITION is in the ACKNOWLEDGED state for an indefinite period. *NOTE The ALARM CONDITION may be indicated below or beside the bell.*
15	 Or 	IEC 60417-5576-5 (2019-03) Combination of: ISO 7000-6334A (2015-06) and IEC 60417-5576-2 (2012-09)	Bell, temporary cancel affirmatively acknowledged; temporarily acknowledged Acknowledge-ment Bell cancel	To identify the control whereby a bell may be affirmatively acknowledged until a time interval has elapsed or to indicate that the bell has been affirmatively acknowledged until a time interval has elapsed. *NOTE 1 The acknowledged state will terminate at the end of a prescribed time interval and the auditory component will reactivate if the alarm conditions have not been cleared.* *NOTE 2 See also variant IEC 60417-5576-4 as a member of the same group of symbols.*	On medical ALARM SYSTEMS this graphical symbol is used as follows: ACKNOWLEDGED To indicate that an ALARM CONDITION is in the ACKNOWLEDGED state until a time interval has elapsed. *NOTE 1 The ALARM CONDITION may be indicated below or beside the bell.* *NOTE 2 A numerical time remaining counter may be placed above, below or beside the bell.*

No.	Graphic (informative)	Reference (normative)	Title (informative)	Description from reference document (informative)	Description for ALARM SYSTEMS (normative)
16		ISO 7000-6335A (2015-06)	Negative acknowledgement; failure; NACK	To indicate the status of negative acknowledgement, or to indicate the failed status.	On medical ALARM SYSTEMS this graphical symbol is used as follows: RESPONSIBILITY REJECTED To identify the control for RESPONSIBILITY REJECTED or to indicate that the ALARM CONDITION is in the RESPONSIBILITY REJECTED state.

Table C.2 – Alternative ALARM SYSTEM related markings

No.	Marking	Description
1	**AUDIO PAUSED** **or** **AUDIO ALARM PAUSED**	AUDIO PAUSED To identify the control whereby an auditory ALARM SIGNAL is AUDIO PAUSED.
2	**ALARM PAUSED**	ALARM PAUSED To identify the control whereby an ALARM SIGNAL is ALARM PAUSED.
3	**AUDIO OFF** **or** **AUDIO ALARM OFF**	AUDIO OFF To identify the control whereby an auditory ALARM SIGNAL is AUDIO OFF.
4	**ALARM OFF**	ALARM OFF To identify the control whereby an ALARM SIGNAL is ALARM OFF.
5	**ALARM RESET**	ALARM RESET To identify the control for ALARM RESET.
6	**INDEFINITE ACKNOWLEDGE**	ACKNOWLEDGED To identify the control whereby an ALARM SIGNAL is ACKNOWLEDGED for an indefinite period.
7	**TIMED ACKNOWLEDGE**	ACKNOWLEDGED To identify the control whereby an ALARM SIGNAL is ACKNOWLEDGED until a time interval has elapsed.
The text within these markings may be translated into the language of the intended OPERATOR.		

Annex D
(informative)

Guidance for auditory ALARM SIGNALS

D.1 General considerations

Parameters that affect the perceived urgency of a BURST of sound include the inter-PULSE interval, the number of repeating BURSTS, the rhythm of the PULSES in the BURST, changes in intra-PULSE duration within a single BURST, the pitch contour, pitch range and musical structure.

It should be noted that volume (loudness or sound pressure) does not appear in Table D.1. While volume can affect the perceived urgency of a sound, it often fails to do so. As an example, OPERATORS cannot remember and compare the volumes of two sounds heard five minutes apart. In addition, ambient noise levels can permit OPERATORS to hear a higher volume sound (as might be used for a HIGH PRIORITY ALARM SIGNAL) but can completely mask a lower volume sound (as might be used for a MEDIUM PRIORITY or LOW PRIORITY ALARM SIGNAL).

On that basis, volume is not a reliable attribute of perceived urgency.

Table D.1 – Attributes of perceived urgency

Parameter	Direction of Effect
Speed	Fast > moderate > slow
Number of repeating BURSTS	4 > 2 > 1
Rhythm	Syncopated > regular
Inter-PULSE duration within a single BURST	Speeding up > regular/slowing
Pitch contour	Random > down/up
Pitch range	Large > moderate> small
Musical structure	Atonal > unresolved > resolved
NOTE Interpret characteristic prior to the > as more urgent than.	

D.2 Frequency range

The frequency range of an ALARM SIGNAL should be between 200 Hz and 5 000 Hz. The preferred range is between 500 Hz and 3 000 Hz. If the ALARM SIGNAL is required to be audible at a long distance, such as a large ward, the frequency should be below 1 000 Hz. If the ALARM SIGNAL is required to be heard around obstacles or through partitions, the frequency should be below 500 Hz. The selected frequency band should differ from the most intense background frequencies in the equipment's expected environment of use.

D.3 Continuous auditory ALARM SIGNALS and INFORMATION SIGNALS

The use of continuous tones for ALARM SIGNALS or INFORMATION SIGNALS should be discouraged as they impede communications between persons, are annoying and provoke a startle reflex. Continuous tones often cause an OPERATOR to invoke the ALARM OFF state of ALARM SYSTEMS.

D.4 Harmonics, timbre, FALL TIME

Despite the restrictive nature of the sound specification in this collateral standard, varying the harmonic content and PULSE FALL TIME, while retaining the distinctive nature of the melody, can create distinctive ALARM SIGNALS. This permits a subtle degree of equipment differentiation, which an OPERATOR can find advantageous.

Sounds with odd harmonics (3,5,7,9,11) have a harsh quality, even harmonics give a church organ type of sound, and combining odd and even results in an oboe-like quality.

Annex E
(informative)

Verbal ALARM SIGNALS

E.1 Guidance

Verbal ALARM SIGNALS should only be considered for equipment intended for continuous OPERATOR attendance.

The use of verbal ALARM SIGNALS in the vicinity of conscious PATIENTS and relatives, who have no way of knowing whether the verbal ALARM SIGNALS refer to them or to another PATIENT can cause increased PATIENT and visitor stress and compromise PATIENT confidentiality.

Verbal ALARM SIGNALS can compete with, or not be heard over other conversations. Verbal ALARM SIGNALS can distract personnel from necessary communication.

The use of verbal ALARM SIGNALS should be validated by USABILITY testing.

E.2 Characteristics of verbal ALARM SIGNALS

E.2.1 General

Verbal ALARM SIGNALS can consist of an initial auditory ALARM SIGNAL composed of 1 BURST of the appropriate auditory ALARM SIGNAL to attract the attention of the OPERATOR and perhaps to identify the general problem, and a brief verbal message to identify the ALARM CONDITION and optionally specify an appropriate action.

E.2.2 Intensity

The speech interference level is the measure of the effectiveness of noise in masking speech. It is the arithmetic mean of the sound pressure levels of interfering noise (in dB referenced to 20 μPa) in the four octave bands centred on the frequencies 500 Hz, 1 000 Hz, 2 000 Hz and 4 000 Hz, respectively. The unit of speech interference is the decibel (dB). Verbal ALARM SIGNALS should be at least 20 dB above the speech interference level at the OPERATOR'S POSITION in the environment where the equipment is likely to be used, but should not exceed 85 dB(A).

E.2.3 Type of voice

The voice used in recording verbal ALARM SIGNALS should be distinctive and mature.

E.2.4 Delivery style

Verbal ALARM SIGNALS should be presented in a formal, impersonal manner.

E.2.5 Speech processing

Verbal ALARM SIGNALS should be processed only if necessary to increase or preserve intelligibility.

EXAMPLE By increasing the strength of consonant sounds relative to vowel strength.

If a verbal ALARM SIGNAL is required to be relatively intense because of high ambient noise, peak-clipping can be used to protect the listener from auditory overload.

E.2.6 Message content

In selecting words to be used in verbal ALARM SIGNALS, words should be chosen on the basis of vocabulary based on intelligibility, aptness and conciseness, in that order.

E.2.7 HIGH PRIORITY verbal ALARM SIGNALS

HIGH PRIORITY verbal ALARM SIGNALS should be repeated with not more than 10 s between the beginnings of messages until the ALARM CONDITION is responded to by the OPERATOR or is no longer present.

E.2.8 Message priorities

A message priority system should be established so that a message of the highest priority will be generated before any message having a lower priority. If two or more ALARM CONDITIONS occur simultaneously, the one indicating a message of higher priority should be generated first. After generating the highest priority message, remaining messages should be generated in descending order of priority.

E.3 Limitations of verbal ALARM SIGNALS

E.3.1 Privacy and security

In an intensive care or ward setting, a PATIENT might hear the verbal ALARM SIGNAL of another PATIENT'S ALARM CONDITION. This is private information that should be secure. Other PATIENTS might become upset because they think that the verbal ALARM SIGNAL applies to them.

E.3.2 Language

Verbal ALARM SIGNALS should be presented in the language of the OPERATOR. In equipment used all over the world, or in a country with multiple national languages, complex equipment capable of many languages can be required.

E.3.3 Clarity

Verbal ALARM SIGNALS can compete with, and not be heard over other conversations with care team members. Alternatively, verbal ALARM SIGNALS can distract personnel from necessary communication.

E.3.4 Multiple ALARM CONDITIONS

In many situations, when one ALARM CONDITION generates ALARM SIGNALS, several others will soon follow. In this case, there would be multiple verbal ALARM SIGNALS presented sequentially or simultaneously.

E.3.5 Emotional responses

Depending upon the gender of the voice of the verbal ALARM SIGNAL and the gender of the OPERATOR, there can be an emotional response that is counter-productive to the intended message.

Annex F
(normative)

* Reserved melodies for ALARM SIGNALS

The following melodies are reserved for the meanings as indicated in Table F.1 and Table F.2. See also 6.3.3.1.

Table F.1 – * Equipment encoded auditory ALARM SIGNALS categorized by ALARM CONDITION and priority complying with Table 3 and Table 4

Cause	MEDIUM PRIORITY	HIGH PRIORITY
General	c c c	c c c – c c
Cardiac	c e g	c e g – g C
Artificial perfusion	c f# c	c f# c – c f#
Ventilation	c a f	c a f – a f
Oxygen	C b a	C b a – g f
Temp / Energy delivery	c d e	c d e – f g
Drug or fluid delivery	C d g	C d g – C d
Equipment or supply failure	C c c	C c c – C c

All PULSES and BURSTS shall comply with the timing and volume requirements of list element a) of 201.3.3.1 d) of 6.3.3.1. The melodies may be sounded in different keys or octaves if the absolute frequency of "c" lies between 150 Hz and 500 Hz.

The "General" BURST may be used for any auditory ALARM SIGNAL in any ALARM SYSTEM.

NOTE 1 The characters c, d, e, f, g, a, b, C refer to relative musical pitches and C is one octave above c.

NOTE 2 A HIGH PRIORITY ALARM SIGNAL is generated with the five PULSES shown, repeated once, for a total of 10 PULSES.

Table F.2 – * Auditory LOW PRIORITY ALARM SIGNAL complying with Table 3 and Table 4

Cause	LOW PRIORITY
Any	e c

NOTE The characters c, d, e, f, g, a, b, C refer to relative musical pitches and C is one octave above c.

The contents of Annex F that were previously included in this document have been deleted. Research has shown that those melodies are not fit for this purpose, which is to say that it is now known that OPERATORS cannot effectively discriminate the melodies [61] [62] [63] [64] [65]. MANUFACTURERS that desire to have equipment-encoded auditory ALARM SIGNALS should use the ALARM SIGNALS of Table G.4 or Table G.5.

Annex G
(normative)

* Auditory ALARM SIGNALS

G.1 General

a) The auditory ALARM SIGNALS shall consist of:

   1) an AUDITORY POINTER complying with Clause G.2;

   2) * for MEDIUM PRIORITY and HIGH PRIORITY ALARM SIGNALS, an AUDITORY POINTER complying with Clause G.2 and an AUDITORY ICON complying with Clause G.3; or

   3) an auditory ALARM SIGNAL complying with Table G.5.

b) The ALARM SIGNALS of any ALARM CONDITIONS of any COMMUNICATOR may utilize an AUDIO POINTER without an AUDITORY ICON (see Table G.3).

Compliance is checked by inspection.

G.2 * AUDITORY POINTERS

The HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY AUDITORY POINTERS shall comply with the requirements of:

a) Table G.1 and Table G.2; or

b) Table G.3.

Figure G.1 and Figure G.2 are intended to show the designation of temporal characteristics and do not illustrate any individual auditory ALARM SIGNAL.

Compliance is checked by inspection.

G.3 * AUDITORY ICONS

For each ALARM CONDITION whose ALARM SIGNAL includes an AUDITORY ICON, the AUDITORY ICON shall:

a) be selected from Table G.4 or Table G.5; or

   1) A COMMUNICATOR need not utilize more than one AUDITORY ICON.

b) be representative of one of the defined categories indicated in Table G.4 and shall be VALIDATED according to Annex H; or

c) be representative of the MANUFACTURER-determined category related to the SOURCE of the ALARM CONDITION and shall be VALIDATED according to Annex H.

Compliance is checked by inspection.

Table G.1 – Characteristics of the BURST of the AUDITORY POINTER

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL[d]
Number of PULSES in BURST [a, e]	10	3	1 or 2
Pointer PULSE spacing (t_s) (see Figure G.1)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$4x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,15 s to 0,65 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$4x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b) (see Figure G.1)	2,5 s to 15,0 s	2,5 s to 30,0 s	> 15 s or no repeat
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB

Where: x shall be a value between 12 ms and 50 ms;

y shall be a value between 50 ms and 100 ms;

the variation of t_d, x and y within a BURST shall not exceed ± 20 %;

MEDIUM PRIORITY t_s shall be greater than or equal to HIGH PRIORITY t_s; and

the PULSE spacing between the 5th and 6th PULSE shall be greater than the PULSE spacing between the 3rd and 4th PULSE and between the 8th and 9th PULSE.

The INTERBURST INTERVAL (t_b) for HIGH PRIORITY auditory ALARM SIGNALS shall not be greater than the INTERBURST INTERVAL for MEDIUM PRIORITY auditory ALARM SIGNALS, which shall not be greater than the INTERBURST INTERVAL for LOW PRIORITY auditory ALARM SIGNALS.

[a] See also Table G.2 for characteristics of the PULSE.

[b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT.

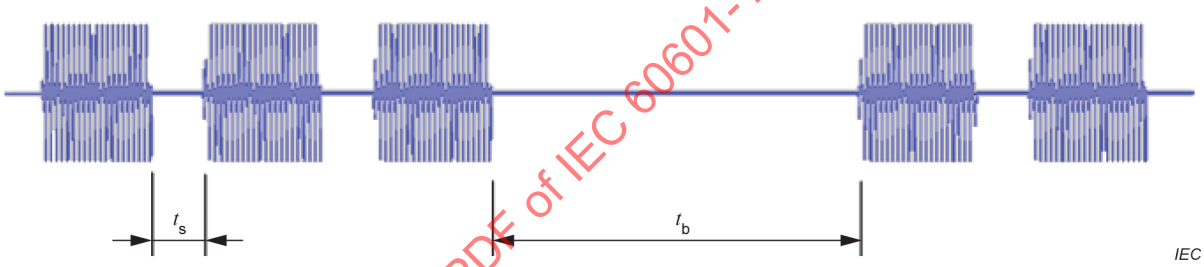
[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the origin of the ALARM CONDITION.

[d] The generation of the auditory component of a LOW PRIORITY ALARM CONDITION is optional.

[e] Unless inactivated by the OPERATOR, MEDIUM PRIORITY and LOW PRIORITY AUDITORY POINTERS shall complete at least one BURST, and a HIGH PRIORITY AUDITORY POINTER shall complete at least half of one BURST.

Table G.2 – Characteristics of the PULSE of the AUDITORY POINTER

Characteristic	Value
Frequency component in the range of 150 Hz to 1 000 Hz	At least one that is among the five frequency components with the largest sound pressure level
Number of peaks in the frequency range of 150 Hz to 4 000 Hz	At least five peaks in the frequency domain
Effective PULSE duration (t_d) (see Figure G.2)	
HIGH PRIORITY	25 ms to 75 ms
MEDIUM PRIORITY	90 ms to 200 ms
LOW PRIORITY	400 ms to 600 ms
RISE TIME (t_r) (see Figure G.2)	[a]
FALL TIME (t_f) (see Figure G.2)	[b]
Within the frequency range of 150 Hz to 4 000 Hz, the relative sound pressure levels of the four frequency components with the largest sound pressure levels should be within 15 dB of each other.	
[a] The RISE TIME should not be so short as to create mechanical speaker noise. Very fast RISE TIMES can lead to sound distortion.	
[b] The FALL TIME should be short enough to ensure that the PULSES do not overlap.	



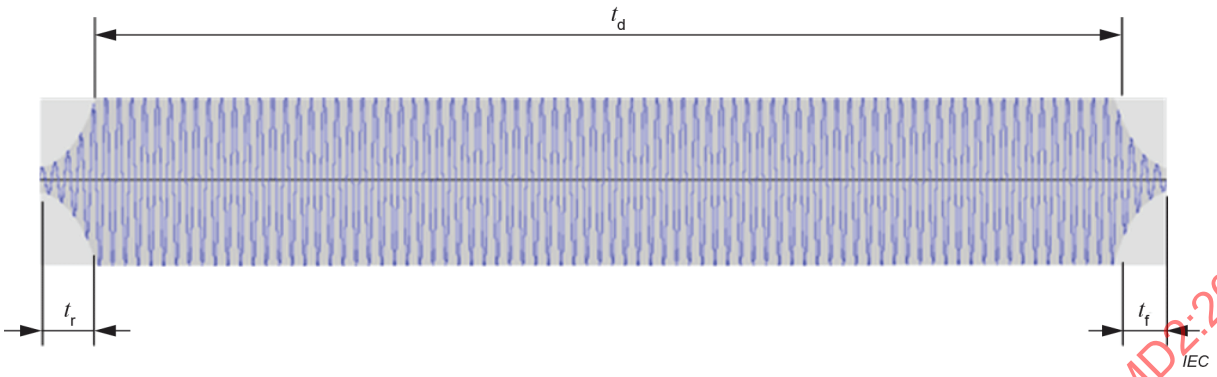
Key

t_s pointer PULSE spacing (time from the end of one PULSE to the start of the next PULSE)

t_b INTERBURST INTERVAL (time from the end of one BURST to the start of the next BURST)

NOTE See Figure 1 for additional information.

Figure G.1 – Illustration of spacing of AUDITORY POINTER



Key

t_d pointer PULSE duration

t_r POINTER RISE TIME

t_f POINTER FALL TIME

NOTE 1 The relative amplitude of a PULSE is a function of time.

NOTE 2 See Figure 1 for additional information.

Figure G.2 – Illustration of temporal characteristics of an AUDITORY POINTER

Table G.3 – Characteristics of the AUDITORY POINTER

ALARM CONDITION priority	File name of AUDITORY POINTER [a]
LOW PRIORITY	low.wav
MEDIUM PRIORITY	medium.wav
HIGH PRIORITY	high.wav
[a] Sound files are available at: https://www.iec.ch/tc62/supportingdocuments or https://isotc.iso.org/livelink/livelink?func=ll&objId=20885884&objAction=browse&viewType=1	

Table G.4 – * Characteristics of the AUDITORY ICON

Category of the SOURCE of the ALARM CONDITION	AUDITORY ICON metaphor	AUDITORY ICON description	File name of AUDITORY ICON [a]
General [b]	none	none	—
Cardiovascular	"Lup-dup"; heartbeat sound	A stylized, square/triangle wave-based "heartbeat" sound with no discernible frequency. Six PULSES formed from three 2-PULSE "lup-dup" sequences	cardiovascular.wav
Artificial perfusion	Liquid disturbance, water churning, bubbles	Two approximately 1 s sequences of a strong water bubbling sound, separated by silence	perfusion.wav
Ventilation	A single inhale followed by an exhale	A 1 s inhaling sound (like white noise), followed by a 0,5 s gap, followed by a slow exhale with a long tail	ventilation.wav
Oxygenation	Irregular, stylized dripping/saturation	Stylized irregular temporal pattern with some discernible pitch; a two-tone sequence superimposed on the six-tone pattern	oxygenation.wav
Temperature/energy delivery	Whistling kettle	Complex sound including high frequency harmonics, rising slowly over approximately 2 s	temperature.wav
Drug or fluid delivery/administration	Shaking pill bottle	Two 0,8 s sequences of a 4-rattle shaking sound	drug_delivery.wav
Equipment or supply failure	Starting up a motor that shuts down suddenly	Spectrally complex sound of a motor revving up (increasing in frequency) over approximately 1,2 s then an abrupt stop tailing off for approximately 0,5 s	failure.wav

[a] Sound files are available at: https://www.iec.ch/tc62/supportingdocuments or https://isotc.iso.org/livelink/livelink?func=ll&objId=20885884&objAction=browse&viewType=1

[b] The "general" category has no AUDITORY ICON; only an AUDITORY POINTER is used.

Table G.5 – Characteristics of the auditory ALARM SIGNAL

Category of the SOURCE of the ALARM CONDITION	File name of AUDITORY POINTER plus AUDITORY ICON [a]	
	HIGH PRIORITY	MEDIUM PRIORITY
Cardiovascular	HP-cardiovascular.wav	MP-cardiovascular.wav
Artificial perfusion	HP-perfusion.wav	MP-perfusion.wav
Ventilation	HP-ventilation.wav	MP-ventilation.wav
Oxygenation	HP-oxygenation.wav	MP-oxygenation.wav
Temperature/energy delivery	HP-temperature.wav	MP-temperature.wav
Drug or fluid delivery/administration	HP-drug_delivery.wav	MP-drug_delivery.wav
Equipment or supply failure	HP-failure.wav	MP-failure.wav

[a] Sound files are available at: https://www.iec.ch/tc62/supportingdocuments or https://isotc.iso.org/livelink/livelink?func=ll&objId=20885884&objAction=browse&viewType=1.

Annex H
(informative)

VALIDATION of AUDITORY ICONS

H.1 Background to the AUDITORY POINTERS and AUDITORY ICONS specified in Table G.1 to Table G.5

H.1.1 How the ALARM SIGNALS specified in Table G.1 to Table G.5 were derived

The reserved AUDITORY POINTERS in Table G.1 and Table G.2 and AUDITORY ICONS in Table G.4 have been developed and benchmarked using evidence-based methods. In the first instance, several sets of possible ALARM SIGNALS were developed using principles derived from the relevant literature, and were tested for both learnability and localizability [36] [67]. All of these prototype sets outperformed the reserved ALARM SIGNALS specified in Annex F of IEC 60601-1-8:2006+A1:2012 on these measures. The best performing prototype sets, which consisted of AUDITORY ICONS plus AUDITORY POINTERS, were then developed and tested further. These tests included performance of the eight HIGH PRIORITY AUDITORY ICONS (using the HIGH PRIORITY AUDITORY POINTER as the ALARM SIGNAL for the general category) in a simulated environment approximating real-world use [68] [71]. These included studies to select the optimal AUDITORY ICONS for the functions [69], and detectability in typical background noise studies [66]. The sets of data for the individual reserved sounds are available in the public domain as peer-reviewed papers [38] [66] [67] [68] [71], and as a report [70].

H.1.2 Results of the benchmarking tests

It is important to note that the suitability of an ALARM SIGNAL, or set of auditory ALARM SIGNALS, for specific functions cannot be determined through the apparent optimization of any single parameter (such as urgency or learnability). Suitability depends on a range of measures, which can vary from specific setting to specific setting, though those parameters determined in the benchmarking are likely to be essential for most settings. The benchmarking data is summarized in Table H.1. A performance range is given in each case based on:

– performance of those AUDITORY ICONS during testing;
– adjustments for slight variations to the sounds tested during development; and
– the performance level that has already been achieved for each of the AUDITORY ICONS and AUDITORY POINTERS.

The fact that some scores are lower than others reflects a combination of the relative ease of developing a strong AUDITORY ICON, which typically influences learnability more than other factors (for example, the cardiovascular AUDITORY ICON) and that some of the sounds are abstract and can therefore be imbued with a resilient and tailored harmonic structure, which can influence audibility in noise (for example the HIGH PRIORITY AUDITORY POINTER).

A range of participants in both the simulation and the audibility studies has been tested. Clinical anaesthesia residents in their 1st to 3rd year of study, attendees, student and clinical nurse anaesthetists, student nurses and medical students in the 3rd and 4th year of study have been tested [66] [68].

These tests were carried out in Europe and in the US. No testing has been performed in Asia. MANUFACTURERS are at liberty to modify or indeed change the AUDITORY ICONS that they use for whatever reasons they see fit, and cultural acceptance would be one of the key reasons for doing this. Culture aside, the committees predict that audibility would be the same, and learnability partially depends on how well the AUDITORY ICONS work in terms of representing their functions for the Asian cultures. Given that the AUDITORY ICONS are based on the actual physiological functions, there is no reason to suppose that they would not work as well in Asia as in Europe and the US. They would certainly work better than the current auditory ALARM SIGNALS. There is no scientific reason why the AUDITORY POINTERS should not be effective

globally, because they are highly detectable in noise. The testing has established that all of the auditory ALARM SIGNALS are highly detectable using typical intensive care unit noise [66].

The tests were performed in a simulated intensive care units (ICU) using actual clinical soundscapes derived from the ICU. The tests show that the AUDITORY ICONS and particularly the HIGH PRIORITY AUDITORY POINTER are audible in noise levels significantly higher than the level of the background noise. In fact, the AUDITORY POINTER can be heard in noise four times louder than its own volume. Even the (relatively) least audible AUDITORY ICONS are audible in signal-to-noise levels of –10 dB to –15 dB [66].

H.2 Developing alternative auditory ALARM SIGNALS

H.2.1 General

The standard allows the generation of other AUDITORY ICONS for the eight categories. The MANUFACTURER shall determine that any new AUDITORY ICON performs at least at the levels indicated in Table H.1 on each of the measures indicated, unless there is an important argument for focusing on one or two of the measurements at the expense of others (see Clause H.3). The benchmarking for the reserved sounds indicated in Table G.4 was derived under controlled laboratory circumstances. In order to carry out a complete test, the MANUFACTURER should consult relevant published literature.

Table H.1 – Performance levels of three AUDITORY POINTERS and seven AUDITORY ICONS based on available data

ALARM SIGNAL	Percentage correct recognition over 10 trials [36]	Localizability in front and at 45° [36] [67]	Signal-to-noise ratio (reference)	Simulation [68]
Cardiovascular	90 % to 95 %	> 80 %	–10 dB to –20 dB	70 % to 80 %
Artificial perfusion	75 % to 85 %	> 80 %	–10 dB to –20 dB	70 % to 80 %
Ventilation	80 % to 85 %	> 80 %	–10 dB to –20 dB	60 % to 70 %
Oxygenation	70 % to 80 %	> 80 %	–10 dB to –20 dB	60 % to 70 %
Temperature/energy delivery	85 % to 90 %	> 80 %	–10 dB to –20 dB	80 % to 90 %
Drug or fluid delivery/administration	90 % to 95 %	> 80 %	–10 dB to –20 dB	80 % to 90 %
Equipment or supply failure	90 % to 95 %	> 80 %	–10 dB to –20 dB	50 % to 60 %
HIGH PRIORITY AUDITORY POINTER (general)	85 % to 90 %	> 80 %	–20 dB to –25 dB	[a]
MEDIUM PRIORITY AUDITORY POINTER	90 % to 95 %	> 80 %	–10 dB to –20 dB	[a]
LOW PRIORITY AUDITORY POINTER	90 % to 95 %	> 80 %	–10 dB to –20 dB	[a]

[a] Simulation data is based on identification of individual AUDITORY ICONS so it is not relevant for the AUDITORY POINTERS. For the AUDITORY POINTERS, the task is to identify that an ALARM CONDITION exists and where the COMMUNICATOR is located; hence learnability, detectability and localizability are most relevant (at least in the case of the HIGH PRIORITY AUDITORY POINTER).

H.2.2 Learnability

The following provides a test method for conducting a simplified learnability test.

a) Present each of the sounds to be learned to the participant one by one, with the names/category of the sounds at the same time.

b) Present each of the sounds once in a random order to the participant without naming them.

1) Note whether the participant names the category correctly or incorrectly.

2) Allowing participants to respond more than once can provide extra data on learnability, if desired.

c) Repeat b) a number of times; 9 times is suggested so as to allow direct comparison with the data results shown in Table H.1.

d) Calculate the percentage correct score obtained for each of the sounds to be learned, and compare with the results in Table H.1.

H.2.3 Localizability

The following provides a test method for conducting a simplified localizability test.

a) Set up at least three speakers in the following positions:

1) straight ahead of the participant;

2) 45° to the left; and

3) 45° to the right of the participant

NOTE The speakers can be cheap, small speakers or ideally use the speakers intended to be used in the equipment when it is used in a clinical setting or use the equipment itself. If one uses more than three speakers, place them progressively at 45° angles around the participant (if a full circle is made, 8 speakers are needed).

b) Present each of the sounds to be tested one by one from each of the positions in a random order.

c) Measure the number of times the participant correctly identifies the position of the speaker from which the sound is coming.

d) Calculate the percentage correct for each sound. Compare these with the results in Table H.1.

A simpler version of this procedure would be to blindfold the participants before the study starts and for the experimenter to physically move around the same space, playing the sounds and asking the participant to indicate the position from which each sound has come by pointing or other simple means of indicating. For localization, it is not necessary for the participant to know the meaning of the sound.

H.2.4 Detectability

For clinical environments with complex noise spectra, a method whereby the spectrum of the ALARM SIGNAL is compared with the spectrum of the noise as described in H.3.2 is the best approach. Otherwise, detectability in typical noise is probably best determined in a controlled laboratory setting using headphones or listening in close proximity to the ALARM SIGNALS. Only these approaches generate useful signal-to-noise ratios. However, a relatively simple and useful detectability test can be conducted in a real clinical environment using a variation of the Hughson-Westlake 2-up-1-down method [72], using the volume control on any equipment that generates ALARM SIGNALS. If this is done in an actual clinical environment, it would be valuable to do the test on a day when the noise background is judged to be typical, rather than extreme either in loudness or quietness.

