SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-90:2025

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Medicinska električna oprema - 2-90. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za respiratorno terapijo z velikim pretokom (ISO/DIS 80601-2-90:2024)

Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment (ISO/DIS 80601-2-90:2024)

Medizinische elektrische Geräte - Teil 2-90: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Geräten für die Beatmungstherapie mit hohem Durchfluss (ISO/DIS 80601-2-90:2024)

Appareils électromédicaux - Partie 2-90: Exigences particulières pour la sécurité de base et les performances essentielles des équipements de thérapie respiratoire à haut débit (ISO/DIS 80601-2-90:2024)

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ISO/DIS 80601-2-90

Medical electrical equipment —

Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

Appareils électromédicaux —

Partie 2-90: Exigences particulières pour la sécurité de base et les performances essentielles des équipements de thérapie respiratoire à haut débit

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Contents

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 or www.iec.ch/members_experts/refdocs).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC 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 (see www.iso.org/patents) or the IEC list of patent declarations received (see patents.iec.ch).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care,* and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 80601-2-90:2021), which has been technically revised.

The main changes are as follows:

— updated normative references;

— clarified *system recovery* requirements;

— added *cybersecurity* requirements; and

— added requirements for SpO_2 *monitoring equipment*.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

Introduction

Respiratory high-flow therapy equipment has been used successfully for years with neonatal *patients*. In recent years there is more information about treating adults with *respiratory high-flow therapy equipment* when it is used as an intermediate therapy to improve oxygenation in adult critical care *patients*, respiratory care units and for palliative care. *High-flow therapy equipment* is also used in the treatment of chronic respiratory disease to reduce exacerbation, improve physiological outcomes and quality of life[31][44][45][48] [1]. The use of *respiratory high-flow therapy equipment* continues to increase as it is easily set up and is well tolerated by *patients*.

Since the outbreak of COVID-19 in January of 2020, its spread has been rapid and fierce. In hospitals across the world, all kinds of *respiratory high-flow therapy equipment* have been widely used. In general, there is a trend to use more non-invasive respiratory therapy. More and more new *manufacturers* of *respiratory high-flow therapy equipment* have rapidly emerged. Neither international nor national standards are available for *respiratory high-flow therapy equipment*. With the spread of the epidemic globally, the demand for this document is clear and very urgent.

The first *respiratory high-flow therapy equipment* was constructed by the connection of a *humidifier*, air/oxygen mixer/blender, flowmeter, breathing tube and cannula. Based on the improvement in technical integration in recent years, there are several technical routes for *respiratory high-flow therapy equipment* on the market. *Respiratory high-flow therapy equipment* is not fully covered by the existing standards for *humidifiers*, gas mixers for medical use, flowmeters or *ventilators*.

This document addresses the *basic safety* and *essential performance* requirements of *respiratory high-flow therapy equipment*, including *risks* related to oxygen (e.g., fires, incorrect oxygen concentration, incorrect flow delivery, etc.).

Specifically, the following *risks* and related requirements were considered in the development of this document.

— Contaminated air entering the *gas intake port* of the *respiratory high-flow therapy equipment*.

— Instability of gas supply from a *high-pressure inlet*.

— Insufficient pressure from a *high-pressure inlet*, and subsequent effects on oxygen delivered to the *patient*.

— Insufficient oxygen being delivered to the *patient*, and related *alarm condition*.

— *Usability* by *operators* wearing personal protective equipment (such as gloves and blurred visors), when setting up equipment, or viewing or changing settings.

— Instability of output delivered to *patients*, necessitating frequent *operator* adjustment.

— *Processing* of equipment, including the surface of the *enclosure* and internal *gas pathways*, particularly after use on infectious *patients*.

— Infectious exhaled gas.

— Overheating of *respiratory high-flow therapy equipment*.

— Insufficient flow capability from a *medical gas pipeline system*, and subsequent effects on oxygen supply to other *patients* in a care area.

