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Guidance on the selection of the appropriate means of ventilation based on the intended patient, use environment, and operator

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*.

Introduction

This document uses common language to describe and clarify the intended PATIENT, intended USE ENVIRONMENT and intended OPERATOR that are applicable to the ventilation categories and SLEEP APNOEA BREATHING THERAPY EQUIPMENT for which there are ISO standards. There is confusion in the marketplace as to which standard (and therefore the related equipment) is appropriate for which type of PATIENT. This document is intended to help answer that question. This document does not categorize PATIENTS by size, weight or age. Throughout this document, the following considerations are delineated:

— the state of the PATIENT'S health (fragility/acuity/stability);

— the PATIENT'S dependency on artificial ventilation;

— the consequence of loss of ventilation;

— the required range of ventilation modes and corresponding PATIENT monitoring;

— how often the PATIENT needs assessing by a HEALTHCARE PROFESSIONAL;

— how often the PATIENT needs respiratory-related care.

Additionally, there are seven annexes.

— Annex A contains the rationale for this document.

— Annex B contains a table that compares some of the most important environmental characteristics and requirements of the HOME HEALTHCARE ENVIRONMENT, PROFESSIONAL HEALTHCARE FACILITY environment, and EMERGENCY MEDICAL SERVICES ENVIRONMENT.

— Annex C contains a table that highlights where the VENTILATORS that are covered by each of the standards are intended to be utilized.

— Annex D contains a table that compares the intended OPERATOR, intended PATIENT and intended USE ENVIRONMENT for each of the standards discussed in this document.

— Annex E contains a table that numerically compares the types of ventilation-related equipment with regard to intended PATIENT care.

— Annex F contains a comparison of selected technical requirements between various international standards for ventilation-related devices.

— Annex G contains an alphabetized list of defined terms used in this document.

TERMS used throughout this document that have been defined in Clause 3 appear in SMALL CAPITALS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Guidance on the selection of the appropriate means of ventilation based on the intended patient, use environment, and operator

1 * Scope

This document considers and identifies criteria about the intended PATIENT, intended USE ENVIRONMENT, and intended OPERATOR across the spectrum of the types of ventilation-related equipment as listed below:

— gas-powered resuscitator as specified in ISO 10651-5[1] [1)];

— OPERATOR-powered resuscitator as specified in ISO 10651-4[2];

— VENTILATOR for critical care as specified in ISO 80601-2-12[3] [2)];

— VENTILATOR for EMERGENCY MEDICAL SERVICES ENVIRONMENT as specified in ISO 80601-2-84[4] [3)], the future replacement for ISO 10651-3[5];

NOTE 1 ISO 80601-2-84 updates the content of ISO 10651-3 and harmonizes it with IEC 60601-1:2005+AMD1:2012[6] and IEC 60601-1-12:2014[7].

— VENTILATOR for VENTILATORY IMPAIRMENT in the HOME HEALTHCARE ENVIRONMENT as specified in ISO 80601-2-79[8];

— VENTILATOR for VENTILATORY INSUFFICIENCY in the HOME HEALTHCARE ENVIRONMENT as specified in ISO 80601-2-80[9];

— VENTILATOR for VENTILATOR-DEPENDENT PATIENTS in the HOME HEALTHCARE ENVIRONMENT as specified in ISO 80601-2-72[10];

— SLEEP APNOEA BREATHING THERAPY EQUIPMENT as specified in ISO 80601-2-70[11].

NOTE 2 SLEEP APNOEA BREATHING THERAPY EQUIPMENT is not considered to be an artificial VENTILATOR. It is included in this discussion to highlight the differences, which indicate why SLEEP APNOEA BREATHING THERAPY EQUIPMENT is not considered a VENTILATOR.

This document is intended to provide guidance that can assist MANUFACTURERS, authorities having jurisdiction and USERS in the development, selection and application of different types of ventilatory equipment based on the intended PATIENT, intended USE ENVIRONMENT and intended OPERATOR.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

1) Numbers in square brackets refer to the Bibliography.

2) Under preparation. Stage at the time of publication: ISO/FDIS 80601-2-12:2018.

3) Under preparation. Stage at the time of publication: ISO/DIS 80601-2-84:2018.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

NOTE For convenience, an alphabetical index of all defined terms used in this document is given in Annex G.

3.1
ACCESSORY
additional part for use with equipment in order to

— achieve the INTENDED USE,

— adapt it to some special use,

— facilitate its use,

— enhance its performance, or

— enable its functions to be integrated with those of other equipment

[SOURCE: IEC 60601-1:2005, 3.3]

3.2
ACCOMPANYING DOCUMENT
document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

[SOURCE: IEC 60601-1:2005, 3.4]

3.3
AIRWAY PRESSURE
P_{aw}
pressure at the PATIENT-CONNECTION PORT

[SOURCE: ISO 80601-2-12:—, 201.3.201]

3.4
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 to entry: An ALARM CONDITION can be invalid, i.e. a false positive ALARM CONDITION.

Note 2 to entry: An ALARM CONDITION can be missed, i.e. a false negative ALARM CONDITION.

[SOURCE: IEC 60601-1-8:2006+AMD1:2012, 3.1]

3.5
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[SOURCE: IEC 60601-1-8:2006, 3.9]

3.6
ALARM SYSTEM
parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

[SOURCE: IEC 60601-1-8:2006, 3.11]

3.7
APPLIED PART
part of ME EQUIPMENT that, in NORMAL USE, necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

[SOURCE: IEC 60601-1:2005, 3.8, modified — deleted notes.]

3.8
BASIC SAFETY
freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION

[SOURCE: IEC 60601-1:2005, 3.10]

3.9
BODY-WORN
TRANSPORTABLE equipment whose INTENDED USE includes operation while being worn by a PATIENT or attached to a PATIENT'S clothing

Note 1 to entry: TRANSPORTABLE equipment can be both BODY-WORN and HAND-HELD.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.144]

3.10
CLASS I
electrical equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for accessible parts of metal or internal parts of metal to be protectively earthed

[SOURCE: IEC 60601-1:2005, 3.13, modified — deleted note.]

3.11
CLASS II
electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions

[SOURCE: IEC 60601-1:2005, 3.14, modified — deleted note.]

3.12
CONTINUOUS POSITIVE AIRWAY PRESSURE
CPAP
therapeutic CONTINUOUS POSITIVE AIRWAY PRESSURE during the respiratory cycle

[SOURCE: ISO 80601-2-70:2015, 201.3.205]

3.13
DISTRIBUTED ALARM SYSTEM
ALARM SYSTEM that involves more than one item of equipment of a ME SYSTEM

Note 1 to entry: The parts of a DISTRIBUTED ALARM SYSTEM can be widely separated in distance.

[SOURCE: IEC 60601-1-8:2006, 3.17]

3.14
EMS VENTILATOR
VENTILATOR FOR EMERGENCY MEDICAL SERVICES ENVIRONMENT
VENTILATOR intended for use in the EMS ENVIRONMENT

[SOURCE: ISO 80601-2-84:—, 201.3.201]

3.15
*** EMS ENVIRONMENT**
EMERGENCY MEDICAL SERVICES ENVIRONMENT
actual conditions and settings, in which OPERATORS interact with the ME EQUIPMENT or ME SYSTEM, in and around the scene of an emergency outside of a PROFESSIONAL HEALTHCARE FACILITY where a PATIENT can be given medical care, basic or advanced life support as well as during professional transport to a PROFESSIONAL HEALTHCARE FACILITY or between PROFESSIONAL HEALTHCARE FACILITIES

[SOURCE: IEC 60601-1-12:2014, 3.1, modified — deleted notes.]

3.16
ESSENTIAL PERFORMANCE
performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

Note 1 to entry: ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.27]

3.17
FIXED
fastened or otherwise secured at a specific location either permanently or so that it can only be detached by means of a TOOL

EXAMPLE 1 Permanently affixed by welding, etc.

EXAMPLE 2 Affixed by means of fasteners (screws, nuts, etc.) making removal/opening impossible without using a TOOL.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.30, modified — deleted note.]

3.18
FUNCTIONAL CONNECTION
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

Note 1 to entry: Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

[SOURCE: IEC 60601-1:2005, 3.33]

3.19
HAND-HELD
equipment that, once installed and placed into service, is intended to be supported by the hand

Note 1 to entry: Equipment can refer to ACCESSORIES or equipment parts.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.37, modified — deleted note 2.]