Essentially, the test method involves turning the loudness of the ALARM SIGNAL up and down in a systematic and measurable manner.

a) Using the loudness control for a piece of equipment, divide the range of loudness available into discrete steps (for example, numbers on the volume control). The steps should be of equal subjective distance in loudness as far as possible, and if a sound level meter can be used, the steps should ideally be about 5 dB apart. Make a record of the relationship between the volume control and the 5 dB (or other value) steps so that you can use them in testing. As far as possible, treat the changes of 5 dB as steps of 1, where 2 steps are 10 dB.

b) Select a loudness level on the equipment at random. However, it should be fairly audible. Ask the participant whether or not they can hear the sound. If they say yes, then drop the level of the sound by another step. If they say no, increase it by two steps. Make a note of each level tested and whether the participant detected the sound or not.

c) Continue with this procedure, dropping the loudness by one step if they can hear the signal and increasing it by two if they cannot, until you have changed direction (up to down, or down to up) at least 6 times. These changes of direction are called pivots.

d) Detectability is determined by the lowest loudness level at which the listener hears the target at least 50 % of the time when you have been through at least 6 pivots. Signal-to-noise ratios can be calculated if the ambient noise level and the loudness level of the sound are each measured separately and then compared, if necessary.

While it is appealing to increase the loudness of the ALARM SIGNAL further than a detectability test might determine, only relatively small increases are likely to be helpful, after which turning up ALARM SIGNALS well above threshold is distracting and leads to performance deficits [71].

Concerns about hearing deficits in older clinical staff can also be relevant. This is better approached through designing/implementing ALARM SIGNALS with a rich harmonic structure (possessing many different frequencies across the spectral range) rather than increasing the volume of less harmonically rich ALARM SIGNALS to unnecessarily high levels. The test method should assess the range of the intended users/responders (nurses, techs, clinicians, etc.), including a range of user ages to ensure that limitations of older users are assessed.

H.2.5 Simulation/testing in a clinical setting

Carrying out a simulation requires access to simulation facilities and both hardware and software resources. If a simulation is possible, the protocol used to benchmark the reserved sounds should be followed where possible [68]. This involves setting up a simulation with simulated PATIENTS, and providing participants with the relevant medical information (e.g. medical history of simulated PATIENT, medical charts of simulated PATIENT, planned procedures for simulated PATIENTS, etc.) to simulate a real-world clinical environment. See IEC 62366-1 for details regarding defining USE SCENARIOS. In this simulation, the signals to be tested are incorporated into a relevant interface (such as an anaesthesia machine), representative participants (clinical staff of any/all types) are subject to the simulation protocol, which should include several incidences of ALARM SIGNALS being generated, and their responses to the sounds measured in terms of correct identification and possibly other measures such as reaction time and resultant actions. Care needs to be taken to ensure that there is representation of all intended USER GROUPS, including a range of ages to ensure that limitations of older OPERATORS are assessed.

If this is not possible, then testing new sounds in a real or realistic clinical setting is still recommended. There are many ways in which this can be done. For example, new sounds could be presented via middleware or cell phone/paging equipment at intervals during either real or simulated clinical work, and responses recorded.

H.3 Circumstances under which new sounds can be required

H.3.1 Developing a new icon for an existing category

A MANUFACTURER might need to generate new AUDITORY ICONS because the ones indicated in Table G.4 are not considered appropriate for cultural or other reasons which could weaken the auditory ALARM SIGNAL-alarm category link (or because the sound-referent link is too obvious, or the proposed AUDITORY ICON is used for some other common function). Prior to the tests recommended in Clause H.2, ideas for the new AUDITORY ICON need to be generated. This is best achieved by surveying the end users in some way, either through the use of focus group(s) or as a survey. If this is done, some ideas are likely to emerge more than once and these should be considered as suitable candidates for the new AUDITORY ICON. The proposed new AUDITORY ICON(s) should then be tested according to Clause H.2, though some of the tests might not be relevant because of the particular circumstances under which the ALARM SIGNAL is intended to be used. As an example, it might be that a particular ALARM SIGNAL needs to be more coded than an AUDITORY ICON would typically be (so as to hide the meaning from PATIENTS or visitors, but to be clear to clinical staff once learned) and therefore learnability would be expected to be lower.

A few words of caution are necessary here. First, it is important that audibility is not compromised through the use of a new AUDITORY ICON (though again the degree to which audibility is relevant needs to be considered). Secondly, to some extent the learnability of an AUDITORY ICON depends on the other AUDITORY ICONS to be used in the same setting. As an example, if a new AUDITORY ICON is developed and is thought to be a "better" AUDITORY ICON than the reserved AUDITORY ICON, but sounds similar to one already in the set, then this can be a possible source of later confusion.

H.3.2 Generating new AUDITORY ICONS because the ones indicated in Table G.4 are inappropriate acoustically

In some environments, the ALARM SIGNALS might need to be particularly resistant to masking (for example, if a piece of equipment such as a surgical saw is used regularly), or particularly quiet (such as in a paediatric intensive care unit (PICU)). In environments where level setting is an issue, there can be other ways of notifying that are not auditory, so these should be explored. If auditory ALARM SIGNALS are deemed necessary, then it is possible to set the spectrum of the auditory ALARM SIGNALS relative to the background noise in a way that ensures detectability without making the ALARM SIGNAL any louder than it needs to be [49]. Determining an appropriate level for auditory ALARM SIGNALS in these environments requires careful measurements of background noise and the spectrum of any auditory ALARM SIGNAL, which the MANUFACTURER intends to use, appropriate models and software allowing comparison [49], and an ability to adjust the spectrum of ALARM SIGNALS accordingly.

H.4 Developing categories other than those in Table G.4

Equipment that does not fall into any of the existing categories can be developed. Also, different clinical settings can require a subdivision of the existing categories, which could be useful (for example, in a cardiac unit, it might be advantageous to have more than one cardiovascular-related AUDITORY ICON, such as an AUDITORY ICON for asystole, and a different AUDITORY ICON for tachycardia/bradycardia or ventricular fibrillation) [52]. In these situations, rather than introducing new categories on an *ad-hoc* basis, it is advisable to use a more empirical approach to the issue.

Because AUDITORY ICONS are much easier to learn and retain than abstract sounds, it is tempting to assume that a larger number can be used than for traditional ALARM SIGNALS. However, proliferation of AUDITORY ICONS should always be avoided because of nuisance noise and unnecessary distraction. Care should be taken when generating new categories because of this, and when generating new categories thought should also be given to categories that might be removed. In any method used to develop new categories, it is also

advisable to put an upper limit on the number of categories available in order to aid focused thinking as to what categories are really necessary.

One useful, low-tech method of determining the nature of the categories to be used is to implement a card-sorting task with end users (for example, nurses) [54]. With this technique, the participant is given a set of cards, each one signifying one of the conditions which needs to be indicated in an environment. These should have already been determined in an exhaustive manner and simply indicated on the cards. The participant is then asked to sort the cards according to one or another of the following instructions (not exhaustive):

a) sort them according to a single criterion which is pre-specified (for example, urgency, equipment);

b) sort them according to their own criteria (here one can put a limit on the number of categories, or allow the participant to use as many categories as they feel necessary).

In b), once the cards have been sorted, the participant should be questioned as to the rationale for the categories. This gives insight into the mental model used to determine the categories. For example, did the participant sort according to the piece of equipment that would be generating ALARM SIGNALS? Did they sort according to the physiological function underpinning the ALARM CONDITION? Or, something else – such as urgency?

This procedure should be repeated with many participants. There needs to be a maximum number of cards, which can be sorted in any one task, probably about 50.

The logic is that the categories for which ALARM SIGNALS will eventually be used should flow from the categorization study.

Bibliography

[1] ISO 11428:1996, *Ergonomics – Visual danger signals – General requirements, design and testing*

[2] ISO 11429:1996, *Ergonomics – System of auditory and visual danger and information signals*

[3] ISO 14971:2000, *Medical devices – Risk management – Application of risk management to medical devices*

[4] IEC 60513:1994, *Fundamental aspects of safety standards for medical electrical equipment*

[5] AAMI EC57-293, *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms*

[6] ANSI/AAMI HE48-1993, *Human factors engineering guidelines and preferred practices for the design of medical devices*

[7] BLOCK, FE. Jr., ROUSE, JD., HAKALA, M., THOMPSON, CL. A proposed new set of alarm sounds which satisfy standards and rationale to encode source information. *J Clin Monit Comput,* 2000, 16, p. 541-546.

[8] BLOCK, FE. Jr., SCHAAF, C. Auditory alarms during anesthesia monitoring with an integrated monitoring system. *Intl J Clin Monit Comput,* 1996, 13, p.81-84.

[9] BLOCK, FE. Jr. Human factors and alarms.Chapter 2 In Lake CL., ed. *Clinical Monitoring for Anesthesia & Intensive Care*. Philadelphia, WB Saunders, 1994, p. 11-34.

[10] BLOCK, FE. Jr., NUUTINEN, L., BAALLAST, B. Optimization of alarms: A study on alarm limits, alarm sounds, and false alarms, intended to reduce annoyance. *J Clin Monit Comput,* 1999, 15, p.75-83.

[11] EDWORTHY J. Urgency mapping in auditory warning signals. In Stanton, N., Editor: *Human Factors in alarm design*. London: Taylor and Francis, 1994.

[12] HEDLEY-WHYTE, J., ed. *Operating Room and Intensive Care Alarms and Information Transfer*, ASTM Special Technical Publication STP 1152, Philadelphia 1992, ASTM

[13] KESTIN, IG; MILLER, BR., LOCKHART, CH. Auditory alarms during anesthesia monitoring. *Anesthesiology*, July, 1988, 69:1, p.106-9.

[14] LAWLESS, ST. Crying Wolf: False alarms in a pediatric intensive care unit. *Crit Care Med,* 1994, 22, p. 981-985

[15] MOMTAHAN, K., HETU, R., TANSLEY, B. Audibility and identification of auditory alarms in the operating room and intensive care unit. *Ergonomics,* 1993, 36, P. 1159-1176,

[16] O'CARROLL, TM. Survey of alarms in an intensive care unit. *Anesthesia,* 1986, 41, p.742-744,

[17] *Optom Vis Sci,* Dec. 2002, 79(12), p.788-92

[18] PATTERSON, RD., EDWORTHY, J., SHAILER, MJ. *Alarm sounds for medical equipment in intensive care and operating areas*. Report AC598 to the Department of Trade and Industry, London, 1985.

[19] PATTERSON, RD. *Guidelines for auditory warning systems on civil aircraft*. Civil Aviation Authority, London 1982, Paper 82017

[20] SALVENDY, G. *Handbook of human factors.* Wiley Interscience, 1987.

[21] SAUNDERS, MS., McCORMICK, EJ., Editors. *Human Factors in engineering and design*. Seventh Edition. New York: McGraw Hill Inc, 1993.

[22] STANFORD, LM., McINTYRE, JWR., NELSON, TM., HOGAN, JT. Affective responses to commercial and experimental auditory alarm signals for anesthesia delivery and physiological monitoring equipment. *Int J Clin Mon Comput.*, 1988, 5, p.111-118.

[23] TSIEN, CL., FACKLER, JC. Poor prognosis for existing monitors in the intensive care unit. *Crit Care Med.*, 1997, 25, p.614-619.

[24] WAGNER, D., BIRT, JA., SNYDER, M., DUNCANSON, JP. *Human Factors Design Guide, FAA Technical Center For Acquisition of Commercial-Off-The-Shelf Subsystems, Final Report and Guide.* Federal Aviation Administration, William J Hughes Technical Center. 1996.

[25] WIKLUND, M. *Medical Device and Equipment Design. Usability engineering and ergonomics* Buffalo Grove Ill.: Interpharm Press, 1995

[26] ISO 9703-2, *Anesthesia and respiratory care alarm signals – Part 2: Auditory alarm signals* (withdrawn)

[27] AAMI, Improving medical alarm systems, Horizons supplement, *Bio Inst & Tech*, 2011, spring

[28] AAMI, *Clinical alarms*, report from the 2011 Summit [cited 2012-07-13]. Available from Internet: <http://www.aami.org/htsi/alarms/pdfs/2011_Alarms_Summit_publication.pdf>

[29] AAMI TIR 66, *Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms*

[30] ISO 8201:2017, *Alarm systems – Audible emergency evacuation signal – Requirements*

[31] IEC TR 80001-2-5, *Application of risk management for IT-networks incorporating medical devices – Part 2-5: Application guidance – Guidance on distributed alarm systems*

[32] IEC 80001-1, *Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities*

[33] ISO 9000:2015, *Quality management systems – Fundamentals and vocabulary*

[34] BELZ, S. M., ROBINSON, G. S., & CASALI, J. G. (1999). A new class of auditory warning signals for complex systems: Auditory icons. *Human factors*, **41**(4), p.608-618

[35] EDWORTHY, J., PAGE, R. , HIBBARD, A. , KYLE, S., RATNAGE, P., and CLAYDON, S. (2014) Learning three sets of alarms for the same medical functions: A perspective on the difficulty of learning alarms specified in an international standard. *Applied Ergonomics* **45**(5) p.1291-1296

[36] EDWORTHY, J. R., REID, S., MCDOUGALL, S., EDWORTHY, J. D., HALL, S., BENNETT, S., KHAN, J. & PYE, E. (2017) The recognizability and localizability of auditory alarms: setting global medical device standards. *Human Factors*, **59**(7), p.1108-1127

[37] GRAHAM, R. (1999). Use of auditory icons as emergency warnings: evaluation within a vehicle collision avoidance application. *Ergonomics*, **42**(9), p.1233-1248

[38] PERRY, N. C., STEVENS, C. J., WIGGINS, M. W., & HOWELL, C. E. (2007). Cough once for danger: Icons versus abstract warnings as informative alerts in civil aviation. Human Factors: *The Journal of the Human Factors and Ergonomics Society*, **49**(6), p.1061-1071

[39] EDWORTHY, J., LOXLEY, S., & DENNIS, I. (1991). Improving auditory warning design: Relationship between warning sound parameters and perceived urgency. *Human factors*, **33**(2), p.205-231

[40] HELLIER, E. J., EDWORTHY, J., & DENNIS, I. (1993). Improving auditory warning design: Quantifying and predicting the effects of different warning parameters on perceived urgency. *Human Factors*, **35**(4), p.693-706

[41] HAAS, E. C., & CASALI, J. G. (1995). Perceived urgency of and response time to multi-tone and frequency-modulated warning signals in broadband noise. *Ergonomics*, **38**(11), p.2313-2326

[42] MONDOR, T. A., & FINLEY, G. A. (2003). The perceived urgency of auditory warning alarms used in the hospital operating room is inappropriate. *Canadian Journal of Anesthesia*, **50**(3), p.221-228

[43] LEWIS, B., EISERT, J., & BALDWIN, C. (2014). Effect of tactile location, pulse duration, and interpulse interval on perceived urgency. Transportation Research Record: *Journal of the Transportation Research Board*, (2423), p.10-14

[44] EDWORTHY, J. (2017) Ch.23 Designing Auditory Alarms. In Information Design: Research and Practice (Ed: BLACK, A, LUNA, P, LUND, O & WALKER, S). London: Routledge, p.377-390

[45] BOLTON, M. L., ZHENG, X., LI, M., EDWORTHY, J. R., & BOYD, A. D. (2019). An experimental validation of masking in IEC 60601-1-8:2006-compliant alarm sounds. *Human factors* [viewed 2020-03-24]. Available at: https://doi.org/10.1177/0018720819862911

[46] ALALI, K. A., & CASALI, J. G. (2011). The challenge of localizing vehicle backup alarms: Effects of passive and electronic hearing protectors, ambient noise level, and backup alarm spectral content. *Noise and Health*, **13**(51), p.99

[47] CATCHPOLE, K. R., MCKEOWN, J. D., & WITHINGTON, D. J. (2004). Localizable auditory warning pulses. *Ergonomics*, **47**(7), p.748-771

[48] HASANAIN, B., BOYD, A. D., EDWORTHY, J., & BOLTON, M. L. (2017). A formal approach to discovering simultaneous additive masking between auditory medical alarms. *Applied Ergonomics*, **58**, p.500-514

[49] LAROCHE, C., GIGUERE, C., VAILLANCOURT, V., SHMIGOL, E., RAHNAMA, M., GRAVEL, A., & ROZON-GAUTHIER, V. (2016). Effect of a level-dependent hearing protector on detection thresholds, perceived urgency, and localization performance of reverse alarms. *The Journal of the Acoustical Society of America*, **140**(4), p.3201

[50] LAROCHE, C., QUOC, H. T., HETU, R., & MCDUFF, S. (1991). 'Detectsound': A computerized model for predicting the detectability of warning signals in noisy workplaces. *Applied Acoustics*, **32**(3), p.193-214

[51] KERR, J. H. (1985). Warning devices. *British Journal of Anaesthesia*, **57**(7), p.696-708

[52] EDWORTHY, J. R., SCHLESINGER, J. J., MCNEER, R. R., KRISTENSEN, M. S., & BENNETT, C. L. (2017). Classifying Alarms: Seeking Durability, Credibility, Consistency, and Simplicity. *Biomedical Instrumentation & Technology*, **51**(s2), p.50-57

[53] EDWORTHY, J., & STANTON, N. (1995). A user-centred approach to the design and evaluation of auditory warning signals: 1. Methodology. *Ergonomics*, **38**(11), p.2262-2280

[54] REESE, T., SEGALL, N., NESBITT, P., DEL FIOL, G., WALLER, R., MACPHERSON, B. C., TONNA, J.E., & WRIGHT, M. C. (2018). Patient information organization in the intensive care setting: expert knowledge elicitation with card sorting methods. *Journal of the American Medical Informatics Association*, **25**(8), 1026-1035

[55] WILKEN, M. et al. (2017). Alarm Fatigue: Causes and Effects. *Stud Health Technol Inform*., **243**, p.107-111

[56] AAMI (2017), Clinical Alarms: Managing the Overload. BI&T Horizons, Spring 2017, Arlington VA

[57] BULLEMER, P. T., TOLSMA, M., REISING, D. V. C., LABERGE, J. C. (2011) Towards improving operator alarm flood responses: alternative alarm presentation techniques. ISA *Automation Week*, Mobile AL

[58] BLOCK FE III, BLOCK FE JR. (2015) Decreasing False Alarms by Obtaining the Best Signal and Minimizing Artifact from Physiological Sensors. *Biomed Instrum Techn*, **49**(6), p.423-431

[59] BLOCK FE III, BLOCK FE JR. (2016) Understanding Caregiver Workflows: A Proposal for Alarm Condition Priorities. *Biomed Instrum Techn*, **50**(2), p.114-116

[60] SIEBIG, S., KUHLS, S., IMHOFF, M., GATHER, U., SCHÖLMERICH, J., WREDE, C. E. (2010) Intensive care unit alarms--how many do we need? *Crit Care Med*. **38**(2), p.451-456

[61] WILLIAMS S., BEATTY PCW. (2005) Measuring the performance of audible alarms for anaesthesia. *Physiol Meas*. **26**(4), p.571-581

[62] SANDERSON P. M., WEE A., LACHEREZ P. (2006) Learnability and discriminability of melodic medical equipment alarms. *Anaesthesia* **61**(2), p.142–147

[63] LACHEREZ P., SEAH L., SANDERSON P. (2006) Overlapping melodic alarms are almost indiscriminable. *Human Factors*. **49**(4), p.37-45

[64] WEE A., SANDERSON P. (2008) Are melodic medical equipment alarms easily learned? *Anesth Analg*. **106**(2), p.501-508

[65] BLOCK FE JR. (2008) For if the trumpet give an uncertain sound, who shall prepare himself to the battle? (I Corinthians 14:8, KJV). *Anesth Analg*. **106**(2), p.357-359

[66] BENNETT, C., DUDARYK, R., CRENSHAW, N., EDWORTHY, J., & MCNEER, R. (2019). Recommendation of New Medical Alarms Based on Audibility, Identifiability, and Detectability in a Randomized, Simulation-Based Study. *Critical Care Medicine*, **47**(8), 1050-1057

[67] EDWORTHY, J., REID, S., PEEL, K., LOCK, S., WILLIAMS, J., NEWBURY, C., FOSTER, J. & FARRINGTON, M. (2018) The impact of workload on the ability to localize audible alarms. *Applied Ergonomics*, **72**, p.88-93

[68] MCNEER, R., BODZIN HORN, D., BENNETT, C. L., REED EDWORTHY, J., & DUDARYK, R. (2018) Auditory icon alarms are more accurately and quickly identified than IEC 60601-1-8 melodic alarms in a simulated clinical setting. *Anesthesiology*, **129**(1), pp.58-66

[69] MCNEER, R., BENNETT, C. L., HORN, D. B., EDWORTHY, J., & DUDARYK, R. (2017) Use of Ordinal Regression Analysis for Assessing and Comparing Individual Alarm Performance in a Simulated Intensive Care Unit Environment. *Anesthesia & Analgesia* **124**, pp.1120-1122, IARS poster, Washington DC, May 2017

[70] EDWORTHY, J., et al., Report on Phase 2 of the IEC 60601-1-8 audible alarms project. Report presented to AAMI upon project completion.

[71] SCHLESINGER et al. (2018) Acoustic features of auditory medical alarms – An experimental study of alarm volume. *J Acoustical Society of America*, **143**(6), p.3688

[72] HUGHSON, WALTER, and HAROLD D. WESTLAKE. (1944) *Manual for Program Outline for Rehabilitation of Aural Casualties Both Military and Civilian,* Sponsored by the American Academy of Ophthalmology and Otolaryngology. Douglas Print Company

[73] AAMI Foundation. (2011) Clinical alarm: 2011 Summit convened by AAMI, FDA, TJA, ACCE and ECRI Institute [viewed 2020-03-24]. Available at: https://www.aami.org/events/eventdetail.aspx?ItemNumber=1153

[74] SENDELBACH S, FUNK M. (2013) Alarm fatigue: a patient safety concern. AACN *Adv Crit Care*, 24(4), pp.378–386

[75] GRAHAM KC, CVACH M. (2010) Monitor alarm fatigue: standardizing use of physiological monitors and decreasing nuisance alarms. *Am J Crit Care*, 19(1), pp.28–34

[76] ISO/IEEE 11073-10201:2004, Health informatics – Point-of-care medical device communication – Part 10201: Domain information model

[77] BLISS, J. P., GILSON, R. D., & DEATON, J. E. (1995). Human probability matching behaviour in response to alarms of varying reliability. *Ergonomics*, **38**(11), pp.2300–2312

[78] RAYO, M. F., & MOFFATT-BRUCE, S. D. (2015) Alarm system management: evidence-based guidance encouraging direct measurement of informativeness to improve alarm response. *BMJ Quality & Safety*, **24**(4), pp.282–286

[79] Wiener, E.L. (1989) Human Factors of Advanced Technology ("Glass Cockpit") Transport Aircraft. NASA Contractor Report 177528, NASA Ames Research Center [viewed 2020-03-24]. Available at: https://ntrs.nasa.gov/archive/nasa/casi.ntrs.nasa.gov/19890016609.pdf

[80] WELCH, J., RAYO, M., KANTER, B., BAGIAN, T., JACOBS, K., SHANAWANI, H., et al. (2016). Framework for Alarm Management Process Maturity. *Biomed Instrum Techn*, **50**(3), pp.165-179

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IEC 60601-1-8

Edition 2.2 2020-07
CONSOLIDATED VERSION

FINAL VERSION

colour inside

Medical electrical equipment –
Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006-10+AMD1:2012-11+AMD2:2020-07 CSV(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-1-8 edition 2.2 contains the second edition (2006-10) [documents 62A/519/CDV and 62A/537A/RVC], its amendment 1 (2012-11) [documents 62A/824/FDIS and 62A/837/RVD] and its amendment 2 (2020-07) [documents 62A/1392/FDIS and 62A/1407/RVD].

This Final version does not show where the technical content is modified by amendments 1 and 2. A separate Redline version with all changes highlighted is available in this publication.

International standard IEC 60601-1-8 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC 3: Lung ventilators and related devices of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as double logo standard.

IEC 60601-1-8 constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

This edition of IEC 60601-1-8 was revised to structurally align it with the 2005 edition of IEC 60601-1 and to implement the decision of IEC Subcommittee 62 A that the clause numbering structure of collateral standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in IEC 60601-1:2005.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type. In addition, in Annex A text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes Subclauses 6.1, 6.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.3.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 60601 series, under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendments will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

INTRODUCTION

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are increasingly used in medical practice. ALARM SIGNALS are frequently used to indicate unsatisfactory physiological PATIENT states, unsatisfactory functional states of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM or to warn the OPERATOR of HAZARDS to the PATIENT or OPERATOR due to the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM. INFORMATION SIGNALS convey information that is independent of an ALARM CONDITION.

Surveys of healthcare personnel have indicated significant discontent with ALARM SIGNALS. Problems include difficulty in identifying the origin of an ALARM SIGNAL, loud and distracting ALARM SIGNALS, and the high incidence of FALSE POSITIVE or NEGATIVE ALARM CONDITIONS [16] [1]. Surveys of MANUFACTURERS of medical monitors demonstrated a wide variety of DEFAULT ALARM PRESETS. The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS. See also bibliography.

Safety of PATIENTS depends on the ability of the OPERATOR to correctly discern the characteristics of ALARM SIGNALS. USABILITY is an important element in the design of ALARM SIGNALS that are readily discernible without being unnecessarily distracting or disturbing. This approach is intended to rationalize the current situation, to reduce confusion by limiting proliferation of ALARM SIGNALS and their control states, and to minimize distraction for other people. This collateral standard was developed with contributions from clinicians, engineers and applied psychologists.

The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for particular standards.

The effectiveness of any ALARM SYSTEM depends critically on its implementation by the RESPONSIBLE ORGANIZATION. It is important that the RESPONSIBLE ORGANIZATION configure the ALARM SYSTEM so that an OPERATOR is not able to compromise it.

INTRODUCTION to Amendment 1

The second edition of IEC 60601-1-8 was published in 2006. Since its publication, an issue has been identified with respect to pulse and burst testing. In addition, issues have been raised by IEC/62D/MT 22, *Electromedical diagnostic and patient monitoring equipment*, during implementation of alarm system requirements in particular standards within their scope of work.

At the Brussels meeting, IEC/SC 62A accepted a proposal, based on ISO/TC 121/SC 3 Resolution Orebro 6, to develop the 1st amendment to IEC 60601-1-8:2006 to address the issues identified above. IEC/SC 62A – ISO/TC 121/SC 3 Joint Working Group 2, *Alarms*, was reactivated as a maintenance team to develop this amendment.

1) Figures in brackets refer to the bibliography.

INTRODUCTION to Amendment 2

The second edition of IEC 60601-1-8 was published in 2006 and amended in 2012. Since the publication of IEC 60601-1-8:2006+A1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the third edition of IEC 60601-1-8, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 20 items were presented to the National Committees present. All 20 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the third edition of IEC 60601-1-8.

The "short list" of issues was documented in the design specification for Amendment 2. As IEC 60601-1-8 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 2. JWG 2 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-8:2006, the style in force at the time of publication of IEC 60601-1-8 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

1 * Scope, object and related standards

1.1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard specifies requirements for ALARM SYSTEMS and ALARM SIGNALS in ME EQUIPMENT and ME SYSTEMS.

It also provides guidance for the application of ALARM SYSTEMS.

1.2 Object

The object of this collateral standard is to specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements and tests for ALARM SYSTEMS in ME EQUIPMENT and ME SYSTEMS and to provide guidance for their application. This is accomplished by defining alarm categories (priorities) by degree of urgency, consistent ALARM SIGNALS and consistent control states and their marking for all ALARM SYSTEMS.

This collateral standard does not specify:

– whether any particular ME EQUIPMENT or ME SYSTEM is required to be provided with ALARM SYSTEMS;

– the particular circumstances which initiate an ALARM CONDITION;

– the allocation of priorities to a particular ALARM CONDITION; or

– the means of generating ALARM SIGNALS.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

– "the general standard" designates IEC 60601-1 alone including any amendments;

– "this collateral standard" designates IEC 60601-1-8 alone, including any amendments;

– "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60417, *Graphical symbols for use on equipment.* Available from: <http://www.graphical-symbols.info/equipment>

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
Amendment 1:2020

ISO 3744:2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering method for an essentially free field over a reflecting plane*

ISO 7000, *Graphical symbols for use on equipment*. Available from: <http://www.graphical-symbols.info/equipment>

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012+A2:2020, IEC 62366-1:2015+A1:2020, and the following definitions apply.

NOTE 1 The term "electrical equipment" is used to mean ME EQUIPMENT or other electrical equipment. This standard also uses the term "equipment" to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

NOTE 2 An index of defined terms is found beginning on page 119.

3.1
*** ALARM CONDITION**
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.

3.2
*** ALARM CONDITION DELAY**
time from the occurrence of a triggering event either in the PATIENT, for PHYSIOLOGICAL ALARM CONDITIONS, or in the equipment, for TECHNICAL ALARM CONDITIONS, to when the ALARM SYSTEM determines that an ALARM CONDITION exists

3.3
*** ALARM LIMIT**
threshold used by an ALARM SYSTEM to determine an ALARM CONDITION

3.4
ALARM OFF
state of indefinite duration in which an ALARM SYSTEM or part of an ALARM SYSTEM does not generate ALARM SIGNALS

3.5
*** ALARM PAUSED**
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate ALARM SIGNALS

3.6
ALARM PRESET
set of stored configuration parameters, including selection of algorithms and initial values for use by algorithms, which affect or modify the performance of the ALARM SYSTEM

3.7
ALARM RESET
OPERATOR action that causes the cessation of an ALARM SIGNAL for which no associated ALARM CONDITION currently exists

3.8
ALARM SETTINGS
ALARM SYSTEM configuration, including but not limited to:

– ALARM LIMITS;

– the characteristics of any ALARM SIGNAL inactivation states; and

– the values of variables or parameters that determine the function of the ALARM SYSTEM

NOTE Some algorithmically-determined ALARM SETTINGS can require time to be determined or re-determined.

