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Anaesthesia and respiratory care alarm signals —

Part 3:
Guidance on application of alarms

Signaux d'alarme pour l'anesthésie et les soins respiratoires —

Partie 3: Lignes directrices relatives à l'application des alarmes

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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9703-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

ISO 9703 consists of the following parts, under the general title *Anaesthesia and respiratory care alarm signals:*

— *Part 1: Visual alarm signals*

— *Part 2: Auditory alarm signals*

— *Part 3: Guidance on application of alarms*

Annex A of this part of ISO 9703 is for information only.

Anaesthesia and respiratory care alarm signals —

Part 3:
Guidance on application of alarms

1 Scope

This part of ISO 9703 provides guidelines for the application of alarms in equipment intended for use in anaesthesia and respiratory care. Particular device standards take precedence over this part of ISO 9703.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 9703. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 9703 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals*.

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals*.

3 Definitions

For the purposes of this part of ISO 9703, the definitions in ISO 9703-1 and ISO 9703-2 and the following definitions apply.

3.1
activated
state of a system in which it is capable of performing its intrinsic function

3.2
default alarm settings
alarm settings intrinsic to the system, which are preset by the manufacturer, a user, or an operator and which the system itself sets, without further intervention, when the alarm system is activated

3.3
disable
inactivate an alarm function

3.4
inhibition
suppression, until revoked intentionally, of alarm signals

3.5
latched alarm
alarm signal for which the visual and auditory components do not stop when the conditions necessary for activation no longer exist, when limits are restored or when the abnormal patient condition no longer exists

3.6
nonlatched alarm
alarm signal for which the visual and/or auditory components cease when the conditions necessary for activation no longer exist

3.7
reset
cause the alarm function to revert to its initial detection state

3.8
silence, verb
mute, verb
cause the cessation and resetting of an auditory alarm by a deliberate action

3.9
suspension
suppression, until revoked automatically, of alarm signals

4 Alarm signal characteristics

The visual and auditory attributes of alarms should comply with ISO 9703-1 and 9703-2.

5 Allocation of alarm priorities

5.1 Principle

The provision of alarms should never be used as a substitute for good design of anaesthesia and respiratory care devices. ISO 9703-1 and ISO 9703-2 specify the characteristics of auditory and visual alarm signals of high-, medium- and low-priority alarm signals, but do not specify which priority is allocated to a particular alarm on a particular device. To allocate a priority to a particular alarm, it is necessary to evaluate the risk to the patient of the event that the alarm indicates.

The term ‘risk’ is usually associated with the potential harm resulting from the event (level of severity) and the likelihood of the occurrence of the event (frequency). The concept of ‘risk’ for alarm priority allocation should be modified by replacing the concept of ‘frequency’ by ‘level of urgency’. (See ISO 14971 and EN 1441 for guidance on risk analysis of medical devices.)

An event develops over time, either incrementally or suddenly, the latter sometimes being so sudden as to allow little or no time for even the most competent operator to take action to avoid potentially hazardous consequences to the patient. IEC 60601-1 requires that the medical device be provided with automatic means to detect and identify sudden, severe events. Some potentially hazardous conditions develop over a period of time sufficient to allow for manual remedial actions, and the purpose of the alarm is to attract the operator’s attention to the event and to indicate the speed of response required.

5.2 Factors to be considered

5.2.1 Level of urgency

The level of urgency of the event should be categorized into the following.

a) Immediate, i.e. having the potential for the event to develop within a period of time not usually sufficient for manual corrective action.

b) Prompt, i.e. having the potential for the event to develop within a period of time usually sufficient for manual corrective action.

c) Delayed, i.e. having the potential for the event to develop within an unspecified time greater than that given under ‘prompt’ in 5.2.1 b).

5.2.2 Level of severity

The level of severity of the event should be categorized into the following, which can also be expressed in a more generic fashion by the corresponding level of physiological threat (as given in parentheses).

a) Severe, i.e. death or irreversible injury (severe physiological threat).

b) Moderate, i.e. reversible injury (moderate physiological threat).

c) Minor, i.e. discomfort or minor injury (minor physiological threat).

