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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).

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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]