Respiratory equipment - Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors (ISO 18778:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 18778:2022 sisaldab Euroopa standardi EN ISO 18778:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18778:2022 consists of the English text of the European standard EN ISO 18778:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.10.2022.	Date of Availability of the European standard is 19.10.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10, 11.040.55

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18778

October 2022

ICS 11.040.10; 11.040.55

Supersedes EN ISO 18778:2009

English Version

Respiratory equipment - Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors (ISO 18778:2022)

Matériel respiratoire - Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs cardiorespiratoires pour nourrissons (ISO 18778:2022)

Medizinische elektrische Geräte - Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von kardiorespiratorischen Überwachungsgeräten für Kleinkinder (ISO 18778:2022)

This European Standard was approved by CEN on 17 June 2022.

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.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 18778:2022 E

European foreword

This document (EN ISO 18778:2022) 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 April 2023, and conflicting national standards shall be withdrawn at the latest by April 2023.

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 EN ISO 18778:2009.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 18778:2022 has been approved by CEN as EN ISO 18778:2022 without any modification.

Contents

Page

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);

— 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.

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.

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*

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