

SLOVENSKI STANDARD

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Medicinska električna oprema - 2-74. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za vlažilne sisteme dihalne opreme (ISO 80601-2-74:2021)

Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (ISO 80601-2-74:2021)

Medizinische elektrische Geräte - Teil 2-74: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Anfeuchtersystemen für Atemgase (ISO 80601-2-74:2021)

Appareils électromédicaux - Partie 2-74: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'humidification respiratoire (ISO 80601-2-74:2021)

Ta slovenski standard je istoveten z: EN ISO 80601-2-74:2021

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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NORME EUROPÉENNE
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EN ISO 80601-2-74

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Supersedes EN ISO 80601-2-74:2020

English Version

Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (ISO 80601-2-74:2021)

Appareils électromédicaux - Partie 2-74: Exigences particulières pour la sécurité de base et les performances essentielles des équipements d'humidification respiratoire (ISO 80601-2-74:2021)

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European foreword

This document (EN ISO 80601-2-74:2021) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by January 2022.

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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The text of ISO 80601-2-74:2021 has been approved by CEN as EN ISO 80601-2-74:2021 without any modification.

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INTERNATIONAL STANDARD

ISO
80601-2-74

Second edition
2021-07

Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

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Appareils électromédicaux —

*Partie 2-74: Exigences particulières pour la sécurité de base et
les performances essentielles des équipements d'humidification
respiratoire*

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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).

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 (see 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.

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.

This document was prepared jointly 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, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*, 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 80601-2-74:2017), which has been technically revised.

The main changes compared to the previous edition are as follows:

- harmonization with the 'A2 project' of the general standard;
- harmonization with ISO 20417;
- addition of category 3 for respiratory high-flow therapy equipment;
- modification of requirements for *humidification output* of category 2 humidifiers;
- addition of requirements for maximum temperature in *normal use*;
- addition of requirements for static and dynamic temperature stability;

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- addition of requirements for low *humidification output alarm condition*;
- modification of audible acoustic energy test *procedure*;
- modification of thermal requirements for *applied parts*;
- modification of *measured gas temperature test procedure*;
- enlarged the $\varnothing W$ dimension of the temperature sensor port; and
- modification of *humidification output test procedure*.

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.

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Introduction

This document specifies requirements for respiratory humidifying equipment intended for use on *patients in home healthcare environment* and in healthcare facilities. *Humidifiers* are used to raise the water content of gases delivered to *patients*. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of *patients* whose upper airways have been bypassed. Inadequate humidity in the inspired gas can cause drying of the upper airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can cause narrowing or even obstruction of the airway^[25] [38]. Heat is employed to increase the water output of the *humidifier*.

In addition, many *humidifiers* utilize heated *breathing tubes* in order to increase operating efficiency and reduce water loss (condensate) as well as heat loss in the *breathing tube*. *Ventilator* and anaesthesia *breathing tubes* in common use might not withstand the heat generated by *humidifiers* and *breathing tube* heating mechanisms.

Many *humidifier manufacturers* use off-the-shelf electrical connectors for their electrically heated *breathing tubes*. However, since different *manufacturers* have used the same electrical connector for different power outputs, electrically heated *breathing tubes* can be physically, but not electrically, interchangeable. Use of improper electrically heated *breathing tubes* has caused overheating, circuit melting, *patient* and *operator* burns and fires. It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between *humidifiers* and *breathing tubes* produced by different *manufacturers*.

Since the safe use of a *humidifier* depends on the interaction of the *humidifier* with its many *accessories*, this document sets total system performance requirements up to the *patient-connection port*. These requirements are applicable to *accessories* such as *breathing tubes* (both heated and non-heated), temperature sensors and equipment intended to control the environment within these *breathing tubes*.

Humidification can also be used by respiratory support *ME equipment* to increase *patient* comfort and compliance with the therapy. Examples are obstructive sleep apnoea and nasal high-flow therapy equipment. The *humidification output* requirements of such *ME equipment* is less demanding as the *patient's* upper airway is not bypassed.

Humidifiers are commonly used with air and air-oxygen mixtures and any *humidifier* should be able to operate with these gases. Care should be taken if using other gas mixes such as helium-oxygen mixtures, as the different physical and thermal properties of these gases may disturb the operation of the *humidifier*.

In this document, the following print types are used:

- Requirements and definitions: roman type;
- *Test specifications and terms defined in Clause 3 of the general standard, in this document or as noted: 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;

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

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

For the purposes of this document, the auxiliary verb:

- “shall” means that conformance with a requirement or a test is mandatory for conformance with this document;
- “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;
- “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);
- “can” is used to describe a possibility or capability; and;
- “must” is used to express an external constraint.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

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.

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Medical electrical equipment —

Part 2-74:

Particular requirements for basic safety and essential performance of respiratory humidifying 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:

This document applies to the *basic safety* and *essential performance* of a *humidifier*, also hereafter referred to as *ME equipment*, in combination with its *accessories*, the combination also hereafter referred to as *ME system*.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to a *humidifier* where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *humidifier*. (standards.iteh.ai)

EXAMPLE 1 Heated *breathing tubes* (heated-wire *breathing tubes*) or *ME equipment* intended to control these heated *breathing tubes* (heated *breathing tube* controllers).

NOTE 1 Heated *breathing tubes* and their controllers are *ME equipment* and are subject to the requirements of IEC 60601-1.

NOTE 2 ISO 5367 specifies other safety and performance requirements for *breathing tubes*.

This document includes requirements for the different medical uses of humidification, such as invasive ventilation, non-invasive ventilation, nasal high-flow therapy, and obstructive sleep apnoea therapy, as well as humidification therapy for tracheostomy *patients*.

NOTE 3 A *humidifier* can be integrated into other equipment. When this is the case, the requirements of the other equipment also apply to the *humidifier*.

EXAMPLE 2 Heated *humidifier* incorporated into a critical care *ventilator* where ISO 80601-2-12^[10] also applies.

EXAMPLE 3 Heated *humidifier* incorporated into a homecare *ventilator* for dependent *patients* where ISO 80601-2-72^[12] also applies.

EXAMPLE 4 Heated *humidifier* incorporated into sleep apnoea therapy equipment where ISO 80601-2-70^[11] also applies.

EXAMPLE 5 Heated *humidifier* incorporated into ventilatory support equipment where either ISO 80601-2-79^[13] or ISO 80601-2-80^[14] also apply.

EXAMPLE 6 Heated *humidifier* incorporated into respiratory high-flow therapy equipment where ISO 80601-2-90^[15] also applies.