3.9
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

3.10
*** ALARM SIGNAL GENERATION DELAY**
time from the onset of an ALARM CONDITION to the generation of its ALARM SIGNAL(S)

3.11
ALARM SYSTEM
parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

3.12
AUDIO OFF
state of indefinite duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

3.13
AUDIO PAUSED
state of limited duration in which the ALARM SYSTEM or part of the ALARM SYSTEM does not generate an auditory ALARM SIGNAL

3.14
BURST
group of PULSES with a distinctive rhythm or pattern

3.15
DE-ESCALATION
PROCESS by which an ALARM SYSTEM decreases the priority of an ALARM CONDITION or decreases the sense of urgency of an ALARM SIGNAL

3.16
DEFAULT ALARM PRESET
ALARM PRESET that can be activated by the ALARM SYSTEM without OPERATOR action

NOTE MANUFACTURER- or RESPONSIBLE ORGANIZATION-configured ALARM PRESETS are possible types of DEFAULT ALARM PRESETS.

3.17
*** DISTRIBUTED ALARM SYSTEM**
DAS
ALARM SYSTEM that involves more than one item of equipment of a ME SYSTEM intended for delivery of ALARM CONDITIONS with technical confirmation

NOTE 1 The parts of a DISTRIBUTED ALARM SYSTEM can be widely separated in distance.

NOTE 2 A DISTRIBUTED ALARM SYSTEM is intended to notify OPERATORS of the existence of an ALARM CONDITION.

NOTE 3 For the purposes of this document, technical confirmation means that each element of a DISTRIBUTED ALARM SYSTEM confirms or guarantees the successful delivery of the ALARM CONDITION to the next element or appropriate TECHNICAL ALARM CONDITIONS are created as described in 6.11.2.2.1.

3.18
ESCALATION
PROCESS by which an ALARM SYSTEM increases the priority of an ALARM CONDITION or increases the sense of urgency of an ALARM SIGNAL

3.19
FALL TIME
t_f
interval over which the PULSE amplitude decreases from 90 % to 10 % of its maximum (see Figure 1)

3.20
FALSE NEGATIVE ALARM CONDITION
absence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE An ALARM CONDITION can be rejected or missed because of spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the ALARM SYSTEM itself.

3.21
FALSE POSITIVE ALARM CONDITION
presence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

NOTE A FALSE POSITIVE ALARM CONDITION can be caused by spurious information produced by the PATIENT, the PATIENT-equipment interface, other equipment or the ALARM SYSTEM itself.

3.22
HIGH PRIORITY
indicating that immediate OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Immediate implies the interruption of current workflow is expected [59], [60].

3.23
*** INFORMATION SIGNAL**
any signal that is not an ALARM SIGNAL or a REMINDER SIGNAL

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO_2 tone

EXAMPLE 3 Fluoroscopy beam-on indication

NOTE An ADVISORY is a type of INFORMATION SIGNAL.

3.24
*** INTELLIGENT ALARM SYSTEM**
ALARM SYSTEM that makes logical decisions based on monitored information without OPERATOR intervention

EXAMPLE 1 An ALARM SYSTEM that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 An ALARM SYSTEM that suppresses an ALARM CONDITION when a related ALARM CONDITION of higher priority has recently generated an ALARM SIGNAL.

3.25
INTERBURST INTERVAL
t_b
period of time between the end of the last PULSE of a BURST and the start of the first PULSE of the next BURST of the same ALARM SIGNAL (see Figure 1 and Figure G.1)

NOTE For the purposes of this document, when an AUDITORY ICON is used, the INTERBURST INTERVAL begins at the end of the AUDITORY ICON.

3.26
LATCHING ALARM SIGNAL
ALARM SIGNAL that continues to be generated after its triggering event no longer exists until stopped by deliberate OPERATOR action

3.27
LOW PRIORITY
indicating that OPERATOR awareness is required and future action might be needed

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Awareness implies the planning of future workflow is expected [59], [60].

3.28
MEDIUM PRIORITY
indicating that prompt OPERATOR response is required

NOTE 1 The priority is assigned through RISK ANALYSIS. See 6.1.2 for the assignment of priority.

NOTE 2 Prompt implies the re-planning of current workflow is expected [59], [60].

3.29
NON-LATCHING ALARM SIGNAL
ALARM SIGNAL that automatically stops being generated when its associated triggering event no longer exists

3.30
OPERATOR'S POSITION
intended position of the OPERATOR with respect to the ALARM SIGNAL generating part of the ALARM SYSTEM

NOTE A DISTRIBUTED ALARM SYSTEM can have multiple OPERATOR'S POSITIONS.

3.31
PHYSIOLOGICAL ALARM CONDITION
ALARM CONDITION arising from a monitored PATIENT-related variable

EXAMPLE 1 High exhaled anesthetic agent concentration.

EXAMPLE 2 Low exhaled tidal volume.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

3.32
PULSE
brief continuous sound having a specific spectral content

3.33
PULSE FREQUENCY
f_o
fundamental frequency (first harmonic) of a PULSE

3.34
*** REMINDER SIGNAL**
periodic signal that reminds the OPERATOR that the ALARM SYSTEM is in an ALARM SIGNAL-inactivation state

3.35
RISE TIME
t_r
interval over which the PULSE increases from 10% to 90% of its maximum amplitude (see Figure 1)

3.36
TECHNICAL ALARM CONDITION
ALARM CONDITION arising from a monitored equipment-related or ALARM SYSTEM-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

3.37
*** ACKNOWLEDGED**
state of an ALARM SYSTEM initiated by OPERATOR action, where the auditory ALARM SIGNAL associated with a currently active ALARM CONDITION is inactivated until the ALARM CONDITION no longer exists or until a predetermined time interval has elapsed

NOTE ACKNOWLEDGED only affects ALARM SIGNALS that are active at the time of the OPERATOR action.

3.38
*** ADVISORY**
ADVISORY SIGNAL
INFORMATION SIGNAL notifying the OPERATOR of a condition of the PATIENT or ME EQUIPMENT providing contextual awareness that is intended to improve the clinical workflow or understanding of the PATIENT condition, the awareness not being intended as a means of RISK CONTROL

NOTE 1 A notification that a lab result is available, where the lab result requires immediate clinical action is not an ADVISORY. It is an ALARM CONDITION.

NOTE 2 A signal associated with an ADVISORY, which is an INFORMATION SIGNAL, is required by this document to be designed so that an OPERATOR does not confuse it with an ALARM SIGNAL. See 6.3.2.2.2 and 6.3.3.2.

EXAMPLE 1 A notification that it is time to draw the next blood sample.

EXAMPLE 2 A battery status notification that replacement will be needed in a day.

EXAMPLE 3 A notification that it is time to bathe the PATIENT.

EXAMPLE 4 A notification that a lab result is available, where the lab results are normal.

3.39
*** ALARM FATIGUE**
situation wherein the presence of frequent ALARM SIGNALS desensitizes an OPERATOR to an ALARM SIGNAL

NOTE 1 A desensitized OPERATOR can fail to perceive, recognize or act on an ALARM SIGNAL.

NOTE 2 The response of a desensitized OPERATOR can be inadequate, delayed or non-existent.

NOTE 3 ALARM FLOOD can cause ALARM FATIGUE.

3.40
ALARM FLOOD
situation wherein OPERATORS receive more ALARM SIGNALS in a time period than they can manage appropriately

NOTE See [56], [57].

3.41
*** ALERT**
synonym for the combination of PHYSIOLOGICAL ALARM CONDITIONS, TECHNICAL ALARM CONDITIONS and ADVISORIES

[SOURCE: ISO/IEEE 11073-10201:2020 [76], 3.3, modified – Replaced "alarms" with "ALARM CONDITIONS", "equipment-user advisory signals" with "ADVISORIES" and deleted "patient related".]

3.42
AUDITORY ICON
sound that creates a strong semantic link to the category it represents

NOTE 1 An AUDITORY ICON is typically a real-world sound or mimics a real-world sound.

NOTE 2 An AUDITORY ICON can aid in locating the COMMUNICATOR and the SOURCE type.

3.43
AUDITORY POINTER
sound that attracts attention, denotes the priority and aids in localization of the COMMUNICATOR

3.44
*** CLINICALLY ACTIONABLE**
type of ALARM CONDITION for which a panel of experts would agree that OPERATOR action is necessary to prevent HARM within the timeframe implied by the priority communicated by the ALARM SYSTEM

NOTE 1 An OPERATOR action can include assessment of a PATIENT or the changing of ALARM LIMITS when they are inappropriately set for the state of the PATIENT.

NOTE 2 A LOW PRIORITY ALARM CONDITION, which requires action within the timeframe of a MEDIUM PRIORITY or HIGH PRIORITY timeframe, is considered CLINICALLY ACTIONABLE. A HIGH PRIORITY ALARM CONDITION, which requires action within the timeframe of a LOW PRIORITY or MEDIUM PRIORITY timeframe, is considered CLINICALLY NONACTIONABLE. In both cases, the ALARM CONDITION priority was improperly assigned.

NOTE 3 A FALSE POSITIVE ALARM CONDITION is never considered CLINICALLY ACTIONABLE even though an unrelated OPERATOR action might be required to prevent a future FALSE POSITIVE ALARM CONDITION.

NOTE 4 A CLINICALLY ACTIONABLE ALARM CONDITION is generally considered useful by the OPERATOR.

3.45
*** CLINICALLY NONACTIONABLE**
type of ALARM CONDITION for which a panel of experts would agree that OPERATOR action is not expected within a timeframe equal to or shorter than the timeframe implied by its priority

NOTE 1 A LOW PRIORITY ALARM CONDITION, which requires action within the timeframe of a MEDIUM PRIORITY or HIGH PRIORITY timeframe, is considered CLINICALLY ACTIONABLE. A HIGH PRIORITY ALARM CONDITION, which requires action within the timeframe of a LOW PRIORITY or MEDIUM PRIORITY timeframe, is considered CLINICALLY NONACTIONABLE. In both cases, the ALARM CONDITION priority was improperly assigned.

NOTE 2 CLINICALLY NONACTIONABLE ALARM CONDITIONS are considered detrimental to OPERATOR performance and PATIENT safety.

NOTE 3 ALARM SIGNALS for an ALARM CONDITION of which the OPERATOR is already aware are considered CLINICALLY NONACTIONABLE.

3.46
COMMUNICATOR
COM
ANNUNCIATOR
function of the ALARM SYSTEM that generates ALARM SIGNALS to notify an OPERATOR (e.g. to the presence of an ALARM CONDITION)

NOTE 1 A COMMUNICATOR can receive an OPERATOR response.

NOTE 2 An OPERATOR response is not limited to direct OPERATOR action.

NOTE 3 See Figure 2.

3.47
DISTRIBUTED ALARM SYSTEM WITH OPERATOR CONFIRMATION
CDAS
DISTRIBUTED ALARM SYSTEM that includes the capability to receive an OPERATOR response

3.48
*** DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS**
DIS
system that involves more than one item of equipment in a ME SYSTEM intended to provide information about ALARM CONDITIONS but does not guarantee delivery of that information

NOTE 1 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended to notify OPERATORS of the existence of an ALARM CONDITION as a RISK CONTROL measure. A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is intended to provide information about an ALARM CONDITION while the OPERATOR is aware of the existence of the ALARM CONDITION by an ALARM SYSTEM.

NOTE 2 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended for confirmed delivery of ALARM CONDITIONS.

3.49
INTEGRATOR
INT
ALARM MANAGER
function of the ALARM SYSTEM that distributes ALARM CONDITIONS, combines ALARM CONDITIONS from SOURCES or handles the communication between those SOURCES and COMMUNICATORS

NOTE 1 An INTEGRATOR can direct or redirect an ALARM CONDITION to another COMMUNICATOR and hence OPERATOR.

NOTE 2 An INTEGRATOR can send the acceptance of responsibility from a COMMUNICATOR to a SOURCE.

NOTE 3 See Figure 2.

3.50
*** NUISANCE ALARM SIGNAL**
ALARM SIGNAL for which a panel of experts would agree that the HARM associated with the ALARM SIGNAL is greater than the benefit associated with action resulting from the ALARM SIGNAL

NOTE 1 A NUISANCE ALARM SIGNAL contributes to ALARM FATIGUE.

NOTE 2 A NUISANCE ALARM SIGNAL can arise from a FALSE POSITIVE ALARM CONDITION.

NOTE 3 A NUISANCE ALARM SIGNAL can arise from a CLINICALLY NONACTIONABLE ALARM CONDITION.

NOTE 4 A NUISANCE ALARM SIGNAL can cause an inappropriate OPERATOR action.

EXAMPLE Causing the OPERATOR to set ALARM LIMITS to inappropriate settings.

NOTE 5 An ALARM SIGNAL that unnecessarily irritates or startles the PATIENT or OPERATOR can be a NUISANCE ALARM SIGNAL.

3.51
REDIRECTION
means by which an INTEGRATOR provides a response hierarchy for directing an ALARM CONDITION to a COMMUNICATOR or transfers an ALARM CONDITION to another COMMUNICATOR

NOTE See Figure 2.

3.52
RESPONSIBILITY ACCEPTED
state created by an OPERATOR response accepting ownership for addressing an ALARM CONDITION

NOTE 1 A RESPONSIBILITY ACCEPTED can be used to initiate an ALARM SIGNAL inactivation state.

NOTE 2 See Figure 2.

3.53
RESPONSIBILITY REJECTED
state created by an OPERATOR response rejecting ownership for addressing an ALARM CONDITION

NOTE 1 A RESPONSIBILITY REJECTED can be used to initiate an ESCALATION or REDIRECTION.

NOTE 2 See Figure 2.

3.54
RESPONSIBILITY UNDEFINED
state, automatically initiated when neither a RESPONSIBILITY ACCEPTED nor RESPONSIBILITY REJECTED is received within a specified period, which indicates that an OPERATOR is not responding

NOTE 1 RESPONSIBILITY UNDEFINED is not used as an indication that the COMMUNICATOR and INTEGRATOR cannot communicate.

NOTE 2 See Figure 2.

3.55
SOURCE
SRC
function that has the capability to initiate an ALARM CONDITION

NOTE 1 The SOURCE transfers the ALARM CONDITION to the INTEGRATOR.

NOTE 2 See Figure 2.

3.56
TRUE NEGATIVE ALARM CONDITION
absence of an ALARM CONDITION when no valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

3.57
TRUE POSITIVE ALARM CONDITION
presence of an ALARM CONDITION when a valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM

4 General requirements

If the MANUFACTURER chooses as a means of RISK CONTROL to have the ME EQUIPMENT or ME SYSTEM notify the OPERATOR that a HAZARDOUS SITUATION can exist, then the ME EQUIPMENT or ME SYSTEM shall include an ALARM SYSTEM complying with this collateral standard for that purpose. See also 12.3 of the general standard.

The RISK ASSESSMENT shall also consider HAZARDS to PATIENTS, OPERATORS, and other persons arising from the ALARM SYSTEM (see 6.8.3).

5 ME EQUIPMENT identification marking and documents

NOTE Additional requirements for the marking on controls and instruments are specified in this collateral standard, together with the technical requirements, giving rise to requirements on markings. These requirements are also listed in Annex B.

5.1 Indicator lights and controls

In addition to the requirements for colours of indicator lights and their meanings in 7.8.1 of the general standard, the requirements of 6.3.2.2 apply.

NOTE Dot matrix or other alphanumeric displays are not considered to be an alarm indicator light unless those displays are used to simulate an alarm indicator lights (see 6.3.2.2).

5.2 ACCOMPANYING DOCUMENTS

NOTE Additional requirements on ACCOMPANYING DOCUMENTS are specified in this collateral standard, together with the technical requirements, giving rise to requirements on ACCOMPANYING DOCUMENTS. These requirements are also listed in Table B.2.

5.2.1 Instructions for use

The instructions for use shall:

- * provide an overview of the ALARM SYSTEM, including a listing and description of every possible ALARM CONDITION and, as appropriate for the intended OPERATOR, a summary of how it is determined;
- indicate any delay inherent in the determination of an ALARM CONDITION;
- disclose the OPERATOR'S POSITION; and
- * include how and when to verify the functionality of the ALARM SYSTEM.

As applicable, the instructions for use shall caution against setting ALARM LIMITS to extreme values that can render the ALARM SYSTEM useless.

NOTE Additional requirements on instructions for use are specified in this collateral standard, together with the technical requirements, giving rise to requirements on instructions for use. These requirements are also listed in Table B.3.

Compliance is checked by inspection of the instructions for use.

5.2.2 Technical description

NOTE Additional requirements on technical description are specified in this collateral standard, together with the technical requirements, giving rise to requirements on technical description. These requirements are also listed in Table B.4.

6 ALARM SYSTEMS

6.1 ALARM CONDITION

6.1.1 * General

If ALARM CONDITIONS are grouped into PHYSIOLOGICAL ALARM CONDITIONS, TECHNICAL ALARM CONDITIONS or other ALARM CONDITION groups by the MANUFACTURER, this shall be disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use.

6.1.2 * Determination of ALARM CONDITIONS and assignment of priority

For each HAZARDOUS SITUATION where the MANUFACTURER has chosen to use an ALARM SYSTEM as a means of RISK CONTROL, the MANUFACTURER shall assign an ALARM CONDITION and its priority using Table 1.

For HAZARDOUS SITUATIONS where the onset of potential HARM is delayed and the potential result of a failure to respond is discomfort or minor reversible injury, the MANUFACTURER may determine that no ALARM CONDITION is required. In such cases, the MANUFACTURER may implement an INFORMATION SIGNAL.

NOTE Not all LOW PRIORITY ALARM CONDITIONS require prompt notification of the OPERATOR. On this basis an auditory ALARM SIGNAL or repeating auditory ALARM SIGNAL can be omitted, when appropriate, since the OPERATOR is expected to check the ME EQUIPMENT at intervals. In the event that the OPERATOR does not check the ME EQUIPMENT in a timely fashion, the ALARM CONDITION should escalate from LOW PRIORITY to MEDIUM PRIORITY or HIGH PRIORITY, and can additionally increase the sound pressure level of the related auditory ALARM SIGNALS, as appropriate.

The priority of each ALARM CONDITION shall be disclosed in the instructions for use. Priorities may be identified in groups.

Compliance is checked by inspection of the instructions for use and RISK MANAGEMENT FILE.

Table 1 – Determination of ALARM CONDITION and assignment of priorities

Potential result of failure to respond to the cause of ALARM CONDITION	Onset of potential HARM [a]		
	Immediate [b]	Prompt [c]	Delayed [d]
Death or irreversible injury	HIGH PRIORITY ALARM CONDITION [e]	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION
Reversible injury	HIGH PRIORITY ALARM CONDITION	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION
Discomfort or reversible minor injury	MEDIUM PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION	LOW PRIORITY ALARM CONDITION, no ALARM CONDITION or INFORMATION SIGNAL

[a] Onset of potential HARM refers to when an injury occurs and not to when it is manifested.

[b] Having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

[c] Having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

[d] Having the potential for the event to develop within an unspecified time greater than that given under “prompt”.

[e] Where practicable, ME EQUIPMENT with a therapeutic function incorporates automatic safety mechanisms to prevent immediate death or irreversible injury caused by the ME EQUIPMENT. See also appropriate particular standards.

6.2 * Disclosures for INTELLIGENT ALARM SYSTEM

If an INTELLIGENT ALARM SYSTEM is provided, the instructions for use shall include, as applicable, an overview of how the ALARM SYSTEM:

a) determines an ALARM CONDITION on the basis of time, weightings, multiple variables, or other advanced processing (including, but not limited to, algorithms, neural networks, fuzzy logic, etc.);

b) generates ALARM SIGNALS for two or more ALARM CONDITIONS of equal priority (including, but not limited to, internal ranking, effect on generation of ALARM SIGNALS);

c) changes the previously-assigned priority or relative prioritization of a particular ALARM CONDITION (e.g., ESCALATION or DE-ESCALATION);

d) changes the ALARM SIGNAL GENERATION DELAY or ALARM CONDITION DELAY; and

e) changes the characteristics of the generated ALARM SIGNALS (for example, volume, pitch, tempo, urgency, AUDITORY ICON category).

Compliance is checked by inspection of the instructions for use.

6.3 Generation of ALARM SIGNALS

6.3.1 General

Each ALARM CONDITION shall cause the generation of visual ALARM SIGNALS by a COMMUNICATOR as specified in this collateral standard. If deemed necessary by RISK ASSESSMENT regarding the environment in which the ALARM SYSTEM is intended to be used, additional ALARM SIGNALS shall be generated. These additional ALARM SIGNALS may be auditory, verbal, vibratory or produced by other means.

EXAMPLE ALARM SYSTEMS with HIGH or MEDIUM PRIORITY ALARM CONDITIONS that are intended not to be continuously attended by an OPERATOR in NORMAL USE should generate additional auditory ALARM SIGNALS.

Compliance is checked by inspection of the ALARM SYSTEM.

6.3.2 * Visual alarm signals

6.3.2.1 General

ALARM SYSTEMS shall generate visual ALARM SIGNALS to indicate the presence of ALARM CONDITIONS, their priority and each specific ALARM CONDITION.

6.3.2.2 * Characteristics of visual ALARM SIGNALS

6.3.2.2.1 * 4 m (distant) visual ALARM SIGNALS

If a visual indicator is necessary for the OPERATOR to identify the equipment or part of the equipment that requires OPERATOR response or awareness, at least one visual ALARM SIGNAL shall be provided that:

a) indicates the priority of the highest priority ALARM CONDITION; and

b) can be perceived correctly at a distance of 4 m from the ALARM SYSTEM.

If an alarm indicator light or graphical simulation of an indicator light is used for these purposes, it shall comply with the colour and flashing requirements given in Table 2.

ALARM SYSTEMS that do not contain HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITIONS are exempt from this requirement if their visual indication cannot be confused with a HIGH PRIORITY or MEDIUM PRIORITY alarm indicator light complying with Table 2.

NOTE 1 This visual indicator is necessary for ALARM SYSTEMS that are intended to be located in the proximity of other ALARM SYSTEMS.

NOTE 2 This visual indicator is not necessary for ALARM SYSTEMS that are worn, e.g., a paging receiver.

NOTE 3 An indicator light can be simulated, e.g. by a graphical display.

Table 2 – Characteristics of alarm indicator lights

Alarm category	Indicator colour	Flashing frequency	Duty cycle
HIGH PRIORITY	Red	1,4 Hz to 2,8 Hz	20 % to 60 % on
MEDIUM PRIORITY	Yellow	0,4 Hz to 0,8 Hz	20 % to 60 % on
LOW PRIORITY	Cyan or yellow	Constant (on)	100 % on

6.3.2.2.2 1 m (OPERATOR'S POSITION) visual ALARM SIGNALS and INFORMATION SIGNALS

At least one visual ALARM SIGNAL that identifies the specific ALARM CONDITION and its priority shall be provided. This signal shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION. This visual indication may be text placed beside an indicator light or text on a display. The presence ofan ALARM CONDITION may be visually indicated (marked) with symbol IEC 60417-5307 (2002-10) (see Symbol 1 of Table C.1). The priority may be indicated by adding one, two or three optional elements, (e.g., **!** for LOW PRIORITY, **!!** for MEDIUM PRIORITY, and **!!!** for HIGH PRIORITY).

NOTE 1 Factors affecting the legibility of a visual indication include the nature and characteristics of the visual indication itself, ambient lighting in the intended environment of use, and viewing angle and distance.

NOTE 2 The use of text that flashes on and off is discouraged because it is often difficult to read. Flashing text that alternates between normal and reverse video or another colour is acceptable.

NOTE 3 Multiple-purpose computer-generated graphic displays should be designed in accordance with modern human interface design principles. Attention is drawn to IEC 62366-1.

NOTE 4 The identification of the ALARM CONDITION is intended to convey information necessary for PATIENT safety and safe use of the equipment.

If multiple ALARM CONDITIONS occur at the same time, each individual ALARM CONDITION shall be visually indicated, either automatically or by OPERATOR action, unless an INTELLIGENT ALARM SYSTEM is provided that prevents a lower internal rank ALARM CONDITION from generating ALARM SIGNALS when a higher internal rank ALARM CONDITION is generating or has recently generated ALARM SIGNALS (see 6.2).

Visual INFORMATION SIGNALS, if provided, shall be correctly perceived as different from HIGH PRIORITY or MEDIUM PRIORITY visual ALARM SIGNALS at a distance of 1 m from the ALARM SYSTEM or from the OPERATOR'S POSITION.

NOTE 5 It is recognized that visual INFORMATION SIGNALS and visual ALARM SIGNALS can sometimes contain identical or similar information. When they are intended to convey different meanings, care needs to be taken to ensure that visual ALARM SIGNALS cannot be confused with visual INFORMATION SIGNALS.

Compliance is checked by inspection of the visual ALARM SIGNAL under the following conditions:

– *the OPERATOR has a visual acuity of 0 on the logMAR* [17] *scale or 6-6 (20/20) vision (corrected if necessary),*
– *the viewpoint is at the OPERATOR'S POSITION or at any point within the base of a cone subtended by an angle of 30° to the axis horizontal to or normal to the centre of the plane of display of the monitoring display or visual indication, and*
– *the ambient illuminance in the range* [21] *of 100 lx to 1 500 lx.*

6.3.3 * Auditory ALARM SIGNALS

6.3.3.1 * Characteristics of auditory ALARM SIGNALS

If a COMMUNICATOR of an ALARM SYSTEM is provided with auditory ALARM SIGNALS:

a) all auditory ALARM SIGNALS shall be priority encoded;

b) of HIGH PRIORITY, the HIGH PRIORITY auditory ALARM SIGNALS of that COMMUNICATOR shall convey a higher level of urgency than the MEDIUM or LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;

c) of MEDIUM PRIORITY, the MEDIUM PRIORITY auditory ALARM SIGNALS of that COMMUNICATOR shall convey a higher level of urgency than the LOW PRIORITY auditory ALARM SIGNALS of that ALARM SIGNAL set as well as a higher level of urgency than any auditory INFORMATION SIGNAL;

d) the COMMUNICATOR shall have at least one set of ALARM SIGNALS that:

1) complies with Annex G; or

i) * A COMMUNICATOR with means to provide more than one set of auditory ALARM SIGNALS should be equipped with at least one set of auditory ALARM SIGNALS that complies with Annex G.

2) * is generated by means of different technology (e.g. voice synthesizing of verbal ALARM SIGNALS) and is VALIDATED (e.g. by clinical or simulated clinical USABILITY testing); or

3) * meets the requirements of Table 3 and Table 4.

Table 3 – * Characteristics of the BURST of auditory ALARM SIGNALS

Characteristic	HIGH PRIORITY ALARM SIGNAL	MEDIUM PRIORITY ALARM SIGNAL	LOW PRIORITY ALARM SIGNAL[d]
Number of PULSES in BURST [a, e]	10	3	1 or 2
PULSE spacing (t_s) (see Figure 1)			
between 1st and 2nd PULSE	x	y	y
between 2nd and 3rd PULSE	x	y	Not applicable
between 3rd and 4th PULSE	$2x + t_d$	Not applicable	Not applicable
between 4th and 5th PULSE	x	Not applicable	Not applicable
between 5th and 6th PULSE	0,35 s to 1,30 s	Not applicable	Not applicable
between 6th and 7th PULSE	x	Not applicable	Not applicable
between 7th and 8th PULSE	x	Not applicable	Not applicable
between 8th and 9th PULSE	$2x + t_d$	Not applicable	Not applicable
between 9th and 10th PULSE	x	Not applicable	Not applicable
INTERBURST INTERVAL [b, c] (t_b)	2,5 s to 15,0 s	2,5 s to 30,0 s	>15 s or no repeat
Difference in amplitude between any two PULSES	Maximum 10 dB	Maximum 10 dB	Maximum 10 dB

Where: x shall be a value between 50 ms and 125 ms,

y shall be a value between 125 ms and 250 ms,

the variation of t_d, x and y within a BURST shall not exceed ± 20 %, and

MEDIUM PRIORITY $t_d + y$ shall be greater than or equal to HIGH PRIORITY $t_d + x$.

The INTERBURST INTERVAL (t_b) for HIGH PRIORITY auditory ALARM SIGNALS shall not be greater than the INTERBURST INTERVAL for MEDIUM PRIORITY auditory ALARM SIGNALS which shall not be greater than the INTERBURST INTERVAL for LOW PRIORITY auditory ALARM SIGNALS.

[a] See also Table 4 for characteristics of the PULSE.

[b] Unless otherwise specified in a particular standard for a particular ME EQUIPMENT.

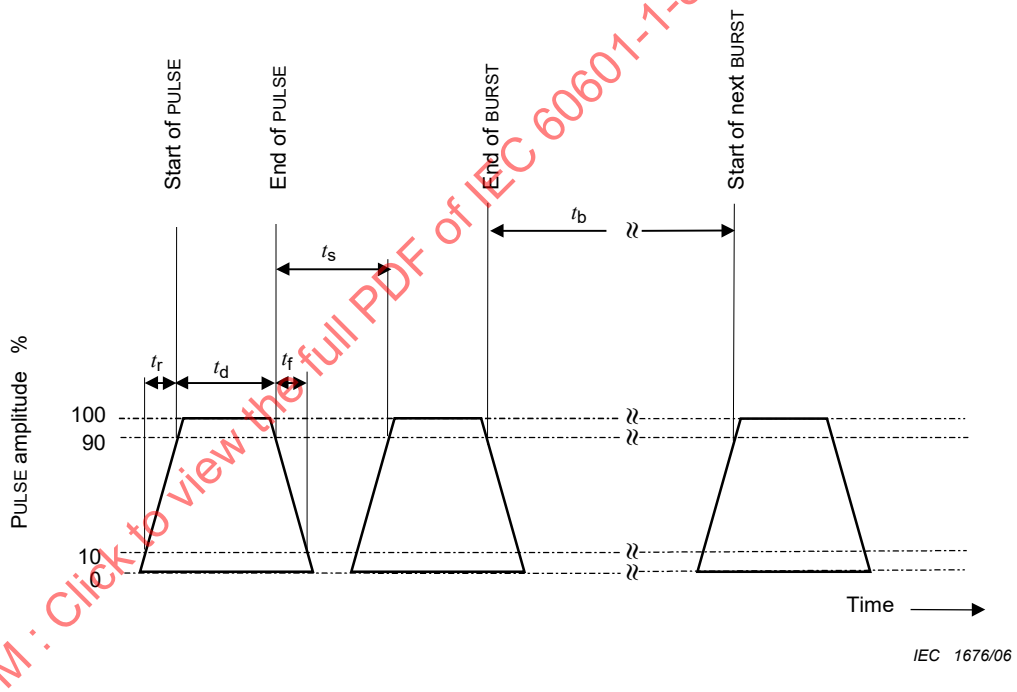
[c] MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application. Long INTERBURST INTERVALS can under certain conditions negatively affect the ability to correctly discern, in a timely manner, the origin of the ALARM CONDITION.

