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ISO 80601-2-80

Medical electrical equipment —

Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

Appareils électromédicaux —

Partie 2-80: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'assistance ventilatoire en cas d'insuffisance ventilatoire

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 or www.iec.ch/members_experts/refdocs).

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This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care,* and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215 *Respiratory and anaesthetic equipment,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-80:2018), which has been technically revised.

The main changes are as follows:

- alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020;
- clarified *maximum limited pressure* requirements;
- clarified high *airway pressure alarm condition* requirements;
- added requirements for *ventilatory support equipment system recovery*; and
- harmonization with ISO 20417, where appropriate.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

Introduction

This document specifies requirements for *ventilatory support equipment* that is intended for use in the *home healthcare environment* for *patients* who are not dependent for *ventilation* for their life support. *Ventilatory support equipment* is frequently used in locations where *supply mains* is not reliable. *Ventilatory support equipment* is often supervised by non-healthcare personnel (*lay operators*) with varying levels of training. *Ventilatory support equipment* conforming with this document can be used elsewhere (i.e. in healthcare facilities).

Varying levels of ventilatory support is often used for *patients* who have stable ventilatory needs and in some cases, changing needs as their disease worsens. This document addresses *patients* who typically have severe enough respiratory function 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. This is best characterised by *lung* functions worse than[36]

— FEV_1/FVC[1] < 70 %, or

— FEV_1 < 50 % predicted

where

FEV_1 is the forced expiratory volume in 1 s, and

FVC is the forced vital capacity.

Examples of diseases that require ventilatory support are:

— moderate to severe Chronic Obstructive Pulmonary Disease (COPD);

— moderate Amyotrophic Lateral Sclerosis (ALS)[44];

— severe bronchopulmonary dysplasia; and

— muscular dystrophy.

Ventilatory support equipment intended for this group of *patients* typically can require *technical alarm conditions* in the event that *essential performance* is absent. 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 hours while *patients* are moving inside or outside the home in order to facilitate mobility and functional independence in the activities of daily living.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *terms defined in Clause 3 of the general standard*[2]*, in this document or as noted: italic type*; and

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

In referring to the structure of this document, the term:

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1 This is also known as the Tiffeneau-Pinelli index.

2 The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.*

— “clause” means one of the five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.); and

— “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

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

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

For the purposes of this document, the auxiliary verb:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— "can" indicates a possibility or capability; and

— "must" is used to express an external constraint.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking.

Medical electrical equipment

Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1, applies, except as follows:

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

This document applies to the *basic safety* and *essential performance* of *ventilatory support equipment,* as defined in 201.3.302, for *ventilatory insufficiency*, as defined in 201.3.302, hereafter also referred to as *ME equipment,* in combination with its *accessories*:

— intended for use in the *home healthcare environment*;

NOTE 2 In the *home healthcare environment*, the *supply mains* driving the *ventilatory support equipment* is often not reliable.

NOTE 3 Such *ventilatory support equipment* can also be used in *professional health care facilities*.

— intended for use by a *lay operator*;

— intended for use with *patients* who have *ventilatory insufficiency* or failure, the most fragile of which would likely experience injury with the loss of this *artificial ventilation*;

— intended for *transit-operable* use; and

— not intended for *patients* who are dependent on *artificial ventilation* for their immediate life support.

EXAMPLE 1 *Patients* with moderate to severe chronic obstructive pulmonary disease (COPD), moderate amyotrophic lateral sclerosis (ALS), severe bronchopulmonary dysplasia or muscular dystrophy.

Ventilatory support equipment is not considered to use a *physiologic closed-loop control system* unless it uses a physiological *patient* variable to adjust the *artificial ventilation* therapy settings.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the *ventilator breathing system* of *ventilatory support equipment* for *ventilatory insufficiency*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilatory support equipment* for *ventilatory insufficiency*.

EXAMPLE 2 Breathing sets, *connectors*, water traps, expiratory valve, *humidifier*, *breathing system filter*, external electrical power source, *distributed alarm system*.