Irish Standard
I.S. EN ISO 80601-2-79:2019&LC:2019

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)

I.S. EN ISO 80601-2-79:2019&LC:2019

Incorporating amendments/corrigenda/National Annexes issued since publication:

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NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 80601-2-79:2019&LC:2019 is the adopted Irish version of the European Document EN ISO 80601-2-79:2019, 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)

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In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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Correction Notice

Reference: EN ISO 80601-2-79:2019

Title: 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)

Work Item: 00215289

Brussels, 2019-10-30

please include the following minor editorial correction(s) in the document related to:

the following language version(s) :
- ☒ English
- ☒ French
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for the following procedure :
- ☐ PQ/UQ
- ☐ Enquiry
- ☐ 2nd Enquiry
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- ☐ 2nd Parallel Formal Vote
- ☐ UAP
- ☐ TC Approval
- ☐ 2nd TC Approval
- ☒ Publication
- ☐ Parallel Publication

It has been brought to our attention that this document, issued on 2019-09-18, requires modification.

The superseding information has been added on the title pages and in the European forewords.

Please find enclosed the updated English and French versions.

We apologise for any inconvenience this may cause.

Rue de la Science, 23 • 1040 Bruxelles
Tel : +32 2 550 08 11 • Fax : +32 2 550 08 19

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-79

September 2019

ICS 11.040.10

Supersedes EN ISO 10651-6:2009

English Version

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)

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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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I.S. EN ISO 80601-2-79:2019&LC:2019

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)

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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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Contents

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]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 INSUFFIENCY, 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.

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.*

INTERNATIONAL STANDARD **ISO 80601-2-79:2018(E)**

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.