[d] The generation of the auditory component of a LOW PRIORITY ALARM CONDITION is optional.

[e] Unless inactivated by the OPERATOR, MEDIUM PRIORITY and LOW PRIORITY auditory ALARM SIGNALS shall complete at least one BURST, and HIGH PRIORITY auditory ALARM SIGNALS shall complete at least half of one BURST.

Table 4 – * Characteristics of the PULSE of auditory ALARM SIGNALS

Characteristic	Value
Frequency component in the range of 150 Hz to 1 000 Hz	At least one that is among the four frequency components with the largest sound pressure level
Number of peaks in the frequency range of 150 Hz to 4 000Hz	At least four peaks in the frequency domain
Effective PULSE duration (t_d) (see Figure 1) HIGH PRIORITY MEDIUM and LOW PRIORITY	 75 ms to 200 ms 125 ms to 250 ms
RISE TIME (t_r) (see Figure 1)	[a]
FALL TIME (t_f) (see Figure 1)	[b]
Within the frequency range of 150 Hz to 4 000 Hz, the relative sound pressure levels of the four frequency components with the largest sound pressure levels should be within 15 dB of each other. NOTE Care is needed to ensure that the MEDIUM PRIORITY ALARM SIGNAL cannot be confused with the audible emergency evacuation signal specified in ISO 8201:2017 [30]. [a] The RISE TIME should not be so short as to create mechanical speaker noise. [b] The FALL TIME should be short enough to ensure that the PULSES do not overlap.	



NOTE 1 Figure 1 is intended to show the designation of temporal characteristics and does not illustrate any individual auditory ALARM SIGNAL.

NOTE 2 See Figure G.1 and Figure G.2 for additional information.

Figure 1 – Illustration of temporal characteristics of auditory ALARM SIGNALS

If the ALARM SYSTEM is additionally provided with other sets of auditory ALARM SIGNALS, the following shall apply:

e) the other auditory ALARM SIGNALS shall be VALIDATED, e.g., by clinical or simulated clinical USABILITY testing;

f) means shall be provided to store a set of auditory ALARM SIGNALS in the DEFAULT ALARM PRESET; and

g) means may be provided to store a set of auditory ALARM SIGNALS in any ALARM PRESET.

NOTE 1 See also Annex D.

NOTE 2 Attention is drawn to IEC 62366-1.

When a TECHNICAL ALARM CONDITION that precludes the generation of the usual ALARM SIGNALS occurs, e.g. power or ALARM SYSTEM failure, the ALARM SYSTEM may generate an auditory ALARM SIGNAL that does not comply with the above requirements.

If selection of auditory ALARM SIGNAL sets is provided, means shall be provided for the RESPONSIBLE ORGANIZATION to prevent the OPERATOR from unauthorized access to changing the auditory ALARM SIGNAL set in use (see 6.7).

Compliance is checked by inspection and functional testing of the ALARM SYSTEM and inspection of any relevant VALIDATION documentation. Measure the drive signal of the audio transducer utilizing an oscilloscope or other suitable instrument to cover the frequencies and the RISE and FALL TIMES of the waveform. Confirm the values of x, y, t_b, t_s, t_f and t_d in Table 3 and Table 4. When the sound files of Annex G are utilized, only testing of t_b is required and testing of the acoustic signal is permitted.

Amongst the required frequency components with the largest sound pressure levels, acoustically confirm the presence of at least one frequency component in range of 150 Hz to 1 000 Hz and at least the required components in the range of 150 Hz to 4 000 Hz in the auditory ALARM SIGNAL at 1 m or the intended OPERATOR's POSITION. Only the AUDITORY POINTERS need be tested when evaluating the ALARM SIGNALS of Annex G.

6.3.3.2 * Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

The auditory HIGH PRIORITY and MEDIUM PRIORITY ALARM SIGNAL sound pressure level range and measurement radius measured in accordance with the method of this subclause, shall be disclosed in the ACCOMPANYING DOCUMENTS.

If auditory INFORMATION SIGNALS are provided, they shall be distinguishable from those of auditory ALARM SIGNALS and their characteristics shall be disclosed in the instructions for use.

NOTE Unless the sound pressure level of INFORMATION SIGNALS is independently adjustable, it should not exceed that of LOW PRIORITY ALARM SIGNALS.

Compliance is checked by inspection of the instructions for use and with the following test:

a) Set the ALARM SIGNAL sound pressure level (volume level) to its maximum setting.

b) If the ALARM SYSTEM is provided with a HIGH PRIORITY ALARM CONDITION, simulate a HIGH PRIORITY ALARM CONDITION.

c) Place the equipment containing the COMMUNICATOR on the floor and use a microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the sound pressure levels at least at positions 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10, as specified in Figure B.1 and Table B.1 of ISO 3744:2010, in a hemisphere with a radius of 1 m from the geometric centre of the COMMUNICATOR. For a large COMMUNICATOR, where d_O, as calculated in Figure 1 a) of ISO 3744:2010, is greater than 0,5 m, utilize a radius such that the distance from the surface of the COMMUNICATOR to the hemisphere is at least 0,5 m everywhere, extended to the next higher value in the series 1,5 m, 2 m, 2,5 m, 3 m, 3,5 m, 4 m.

d) Measure the maximum time-weighted sound pressure level using frequency weighting A and the time weighting F of the sound level meter (i.e. L_{AFmax}).

e) For ALARM SIGNALS utilizing AUDITORY POINTERS complying with Annex G, confirm that the drive signal of the audio transducer utilizing an oscilloscope or other suitable instrument is not clipped.

f) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.

g) If the ALARM SYSTEM is provided with a MEDIUM PRIORITY ALARM CONDITION, simulate a MEDIUM PRIORITY ALARM CONDITION and repeat c) to f).

h) If the ALARM SYSTEM is provided with a LOW PRIORITY ALARM CONDITION, simulate a LOW PRIORITY ALARM CONDITION and repeat c) to f).

i) Set the ALARM SIGNAL sound pressure level (volume level) to its minimum setting.

j) Repeat b) to h).

k) Confirm that the criteria for background noise, including any INFORMATION SIGNALS, specified in 4.2 of ISO 3744:2010 are fulfilled.

l) Confirm that the measured sound pressure level range is in compliance with the values indicated in the ACCOMPANYING DOCUMENTS.

6.3.3.3 * OPERATOR-adjustable sound pressure level

If an ALARM SYSTEM is provided with a HIGH PRIORITY ALARM CONDITION and an OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level, the instructions for use shall include a warning to the effect that auditory alarm signal sound pressure levels that are less than ambient levels can impede OPERATOR recognition of ALARM CONDITIONS and the ALARM SYSTEM shall:

a) provide a restricted means for the RESPONSIBLE ORGANIZATION to configure the minimum OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level (see 6.7); or

b) provide a visual indication that the current sound pressure level might be inaudible when the auditory ALARM SIGNAL sound pressure level is below a threshold that is configured:

   – by a means restricted to the RESPONSIBLE ORGANIZATION (see 6.7); or

   – by the MANUFACTURER.

   This condition may be visually indicated (marked) with symbol IEC 60417-5576 (2002-11) (see Symbol 5 of Table C.1). If this symbol is used as that visual indication, an INFORMATION SIGNAL or other additional visual indication may be provided to distinguish this state from AUDIO OFF.

An ALARM SYSTEM may be equipped with a dynamically algorithm-adjusted minimum auditory ALARM SIGNAL sound pressure level. If equipped, the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7) to enable and disable the algorithm-adjusted minimum auditory ALARM SIGNAL sound pressure level. If equipped, the instructions for use shall describe the algorithm and the minimum and maximum levels.

EXAMPLE 1 An algorithm that sets the minimum auditory ALARM SIGNAL sound pressure level in response to current ambient sound pressure levels, time of day, evidence of OPERATOR attendance or other variables.

EXAMPLE 2 An algorithm that escalates unresolved active auditory ALARM SIGNALS by increasing their sound pressure level over time.

Compliance is checked by inspection.

6.3.4 * Characteristics of verbal ALARM SIGNALS

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with verbal ALARM SIGNALS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

6.4 * Disclosure of delays

6.4.1 * ALARM SYSTEM delays

If the sum of the maximum ALARM CONDITION DELAY plus the maximum ALARM SIGNAL GENERATION DELAY is greater than 10 s, then the statistics of each distribution or statistics of the distribution of the sum shall be disclosed in the instructions for use.

If the sum of the mean ALARM CONDITION DELAY plus the mean ALARM SIGNAL GENERATION DELAY is greater than 5 s, then each delay or their sum shall be disclosed in the instructions for use.

Compliance is checked by inspection of the instructions for use.

6.4.2 * Delays to or from a DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) or a DISTRIBUTED ALARM SYSTEM (DAS)

If an ALARM SYSTEM is provided with a means to send or receive ALARM CONDITIONS in a DIS or DAS:

a) the delay time from the onset of the ALARM CONDITION to the point that the representation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART shall be disclosed in the instructions for use; and

b) the maximum ALARM SIGNAL GENERATION DELAY of the COMMUNICATOR, including the method used to determine the maximum ALARM SIGNAL GENERATION DELAY, or the time to determine the generation of the TECHNICAL ALARM CONDITION (see 6.11.2.2.1 b)) shall be disclosed in the instructions for use.

The following methods may be used to determine the ALARM SIGNAL GENERATION DELAY contribution for each component of a DIS or DAS, as applicable:

c) from:
   1) the onset of the ALARM CONDITION;
   2) the time of the ALARM SIGNAL generation at the SOURCE;
   3) the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART of the SOURCE or INTEGRATOR; or
   4) the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART of the INTEGRATOR or COMMUNICATOR;

d) to:
   1) the point that the presentation of the ALARM CONDITION leaves the SIGNAL INPUT/OUTPUT PART of the SOURCE or INTEGRATOR;
   2) the point that the presentation of the ALARM CONDITION arrives at the SIGNAL INPUT/OUTPUT PART of the INTEGRATOR or COMMUNICATOR; or
   3) the time of the ALARM SIGNAL generation at the COMMUNICATOR.

Compliance is checked by functional testing under maximum load conditions of NORMAL USE and inspection of the instructions for use.

6.5 ALARM PRESETS

6.5.1 * General requirements

Any ALARM PRESET that uses mechanical adjustment is exempt from the requirements of 6.5.

Example 1 A switch that indicates the value of a set point.

An ALARM SYSTEM is exempt from the requirements of 6.5 if in NORMAL USE it:

a) can only retain current ALARM SETTINGS, and

b) does not otherwise provide ALARM PRESETS, and

c) displays each adjustable ALARM SETTINGS continuously.

EXAMPLE 2 A simple monitor that always initializes with the previous ALARM LIMIT and that limit is continuously displayed.

ALARM PRESETS shall include the ALARM LIMIT used to trigger each ALARM CONDITION and its priority, or they shall be determined from information available to the ALARM SYSTEM concerning the current PATIENT. ALARM PRESETS may include other parameters that affect or modify performance of the ALARM SYSTEM.

EXAMPLE 3 An ALARM LIMIT calculated from entered data, e.g. PATIENT weight and gender.

EXAMPLE 4 An ALARM LIMIT calculated from current physiological status of the PATIENT, e.g. 1,2 times the current heart rate.

The instructions for use shall contain a warning statement to the effect that a HAZARD can exist if different ALARM PRESETS are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theatre.

Compliance is checked by inspection of the ALARM SYSTEM and the instructions for use.

6.5.2 MANUFACTURER-configured ALARM PRESETS

An ALARM SYSTEM shall be provided with at least one MANUFACTURER-configured ALARM PRESET.

The ALARM LIMITS and a summary of any algorithms used in any MANUFACTURER-configured ALARM PRESETS shall be disclosed in the instructions for use.

Compliance is checked by inspection of the ALARM SYSTEM and the instructions for use.

6.5.3 * RESPONSIBLE ORGANIZATION- and OPERATOR-configured ALARM PRESETS

6.5.3.1 ALARM SYSTEMS with one ALARM PRESET

If the ALARM SYSTEM can store only one ALARM PRESET:

a) means shall be provided to prevent the OPERATOR from saving changes to this ALARM PRESET. Saving changes to this ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7); and

b) means shall be provided to the RESPONSIBLE ORGANIZATION to restore the ALARM PRESET to its MANUFACTURER-configured state.

Compliance is checked by inspection.

6.5.3.2 ALARM SYSTEMS with more than one ALARM PRESET

If the ALARM SYSTEM provides means to store or activate one or more RESPONSIBLE ORGANIZATION-configured or OPERATOR-configured ALARM PRESETS in addition to any MANUFACTURER-configured ALARM PRESETS:

a) means shall be provided for the OPERATOR to choose between the available ALARM PRESETS;

b) means shall be provided for the OPERATOR to readily identify which ALARM PRESET is in use;

c) the instructions for use shall contain a warning statement to the effect that the OPERATOR should check that the current ALARM PRESET is appropriate prior to use on each PATIENT;

d) the means for configuration and storage of ALARM PRESETS shall be disclosed in the ACCOMPANYING DOCUMENTS;

e) means shall be provided to prevent the OPERATOR from saving changes to any RESPONSIBLE ORGANIZATION-configured or MANUFACTURER-configured ALARM PRESET. Saving

changes to any RESPONSIBLE ORGANIZATION-configured or MANUFACTURER-configured ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7);

f) means shall be provided to prevent an individual OPERATOR from saving changes to ALARM PRESETS that were stored by any other OPERATOR (see 6.7); and

g) the ALARM SYSTEM may store the current ALARM SETTINGS for later recall.

EXAMPLE Temporary storage can permit a return to ALARM SETTINGS that were in use prior to choosing an ALARM PRESET.

Compliance is checked by inspection.

6.5.4 DEFAULT ALARM PRESET

6.5.4.1 General requirements

If the DEFAULT ALARM PRESET can be set to values that differ from the MANUFACTURER-configured values:

a) means shall be provided to prevent any OPERATOR from storing changes to the DEFAULT ALARM PRESET. Storing changes to the DEFAULT ALARM PRESET shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7); and

b) means shall be provided to the RESPONSIBLE ORGANIZATION to restore the DEFAULT ALARM PRESET to its MANUFACTURER-configured values.

Compliance is checked by inspection.

6.5.4.2 * Selection of DEFAULT ALARM PRESET

Whenever:

a) the OPERATOR switches the ALARM SYSTEM on after an interval specified by the MANUFACTURER as being longer than might be considered unintentional; or

b) the ALARM SYSTEM is enabled; or

c) the OPERATOR indicates to the ALARM SYSTEM, preferably through an “admit new PATIENT” function, that a different PATIENT has been connected to the ALARM SYSTEM; or

d) power is restored to the ALARM SYSTEM after it has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) beyond the time that it automatically restores the ALARM SETTINGS (see 6.5.5);

then:

e) the DEFAULT ALARM PRESET shall be automatically selected; or

f) means shall be provided for the OPERATOR to select an ALARM PRESET; or

g) means may be provided for the OPERATOR to select the retained ALARM SETTINGS from the previous use.

NOTE Care is needed to ensure that the OPERATOR is aware of which previously retained ALARM SETTINGS are being restored when the OPERATOR selects the retained ALARM SETTINGS.

The MANUFACTURER shall disclose in the instructions for use an estimate of the duration of the power interruption after which the ALARM SYSTEM is unable to restore the ALARM SETTINGS and the subsequent behaviour of the ALARM SYSTEM.

Compliance is checked by observing the equipment’s ALARM SETTINGS, then temporarily disconnecting the power for a period exceeding that indicated in the instructions for use and then inspecting the state of the ALARM SETTINGS. The mains switch, if provided, shall remain in the ‘on’ position during this test. Inspect the ALARM SETTINGS and compare them to the appropriate behaviour.

6.5.5 * Interruptions of less than or equal to 30 s

When power is lost for less than or equal to 30 s, the ALARM SETTINGS prior to the power loss shall be restored automatically. This behaviour shall be described in the instructions for use.

NOTE Power refers to external SUPPLY MAINS, any INTERNAL ELECTRICAL POWER SOURCE exchangeable in NORMAL USE, or external batteries.

Compliance is checked by observing the ALARM SYSTEM'S operating mode and ALARM LIMIT(S), then temporarily disconnecting the power for 30 s – 3 s + 0 s. Then after power is restored, compare the ALARM SETTINGS with those preceding the disconnection. The mains switch, if provided, shall remain in the "on" position during this test.

6.6 ALARM LIMIT

6.6.1 General requirements

An ALARM LIMIT may be non-adjustable, a simple OPERATOR-adjustable setpoint or an algorithmically determined criterion.

Compliance is checked by inspection.

6.6.2 * Adjustable ALARM LIMIT

6.6.2.1 Indication of OPERATOR-adjustable ALARM LIMIT

If an OPERATOR-adjustable ALARM LIMIT is provided, the ALARM LIMIT shall be indicated continuously or by OPERATOR action. The means of control to display the ALARM LIMITS may be visually indicated (marked) with symbol IEC 60417-5649 (2002-10) (see symbol 10 of Table C.1), IEC 60417-5650 (2002-10) (see symbol 11 of Table C.1) or IEC 60417-5651 (2002-10) (see symbol 12 of Table C.1), as appropriate.

Compliance is checked by inspection.

6.6.2.2 * Indication of automatically set ALARM LIMIT

An ALARM LIMIT may be automatically set, with or without OPERATOR action, to ranges or percentages above or below:

a) the value of a monitored variable at a point in time; or

b) recent values of a monitored variable; or

c) a current control setting.

If such an automatically set ALARM LIMIT is provided, its value shall be indicated continuously or by OPERATOR action, unless:

d) this ALARM LIMIT is obvious from the associated control setting and the behaviour is described in the instructions for use; or

e) the ALARM LIMIT is determined by an INTELLIGENT ALARM SYSTEM (see 6.2).

Compliance is checked by functional testing and inspection of the instructions for use.

6.6.2.3 * ALARM SYSTEM operation during adjustment of ALARM LIMIT or ALARM PRESET

During adjustment of any ALARM LIMIT or OPERATOR-adjustable ALARM PRESET, the ALARM SYSTEM shall continue to operate normally.

Compliance is checked by functional testing.

6.7 * ALARM SYSTEM security

Means of restricting access to changing or to the storage of changes shall be described in the technical description (see 6.3.3.1, 6.3.3.3, 6.5.3.1, 6.5.3.2, 6.5.4.1, 6.8.2 b) and c), 6.8.3 b), 6.8.5, 6.10, 6.11.2.2.1 and 6.12.3):

EXAMPLE 1 Access controlled by a tool.

EXAMPLE 2 Access controlled by RESPONSIBLE ORGANIZATION password and a technical description that is separate from the instructions for use.

EXAMPLE 3 Access controlled by individual OPERATOR password.

NOTE 1 For a password to be considered secure, the owner of the password needs to be capable of changing the password.

EXAMPLE 4 Access controlled by voice recognition.

EXAMPLE 5 Access controlled by fingerprints.

NOTE 2 Multiple means of restriction can be needed, e.g., one for the RESPONSIBLE ORGANIZATION and one for each OPERATOR.

Compliance is checked by inspection of the technical documentation.

6.8 * ALARM SIGNAL inactivation states

6.8.1 * General

Means shall be provided for the OPERATOR to inactivate the auditory, or the visual and auditory, generation of ALARM SIGNALS. Means may be provided to inactivate the generation of other ALARM SIGNALS. Inactivation may apply to an individual ALARM CONDITION, to a group of ALARM CONDITIONS, to the entire ALARM SYSTEM or to any part of a DISTRIBUTED ALARM SYSTEM. The inactivation of the generation of ALARM SIGNALS may be indefinite (i.e., ALARM OFF, AUDIO OFF) or indeterminate (indefinite ACKNOWLEDGED) or timed (i.e., ALARM PAUSED, AUDIO PAUSED or timed ACKNOWLEDGED).

Means shall be provided for the OPERATOR to determine the ALARM CONDITIONS for which ALARM SIGNALS are inactivated.

NOTE 1 A group can be predetermined or not.

EXAMPLE 1 All ventilation ALARM CONDITIONS.

EXAMPLE 2 An ALARM SYSTEM that has not received valid data since it was enabled (e.g. after power-up or before a PATIENT has been connected).

NOTE 2 Additional requirements regarding global ALARM OFF or AUDIO OFF are found in 6.8.3.

If ALARM SIGNAL inactivation applies to an individual ALARM CONDITION or a group of ALARM CONDITIONS, the generation of ALARM SIGNALS from other ALARM CONDITIONS shall be unaffected.

During the ALARM OFF or ALARM PAUSED ALARM SIGNAL inactivation states, the ALARM SYSTEM may discontinue the processing of signals used to generate the inactivated ALARM CONDITIONS.

NOTE 3 If the ALARM SYSTEM discontinues the processing of a signal used to generate an ALARM CONDITION, the ALARM SYSTEM log cannot log that ALARM CONDITION.

AUDIO PAUSED or AUDIO OFF shall not inactivate the 1 m visual ALARM SIGNALS specified in 6.3.2.2.2.

AUDIO PAUSED or AUDIO OFF may inactivate some or all of the 4 m visual ALARM SIGNALS specified in 6.3.2.2.1 or may cause DE-ESCALATION of the ALARM CONDITION priority.

NOTE 4 An INTELLIGENT ALARM SYSTEM can use the OPERATOR'S activation of AUDIO PAUSED or AUDIO OFF to cause DE-ESCALATION or to re-evaluate the need for an ALARM CONDITION.

ACKNOWLEDGED, if provided, shall inactivate the auditory ALARM SIGNALS of currently active ALARM CONDITIONS and shall not affect the ALARM SIGNALS of inactive ALARM CONDITIONS.

ACKNOWLEDGED shall terminate automatically, ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists. See also 6.8.4.

A timed ACKNOWLEDGED shall terminate after a defined duration. An indefinite ACKNOWLEDGED shall not terminate after a defined duration.

ACKNOWLEDGED shall not inactivate the 1 m visual ALARM SIGNALS specified in 6.3.2.2.2.

ACKNOWLEDGED may inactivate some or all of the 4 m visual ALARM SIGNALS specified in 6.3.2.2.1.

ACKNOWLEDGED may cause the DE-ESCALATION of the ALARM CONDITION priority, including DE-ESCALATION of the ALARM SIGNALS of a LOW PRIORITY ALARM CONDITION into an INFORMATION SIGNAL.

Compliance is checked by inspection and functional testing.

6.8.2 * REMINDER SIGNALS

The ALARM SYSTEM may be provided with a REMINDER SIGNAL. If an ALARM SYSTEM is provided with a REMINDER SIGNAL:

a) the nature of the REMINDER SIGNAL and the intervals between REMINDER SIGNALS shall be disclosed in the instructions for use;

b) the ALARM SYSTEM shall include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7):
   - to enable and disable the REMINDER SIGNAL; and
   - to configure the maximum REMINDER SIGNAL interval, if adjustment is provided.

c) the ALARM SYSTEM may include a means, accessible only to the RESPONSIBLE ORGANIZATION (see 6.7):
   - to permit designated (see 6.7) OPERATORS to enable and disable the REMINDER SIGNAL;
   - to permit any OPERATOR to enable and disable the REMINDER SIGNAL.

Compliance is checked by inspection.

6.8.3 * Global indefinite ALARM SIGNAL inactivation states

If deemed acceptable by RISK ASSESSMENT with regard to the intended environment of use of the ALARM SYSTEM, a global ALARM OFF or AUDIO OFF may be provided. If an ALARM SYSTEM is provided with a global ALARM OFF or AUDIO OFF, the ALARM SYSTEM shall be provided with:

a) a REMINDER SIGNAL; and

b) means to configure (enable or disable) any global ALARM OFF or AUDIO OFF. Such means shall be restricted to the RESPONSIBLE ORGANIZATION and shall prevent the clinical OPERATOR from changing the configuration in NORMAL USE (see 6.7).

NOTE 1 For the purposes of this standard, a global ALARM OFF or AUDIO OFF ALARM SIGNAL inactivation state can affect all ALARM CONDITIONS or all PHYSIOLOGICAL ALARM CONDITIONS in an ALARM SYSTEM.

NOTE 2 See also 6.8.2 for requirements for REMINDER SIGNALS.

Compliance is checked by inspection.

6.8.4 * Termination of inactivation of ALARM SIGNALS

Means shall be provided for the OPERATOR to terminate any ALARM SIGNAL inactivation state.

An ALARM SIGNAL inactivation state may terminate automatically, ALARM CONDITION by ALARM CONDITION, when the affected ALARM CONDITION no longer exists.

EXAMPLE 1 A non-latching PHYSIOLOGICAL ALARM CONDITION automatically terminates when the monitored parameter returns within its ALARM LIMITS.

EXAMPLE 2 When an ALARM CONDITION has been ACKNOWLEDGED, the resulting state automatically terminates when the underlying ALARM CONDITION no longer exists.

When an ALARM SIGNAL inactivation state is terminated, the ALARM SYSTEM shall re-evaluate the need for ALARM CONDITIONS and generate ALARM SIGNALS if appropriate.

Compliance is checked by functional testing.

6.8.5 * Indication and access

The ALARM SIGNAL inactivation states AUDIO PAUSED, ALARM PAUSED, AUDIO OFF, ALARM OFF and ACKNOWLEDGED shall be visually indicated (marked) with the appropriate symbol referenced in Table 5. This indication shall be perceived correctly (be legible) at a distance of 1 m from the equipment or part of the equipment or from the OPERATOR'S POSITION.

The means of control used to enter one of the ALARM SIGNAL inactivation states may be marked with a symbol referenced in Table 5. If a symbol that is referenced in Table 5 is used, it shall initiate the associated ALARM SIGNAL inactivation state.

The duration of AUDIO PAUSED, ALARM PAUSED or a timed ACKNOWLEDGED, if provided, shall be disclosed in the instructions for use.

If the AUDIO PAUSED, ALARM PAUSED or a timed ACKNOWLEDGED interval is OPERATOR adjustable, means to adjust the maximum interval shall only be provided to the RESPONSIBLE ORGANIZATION (see 6.7) and means may be provided for the OPERATOR to adjust the interval up to the maximum interval.

Compliance is checked by inspection.

Table 5 – ALARM SIGNAL inactivation states

ALARM SIGNAL inactivation state	Usual termination event	Visual indication (marking) of state (mandatory) (row of symbol in Table C.1)	Marking of controls (optional)	
			(row of symbol in Table C.1)	(row of marking in Table C.2)
AUDIO PAUSED	Time interval elapsed	6	6	1
ALARM PAUSED	Time interval elapsed	4 or (4 and 6)	4	2
AUDIO OFF	OPERATOR action	5	5	3
ALARM OFF	OPERATOR action	3 or (3 and 5)	3	4
Indefinite ACKNOWLEDGED	ALARM CONDITION no longer exists	5 or 8 or 14	7 or 13 or 8 or 14	6
Timed ACKNOWLEDGED	ALARM CONDITION no longer exists or time interval elapsed	6 or 9 or 15	7 or 13 or 9 or 15	7

6.9 * ALARM RESET

The means of ALARM RESET may be marked with symbol IEC 60417-5309 (DB-2002-10) (see symbol 2 of Table C.1) or marking 5 of Table C.2.

Compliance is checked by inspection.

6.10 * NON-LATCHING and LATCHING ALARM SIGNALS

A NON-LATCHING ALARM SIGNAL shall automatically cease being generated when its triggering event no longer exists. A LATCHING ALARM SIGNAL shall continue to be generated after its triggering event no longer exists. An ALARM SYSTEM may consist of a mixture of LATCHING ALARM SIGNALS and NON-LATCHING ALARM SIGNALS.

NOTE 1 An INTELLIGENT ALARM SYSTEM can decrease the priority of a LATCHING ALARM SIGNAL.

In the case of an ALARM CONDITION of short duration, a MEDIUM PRIORITY auditory ALARM SIGNAL shall complete at least one full BURST and a HIGH PRIORITY auditory ALARM SIGNAL shall complete one half of one full BURST, unless inactivated by the OPERATOR.

NOTE 2 If the ALARM CONDITION clears quickly, the OPERATOR might be unable to discover what event triggered the ALARM CONDITION. Alternatives include:

– a visual ALARM SIGNAL that indicates the specific ALARM CONDITION and which continues to be generated for a limited period of time (e.g., 30 s) after the ALARM CONDITION has cleared;
– an ALARM CONDITION log that the OPERATOR can view, print, or record;
– an ALARM CONDITION trend that the OPERATOR can view, print, or record.

Auditory ALARM SIGNALS shall cease being generated when:

a) an OPERATOR has initiated the AUDIO PAUSED, AUDIO OFF, ACKNOWLEDGED, ALARM PAUSED or ALARM OFF state; or
b) an OPERATOR has ALARM RESET the ALARM CONDITION.

Means shall be provided to prevent the OPERATORS from selecting between LATCHING and NON-LATCHING ALARM SIGNALS. The selection between LATCHING and NON-LATCHING ALARM SIGNALS shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7).

