Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment (ISO 80601-2-79:2018) (corrected version 11.2019)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-79:2019 sisaldab Euroopa standardi EN ISO 80601-2-79:2019 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-79:2019 consists of the English text of the European standard EN ISO 80601-2-79:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.09.2019.	Date of Availability of the European standard is 18.09.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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Appareils électromédicaux - Partie 2-79: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'assistance ventilatoire en cas de trouble ventilatoire (ISO 80601-2-79:2018)

Medizinische elektrische Geräte - Teil 2-79: Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten zur Atemunterstützung von Patienten mit Atmungsbeeinträchtigungen (ISO 80601-2-79:2018)

This European Standard was approved by CEN on 28 July 2019.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 30 October 2019.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

The text of ISO 80601-2-79:2018 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 80601-2-79:2019 by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2020, and conflicting national standards shall be withdrawn at the latest by March 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes l'EN ISO 10651-6:2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-79:2018 has been approved by CEN as EN ISO 80601-2-79:2019 without any modification.

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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 on 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 complying with this document can be used elsewhere (i.e. in healthcare facilities).

Ventilatory support is often needed for PATIENTS who have stable ventilatory needs. This document addresses PATIENTS who have significant respiratory dysfunction resulting in an abnormality of a sufficient degree to be noticeable by the PATIENT. This is best characterized by lung functions not worse than[3]:

— FEV_1/FVC[2] < 70 %; or

— 50 % ≤ FEV_1 < 80 % predicted

where

FEV_1 is the forced expiratory volume in 1 s, and

FVC is the forced vital capacity.

Examples of diseases that require ventilation support are

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

— neuromuscular/ amyotrophic lateral sclerosis (ALS);

— obese PATIENTS Obese Hypoventilation Syndrome (OHS);

— Cheyne–Stokes respiration (CSR/CSA).

CSR/CSA is an abnormal pattern of breathing characterized by progressively deeper and sometimes faster breathing, followed by a gradual decrease that results in a temporary stop in breathing called an apnoea. The pattern repeats, with each cycle usually taking 30 s to 2 min.

Cardiac PATIENTS with CSR/CSA might be breathless without having significant reduction in FEV_1. Reducing the work of breathing can help normalize their breathing.

This VENTILATORY SUPPORT EQUIPMENT is intended for PATIENTS who are spontaneously breathing and do not require ventilation for life support or intermittent periods of ventilation to maintain vital signs. VENTILATORY SUPPORT EQUIPMENT intended for this group of PATIENTS typically does not require PHYSIOLOGICAL ALARM CONDITIONS as no ESSENTIAL PERFORMANCE exists. 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.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

— Requirements and definitions: roman type;

[2] This is also known as the Tiffeneau-Pinelli index.

— *Test specifications: italic type*;

— 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;

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD[3], IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

— "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);

— "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.

The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve compliance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used express an external constraint.

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 AA.

The ISO and IEC 80601 family of documents are also parts of the IEC 60601 family of documents

[3] The general standard is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Medical electrical equipment

Part 2-79:
Particular requirements for the basic safety and essential performance of ventilatory support equipment for ventilatory impairment

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of VENTILATORY SUPPORT EQUIPMENT, as defined in 201.3.205, for VENTILATORY IMPAIRMENT, as defined in 201.3.202, hereafter also referred to as ME EQUIPMENT, in combination with its ACCESSORIES:

— intended for use in the HOME HEALTHCARE ENVIRONMENT;

— intended for use by a LAY OPERATOR; and

— intended for use with PATIENTS who have VENTILATORY IMPAIRMENT, the most fragile of these PATIENTS, would not likely experience injury with the loss of this artificial ventilation; and

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

EXAMPLE 1 PATIENTS with mild to moderate chronic obstructive pulmonary disease (COPD).

NOTE 1 In the HOME HEALTHCARE ENVIRONMENT, the SUPPLY MAINS is often not reliable.

NOTE 2 Such VENTILATORY SUPPORT EQUIPMENT can also be used in non-critical care applications of professional health care facilities.

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to the BREATHING SYSTEM of VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT for VENTILATORY IMPAIRMENT.

EXAMPLE 2 Breathing sets, connectors, water traps, expiratory valve, HUMIDIFIER, BREATHING SYSTEM FILTER, external electrical power source, DISTRIBUTED ALARM SYSTEM.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 3 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for:

— VENTILATORS or ACCESSORIES for VENTILATOR-DEPENDENT PATIENTS intended for critical care applications, which are given in ISO 80601-2-12;

— VENTILATORS or ACCESSORIES intended for anaesthetic applications, which are given in ISO 80601-2-13[4];

— VENTILATORS or ACCESSORIES intended for the emergency medical services environment, which are given in ISO 80601-2-84 [5] [4], the future replacement for ISO 10651-3[6];

— VENTILATORS or ACCESSORIES intended for VENTILATOR-DEPENDENT PATIENTS in the HOME HEALTHCARE ENVIRONMENT, which are given in ISO 80601-2-72;

— VENTILATORY SUPPORT EQUIPMENT or ACCESSORIES intended for VENTILATORY INSUFFICIENCY, which are given in ISO 80601-2-80[1];

— sleep apnoea therapy ME EQUIPMENT, which are given in ISO 80601-2-70[7];

— continuous positive airway pressure (CPAP) ME EQUIPMENT;

— high-frequency jet VENTILATORS (HFJVs);

— high-frequency oscillatory VENTILATORS (HFOVs)[8];

— oxygen therapy constant flow ME EQUIPMENT;

— cuirass or “iron-lung” ventilation equipment.

This document is a document in the IEC 60601 and IEC/ISO 80601 series of documents.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for VENTILATORY SUPPORT EQUIPMENT, as defined in 201.3.205, and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the VENTILATORY SUPPORT EQUIPMENT and the ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT.

[4] Under preparation. Stage at the time of publication: ISO/DIS 80601-2-84:2017.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

IEC 60601-1-2:2014, IEC 60601-1-6:2010+AMD1:2013, and IEC 60601-1-11:2015 apply as modified in Clauses 202, 206 and 211 respectively. IEC 60601-1-3[26] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx", where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

IEC 60601-1:2005+AMD1:2012, Clause 2, applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010[5], Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability *+Amendment 1:2013*+Amendment 1:2013

IEC 60601-1-8:2006[6], *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*+Amendment 1:2012

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 8836:2014, *Suction catheters for use in the respiratory tract*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

[5] There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

[6] There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and its Amendment 1:2012.

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17510:2015, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80369-7:2016, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80601-2-12:—[7], *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

ISO 80601-2-72:2015, *Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005[8], Medical electrical equipment — Part 1: General requirements for basic safety and essential performance *+Amendment 1:2012*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

[7] To be published. Stage at time of publication ISO/FDIS 80601-2-12:2018.

[8] There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1:2012.

