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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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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

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

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]

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]

4 General requirements

4.1 General

Clause 4 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies with the following modifications:

4.2 *Essential performance*

NOTE There is guidance or rationale for this subclause contained in Clause A.3.

In addition to subclause 4.3 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, additional *essential performance* requirements are given in the subclauses listed in Table 1.

Table 1 — Distributed *essential performance* requirements

Requirement	Subclause
Generating the apnoeic *patient alarm condition* or Generation of a *technical alarm condition* Sensor fault *Internal electrical power source* 5 min remaining	12.3.6 [a] 12.3.7 11.5.2 f) 1) iii)
[a] Subclause 21.4 b) 5) indicates the method of evaluating generating the apnoeic *alarm condition* as acceptance criteria following specific tests required by this document.	

4.3 *ME equipment* or *ME system* parts that contact the *patient*

In addition to subclause 4.6 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies prior to the compliance check:

The parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause.

4.4 *Single fault condition* for *ME equipment*

In addition to subclause 4.7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies:

An *infant cardiorespiratory monitor* shall include at least one direct measurement of respiration and one indirect measurement of apnoeic activity such as pulse rate or oxygen saturation.

5 General requirements for testing of *ME equipment*

5.1 General

Clause 5 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

5.2 *Infant cardiorespiratory monitor* testing errors

NOTE There is guidance or rationale for this subclause contained in Clause A.3.

a) For the purposes of this document, acceptance criteria for testing declared tolerances shall use the type A evaluation method (statistical uncertainty) *procedure* from IEC Guide 115:2021, 4.4.2.

b) Test equipment and methods shall be selected and controlled to ensure that the uncertainty (with coverage factor k = 2, for confidence of ~95 %) is no more than 30 % of the disclosed tolerance for the parameter being tested.

c) The *manufacturer* shall disclose the measurement uncertainty of each disclosed tolerance in the *technical description*.

Check conformance by inspection of the *instructions for use* and the *technical description*.

6 Classification of *ME equipment* and *ME systems*

6.1 General

Clause 6 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

6.2 Additional requirements for classification of *ME equipment* and *ME systems*

An *infant cardiorespiratory monitor* shall be *transit-operable*.

7 *ME equipment* identification, *marking* and documents

7.1 General

Clause 7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

7.2 *Information to be supplied by the manufacturer*

a) The *information supplied by the manufacturer* of an *infant cardiorespiratory monitor* and its *accessories* shall conform with ISO 20417.

b) In applying ISO 20417:2021, the terms in this document and those in IEC 60601-1:2005+AMD1:2012+AMD2:2020 shall be used as follows.

   1) The term "*accompanying information*" shall assume the same meaning as *accompanying documents*.

   2) The term "*medical device*" shall assume the same meaning as *ME equipment*.

   3) The term "*user*" shall assume the same meaning as *operator*.

   4) The term "*patient*" shall include animals.

Check conformance by application of ISO 20417:2021.

7.3 Additional requirements for *accessories*

In addition to subclause 7.2.4 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies:

Accessories supplied separately shall:

a) fulfil the requirements of 7.4; and

b) be *marked* with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *infant cardiorespiratory monitor*, if applicable.

   1) If *marking* the *accessory* is not practicable, this information may be placed in the *instructions for use*.

NOTE The *manufacturer* of the *accessory* can be the *infant cardiorespiratory monitor manufacturer* or another entity ("third-party manufacturer", healthcare provider or durable medical equipment provider) and all these entities are expected to verify conformance with this requirement. Additional requirements are found in 18.1.

Check conformance by inspection and inspection of the *risk management file* for any limitations or adverse effects of the *accessory*.

7.4 Additional requirements for *marking* on the outside of *ME equipment* or *ME equipment* parts

In addition to subclause 7.2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies:

a) For an *infant cardiorespiratory monitor* intended to be used in the magnetic resonance (MR) environment, the *infant cardiorespiratory monitor*, its parts and *accessories* shall have *clearly legible markings* conforming with:

   1) *symbol* 7.3.1-1 of IEC 62570:2014 (see Table D.1, *symbol* 1) if 'MR Safe';

   2) *symbol* 7.3.1-2 of IEC 62570:2014 (see Table D.1, *symbol* 2) if 'MR Safe'; or

   3) *symbol* 7.3.2 of IEC 62570:2014 (see Table D.1, *symbol* 3) if 'MR Conditional'.

b) For an *infant cardiorespiratory monitor* not intended to be used in the magnetic resonance (MR) environment, the *infant cardiorespiratory monitor*, its parts and *accessories* shall have *clearly legible markings* conforming with IEC 62570:2014 *symbol* 7.3.3 (see Table D.1, *symbol* 4) if 'MR Unsafe'.

Check conformance by inspection.

7.5 General *instructions for use*

In addition to subclause 7.9.2.1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies.

Add as third bullet following the first paragraph:

— the intended position of the *operator*;

Add after note 5:

a) Separate *instructions for use* shall be provided for:

   1) the *lay operator*; and

   2) the *healthcare professional operator*.

b) The *manufacturer* may choose in which *instructions for use* to place the information required by this document unless otherwise indicated in this document based on *risk management* and *usability* considerations.

c) The *healthcare professional operator instructions for use* shall include the information contained in the *lay operator instructions for use*.

Check conformance by inspection of the *instructions for use*, the *risk management file* and the *usability engineering file*.

7.6 Additional requirements for warnings and safety notices

In addition to subclause 7.9.2.2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies.

The *instructions for use* shall include:

a) advice of other *hazards* and *risks* associated with the *infant cardiorespiratory monitor*, including applicable examples.