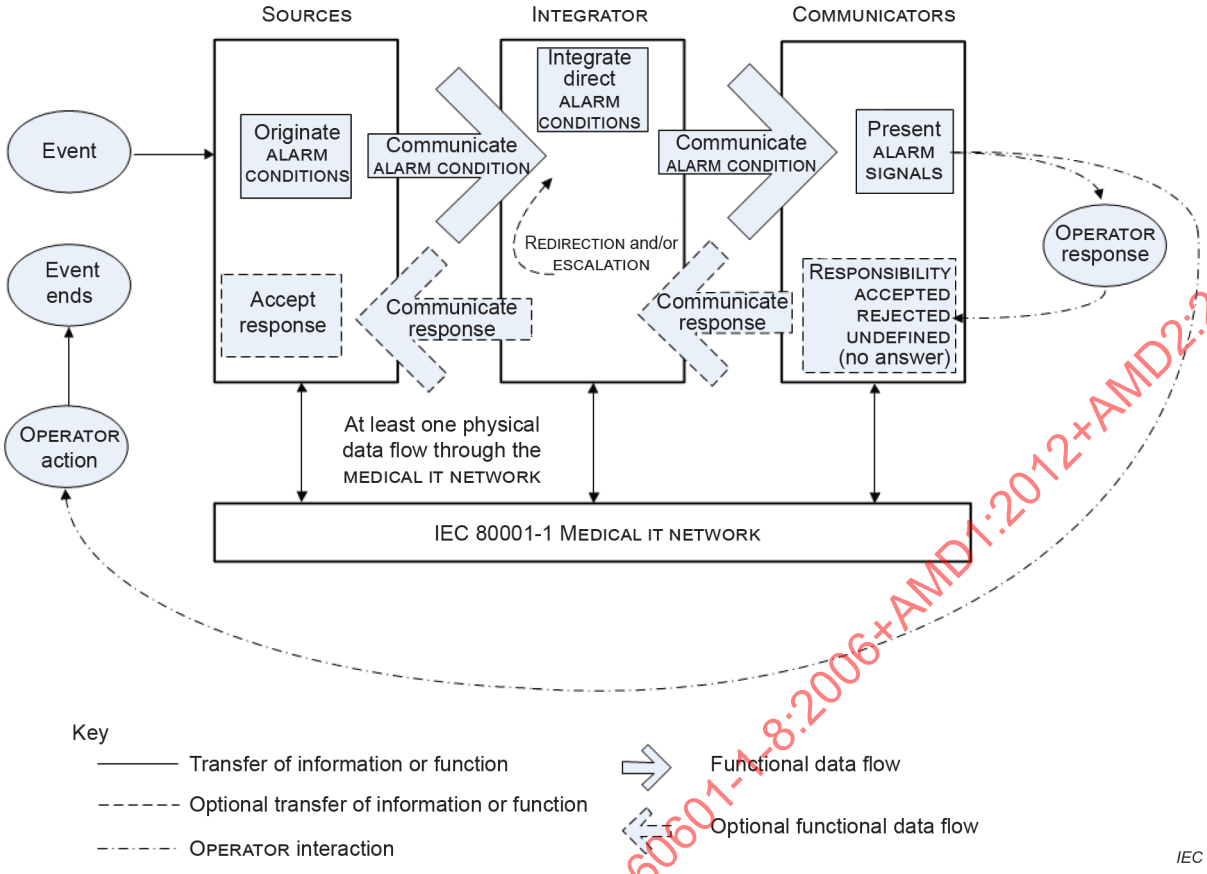
Compliance is checked by functional testing.

6.11 * DISTRIBUTED ALARM SYSTEMS and DISTRIBUTED INFORMATION SYSTEMS ABOUT ALARM CONDITIONS

6.11.1 * Existence of a DIS or DAS

The details necessary for the safe use of a DIS or a DAS shall be disclosed in the technical description. A DIS or a DAS is a permitted form of an ALARM SYSTEM. Figure 2 illustrates the functions of a DISTRIBUTED ALARM SYSTEM utilizing a MEDICAL IT NETWORK.

NOTE Additional information is found in IEC 80001-2-5 [31].



NOTE This is a functional diagram and does not imply that these functions are in separate components. It is possible for functionality to be provided in one or more components.

Figure 2 – Functions of a DISTRIBUTED ALARM SYSTEM utilizing a MEDICAL IT NETWORK

An ALARM SYSTEM is permitted to send or receive data, including the indication of INFORMATION SIGNALS and ALARM CONDITIONS, to or from other parts of a DIS or a DAS. A DIS or a DAS is permitted to be located outside of the PATIENT ENVIRONMENT. Part(s) of a DIS or a DAS are permitted to be located outside of the PATIENT ENVIRONMENT. Data are permitted to be transmitted between different parts of a DIS or a DAS by wire, by telemetry or by other means.

EXAMPLE 1 A central station.

EXAMPLE 2 An electronic record-keeping device.

EXAMPLE 3 Remote viewing from home or office.

EXAMPLE 4 Bed-to-bed viewing of ALARM CONDITIONS (e.g. one nurse for two beds).

EXAMPLE 5 Transmission of ALARM CONDITIONS to pagers, cell phones, hand-held computers, etc.

Compliance is checked by inspection of the technical description.

6.11.2 Requirements for communication of ALARM CONDITIONS

6.11.2.1 SOURCE and identification of ALARM CONDITIONS

In a DAS or DIS, means shall be provided to identify the SOURCE of the ALARM CONDITION at every COMMUNICATOR that generates ALARM SIGNALS for that ALARM CONDITION.

ALARM SIGNALS that indicate the urgency of the response required, categorization of the cause of the ALARM CONDITION and identification of the PATIENT, equipment or PATIENT's location should also be generated by the DISTRIBUTED ALARM SYSTEM.

Compliance is checked by inspection.

6.11.2.2 * Failure of remote communication of ALARM CONDITIONS

6.11.2.2.1 * DAS or CDAS

A DAS or CDAS shall be so designed that a communications failure or failure in any remote component of the DAS or CDAS:

a) shall not adversely affect any part of the DAS or CDAS other than the loss of the distributed functionality; and

b) shall initiate a TECHNICAL ALARM CONDITION for all relevant COMMUNICATORS of the DAS or CDAS.

1) The ALARM SYSTEM should provide a means for the OPERATOR to inactivate any auditory ALARM SIGNALS of this TECHNICAL ALARM CONDITION.

MANUFACTURERS should take care in the design of ME EQUIPMENT to ensure that it reverts to a safe mode of operation, which can include ESCALATION of the volume of auditory ALARM SIGNALS or utilization of a redundant communication pathway.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.2.2 * DIS

A DIS shall be so designed that a communications failure or failure in any remote component of the DIS:

a) shall not adversely affect any part of the DIS other than the loss of the distributed functionality; and

b) any remote COMMUNICATOR of a DIS that cannot comply with 6.11.2.2.1 shall be marked with a warning to the effect that it shall not be relied upon for receipt of ALARM SIGNALS.

EXAMPLE A one-way paging system requires such a warning.

NOTE Inability to successfully send or receive ALARM CONDITIONS or INFORMATION SIGNALS is considered a failure.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.2.3 * SOURCE with a global AUDIO OFF in a DISTRIBUTED ALARM SYSTEM

If there is a communications failure between a SOURCE with a global AUDIO OFF and the DISTRIBUTED ALARM SYSTEM, the affected SOURCE shall terminate the global AUDIO OFF state, if active.

If the OPERATOR subsequently activates AUDIO OFF or a global AUDIO OFF in the SOURCE, continuing failure of the link need not cause additional auditory ALARM SIGNALS.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.3 * Remote ALARM SYSTEM controls

A DAS or CDAS may provide remote OPERATOR access to some or all ALARM SYSTEM controls. If provided:

a) the ALARM SYSTEM shall provide a means for the RESPONSIBLE ORGANIZATION to restrict remote OPERATOR access to the available remote controls; and

b) such means shall be restricted to the RESPONSIBLE ORGANIZATION, preventing the clinical OPERATOR from changing the configuration (see 6.7).

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.11.2.4 * CDAS

In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION shall have means to create the OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) and transfer them to the INTEGRATOR.

a) In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION and initiates an OPERATOR response (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) shall indicate the OPERATOR response state (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED).

The means of control used to initiate an OPERATOR response or indication of state may be marked with:

b) symbol ISO 7000-6334A (2015-06) (see Symbol 13 of Table C.1) for RESPONSIBILITY ACCEPTED; or

c) symbol ISO 7000-6335A (2015-06) (see Symbol 16 of Table C.1) for RESPONSIBILITY REJECTED.

Means shall be provided for the OPERATOR to terminate RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED while the related ALARM CONDITION is active. Initiating RESPONSIBILITY REJECTED may be used to terminate RESPONSIBILITY ACCEPTED. Initiating RESPONSIBILITY ACCEPTED may be used to terminate RESPONSIBILITY REJECTED.

In a CDAS, RESPONSIBILITY ACCEPTED may initiate an ALARM SIGNAL inactivation state.

NOTE RESPONSIBILITY ACCEPTED is a different function than an ALARM SIGNAL inactivation state.

In a CDAS, the INTEGRATOR shall have means to accept OPERATOR responses from the COMMUNICATOR.

In a CDAS, the SOURCE may receive OPERATOR responses from the INTEGRATOR.

Compliance is checked by functional testing and inspection of the ALARM SYSTEM.

6.12 * ALARM SYSTEM logging

6.12.1 General

An ALARM SYSTEM may be equipped with an OPERATOR ALARM SYSTEM log or a RESPONSIBLE ORGANIZATION ALARM SYSTEM log.

An OPERATOR ALARM SYSTEM log is intended to be utilized while the ALARM SYSTEM is being used for a PATIENT. A RESPONSIBLE ORGANIZATION ALARM SYSTEM log is intended to be utilized after PATIENT use has been concluded.

An OPERATOR ALARM SYSTEM log is typically a subset of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log.

6.12.2 * OPERATOR ALARM SYSTEM logging

If an ALARM SYSTEM is provided with an OPERATOR ALARM SYSTEM log:

a) the ALARM SYSTEM should log every ALARM CONDITION, including the date and time of beginning and end as well as the associated ALARM LIMITS for that ALARM CONDITION, if OPERATOR-adjustable and, where feasible, the data that caused the ALARM CONDITION;

EXAMPLE 1 The downstream infusion pressure ALARM CONDITION is logged with start time and date, end time (date stamp), pressure ALARM LIMIT, the pressure value and auditory ALARM SIGNAL volume setting.

b) the ALARM SYSTEM shall log the occurrence and identity of all HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITIONS;

c) for each logged ALARM CONDITION, the ALARM SYSTEM shall log:

– the date and time of the occurrence, or

– the elapsed time since the occurrence of the ALARM CONDITION, or

– the elapsed time of the occurrence from the start of use of the ME EQUIPMENT;

d) the ALARM SYSTEM should log the occurrence and identity of all ALARM SIGNAL inactivation states and, for a CDAS, OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED);

1) for each logged ALARM SIGNAL inactivation state, the ALARM SYSTEM shall log:

– the date and time of the occurrence, or

– the elapsed time since the occurrence of the ALARM CONDITION or ALARM SIGNAL inactivation state, or

– the elapsed time of the occurrence from the start of use of the ME EQUIPMENT;

e) if a means is provided for the OPERATOR to indicate to the ALARM SYSTEM that a different PATIENT has been connected, then that event should be logged in the OPERATOR ALARM SYSTEM log;

f) means may be provided for the logging of changes to the OPERATOR-adjustable ALARM SETTINGS in the OPERATOR ALARM SYSTEM log;

g) means may be provided for the OPERATOR to add explanatory notes or comments to the OPERATOR ALARM SYSTEM log, and if provided:

– means should be provided to record the identity of the annotator and the date and time of the annotation;

h) means shall not be provided for the OPERATOR to edit or delete entries in the OPERATOR ALARM SYSTEM log, unless a new PATIENT is admitted or a RESPONSIBLE ORGANIZATION ALARM SYSTEM log is provided;

i) the log may be provided either within the equipment or remotely through a communications interface; and

j) the instructions for use shall indicate:

1) the means for the OPERATOR to access the OPERATOR ALARM SYSTEM log,

2) whether the log is maintained when the ALARM SYSTEM is powered down and whether or not the time of powering down is captured in the log,

3) what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration,

4) the capacity of the log, and

5) what happens to the contents of the log as it reaches capacity.

EXAMPLE 2 The ALARM SYSTEM discards the oldest data when the log becomes full.

Compliance is checked by inspection.

6.12.3 * RESPONSIBLE ORGANIZATION ALARM SYSTEM logging

If an ALARM SYSTEM is provided with a RESPONSIBLE ORGANIZATION ALARM SYSTEM log:

a) viewing the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall be restricted to the RESPONSIBLE ORGANIZATION (see 6.7);

b) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall contain all of the information contained in the OPERATOR ALARM SYSTEM log;

c) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall contain the ALARM SETTINGS and each change of those settings;

EXAMPLE 1 The name of the ALARM PRESET in use and any changes made to it.

d) means shall not be provided for the OPERATOR or RESPONSIBLE ORGANIZATION to edit or delete entries in the RESPONSIBLE ORGANIZATION ALARM SYSTEM log;

e) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log shall be retained when the ALARM SYSTEM is powered down;

f) the instructions for use shall indicate what happens to the contents of the log after the ALARM SYSTEM has experienced a total loss of power (SUPPLY MAINS and/or INTERNAL ELECTRICAL POWER SOURCE) for a finite duration;

g) the instructions for use shall indicate:

   2) the RESPONSIBLE ORGANIZATION ALARM SYSTEM log capacity, and

   3) what happens to the contents of the RESPONSIBLE ORGANIZATION ALARM SYSTEM log as it reaches capacity;

   EXAMPLE 2 The ALARM SYSTEM discards the oldest data when the log becomes full.

h) the ALARM SYSTEM should log TECHNICAL ALARM CONDITIONS for servicing and maintenance purposes. This log should not be resettable or editable by OPERATOR action; and

i) the log may be provided either within the equipment or remotely through a communications interface.

Compliance is checked by inspection.

6.13 ALARM SYSTEM functions

6.13.1 General

An ALARM SYSTEM shall have at least one:

a) SOURCE;

b) INTEGRATOR; and

c) COMMUNICATOR.

Figure 3 illustrates the functions of an ALARM SYSTEM of ME EQUIPMENT.

Compliance is checked with the tests of 6.3.1.

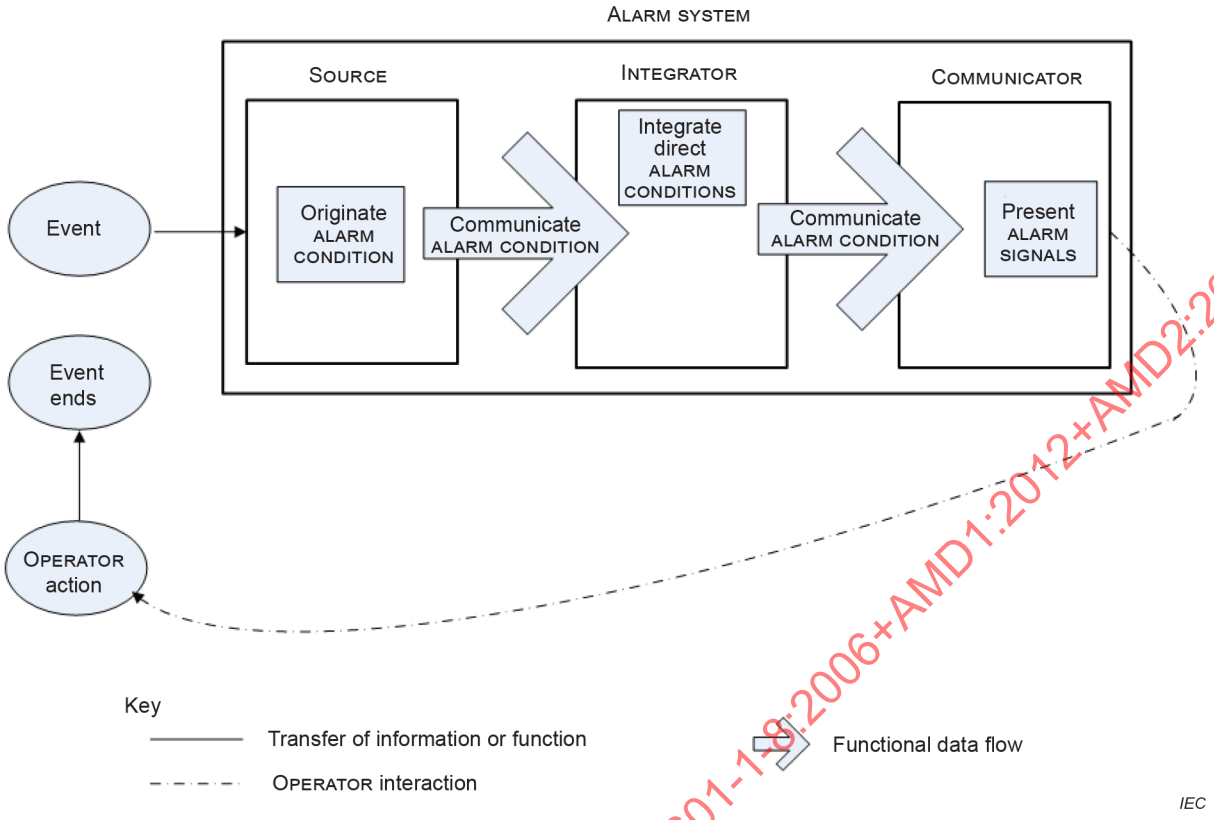


Figure 3 – Functions of an ALARM SYSTEM

6.13.2 SOURCE (SRC)

An ME EQUIPMENT, a DIS or a DAS may have more than one SOURCE.

An ALARM CONDITION shall only originate from a SOURCE.

A SOURCE may receive an indication of RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED or RESPONSIBILITY UNDEFINED originating at a COMMUNICATOR (from an OPERATOR) that was transferred from an INTEGRATOR.

Compliance is checked by inspection.

6.13.3 INTEGRATOR (INT)

An INTEGRATOR shall map SOURCES and their ALARM CONDITIONS to one or more specific COMMUNICATORS.

An INTEGRATOR may receive an indication of RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED or RESPONSIBILITY UNDEFINED originating at a COMMUNICATOR (from an OPERATOR) and may transfer it to a SOURCE.

An INTEGRATOR may provide REDIRECTION to additional or different COMMUNICATORS based on the response or lack of response from COMMUNICATORS. The MANUFACTURER should consider a means for the RESPONSIBLE ORGANIZATION to manage the REDIRECTION to assure an appropriate OPERATOR response.

An INTEGRATOR may:

a) contain a SOURCE that performs the functions of an INTELLIGENT ALARM SYSTEM (see 6.2);

EXAMPLE 1 Removing redundant ALARM CONDITIONS.

EXAMPLE 2 Creating an ALARM CONDITION from multiple inputs.

EXAMPLE 3 Suppressing superfluous ALARM SIGNALS.

b) generate the RESPONSIBILITY UNDEFINED state;

c) generate an ALARM SIGNAL inactivation state.

The ME EQUIPMENT, a DIS or a DAS may have more than one INTEGRATOR.

Compliance is checked by inspection.

6.13.4 COMMUNICATOR (COM)

A COMMUNICATOR receives ALARM CONDITIONS from one or more INTEGRATORS. A COMMUNICATOR may also PROCESS or direct an OPERATOR response (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) to the INTEGRATOR.

An OPERATOR response need not be limited to direct OPERATOR action and can be achieved by other means (e.g. an OPERATOR locator system).

If OPERATOR response is achieved by other means than direct OPERATOR action, the ALARM SYSTEM shall provide means to indicate to the corresponding OPERATOR that RESPONSIBILITY ACCEPTED is active for the affected COMMUNICATOR.

An ME EQUIPMENT, a DIS or a DAS may have more than one COMMUNICATOR.

Annex A
(informative)

General guidance and rationale

A.1 General guidance

A.1.1 Overview

This annex provides a rationale for the important requirements of this collateral standard. Its purpose is to promote effective application of the standard by explaining the reasons for the requirements, providing examples of how they address certain alarm-related HAZARDS and providing additional guidance where appropriate.

From the standpoint of PATIENT safety, ALARM SYSTEMS can be hazardous for PATIENTS or OPERATORS if they fail to effectively warn of potential or actual HAZARDS, cause inappropriate responses, reduce vigilance or interfere with the performance of the OPERATOR, RESPONSIBLE ORGANIZATION, or other persons.

In addition, in this annex text in italics indicates guidance that describes means to achieve the safety objectives of this collateral standard.

A.1.2 ALARM SYSTEMS

As part of the RISK MANAGEMENT PROCESS, the MANUFACTURER identifies RISK CONTROL measure(s) that are appropriate for reducing the RISK(S) to an acceptable level.

RISK CONTROL consists of an integrated approach in which the MANUFACTURER uses one or more of the following in the priority order listed.

a) inherent safety by design;

b) protective measures in the equipment;

c) information for safety, e.g., warnings and instructions for use, values of monitored variables.

ALARM SYSTEMS as described in this collateral standard, address b) and c) above by communicating information that requires a response or awareness by the OPERATOR. The following general principles apply.

d) The ALARM SYSTEM should result in a greater probability that the OPERATOR will correctly detect and appropriately respond to the condition that requires their awareness or action than would be the case in the absence of the ALARM SIGNALS.

NOTE 1 Causing too many ALARM SIGNALS from FALSE POSITIVE ALARM CONDITIONS can cause ALARM FATIGUE, which can reduce the effectiveness of an ALARM SYSTEM [73], [74], [75].

NOTE 2 ALARM FLOOD can lead to ALARM FATIGUE, which can reduce the effectiveness of an ALARM SYSTEM [56], [57].

e) ALARM SIGNALS should indicate the onset and continuing presence of an ALARM CONDITION.

f) ALARM CONDITIONS should be prioritized based on the urgency of the required OPERATOR response (or awareness).

g) ALARM SIGNALS should be CLINICALLY ACTIONABLE and help the OPERATOR:

- determine the urgency of the response required;
- locate the room or part of the room where a response or awareness is required;
- locate the specific PATIENT or equipment where a response or awareness is required;

– determine or categorize the cause of the ALARM CONDITION; and

– determine or categorize the nature of the response or awareness that is required.

h) The algorithms and ALARM SETTINGS that determine ALARM CONDITIONS should be designed to minimize the number of FALSE NEGATIVE, FALSE POSITIVE and CLINICALLY NONACTIONABLE ALARM CONDITIONS. FALSE NEGATIVE, FALSE POSITIVE and CLINICALLY NONACTIONABLE ALARM CONDITIONS are potentially hazardous. Too many TRUE POSITIVE ALARM CONDITIONS but CLINICALLY NONACTIONABLE ALARM SIGNALS can result in inappropriate OPERATOR action or reduce vigilance. TRUE POSITIVE ALARM CONDITIONS that are CLINICALLY NONACTIONABLE lead to ALARM FATIGUE. Algorithms and ALARM SETTINGS that determine ALARM CONDITIONS should be carefully optimized to provide, on balance, an overall benefit to PATIENT care [55], [58].

i) ALARM SYSTEMS that are continuously attended by an OPERATOR in NORMAL USE should have different characteristics from ALARM SYSTEMS that are unattended by the OPERATOR in NORMAL USE.

j) The design of an ALARM SYSTEM should be based on the TRAINING and skill of the OPERATOR who is intended to use it.

k) The ALARM SYSTEM should reflect the problems and needs of the intended environment of use.

l) ALARM SIGNALS should not be excessively intrusive or degrade the performance of the OPERATOR.

A.1.3 Algorithm quality and performance

ALARM SYSTEM algorithms should aim at approaching 100 % sensitivity and 100 % specificity. [7],[8],[9],[10] The leading reason for disabling ALARM SIGNALS is the large number of ALARM SIGNALS associated with FALSE POSITIVE ALARM CONDITIONS, CLINICALLY NONACTIONABLE ALARM CONDITIONS or nuisance ALARM CONDITIONS. CLINICALLY NONACTIONABLE ALARM CONDITIONS are TRUE POSITIVE ALARM CONDITIONS that are unhelpful because they indicate states that the OPERATOR is already aware of or does not need to know about [11], [29]. They commonly occur when the ALARM LIMITS have been set inappropriately close to an acceptable value but also occur when multiple redundant ALARM CONDITIONS occur in response to a single underlying problem. Often, ALARM SIGNALS are more confusing than enlightening. Many OPERATORS respond to ALARM SIGNALS by disabling the ALARM SYSTEM or by adjusting an ALARM LIMIT to such an extreme value that the ALARM SYSTEM is effectively disabled. [12]

Where practical, MANUFACTURERS or writers of particular standards are encouraged to utilize standardized physiological databases to validate the algorithms used to determine ALARM CONDITIONS. Determining and reporting the FALSE POSITIVE, FALSE NEGATIVE, TRUE POSITIVE and TRUE NEGATIVE ALARM CONDITION accuracy in a standardized format allows OPERATORS and RESPONSIBLE ORGANIZATIONS to understand the performance of equipment.

EXAMPLE ANSI/AAMI EC57:1998, *Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms.[5]*

Other techniques to reduce the number of FALSE POSITIVE and FALSE NEGATIVE ALARM CONDITIONS include:

a) marking the ALARM SYSTEM with symbol ISO 7000-0435 when an algorithm cannot classify or resolve the available data; or

b) using an ALARM CONDITION DELAY to delay the generation ALARM SIGNALS for an ALARM CONDITION to ensure that it remains valid.

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this collateral standard, with clause and subclause numbers parallel to those in the body of the document.

Clause 1 – Scope, object and related standards

This collateral standard provides the general requirements for the implementation of ALARM SYSTEMS in ME EQUIPMENT and ME SYSTEMS to provide information necessary for the safety of PATIENTS, OPERATORS and others involved with PATIENT care. As the urgency of the OPERATOR'S attention is dependent on the cause of the ALARM CONDITION, this collateral standard specifies ALARM CONDITION priorities and their ALARM SIGNAL characteristics so that the OPERATOR can perceive the urgency of the situation and the necessary action independent of the type, brand, etc. of the ME EQUIPMENT that is generating ALARM SIGNALS. [13], [14], [15], [16] In addition, a standardized unambiguous ALARM SYSTEM vocabulary is presented as a means to improve PATIENT safety that will be used in ME EQUIPMENT and ME SYSTEM design and markings as well as in the ACCOMPANYING DOCUMENTS.

Because this standard applies equally to simple INTERNAL ELECTRICAL POWER SOURCE operated or home-care ME EQUIPMENT as well as complex ME EQUIPMENT or ME SYSTEMS that include at least one function intended actively to keep alive or resuscitate a PATIENT, it has not been possible to provide specific requirements for many important issues. Particular standards should provide, as appropriate, more detailed requirements for their equipment category. The nomenclature and basic requirements of this standard should ensure a consistent approach for ALARM SYSTEMS across a wide range of equipment types.

Definition 3.1 – ALARM CONDITION

One consideration was the fact that an ALARM SYSTEM might generate ALARM SIGNALS for an ALARM CONDITION when no valid ALARM CONDITION existed (i.e. a FALSE POSITIVE ALARM CONDITION). A second was the issue that non-numerical values or conditions, or the use of an INTELLIGENT ALARM SYSTEM, might be used to determine the presence of an ALARM CONDITION, yet these factors might not have been included in previous definitions of ALARM LIMIT.

On this basis, the committee defined ALARM CONDITION as: “state of the ALARM SYSTEM when it has determined that a potential or actual HAZARD exists.” This definition recognizes that the ALARM SYSTEM can be correct or incorrect in its determination. It also indicates that this state will cause the ALARM SYSTEM, if it is enabled, to generate ALARM SIGNALS for the ALARM CONDITION to bring about OPERATOR response or awareness.

The committee then defined ALARM LIMIT as: “threshold used by an ALARM SYSTEM to determine an ALARM CONDITION.” The obvious example would be a numerical threshold (such as a threshold for a high heart rate ALARM CONDITION), but some thresholds might be non-numerical. Non-numerical conditions, such as a switch in the incorrect position, failure of the OPERATOR to enter certain data or the failure of the ALARM SYSTEM, can also cause an ALARM CONDITION. Furthermore, an INTELLIGENT ALARM SYSTEM can be used to determine an ALARM CONDITION, using an algorithm rather than a simple threshold value. Such an algorithm may have multiple inputs, perform logic-based or time-dependent averaging, use intelligent artefact filtering or employ other techniques so that the actual threshold changes over time or in response to other circumstances.

Definition 3.2 – ALARM CONDITION DELAY

Filtering in the algorithm that is monitoring for an ALARM CONDITION often causes ALARM CONDITION DELAY. For instance, a heart rate monitor can average the R-R interval for several heartbeats. An abrupt change in R-R interval will not immediately cause a heart rate ALARM CONDITION because it will take several consecutive heartbeats for the calculated heart rate to exceed the ALARM LIMIT. Similarly, a median filter will cause an ALARM CONDITION DELAY. See also the rationale for Subclause 6.10.

Definition 3.3 – ALARM LIMIT

ALARM LIMIT refers to the criteria that cause the ALARM SYSTEM to generate ALARM SIGNALS. For a simple variable with a single level of urgency, a value selected by the OPERATOR can

constitute the ALARM LIMIT. ALARM LIMIT can also refer to algorithmically determined criteria, the exact nature of which the OPERATOR cannot be aware, as well as the criteria structure applicable to a simple ALARM CONDITION variable for which there are multiple urgencies. See also the rationale for Definition 3.1.

Definition 3.5 – ALARM PAUSED

An OPERATOR can use ALARM PAUSED to avoid generation of NUISANCE ALARM SIGNALS before performing an action that is known to likely cause an ALARM CONDITION.

EXAMPLE 1 Intentional disconnection of a PATIENT breathing circuit to perform suction of the trachea.

EXAMPLE 2 Opening a transducer to air for zero calibration.

Definition 3.10 – ALARM SIGNAL GENERATION DELAY

Operating systems, microprocessor speed, software or network performance can influence the time between the onset of the ALARM CONDITION and generation of ALARM SIGNALS. If the delay is significant, the OPERATOR needs to know not only the mean time but also the distribution of times of the ALARM SIGNAL GENERATION DELAY, since with modern equipment it cannot always be possible to determine the absolute maximum time. If equipment is provided with a DISTRIBUTED ALARM SYSTEM, this duration should be for a typical set-up in its intended area of use. Problems that can be beyond the control of the MANUFACTURER include the speed and throughput of the network components. See also the rationale for Definition 3.2.

Definition 3.17 – DISTRIBUTED ALARM SYSTEM

In simple equipment, the SOURCE, INTEGRATOR and COMMUNICATOR are all within that single piece of equipment. Typical examples would be a stand-alone PATIENT monitor or a stand-alone ventilator.

In networked equipment, in a system with a central station, or with COMMUNICATORS for caregivers (OPERATORS) at some distance from the PATIENT, more complicated ALARM SYSTEMS are used.

In a DISTRIBUTED ALARM SYSTEM, one of the following functions is located in a different part of the ME SYSTEM:

a) the SOURCE;

b) the INTEGRATOR; or

c) the COMMUNICATOR.

A DISTRIBUTED ALARM SYSTEM typically comprises at least two devices:

d) a SOURCE and INTEGRATOR (and likely a COMMUNICATOR) that is generally connected directly to the PATIENT, and

e) a remote COMMUNICATOR (part of an ME SYSTEM) that might or might not be in the vicinity of the PATIENT.

Thus, in a network of bedside PATIENT monitors, one bedside PATIENT monitor can act as a COMMUNICATOR for ALARM CONDITIONS from a different bedside PATIENT monitor. A central station can act as a COMMUNICATOR for ALARM CONDITIONS from multiple PATIENTS. A two-way wireless communication system can act as a COMMUNICATOR for ALARM CONDITIONS to a caregiver in an area far removed from the PATIENT. All these are examples of DISTRIBUTED ALARM SYSTEMS.

A central station that processes incoming signals from multiple PATIENTS and as a SOURCE passes ALARM CONDITIONS back to bedside ME EQUIPMENT to act as a COMMUNICATOR is a DISTRIBUTED ALARM SYSTEM.

Definition 3.23 – INFORMATION SIGNAL

ALARM SIGNALS are only generated because of the presence of ALARM CONDITIONS. In contrast, INFORMATION SIGNALS are those which are generated regardless of whether or not an ALARM CONDITION is present, e.g. the tone of the pulse oximeter, the tone of the electrocardiograph, the waveform of the electrocardiograph, the heart rate numeric. INFORMATION SIGNALS are independent of ALARM CONDITIONS, although INFORMATION SIGNALS can frequently convey information that is "alarming" to the OPERATOR.

EXAMPLE 1 The decreasing tonal frequency of the auditory INFORMATION SIGNAL of some pulse oximeters. The decreased tone is "alarming" to the OPERATOR, but in itself is not an ALARM SIGNAL.

EXAMPLE 2 An electrocardiograph waveform indicating ventricular fibrillation.

EXAMPLE 3 A heart rate of 20 beats per minute.

Definition 3.24 – INTELLIGENT ALARM SYSTEM

An INTELLIGENT ALARM SYSTEM can use one or more variables or patterns of a variable or variables to make decisions that determine the presence or absence of an ALARM CONDITION and its priority. INTELLIGENT ALARM SYSTEM methodologies can include but are not restricted to analysis of trends, limit comparisons, data redundancy, data fusion, rules, fuzzy logic controllers and neural networks. INTELLIGENT ALARM SYSTEMS are also known as smart ALARM SYSTEMS.

Definition 3.34 – REMINDER SIGNAL (see also the rationale for 6.8.1)

A REMINDER SIGNAL reminds an OPERATOR that an ALARM CONDITION still exists although an ALARM SIGNAL is not being generated because it has been previously inactivated by an ALARM SIGNAL inactivation state. Appropriate application of REMINDER SIGNALS should reduce the chance that the ALARM SYSTEM is unintentionally left in an ALARM SIGNAL inactivation state, thereby reducing the incidence of FALSE NEGATIVE ALARM CONDITIONS, without unreasonably increasing the chance that the REMINDER SIGNAL will itself be a nuisance signal.

A REMINDER SIGNAL should be considered when the equipment is expected to have multiple OPERATORS or when the equipment is expected to be unattended by an OPERATOR in NORMAL USE.

There are two possible modes of operation for a REMINDER SIGNAL. In the first mode, the REMINDER SIGNAL signals periodically when the ALARM SYSTEM is in an ALARM SIGNAL inactivation state, whether or not any ALARM CONDITION is present. In the second mode, the REMINDER SIGNAL signals only when the ALARM SYSTEM is in an ALARM SIGNAL inactivation state and an ALARM CONDITION is present.

The second mode provides the advantage of less signal pollution in the healthcare environment. There is a HAZARD with the second mode, however, if the OPERATOR forgets to enable the COMMUNICATOR at the appropriate time.

An example of this situation is when an intubated and ventilated PATIENT requires suctioning in a critical care unit. In order to perform the suctioning, the ventilator is disconnected from the PATIENT. This would cause several ALARM SIGNALS to be generated. The time to repeatedly suction the PATIENT can take longer than the maximum AUDIO PAUSE interval and the OPERATOR would instead choose the AUDIO OFF state. After the suctioning is finished, the OPERATOR would have no auditory ALARM SIGNAL. In this situation, it might be preferable to have a REMINDER SIGNAL that the ALARM SYSTEM was put into AUDIO OFF state. After suctioning the PATIENT, the OPERATOR would hear the REMINDER SIGNAL and would be reminded to terminate the AUDIO OFF state.

In other settings, however, the second mode might be appropriate.

Depending on the design of the ALARM SYSTEM and the INTENDED USE of the ME EQUIPMENT, REMINDER SIGNALS can be auditory, visual, a combination of both or by another means.

Definition 3.37 – ACKNOWLEDGED

The ALARM SIGNAL inactivation state ACKNOWLEDGED differs significantly from the global AUDIO OFF or AUDIO PAUSE. Therefore using the same indication for either AUDIO OFF or AUDIO PAUSE and for this inactivation state would lead to confusion.

When initiating the state ACKNOWLEDGED, the OPERATOR is explicitly acknowledging the presence of the existing ALARM CONDITIONS while at the same time allowing the ALARM SYSTEM to generate ALARM SIGNALS for all other future ALARM CONDITIONS. Furthermore, the ALARM SYSTEM will self-terminate the ACKNOWLEDGED state for a specific ALARM CONDITION when that ALARM CONDITION is no longer true.

This way the OPERATOR acknowledges the fact that certain ALARM CONDITIONS are present, for which the OPERATOR does not want to receive auditory ALARM SIGNALS any more, but that at the same time the OPERATOR wishes to be alerted to any new ALARM CONDITION that might arise to draw attention to a potentially new situation.

EXAMPLE 1 A TECHNICAL ALARM CONDITION that cannot be resolved at the moment or that arises from an intended OPERATOR action, but that can be ACKNOWLEDGED without suppressing PHYSIOLOGICAL ALARM CONDITIONS from other causes not affected by the TECHNICAL ALARM CONDITION.

EXAMPLE 2 Certain PHYSIOLOGICAL ALARM CONDITIONS (e.g. arrhythmia) that are known to be present can be ACKNOWLEDGED without suppressing other ALARM CONDITIONS from the same physiological source.

EXAMPLE 3 A PATIENT on home oxygen is being monitored with a portable monitor. When the PATIENT gets up and moves to a different room, the oxygen saturation falls with exercise. This fall in oxygen saturation is anticipated and it is expected to last only as long as the exercise itself, and then to recover to normal level within a few minutes. This ALARM CONDITION could be an appropriate use of indefinite ACKNOWLEDGED.

In contrast AUDIO OFF or AUDIO PAUSE is frequently associated with disabling the generation of auditory ALARM SIGNALS on a global scale for all ALARM CONDITIONS or a predetermined group of ALARM CONDITIONS.

Definition 3.38 – ADVISORY

See the rationale for Definition 3.41.

Definition 3.39 – ALARM FATIGUE

There is no universally accepted definition of ALARM FATIGUE. The term is commonly used to describe one or more related conditions that cause degradation of OPERATOR response to ALARM SIGNALS. The degraded response can be delayed, inadequate, inappropriate or absent. ALARM FATIGUE means a degraded response caused by one or more of the following:

– ALARM FLOOD;
– high number of FALSE POSITIVE ALARM SIGNALS;
– high number of CLINICALLY NONACTIONABLE ALARM SIGNALS, including receiving ALARM SIGNALS from other PATIENTS in the area for whom the OPERATOR is not responsible;
– high number of auditory ALARM SIGNALS that are insufficient for detection, identification, localization or prioritization;
– volume (sound pressure level) of the auditory ALARM SIGNAL (too quiet or too loud);
– ALARM SIGNALS that contain insufficient information to support planning a response to the underlying cause of the ALARM CONDITION (e.g. single ALARM SIGNAL to announce a large number of ALARM CONDITIONS or a visual ALARM SIGNAL that is non-specific); or
– other environmental aspects (i.e. ambient noise, ambient light and glare, level of OPERATOR rest, work area temperature, additional workflow interrupts) that impair the OPERATOR's cognitive abilities.

Given OPERATORS' response to the ALARM SIGNAL is based on the percentage of ALARM CONDITIONS they believe are not false [77], it stands to reason that ALARM SYSTEM design is a key factor to help prevent an OPERATOR from experiencing ALARM FATIGUE, and the resulting potential for HARM.

While it stands to reason that the total rate of ALARM SIGNALS is a contributor to ALARM FATIGUE [73], [74], [75], there exists some controversy to contradict that position [78]. There is available evidence that ALARM FATIGUE can be mitigated through the usage of better ALARM SYSTEMS, algorithms and ALARM SETTINGS, and careful consideration to deployment environment, policy, training, and technology selection [58], [59], [79], [80].

Definition 3.41 – ALERT

The committees received comments requesting that a definition for ALERT be added to the document. It is recognized that the terms ALERT and ALARM CONDITION have been used interchangeably and typically, the MANUFACTURERS of electronic medical record software have purposefully used the term ALERT instead of ALARM CONDITION so that their products are not construed as being part of the PATIENT monitoring system regardless of whether or not the notification was being used as a RISK CONTROL. Some standards [76] have defined an ALERT as a synonym for both what this document calls an ALARM CONDITION and an ADVISORY. These standards also define an ALERT as a signal while this document considers both an ALARM CONDITION and an ADVISORY to be a state that are communicated by signals.

The committees discussed the fact that an ALARM CONDITION is defined as providing a means of RISK CONTROL relating to HARM while a condition resulting in an ADVISORY does not, but the committees agreed that definitions should be provided to clarify the difference. And, it is noted that this document had not previously used the term ALERT or ADVISORY in any context. Since a direct RISK CONTROL is not an outcome of an ADVISORY notification, the definitions have been carefully worded to ensure that an ADVISORY would not be confused with ALARM CONDITION. ADVISORIES are then a type of INFORMATION SIGNAL that notifies an OPERATOR of conditions that relate to the PATIENT, equipment or workflow, but are not an indicator of potential HARM.

The examples provided are types of ADVISORIES that help the OPERATOR's workflow or raise the OPERATOR's cognitive awareness of a condition of the PATIENT, equipment or system.

EXAMPLE 1 An ADVISORY that the next blood draw is needed in approximately two hours notifies the OPERATOR that workflow includes obtaining a blood sample. This ADVISORY does not provide a RISK CONTROL, but rather is a notification to the OPERATOR that in the near future they should perform that task.

EXAMPLE 2 The battery status indicator shows the amount of battery charge remaining which notifies the OPERATOR of the condition of the ME EQUIPMENT and can notify them of a step in their workflow that will need to be done hours in the future, but they have not yet received an ALARM CONDITION for the state of the battery. A low battery LOW PRIORITY TECHNICAL ALARM CONDITION would be treated differently in that continued use of the ME EQUIPMENT will result in loss of power (and therefore loss of monitoring capability) and there is a RISK of PATIENT HARM.

EXAMPLE 3 Consider the case where a PATIENT has a high INR (International Normalised Ratio, an indication of clotting time). In the order entry system, the notification to the OPERATOR that an additional anticoagulant dose is contraindicated could be an ADVISORY since there are many additional workflow steps prior to the administration of the anticoagulant. The type of OPERATOR notification depends on where the anticoagulant dose administration is in the clinical workflow. If the dose is hours away, the notification to the clinical OPERATOR can be an ADVISORY – an INFORMATIONAL SIGNAL. On the other hand, if the clinical OPERATOR is about to administer the dose, a HIGH PRIORITY or at least MEDIUM PRIORITY ALARM CONDITION is appropriate because immediate or prompt action will be needed to prevent the HARM that would likely result from an overdose of anticoagulant.

Definition 3.44 – CLINICALLY ACTIONABLE

It can sometimes be difficult to determine if an event is CLINICALLY ACTIONABLE or not. One specific caregiver (physician, nurse, respiratory therapist, other) can notice an ALARM SIGNAL and make their own decision about whether to take action or not. Other caregivers can or might not agree with the decision of that caregiver. Indeed, reasonable, well-trained, expert caregivers frequently have different opinions about optimal PATIENT care.

For the purposes of this document, a single caregiver does not suffice to determine if an event is CLINICALLY ACTIONABLE or not. Instead, one needs to defer to a hypothetical "panel of experts" (physicians, nurses, respiratory therapists, or others) to make that determination. The hypothetical "panel of experts" is analogous to the concept of state-of-the-art. For the purposes of this document, such a panel is not required to be convened by any group (MANUFACTURER, RESPONSIBLE ORGANIZATION, OPERATOR, etc.) under any circumstances. It should be noted, however, that such panels are commonly convened by RESPONSIBLE ORGANIZATIONS to review situations of potential or actual PATIENT injury. A common example is a Hospital Quality Assurance Committee. In any case, if a majority of a hypothetical "panel of experts" would agree that action should be taken, then the event can be considered CLINICALLY ACTIONABLE. Table A.1 maps ALARM SYSTEM output to perceived OPERATOR action [29].

Table A.1 – ALARM SYSTEM output to perceived OPERATOR action

ALARM SYSTEM output	Resulting OPERATOR perception	Scientific definition	CLINICALLY ACTIONABLE ALARM CONDITION?
ALARM SYSTEM generates an ALARM SIGNAL for a HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITION	ALARM SYSTEM made a mistake	FALSE POSITIVE ALARM CONDITION	No
	ALARM SYSTEM performed correctly but the OPERATOR decides no action is required to prevent HARM.	Irrelevant POSITIVE ALARM CONDITION A valid triggering event has occurred in the PATIENT, the equipment or the ALARM SYSTEM, but based on the clinical context, the OPERATOR concludes that no action is required to prevent HARM.	
	ALARM SYSTEM performed correctly and the OPERATOR takes action.	TRUE POSITIVE ALARM CONDITION	Yes
ALARM SYSTEM does not generate an ALARM SIGNAL for a HIGH PRIORITY or MEDIUM PRIORITY ALARM CONDITION [a]	ALARM SYSTEM made a mistake	FALSE NEGATIVE ALARM CONDITION	Yes
	ALARM SYSTEM performed correctly but the OPERATOR decides action is required.	Relevant NEGATIVE ALARM CONDITION [b] Absence of an ALARM CONDITION when a valid triggering event has not occurred in the PATIENT, the equipment or the ALARM SYSTEM, but based on the clinical context, the OPERATOR concludes an action is required to prevent HARM.	
	ALARM SYSTEM performed correctly and the OPERATOR takes no action.	TRUE NEGATIVE ALARM CONDITION	No

[a] It could be that the ALARM SYSTEM reports a LOW PRIORITY ALARM CONDITION or no ALARM CONDITION – No action.

[b] It is recognized that a special case of the relevant FALSE NEGATIVE ALARM CONDITION can effectively be caused by an ALARM SIGNAL inactivation state.

Definition 3.45 – CLINICALLY NONACTIONABLE

See the rationale for 3.44.

Definition 3.48 – DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS

A DIS is equivalent to "a DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM CONDITIONS" as described in IEC 60601-1-8:2006+A1:2012, 6.11.2.2.2.

Definition 3.50 – NUISANCE ALARM SIGNAL

See the rationale for 3.44.

Subclause 5.2.1 – Instructions for use

[First bullet]

OPERATORS have found that in legacy equipment the terminology for the ALARM SIGNAL inactivation states has been ambiguous [18]. This has caused confusion and OPERATOR error when an OPERATOR has accidentally indefinitely inactivated (ALARM OFF, AUDIO OFF) instead of temporarily inactivating the generation of ALARM SIGNALS (ALARM PAUSED, AUDIO PAUSED) due to terminology confusion and inconsistent markings of controls (mode error).

EXAMPLE Some legacy equipment uses the control marking “silence” for ALARM OFF while other equipment uses the control marking “silence” for ALARM PAUSED.

When providing an overview of the ALARM SYSTEM in the instructions for use, it is highly desirable that MANUFACTURERS use the terminology for the ALARM SIGNAL inactivation states that are used in this collateral standard. Writers of particular standards should also use this terminology.

[Fourth bullet]

The instructions for use should provide details of any pre-use checks necessary for safe use. [19] These checks could be automatic or be provided by a pre-use checklist. Most equipment will not be fail-safe against a single functional failure such as loudspeaker failure. A faulty loudspeaker can result in an ALARM CONDITION not being recognized due to the absence of an auditory ALARM SIGNAL. To reduce the probability of a FALSE NEGATIVE ALARM CONDITION, the ALARM SYSTEM should be checked at regular intervals.

Long and difficult pre-use checkouts will be resisted by OPERATORS. [20],[22],[24] Ideally, equipment would have an automated or semi-automated checkout to reduce the burden on the OPERATOR. This checkout could include testing of the ALARM SYSTEM, for instance by testing auditory and visual ALARM SIGNALS and asking the OPERATOR to verify their function.

Alternatively, the checkout might include setting the ALARM LIMITS and deliberately introducing a condition that violates those limits, or other means to deliberately generate an ALARM SIGNAL.

Subclause 6.1.1 – General

It can be difficult to classify some ALARM CONDITIONS as to whether they are a PHYSIOLOGICAL ALARM CONDITION (PATIENT-related) or a TECHNICAL ALARM CONDITION (equipment–related).

Subclause 6.1.2 – Determination of ALARM CONDITIONS and assignment of priority

ALARM CONDITIONS should be prioritized based on the urgency of the required OPERATOR response or awareness of the situation that triggered the ALARM CONDITION. Priority is assigned through RISK ANALYSIS, either by the writer(s) of a particular standard or by the MANUFACTURER.

NOTE Some ALARM SYSTEMS have OPERATOR-configured or RESPONSIBLE ORGANIZATION-configured priorities.

MANUFACTURERS assign ALARM CONDITION priorities based on RISK ANALYSIS. This RISK ANALYSIS should primarily consider the severity and rapidity of onset of HARM if the ALARM CONDITION is not corrected. It should also consider other factors such as the sensitivity and specificity of the ALARM CONDITION for the actual event in the PATIENT or the equipment. The level of the priority of ALARM SIGNAL only suggests to the OPERATOR the speed at which the OPERATOR should respond to, or be aware of, an ALARM CONDITION. The actual speed of response or awareness required is ultimately based on the assessment by the OPERATOR.

"Immediate" category problems are those that are likely to cause PATIENT injury or death within seconds to several minutes if uncorrected. Few problems fall into the "immediate" category.

EXAMPLE 1 Asystole

EXAMPLE 2 Ventricular fibrillation

EXAMPLE 3 Failure of a cardiac support device (intra-aortic balloon pump, cardiopulmonary bypass machine)

EXAMPLE 4 Sustained high airway pressure

EXAMPLE 5 Extreme hypoxemia

EXAMPLE 6 Sustained high-energy radiation beam

"Prompt" category problems, on the other hand, do not cause PATIENT injury or death until at least several to many minutes have elapsed.

EXAMPLE 7 Many cardiac arrhythmias

NOTE Most cardiac arrhythmias would be prompt or delayed.

EXAMPLE 8 High or low blood pressure

EXAMPLE 9 Apnea (unless prolonged or associated with extreme hypoxia)

EXAMPLE 10 Mild hypoxemia

EXAMPLE 11 High or low pCO_2

"Delayed" category problems cause PATIENT injury only after many minutes to hours have passed.

EXAMPLE 12 Failure of an infusion pump for maintenance of intravenous fluids

EXAMPLE 13 Failure of an enteral feeding pump

EXAMPLE 14 Failure of a PATIENT weighing system

The choice of priority should be based upon RISK ANALYSIS. In general, the lowest priority compatible with the RISK ANALYSIS should be selected. In particular, HIGH PRIORITY ALARM SIGNALS should be reserved for those few ALARM CONDITIONS that truly require immediate response for PATIENT safety—that is, a response within seconds to a couple of minutes. Many types of equipment will not require any HIGH PRIORITY ALARM SIGNALS.

ME EQUIPMENT ALARM SYSTEMS are a protective measure used to minimize risks to PATIENT, personnel, and equipment. In certain therapeutic ME EQUIPMENT, a HAZARDOUS SITUATION could develop so rapidly and cause injury or damage so rapidly, that OPERATOR response to even a well-designed ALARM SYSTEM would be too slow. In such ME EQUIPMENT, an automatic system of mitigating the HAZARDOUS SITUATION is highly desirable, if not essential. The general standard and many particular standards require such safety mechanisms. It is recognized, however, that no ME EQUIPMENT could have protection against every possible HAZARD, or in the presence of multiple fault conditions.

It should be recognized that, almost without exception, OPERATORS have many additional duties in addition to responding to ALARM SIGNALS. The occurrence of a HIGH PRIORITY ALARM SIGNAL, whether the result of a true positive ALARM CONDITION or a FALSE POSITIVE ALARM CONDITION, generally requires the OPERATOR to immediately stop what he or she is doing and address the cause of the ALARM CONDITION. As an example, the OPERATOR might be in the middle of a sterile procedure on a different PATIENT, and that procedure would be interrupted and delayed by the need to respond to a HIGH PRIORITY ALARM SIGNAL.

A MEDIUM PRIORITY ALARM SIGNAL is also an interruption to the OPERATOR, but it allows a minute or a few minutes for the OPERATOR to finish a brief task before addressing the cause of the ALARM CONDITION, or to find an alternate person who can address the cause.

A LOW PRIORITY ALARM SIGNAL should not interrupt the OPERATOR, but rather the OPERATOR should be able to address the cause of the ALARM CONDITION at a convenient time, for instance, after many minutes, or when he or she next checks the ME EQUIPMENT. Even ME EQUIPMENT that is not continuously attended is checked by the OPERATOR at regular

intervals. Events that require interruption of the OPERATOR should not be LOW PRIORITY ALARM CONDITIONS, but rather they should be MEDIUM PRIORITY or even HIGH PRIORITY ALARM CONDITIONS. In addition, if the OPERATOR fails to address a LOW PRIORITY ALARM CONDITION in a timely fashion, the ALARM CONDITION should ESCALATE to a MEDIUM PRIORITY or even a HIGH PRIORITY ALARM CONDITION.

Subclause 6.2 – Disclosures for INTELLIGENT ALARM SYSTEM

Every effort should be made in designing equipment to integrate ALARM SYSTEMS into a coordinated system, minimizing the total number of ALARM SIGNALS to which an OPERATOR needs to respond. This is important as multiple ALARM CONDITIONS can generate ALARM SIGNALS when one problem occurs.

An INTELLIGENT ALARM SYSTEM need not simultaneously generate ALARM SIGNALS for all active ALARM CONDITIONS. The equivalent safety objective can be achieved by priority ranking and generating ALARM SIGNALS for a subset of the current active ALARM CONDITIONS. When multiple concurrent ALARM CONDITIONS exist, the relative importance of each ALARM CONDITION can be used to internally rank the ALARM CONDITION within a given priority. This internal priority ranking can be used to determine which particular ALARM CONDITION is causing the generation of ALARM SIGNALS or can be used to suppress the generation of ALARM SIGNALS for lower internal priority ALARM CONDITIONS. Multiple ALARM CONDITIONS of the same priority and the same or very similar meaning can also be incorporated into a single message (visual ALARM SIGNAL). These techniques are used to reduce the number of ALARM SIGNALS that an OPERATOR is required to respond to on ALARM SYSTEMS with multiple, related ALARM CONDITIONS. The use of INTELLIGENT ALARM SYSTEMS can be an effective way of reducing the number of ALARM SIGNALS that are generated during transient events, thus reducing the number of CLINICALLY NONACTIONABLE ALARM CONDITIONS. The use of INTELLIGENT ALARM SYSTEMS also can be an effective way of reducing the number of FALSE NEGATIVE ALARM CONDITIONS.

To assign an ALARM CONDITION priority, an algorithm of an INTELLIGENT ALARM SYSTEM might consider the magnitude of the deviation of a monitored variable from the ALARM LIMIT, the rate of change of the variable, the duration of the ALARM CONDITION and the presence or absence of any other concurrent ALARM CONDITIONS, redundant information or values of other variables.

After an ALARM CONDITION has generated ALARM SIGNALS, subsequent or persisting ALARM CONDITION(S) can cause the ALARM SYSTEM to change the priority of the ALARM CONDITION or to reassess the initial ALARM CONDITION (and perhaps cancel its ALARM SIGNAL generation) through the use of an INTELLIGENT ALARM SYSTEM algorithm.

INTELLIGENT ALARM SYSTEMS are permitted change characteristics of the ALARM SIGNALS to indicate a change in urgency. These changes can include, but are not limited to, changing the intensity of BURST volume, INTERBURST INTERVAL or PULSE FREQUENCY.

The algorithms of INTELLIGENT ALARM SYSTEMS should be evaluated and validated to ensure that the equipment meets the operational needs of the expected OPERATOR in the expected environment of its INTENDED USE. For methods of evaluation of USABILITY see IEC 62366-1.

Subclause 6.3.2 – Visual ALARM SIGNALS

Visual ALARM SIGNALS should indicate to the OPERATOR the presence and level of urgency of any ALARM CONDITION, help the OPERATOR to locate the specific PATIENT or equipment where an OPERATOR response or awareness is required, and identify to the OPERATOR the specific ALARM CONDITION.

There are two requirements for visual ALARM SIGNALS:

– *a "distant" requirement that the presence of an ALARM CONDITION and its priority are correctly perceived from a distance of 4 m (far away); and*

– *an "OPERATOR'S POSITION" requirement that the visual ALARM SIGNAL indicating the specific ALARM CONDITION and its priority are legible from at least 1 m or from the OPERATOR'S POSITION.*

It is possible to comply with the requirements of this collateral standard using either a single visual ALARM SIGNAL or with separate "distant" and "OPERATOR'S POSITION" visual ALARM SIGNALS.

The "distant" requirements are only required when they are necessary to allow the OPERATOR to locate the part of the ALARM SYSTEM that is generating ALARM SIGNALS. The ability to identify the priority of visual ALARM SIGNALS from a distance of 4 m allows the OPERATOR to decide which equipment to respond to first when simultaneous ALARM SIGNALS occur in a multi-equipment environment without having first to go to the OPERATOR'S POSITION.

The ability to discriminate between specific ALARM CONDITIONS and their priorities from a distance of 1 m or the OPERATOR'S POSITION aids the OPERATOR in deciding what actions need to be taken. MANUFACTURERS can choose to also make this "OPERATOR'S POSITION" visual ALARM SIGNAL legible from a distance of 4 m.

The committee considered the use of the standard general alarm symbol and urgent alarm symbol (triangle with 1 or 2 and extended to 3 curved lines) to represent LOW, MEDIUM or HIGH PRIORITY ALARM CONDITIONS. Concern was raised that they are too similar and would be impossible to distinguish on many displays at a viewing distance of 1 m to 4 m.

The committee recognized this limitation, and decided that adding optional elements could be used to indicate the priority.

MANUFACTURERS are free to enhance legibility by any of several means. For instance, the symbols could be coloured red or yellow, or placed on a red or yellow background. Additional symbols, letters, or words could be added to these symbols to enhance distinctiveness. One suggestion was to use three identical symbols to indicate HIGH PRIORITY, two identical symbols for MEDIUM PRIORITY and a single symbol for LOW PRIORITY.

Subclause 6.3.2.2.1 – 4 m (distant) visual ALARM SIGNALS

The committee considered using the triangle symbol (IEC 60417-5307) with 1, 2 (IEC 60417-5308) or 3 curved lines to represent the presence of LOW, MEDIUM OR HIGH PRIORITY ALARM CONDITIONS. Some comments suggested that such symbols were too similar and would be impossible to distinguish on many displays, particularly at a viewing distance of 4 m.

The committee recognized this limitation and decided to allow other methods to indicate priority. For instance, the visual ALARM SIGNAL representing a HIGH PRIORITY ALARM CONDITION could be coloured red, or placed on a red background. Additional symbols, letters or words could be added to improve distinctiveness. One suggestion was to use three identical triangles for HIGH PRIORITY ALARM CONDITION, two identical triangles for MEDIUM PRIORITY and a single triangle for LOW PRIORITY.

In Table 2, cyan is added as an option for indicating LOW PRIORITY. Differentiating LOW PRIORITY from MEDIUM PRIORITY by colour is an improvement in USABILITY. Historically, only red, yellow and green coloured lamps were readily available. A much broader range of colours is readily available today. The committee has chosen one of the complementary colours that is readily available.

Subclause 6.3.3 – Auditory ALARM SIGNALS

The primary purpose of auditory ALARM SIGNALS is to get the OPERATOR'S attention. Additionally, they should help the OPERATOR identify:

– the onset or presence of ALARM CONDITIONS;

– the urgency of the required OPERATOR response; and

– the location of the COMMUNICATOR generating ALARM SIGNALS.

The requirements of this subclause are intended to ensure that auditory ALARM SIGNALS in equipment are able to fulfill this purpose.

Equipment that is continuously attended by the OPERATOR in NORMAL USE has different auditory ALARM SIGNAL requirements from equipment that is unattended by the OPERATOR in NORMAL USE.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List element d), 1) i)]

It is the intent of the committees to make the ALARM SIGNALS of Annex G mandatory at the next amendment or edition of this document. MANUFACTURERS that utilize the ALARM SIGNALS of Annex G should report their experiences to the committees. IEC/62A can be reached at https://www.iec.ch/dyn/www/f?p=103:7:0::::FSP_ORG_ID:1359 [viewed 2020-07-09]. ISO/SC3 can be reached at: https://www.iso.org/committee/52012.html [viewed 2020-07-09].

[List element d), 2)]

A different technology implies something other than electronically generated tones. There are a variety of means for generating auditory ALARM SIGNALS, including buzzers, electronic sound generators and speech synthesizers. At least some of the methods described above can be used to indicate priority regardless of the means of generating the signal.

