

INTERNATIONAL
STANDARD

ISO
80601-2-79

First edition
2018-07

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

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



Reference number
ISO 80601-2-79:2018(E)

© ISO 2018

ISO 80601-2-79:2018(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

Foreword.....	iv
Introduction.....	vi
201.1 Scope, object and related standards.....	1
201.2 Normative references	4
201.3 Terms and definitions	6
201.4 General requirements	7
201.5 General requirements for testing of ME EQUIPMENT.....	9
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	10
201.7 ME EQUIPMENT identification, marking and documents.....	10
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	16
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS	16
201.10 Protection against unwanted and excessive radiation HAZARDS.....	17
201.11 Protection against excessive temperatures and other HAZARDS	17
201.12 Accuracy of controls and instruments and protection against hazardous outputs	20
201.13 Hazardous situations and fault conditions for ME EQUIPMENT	30
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	30
201.15 Construction of ME EQUIPMENT.....	30
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	31
201.101 Gas connections	31
201.102 Requirements for the VBS and ACCESSORIES.....	33
201.103 * Training	34
201.104 * Indication of duration of operation	34
201.105 FUNCTIONAL CONNECTION	35
201.106 Display loops.....	35
201.107 Spontaneous breathing during loss of ventilation	36
202 Electromagnetic disturbances — Requirements and tests.....	36
206 Usability.....	37
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	38
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	40
Annex D (informative) Symbols on marking	46
Annex AA (informative) Particular guidance and rationale	48
Annex BB (informative) Data interface requirements.....	61
Annex CC (informative) Reference to the ESSENTIAL PRINCIPLES	67
Annex DD (informative) Terminology — Alphabetized index of defined terms	71
Bibliography	75

ISO 80601-2-79:2018(E)

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. 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. 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.

ISO 80601-2-79 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-79, in combination with ISO 80601-2-80^[1], cancels and replaces ISO 10651-6:2004^[2]. This edition of ISO 80601-2-79 constitutes a major technical revision of ISO 10651-6:2004 and includes an alignment with the third edition of IEC 60601-1, the fourth edition of IEC 60601-1-2, the third edition of IEC 60601-1-6, the second edition of IEC 60601-1-8 and the second edition of IEC 60601-1-11.

The most significant changes are the following modifications:

- splitting the scope of ISO 10651-6:2004^[2] into two parts:
 - one for VENTILATORY IMPAIRMENT, also known as RESPIRATORY IMPAIRMENT, (this document) and
 - one for VENTILATORY INSUFFICIENCY, also known as RESPIRATORY INSUFFICIENCY (ISO 80601-2-80);
- extending the scope to include the VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the VENTILATORY SUPPORT EQUIPMENT, and thus not the VENTILATORY SUPPORT EQUIPMENT itself;
- identification of ESSENTIAL PERFORMANCE for VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES;

and the following additions:

- tests for ventilation performance;

¹ Numbers in square brackets refer to the Bibliography.

- tests for mechanical strength (via IEC 60601-1-11);
- new symbols;
- requirements for VENTILATORY SUPPORT EQUIPMENT as a component of an ME SYSTEM;
- tests for ENCLOSURE integrity (water ingress via IEC 60601-1-11);
- tests for CLEANING and DISINFECTION PROCEDURES (via IEC 60601-1-11);
- consideration of contamination of the breathing gas delivered to the PATIENT from the GAS PATHWAYS.

ISO 80601-2-79:2018(E)

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
- $50 \% \leq FEV_1 < 80 \%$ 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 STANDARD³, 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.

ISO 80601-2-79:2018(E)

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.