   EXAMPLE WARNING: Do not use the monitor with another impedance monitor as interference can cause missed apnoea events.

b) if the *infant cardiorespiratory monitor* only detects *central apnoea*, a warning to the effect that: Warning: Do not attempt to use this monitor to detect obstructive sleep apnoea. Obstructive sleep apnoea cannot be detected by this monitor.

c) if the *infant cardiorespiratory monitor* is not 'MR safe' or 'MR Conditional', a warning to the effect that: Warning: It is unsafe to bring this monitor into an area of magnetic resonance (MR) equipment.

Check conformance by inspection of the *instructions for use*.

7.7 Additional requirements for start-up *procedure*

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.3.

In addition to subclause 7.9.2.8 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies.

NOTE 2 For the purposes of this document, a start-up *procedure* is a pre-use functional test that is used for the initial setup for a *patient* to determine whether the *infant cardiorespiratory monitor* is ready for use.

a) The *instructions for use* for the *lay operator* shall disclose a method by which the following can be functionally tested to determine if operating correctly:

   1) the assembled sensors and related *accessories*; and

   2) the switchover to and operation from the *internal electrical power supply.*

   NOTE 3 Additional requirements are also found in 15.3.

b) The *instructions for use* for the *healthcare professional operator* shall disclose a test method:

   1) by which functions necessary for *normal use* can be tested to determine if they are operating correctly; and

   2) by which one can determine whether or not the sensors and related *accessories* are suitable for use.

c) These test methods, or portions thereof, may:

   1) be performed automatically by the *infant cardiorespiratory monitor;* or

   2) require *operator* action.

d) These test methods should be as automated as practicable.

Check conformance by inspection of the *instructions for use*.

7.8 Additional requirements for operating instructions

7.8.1 General

In addition to subclause 7.9.2.8 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies.

7.8.2 *Lay operator* operating instructions

The *instructions for use* intended for the *lay operator* shall include:

a) a description of a means to determine the operation time of the *internal electrical power source.*

b) a description of how to connect and test the connection of a *distributed alarm system,* if provided.

7.8.3 *Healthcare professional operator* operating instructions

The *instructions for use* intended for the *healthcare professional operator* shall include

a) a description of how at least the following *alarm conditions* can be functionally tested:

   1) *apnoea*; and

   2) sensor fault.

Check conformance by inspection of the *instructions for use*.

7.9 *Cleaning*, *disinfection*, and *sterilization*

Subclause 7.9.2.12 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies with the following modification:

Add after normal use:

and *single fault condition*

Add to the bulleted list:

a) any pre-use *cleaning* and *disinfection* or *cleaning* and *sterilization procedures* for the *infant cardiorespiratory monitor* and any *accessories* including any specific *procedures* necessary before the *infant cardiorespiratory monitor* is transferred to another *patient*;

b) *procedures* for *cleaning*, *disinfection* or *sterilization* and their recommended frequencies;

c) any limitations on the number of *cleaning*, *disinfection* or *sterilization* cycles.

7.10 Additional requirements for maintenance

In addition to subclause 7.9.2.13 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies.

The *instructions for use* shall disclose

a) a description of periodic safety inspections that should be performed by the *operator*.

b) the care and maintenance *procedures* for the *internal electrical power source*, including instructions for recharging and, if applicable, replacement.

Check conformance by inspection of the *instructions for use*.

7.11 Additional requirements for *accessories*, supplementary equipment, used material

In addition to subclause 7.9.2.14 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies.

If applicable, the *instructions for use* shall disclose the positioning of sensors.

7.12 Additional requirements for the *technical description*

In addition to subclause 7.9.3 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies.

a) The *technical description* shall include a description of a method for checking the proper functioning of the *alarm system* for each of the *alarm conditions* specified in this document, if not performed automatically during the start-up *procedure*.

b) The *technical description* shall disclose which checks are performed automatically.

Check conformance by inspection of the *technical description*.

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

Clause 8 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

9 Protection against *mechanical hazards* of *ME equipment* and *ME systems*

9.1 General

Clause 9 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies including the following additional subclauses.

9.2 Additional requirements for instability from unwanted lateral movement

In addition to subclause 9.4.3 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, the following applies:

a) An *infant cardiorespiratory monitor* shall include a means by which the *infant cardiorespiratory monitor* can be secured without the use of a *tool* to prevent unwanted movement during transport while in use.

EXAMPLE 1 Means to restrain physically the *infant cardiorespiratory monitor* during transport in a personal vehicle or in a baby carriage.

b) The means shall secure the *infant cardiorespiratory monitor* to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward) and 1,0 g transverse (left, right) for at least 3 s in each orientation.

EXAMPLE 2 Attach the *infant cardiorespiratory monitor* to an armature at a 1 m radius from an axis of horizontal rotation. When rotating through a circle every 2 s at constant speed, the lateral (centripetal) acceleration is approximately 1,0 g[9].

Check conformance by functional testing.

9.3 Grips and other handling devices

Subclause 9.4.4 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies with the following modifications.

Replace list item b) with the following:

b) An *infant cardiorespiratory monitor* shall require only one hand to be carried.

EXAMPLE 1 Small enough that it does not require a handle.

EXAMPLE 2 Equipped with a handle that does not require more than one hand.

EXAMPLE 3 Equipped with a carrying strap.

Check conformance by carrying with one hand.

10 Protection against unwanted and excessive radiation *hazards*

Clause 10 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

11 Protection against excessive temperatures and other *hazards*

11.1 General

Clause 11 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies including the following additions.

11.2 *Cleaning* and *disinfection* of *ME equipment* or *ME system*

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.3.