[List element d), 3)]

Distinctively different auditory ALARM SIGNALS for HIGH PRIORITY, MEDIUM PRIORITY and LOW PRIORITY are specified in Table 3 and Table 4. For any OPERATOR to identify the onset or presence of ALARM CONDITIONS by means of auditory ALARM SIGNALS, they should be audibly different from other sounds in the PATIENT care area. The HIGH PRIORITY auditory ALARM SIGNAL is designed to be very different from most other sounds (e.g. pagers, telephones, etc.).

The ALARM SIGNALS are priority encoded so that the OPERATOR can readily discern the priority of the associated ALARM CONDITION by auditory means alone.

Mandating the presence of at least one set of auditory ALARM SIGNALS that complies with Annex G, Table 3 and Table 4 or uses alternative technology (i.e., not based on PULSES and BURSTS) such as voice synthesis ensures that the RESPONSIBLE ORGANIZATION always has the option of selecting one recognizable, standard set of auditory ALARM SIGNALS on all ALARM SYSTEMS. Additional sets that comply with Table 3 and Table 4 and Annex G can be provided without any need for VALIDATION. Additional sets that do not comply with Table 3 and Table 4 can be provided so long as they are priority encoded and are appropriately validated. The RESPONSIBLE ORGANIZATION can configure any one of these as the DEFAULT ALARM PRESET.

Table 3 and Table 4 indicate the difference in priority primarily by the number of PULSES in a BURST and their rhythm. A HIGH PRIORITY BURST comprises 10 PULSES, repeating two identical groups of 5 PULSES with a pause between each group. A MEDIUM PRIORITY BURST comprises 3 PULSES and LOW PRIORITY BURSTS can contain one or two PULSES. Other factors can be used to provide additional priority or relative urgency information. Examples include inter-PULSE interval, inter-BURST interval, PULSE width and other PULSE characteristics. Higher priority auditory ALARM SIGNALS should use faster BURSTS with shorter PULSES that are repeated more frequently than lower priority ALARM SIGNALS.

Auditory ALARM SIGNALS that comply with this standard should sound almost identical to auditory ALARM SIGNALS that comply with ISO 9703-2.

Mandating auditory ALARM SIGNALS in Table 3 and Table 4 or Annex G ensures that the RESPONSIBLE ORGANIZATION always has the option of selecting recognizable, standard auditory ALARM SIGNALS for an ALARM SYSTEM.

Urgency of the required OPERATOR response is indicated by the different BURST patterns, BURST speeds, PULSE widths, repetition rates and relative volumes that are specified for LOW, MEDIUM and HIGH PRIORITY ALARM SIGNALS in Table 3 and Table 4. Annex D indicates factors that affect the perceived urgency of a BURST. MANUFACTURERS can find this helpful when choosing values that comply with Table 3 and Table 4 and are appropriate for the relative degree of urgency of OPERATOR response to a particular ALARM CONDITION. ESCALATION of ALARM CONDITION urgency within a priority ranking can be indicated to the OPERATOR by similar means.

Often (as has already been stated), many ALARM SYSTEMS generate ALARM SIGNALS in one PATIENT care area [23]. Even if the pitch of all PULSES in a BURST is the same, many OPERATORS can learn to recognize differences in tone, overall pitch, and repetition rate. If the pitch of individual PULSES is varied in such a way as to create simple standard "melodies", the average person can learn to recognize approximately six to eight melodies and to associate them with categories of equipment.

Multifunctional equipment can either use one ALARM SIGNAL that indicates the primary function of the equipment or can apply a different ALARM SIGNAL to each functional sub-system of the equipment. A specific ALARM SIGNAL that indicates equipment failure or power down can additionally be used on any equipment in addition to the ALARM SIGNAL indicating the primary function of the equipment.

Table 3 – Characteristics of the BURST of auditory ALARM SIGNALS
Table 4 – Characteristics of the PULSE of auditory ALARM SIGNALS

Table 3 and Table 4 are based on the requirements for auditory ALARM SIGNALS that were found in ISO 9703-2 [26]. These distinctive patterns or rhythms have been used for more than a decade and have been well accepted clinically. Table 3 and Table 4 are slightly different from the equivalent tables in ISO 9703-2. The modifications were intended to simplify interpretation and increase flexibility rather than introduce significant change. Auditory ALARM SIGNALS that complied with ISO 9703-2 should also comply with this collateral standard.

Spatial localization of an auditory ALARM SIGNAL is useful because it helps the OPERATOR to identify the origin of the ALARM SIGNAL promptly. Ensuring that at least four different frequency components are audible, the upper limit for them is set to 4 000 Hz. In addition, for one frequency component of them, the upper limit is set to 1 000 Hz, which makes it audible in distant areas (e.g. outside of an open door). *An even better approach is to create multiple notes at the same time (i.e. a chord), with each note having several harmonics. The more audible peaks in the frequency domain within the indicated band, the better the localization.*

Selection of the INTERBURST INTERVAL requires RISK ANALYSIS and careful consideration. Shorter INTERBURST INTERVALS can result in noise pollution and impair communication among OPERATORS or other personnel who are trying to address the problem, and are inappropriate for equipment that is intended to be continuously attended by the OPERATOR in NORMAL USE. On the other hand, longer INTERBURST INTERVALS can negatively affect the ability of the OPERATOR to identify, in a timely manner, the origin of the ALARM SIGNAL. This is particularly true for equipment intended to be unattended by the OPERATOR in NORMAL USE. MANUFACTURERS are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Writers of particular standards are encouraged to consider the longest appropriate INTERBURST INTERVAL of the auditory ALARM SIGNAL for the particular ALARM SYSTEM application.

The main differences between ISO 9703-2 and this collateral standard and the reasons for the current requirements, are described below:

a) The new PULSE spacing intervals are defined differently from ISO 9703-2 and provide greater design flexibility. PULSE spacing is now defined as the time from the end of one PULSE to the start of the next. As a result there is no possibility of overlap, which could occur in ISO 9703-2. The actual values permit all auditory ALARM SIGNALS complying with ISO 9703-2 except for HIGH PRIORITY ALARM SIGNALS in which the PULSES almost overlap. For obvious reasons, very few MANUFACTURERS actually did this. The committee considered that PULSES should have reasonable gaps between them, and that near-overlapping of PULSES should not be permitted.

b) In ISO 9703-2, the intended rhythm could not be achieved if each PULSE spacing was the same. The redrafted Table 3 addresses this problem. To ensure that the distinctive pattern is achieved, yet provide some flexibility in overall timing, this standard requires all INTERBURST INTERVALS within a BURST to have the same duration. A tolerance of ±5 % seemed appropriate.

c) The time between the two five-PULSE groups that comprise a HIGH PRIORITY ALARM SIGNAL (time between 5th and 6th PULSES) is now defined as the time from the end of the last PULSE in the first group to the start of the first PULSE in the next. The equivalent requirement in ISO 9703-2 was defined as the time from the start of the first group to the start of the next. In practice, this time could be unacceptably short. Therefore, few MANUFACTURERS actually complied with this ISO 9703-2 requirement. Instead, they chose the interpretation that is now used in this collateral standard. The intent of the pause was that the first group of PULSES would attract the OPERATOR'S attention, and the second group would emphasize the importance of the ALARM CONDITION and aid in identifying the origin of the ALARM SIGNAL once the OPERATOR'S attention had been gained.

d) A greater range of INTERBURST INTERVALS is permitted. The existing requirement in ISO 9703-2 is not suitable for ALARM SYSTEMS that are unattended by the OPERATOR in NORMAL USE. Selection of the most appropriate INTERBURST INTERVAL requires RISK ANALYSIS and careful consideration of the clinical requirement for the ALARM CONDITION in its intended environment of use. Short INTERBURST INTERVALS can result in noise pollution and impair communication among OPERATORS or other personnel who are trying to address the problem, and are inappropriate for ALARM SYSTEMS that are always attended by the OPERATOR in NORMAL USE. On the other hand, long INTERBURST INTERVALS can negatively affect the ability of the OPERATOR to promptly identify the origin of the ALARM SIGNAL. MANUFACTURERS and writers of particular standards are encouraged to use the longest INTERBURST INTERVAL consistent with the RISK ANALYSIS. Factors to consider include:

   – whether the ALARM SYSTEM is intended to be always attended by the OPERATOR in NORMAL USE. In this case a longer INTERBURST INTERVAL is appropriate;

     EXAMPLE Anesthesia machines.

   – the kind of equipment involved;

     EXAMPLE An enteral feeding pump should have a longer INTERBURST INTERVAL than a critical care ventilator.

   – whether the ALARM SYSTEM is connected to a DISTRIBUTED ALARM SYSTEM, e.g. a central monitoring system. An ALARM SYSTEM that is not so connected (standalone equipment) should consider a shorter INTERBURST INTERVAL, in order to facilitate identification;

     the presence and effectiveness of additional or alternative notification systems (secondary visual ALARM SIGNALS, vibratory ALARM SIGNALS, ALARM SIGNAL lights in hallways, alarm paging systems, etc). Effective alternative COMMUNICATORS will permit longer INTERBURST INTERVALS.

e) HIGH PRIORITY auditory ALARM SIGNAL PULSES should be “faster” than MEDIUM PRIORITY auditory ALARM SIGNAL PULSES to ensure that they are perceived as being more urgent. Hence, the requirement that the effective PULSE duration for HIGH PRIORITY ALARM SIGNALS is less than that for MEDIUM PRIORITY.

f) The LOW PRIORITY auditory ALARM SIGNAL is optional, but if present can comprise one or two PULSES. It should be relatively unobtrusive and perceived as less urgent than a MEDIUM PRIORITY ALARM SIGNAL.

g) Pitch is now permitted to rise and fall during a BURST. ISO 9703-2 required that changes in pitch proceed in one direction only. The committee considered this to be without safety advantage and excessively design restrictive.

h) The ISO 9703-2 requirement for the presence of four harmonics has been slightly modified. Reflections and standing waves from pure sine wave auditory ALARM SIGNALS can make it very difficult to determine where they are coming from. Ensuring that four or more audible frequencies are present in an auditory ALARM SIGNAL enhances spatial localization. These frequencies should be neither so soft as to be inaudible nor so loud as to be excessively dominant. Because tight control of frequency can be extremely difficult in simple systems, a value of plus or minus 15 dB (relative sound pressure level) was chosen as a reasonably achievable goal. Decibels were used to express the ratio between the sound pressure levels of the frequencies because they are commonly used to describe relative sound pressure levels. The choice of frequency content is very flexible and permits sounds of very different tonal quality to be created. *Using chords instead of single notes is another means to increase the frequency content of the sound and thereby improving localizability.*

i) FALL TIME for PULSES is now less restrictive. It can be any duration that does not overlap the next PULSE. In contrast, ISO 9703-2 sounds were required to have the same FALL TIME as RISE TIME. The committee found this to be excessively design restrictive. MANUFACTURERS are now permitted to create sounds with more distinctive envelopes (e.g. bell-like decays or reverberation effects).

– The RISE TIME of a PULSE influences both the perceived urgency and the intrusiveness of the auditory ALARM SIGNAL. More rapid RISE TIMES provide psychoacoustic cues of greater urgency and better reflect the intent of HIGH PRIORITY auditory ALARM SIGNALS, but they can be intrusive and startling. In contrast, slower RISE TIMES are generally perceived as being less urgent, and can be more appropriate for lower priority auditory ALARM SIGNALS or INFORMATION SIGNALS.

  With amendment 1, RISE TIME for PULSES is specified as 10 % to 40 % of PULSE duration with a recommendation that they should not be less than 10 ms. This is a relaxation from ISO 9703-2 and previous versions of this standard. Very short RISE TIMES can cause mechanical distortion arising from the speaker (typically a "thump", "click" or "pop"). Previously the shortest possible RISE TIME was 7,5 ms. This was only possible with a combination of the shortest possible PULSE duration of 75 ms and the shortest possible RISE TIME of 10%, so this is not a big change. Second, the maximum permitted RISE TIME, which had been 20 % of the PULSE duration, has been doubled to 40%, permitting even less intrusive or startling auditory ALARM SIGNALS than previously permitted. This can be advantageous for lower priority ALARM SIGNALS or INFORMATION SIGNALS.

– There is no change in the PULSE frequency requirement. Spatial localization is poor at low frequencies, so the lower limit for fundamental frequency is set at 150 Hz. Hearing impairment from noise exposure or age usually impairs perception of higher frequencies, so that to ensure that all harmonics are audible, the upper limit for fundamental frequency is set at 1 000 Hz. MANUFACTURERS can choose any frequency they like from within this range. Higher pitch is associated with greater urgency. [11]

– The difference in amplitude between any two PULSES in a BURST should not exceed 10 dB. Again, this refers to a relative sound pressure level ratio (i.e., not an absolute volume difference in dBA). This requirement is unchanged from ISO 9703-2. It is easier to make all PULSES the same amplitude, but if the amplitude of the early PULSES in a BURST is a little less than subsequent PULSES, it can be less startling.

The MEDIUM PRIORITY auditory ALARM SIGNAL can be better differentiated from the auditory emergency evacuation signal as specified in ISO 8201:2017 [30] if the three tones use different pitches or if the PULSE pacing and PULSE duration are short. Annex G ALARM SIGNALS are designed to be clearly distinct from the emergency evacuation signal.

Subclause 6.3.3.1 – Characteristics of auditory ALARM SIGNALS

[List elements a) to c) and f)]

The MANUFACTURER can provide more than one set of auditory ALARM SIGNALS. VALIDATION by USABILITY testing is not required if each set complies with Table 3 and Table 4 (or Annex G). If additional non-standard auditory ALARM SIGNAL sets (i.e., those that do not comply with Table 3 and Table 4 or Annex G) are provided, they require clinical VALIDATION to ensure that they provide at least an equivalent degree of safety as the standard sounds. Permission to provide non-standard sounds is intended to allow a RESPONSIBLE ORGANIZATION to continue to use non-standard but "historically validated" sound sets that have been successfully used for significant periods of time in their PATIENT care areas, and to ensure that this collateral standard is not excessively design restrictive. For example, the RESPONSIBLE ORGANIZATION might prefer some ventilators in their ICU to make one ALARM SIGNAL sound and ventilators of another type to make a different sound. Finally, this flexible approach should ensure that this collateral standard is not excessively design restrictive and that future development of improved auditory ALARM SIGNALS is not hindered.

When choosing an auditory ALARM SIGNAL set, a RESPONSIBLE ORGANIZATION should check that other devices in the PATIENT care area (e.g., pagers, mobile phones) do not generate sounds that could be confused with the medical auditory ALARM SIGNALS of that set unless their meaning is the same.

Every effort should be made in designing equipment to integrate ALARM SYSTEMS into a coordinated system, minimizing the total number of ALARM SIGNALS to which an OPERATOR needs to respond. This is important as multiple ALARM CONDITIONS can generate ALARM SIGNALS when one problem occurs.

Sounds from non-medical devices, such as pagers and telephones can resemble medical ALARM SYSTEM auditory ALARM SIGNALS. Care needs to be taken when designing auditory ALARM SIGNALS that the spectral content and amplitude of the ALARM SIGNALS facilitate the localization and identification of the origin of the ALARM SIGNAL, taking into account the usual environmental conditions in which the equipment is intended to be used. (See also Annex D.)

NOTE 1 When auditory ALARM SIGNALS are provided, this collateral standard requires that one set of auditory ALARM SIGNALS be encoded to convey the level of urgency of OPERATOR response required. In addition, other sets of auditory ALARM SIGNALS have been devised based on categorization of the nature of the response or awareness and the level of urgency of response required. [18]

A USABILITY test differs significantly from a clinical trial, but is equally important in producing usable, safe equipment. This test spotlights the OPERATOR interface and reactions of the OPERATOR to it. A USABILITY test can take up to a week per use model, depending on the number of OPERATORS involved. Such tests can be conducted in an office-like setting, away from the medical practice environment. This eliminates interference that would occur in the actual-use environment. While USABILITY test formats vary, typically one individual at a time performs self-exploration as well as directed tasks with the equipment. Test administrators can provide special prompts and feedback as required to add realism. As the OPERATOR performs tasks with the equipment, researchers observe and record results. The PROCESS gives the OPERATOR time to concentrate on using the equipment. An OPERATOR can spend weeks learning to use the equipment. Whether they encounter operating difficulties or causes for dissatisfaction over this time depends largely on how much they use the equipment and which tasks they perform. A USABILITY test compresses the initial use experience into a shorter time frame, usually 1 h to 4 h.

In hunting for USABILITY problems, researchers ask OPERATORS to talk their way through each task, describing what they are thinking, decisions they are contemplating, irritants, advantages, and so on. Sometimes USABILITY problems surface immediately, such as when an OPERATOR tries to turn on the equipment and cannot find the power switch. In such a case the OPERATOR can say:

> *Now, I'll turn the power on. I am looking at the front panel but nothing jumps out at me. I see a switch labelled "standby," but I don't think that turns it on. You*

probably press that button to save power without turning it off. I'm reaching around the back for a switch, but I don't feel anything. I would expect to find a switch right here [OPERATOR points to lower right side of control panel]. This green light probably illuminates when you turn the power on. Oh, I see [OPERATOR presses the light]. This light is the switch. You press it in to turn the power on. That wasn't obvious to me.

USABILITY test protocols should include frequent USE SCENARIOS and critical USE SCENARIOS. The effect of stress on how an OPERATOR uses the equipment can be studied by introducing time limits, removing equipment labelling, or the OPERATOR'S manual, and introducing equipment failures. Researchers can create a worst-case scenario and see how OPERATORS react. Test outcomes can be compared across several OPERATORS. MANUFACTURERS performing such tests commonly find that researchers collect a large set of USABILITY problems that may have escaped detection during a clinical trial, since such trials do not explicitly address USABILITY. [25]

NOTE 2 Attention is drawn to IEC 62366-1.

[List element g)]

When an ALARM SYSTEM is provided with more than one auditory ALARM SIGNAL set, the MANUFACTURER is required to select one set for the DEFAULT ALARM PRESET. The committee chose to require this because it can be hazardous when ALARM SYSTEMS have inconsistent or unknown sounds following resets and power failures.

The RESPONSIBLE ORGANIZATION should be able to change that selection and choose their desired auditory ALARM SIGNAL set for the DEFAULT ALARM PRESET, e.g., RESPONSIBLE ORGANIZATIONS need to be able select the auditory ALARM SIGNAL set that is familiar to their OPERATORS or to differentiate between different types of equipment.

[List element h)]

An ALARM PRESET can store any configuration parameters that affect the performance of the ALARM SYSTEM. One such configuration parameter can be the selection between auditory ALARM SIGNAL sets. A particular set can then become active when a particular ALARM PRESET is loaded. RESPONSIBLE ORGANIZATIONS may find this capability helpful when defining ALARM PRESETS for equipment that is used in a variety of PATIENT care areas. If OPERATORS can store ALARM PRESETS they can find this capability helpful to quickly configure ALARM SYSTEMS with the auditory ALARM SIGNALS that they are most familiar with.

[Signals in case of failure]

There are some failures, such as a power failure of the ALARM SYSTEM, which make it impossible for the ALARM SYSTEM to perform its intended function. In these cases, other means, such as a simple battery-backed tone generator, can be used to generate an ALARM SIGNAL to indicate such a TECHNICAL ALARM CONDITION. It would be best, if possible, for the ALARM SYSTEM to generate an auditory ALARM SIGNAL that complies with Table 3 and Table 4 and the "equipment or supply failure" ALARM SIGNAL from Annex G, but it is recognized that this can be impractical and that a non-standard auditory ALARM SIGNAL can be acceptable for this purpose.

A power or ALARM SYSTEM failure auditory ALARM SIGNAL should be generated for at least 120 s. This is particularly important for life-supporting equipment or life-sustaining equipment where the loss of function without immediate OPERATOR action can lead to a HAZARDOUS SITUATION for the PATIENT. Such a signal should also be considered for vital signs monitors to ensure that the OPERATORS are aware of the malfunction and can alter their clinical practice appropriately.

Allowing the OPERATOR to select LATCHING versus NON-LATCHING ALARM SIGNALS other than those determined to be appropriate by the RESPONSIBLE ORGANIZATION, can lead to HAZARDS

when a new OPERATOR becomes responsible for the equipment. See also the rationale for Subclause 6.7.

[Compliance test for timing]

In the past, there have been different test methods used for the verification of the timing of the AUDITORY POINTER. There are four different methods under use that have given different results. They are:

– analyzing of the timing of the sound file (e.g. .wav);
– analyzing of the electrical signal (e.g. loudspeaker input, sound chip output);
– analyzing of the acoustical time signal (sound pressure vs. time); and
– analyzing of the acoustical signal using sound pressure level vs. time analysis.

These different methods create non-comparable measurement results and have caused discussions between test labs, MANUFACTURERS and authorities having jurisdiction. The acoustic methods for determining timing are not very reproducible. For these reasons, the committees made the decision that the acoustical methods are inappropriate and that standardizing on measuring the drive signal of the audio transducer would give the most consistent results. Furthermore, when the wave files of Annex G are used, no testing is needed as those files are known to have appropriate timing.

Subclause 6.3.3.2 – Volume and characteristics of auditory ALARM SIGNALS and INFORMATION SIGNALS

For the OPERATOR to identify the onset or presence of ALARM CONDITIONS by means of auditory ALARM SIGNALS, those signals need to be audible above the background noise level and different from other sounds.

High background noise levels can mask or conceal the presence of auditory ALARM SIGNALS to such an extent that the OPERATOR can fail to hear them. Conversely, an auditory ALARM SIGNAL can be excessively intrusive or startling if its level is very high in relation to the background noise level. The OPERATOR might then seek to inappropriately disable or deactivate the ALARM SYSTEM.

In any PATIENT care environments where the background noise level is known and constant, a fixed auditory ALARM SIGNAL volume can be reasonable. The volume level of such a fixed auditory ALARM SIGNAL should exceed the background noise level to such an extent that it will be reliably detected but not to such an extent that it would be excessively startling or intrusive. Clinical experience has shown that values between 45 dB and 85 dB can be reliably detected without being too intrusive in most situations.

In many PATIENT care environments the background noise level is not constant. In operating rooms the background noise can vary from 50 dBA to 85 dBA. Additionally, one type of equipment can be used in several different kinds of PATIENT care environments; for example a ventilator that can be used in the home, in the intensive care area or for PATIENT transport.

Given the wide range of possible background noise levels in all possible PATIENT care environments, the committee did not consider it appropriate to specify any absolute volume level or range of levels for auditory ALARM SIGNALS. Designers of ALARM SYSTEMS should therefore be aware of the typical background noise level (and how variable it can be) in the intended environments of use. ALARM SYSTEMS that are to be used when background noise levels are variable should be provided with means for manual adjustment of the auditory ALARM SIGNAL level or should automatically adjust the auditory ALARM SIGNAL level so that the perceived loudness remains the same despite changes in background noise levels.

Because louder sounds are generally perceived to be more urgent, lower priority auditory ALARM SIGNALS should not be louder than higher priority ALARM SIGNALS. If higher priority

auditory ALARM SIGNALS are much louder than lower priority signals, they can be startling or intrusive. A reasonable compromise is for HIGH PRIORITY auditory ALARM SIGNALS to be approximately +6 dB louder than MEDIUM PRIORITY auditory ALARM SIGNALS, with an acceptable range from equal in volume (0 dB) to a maximum of +12 dB louder. MEDIUM and LOW PRIORITY ALARM SIGNALS should be equal in volume, but if they are different, MEDIUM PRIORITY auditory ALARM SIGNALS should not be more than 6 dB louder than LOW PRIORITY auditory ALARM SIGNALS.

It should be possible to adjust the volume level of auditory INFORMATION SIGNALS (e.g., pulse oximeter "beeps" or the "in-use" indicators on electro-surgical units) and the volume level of auditory ALARM SIGNALS independently, so that both can be set to appropriate levels. If the volume levels of auditory ALARM SIGNALS and auditory INFORMATION SIGNALS are not independently adjustable, then INFORMATION SIGNALS should have no greater volume level than LOW PRIORITY auditory ALARM SIGNALS, and both should have lower volume levels than those of MEDIUM PRIORITY and HIGH PRIORITY auditory ALARM SIGNALS. The auditory INFORMATION SIGNAL should be non-intrusive, non-startling and discontinuous in nature.

The volume (and range of adjustment of volume, if provided) of auditory ALARM SIGNALS in an ALARM SYSTEM are required to be disclosed to the RESPONSIBLE ORGANIZATION so that they will be able to determine if the volume of the auditory ALARM SIGNALS is appropriate for the intended environment of use.

Subclause 6.3.3.3 – OPERATOR-adjustable sound pressure level

In previous editions of this standard, MANUFACTURERS were permitted to allow OPERATOR-adjustable auditory ALARM SIGNAL sound pressure levels without restriction. This permission has now been restricted for ME EQUIPMENT provided with HIGH PRIORITY ALARM CONDITIONS. The reason is that, in general, MANUFACTURERS cannot anticipate every environment in which their ME EQUIPMENT might be used and a RESPONSIBLE ORGANIZATION needs the ability to control the minimum sound pressure level for ME EQUIPMENT provided with HIGH PRIORITY ALARM CONDITIONS. As an example, an item ME EQUIPMENT might be used in a helicopter, while another unit of the same ME EQUIPMENT might be used in a quiet home environment. The minimum auditory ALARM SIGNALS required are extremely different in these environments.

In the future, it is anticipated that ME EQUIPMENT will incorporate a microphone, both to determine the ambient (background) noise level and to set the auditory ALARM SIGNALS to an appropriate volume, and to verify that the ALARM SIGNALS are actually audible.

Another approach involves the use of auditory ALARM SIGNALS that ESCALATE in volume if they are not responded to within a reasonable period. In other words, if the OPERATOR does not attend to an ALARM SIGNAL within the expected timeframe, the auditory ALARM SIGNALS becomes louder in an attempt to attract the OPERATOR'S attention. In a DISTRIBUTED ALARM SYSTEM, the auditory ALARM SIGNALS can also be presented in additional locations. These approaches are useful not only if the auditory ALARM SIGNALS are too soft to be heard in the present noise environment, but if the OPERATOR does not hear or respond to the auditory ALARM SIGNALS for any reason, including being out of the immediate area, tending to another PATIENT, etc.

Care needs to be exercised with the auditory ALARM SIGNALS of HIGH PRIORITY ALARM CONDITIONS when OPERATOR-adjustable auditory ALARM SIGNAL sound pressure levels are available in the ME EQUIPMENT. Unless the RESPONSIBLE ORGANIZATION can configure the minimum OPERATOR-adjustable auditory ALARM SIGNAL sound pressure level, this standard requires that the ME EQUIPMENT visually indicate that the current sound pressure level might be inaudible. This is required since selecting a sound pressure level that is less than that which can be readily heard is effectively the AUDIO OFF state or the speaker muted state. As an alternative, this standard permits the RESPONSIBLE ORGANIZATION to select the minimum available sound pressure level to ensure that the ALARM SIGNALS are not inadvertently reduced below audible levels.

Subclause 6.3.4 – Characteristics of verbal ALARM SIGNALS

Verbal ALARM SIGNALS are permissible for HIGH, MEDIUM or LOW PRIORITY ALARM SIGNALS as well as INFORMATION SIGNALS. See also Annex E.

Verbal ALARM SIGNALS should only be considered for an ALARM SYSTEM intended for continuous OPERATOR attendance.

Subclause 6.4 – Disclosure of delays

If an event occurs in the PATIENT or the equipment that should result in the generation of ALARM SIGNALS, the generation should occur promptly. For example, clinicians would expect an ALARM SIGNAL soon after an abrupt fall in heart rate to a value below the lower ALARM LIMIT for heart rate, or once apnea or asystole has occurred. This is usually the case.

However, in some situations, ALARM SIGNAL generation can be delayed to such an extent that the delay can be clinically significant. This collateral standard recognizes that there are two fundamentally different potential causes for these delays.

First, it can take some time for the ALARM SYSTEM to determine that an ALARM CONDITION is present after the occurrence of a valid triggering event in the PATIENT. This delay is defined as the ALARM CONDITION DELAY. It can be due to:

– *artifact rejection algorithms, or*
– *INTELLIGENT ALARM SYSTEMS that include event duration as part of the algorithm, or*
– *aperiodic measurement (e.g., intermittent non-invasive blood pressure monitoring).*

When the ALARM SYSTEM is aperiodically measuring rather than continuously monitoring a variable, there can be a significant delay between the time that an event occurs in the PATIENT and when that event is detected. If the OPERATOR is unaware of this, incorrect treatment decisions can occur. The time between measurements is considered to be part of the ALARM CONDITION DELAY.

In the case of apnea or asystole, the valid triggering event in the PATIENT has not occurred until the absence of respiration or heart rate has existed for a defined period of time. Because this defined period of time is required to pass before the event itself exists, it is not included as part of the ALARM CONDITION DELAY. See also the rationale for Definition 3.2.

Second, the generation of ALARM SIGNALS can lag some time after the ALARM SYSTEM has determined that an ALARM CONDITION exists. This delay is defined in this document as the ALARM SIGNAL GENERATION DELAY. In most ALARM SYSTEMS this delay is usually clinically insignificant, but can be important, for example, when paging systems or networked COMMUNICATORS are used to generate ALARM SIGNALS. See also the rationale for Subclause 6.10.

A further complication can occur when the ALARM SYSTEM is not continuously monitoring, but is aperiodically measuring the variable that causes an ALARM CONDITION, e.g. a non-invasive blood pressure monitor. There can be a significant delay between when an event occurs in the PATIENT and when that event is detected. If OPERATORS are unaware of this likelihood, incorrect treatment decisions can occur.

In that case, the time between measurements is considered to be part of the ALARM CONDITION DELAY.

Figure A.1 illustrates the components of ALARM SYSTEM delay for a PHYSIOLOGICAL ALARM CONDITION normalized variable.

