SLOVENSKI STANDARD
oSIST prEN ISO 18778:2021

01-september-2021

Respiratorna oprema - Posebne zahteve za osnovno varnost in bistveno učinkovitost opreme za srčnospiratorne monitorje za otroke (ISO/DIS 18778:2021)

Respiratory equipment - Particular requirements for basic safety and essential performance of equipment for infant cardiorespiratory monitors (ISO/DIS 18778:2021)

Medizinische elektrische Geräte - Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von kardiorespiratorischen Überwachungsgeräten für Kleinkinder (ISO/DIS 18778:2021)

Appareils électromédicaux - Exigences particulières relatives à la sécurité de base et aux performances essentielles des appareils de surveillance cardiorespiratoire des nourrissons (ISO/DIS 18778:2021)

Ta slovenski standard je istoveten z: **prEN ISO 18778**

ICS:

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

oSIST prEN ISO 18778:2021 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 18778

ISO/TC **121**/SC **3**

Secretariat: **ANSI**

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Respiratory equipment — Particular requirements for 6 basic safety and essential performance of equipment for 7 infant cardiorespiratory monitors —

Part :

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

ICS: 11.040.55; 11.040.10

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

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105 ## FOREWORD

106 ISO (the International Organization for Standardization) is a worldwide federation of
107 national standards bodies (ISO member bodies). The work of preparing International
108 Standards is normally carried out through ISO technical committees. Each member body
109 interested in a subject for which a technical committee has been established has the right
110 to be represented on that committee. International organizations, governmental and non-
111 governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with
112 the International Electrotechnical Commission (IEC) on all matters of electrotechnical
113 standardization.

114 The procedures used to develop this document and those intended for its further
115 maintenance are described in the ISO/IEC Directives, Part 1. In particular the different
116 approval criteria needed for the different types of ISO documents should be noted. This
117 document was drafted in accordance with the editorial rules of the ISO/IEC Directives,
118 Part 2. www.iso.org/directives

119 Attention is drawn to the possibility that some of the elements of this document may be
120 the subject of patent rights. ISO shall not be held responsible for identifying any or all such
121 patent rights. Details of any patent rights identified during the development of the
122 document will be in the Introduction and/or on the ISO list of patent declarations received.
123 www.iso.org/patents

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

126 ISO 18778 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory*
127 *equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* in collaboration
128 with the European Committee for Standardization (CEN) Technical Committee CEN/TC
129 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on
130 technical cooperation between ISO and CEN (Vienna Agreement). The draft was circulated
131 for voting to the national bodies of ISO.

This second edition of ISO 18778, cancels and replaces the first edition of ISO 18778:2005[3] [1]. This edition of ISO 18778 constitutes a major technical revision of ISO 18778:2005 and includes harmonization with the third edition of IEC 60601-1 and its two amendments, the fourth edition of IEC 60601-1-2 and its amendment, the third edition of IEC 60601-1-6 and its two amendments, the second edition of IEC 60601-1-8 and its two amendments and the second edition of IEC 60601-1-11 and its amendment.

The most significant changes are the following modifications:

– 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*;

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*;

– 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.

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

INTRODUCTION

This document specifies requirements for an *infant cardiorespiratory monitor* 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).

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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).

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

The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2. 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

194 – "must" is used to express an external constraint.

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

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

197 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table
198 title indicates that there is guidance or rationale related to that item in 0.

199 The ISO and IEC 80601 family of documents are also parts of the IEC 60601 family of
200 documents.

201

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

201.1 Scope, object and related standards

Clause 1 of the general standard, 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 an *infant cardiorespiratory monitor,* as defined in 201.3.203, 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 1 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*

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, 7.2.13 and 8.4.1.

NOTE 2 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

201.1.2 Object

Replacement:

The object of this document is to establish particular *basic safety* and *essential performance* requirements for an *infant cardiorespiratory monitor,* as defined in 201.3.203, 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 1 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 DD.

NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex EE.

NOTE 3 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 FF.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in Clauses 202, 206, 208 and 211 respectively. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard, including the collateral standards as appropriate for the particular *ME equipment* under consideration.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx”, where xx is the final digits of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11

collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Clauses, subclauses, figures or tables that are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 208 for IEC 60601-1-8, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this particular document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 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.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography.

Clause 2 of the general standard, applies, except as follows:

Addition:

ISO 7000:2019, *Graphical symbols for use on equipment — Registered symbols*

306 ISO 15223-1:—[2], *Medical devices — Symbols to be used with medical device labels, labelling*
307 *and information to be supplied — Part 1: General requirements*

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

310 ISO 14937:2009, *Sterilization of health care products — General requirements for*
311 *characterization of a sterilizing agent and the development, validation and routine control*
312 *of a sterilization process for medical devices*

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

317 ISO 17664:2017, *Processing of health care products -- Information to be provided by the*
318 *medical device manufacturer for the processing of medical devices*

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

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

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

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

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

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

331 IEC Guide 115:2001, *Application of uncertainty of measurement to conformity assessment*
332 *activities in the electrotechnical sector*

333 201.3 Terms and definitions

334 For the purposes of this document, the terms and definitions given in ISO 16142-1:2016,
335 ISO 17664:2017, ISO 18562-1:2017, IEC 60601-1:2005+AMD1:2012+AMD2:2020,
336 IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020,
337 IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-11:2015+AMD1:2020,
338 IEC 62366-1:2015+AMD1:2020, and the following apply.

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[2] Under preparation. Stage at the time of publication: ISO/FDIS 15223-1:2021.

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

– IEC Electropedia: available at http://www.electropedia.org/

– ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An alphabetized index of defined terms is found Annex GG.

201.3.201
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.]

201.3.202
apnoea
cessation of breathing lasting 10 s or more

201.3.203
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]

201.3.204
central apnoea
apnoea where there is a cessation of output from the central respiratory centres, and no respiratory effort

201.3.205
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 17664:2017, 3.1, modified — replaced "and/or" with "or" in note 1.]