5.3 Derivation and allocation of alarm priorities

The allocation of priority to a particular alarm on a particular device should be based on the potential for the development of injury derived from the combination of the factors given in 5.2, as illustrated in figure 1. From this it can be seen that some events develop immediately at a stated level of severity, whereas others undergo delayed development. Each of the nine fields in figure 1 represents an alarm priority as given in table 1, and the allocation of priority should be made in accordance with table 1.

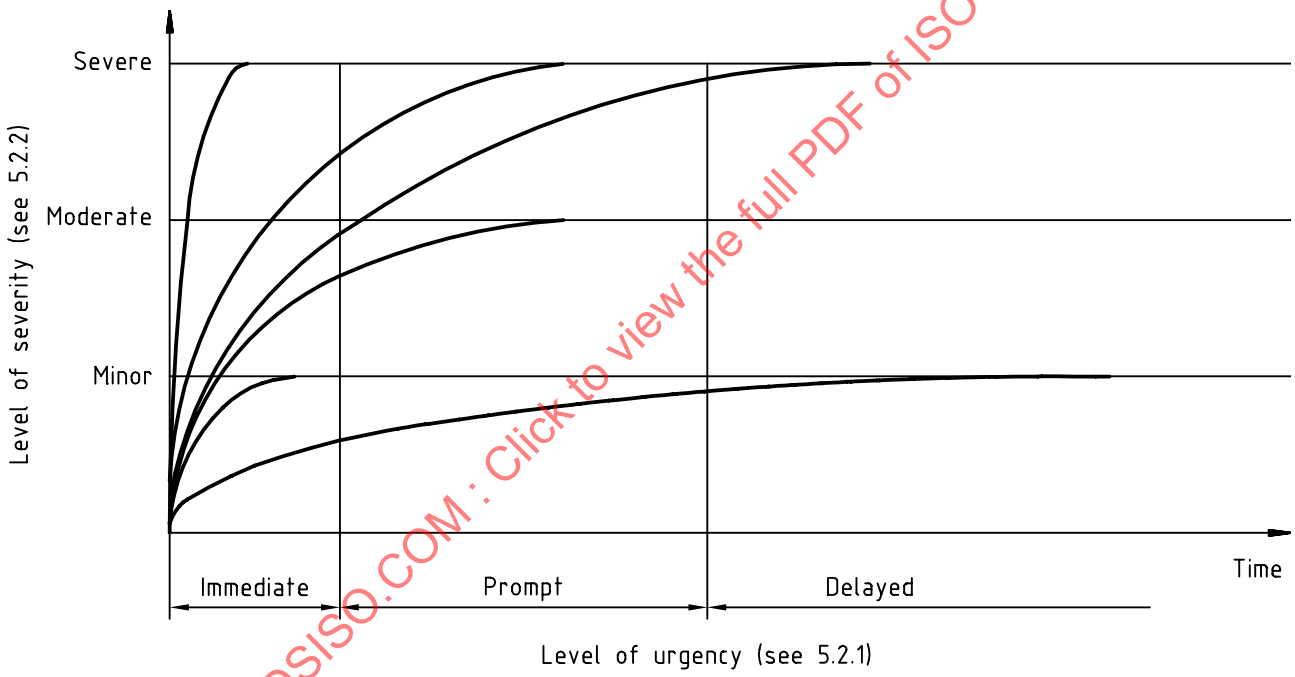

Figure 1 — Severity and urgency of events

Table 1 — Allocation of alarm priorities

Level of severity	Level of urgency		
	Immediate	**Prompt**	**Delayed**
Severe	High priority[1)]	High priority	Medium priority
Moderate	High priority	Medium priority	Low priority
Minor	Medium priority	Low priority	No alarm signal required

1) Medical devices should be designed with a view to preventing devices from causing or contributing to this state, for example, by incorporating automatic safety mechanisms. The high priority alarm should be combined with supplementary means for patient protection whenever possible.

5.4 Information signals

Information signals are used to convey messages that may or may not require increased vigilance on the part of the operator, but which, contrary to alarm signals, do not require operator intervention. Information signals should not be used or regarded as a fourth level of priority of alarm signal.

6 Alarm limits and settings

6.1 Alarm default settings

6.1.1 Manufacturer's default alarm settings

Manufacturer's alarm default settings should be provided for critical alarms. These settings should be:

a) sufficiently wide to minimize unnecessary alarms and sufficiently narrow to alert the operator to a situation that would be dangerous in a typical patient;

b) selectable by the operator by a convenient means on the device.

6.1.2 User-chosen default alarm settings

It should be possible for the device to store one or more sets of default alarm settings chosen by the user. If it is possible for more than one set to be stored, activation of a particular set of alarm settings should require deliberate action by the operator.

The device should indicate when user-chosen default alarm settings are in use.

6.1.3 Activation of default alarm settings

It should be possible for the operator to choose to activate either the manufacturer's default alarm settings or user-chosen default alarm settings. The chosen set of settings should be activated whenever any of the following occur.

a) The device is switched on by the operator.

b) Power is restored to the device after it has experienced a total loss of power (mains and/or battery) for a duration specified by the manufacturer.

c) The operator indicates to the device, preferably through an admit-new-patient function, that a different patient has been connected to the device.

6.2 Adjustable alarm settings

6.2.1 General

The settings of adjustable alarms should be indicated either continuously or on operator demand.

The device should be designed such that it is possible to review the alarm settings quickly.

Care should be taken in the design of devices that permit the operator to set alarm settings to extreme values. Such an action by the operator can have the effect of disabling both the auditory and visual alarm signals without indicating that the alarm has been effectively disabled. It is recommended that a visual indication is provided if an alarm setting has been set to a value inappropriate for a typical patient or in a typical situation.

6.2.2 Monitoring during setting of alarm settings

While the operator is setting the alarm settings, the device should permit monitoring to continue and alarm conditions to elicit the appropriate alarms.

6.2.3 Automatic setting of alarm settings

Care should be taken in the design of automatic setting systems so as to minimize nuisance alarms for variables that are changing within acceptable ranges. In some instances, wider or narrower settings may be required.

6.2.4 Alarm settings after loss and restoration of power

When power is restored to the device after it has experienced a total loss of power (mains and/or battery) for a duration of 5 min or less, the alarm settings prior to the power loss should have been retained [see 6.1.3 b) for default alarm settings].

7 Alarm silencing, suspension and inhibition

7.1 Silencing

The device should permit the auditory component of alarm signals to be silenced by operator action. New alarm conditions that develop during the silencing period should initiate appropriate auditory and visual signals, although this does not preclude the development of intelligent alarm systems. Momentary silencing of an alarm should not affect the visual representation of the alarm and should not disable the alarm. A periodic auditory indicator can be used while the signal is silenced.

7.2 Suspension

The device should permit an auditory high- or medium-priority alarm signal to be temporarily overridden for an interval (for example, 120 s) by operator action. After the suspension period, the alarm should begin sounding again if the alarm condition persists or if the condition had been temporarily corrected but has returned.

Suspension of auditory alarms should be visually indicated.

7.3 Inhibition

The device should permit a high- or medium-priority alarm signal to be inhibited (for instance because of the failure of a sensor). Inhibition can be appropriate when the continuous annunciation of the auditory component is likely to degrade operator performance of associated tasks to an unacceptable extent and in cases when operators would otherwise be likely to disable the device.

If provided, inhibition should require the operator to either confirm the intent to inhibit a critical-life-support alarm or to take more than one step to effect such action. Inhibition should not remain in effect in the event of total power loss for more than a brief interval when the device is turned off by the operator, or when the device is disconnected from the patient.

8 Nonlatched alarms

The auditory and/or visual alarm signals of nonlatched alarms should reset automatically when the condition causing the alarm has cleared or has been corrected. A means may be provided for the user to select between latched and nonlatched alarms.

If the alarm condition clears quickly, the operator may be unable to discover what triggered the alarm and therefore care should be taken in the design of alarm systems to make sure that the cause of an alarm can be identified. Possible solutions include:

a) use of an alarm of a prolonged minimum duration , e.g. 10 s;

b) a message that persists after the alarm condition has cleared;

c) an alarm log that the operator can call up from the memory, print or use to record functions of the device.