3.20
HARM
physical injury or damage to the health of people or animals, or damage to property or the environment

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.38]

3.21
HAZARD
potential source of HARM

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.39]

3.22
HAZARDOUS SITUATION
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.40]

3.23
HEALTHCARE PROFESSIONAL
individual with relevant specialized training, knowledge and skills who provides preventive, curative, promotional or rehabilitative health care services in a systematic way to people, families or communities

[SOURCE: ISO 60601-2-12:—, 201.3.210]

3.24
*** HOME HEALTHCARE ENVIRONMENT**
dwelling place in which a PATIENT lives or other places where PATIENTS are present, excluding PROFESSIONAL HEALTHCARE FACILITY environments where OPERATORS with medical training are continually available when PATIENTS are present

EXAMPLE In a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

Note 1 to entry: Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services.

Note 2 to entry: For the purpose of this document, nursing homes are considered HOME HEALTHCARE ENVIRONMENTS.

Note 3 to entry: Other places where a PATIENT is present include the outdoor environment, while working and in vehicles.

[SOURCE: IEC 60601-1-11:2015, 3.1]

3.25
INTENDED USE
use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

Note 1 to entry: INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.44]

3.26
LAY, adj.
non-professional or professional without relevant specialized training

EXAMPLE LAY OPERATOR, LAY RESPONSIBLE ORGANIZATION.

[SOURCE: IEC 60601-1-11:2015, 3.2]

3.27
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

Note 1 to entry: ISO 13485[15] defines "labelling" as written, printed or graphic matter

— affixed to a medical device or any of its containers or wrappers, or

— accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this document, that material is described as markings and ACCOMPANYING DOCUMENTS.

Note 2 to entry: "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

Note 3 to entry: In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

Note 4 to entry: Adapted from ISO 14971:2007, 2.8.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.55, modified — replaced 'standard' by 'document'.]

3.28
MAXIMUM LIMITED PRESSURE

P_{LIM} max

highest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

[SOURCE: ISO 80601-2-12:—, 201.3.214]

3.29
ME EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS;

b) intended by its MANUFACTURER to be used

   1) in the diagnosis, treatment, or monitoring of a PATIENT, or

   2) for compensation or alleviation of disease, injury or disability

Note 1 to entry: ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT.

Note 2 to entry: Not all electrical equipment used in medical practice falls within this definition (e.g. some *in vitro* diagnostic equipment).

Note 3 to entry: The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this document by appropriate wording in Clause 1.

Note 4 to entry: This document uses the term "electrical equipment" to mean ME EQUIPMENT or other electrical equipment.

[SOURCE: IEC 60601-1:2005, 3.63, modified — deleted note 5 and replaced 'standard' by 'document'.]

3.30
ME SYSTEM

MEDICAL ELECTRICAL SYSTEM

combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

Note 1 to entry: Equipment, when mentioned in this document, should be taken to include ME EQUIPMENT.

[SOURCE: IEC 60601-1:2005, 3.64, modified — replaced 'standard' by 'document'.]

3.31
MOBILE

TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.65, modified — deleted note.]

3.32
MONITORING EQUIPMENT
ME EQUIPMENT or part that continuously or continually measures and indicates the value of a variable to the OPERATOR

[SOURCE: ISO 80601-2-12:—, 201.3.216]

3.33
MULTIPLE SOCKET-OUTLET
MSO
one or more socket-outlets intended to be connected to, or integral with, flexible cables, cords or ME EQUIPMENT providing SUPPLY MAINS or equivalent voltage

Note 1 to entry: A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.67]

3.34
NORMAL CONDITION
NC
condition in which all means provided for protection against HAZARDS are intact

[SOURCE: IEC 60601-1:2005, 3.70, modified — added the alternative term 'NC'.]

3.35
NORMAL USE
operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.71]

3.36
OPERATOR
USER
person handling equipment

[SOURCE: IEC 60601-1:2005, 3.73, modified — added the alternative term 'USER'.]

3.37
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.76]

3.38
PATIENT-CONNECTION PORT
port at the PATIENT end of a VENTILATOR BREATHING SYSTEM intended for connection to an airway device

EXAMPLE A tracheal tube, tracheostomy tube, face mask and supralaryngeal airway are all airway devices.

Note 1 to entry: The PATIENT-CONNECTION PORT is the end of the VENTILATOR BREATHING SYSTEM proximal to the PATIENT.

[SOURCE: ISO 80601-2-12:—, 201.3.217]

3.39
POSITIVE END-EXPIRATORY PRESSURE
PEEP
positive AIRWAY PRESSURE at the end of an expiratory phase

[SOURCE: ISO 4135:2001, 3.3.11]

3.40
PERMANENTLY INSTALLED
electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL

[SOURCE: IEC 60601-1:2005, 3.84]

3.41
PHYSIOLOGICAL ALARM CONDITION
ALARM CONDITION arising from a monitored PATIENT-related variable

EXAMPLE 1 High exhaled anaesthetic 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.

[SOURCE: IEC 60601-1-8:2006, 3.31]

3.42
PORTABLE
TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons

Note 1 to entry: Equipment can refer to ACCESSORIES or equipment parts.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.85, modified — deleted note 2.]

3.43
PROCESS
set of interrelated or interacting activities which transforms inputs into outputs

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.89]

3.44
*** PROFESSIONAL HEALTHCARE FACILITY**
facility including hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services

Note 1 to entry: PROFESSIONAL HEALTHCARE FACILITIES are supervised by suitably trained HEALTHCARE PROFESSIONAL OPERATORS.

[SOURCE: ISO 80601-2-12:—, 201.3.218]

3.45
PROTECTION DEVICE
part or function of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

[SOURCE: ISO 80601-2-12:—, 201.3.219]

3.46
RATED
<value> value assigned by the MANUFACTURER for a specified operating condition

[SOURCE: IEC 60601-1:2005, 3.97]

3.47
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

Note 2 to entry: Education and training is included in "use."

[SOURCE: IEC 60601-1:2005, 3.101]

3.48
RISK
combination of the probability of occurrence of HARM and the SEVERITY of that HARM

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.102]

3.49
SAFETY
freedom from unacceptable RISK

[SOURCE: ISO 14971:2007, 2.24]

3.50
SEVERITY
measure of the possible consequences of a HAZARD

[SOURCE: IEC 60601-1:2005, 3.114]

3.51
SINGLE FAULT CONDITION
SFC
condition of ME EQUIPMENT in which a single means for reducing a RISK is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.116, modified — deleted note and added the alternative term 'SFC'.]

3.52
SLEEP APNOEA BREATHING THERAPY EQUIPMENT
ME EQUIPMENT intended to alleviate the symptoms of a PATIENT who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the PATIENT

[SOURCE: ISO 80601-2-70:2015, 201.3.212]

3.53
SUPPLY MAINS
source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

Note 1 to entry: This also includes battery systems and converter systems in ambulances and the like.

[SOURCE: IEC 60601-1:2005, 3.120]

3.54
TOOL
extra-corporeal object that can be used to secure or release fasteners or to make adjustments

Note 1 to entry: Coins and keys are considered TOOLS within the context of this document.

[SOURCE: IEC 60601-1:2005, 3.127, modified — replaced 'standard' with 'document']

3.55
TRANSIT-OPERABLE, adj.
TRANSPORTABLE equipment whose INTENDED USE includes operation while it is being moved

EXAMPLE TRANSPORTABLE ME EQUIPMENT that is BODY-WORN, HAND-HELD, attached to a wheelchair, or used in a car, bus, train, boat or plane.

Note 1 to entry: For the purpose of this document, TRANSIT-OPERABLE use in the HOME HEALTHCARE ENVIRONMENT can include use indoors, outdoors and in vehicles.

[SOURCE: IEC 60601-1-11:2015, 3.4, modified — replaced 'standard' with 'document'.]

3.56
TRANSPORTABLE
equipment that, once installed and placed into service, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

EXAMPLE MOBILE equipment, PORTABLE equipment and BODY-WORN equipment.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.130, modified — deleted note.]

3.57
USABILITY
characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and USER satisfaction in the intended USE ENVIRONMENT

Note 1 to entry: All aspects of USABILITY, including effectiveness, efficiency and user satisfaction, can either increase or decrease SAFETY.

[SOURCE: IEC 62366-1:2015, 3.16]

3.58
USE ENVIRONMENT
actual conditions and setting in which USERS interact with the ME EQUIPMENT or ME SYSTEM

Note 1 to entry: The conditions of use or attributes of the USE ENVIRONMENT can include hygienic requirements, frequency of use, location, lighting, noise, temperature, mobility, and degree of internationalization.

[SOURCE: IEC 62366-1:2015, 3.20, modified — replaced medical device with "ME EQUIPMENT" or "ME SYSTEM".]

