INTERNATIONAL STANDARD

ISO 18778

Second edition
2022-06

Respiratory equipment — Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors

Matériel respiratoire — Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs cardiorespiratoires pour nourrissons

Reference number
ISO 18778:2022(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 (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 by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related 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 (ISO 18778:2005), which has been technically revised.

The main changes are as follows:

— extending the scope to include the *infant cardiorespiratory monitor* and its *accessories,* where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *infant cardiorespiratory monitor,* and thus not only the *infant cardiorespiratory monitor* itself;

— identification of *essential performance* of an *infant cardiorespiratory monitor* and its *accessories*;

— harmonization with the third edition of IEC 60601-1;

and the following additions:

— tests for *infant cardiorespiratory monitor* performance;

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

— requirements for *transit-operable* use;

— new *symbols*;

— requirements for an *infant cardiorespiratory monitor* as a component of an *ME system*;

— requirement for both a direct measurement of respiration, and an indirect measurement of apnoeic activity;

— tests for *enclosure* integrity (water ingress via IEC 60601-1-11);

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— tests for *cleaning* and *disinfection procedures* (via IEC 60601-1-11); and

— harmonization with ISO 20417.

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 *infant cardiorespiratory monitors* called in previous working documents "infant apnoea monitors or infant monitors". *Infant cardiorespiratory monitors* are intended to be used primarily to monitor cardiorespiratory parameters for *patients* less than 3 years of age. *Infant cardiorespiratory monitors* are required to include at least one direct measurement of respiration and one indirect measurement of apnoeic activity such as heart rate or oxygen saturation. *Infant cardiorespiratory monitors* are intended for use in the *home healthcare environment. Infant cardiorespiratory monitors* are frequently used in locations where *supply mains* is not reliable. *Infant cardiorespiratory monitors* are often supervised by non-healthcare personnel (*lay operators*) with varying levels of training. An *infant cardiorespiratory monitor* conforming with this document can be used elsewhere (i.e., in healthcare facilities).

Annex A contains guidance or rationale to indicated clauses and subclauses.

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.

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+AMD2:2020, 7.2.13 and 8.4.1.

NOTE 1 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

The object of this document is to establish particular *basic safety* and *essential performance* requirements for an *infant cardiorespiratory monitor,* as defined in 3.10, and its *accessories*.

Accessories are included because the combination of the *infant cardiorespiratory monitor* and the *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of the *infant cardiorespiratory monitor*.

NOTE 2 This document has been prepared to address the relevant *essential principles*[6] and labelling[7] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex P.

NOTE 3 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex Q.

NOTE 4 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745[8] as indicated in Annex R.

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Respiratory equipment — Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors

1 Scope

This document applies to the *basic safety* and *essential performance* of an *infant cardiorespiratory monitor,* as defined in 3.10, 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*;

— intended to monitor cardiorespiratory parameters in sleeping or resting children under three years of age; and

— intended for *transit-operable* use.

NOTE An *infant cardiorespiratory monitor* can also be used in professional health care facilities.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the *infant cardiorespiratory monitor*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *infant cardiorespiratory monitor*.

EXAMPLE probes, cables *distributed alarm system*

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2018, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14155:2020, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 80601-2-61:2017, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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IEC 60601-1-2:2014+AMD1:2020, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances - Requirements and tests*

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-11:2015+AMD1:2020, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-2-27:2011, *Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

IEC 62366-1:2015+AMD1:2020, *Medical devices — Application of usability engineering to medical devices*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

IEC Guide 115:2021, *Application of uncertainty of measurement to conformity assessment activities in the electrotechnical sector*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 16142-1, ISO 17664-2, ISO 18562-1, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-11, IEC 62366-1, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
accompanying information
information accompanying or *marked* on a *medical device* or *accessory* for the *user* or those accountable for the installation, use, *processing*, maintenance, decommissioning and disposal of the *medical device* or *accessory*, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the *medical device* or *accessory.*

Note 2 to entry: The *accompanying information* can consist of the *label*, *marking*, *instructions for use*, *technical description*, installation manual, quick reference guide, etc.

Note 3 to entry: *Accompanying information* is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g., CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — deleted note 4.]

3.2
apnoea
cessation of breathing lasting 10 s or more

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3.3
biocompatibility
ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: Medical devices may produce some level of adverse effect, but that level may be determined to be acceptable when considering the benefits provided by the medical device.

[SOURCE: ISO 18562-1:2017, 3.2]

3.4
central apnoea
apnoea where there is a cessation of output from the central respiratory centres, and no respiratory effort

3.5
cleaning
removal of contaminants to the extent necessary for further *processing* or for *intended use*

Note 1 to entry: *Cleaning* consists of the removal, usually with detergent and water, of adherent soil (e.g. blood, protein substances, and other debris) from the surfaces, crevices, serrations, joints, and lumens of a medical device by a manual or automated *process* that prepares the items for safe handling or further *processing*.

