SLOVENSKI STANDARD
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01-januar-2023

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Respiratorna oprema - Posebne zahteve za osnovno varnost in bistveno učinkovitost opreme za kardiorespiratorne monitorje za otroke (ISO 18778:2022)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 18778:2022**

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NORME EUROPÉENNE

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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)

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Contents

Page

European foreword **3**

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SIST EN ISO 18778:2023
https://standards.iteh.ai/catalog/standards/sist/6f9a5798-430b-4a25-84f5-d761b57bc7e3/sist-en-iso-18778-2023

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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of an identical text or by endorsement, at the latest by April 2023, and conflicting national standards shall be withdrawn at the latest by April 2023.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.

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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

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SIST EN ISO 18778:2023

Contents

Page

Foreword ... **vi**

Introduction ... **viii**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **2**

4 General requirements ... **6**
4.1 General ... 6
4.2 *Essential performance* ... 6
4.3 *ME equipment* or *ME system* parts that contact the *patient* ... 6
4.4 *Single fault condition* for *ME equipment* ... 6

5 General requirements for testing of *ME equipment* ... **6**
5.1 General ... 6
5.2 *Infant cardiorespiratory monitor* testing errors ... 6

6 Classification of *ME equipment* and *ME systems* ... **7**
6.1 General ... 7
6.2 Additional requirements for classification of *ME equipment* and *ME systems* ... 7

7 *ME equipment* identification, *marking* and documents ... **7**
7.1 General ... 7
7.2 *Information to be supplied by the manufacturer* ... 7
7.3 Additional requirements for *accessories* ... 7
7.4 Additional requirements for *marking* on the outside of *ME equipment* or *ME equipment* parts ... 8
7.5 General *instructions for use* ... 8
7.6 Additional requirements for warnings and safety notices ... 8
7.7 Additional requirements for start-up *procedure* ... 9
7.8 Additional requirements for operating instructions ... 9
7.8.1 General ... 9
7.8.2 *Lay operator* operating instructions ... 9
7.8.3 *Healthcare professional operator* operating instructions ... 10
7.9 *Cleaning*, *disinfection*, and *sterilization* ... 10
7.10 Additional requirements for maintenance ... 10
7.11 Additional requirements for *accessories*, supplementary equipment, used material ... 10
7.12 Additional requirements for the *technical description* ... 10

8 Protection against electrical *hazards* from *ME equipment* ... **11**

9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* ... **11**
9.1 General ... 11
9.2 Additional requirements for instability from unwanted lateral movement ... 11
9.3 Grips and other handling devices ... 11

10 Protection against unwanted and excessive radiation *hazards* ... **11**

11 Protection against excessive temperatures and other *hazards* ... **11**
11.1 General ... 11
11.2 *Cleaning* and *disinfection* of *ME equipment* or *ME system* ... 12
11.3 *Sterilization* of *ME equipment* or *ME system* ... 12
11.4 *Biocompatibility* of *ME equipment* and *ME systems* ... 12
11.5 Interruption of the power supply / *supply mains* to *ME equipment* ... 13
11.5.1 General ... 13
11.5.2 Power sources ... 13
11.5.3 Alternative power supply/*supply mains* ... 14

12 Accuracy of controls and instruments and protection against hazardous outputs ... **14**

iTeh STANDARD PREVIEW
(standards.iteh.ai)
https://standards.iteh.ai/catalog/standards/sist/d9a5798-430b-4a25-84f5-

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SIST EN ISO 18778:2023

12.1 General ... 14
12.2 Accuracy of controls and instruments ... 14
12.3 Accuracy of controls and instruments ... 15
12.3.1 General ... 15
12.3.2 Cardiorespiratory monitoring ... 15
12.3.3 Direct monitoring - respiration ... 15
12.3.4 Indirect monitoring – heart rate ... 15
12.3.5 Indirect monitoring from pulse oximetry ... 15
12.3.6 Apnoeic *patient alarm condition* ... 16
12.3.7 Sensor fault ... 17
12.3.8 Clinical performance evaluation ... 17
12.4 *Usability* of *ME equipment* ... 17

13 *Hazardous situations* and fault conditions for *ME equipment* ... **18**

14 *Programmable electrical medical systems (PEMS)* ... **18**

15 Construction of *ME equipment* ... **18**
15.1 General ... 18
15.2 Mode of operation ... 18
15.3 Pre-use check ... 18

16 *ME systems* ... **19**

17 Electromagnetic compatibility of *ME equipment* and *ME systems* ... **19**

18 Requirements for the *accessories* ... **19**
18.1 General ... 19
18.2 Labelling ... 19

19 Training ... **19**

20 *Functional connection* ... **19**
20.1 General ... 19
20.2 Connection to an electronic health record ... 19
20.3 Connection to a *distributed alarm system* ... 19

21 Electromagnetic disturbances – Requirements and tests ... **20**
21.1 General ... 20
21.2 Compliance criteria ... 20
21.3 Requirements applicable to all *ME equipment* and *ME systems* ... 20
21.4 Additional general requirements ... 20

22 *Usability* ... **20**
22.1 General ... 20
22.2 *Primary operating functions* ... 21

23 General requirements, tests and guidance for *alarm systems* in *medical electrical equipment* and *medical electrical systems* ... **21**
23.1 General ... 21
23.2 Volume and characteristics of auditory *alarm signals* and *information signals* ... 21
23.3 Additional requirements for termination of *alarm signal* inactivation ... 21
23.4 Additional requirements for *alarm system* logging ... 22

24 Requirements for *medical electrical equipment* and *medical electrical systems* used in the *home healthcare environment* ... **22**

Annex A (informative) **General guidance and rationale** ... **23**

Annex B (informative) **Sequence of testing** ... **28**

Annex C (informative) **Guide to *marking* and labelling requirements for *ME equipment* and *ME systems*** ... **29**

Annex D (informative) ***Symbols* on *marking*** ... **32**

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 18778:2023
https://standards.iteh.ai/catalog/standards/sist/6f9a5798-430b-4a23-8415-d761b57bc7e3/sist-en-iso-18778-2023

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SIST EN ISO 18778:2023

Annex E (informative) **Examples of the connection of the measuring device (MD) for measurement of the *patient leakage current* and *patient auxiliary current*** **33**

Annex F (informative) **Suitable measuring supply circuits** **34**

Annex G (informative) **Protection against *hazards* of ignition of flammable anaesthetic mixtures** **35**

Annex H (informative) ***PEMS* structure, *PEMS development life-cycle* and documentation** **36**

Annex I (informative) ***ME systems* aspects** **37**

Annex J (informative) **Survey of insulation paths** **38**

Annex K (informative) **Simplified *patient leakage current* diagrams** **39**

Annex L (informative) **Insulated winding wires for use without interleaved insulation** **40**

Annex M (informative) **Reduction of pollution degrees** **41**

Annex N (informative) **Data interface requirements** **42**

Annex O (informative) **Considerations for a clinical performance study** **45**

Annex P (informative) **Reference to the IMDRF *essential principles* and labelling guidances** **47**

Annex Q (informative) **Reference to the *essential principles*** **49**

Annex R (informative) **Reference to the general safety and performance requirements** **51**

Bibliography **54**

Terminology — Alphabetized index of defined terms **55**

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 18778:2023
https://standards.iteh.ai/catalog/standards/sist/6f9a5798-430b-4a25-84f5-d761b57bc7e3/sist-en-iso-18778-2023

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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).

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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.

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SIST EN ISO 18778:2023
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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*

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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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