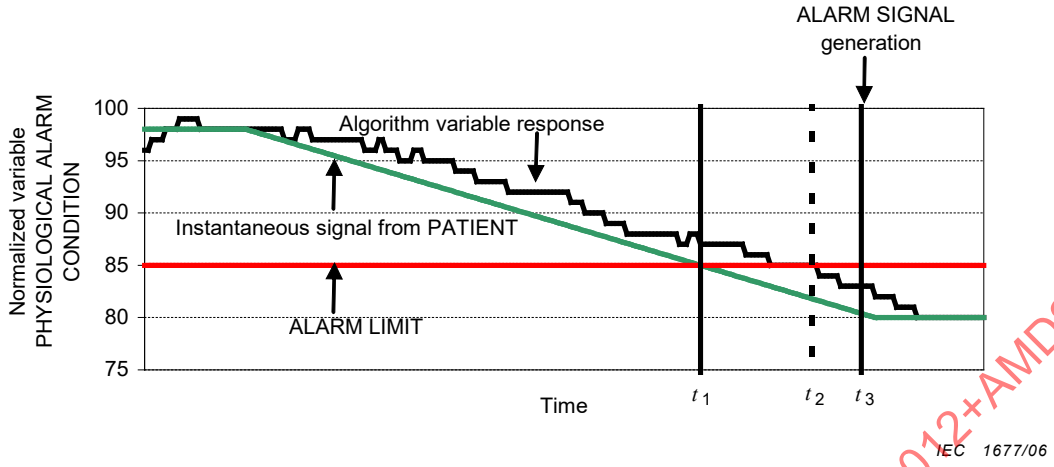


Figure A.1 – Graphical representation of components of ALARM SYSTEM delay

A valid triggering event occurs in the PATIENT at t_1. At t_2 the ALARM SYSTEM determines that an ALARM CONDITION exists.

NOTE In this example, the ALARM LIMIT is less than 85, not less than or equal to 85.

The ALARM CONDITION DELAY is $t_2 - t_1$. This delay is due to the ALARM SYSTEM processing and averaging. The ALARM SIGNAL GENERATION DELAY is $t_3 - t_2$. This delay is attributed to the ALARM SYSTEM strategy and the communication time to the ALARM SYSTEM generating device or DISTRIBUTED ALARM SYSTEM (e.g. PATIENT monitor or central station). At t_3 the ALARM SYSTEM begins to generate ALARM SIGNALS. Thus, the overall ALARM SYSTEM delay time is $t_3 - t_1$.

Subclause 6.4.1 – ALARM SYSTEM delays

The delay times are based on clinical judgement. Delay times shorter than those specified in this collateral standard are considered clinically insignificant.

Subclause 6.4.2 – Delays to or from a DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) or a DISTRIBUTED ALARM SYSTEM (DAS)

A DIS or DAS further complicates the consideration of ALARM SYSTEM delays. See also the rationale for Definition 3.2. When an OPERATOR is depending on remote COMMUNICATOR from a DISTRIBUTED ALARM SYSTEM for treatment decisions, then knowledge about the delays associated with DISTRIBUTED ALARM SYSTEMS is necessary for safety.

ALARM SIGNALS are being delivered to caregivers (OPERATORS) that are at short, medium or long distances away from the PATIENT. Such DISTRIBUTED ALARM SYSTEMS can include ALARM SYSTEM components made by several different MANUFACTURERS, for example:

– *a PATIENT monitor and a central station network;*
– *a specialized system that connects to the central station network and transmits ALARM CONDITIONS over another network; or*
– *a wireless transmission system that picks up an ALARM CONDITION from the network and transmits it to a wireless COMMUNICATOR.*

Each component of such a DISTRIBUTED ALARM SYSTEM can add to the ALARM SIGNAL GENERATION DELAY. The MANUFACTURER of each component of a DISTRIBUTED ALARM SYSTEM should disclose its contribution to the ALARM SIGNAL GENERATION DELAY. Depending upon which ALARM SYSTEM is considered, the contribution to the ALARM SIGNAL GENERATION DELAY can be the time from the:

– *ALARM CONDITION to the of ALARM SIGNALS of the COMMUNICATOR at the SOURCE or to the time that the indication of the ALARM CONDITION leaves a communications interface on the ALARM SYSTEM at the SOURCE; or*

– *receipt of the indication of the ALARM CONDITION by a component to its retransmission; or*

– *receipt of the indication of the ALARM CONDITION by a COMMUNICATOR to its ALARM SIGNAL generation.*

Ideally, the maximum time interval added to the original ALARM SIGNAL GENERATION DELAY should be reported as the remote ALARM SIGNAL GENERATION DELAY. It is recognized, though, that some components can have unpredictable, stochastic delays because of the nature of their non-deterministic networks. Still these components should have a "time out" function as described in the following paragraph.

Any component in a DISTRIBUTED ALARM SYSTEM might fail or experience a delay in passing along the indication of the ALARM CONDITION. ALARM SYSTEMS should be designed so that a communication failure (lack of receipt of an acknowledgement signal or failure of a "handshake" or other "time-out" function) results in a TECHNICAL ALARM CONDITION after a finite period. In lieu of the time to pass along the indication of the ALARM CONDITION (that is, the ALARM SYSTEM'S contribution to the ALARM SIGNAL GENERATION DELAY), the MANUFACTURER can disclose the time from detection of the indication of the ALARM CONDITION or receipt of the indication of the ALARM CONDITION to creation of the TECHNICAL ALARM CONDITION. When appropriate, both times (contribution to the ALARM SIGNAL GENERATION DELAY and the time to TECHNICAL ALARM CONDITION) should be disclosed.

It is important for the OPERATOR and the RESPONSIBLE ORGANIZATION to know both of these times for the safety of the PATIENT.

Writers of particular standards should carefully consider whether the maximum remote ALARM SIGNAL GENERATION DELAY or the time to determine the generation of the TECHNICAL ALARM CONDITION needs to be limited for a particular type of ME EQUIPMENT.

Subclause 6.5.1 – General requirements

It is important for OPERATORS to know the how the ALARM SYSTEM will operate when they start to use equipment. As a result, an ALARM SYSTEM is required to have a known priority and ALARM LIMIT for each ALARM CONDITION in every ALARM PRESET.

Subclause 6.5.3 – RESPONSIBLE ORGANIZATION- and OPERATOR-configured ALARM PRESETS

Allowing the OPERATOR to change RESPONSIBLE ORGANIZATION-configured or other OPERATOR-configured ALARM PRESETS can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for Subclause 6.7.

A MANUFACTURER-configured default ALARM LIMIT should be sufficiently wide to minimize unnecessary ALARM CONDITIONS and sufficiently narrow to alert the OPERATOR to a situation that can be dangerous.

Subclause 6.5.4.2 – Selection of DEFAULT ALARM PRESET

The start-up sequence of an ALARM SYSTEM needs careful design to prevent nuisance ALARM SIGNALS. In older ME EQUIPMENT, when it was switched on, any ALARM LIMIT in violation immediately caused an ALARM SIGNAL, even though no PATIENT was connected to the ME EQUIPMENT! Later ME EQUIPMENT, when it was switched on, entered a state of ALARM OFF, or AUDIO OFF, and the state had to be deliberately terminated by OPERATOR action. Additional safety was provided with the introduction of ME EQUIPMENT with automatic enabling of the ALARM SYSTEM when a PATIENT was connected to the ME EQUIPMENT, or when a valid physiologic signal was first present (for instance, five normal breaths or five heartbeats within a certain time interval), or through an "admit new PATIENT" function which was activated by the OPERATOR.

Another situation is the desire to set up the ME EQUIPMENT, including the ALARM SYSTEM, before the PATIENT is connected. In this instance, it is desirable for the OPERATOR to select the ALARM PRESET, and perhaps to modify values from the ALARM PRESET for the PATIENT planned, without

enabling the ALARM SYSTEM. The ALARM SYSTEM would then be enabled, either manually or preferably automatically, when the PATIENT is later connected to the ME EQUIPMENT.

A final situation is when the ALARM SYSTEM, or part of the ALARM SYSTEM, is in separate equipment. For instance, a gas delivery system might incorporate a separate gas monitor with its own ALARM SYSTEM, or an electronic recordkeeper or another equipment might combine the ALARM CONDITIONS from several items of ME EQUIPMENT into a single ALARM SYSTEM. In this instance the ME EQUIPMENT with the SOURCE and its ALARM SYSTEM might be switched on separately. Another example is a DISTRIBUTED ALARM SYSTEM of a PATIENT monitor with a central station. The ALARM SYSTEM of a central station should not be enabled when no PATIENT is connected! As in the earlier example, it would not be desirable to have the ALARM SYSTEM enabled until the ME EQUIPMENT is in actual clinical use.

When choosing the DEFAULT ALARM PRESET, a RESPONSIBLE ORGANIZATION should check that other devices in the PATIENT care area (e.g., pagers, mobile phones) do not generate sounds that could be confused with the auditory ALARM SIGNALS that are being chosen, unless their meaning is the same.

Subclause 6.5.5 – Interruptions of less than or equal to 30 s

For equipment with ALARM SYSTEMS, interruption of the SUPPLY MAINS for 30 s or less is considered NORMAL CONDITION. 30 s is sufficient time to restore power to the equipment by either plugging it back into SUPPLY MAINS or having the emergency generator initiate operation. Equipment with an OPERATOR-exchangeable INTERNAL ELECTRICAL POWER SOURCE, when they can be quickly replaced, is also expected to maintain its ALARM SETTINGS. The ALARM PRESET is expected to remain unchanged after such interruptions.

Subclause 6.6.2 – Adjustable ALARM LIMIT

Care should be used in the design of an ALARM SYSTEM if an OPERATOR is permitted to set an ALARM LIMIT to extreme values. Such action by the OPERATOR can have the effect of defeating both the auditory and visual ALARM SIGNALS, without providing a visual indication that the ALARM CONDITION is effectively disabled (see the second paragraph of 5.2.1).

Care also needs to be taken that any absolute lower and upper ALARM LIMITS will not be reached by PATIENTS in clinical practice, as this would cause a situation in which an ALARM CONDITION is continuously and erroneously indicated by ALARM SIGNALS.

The provision and use of a pre-use checklist to verify ALARM LIMIT(S) is encouraged.

Subclause 6.6.2.2 – Indication of automatically set ALARM LIMIT

Care should be used in the design of means to automatically set an ALARM LIMIT to help prevent FALSE POSITIVE or NEGATIVE ALARM CONDITIONS. In some cases, a wider or narrower ALARM LIMIT can be required.

Subclause 6.6.2.3 – ALARM SYSTEM operation during adjustment of ALARM LIMIT or ALARM PRESET

It is important for an ALARM SYSTEM to continue to function normally while the OPERATOR adjusts one part of the ALARM SYSTEM. In the past, some equipment has been designed such that all ALARM CONDITIONS were effectively disabled while the ALARM LIMITS for one ALARM CONDITION were being adjusted. Furthermore in this equipment, once the change had been completed, ALARM CONDITIONS that occurred during the adjustment PROCESS did not generate ALARM SIGNALS.

Subclause 6.7 – ALARM SYSTEM security

The need for and complexity of security for ALARM PRESETS depend on the complexity of the ALARM SYSTEM and the importance of the ALARM SYSTEM to PATIENT or OPERATOR safety. The

effectiveness of any security system depends critically on its implementation by the RESPONSIBLE ORGANIZATION. Only the RESPONSIBLE ORGANIZATION can adequately control the security system so that OPERATORS cannot compromise it.

In some legacy equipment, access to configuration of an ALARM PRESET (including DEFAULT ALARM PRESET) has not been restricted. In such instances, OPERATORS have, intentionally or unintentionally, changed an ALARM PRESET (including the DEFAULT ALARM PRESET). PATIENT safety can be compromised when an OPERATOR expects certain ALARM PRESETS on equipment, but the equipment actually has different ALARM PRESETS.

To prevent this problem, MANUFACTURERS need to use care in designing the means to store ALARM PRESETS. Access to configuration of an ALARM PRESET is restricted to authorized persons. There can be more than one level of restriction. For example, OPERATORS should be able to store OPERATOR-configured ALARM PRESETS, but should not be able to store RESPONSIBLE ORGANIZATION-configured ALARM PRESETS. RESPONSIBLE ORGANIZATIONS should be able to store RESPONSIBLE ORGANIZATION-configured ALARM PRESETS. Only MANUFACTURERS should be able to store MANUFACTURER DEFAULT ALARM PRESETS.

In some instances, the password for RESPONSIBLE ORGANIZATION-configured ALARM PRESETS has been printed in the technical description (service manual). These manuals have then been placed where they are accessible to an OPERATOR, and the OPERATOR has learned the password. Such passwords should be made available only to the RESPONSIBLE ORGANIZATION. Both the MANUFACTURER and RESPONSIBLE ORGANIZATION should avoid disclosure of such passwords to an OPERATOR. Therefore, the MANUFACTURER should emphasize the need to maintain password privacy in the technical description (instructions to RESPONSIBLE ORGANIZATIONS).

Similarly, an OPERATOR should not be permitted to change the OPERATOR-configured ALARM PRESETS of other OPERATORS. One solution would be password-protection for each OPERATOR to store his or her own OPERATOR-configured ALARM PRESETS.

Subclause 6.8 – ALARM SIGNAL inactivation states

The committee spent extensive time in discussion of the names of the ALARM SIGNAL inactivation states. In the past, equipment has used a variety of names to describe these inactivation states:

- Silence
- Silence/Reset
- Pre-Silence
- Mute
- Suspend
- Disable
- Inhibit
- Prevent
- Pause
- Off

The situation is problematic because different MANUFACTURERS have used these names to mean different things. “Silence” has been used to mean both a temporary or limited duration (timed) and a permanent (indefinite) state. In addition, some MANUFACTURERS have used these terms and states to apply only to those ALARM CONDITIONS which are generating ALARM SIGNALS, while others have used them to apply to every possible ALARM CONDITION in the ALARM SYSTEM. Also, some MANUFACTURERS used the term “alarms” to mean only the auditory ALARM SIGNALS, while others used it to mean both auditory and visual ALARM SIGNALS. The result has been confusion among OPERATORS about what the various names really mean.

Previous standards used terms such as “Suspend”, “Disable”, and “Inhibit”. These terms had two problems: first, they were not intuitively obvious as to their meaning. Second, they sometimes applied to the auditory ALARM SIGNALS only, and sometimes to both the auditory and visual ALARM SIGNALS. As a result, the confusion continued.

Additional difficulties were encountered in trying to translate these terms into multiple languages.

Early drafts of this collateral standard described multiple ALARM SIGNAL inactivation states, with tables with multiple columns to indicate the effect of each state on ALARM SIGNAL generation and non-generation, present and future ALARM CONDITIONS, recurrent or persisting ALARM CONDITIONS, auditory ALARM SIGNALS, and both near- and far-visible ALARM SIGNALS. There was no consensus on the correct content of the cells of the table and, even if there had been a consensus, OPERATORS would never have remembered the distinction among the multiple various states.

The committee therefore decided to use a small set of names with the same obvious meanings in various languages.

The names selected were:

– AUDIO OFF
– AUDIO PAUSED
– ALARM OFF
– ALARM PAUSED

The use of the distinctive terms “Audio” and “Alarm” should make clear to OPERATORS that “Audio” refers only to the auditory ALARM SIGNAL, while “Alarm” refers to both the auditory and visual ALARM SIGNALS. Similarly, the use of the terms “Off” and “Paused” should be intuitively obvious. Intuitively, one would anticipate that something that is “Off” remains off until it is turned back on again. Something that is “Paused” is expected to start again at a later time. By using a simple two-by-two matrix of “Audio/Alarm” and “Off/Paused,” all the ALARM SIGNAL inactivation states can be reasonably described.

Great simplification also occurred with the decision that these states might apply to a single ALARM CONDITION, a group of ALARM CONDITIONS or the entire ALARM SYSTEM. Thus all the legacy names for the ALARM SIGNAL inactivation states used in legacy ME EQUIPMENT, and in various standards, can be understood in terms of these new names.

MANUFACTURERS are strongly encouraged to use the provided names for the ALARM SIGNAL inactivation states in their equipment and its instructions for use when they have inactivation states as defined in this collateral standard. In this way, OPERATORS will learn to understand the consistent names for consistent functions across all ALARM SYSTEMS.

Subclause 6.8.1 – General

The continuous presence of ALARM SIGNALS can degrade task performance, and impair detection of new ALARM CONDITIONS and the ability to distinguish between existing and new ALARM CONDITIONS. It is important to provide any OPERATOR with deliberate means to initiate states such as AUDIO PAUSED, ALARM PAUSED, ACKNOWLEDGED, AUDIO OFF and ALARM OFF, by which they can stop the generation of ALARM SIGNALS.

An ALARM SYSTEM is not required to have OPERATOR control functions that initiate all of these states. An ALARM SYSTEM is required to have at least one means to inactivate the generation of ALARM SIGNALS from each COMMUNICATOR.

The presence of unnecessary visual ALARM SIGNALS can clutter the display and degrade the response to new ALARM SIGNALS. The OPERATOR can want to inactivate visual ALARM SIGNALS when some:

– functions of the equipment or system are not in use;

– functions of the equipment or system are not functional;

– monitored variables are generating frequent FALSE POSITIVE ALARM CONDITIONS; or

– monitored variables are known to be in ALARM CONDITION.

In recognition of this, MANUFACTURERS should consider whether the AUDIO PAUSED or AUDIO OFF ALARM SIGNAL inactivation states affect visual ALARM SIGNALS and in particular alarm indicator lights.

The committee wrestled with the behaviour of currently generated ALARM SIGNALS of ALARM CONDITIONS with respect to one, some or all non-currently generated ALARM SIGNALS and other issues. The consensus was that the inactivation could apply to one, a group or to all ALARM CONDITIONS, or (in the case of a DISTRIBUTED ALARM SYSTEM) to part or all of the ALARM SYSTEM. It was further recognized that the definition of a "group" of ALARM SIGNALS need not follow the traditional physiological grouping such as respiratory, cardiac, temperature, and so on. Instead a group could be defined as all currently generated ALARM SIGNALS, all ALARM SIGNALS chosen from a list by the OPERATOR, etc.

In Amendment 1, the committee added a new ALARM SIGNAL inactivation state to clarify which ALARM SIGNALS are and are not affected when the OPERATOR selects an inactivation state. Activation of the new indefinite ACKNOWLEDGED state affects those ALARM CONDITIONS that are currently active and no others. In this state, those ALARM CONDITIONS will be quiet indefinitely, until the ALARM CONDITION is no longer true. It is important for the OPERATOR to understand that this indefinite ACKNOWLEDGED state can last for hours or days, for instance until a variable comes back into range.

As an example, if the pulse oximeter oxygen saturation is 80 %, and the OPERATOR activates the ACKNOWLEDGED feature, then the oxygen saturation can remain at 80 % (or anywhere below the lower limit) for hours or days and the auditory ALARM SIGNALS and the 4 m visual ALARM SIGNALS remain inactivated. Indeed the oxygen saturation could fall further, for instance, to 50 % and these ALARM SIGNALS remain inactive!

While some OPERATORS have used this sort of ACKNOWLEDGED function safely for many years, other OPERATORS have not encountered this function before and might not understand the implications of its use.

The committee therefore believes that PATIENT safety can be enhanced by permitting the MANUFACTURERS to use a "time out" function on top of the ACKNOWLEDGED function. In this timed ACKNOWLEDGED function, the period during which the auditory ALARM SIGNALS and the 4 m visual ALARM SIGNALS are inactive automatically ends after a predetermined time interval, at which time the ALARM SIGNALS become active again. This timed ACKNOWLEDGED should prevent the situation in which the OPERATOR is unaware of the inactive ALARM CONDITIONS.

In any case, it should be made obvious to the OPERATOR which ALARM CONDITIONS are, and are not, in an inactive state such as ACKNOWLEDGED.

Furthermore, MANUFACTURERS might wish to include additional safety features such as safety or extreme ALARM LIMITS. An example of a safety ALARM LIMIT could be an additional HIGH PRIORITY oxygen saturation ALARM CONDITION with an ALARM LIMIT set 10 % below the primary MEDIUM PRIORITY ALARM CONDITION ALARM LIMIT. This allows for ALARM SIGNALS even if the primary "low oxygen saturation" ALARM SIGNALS have been ACKNOWLEDGED. There are other ways that an INTELLIGENT ALARM SYSTEM could contribute to PATIENT safety when the indefinite ACKNOWLEDGED function is used.

Smart enabling of an ALARM SYSTEM is intended to minimise NUISANCE ALARM SIGNALS when the ALARM SYSTEM is enabled. Often monitoring ME EQUIPMENT is powered up, with monitoring cables attached to it, before all cables are attached to the PATIENT. The ALARM SYSTEM should either:

a) automatically be in AUDIO OFF or ALARM OFF, until a valid signal is detected from the monitored parameter; or
b) generate auditory ALARM SIGNALS to alert the OPERATOR to the TECHNICAL ALARM CONDITION that some monitoring components are not connected.

If the ALARM SYSTEM doesn't generate auditory ALARM SIGNALS until a valid signal is detected, the ALARM SYSTEM should, for the relevant monitored parameters:

- *visually indicate AUDIO OFF in association with the affected parameters, and not present an auditory ALARM SIGNAL; and*
- *optionally provide additional visual INFORMATION SIGNALS or REMINDER SIGNALS to assist the OPERATOR; and*

  EXAMPLES 1 Displaying the text "leads off" in the ECG waveform area or "static pressure" in the arterial pressure waveform area.
- *automatically terminate the AUDIO OFF state individually for each parameter when valid data is received, thereby returning the ALARM SYSTEM to its normal monitoring status.*

If the ALARM SYSTEM does generate auditory ALARM SIGNALS while waiting for a valid signal to be detected, the ALARM SYSTEM should:

- *provide a means to inactivate these ALARM SIGNALS, such action resulting in the affected parameters entering the ACKNOWLEDGE state, and*
- *optionally provide additional visual INFORMATION SIGNALS or REMINDER SIGNALS to assist the OPERATOR.*

  EXAMPLES 2 Displaying the text "leads off" in the ECG waveform area or "static pressure" in the arterial pressure waveform area.

  NOTE Since ACKNOWLEDGE automatically terminates individually for each parameter when valid data is received, the ALARM SYSTEM returns to its normal monitoring status as valid signals are detected.

Subclause 6.8.2 – REMINDER SIGNALS

REMINDER SIGNALS are not desirable in all equipment. For example, for operating room monitors that are continuously attended, REMINDER SIGNALS can be annoying, distracting, and disturb other operating room personnel.

ALARM SYSTEMS are required to allow the RESPONSIBLE ORGANIZATION (and only the RESPONSIBLE ORGANIZATION) to determine whether or not REMINDER SIGNALS are appropriate for use. Allowing one OPERATOR to disable REMINDER SIGNALS can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment.

Allowing the OPERATOR to set the duration of a REMINDER SIGNAL interval longer than that determined to be appropriate by the RESPONSIBLE ORGANIZATION can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for 6.7.

Subclause 6.8.3 – Global indefinite ALARM SIGNAL inactivation states

The provision of a global ALARM OFF or AUDIO OFF function requires a careful RISK ANALYSIS. The RISK ANALYSIS needs to weigh the RISK of frequent or constant ALARM SIGNALS (including those from FALSE POSITIVE ALARM CONDITIONS) versus the RISK of an ALARM CONDITION with inadequate or no ALARM SIGNALS being generated. In addition, whether or not the ALARM SYSTEM is intended to be continuously attended by an OPERATOR in NORMAL USE and the presence or absence of a DISTRIBUTED ALARM SYSTEM need to be considered.

If a global ALARM OFF or AUDIO OFF function is provided, MANUFACTURERS are required to provide periodic REMINDER SIGNALS to mitigate the RISK of an OPERATOR forgetting that all auditory ALARM SIGNALS are inactivated.

If a global ALARM OFF or AUDIO OFF function is provided, MANUFACTURERS are required to provide the RESPONSIBLE ORGANIZATION with means to enable or disable the global function. ALARM SYSTEMS are required to allow the RESPONSIBLE ORGANIZATION (and only the RESPONSIBLE ORGANIZATION) to determine whether or not global ALARM SIGNAL inactivation states are appropriate for use.

Subclause 6.8.4 – Termination of inactivation of ALARM SIGNALS

It is important for an OPERATOR to be able to undo an action made in error. PATIENT safety requires this, as human error is inevitable and the ability to mitigate error needs to be provided.

Subclause 6.8.5 – Indication and access

The committee strongly believed that the markings required for ALARM SIGNAL inactivation states needed to be standardized. This is even more important than the standardization of the names of ALARM SIGNAL inactivation states that are standardized to eliminate the confusion of multiple names with different meanings. OPERATOR confusion regarding the status of an ALARM SIGNAL inactivation state is a known HAZARD. The committee has chosen internationally standardized symbols for this marking. Overall, safety will be increased when OPERATORS find consistent marking (symbols) with consistent meaning for the ALARM SIGNAL inactivation states across all equipment.

This collateral standard does not specify how the various ALARM SIGNAL inactivation states are to be invoked. Many approaches currently exist. They include:

– single-function hard keys;

– hard keys that cycle through various states (e.g., AUDIO PAUSED, AUDIO OFF, and all ALARM SIGNALS active);

– soft keys;

– menu selections.

The committee anticipates that ALARM SYSTEMS designed to comply with this collateral standard will continue to use these methods and also might use new methods such as voice recognition.

When a "control" is used to invoke an ALARM SIGNAL inactivation state, this collateral standard permits that it be marked with the appropriate symbol as indicated in Table 5. Certainly, the symbols from Table 5 should only be used for the functions indicated. In the case of a multifunction control, a different marking (symbol or wording) can be used, e.g., a hard key that cycles through ALARM PAUSED, ALARM OFF, and all ALARM SIGNALS active could be marked with IEC 60417-5307(DB:2002-10).

The committee faced a dilemma in the choice of symbols for ALARM CONDITIONS and for ALARM SIGNAL inactivation states. The familiar Bell-X symbol (IEC 60417-5576 (DB:2002-10)) has been used for many years, but some MANUFACTURERS have used it to mean "AUDIO OFF" or "AUDIO PAUSED" while other MANUFACTURERS have used it to mean "ALARM OFF" or "ALARM PAUSED". Thus there is substantial confusion about what the symbol means among clinicians (OPERATORS). Both what is off (just auditory signals or auditory signals and visual signals), as well as whether this is a permanent loss or a timed loss of ALARM SIGNALS, have been indicated by Bell-X. In either case, however, OPERATORS have recognized that the Bell-X includes the loss of alarm sound.

A HAZARD occurs, however, if an OPERATOR looks for the familiar Bell-X, does not see it, and mistakenly concludes that the auditory ALARM SIGNALS are on. In other words, OPERATORS can not understand that the Triangle-X symbol (IEC 60417-5319 (DB:2002-10)) indicates that part of the ALARM SYSTEM is in the AUDIO OFF or AUDIO PAUSED state. On that basis, the committee decided to permit, or perhaps encourage, the use of the Bell-X as an additional symbol whenever the Triangle-X is used. In that way, OPERATORS would see the familiar Bell-X at any

time that a portion of the ALARM SYSTEM is in the AUDIO OFF or AUDIO PAUSED state. Alternatively or additionally, a text message could be added.

Another possible symbol that the committee considered is the Loudspeaker-X (IEC 60417-5436 (DB:2002-10)). This has traditionally been used to mean “sound mute” and it could be interpreted to produce an effect upon both ALARM SIGNALS and INFORMATION SIGNALS. This collateral standard requires that if this symbol is used as an indicator for muting both INFORMATION SIGNALS and ALARM SIGNALS, the appropriate Bell-X is also indicated.

In the event of ALARM PAUSED or AUDIO PAUSED, the X becomes a dashed-X where the dashed-X means limited duration or timed rather than the solid-X that means permanent.

Concern was raised about the amount of dark and light spaces of the dashed-X so that it can be legible on displays of differing resolution. MANUFACTURERS are reminded that icons made from symbol graphics need to be adapted to the display resolution when used.

The use of a countdown timer (which shows the time remaining in ALARM or AUDIO PAUSED state), adjoining the icon, is encouraged. The presence of a countdown timer adds additional distinctiveness to the icon for ALARM PAUSED or AUDIO PAUSED so that they can more easily be distinguished from ALARM OFF or AUDIO OFF.

Allowing the OPERATOR to set duration of an AUDIO PAUSED or ALARM PAUSED interval longer than that determined to be appropriate by the RESPONSIBLE ORGANIZATION can lead to HAZARDS when a new OPERATOR becomes responsible for the equipment. See also the rationale for 6.7.

Subclause 6.9 – ALARM RESET

The committee received many comments on LATCHING ALARM SIGNALS and ALARM RESET and discussed the topic at length. There were two different philosophies on the operation of the ALARM RESET that the committee considered.

One philosophy holds that ALARM RESET should:

– terminate a LATCHING ALARM SIGNAL and should be the only means of terminating the LATCHING ALARM SIGNAL;

– cause the ALARM SYSTEM to be enabled or re-enabled to respond to future ALARM CONDITIONS;

– terminate any existing AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF state thus re-enabling the ALARM SYSTEM.

In addition, if the OPERATOR wished to enter the state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF, a second, deliberate action should be required. It is believed that this two-step PROCESS should be required at least for the clearing of visual LATCHING ALARM SIGNALS. The concern was that an OPERATOR might cause the removal of visual ALARM SIGNALS before the OPERATOR had had an opportunity to identify the ALARM CONDITION.

The second philosophy holds that the desired response of an OPERATOR to an auditory ALARM SIGNAL is to cause it to stop. This philosophy holds that activation of the states of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF should serve as the acknowledgement by the OPERATOR of any auditory ALARM SIGNAL, and that a separate ALARM RESET function is unnecessary. This second philosophy thus holds that activation of the functions AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF should terminate the generation of any auditory ALARM SIGNAL, and that the ALARM SIGNAL should not recur at the end of AUDIO PAUSED or ALARM PAUSED unless the ALARM CONDITION is still present. This second philosophy holds that, if the ALARM RESET function is provided, it should terminate the generation of any ALARM SIGNAL, but it should not cause the ALARM SYSTEM to be re-enabled. This philosophy also holds that, if an ALARM RESET function was provided and activated, it should not terminate any existing state of AUDIO PAUSED, AUDIO OFF, ALARM PAUSED or ALARM OFF (for other parts of the ALARM SYSTEM). These states would thus remain as they had been previously.