In this document, the following print types are used:

— requirements and definitions: roman type;

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

222 — *terms defined in Clause 3 of the general standard, in this document or as noted: italic type*;

223 — informative material appearing outside of tables, such as notes, examples and references: in smaller type.
224 Normative text of tables is also in a smaller type.

225 In referring to the structure of this document, the term:

226 — “clause” means one of the five numbered divisions within the table of contents, inclusive of all
227 subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

228 — “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses
229 of Clause 201).

230 References to clauses within this document are preceded by the term “Clause” followed by the clause
231 number. References to subclauses within this particular document are by number only.

232 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination
233 of the conditions is true.

234 For the purposes of this document, the auxiliary verb:

235 — “shall” indicates a requirement;

236 — “should” indicates a recommendation;

237 — “may” indicates a permission;

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

239 — "must" is used express an external constraint.

240

Medical electrical equipment —

Part 2-90:
Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 Scope

Replacement:

NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

This document applies to the *basic safety* and *essential performance* of *respiratory high-flow therapy equipment,* as defined in 201.3.262, hereafter also referred to as *ME equipment* or *ME system,* in combination with its *accessories*:

— intended for use with *patients* who can breathe spontaneously; and

— intended for *patients* who would benefit from improved alveolar gas exchange; and who would benefit from receiving high-flow humidified respiratory gases, which can include a *patient* whose upper airway is bypassed.

EXAMPLE 1 *Patients* with Type 1 Respiratory Failure who exhibit a reduction in arterial blood oxygenation.

EXAMPLE 2 *Patients* who would benefit from reduced work of breathing, as needed in Type 2 Respiratory Failure, where arterial carbon dioxide is high.

EXAMPLE 3 *Patients* requiring humidification to improve mucociliary clearance.

Respiratory high-flow therapy equipment can be intended for use in the *home healthcare environment* or intended for use in professional healthcare facilities.

NOTE 2 In the *home healthcare environment*, the *supply mains* is often not reliable.

Respiratory high-flow therapy equipment can be:

— fully integrated *ME equipment*; or

— a combination of separate items forming a *ME system*.

This document also applies to other types of respiratory equipment when that equipment includes a respiratory high-flow therapy mode.

NOTE 3 This document and ISO 80601-2-12 are applicable to a critical care *ventilator* with a high-flow therapy mode.

Respiratory high-flow therapy equipment can be *transit-operable*.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the *respiratory high-flow therapy equipment*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *respiratory high-flow therapy equipment*.

EXAMPLE 4 Breathing sets, *connectors*, *humidifier*, *breathing system filter*, external electrical power source, *distributed alarm system*, *high-flow nasal cannula*, tracheal tube, tracheostomy tube, face *mask* and supra-laryngeal airway.

NOTE 4 *Accessories* are assessed with the relevant clauses of this document when configured as part of *respiratory high-flow therapy equipment*.

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 the general standard, 7.2.13 and 8.4.1.

NOTE 5 Additional information can be found in the general standard, 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;

— *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given in ISO 80601-2-84;

— *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 *patients* with ventilatory impairment, which are given in ISO 80601-2-79;

— ventilatory support equipment or *accessories* intended for *patients* with ventilatory insufficiency, which are given in ISO 80601-2-80;

— sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70;

— continuous positive airway pressure (CPAP) *ME equipment;*

— high-frequency jet *ventilators* (HFJVs)[33], which are given in ISO 80601-2-87;

— gas mixers for medical use, which are given in ISO 11195;

— flowmeters, which are given in ISO 15002;

— high-frequency oscillatory *ventilators* (HFOVs), which are given in ISO 80601-2-87; and

— cuirass or “iron-lung” ventilation equipment.

This document is a particular standard in the IEC 60601 series, the IEC 80601 series and the ISO 80601 series.

201.1.2 Object

Replacement: