



BSI Standards Publication

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

This is a preview of "BS EN ISO 18778:2022". [Click here to purchase the full version from the ANSI store.](#)

National foreword

This British Standard is the UK implementation of EN ISO 18778:2022. It is identical to ISO 18778:2022. It supersedes BS EN ISO 18778:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/9, Lung Ventilators & Related Equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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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)

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

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

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of an identical text or by endorsement, at the latest by April 2023, and conflicting national standards shall be withdrawn at the latest by April 2023.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

This document supersedes EN ISO 18778:2009.

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Endorsement notice

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

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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 <i>Essential performance</i>	6
4.3 <i>ME equipment or ME system parts that contact the patient</i>	6
4.4 <i>Single fault condition for ME equipment</i>	6
5 General requirements for testing of ME equipment	6
5.1 General.....	6
5.2 <i>Infant cardiorespiratory monitor testing errors</i>	6
6 Classification of ME equipment and ME systems	7
6.1 General.....	7
6.2 <i>Additional requirements for classification of ME equipment and ME systems</i>	7
7 ME equipment identification, marking and documents	7
7.1 General.....	7
7.2 <i>Information to be supplied by the manufacturer</i>	7
7.3 <i>Additional requirements for accessories</i>	7
7.4 <i>Additional requirements for marking on the outside of ME equipment or ME equipment parts</i>	8
7.5 <i>General instructions for use</i>	8
7.6 <i>Additional requirements for warnings and safety notices</i>	8
7.7 <i>Additional requirements for start-up procedure</i>	9
7.8 <i>Additional requirements for operating instructions</i>	9
7.8.1 <i>General</i>	9
7.8.2 <i>Lay operator operating instructions</i>	9
7.8.3 <i>Healthcare professional operator operating instructions</i>	10
7.9 <i>Cleaning, disinfection, and sterilization</i>	10
7.10 <i>Additional requirements for maintenance</i>	10
7.11 <i>Additional requirements for accessories, supplementary equipment, used material</i>	10
7.12 <i>Additional requirements for the technical description</i>	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 <i>Additional requirements for instability from unwanted lateral movement</i>	11
9.3 <i>Grips and other handling devices</i>	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 <i>Cleaning and disinfection of ME equipment or ME system</i>	12
11.3 <i>Sterilization of ME equipment or ME system</i>	12
11.4 <i>Biocompatibility of ME equipment and ME systems</i>	12
11.5 <i>Interruption of the power supply / supply mains to ME equipment</i>	13
11.5.1 <i>General</i>	13
11.5.2 <i>Power sources</i>	13
11.5.3 <i>Alternative power supply/supply mains</i>	14
12 Accuracy of controls and instruments and protection against hazardous outputs	14

This is a preview of "BS EN ISO 18778:2022". [Click here to purchase the full version from the ANSI store.](#)

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 <i>patient alarm condition</i>	16
12.3.7	Sensor fault.....	17
12.3.8	Clinical performance evaluation.....	17
12.4	<i>Usability of ME equipment</i>	17
13	<i>Hazardous situations and fault conditions for ME equipment</i>	18
14	<i>Programmable electrical medical systems (PEMS)</i>	18
15	<i>Construction of ME equipment</i>	18
15.1	General.....	18
15.2	Mode of operation.....	18
15.3	Pre-use check.....	18
16	<i>ME systems</i>	19
17	<i>Electromagnetic compatibility of ME equipment and ME systems</i>	19
18	<i>Requirements for the accessories</i>	19
18.1	General.....	19
18.2	Labelling.....	19
19	<i>Training</i>	19
20	<i>Functional connection</i>	19
20.1	General.....	19
20.2	Connection to an electronic health record.....	19
20.3	Connection to a <i>distributed alarm system</i>	19
21	<i>Electromagnetic disturbances – Requirements and tests</i>	20
21.1	General.....	20
21.2	Compliance criteria.....	20
21.3	Requirements applicable to all <i>ME equipment</i> and <i>ME systems</i>	20
21.4	Additional general requirements.....	20
22	<i>Usability</i>	20
22.1	General.....	20
22.2	<i>Primary operating functions</i>	21
23	<i>General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems</i>	21
23.1	General.....	21
23.2	Volume and characteristics of auditory <i>alarm signals</i> and <i>information signals</i>	21
23.3	Additional requirements for termination of <i>alarm signal</i> inactivation.....	21
23.4	Additional requirements for <i>alarm system</i> logging.....	22
24	<i>Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment</i>	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

This is a preview of "BS EN ISO 18778:2022". [Click here to purchase the full version from the ANSI store.](#)

Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the <i>patient leakage current</i> and <i>patient auxiliary current</i>	33
Annex F (informative) Suitable measuring supply circuits	34
Annex G (informative) Protection against <i>hazards</i> of ignition of flammable anaesthetic mixtures	35
Annex H (informative) <i>PEMS</i> structure, <i>PEMS development life-cycle</i> and documentation	36
Annex I (informative) <i>ME systems</i> aspects	37
Annex J (informative) Survey of insulation paths	38
Annex K (informative) Simplified <i>patient leakage current</i> 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 <i>essential principles</i> and labelling guidances	47
Annex Q (informative) Reference to the <i>essential principles</i>	49
Annex R (informative) Reference to the general safety and performance requirements	51
Bibliography	54
Terminology — Alphabetized index of defined terms	55

This is a preview of "BS EN ISO 18778:2022". Click here to purchase the full version from the ANSI store.

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*