Subclause 11.6.6 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies with the following modifications:

Add the following additional requirements as the last requirements and replace the conformance test:

a) *Infant cardiorespiratory monitor enclosures* and carry cases not intended for *single use* shall be designed to allow for surface *cleaning* and *disinfection* to reduce to acceptable levels the *risk* of infection of *operators*, bystanders, or the *patient*.

b) Instructions for *processing* the *infant cardiorespiratory monitor*, its parts and *accessories* shall

   1) conform with ISO 17664-2:2021; and

   2) be disclosed in the *instructions for use*.

NOTE 2 ISO 14159[4] provides guidance for the design of *enclosures*.

Check conformance by inspection of the *risk management file*. When conformance with this document could be affected by the *cleaning* or the *disinfecting* of the *infant cardiorespiratory monitor*, its parts and *accessories*, clean and disinfect them for the number of cycles determined by the *expected service life* in accordance with the methods indicated in the *instructions for use*, including any cooling or drying period. Confirm that *basic safety* and *essential performance* are maintained after these *procedures*. Confirm that the *manufacturer* has evaluated the effects of multiple *processing* cycles and the effectiveness of those cycles.

11.3 *Sterilization* of *ME equipment* or *ME system*

Subclause 11.6.7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies with the following modifications:

Add note before compliance test:

NOTE Additional requirements are found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 11.6.6 and IEC 60601-1-11:2015, Clause 8.

11.4 *Biocompatibility* of *ME equipment* and *ME systems*

Subclause 11.7 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies with the following modifications:

Add after existing text prior to the compliance statement:

a) The *manufacturer* of any *infant cardiorespiratory monitor*, its parts and *accessories* shall address in the *risk management process* the *risks* associated with the *biocompatibility* and potential contamination of any gas stream arising from the *gas pathways*.

b) *Accessories* with *patient* contact, such as electrodes, shall be evaluated for *biocompatibility* according to ISO 10993-1:2018.

   1) *Accessories* with *patient* contact shall be considered as having permanent duration.

c) Any *gas pathways* shall be evaluated for *biocompatibility* according to ISO 18562-1:2017.

Check conformance by inspection of the *risk management file*, confirming conformity to ISO 10993-1:2018 and, if appropriate, to ISO 18562-1:2017.

11.5 Interruption of the power supply / *supply mains* to *ME equipment*

11.5.1 General

Subclause 11.8 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies including the following additions.

11.5.2 Power sources

a) An *infant cardiorespiratory monitor* shall be equipped with an *internal electrical power source*.

b) If equipped with a connection to *supply mains*, an *infant cardiorespiratory monitor* shall be equipped with an automatic switchover to the *internal electrical power source* when the *supply mains* falls outside the values necessary to maintain normal operation within 5 s.

c) A fully charged *internal electrical power source* shall be capable of powering the *infant cardiorespiratory monitor* for at least 8 h.

d) A means shall be provided for determining the state of this *internal electrical power source.*

e) A means shall be provided to indicate that the *infant cardiorespiratory monitor* is powered from the *internal electrical power source.*

f) The *infant cardiorespiratory monitor* shall either

   1) be equipped with an *alarm system* that:

      i) detects an *alarm condition* of at least a *low priority* to indicate the switchover to the *internal electrical power source*;

      ii) detects an *alarm condition* of at least a *low priority* to indicate there is at least 30 min of remaining power available in the *internal electrical power source;*

         a) The *alarm condition* to indicate there is at least 30 min of remaining power available shall include an auditory *alarm signal*.

      iii) detects an *alarm condition* of at least a *medium priority* to indicate there is at least 5 min of remaining power available in the *internal electrical power source;*

      iv) provides at least 5 min between the start of these two *internal electrical power source* failure *alarm conditions;*

      v) detects an *alarm condition* of at least a *high priority* to indicate there is an indication of immediate turn off; or

   2) be equipped with an *intelligent alarm system*, based on additional information, determines that the impending *internal electrical power source* failure *alarm condition*:

      i) is suppressed; or

      ii) priority is changed.

   NOTE The *operator* needs sufficient time “prior to the loss of all power” to take action to ensure that alternative arrangements can be made to continue the function of the *infant cardiorespiratory monitor*.

g) The *instructions for use* shall disclose

   1) the operational time of the *infant cardiorespiratory monitor* when powered from a fully charged *internal electrical power source*.

   2) the behaviour of the *infant cardiorespiratory monitor* after a switchover to

      i) the *internal electrical power source*; or

ii) an alternative *supply mains*.

3) the behaviour of the *infant cardiorespiratory monitor* during the recharging of:

i) the *internal electrical power source*; or

ii) an alternative *supply mains*.

4) the minimum time between complete loss of the *internal electrical power source* and

i) the start of the *low priority* impending *internal electrical power source* failure *alarm condition*; and

ii) the *medium priority* impending *internal electrical power source* failure *alarm condition*.

Check conformance by functional testing and inspection of the *instructions for use*.

11.5.3 Alternative power supply/*supply mains*

a) An *infant cardiorespiratory monitor* shall have a means of connection to an alternative *supply mains*.

EXAMPLE 1 A 12 V d.c., 100 W connector for connection to an automotive vehicle power source.

EXAMPLE 2 A connection to alternative d.c. power source.

b) The *instructions for use* shall include

1) a description of the means of connection.

2) the *rated* voltage range.

3) the *nominal* voltage range.

4) the maximum current required.

Check conformance by inspection and inspection of the *instructions for use*.

12 Accuracy of controls and instruments and protection against hazardous outputs

12.1 General

Clause 12 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

12.2 Accuracy of controls and instruments

Subclause 12.1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies with the following modifications:

Add after existing text prior to the compliance statement:

a) An *infant cardiorespiratory monitor* may provide means to reduce the visibility of its controls and indicators either automatically or by *operator* action.

b) If a means to reduce the visibility is provided, the *infant cardiorespiratory monitor* shall automatically resume normal visibility during an *alarm condition*.

c) The controls and indicators of an *infant cardiorespiratory monitor* shall be *clearly legible* under the conditions specified in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2, but with the light level extended from the range of '100 lx to 1 500 lx' to the range of '100 lx to 10 000 lx'.

