

ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-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

Medizinische elektrische Geräte - Teil
2-79: Besondere Festlegungen für die
grundlegende Sicherheit und die
wesentlichen Leistungsmerkmale von

Appareils électromédicaux - Partie 2-79:
Exigences particulières pour la sécurité
de base et les performances essentielles
des équipements d'assistance

09/2019



National Foreword

This European Standard EN ISO 80601-2-79:2019 was adopted as Luxembourgish Standard ILNAS-EN ISO 80601-2-79:2019.

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ILNAS-EN ISO 80601-2-79:2019

EUROPEAN STANDARD **EN ISO 80601-2-79**

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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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.

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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.

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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Published in Switzerland

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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. www.iso.org/directives

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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.