3.59
USER GROUP
subset of intended USERS who are differentiated from other intended USERS by factors that are likely to influence USABILITY, such as age, culture, expertise or type of interaction with ME EQUIPMENT or ME SYSTEM

[SOURCE: IEC 62366-1:2015, 3.25, modified — replaced 'a medical device' with 'ME EQUIPMENT or ME SYSTEM'.]

3.60
VENTILATOR BREATHING SYSTEM
VBS
inspiratory or expiratory pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the PATIENT-CONNECTION PORT and the exhaust port

[SOURCE: ISO 80601-2-12:—, 201.3.220]

3.61
VENTILATOR
ME EQUIPMENT intended to automatically augment or provide ventilation of the lungs of the PATIENT when connected to the airway of the PATIENT

[SOURCE: ISO 80601-2-12:—, 201.3.221]

3.62
VENTILATOR-DEPENDENT
PATIENT that is dependent upon artificial ventilation in order to prevent serious deterioration of health or death

EXAMPLE PATIENTS with severe Duchennes Muscular Dystrophy or other degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life.

Note 1 to entry: A VENTILATOR-DEPENDENT PATIENT cannot breathe well enough to maintain life-sustaining levels of oxygen and carbon dioxide in the blood.

[SOURCE: ISO 80601-2-12:—, 201.3.222]

3.63
VENTILATORY IMPAIRMENT
RESPIRATORY IMPAIRMENT
clinically significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the patient

EXAMPLE Mild to moderate chronic obstructive pulmonary disease (COPD).

Note 1 to entry: PATIENTS with VENTILATORY IMPAIRMENT exhibit a minimal level of illness acuity, fragility, or instability. Their dependence on the VENTILATORY SUPPORT EQUIPMENT to maintain adequate gas exchange is minimal. Without such support as needed, these PATIENTS would likely experience some difficulty with activities that they might normally pursue and this might interfere with daily living. Without ventilatory support as needed, these PATIENTS are likely to experience short periods of abnormal lung gas exchange which can result in them becoming more sedentary.

Note 2 to entry: VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT is suitable for use where PHYSIOLOGICAL ALARM CONDITION monitoring is usually not required because the absence or degradation of the VENTILATORY SUPPORT is not likely to cause injury to the PATIENT (i.e. VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT has no ESSENTIAL PERFORMANCE).

[SOURCE: ISO 80601-2-79:2018, 201.3.202]

3.64
VENTILATORY INSUFFICIENCY
RESPIRATORY INSUFFICIENCY
degradation in respiratory function severe enough to prohibit certain activities that the PATIENT might normally pursue, and to interfere with daily living; occurring in association with measurements of respiratory mechanics or gas exchange that are markedly abnormal

EXAMPLE Moderate to severe chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia and muscular dystrophy.

Note 1 to entry: PATIENTS with VENTILATORY INSUFFICIENCY exhibit an illness acuity, fragility or instability level up to and including a moderate to severe degradation in respiratory function. Their dependence on the VENTILATORY SUPPORT EQUIPMENT to maintain adequate gas exchange can range from minimal to moderate dependence. Without such support, the most fragile of these PATIENTS would likely be prohibited from certain activities that they might normally pursue and this would likely interfere with their daily living. The most fragile of these PATIENTS would likely experience injury with the loss of this artificial ventilation.

Note 2 to entry: VENTILATORY SUPPORT EQUIPMENT for VENTILATORY INSUFFICIENCY is suitable for use where some PHYSIOLOGICAL ALARM CONDITION monitoring is required to prevent the absence or degradation of the ventilatory support, which in turn could cause the compromise of the health of the PATIENT.

[SOURCE: ISO 80601-2-80:2018, 201.3.204]

3.65
VENTILATORY SUPPORT EQUIPMENT
ME EQUIPMENT, suitable for domiciliary use without continuous professional supervision, intended to augment or provide ventilation of the lungs of a PATIENT who is not VENTILATOR-DEPENDENT

Note 1 to entry: VENTILATORY SUPPORT EQUIPMENT is a type of VENTILATOR, but is not a ventilator for VENTILATOR-DEPENDENT PATIENT.

Note 2 to entry: A PATIENT suitable for VENTILATORY SUPPORT EQUIPMENT requires a narrow spectrum of ventilation modalities and monitoring for appropriate management.

[SOURCE: ISO 80601-2-80:2018, 201.3.205]

4 * Applications of means of ventilation

4.1 Critical care VENTILATOR

4.1.1 Appropriate standard

The appropriate standard for this application is ISO 80601-2-12.

4.1.2 Intended PATIENT

The intended PATIENTS are those who exhibit an illness acuity, fragility or instability level up to and including the most severe level [e.g.acute respiratory distress syndrome (ARDS), sepsis, etc.]. In the worst-case scenario, they are dependent upon the VENTILATOR to maintain adequate gas exchange (i.e. they are VENTILATOR-DEPENDENT). Without such support, the most fragile of these PATIENTS would likely experience serious deterioration of health or death.

These PATIENTS require up to and including the widest spectrum of ventilation modalities and monitoring methods for appropriate management. The need for these PATIENTS to be assessed by appropriate HEALTHCARE PROFESSIONALS can range from infrequent to nearly constant. These PATIENTS require up to and including the highest need of ventilation-related care from a caregiver.

4.1.3 USE ENVIRONMENT

The intended USE ENVIRONMENT is the acute-care environment in a PROFESSIONAL HEALTHCARE FACILITY including transport within the PROFESSIONAL HEALTHCARE FACILITY.

Generally, the USE ENVIRONMENT for a critical care VENTILATOR is described as follows:

— indoor with stable temperature and humidity with little direct exposure to sunlight, water or pollutants;

— stable facility SUPPLY MAINS with backup in the event of power system failure;

NOTE This is the facility power, not VENTILATOR power.

— reliable protective earth;

— continuously supervised by HEALTHCARE PROFESSIONAL OPERATOR;

— intra-facility transport as required.

Other non-acute-care environments, if under continuous supervision by an appropriate HEALTHCARE PROFESSIONAL OPERATOR, for a critical care VENTILATOR include:

— hospitals,

— physician offices,

— freestanding surgical centres,

— dental offices,

— freestanding birthing centres,

— limited care facilities,

— first aid rooms or rescue rooms,

— multiple treatment facilities, and

— general care wards.

Typically, the intended USE ENVIRONMENTS for a critical care VENTILATOR do not include:

— the EMERGENCY MEDICAL SERVICES ENVIRONMENT, as these VENTILATORS typically do not meet the more stringent environmental requirements;

— the HOME HEALTHCARE ENVIRONMENT, as these VENTILATORS typically do not meet the higher requirements for shock and vibration, electromagnetic compatibility, power supply variability and wider environmental operating limits. Furthermore, this domain is generally not supervised by an appropriate HEALTHCARE PROFESSIONAL OPERATOR.

4.1.4 Intended OPERATOR

The intended OPERATOR is a HEALTHCARE PROFESSIONAL trained in the application and management of artificial ventilation.

4.2 VENTILATOR for a VENTILATOR-DEPENDENT PATIENT in the HOME HEALTHCARE ENVIRONMENT

4.2.1 Appropriate standard

The appropriate standard for this application is ISO 80601-2-72.

4.2.2 Intended PATIENT

The intended PATIENTS are those who exhibit an illness acuity, fragility or instability level up to and including a moderate level (e.g. traumatic spinal cord injury, moderate to severe restrictive airway disease, moderate to severe obstructive airway disease or degenerative disease resulting in their unsupported respiratory effort being insufficient to sustain life). In the worst-case scenario, they are dependent on the VENTILATOR to maintain adequate gas exchange (i.e. they are VENTILATOR-DEPENDENT). Without such support, the most fragile of these PATIENTS would likely experience serious deterioration of health or death.

These PATIENTS require up to and including a moderate spectrum of ventilation modalities and monitoring methods for appropriate management. The need for these PATIENTS to be assessed by

appropriate HEALTHCARE PROFESSIONALS can range from infrequent to moderate. These PATIENTS require up to and including a moderate need of ventilation-related intervention care from a caregiver.

4.2.3 USE ENVIRONMENT

The intended USE ENVIRONMENT is the HOME HEALTHCARE ENVIRONMENT including transport within that domain, which includes transport by wheelchair, automobile, commercial aircraft (if intended for that use by the MANUFACTURER) and the like, but not in EMERGENCY MEDICAL SERVICES ENVIRONMENT vehicles, including aircraft.

Generally, the USE ENVIRONMENT for a VENTILATOR for a VENTILATOR-DEPENDENT PATIENT in the HOME HEALTHCARE ENVIRONMENT is described as follows:

— residential-like, including non-PROFESSIONAL HEALTHCARE FACILITY workplaces, with variable temperature and humidity, likely exposure to sunlight, water and pollutants;

— potentially unreliable SUPPLY MAINS;

— protective earth, if provided, can be unreliable and therefore cannot be relied upon for safety;

— non-continuous support by a LAY OPERATOR.

