SLOVENSKI STANDARD
SIST EN ISO 80601-2-80:2019

01-november-2019

Medicinska električna oprema - 2-80. del: Posebne zahteve za osnovno varnost in bistvene lastnosti pomožne ventilacijske opreme pri nezadostnem prezračevanju (ISO 80601-2-80:2018)

Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency (ISO 80601-2-80:2018)

Medizinische elektrische Geräte - Teil 2-80: Besondere Festlegungen für die grundlegende Sicherheit und die wesentlichen Leistungsmerkmale von Heimbeatmungsgeräten zur Atemunterstützung von Patienten mit Atmungsinsuffizienz (ISO 80601-2-80:2018)

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 (ISO 80601-2-80:2018)

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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EUROPEAN STANDARD

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English Version

Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency (ISO 80601-2-80:2018)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

The text of ISO 80601-2-80:2018 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 80601-2-80:2019 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of an identical text or by endorsement, at the latest by March 2020, and conflicting national standards shall be withdrawn at the latest by March 2020.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.

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Endorsement notice

The text of ISO 80601-2-80:2018 has been approved by CEN as EN ISO 80601-2-80:2019 without any modification.

INTERNATIONAL STANDARD ISO 80601-2-80

First edition
2018-07

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) 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 (see www.iso.org/directives).

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This document 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 80601-2-80, in combination with ISO 80601-2-79[1] [1], cancels and replaces the second edition of ISO 10651-6:2004[2]. This edition of ISO 80601-2-80 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 (ISO 80601-2-79);

  — one for ventilatory insufficiency, also known as respiratory insufficiency (this document);

— 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 only the VENTILATORY SUPPORT EQUIPMENT itself;

[1] Numbers in square brackets refer to the Bibliography.

— identification of ESSENTIAL PERFORMANCE for VENTILATORY SUPPORT EQUIPMENT and its ACCESSORIES;

and the following additions:

— tests for ventilation performance;

— tests for mechanical strength (via IEC 60601-1-11);

— requiring capable of TRANSIT-OPERABLE use;

— 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.