Check conformance by functional testing and application of the tests of IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2.

12.3 Accuracy of controls and instruments

12.3.1 General

Subclause 12.1 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies including the following additions.

12.3.2 Cardiorespiratory monitoring

For the purposes of detecting and creating *alarm conditions* for episodes of *apnoea*, an *infant cardiorespiratory monitor* shall include:

a) at least one direct measurement of respiration; and

b) one indirect measurement of apnoeic activity such as pulse rate, heart rate or oxygen saturation.

12.3.3 Direct monitoring - respiration

a) An *infant cardiorespiratory monitor* shall have a primary means for detecting:

   1) *central apnoea*;

   2) *obstructive apnoea;* or

   3) both.

b) The *instructions for use* shall describe the methods for detecting *apnoea.*

   1) If the *infant cardiorespiratory monitor* can determine the type of *apnoea*, the *instructions for use* shall describe the method for determining the type of *apnoea* detected.

      EXAMPLE Impedance pneumology for detecting *central apnoea*; airway thermistor for detecting *central apnoea* and *obstructive apnoea*.

Check conformance by functional testing.

12.3.4 Indirect monitoring – heart rate

If equipped with heart rate monitoring using ECG, the heart rate monitoring shall conform with the following parts of IEC 60601-2-27:2011:

a) 201.8.3; and

b) 201.15.3.4.101.

Check conformance by functional testing and the application of the tests of IEC 60601-2-27:2011.

12.3.5 Indirect monitoring from pulse oximetry

12.3.5.1 Indirect monitoring – oxygen saturation

If equipped with oxygen saturation monitoring using pulse oximetry, the oxygen saturation monitoring shall conform with the following parts of ISO 80601-2-61:2017:

a) 201.7.9.2.1.101 c);

b) 201.7.9.2.1.101 g);

c) 201.7.9.2.2.101;

d) 201.7.9.2.9.101;

e) 201.7.9.2.14.101 a);

f) 201.7.9.2.14.101 b);

g) 201.10.4;

h) 201.11.1.2.2;

i) 201.12.1;

j) 201.12.4;

k) 201.13.101; and

l) 201.101.

Check conformance by application of the tests of ISO 80601-2-61:2017.

12.3.5.2 Indirect monitoring – pulse rate

If equipped with pulse rate monitoring using pulse oximetry, the pulse rate monitoring shall conform with the following parts of ISO 80601-2-61:2017:

a) 201.7.9.2.1.101 c);

b) 201.7.9.2.1.101 g);

c) 201.7.9.2.2.101;

d) 201.7.9.2.9.101;

e) 201.7.9.2.14.101 a);

f) 201.7.9.2.14.101 b);

g) 201.10.4;

h) 201.11.1.2.2;

i) 201.12.4.102;

j) 201.13.101; and

k) 201.101.

Check conformance by application of the tests of ISO 80601-2-61:2017.

12.3.6 Apnoeic *patient alarm condition*

a) An *infant cardiorespiratory monitor* shall be equipped with an *alarm system* that detects an *alarm condition* to indicate that the *patient* is *apnoeic*.

   1) The *alarm limits* for the apnoeic *patient alarm condition* shall be *responsible organization*-adjustable over the range of 5 s to 20 s.

   2) The *alarm limits* for the apnoeic *patient alarm condition* shall not be *lay operator*-adjustable (see IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.7).

   3) The *infant cardiorespiratory monitor* may provide the *lay operator* more than one preset apnoeic *patient alarm limits*.

   EXAMPLE An awake *alarm limit* and a sleeping *alarm limit*.

b) The *patient* apnoeic *alarm condition* shall be *high priority* unless an *intelligent alarm system*, based on additional information, determines that the *apnoea alarm condition*:

1) is suppressed; or

2) priority is changed.

c) The sum of the *apnoea alarm condition delay* and *alarm signal generation delay* shall not exceed 10 s.

Check conformance by functional testing.

12.3.7 Sensor fault

a) An *infant cardiorespiratory monitor* shall be equipped with an *alarm system* that detects an *alarm condition* to indicate a sensor fault or sensor disconnection.

b) The sensor fault or sensor disconnection *alarm condition* shall be at least *medium priority* unless an *intelligent alarm system*, based on additional information, determines that the *apnoea alarm condition*:

1) is suppressed; or

2) priority is changed.

c) The maximum *alarm condition delay* for the sensor fault or sensor disconnection *alarm condition* shall not be greater than 20 s.

d) The *alarm system* should indicate which sensor is faulty or disconnected.

e) The *alarm system* should discriminate between:

1) *apnoea*;

2) sensor fault; and

3) sensor disconnection.

Check conformance by functional testing.

12.3.8 Clinical performance evaluation

a) An *infant cardiorespiratory monitor* shall be evaluated utilizing a *clinical investigation*.

b) The *clinical investigation* shall conform with the requirements of ISO 14155:2020.

c) Annex C may be used for the *clinical investigation*.

Check conformance by inspection of the *clinical investigation* report.

12.4 *Usability* of *ME equipment*

Subclause 12.2 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies including the following additions.

a) An *infant cardiorespiratory monitor* shall provide the *responsible organization* with a means to allow the *healthcare professional operator* to have direct access to settings and *alarm limits* (see IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.7).

b) An *infant cardiorespiratory monitor* shall provide the *responsible organization* or the *healthcare professional operator* with a means to restrict the *lay operator* from adjusting the *alarm settings* (see IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 6.7).

Check conformance by functional testing.

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

Clause 13 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies with the following modifications:

Addition:

A *single fault condition* shall not cause the simultaneous failure of:

a) the direct measurement of respiration; and

b) any indirect measurement of apnoeic activity.

Check conformance by inspection and functional testing.

14 *Programmable electrical medical systems (PEMS)*

Clause 14 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

15 Construction of *ME equipment*

15.1 General

Clause 15 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, including the following additions:

15.2 Mode of operation

An *infant cardiorespiratory monitor* shall be suitable for *continuous operation*.

Check conformance by inspection.

15.3 Pre-use check

a) An *infant cardiorespiratory monitor* shall be provided with means that allow the following to be functionally tested by the *lay operator* to determine if they are operating correctly and ready for use:

   1) the *patient* cables;

   2) switchover to and operation from the *internal electrical power source*; and

   3) all *alarm signals* including the *alarm signals* from a *distributed alarm system*.

b) This test method:

   1) if practicable, shall be performed automatically by the *infant cardiorespiratory monitor*; but

   2) may require *operator* action.

   EXAMPLE Combination of the power-on self-test routines and *operator* actions that functionally check the *alarm signals*.

   NOTE Additional requirements are found in 7.7.

c) The *model or type reference* of any required *accessories* or test equipment needed to perform these tests shall be disclosed in the *instructions for use* for the *lay operator*.

d) The *instructions for use* for the *lay operator* shall disclose the *procedure* by which these tests are performed.

Check conformance by inspection of the *instructions for use* and functional testing.

16 *ME systems*

Clause 16 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

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

Clause 17 of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

18 Requirements for the *accessories*

18.1 General

The parts and *accessories* of an *infant cardiorespiratory monitor* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *infant cardiorespiratory monitor* or by another entity ("third-party manufacturer").

Check conformance by the tests of this standard.

18.2 Labelling

The *accompanying document* provided with each *accessory*, conforming with 18.1, shall include at least one *model or type reference* of a compatible *infant cardiorespiratory monitor*.

Check conformance by inspection of the *accompanying document*.

19 Training

NOTE 1 There is guidance or rationale for this clause contained in Clause A.3.

In the application of the requirements of IEC 62366-1:2015+AMD1:2020, 5.6, 5.7.1 b), 5.7.3 d) and 5.8 training shall be considered necessary for both the *lay operator* and *healthcare professional operator*.

NOTE 2 Requirements for training are found in IEC 62366-1:2015+AMD1:2020, 5.8.

Check conformance by inspection of the *accompanying document* and the *usability engineering file*.

20 *Functional connection*

20.1 General

Basic safety and *essential performance* shall be maintained if a connection to the *functional connection* of an *infant cardiorespiratory monitor* is disrupted or if the equipment connected to those parts fails.

Check conformance by functional testing.

20.2 Connection to an electronic health record

NOTE There is guidance or rationale for this subclause contained in Clause A.3.

An *infant cardiorespiratory monitor* should be equipped with a *functional connection* that permits data transmission from the *infant cardiorespiratory monitor* to e.g. an electronic health record.

20.3 Connection to a *distributed alarm system*

NOTE There is guidance or rationale for this subclause contained in Clause A.3.

a) An *infant cardiorespiratory monitor* shall be equipped with a *functional connection* that permits connection to a *distributed alarm system*.

b) The *distributed alarm system* shall not cause a *hazardous situation* to the *patient* under both *normal condition* and under *single fault condition*.

21 Electromagnetic disturbances – Requirements and tests

21.1 General

IEC 60601-1-2:2014+AMD1:2020 applies, except as follows:

21.2 Compliance criteria

Subclause 4.3.1 of IEC 60601-1-2:2014+AMD1:2020 applies with the following addition:

Amendment (add an additional dash between the second dash and third dash of 4.3.1):

— an *infant cardiorespiratory monitor* is operated using the conditions and test configuration to detect an *apnoea* event per 12.3.6.

21.3 Requirements applicable to all *ME equipment* and *ME systems*

Subclause 5.2.2.1 of IEC 60601-1-2:2014+AMD1:2020 applies with the following modifications:

Add note to list element b):

NOTE The requirements of this document are not considered deviations or allowances.

21.4 Additional general requirements

Subclause 8.1 of IEC 60601-1-2:2014+AMD1:2020 applies with the following additions:

a) An *infant cardiorespiratory monitor* shall be tested according to the requirements for the *home healthcare environment*.

b) The following degradations, if associated with *basic safety* or *essential performance*, shall not be allowed:

   1) component failures;

   2) changes in programmable parameters or settings;

   3) reset to default settings;

   4) loss of an auditory or visual *alarm signal*;

   5) loss of apnoeic event detection.

c) During testing, the *infant cardiorespiratory monitor* shall be capable of generating the apnoeic *patient alarm condition*.

22 *Usability*

22.1 General

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 applies with the following addition.

22.2 *Primary operating functions*

a) For an *infant cardiorespiratory monitor*, the following shall be considered *primary operating functions* for all *operator profiles*:

   1) connecting all required sensors to the *infant cardiorespiratory monitor*;

   2) proper placement of sensors on the *patient*;

   3) starting the *infant cardiorespiratory monitor* from power off;

   4) setting *lay operator*-adjustable *alarm system* controls;

      i) setting *alarm limits*, and

      ii) inactivating *alarm signals*;

   5) turning off the *infant cardiorespiratory monitor*;

   6) charging the *internal electrical power source*;

   7) *processing* a soiled *infant cardiorespiratory monitor* between uses;

   8) selecting between preset apnoeic *patient alarm limits*, if so equipped;

   9) performing basic pre-use functional check of the *infant cardiorespiratory monitor* including the *alarm system*; and

   10) connecting the *infant cardiorespiratory monitor* to the *distributed alarm system*.

b) For an *infant cardiorespiratory monitor*, the following *professional operator*-adjustable *alarm system* controls shall also be considered *primary operating functions*:

   1) setting *healthcare professional operator*-adjustable *alarm system* controls:

      i) setting *alarm limits*, and

      ii) inactivating *alarm signals*.

23 General requirements, tests and guidance for *alarm systems* in *medical electrical equipment* and *medical electrical systems*

23.1 General

IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 applies except as follows:

23.2 Volume and characteristics of auditory *alarm signals* and *information signals*

Subclause 6.3.3.2 of IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 applies with the following additions:

a) For *high priority* and *medium priority alarm signals*, the *infant cardiorespiratory monitor* shall be capable of generating a sound pressure level of at least 70 dBA.

b) For *high priority* and *medium priority alarm signals*, the *infant cardiorespiratory monitor* shall not be capable of generating a sound pressure level greater than 90 dBA.

c) The *infant cardiorespiratory monitor* should automatically adjust the auditory *alarm signal* sound pressure level in response to current ambient sound pressure levels.

23.3 Additional requirements for termination of *alarm signal* inactivation

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.3.

Subclause 6.8.4 of IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 applies with the following additions:

a) An *infant cardiorespiratory monitor* shall not be equipped with:

   1) *alarm off*; or

   2) *audio off*.

b) The duration of *alarm paused*, *audio paused* or *acknowledged* for the *alarm conditions* required by this document shall not exceed 120 s without *operator* intervention.

NOTE 2 This permits an *operator* to deliberately extend the duration of *audio paused* by direct action.

Check compliance by functional testing.

23.4 Additional requirements for *alarm system* logging

NOTE There is guidance or rationale for this subclause contained in Clause A.3.

Subclause 6.12 of IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 applies with the following additions:

a) Notwithstanding the requirements of IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, an *infant cardiorespiratory monitor* shall

   1) be equipped with an *alarm system* log for all *alarm conditions* and all *alarm signal* inactivation states with a capacity of at least 1 000 events.

   2) not lose the contents of the *alarm system* log during a loss of power for less than 365 d unless deleted by *responsible organization* action.

   3) not permit the *lay operator* to erase the contents of the *alarm system* log (see 201.109).

b) This log shall also include at least the following events:

   1) initial state of the *infant cardiorespiratory monitor*;

   2) change of *alarm settings*;

   3) power supply source change;

   4) access mode; and

   5) result of the last pre-use check.

c) The log may consist of multiple individual logs.

Check conformance by inspection and functional testing.

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

IEC 60601-1-11:2015+AMD1:2020 applies except for subclause 8.4 which does not apply.

Annex A
(informative)

General guidance and rationale

A.1 General

Annex A of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, with the following additions:

A.2 General guidance

This Annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

A.3 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this document, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

— **4.2 – *Essential performance***

Footnote [a] to Table 1 indicates methods of evaluating the monitoring of cardiorespiratory parameters as acceptance criteria following specific tests required by this document. It is intended to provide criteria which can be used to easily verify that *essential performance* has been maintained. Although the degradations detailed within 21.3 are associated with *immunity* testing, the same criteria are intended to be used when the conformance criteria from any other clause or subclause requires confirmation that *essential performance* is or has been maintained.

Those aspects of *essential performance* that cannot be reasonably linked to the conformance criteria within 21.3 need to be confirmed via other means. But, one need only confirm that the specific requirements indicated in 21.3 that are likely to have an impact on specific clinical performance are maintained after testing.

— **5.2 – *Infant cardiorespiratory monitor* testing errors**

When testing an *infant cardiorespiratory monitor* performance several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flowrates.

Because of the relative significance of these uncertainties, it is important that *manufacturers* allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester to recognise the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a *manufacturer* determines that a parameter has an intended tolerance of ±10 %, but the measurement uncertainty is ±3 % then test acceptance criteria is ±7 %. If a third party is testing to this document, they also need to include measurement uncertainty in their testing. If they subsequently obtain an error of the measured value for that

parameter of ±15%, with a measurement uncertainty of ±5 %, then the third-party tester could neither accept nor refute the *manufacturer's* claim.

Furthermore, the *manufacturer* is required to disclose the measurement uncertainty for each declared value in order to provide both information to the *responsible organization* and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

— 7.7 – **Additional requirements for start-up *procedure***

In some designs, adequate checking of the *alarm system* can be performed with a combination of *operator* action and the power-on self-test routines that verify the integrity of the software and the integrity of the computer controlling the *infant cardiorespiratory monitor*, as well as the measuring sensors and the *alarm signal* generation.

— 11.2 – ***Cleaning* and *disinfection* of *ME equipment* or *ME system***

The *essential principles* of ISO 16142-1 require that medical devices are "not [to] compromise the clinical condition or the safety of *patients*, or the safety and health of users or, where applicable, other persons, provided that any *risks* which may be associated with their use constitute acceptable *risks* when weighed against benefits to the *patient* and are compatible with a high level of protection of health and safety."

This means that an *infant cardiorespiratory monitor*, its *accessories* and parts should not be used if there is an unacceptable *risk* of the *patient*, *operator* or other person being infected as a result of contact with the *infant cardiorespiratory monitor*, *accessory* or part.

Therefore, after long-term use in the home, an *infant cardiorespiratory monitor*, its *accessories* and parts, if transferred to a new *patient,* require an appropriate level of *disinfection*, depending on their use, but rarely need to be *sterile*.

Recommendations for hygienic *processing* of an *infant cardiorespiratory monitor*, its *accessories* and parts are based on the general hygiene requirements for the *processing* of medical devices and need to take into consideration the special requirements and needs of *patient* care in the clinical environment. The requirements for hygienic *processing* of this document are intended to:

— make the *responsible organization* for *processing* the *infant cardiorespiratory monitor* aware of how to implement these tasks in a responsible manner through appropriate delegation; and

— help all parties involved in the *processing* of an *infant cardiorespiratory monitor*, its *accessories* and parts to comply with the *manufacturer's* instructions.

The *cleaning* and *disinfection procedures* of the *manufacturer* are also intended to provide practical support to all those involved in *patient* care in the clinical environment with regard to implementing the hygiene measures required for the *patient's* safety.

It should be noted that an *infant cardiorespiratory monitor*, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any *infant cardiorespiratory monitor* that has already been used on another *patient* is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and *processing procedures* are essential to protect the next person handling the equipment or the next *patient* on whom the equipment is used. Hence, an *infant cardiorespiratory monitor*, its re-usable *accessories* and parts that have been used are required to undergo a *processing procedure*, following the *manufacturer's* instructions, prior to reuse by another *patient*.

The following basic considerations need to be addressed by the *manufacturer* when specifying the *processing* instructions of an *infant cardiorespiratory monitor*, its *accessories* or parts:

— protecting the *patient*, the *operator* and the *responsible organization* (including personnel involved in performing the *processing*);

— the limits of the *procedures* used for *processing* (such as the number of *processing* cycles); and

— the necessity to guarantee the proven standardised *procedures* to a consistently high and verifiable quality, based on an established quality management system.

The recommended *processing procedures* should be determined by:

— the potential degree and type of contamination of the *infant cardiorespiratory monitor*, *accessories* or parts; and

— the *risk* of infecting another *patient* resulting from their reuse and the type of application of the *infant cardiorespiratory monitor*.

Special consideration of the possible *risk* associated with the contamination of gas-conducting components due to the *patient's* re-breathing under *single fault condition* should be considered.

On the basis of the above, a *verified* and *validated* documented *processing procedure* needs to be specified in such detail so that the outcome is reproducible. An acceptable *residual risk* from the *hazard* of infection for the next *patient* can be assumed if the:

— documented *processing procedure's* effectiveness has been *verified* through appropriate scientific methods by the *manufacturer*; and

— reliability of the documented *processing procedures* has been *verified* in practice through appropriate quality assurance measures by the *responsible organization* carrying out the *processing procedures*.

When selecting and evaluating the *processing procedures*, the *manufacturer* should consider:

— the amount and type of pathogenic microorganisms expected to contaminate the *infant cardiorespiratory monitor*, *accessories* or parts;

— the *risk* for the pathogenic microorganisms to be transmitted to the *patient*, *operator* or other persons; and

— the microorganism's resistance to the recommended *processing procedures*.

The *risks* posed by *processing* an *infant cardiorespiratory monitor*, its *accessories* or parts are determined by the following factors:

a) undesired effects, which can result from:

— the previous use,

— the previous *processing*, and

— transportation and storage;

b) the *risks* from subsequent uses, such as the following:

— residues from the previous use (such as secretions, other body fluids, and drugs),

— residues from the previous *processing* (such as *cleaning* agents, disinfectants and other substances, including their reaction products),

— changes of physical, chemical or functional properties of the device, and

— changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints); and

c) the *risk* of transmission of any pathogenic microorganisms.

When considering the suitability and the feasibility of the *processing procedure* for the *infant cardiorespiratory monitor*, *accessories* or parts, the *manufacturer* should consider the following points:

— the *risks* involved in the *processing*;

— the cost effectiveness of the *processing*;

— the practicability of the *processing*;

— the availability of the *cleaning* equipment and the *cleaning* agents specified in the *processing*;

— the efficiency of the *processing*;

— the reproducibility of the *processing*;

— quality management requirements of the *processing*; and

— the environmental impact of the *processing* and the disposal of the *infant cardiorespiratory monitor accessories* or parts.

The *manufacturer* should verify all *cleaning* agents and *processing procedures* used with regard to their suitability and repeatability with the *infant cardiorespiratory monitor*, *accessories* or parts, depending on the type of use.

The *responsible organization* should verify that manual *cleaning* and *disinfection* of the *infant cardiorespiratory monitor*, *accessories* or parts are always carried out in accordance with the *procedures* specified in the *accompanying document*.

The *manufacturer* should specify *validated* automated *cleaning* and *disinfection procedures*. If they are not followed, the effectiveness of the *cleaning* and *disinfection* cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of *cleaning* agents and disinfectants, and residence time.

To ensure the reproducibility of automated *processing procedures*, tests should be carried out on a regular basis.

The *manufacturer* should ensure that the specified *disinfection procedures* are *verified* to be bactericidal, fungicidal and virucidal so that the cleaned and disinfected *infant cardiorespiratory monitor*, its *accessories* or parts do not pose an unacceptable *risk* of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually, comes in contact with the next *patient*, *operator* or person.

Effective *disinfection* requires that the instructions for the disinfectant, especially regarding concentration and residence time, are followed.

Following any *processing procedure*, safety and functional testing of the *infant cardiorespiratory monitor* (as specified by the *manufacturer's* instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the *infant cardiorespiratory monitor*.

The extent and type of the tests depends on the *infant cardiorespiratory monitor*, *accessory* or part and these need to be defined in the *accompanying document*.

— **Clause 19 – Training**

The modern *infant cardiorespiratory monitor* is complex equipment whose use by a *lay operator* requires specific training for each *manufacturer's* make and model.

— **20.2 – Connection to an electronic health record**

Electronic documentation of *patient* care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual *patient* through accurate and complete documentation, and to improve the completeness and accuracy of aggregate data to facilitate continuous quality improvement. Providing remote supervisory capability is rapidly becoming the standard of care in the *home healthcare environment*.