PROFESSIONAL HEALTHCARE FACILITIES such as the following are also appropriate environments of use.

— Non-critical-care applications within hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and general care wards.

Typically, the intended USE ENVIRONMENT for a VENTILATOR for a VENTILATOR-DEPENDENT PATIENT in the HOME HEALTHCARE ENVIRONMENT does not include:

— the EMERGENCY MEDICAL SERVICES ENVIRONMENT, as these VENTILATORS typically do not meet the more stringent environmental requirements.

4.2.4 Intended OPERATOR

The intended OPERATOR is a LAY OPERATOR as well as the supervising clinician or the HEALTHCARE PROFESSIONAL OPERATOR. The MANUFACTURER has to define the intended USER GROUPS (e.g. LAY OPERATOR, supervising clinician, HEALTHCARE PROFESSIONAL OPERATOR) in the instruction for use.

It is the responsibility of the supervising clinician or the HEALTHCARE PROFESSIONAL OPERATOR to set up the VENTILATOR for the initial use and to train the LAY OPERATOR in the safe use of the VENTILATOR. Also, when used in a PROFESSIONAL HEALTHCARE FACILITY, the VENTILATOR is expected to be managed by a HEALTHCARE PROFESSIONAL OPERATOR.

4.3 VENTILATOR for the EMERGENCY MEDICAL SERVICES ENVIRONMENT

4.3.1 Appropriate standard

The appropriate standard for this application is ISO 80601-2-84.

4.3.2 Intended PATIENT

The intended PATIENTS are those who exhibit an illness acuity, fragility or instability level up to and including the most severe level (e.g. ARDS, sepsis, or life-threatening bodily injury, etc.).

In the worst-case scenario, they are dependent on the VENTILATOR to maintain adequate gas exchange (i.e. they are VENTILATOR-DEPENDENT). Without such support, the most fragile of these PATIENTS would likely experience serious deterioration of health or death.

These PATIENTS require up to and including a moderate spectrum of ventilation modalities and monitoring methods for appropriate management. The need for these PATIENTS to be assessed by appropriate HEALTHCARE PROFESSIONALS can range from infrequent to nearly constant. These PATIENTS require up to and including the highest need of ventilation-related intervention care from a caregiver.

4.3.3 USE ENVIRONMENT

The intended USE ENVIRONMENT is the interior of specially equipped emergency ground and air transport vehicles as well as removal from the vehicle and use (including outdoors) at the scene of an emergency where the VENTILATOR is carried by the OPERATOR and transient operating conditions can exist. Typically, such emergency vehicles are specially designed and equipped to provide adequate medical care (e.g. medical supplies, electrical power, breathing gasses and water). HEALTHCARE PROFESSIONAL OPERATORS are continually present to administer appropriate medical care.

Although the EMS ENVIRONMENT is generally outside of a PROFESSIONAL HEALTHCARE FACILITY, such facilities frequently utilize an EMS VENTILATOR for intra-facility transport.

The levels of shock and vibration experienced in the EMS ENVIRONMENT are expected to exceed the levels found in PROFESSIONAL HEALTHCARE FACILITIES and in the HOME HEALTHCARE ENVIRONMENT. The ambient noise level can be quite high during transport. The ambient light levels range from full daylight to twilight.

4.3.4 Intended OPERATOR

An EMS VENTILATOR is intended to be used by HEALTHCARE PROFESSIONAL OPERATOR with varying levels of training and education. When used in emergency transport, the OPERATOR will likely be an emergency medical technician (EMT), paramedic or emergency physician.

The MANUFACTURER has to define the intended USER GROUPS [e.g. paramedics, emergency medical technicians (EMTs), emergency nurses, emergency physicians, respiratory therapists, etc.] in the instructions for use.

4.4 HOME HEALTHCARE ENVIRONMENT VENTILATOR for a PATIENT with VENTILATORY INSUFFICIENCY

4.4.1 Appropriate standard

The appropriate standard for this application is ISO 80601-2-80.

4.4.2 Intended PATIENT

The intended PATIENTS are those who exhibit an illness acuity, fragility or instability level up to and including a moderate level [e.g. severe chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia and muscular dystrophy, etc.].

In the worst-case scenario, their dependence on the VENTILATOR to maintain adequate gas exchange is moderate These PATIENTS might be prohibited from certain activities that they might normally pursue and this would likely interfere with daily living. The most fragile of these PATIENTS would likely experience injury, but not serious injury or death, with the loss of this artificial ventilation. For these PATIENTS, it is likely that ventilatory support is needed during waking and moving hours in order to facilitate mobility and functional independence in the activities of daily living.

These PATIENTS require a narrow spectrum of ventilation modalities and monitoring for appropriate management. The need for these PATIENTS to be assessed by appropriate HEALTHCARE PROFESSIONALS is infrequent. These PATIENTS require only a low level of ventilation-related intervention care from a caregiver.

4.4.3 USE ENVIRONMENT

The intended USE ENVIRONMENT is the HOME HEALTHCARE ENVIRONMENT including transport within that domain, which includes transport by wheelchair, automobile, commercial aircraft (if intended for that use by the MANUFACTURER) and the like, but not in EMERGENCY MEDICAL SERVICES ENVIRONMENT vehicles, including aircraft.

Generally, the USE ENVIRONMENT for a VENTILATORY INSUFFICIENCY HOME HEALTHCARE ENVIRONMENT VENTILATOR is described as follows:

— residential-like, including non-PROFESSIONAL HEALTHCARE FACILITY workplaces, with variable temperature and humidity, likely exposure to sunlight, water and pollutants;

— potentially unreliable SUPPLY MAINS;

— protective earth, if provided, can be unreliable and therefore cannot be relied upon for safety;

— non-continuous support by a LAY OPERATOR.

PROFESSIONAL HEALTHCARE FACILITIES such as the following are also appropriate USE ENVIRONMENTS:

— hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and general care wards.

Typically, the intended USE ENVIRONMENT for a VENTILATORY INSUFFICIENCY HOME HEALTHCARE ENVIRONMENT VENTILATOR does not include:

— the EMERGENCY MEDICAL SERVICES ENVIRONMENT, as these VENTILATORS typically do not meet the more stringent environmental requirements.

4.4.4 Intended OPERATOR

The intended OPERATOR is a LAY OPERATOR as well as the supervising clinician or the HEALTHCARE PROFESSIONAL OPERATOR. The MANUFACTURER has to define in the instruction for use the intended USER GROUPS (e.g. LAY OPERATOR, supervising clinician, HEALTHCARE PROFESSIONAL OPERATOR).

It is the responsibility of the supervising clinician or the HEALTHCARE PROFESSIONAL OPERATOR to set up the VENTILATOR for the initial use and to train the LAY OPERATOR in the safe use of the VENTILATOR. Also, when used in a PROFESSIONAL HEALTHCARE FACILITY, the VENTILATOR is expected to be managed by a HEALTHCARE PROFESSIONAL OPERATOR.

4.5 HOME HEALTHCARE ENVIRONMENT VENTILATOR for a PATIENT with VENTILATORY IMPAIRMENT

4.5.1 Appropriate standard

The appropriate standard for this application is ISO 80601-2-79.

4.5.2 Intended PATIENT

The intended PATIENTS are those who exhibit a minimal level of illness acuity, fragility, or instability [e.g. mild to moderate chronic obstructive pulmonary disease (COPD), etc.]. Their dependence on the VENTILATOR to maintain adequate gas exchange is minimal. Without such support, these PATIENTS would likely experience some difficulty with activities that they might normally pursue and this might interfere with daily living but would not experience injury. These PATIENTS can gain adequate relief from fatigue related to the work of breathing by using VENTILATORY SUPPORT EQUIPMENT during the night and while taking breaks during the day. This can enable a PATIENT with VENTILATORY-IMPAIRMENT to continue to move about and participate in the activities of daily living. Non-TRANSIT-OPERABLE

VENTILATORY SUPPORT EQUIPMENT that provides ventilatory support at the bedside and beside a chair or other resting place should be adequate in this application.

These PATIENTS require a narrow spectrum of ventilation modalities and monitoring for appropriate management. The need for these PATIENTS to be assessed by appropriate HEALTHCARE PROFESSIONALS is infrequent. These PATIENTS require a low need of ventilation-related intervention care from a caregiver.