[SOURCE: ISO 17664-2:2017, 3.1, modified — replaced "and/or" with "or" in note 1.]

3.6
clinical investigation
systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness or safety of a medical device

Note 1 to entry: For the purpose of this document, “clinical trial” or “clinical study” are synonymous with “clinical investigation”.

[SOURCE: ISO 14155:2020, 3.8]

3.7
clinical investigation plan
CIP
document that states the rationale, objectives, design and pre-specified analysis, methodology, organization, monitoring, conduct and record-keeping of the *clinical investigation* (3.6)

Note 1 to entry: For the purpose of this document “protocol” is synonymous with “*CIP*”. However, protocol has many different meanings, some not related to *clinical investigation*, and these can differ from country to country. Therefore, the term *CIP* is used in this document.

[SOURCE: ISO 14155:2020, 3.9]

3.8
disinfection
process to reduce the number of viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 17664-2:2021, 3.3]

3.9
healthcare professional
individual with appropriate training, knowledge and skills who provides preventive, curative, promotional or rehabilitative healthcare services in a systematic way to people, families or communities

[SOURCE: ISO 4135:2022, 3.1.6.2]

3.10
infant cardiorespiratory monitor
ME equipment intended to monitor cardiorespiratory parameters for *patients* less than 3 years of age

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3.11
information supplied by the manufacturer
information related to the identification and use of a *medical device* or *accessory*, in whatever form provided, intended to ensure the safe and effective use of the *medical device* or *accessory*

Note 1 to entry: For the purposes of this document, e-documentation is included in *information supplied by the manufacturer*.

Note 2 to entry: For the purposes of this document, shipping documents and promotional material are excluded from *information supplied by the manufacturer*. However, some authorities having jurisdiction can consider such supplemental information as *information supplied by the manufacturer*.

Note 3 to entry: The primary purpose of *information supplied by the manufacturer* is to identify the *medical device* and its *manufacturer*, and provide essential information about its safety, performance, and appropriate use to the *user* or other relevant persons.

[SOURCE: ISO 20417:2021, 3.10, modified — deleted note 4.]

3.12
instructions for use
IFU
portion of the *accompanying information* that is essential for the safe and effective use of a *medical device* or *accessory* directed to the *user* of the *medical device*

Note 1 to entry: For the purposes of this document, a *user* can be either a *lay user* or professional *user* with relevant specialized training.

Note 2 to entry: For the purposes of this document, instructions for the professional *processing* between uses of a *medical device* or *accessory* can be included in the *instructions for use*.

Note 3 to entry: The *instructions for use*, or portions thereof, can be located on the display of a *medical device* or *accessory*.

Note 4 to entry: *Medical devices* or *accessories* that can be used safely and effectively without *instructions for use* are exempted from having *instructions for use* by some *authorities having jurisdiction*.

[SOURCE: ISO 20417:2021, 3.11, modified — deleted note 5.]

3.13
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *medical device* or *accessory*

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, *marking* is different from 'direct marking' as commonly described in unique device identification (UDI) standards and regulations. A UDI 'direct marking' is a type of *marking*.

[SOURCE: ISO 20417:2021, 3.16, modified — deleted note 3.]

3.14
obstructive apnoea
apnoea due to airway obstruction

3.15
processing
<preparation of medical device, *accessory*> activity to prepare a new or used *medical device* or *accessory* for its *intended use*

[SOURCE: ISO 20417:2021, 3.20]

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3.16
single use
<medical device, *accessory*> intended by the *manufacturer* to be used on an individual *patient* or specimen during a single *procedure* and then disposed of

Note 1 to entry: A *single use* medical device or *accessory* is not intended by its *manufacturer* to be further processed and used again.

[SOURCE: ISO 20417:2021, 3.26]

3.17
sterile
free from viable microorganisms

[SOURCE: ISO 20417:2021, 3.28]

3.18
sterilization
process used to render product free from viable microorganisms

Note 1 to entry: In a *sterilization process*, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO 17664-2:2021, 3.17]

3.19
symbol
graphical representation appearing on the label and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The *symbol* can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters (with sufficient justification).

[SOURCE: ISO 20417:2021, 3.29]

3.20
technical description
portion of the *accompanying information* directed to the *responsible organization* and *service personnel* that is essential for preparation for the first use and safe use, maintenance or repair as well as *processing*, transport or storage for the *expected service life* of a *medical device*

Note 1 to entry: The *technical description* may be included in the *instructions for use*.

[SOURCE: ISO 20417:2021, 3.30, modified — deleted note 2.]

3.21
validation
confirmation, through the provision of *objective evidence*, that the requirements for a specific *intended use* or application have been fulfilled

Note 1 to entry: The *objective evidence* needed for a *validation* is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The term "*validated*" is used to designate the corresponding status.

Note 3 to entry: The use conditions for *validation* can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13]

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