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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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

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).

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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]

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