4.5.3 USE ENVIRONMENT

The intended USE ENVIRONMENT is the HOME HEALTHCARE ENVIRONMENT, including transport within that domain, which includes transport by wheelchair, automobile, commercial aircraft (if intended for that use by the MANUFACTURER) and the like, but not in EMERGENCY MEDICAL SERVICES ENVIRONMENT vehicles, including aircraft.

Generally, the USE ENVIRONMENT for a VENTILATORY IMPAIRMENT HOME HEALTHCARE ENVIRONMENT VENTILATOR is described as follows:

— residential-like, including non-PROFESSIONAL HEALTHCARE FACILITY workplaces, with variable temperature and humidity, likely exposure to sunlight, water and pollutants;

— potentially unreliable SUPPLY MAINS;

— protective earth, if provided, can be unreliable and therefore cannot be relied upon for safety;

— non-continuous support by a LAY OPERATOR.

PROFESSIONAL HEALTHCARE FACILITIES such as the following are also appropriate environments of use:

— hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, multiple treatment facilities and general care wards.

Typically, the intended USE ENVIRONMENT for a VENTILATORY IMPAIRMENT HOME HEALTHCARE ENVIRONMENT VENTILATOR does not include:

— the EMERGENCY MEDICAL SERVICES ENVIRONMENT, as these VENTILATORS typically do not meet the more stringent environmental requirements.

4.5.4 Intended OPERATOR

The intended OPERATOR is a LAY OPERATOR as well as the supervising clinician or the HEALTHCARE PROFESSIONAL OPERATOR. The MANUFACTURER has to define the intended USER GROUPS (e.g. LAY OPERATOR, supervising clinician, HEALTHCARE PROFESSIONAL OPERATOR) in the instruction for use.

It is the responsibility of the supervising clinician or the HEALTHCARE PROFESSIONAL OPERATOR to set up the VENTILATOR for the initial use and to train the LAY OPERATOR in the safe use of the VENTILATOR. Also, when used in a PROFESSIONAL HEALTHCARE FACILITY, the VENTILATOR is expected to be managed by a HEALTHCARE PROFESSIONAL OPERATOR.

4.6 Gas-powered emergency resuscitators

4.6.1 Appropriate standard

The appropriate standard for this application is ISO 10651-5.

4.6.2 Intended PATIENT

The intended PATIENTS are those for whom resuscitation is essential at the scene of an emergency or rescue where a PATIENT can be given temporary medical care prior to being placed on an EMS VENTILATOR.

EXAMPLE 1 PATIENT undergoing cardiopulmonary resuscitation (CPR).

EXAMPLE 2 Victim being carried from a fire.

4.6.3 USE ENVIRONMENT

The intended USE ENVIRONMENT is rescue or emergency field use by a first responder (e.g. fire fighter or emergency medical technician). A gas-powered emergency resuscitator is small, lightweight and HAND-HELD. It can be carried on the belt of a first responder. Its use is intended to be temporary (i.e. until the PATIENTS can breathe on their own following CPR or until an EMS VENTILATOR is available).

Rough handling is expected as this is an extension of the EMS ENVIRONMENT. The levels of shock and vibration experienced in the EMS ENVIRONMENT are expected to exceed the levels found in PROFESSIONAL HEALTHCARE FACILITIES and in the HOME HEALTHCARE ENVIRONMENT.

4.6.4 Intended OPERATOR

A gas-powered emergency resuscitator is intended to be used by minimally trained first responders including bystanders administering CPR as well as firefighters and EMTs.

4.7 OPERATOR-powered resuscitators

4.7.1 Appropriate standard

The appropriate standard for this application is ISO 10651-4.

4.7.2 Intended PATIENT

The intended patient is any PATIENT requiring resuscitation or any ventilated PATIENT who requires manual ventilation in place of a VENTILATOR or as backup for a failed VENTILATOR.

4.7.3 USE ENVIRONMENT

Any environment where a VENTILATOR is utilized.

4.7.4 Intended OPERATOR

The intended OPERATOR is a trained LAY OPERATOR as well as a HEALTHCARE PROFESSIONAL OPERATOR.

4.8 SLEEP APNOEA BREATHING THERAPY EQUIPMENT

4.8.1 Appropriate standard

The appropriate standard for this application is ISO 80601-2-70.

4.8.2 Intended PATIENT

The intended PATIENTS are those who exhibit a minimal level of illness acuity, fragility or instability. Their dependence on the ME EQUIPMENT is solely for the purpose of treating obstructive sleep apnoea. Without such support these PATIENTS would likely experience obstructive sleep apnoea.

These PATIENTS require a narrow spectrum of ventilation modalities and monitoring for appropriate management. The need for these PATIENTS to be assessed by appropriate HEALTHCARE PROFESSIONALS is infrequent. These PATIENTS require a little or no ventilation-related intervention care from a caregiver.

4.8.3 USE ENVIRONMENT

The intended environment of use is the HOME HEALTHCARE ENVIRONMENT where the PATIENT sleeps.

Generally, the USE ENVIRONMENT for SLEEP APNOEA BREATHING THERAPY EQUIPMENT is described as follows:

— residential-like, including non-PROFESSIONAL HEALTHCARE FACILITY workplaces, with variable temperature and humidity, likely exposure to sunlight, water and pollutants;

— potentially unreliable SUPPLY MAINS;

— protective earth, if provided, can be unreliable and therefore cannot be relied upon for safety;

— non-continuous support by a LAY OPERATOR.

PROFESSIONAL HEALTHCARE FACILITIES such as these are also appropriate environments of use:

— hospitals, freestanding birthing centres, limited care facilities, and general care wards where the PATIENT is expected to sleep.

4.8.4 Intended OPERATOR

SLEEP APNOEA BREATHING THERAPY EQUIPMENT is designed to be used by the PATIENT, a LAY OPERATOR, as well as a HEALTHCARE PROFESSIONAL OPERATOR. Initial set up of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, in either the HOME HEALTHCARE ENVIRONMENT or the PROFESSIONAL HEALTHCARE FACILITY, is performed by a HEALTHCARE PROFESSIONAL OPERATOR. In the HOME HEALTHCARE ENVIRONMENT, a HEALTHCARE PROFESSIONAL OPERATOR trains the PATIENT in the safe operation of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

The clauses and subclauses in this annex have been so numbered to correspond to the clauses and subclauses in this document to which they refer. The numbering is, therefore, not consecutive.

A.2 Rationale for particular clauses and subclauses

Introduction

It has become apparent that there were different opinions as to which VENTILATOR should be used in what type of environment for which type of PATIENT as indicated by the relevant standards. For example, could a HOME HEALTHCARE ENVIRONMENT VENTILATOR complying with ISO 80601-2-72 or a SLEEP APNOEA BREATHING THERAPY EQUIPMENT complying with ISO 80601-2-70 be used in the PROFESSIONAL HEALTHCARE FACILITY? Could a critical care VENTILATOR complying with ISO 80601-2-12 be used in the HOME HEALTHCARE ENVIRONMENT or an EMS ENVIRONMENT? Which VENTILATOR is appropriate for which PATIENT? This confusion prompted the creation of this document to provide guidance on these matters.

This document identifies and defines the issues using a PATIENT-centric language, based on a hierarchy of *intended PATIENT*, *intended-USE ENVIRONMENT* and *intended OPERATOR.* With this approach, the document seeks to put the emphasis on PATIENT need, rather than on the equipment. In this manner, the committees believe that MANUFACTURERS, authorities having jurisdiction and USERS would gain broad insight into the issue of PATIENT *need,* where and by whom, which ultimately drives the design of the appropriate ventilation equipment. To this end, this document focuses on the full spectrum of PATIENT need – from resuscitation to the intensive care unit (ICU) to obstructive sleep apnoea and in which place of care/therapy is defined by the PATIENT, who at the same time can be the OPERATOR.

3.15 — EMS ENVIRONMENT

The EMERGENCY MEDICAL SERVICE (EMS) ENVIRONMENT is considered uncontrolled. The environment includes, but is not limited to, vehicles, aircraft and PATIENTS' homes (all including use outdoors), as well as PROFESSIONAL HEALTHCARE FACILITIES. As a result, ME EQUIPMENT operating in the EMS ENVIRONMENT can experience AC and DC power fluctuations and outages. The environmental conditions (temperature, humidity, and altitude) in the EMS ENVIRONMENT are uncontrollable and therefore ME EQUIPMENT can experience a wide range of temperature, humidity and altitude. In addition, ME EQUIPMENT can experience rapid changes in temperature, humidity and altitude conditions in going from indoor or vehicle use into outdoor conditions.

In the EMS ENVIRONMENT, ME EQUIPMENT typically experiences high levels of mechanical shock and vibration due to the variety of operating environments.

In the EMS ENVIRONMENT, ME EQUIPMENT can experience high levels of electromagnetic disturbances from nearby electronic and wireless equipment. Examples are two-way radios, cell phones, overhead power lines and nearby electronic equipment.

3.22 — HOME HEALTHCARE ENVIRONMENT

The HOME HEALTHCARE ENVIRONMENT is considered uncontrolled and therefore ME EQUIPMENT experiences a wide range of temperature, humidity and altitude. For instance, the input SUPPLY MAINS can experience fluctuations or outages that can affect the operation of ME EQUIPMENT. The protective earth connection in some dwellings might not be designed to current electrical installation codes and therefore cannot be relied upon for a robust connection to protective earth. Input power from DC power sources, especially from motor vehicle batteries, can also experience wide fluctuations in output voltage. In the HOME HEALTHCARE ENVIRONMENT, ME EQUIPMENT will experience higher levels of mechanical shock and vibration and experience more drops and bumps than ME EQUIPMENT used in PROFESSIONAL HEALTHCARE FACILITIES. In the HOME HEALTHCARE ENVIRONMENT, ME EQUIPMENT can experience high levels of electromagnetic disturbances from nearby electronic and wireless equipment. Example are cell phones, power lines and nearby electronic equipment. The HOME HEALTHCARE ENVIRONMENT typically does not have any supervision by trained HEALTHCARE PROFESSIONAL OPERATORS.

3.43 — PROFESSIONAL HEALTHCARE FACILITY

Unlike the HOME HEALTHCARE ENVIRONMENT (see 3.23), the environment in a PROFESSIONAL HEALTHCARE FACILITY is considered to be a controlled environment. That is, SUPPLY MAINS is reliable with minimum variations and sometimes with backup power. The protective earth connection is robust. Temperature, humidity and altitude conditions are stable, and disruptions from electromagnetic disturbances are controlled.

Clause 4 — Applications of means of ventilation

Inherent in this hierarchical paradigm of applications is the recognition that PATIENTS with less ventilatory dysfunction (and therefore lower levels of need) can be managed using equipment that is less capable than can be used to manage PATIENTS with greater levels of ventilatory dysfunction.

As the USE ENVIRONMENT becomes less sophisticated, there is diminished SAFETY and OPERATOR expertise. On the other hand, areas with higher levels of sophistication require more means of PATIENT protection as well as more OPERATOR training and skill.

Ultimately the committees concluded that PATIENT need and USE ENVIRONMENT should determine the choice of equipment to render the appropriate care.

Annex B
(informative)

Comparison of the most important environmental characteristics

The information in Table B.1 is intended to highlight characteristic differences between the PROFESSIONAL HEALTHCARE FACILITY environment, HOME HEALTHCARE ENVIRONMENT and EMERGENCY MEDICAL SERVICES ENVIRONMENT. By highlighting differences in AC voltages, temperature ranges, shock/vibration testing levels and other requirements, the reader can compare equipment specifications with specific USER needs.

Table B.1 contains a comparison of the environmental characteristics.

Table B.1 — Comparison of the environmental characteristics

	Attribute	PROFESSIONAL HEALTHCARE FACILITY environment	HOME HEALTHCARE ENVIRONMENT	EMS ENVIRONMENT
1	AC SUPPLY MAINS input voltage range	90 % to 110 % of RATED	80 % to 110 % of RATED (for VENTILATOR-DEPENDENT PATIENTS) 85 % to 110 % of RATED (other)	85 % to 110 % of RATED
2	AC SUPPLY MAINS input frequency range	— a frequency of ≤1 kHz, and — a frequency deviation of ≤ 1Hz from the nominal frequency up to 100 Hz and ≤1 % from the nominal frequency from 100 Hz to 1 kHz	— a frequency of ≤1 kHz, and — a frequency deviation of ≤ 1Hz from the nominal frequency up to 100 Hz and ≤1 % from the nominal frequency from 100 Hz to 1 kHz	85 % to 125 % of RATED range Airborne equipment only Section 16 of RTCA DO-160G[18]
3	DC SUPPLY MAINS input voltage range	—	12 V_{DC}: 12,4 V to 15,1 V 30 s dip to 10 V 24 V_{DC}: 24,8 V to 30,3 V 30 s dip to 20 V	12 V_{DC}: 12,4 V to 15,1 V 30 s dip to 10 V 24 V_{DC}: 24,8 V to 30,3 V 30 s dip to 20 V
4	Aircraft-provided SUPPLY MAINS	—	—	Section 16 of RTCA DO-160G[18]
5	Environmental conditions of transport and storage between uses	MANUFACTURER-specified	−25 °C to +5 °C (no relative humidity (RH) control) 5 °C to 35 °C (up to 90 % RH) > 35 °C to +70 °C (at a water vapour pressure up to 50 hPa) Reduced requirements are possible with marking	−40 °C to +5 °C (no RH control) 5 °C to 35 °C (up to 90 % RH) > 35 °C to +70 °C (at a water vapour pressure up to 50 hPa) Reduced requirements are possible with marking
6	Environmental operating pressure (altitude)	MANUFACTURER-specified	70 hPa to 106 kPa (~3 050 m to −450 m) Reduced requirements are possible with marking	62 hPa to 106 kPa (~3 660 m to −450 m) Reduced requirements are possible with marking

Table B.1 *(continued)*

	Attribute	PROFESSIONAL HEALTHCARE FACILITY environment	HOME HEALTHCARE ENVIRONMENT	EMS ENVIRONMENT
7	Environmental operating temperature and humidity	MANUFACTURER-specified	+5 °C to +40 °C 15 % to 93 % RH Reduced requirements are possible with marking	0 °C to +40 °C 15 % to 90 % RH Reduced requirements are possible with marking
8	Transient environmental operating temperature and humidity	—	5 °C to 40 °C. [test is thermal shock: high to low, then low to high; not a cold start test] Reduced requirements are possible with marking	−20 °C to +50 °C 15 % to 90 % RH [test always starts at room temperature with, 20 min test at extremes] Reduced requirements are possible with marking
9	Electrical classification	Class I, Class II, or Internally Powered B, BF or CF Applied Parts	Class II or Internally Powered Class I permitted only if installed by electrician No functional earth terminal BF or CF Applied Parts	Class II or Internally Powered No functional earth terminal BF or CF Applied Parts
10	Marking/display	Legible in hallway lighting and bright lighting (100 lx to 1 500 lx)	Legible in hallway lighting and bright lighting (100 lx to 10 000 lx)	Legible in twilight and full daylight (10 lx to 10 000 lx)
11	Ingress protection[19]	IP21 IP22 recommended	At least IP21 Transit-operable: At least IP22	Transportable: at least IP33 Fixed: at least IP22
12	Interruption of SUPPLY MAINS power/internal electrical power source	None (future update will mandate an internal electrical power source providing at least a 30 min run time)	ISO 80601-2-72: internal electrical power source ISO 80601-2-80: internal electrical power source ISO 80601-2-70: none and ISO 80601-2-79: optional	Internal electrical power source or manually driven resuscitator, 20 min minimum
13	Mechanical strength types	TRANSIT-OPERABLE and MOBILE (on wheels) PORTABLE (carried)	TRANSIT-OPERABLE and PORTABLE TRANSIT-OPERABLE and MOBILE (cart)	TRANSIT-OPERABLE and FIXED or PERMANENTLY INSTALLED road ambulance with mounting Transportable Airborne equipment with mounting
14	Free fall (by mass)	PORTABLE only ≤1 kg: 0,25 m >1 kg and <10 kg: 0,1 m >10 kg and <50 kg: 0,05 m >50 kg: 0,01 m	≤1 kg: 0,25 m >1 kg and <10 kg: 0,1 m >10 kg and <50 kg: 0,05 m >50 kg: 0,01 m	TRANSPORTABLE only ≤1 kg: 1,0 m >1 kg and <10 kg: 0,5 m >10 kg and <50 kg: 0,25 m >50 kg: 0,1 m

Table B.1 *(continued)*

	Attribute	PROFESSIONAL HEALTHCARE FACILITY environment	HOME HEALTHCARE ENVIRONMENT	EMS ENVIRONMENT
15	Shock	MOBILE only 150 m/s² (15 g) for 11 ms or 300 m/s² (30 g) for 6 ms PORTABLE only 50 m/s² (5 g); 6 ms	TRANSIT-OPERABLE only 150 m/s² (15 g) for 11 ms or 300 m/s² (30 g) for 6 ms	TRANSPORTABLE only 300 m/s² (30 g) for 11 ms or 1 000 m/s² (100 g) for 6 ms FIXED airborne equipment only 300 m/s² (30 g) for 11 ms
16	Vibration	MOBILE only 10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$ 100 Hz to 500 Hz: −6 db per octave PORTABLE only 10 Hz to 100 Hz: 0,33 $(m/s^2)^2/Hz$ 100 Hz to 500 Hz: −6 db per octave	TRANSIT-OPERABLE only 10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$ 100 Hz to 200 Hz: −3 db per octave 200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$	TRANSPORTABLE only 10 Hz to 100 Hz: 5,0 $(m/s^2)^2/Hz$ 100 Hz to 200 Hz: −7 db per octave 200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2/Hz$ FIXED airborne equipment only Section 8 of RTCA DO-160G[18] Category S for fixed wing Category U for rotary wing
17	Mounting provisions	Manufacturer-specified	ISO 80601-2-72 and ISO 80601-2-80: Means to immobilize without the use of a TOOL	Provide means to securely mount the equipment
18	Electromagnetic emissions (not applicable for an non-electrical resuscitator)	IEC 60601-1-2[20], Class A or Class B	IEC 60601-1-2[20], Class B Airborne equipment only Section 21 of RTCA DO-160G Category M, electromagnetic emissions	IEC 60601-1-2[20], Class B Airborne equipment only Section 21 of RTCA DO-160G[18] Category M, electromagnetic emissions
19	EMC immunity (not applicable for an non-electrical resuscitator)	IEC 60601-1-2[20]	IEC 60601-1-2[20], HOME HEALTHCARE ENVIRONMENT	IEC 60601-1-2[20], HOME HEALTHCARE ENVIRONMENT

Annex C
(informative)

Applicable standard for the USE ENVIRONMENT

The information in Table C.1 is intended to link the appropriate product standard with its appropriate USE ENVIRONMENT. "X" represents the primary standard applicable for the USE ENVIRONMENT noted. "O" indicates this is not the primary product standard for the USE ENVIRONMENT although the product standard can be applicable, depending on the PATIENT needs being addressed. "N" indicates this product standard by itself does not confirm if the equipment is appropriate for use within this USE ENVIRONMENT. For equipment intended to be used in multiple environments, multiple standards can be appropriate.

Table C.1 — Applicable standards for the intended USE ENVIRONMENT

	Use environment	Applicable standard										
		ISO 80601-2-12[3]	ISO 80601-2-72[10]	ISO 10651-3[5] a	ISO 80601-2-80[9]	ISO 80601-2-79[7]	ISO 80601-2-70[11]	IEC 60601-1-11[14]	IEC 60601-1-12[7]	RTCA DO-160[18]	ISO 10651-4[2]	ISO 10651-5[1]
1	PROFESSIONAL HEALTHCARE FACILITY – emergency department	X	O	X	O	O	O	N	N	N	O	O
2	PROFESSIONAL HEALTHCARE FACILITY – intensive care unit	X	O	N	O	O	O	N	N	N	O	N
3	PROFESSIONAL HEALTHCARE FACILITY – general care ward	O	O	N	O	O	O	N	N	N	O	N
4	PROFESSIONAL HEALTHCARE FACILITY – outpatient clinic or step down/long-term care	X	O	N	O	O	O	N	N	N	O	N
5	PROFESSIONAL HEALTHCARE FACILITY – intra-facility transport	O	O	X	N	N	N	N	N	N	O	O
6	Emergency medical transport and inter-facility transport (land ambulance)	N	N	X	N	N	N	N	X	N	O	X
7	Emergency medical transport and inter-facility transport (air ambulance)	N	N	X	N	N	N	N	X	X	O	N
8	HOME HEALTHCARE ENVIRONMENT (non-TRANSIT-OPERABLE)	N	X	N	X	X	X	X	N	N	O	N

where

X is a primary standard for this USE ENVIRONMENT (choice based on specific PATIENT need);

O is a standard permitted to be used in this USE ENVIRONMENT (choice based on specific PATIENT need);

N is a standard not needed for this USE ENVIRONMENT.

a ISO 80601-2-84 will replace ISO 10651-3.

b Use on commercial aircraft is ultimately determined by the airline and the pilot.

Table C.1 *(continued)*

	Use environment	Applicable standard										
		ISO 80601-2-12[3]	ISO 80601-2-72[10]	ISO 10651-3[5] a	ISO 80601-2-80[9]	ISO 80601-2-79[7]	ISO 80601-2-70[11]	IEC 60601-1-11[14]	IEC 60601-1-12[7]	RTCA DO-160[18]	ISO 10651-4[2]	ISO 10651-5[1]
9	HOME HEALTHCARE ENVIRONMENT (TRANSIT-OPERABLE) wheelchair, walking, etc.	N	N	N	N	N	N	X	X	N	O	X
10	HOME HEALTHCARE ENVIRONMENT (TRANSIT-OPERABLE) on cars, busses, boats, private airplanes, etc.	N	X	N	X	X	O	X	N	N	O	N
11	HOME HEALTHCARE ENVIRONMENT (TRANSIT-OPERABLE) on commercial aircraft[b]	N	X	N	X	X	X	X	N	X	O	O

where

X is a primary standard for this USE ENVIRONMENT (choice based on specific PATIENT need);

O is a standard permitted to be used in this USE ENVIRONMENT (choice based on specific PATIENT need);

N is a standard not needed for this USE ENVIRONMENT.

a ISO 80601-2-84 will replace ISO 10651-3.

b Use on commercial aircraft is ultimately determined by the airline and the pilot.

Annex D
(informative)

Comparison of the appropriate product standard to the intended PATIENT, USE ENVIRONMENT and OPERATOR

The information in Table D.1 describes the intended USE ENVIRONMENT, intended PATIENT and intended OPERATOR for each product standard. This information allows the one to confirm whether the correct product standard has been applied to equipment. Equipment intended for use with multiple PATIENTS, USE ENVIRONMENTS or OPERATORS will likely need to comply with multiple product standards.

Table D.1 — Comparison of the appropriate product standard to the intended PATIENT, USE ENVIRONMENT and OPERATOR

	Product standard	Intended PATIENT	Intended USE ENVIRONMENT	Intended OPERATOR
1	ISO 80601-2-12[3]	PATIENT with a mild to severe level of illness acuity, fragility or instability (e.g. ARDS, sepsis, etc.) who can be VENTILATOR-DEPENDENT and can require a full spectrum of ventilation modalities and monitoring methods to maintain adequate gas exchange and prevent serious deterioration of health or death	PROFESSIONAL HEALTHCARE ENVIRONMENT: — critical care environment; — emergency department; — general care wards; — transport within the facility.	Setup and operation: HEALTHCARE PROFESSIONAL OPERATOR
2	ISO 80601-2-72[10]		HOME HEALTHCARE ENVIRONMENT	Operation: trained LAY OPERATOR Setup: HEALTHCARE PROFESSIONAL OPERATOR
			PROFESSIONAL HEALTHCARE FACILITIES for non-critical care applications as dictated by PATIENT need	Setup and operation: HEALTHCARE PROFESSIONAL OPERATOR
3	ISO 10651-3[4][a]	PATIENT with a mild to severe level of illness acuity, fragility or instability (e.g. ARDS, sepsis, life-threatening bodily injury, etc.) who can be VENTILATOR-DEPENDENT and require a moderate spectrum of modalities and monitoring methods to maintain adequate gas exchange and prevent serious deterioration of health or death	EMS ENVIRONMENT PROFESSIONAL HEALTHCARE FACILITIES	Setup and operation: HEALTHCARE PROFESSIONAL OPERATOR

[a] ISO 80601-2-84 will replace ISO 10651-3.

Table D.1 *(continued)*

	Product standard	Intended PATIENT	Intended USE ENVIRONMENT	Intended OPERATOR
4	ISO 80601-2-80[9]	PATIENT with a mild to moderate level of illness acuity, fragility or instability [e.g. severe chronic obstructive pulmonary disease (COPD) or amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia, muscular dystrophy, etc.] who has no more than a moderate level of ventilator dependence and requires only a narrow spectrum of modalities and monitoring methods to maintain adequate gas exchange and prevent interference with activities that the PATIENT might normally pursue as part of daily living	HOME HEALTHCARE ENVIRONMENT	Operation: trained LAY OPERATOR Setup: HEALTHCARE PROFESSIONAL OPERATOR
			PROFESSIONAL HEALTHCARE FACILITIES for non-critical care applications as dictated by specific PATIENT need	Setup and operation: HEALTHCARE PROFESSIONAL OPERATOR
5	ISO 80601-2-79[7]		HOME HEALTHCARE ENVIRONMENT	Operation: trained LAY OPERATOR Setup: HEALTHCARE PROFESSIONAL OPERATOR
			PROFESSIONAL HEALTHCARE FACILITIES for non-critical care applications as dictated by specific PATIENT need	Setup and operation: HEALTHCARE PROFESSIONAL OPERATOR
6	ISO 10651-4[2]		HOME HEALTHCARE ENVIRONMENT	Operation: trained LAY OPERATOR
			PROFESSIONAL HEALTHCARE FACILITIES	Operation: HEALTHCARE PROFESSIONAL OPERATOR
7	ISO 10651-5[1]	PATIENTS for whom resuscitation is essential at the scene of an emergency or rescue where a PATIENT can be given temporary medical care prior to being placed on a EMS VENTILATOR.	Rescue or emergency use. Its use is intended to be temporary (i.e. until the PATIENT can breathe spontaneously following CPR or until a EMS VENTILATOR is available)	Operation: minimally trained first responders including bystanders administering CPR as well as firefighters and EMTs (emergency medical technicians).
8	ISO 80601-2-70[11]	PATIENTS with obstructive sleep apnoea	HOME HEALTHCARE ENVIRONMENT	Operation: trained LAY OPERATOR Setup: HEALTHCARE PROFESSIONAL OPERATOR
			PROFESSIONAL HEALTHCARE FACILITIES dictated by specific PATIENT need	Setup and operation: HEALTHCARE PROFESSIONAL OPERATOR

[a] ISO 80601-2-84 will replace ISO 10651-3.

Annex E
(informative)

Comparison of the categories of PATIENT acuity to the appropriate product standard

The information in Table E.1 highlights PATIENT attributes for which specific product standards have been written. The attributes include:

— the state of the PATIENT's health (fragility/acuity/stability);

— the PATIENT's dependency on artificial ventilation;

— the consequence of loss of ventilation;

— the required range of ventilation modes and corresponding PATIENT monitoring;

— how often the PATIENT needs assessing by a HEALTHCARE PROFESSIONAL;

— how often the PATIENT needs respiratory-related care.

Comparing these attributes across several product standards can assist a clinician in selecting the appropriate equipment to meet a PATIENT's needs.

Table E.1 contains a comparison of the categories of PATIENT acuity to the appropriate VENTILATOR product standard. Not included in Table E.1 are:

— SLEEP APNOEA THERAPY EQUIPMENT (ISO 80601-2-70[11]) is only suitable for PATIENTS with sleep apnoea. SLEEP APNOEA THERAPY EQUIPMENT is not intended for PATIENTS requiring any form of VENTILATOR support.

— OPERATOR-powered resuscitators (ISO 10651-4[2]) are used in all environments as an alternative (backup) to the primary means of ventilation.

— Gas-powered emergency resuscitators (ISO 10651-5[1]) are only suitable for PATIENTS for whom resuscitation is essential at the scene of an emergency or rescue where a PATIENT can be given temporary medical care prior to being placed on a EMS VENTILATOR.

Table E.1 — Comparison of the categories of PATIENT acuity to the appropriate product standard

	PATIENT attribute	Product standard				
		ISO 80601-2-12[3] Critical care	ISO 80601-2-72[10] Dependent	ISO 80601-2-80[9] Insufficiency	ISO 80601-2-79[7] Impairment	ISO 10651-3[4] ISO 80601-2-84[4] EMS
1	PATIENT ventilatory support dependence: Worst-case measure of the PATIENT'S reliance on the VENTILATOR to maintain adequate gas exchange	VENTILATOR-DEPENDENT	VENTILATOR-DEPENDENT	Moderate	Minimal	VENTILATOR-DEPENDENT
2	Consequences of loss of artificial ventilation	The most fragile PATIENT would likely experience serious deterioration of health or death.	The most fragile PATIENT would likely experience serious deterioration of health or death.	The most fragile PATIENT would likely experience injury but not serious injury or death. These PATIENTS might be prohibited from certain activities that the PATIENT might normally pursue and this would interfere with daily living.	This PATIENT would likely experience some difficulty with activities that the PATIENT might normally pursue, and this would interfere with daily living but would not experience injury.	The most fragile PATIENT would likely experience serious deterioration of health or death.
3	Variety of ventilation delivery and monitoring methods required. Spectrum of ventilation modalities, monitoring methods and procedures necessary for ventilatory management	Up to and including the widest spectrum of ventilation modalities, monitoring methods and procedures for appropriate ventilatory management	Up to and including a moderate spectrum of ventilation modalities, monitoring methods and procedures for appropriate ventilatory management	A narrow spectrum of ventilation modalities and monitoring for appropriate ventilatory management	A narrow spectrum of ventilation modalities and monitoring for appropriate ventilatory management	Up to and including a moderate spectrum of ventilation modalities and monitoring methods for appropriate ventilatory management

Table E.1 *(continued)*

	PATIENT attribute	Product standard				
		ISO 80601-2-12[3] **Critical care**	**ISO 80601-2-72**[10] **Dependent**	**ISO 80601-2-80**[9] **Insufficiency**	**ISO 80601-2-79**[7] **Impairment**	**ISO 10651-3**[4] **ISO 80601-2-84**[4] **EMS**
4	Illness acuity or fragility	Up to and including the most severe (e.g. ARDS, sepsis, etc.)	Up to and including a moderate level [e.g. traumatic spinal cord injury, severe chronic obstructive pulmonary disease (COPD), amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia or muscular dystrophy, etc.]	Up to and including a moderate level [e.g. severe chronic obstructive pulmonary disease (COPD) and amyotrophic lateral sclerosis (ALS), etc.]	Minimal level [e.g. mild to moderate chronic obstructive pulmonary disease (COPD), etc.]	Up to and including the most severe (e.g. ARDS, sepsis, life-threatening bodily injury, etc.)
5	PATIENT stability: How often the PATIENT'S ventilatory management needs assessing by a HEALTHCARE PROFESSIONAL	From infrequent (stable) to nearly constant (unstable)	From infrequent (stable) to moderate need (moderately unstable)	Infrequent (stable)	Infrequent (stable)	From infrequent (stable) to nearly constant (unstable)
6	How often the PATIENT requires some form of ventilation-related care from a caregiver	Up to and including the highest need of ventilation-related intervention	Up to and including a moderate need of ventilation-related intervention	A low need of ventilation-related intervention	A low need of ventilation-related intervention	Up to and including the highest need of ventilation-related intervention

Annex F
(informative)

Comparison of respiratory standards technical requirements

The information in Table F.1 compares a cross-section of the technical requirements within several product standards. By comparing similar requirements across multiple product standards, one can better understand the requirement continuum from PATIENT comfort equipment up to and including equipment providing the highest level of respiratory support and monitoring. This annex is also intended to guide product standard development and authorities having jurisdiction.

Table F.1 — Comparison of respiratory standards technical requirements

	Equipment attribute	ISO 80601-2-12: —[3]a Critical care	ISO 80601-2-72: 2015[10] Dependent	ISO 10651-3:1997 [5]b EN 794-3:1998 EMS	ISO 10651-6:2004 [21]c Non-dependent	ISO 80601-2-80:2018 [9]d Insufficiency (N2096)	ISO 80601-2-79:2018 [8]d Impairment (N2094)	ISO 10651-5:2006 [1] Gas powered	ISO 10651-4:2002 [2] OPERATOR powered	ISO 80601-2-70: 2015[11] Sleep apnoea
1	**Supply mains**	AC	AC + alternative + DC should	AC + DC	AC	AC + DC	AC + alternative + DC should	gas	No	AC
2	**Battery backup**	Optionale	Required	Optionale	Optional	Required	Optional	No	No	No
3	**Mechanical fixation feature**	No	Required	No	No	Required	Optional	No	No	No
4	**Essential performance**	Required	Required	No	No	Required	No	No	No	No
5	**Gas pipeline Gas input connection**	Required	Optional	Optional	No	Optional	No	Optional	Optional	No
6	**Gas pipeline SFC for gas input pressure**		1 000 kPa (or twice RATED pressure in excess of 600 kPa)	1 000 kPa (or twice RATED pressure in excess of 600 kPa)	No	1 000 kPa (or twice RATED pressure in excess of 600 kPa)	No	1 000 kPa	1 000 kPa (or twice RATED pressure in excess of 600 kPa)	No

No: Feature or attribute is not mentioned or requirement is specifically excluded.

Required: Feature is explicitly required by the standard.

Optional: Feature is optional-one way to implement a requirement.

Should: Feature is recommended by the standard.

a A new edition is being developed.

b Is being replaced by ISO 80601-2-84[4].

c Is being replaced by ISO 80601-2-79[7] and ISO 80601-2-80[9].

d Is a partial replacement for ISO 10651-6[21].

e Under consideration with next revision.

f Required to be equipped with or an external MONITORING EQUIPMENT is required prior to being put into service.