— **20.3 – Connection to a *distributed alarm system***

Patients who are monitored by an *infant cardiorespiratory monitor* are not always located near enough to the *lay operator* to ensure that *alarm signals* coming from the *patient's* room can be heard. It is reasonably foreseeable that some rooms of a *patient's* home are out of earshot of other rooms. As a result, it is necessary for an *infant cardiorespiratory monitor* intended for use in the *home healthcare environment* to be equipped with a means to connect to a *distributed alarm system* that can provide additional *alarm signal* presentation points. A *distributed alarm system* facilitates delivery of *alarm signals* to other rooms where the *operator* might be located, thereby permitting a timely response and intervention to support *patient* care.

— **23.3 – Additional requirements for termination of *alarm signal* inactivation**

Permitting very long pauses of *alarm signals* can be hazardous for the *patient* since the *operator* will not be notified of the existence of an *alarm condition*. However, *patient* management often requires *procedures* that can be disrupted by auditory *alarm signals*. Therefore, extending *audio paused* by *operator* action is useful to prevent the *infant cardiorespiratory monitor* from disturbing the *operator* or others in the vicinity.

An *infant cardiorespiratory monitor* should be equipped with an *audio paused* capability that permits the *operator* to pause the *alarm signals* prior to the creation of an *alarm condition*. Such a capability permits the *operator* to minimize nuisance auditory *alarm signals* in situations that are known to be associated with creation of nuisance *alarm conditions*. A 'planned' disconnect is a common situation where this capability is needed.

— **23.4 – Additional requirements for *alarm system* logging**

Optimal management of a *patient* requires the ability to review the history of important *alarm conditions*. This is a more reasonable means of *risk control* in the *home healthcare environment* for equipment than *latching alarm signals*. Additional information is also found in IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, Annex A, for 6.12 – *alarm condition* logging

Annex B
(informative)

Sequence of testing

Annex B of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex C
(informative)

Guide to *marking* and labelling requirements for *ME equipment* and *ME systems*

C.1 General

Annex C of IEC 60601-1:2005+AMD1:2012+AMD2:2020, applies, with the following additions:

C.2 *Marking* on the outside of *ME equipment*, *ME systems* or their parts

Additional requirements for *marking* on the outside of an *infant cardiorespiratory monitor*, its parts and *accessories* are found in Table C.1.

Table C.1 — *Marking* on the outside of an *infant cardiorespiratory monitor*, its parts or *accessories*

Description of *marking*	Subclause
Accessories, indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *infant cardiorespiratory monitor*, if applicable	7.3 b)
Accessories, requirements of 7.4	7.3 a)
MR safe or conditional, if applicable	7.4 a)
MR unsafe, if applicable	7.4 b)
Requirements of ISO 20417	7.2

C.3 Accompanying documents, general

Additional requirements for general information to be included in the *accompanying documents* of an *infant cardiorespiratory monitor* or its parts are found in Table C.2.

Table C.2 — *Accompanying documents*, general

Description of requirement	Subclause
Declared tolerances shall include the measurement uncertainty	5.2 c)
For *accessories*, at least one *model or type reference* of a compatible *infant cardiorespiratory monitor*	18.2
Requirements of ISO 20417	7.2

C.4 Accompanying documents, instructions for use

Additional requirements for information to be included in the *instructions for use* of an *infant cardiorespiratory monitor* or its parts are found in Table C.3.

Table C.3 — *Instructions for use*

Description of requirement	Subclause
Accessories, indication of any limitations or adverse effects of the *accessory* on the *basic safety* or *essential performance* of the *infant cardiorespiratory monitor*, if not *marked* and if applicable	7.3 b) 1)
Advice of other *hazards* and *risks* associated with the *infant cardiorespiratory monitor*, with examples	7.6 a)
Alternative *supply mains*, a description of the means of connection	11.5.3 b) 1)
Alternative *supply mains,* the maximum current required	11.5.3 b) 4)
Alternative *supply mains,* the *nominal* voltage range	11.5.3 b) 3)
Alternative *supply mains,* the *rated* voltage range	11.5.3 b) 2)
Any *accessories* including any specific *procedures* necessary before the *infant cardiorespiratory monitor* is transferred to another *patient*	7.9 a)
Any pre-use *cleaning* and *disinfection* or *cleaning* and *sterilization procedures* for the *infant cardiorespiratory monitor*	7.9 a)
Behaviour of the *infant cardiorespiratory monitor* after a switchover to the *internal electrical power source*	11.5.2 g) 2) i)
Behaviour of the *infant cardiorespiratory monitor* after a switchover to an alternative *supply mains*	11.5.2 g) 2) ii)
Behaviour of the *infant cardiorespiratory monitor* during the recharging of the *internal electrical power source*	11.5.2 g) 3) i)
Behaviour of the *infant cardiorespiratory monitor* during the recharging of an alternative *supply mains*	11.5.2 g) 3) ii)
Care and maintenance *procedures* for the *internal electrical power source*, including instructions for recharging and, if applicable, replacement	7.10 b)
Description of periodic safety inspections that should be performed by the *operator*	7.10 a)
Healthcare professional operator instructions for use, a description of how the apnoea *patient alarm condition* can be functionally tested	7.8.3 a) 1)
Healthcare professional operator instructions for use, a description of how the sensor fault *alarm condition* can be functionally tested	7.8.3 a) 2)
Healthcare professional operator instructions for use, method by which functions necessary for *normal use* can be tested to determine if they are operating correctly	7.7 b) 1)
Healthcare professional operator instructions for use, method by which one can determine whether or not the sensors and related *accessories* are suitable for use	7.7 b) 2)
Healthcare professional operator instructions for use, the information contained in the *lay operator instructions for use*	7.5 d)
Infant cardiorespiratory monitor is not safe in MR environment warning, if applicable	7.6 c)
Instructions for *processing* the *infant cardiorespiratory monitor*, its parts and *accessories*	11.2 b)
Intended position of the *operator*	7.5
Lay operator instructions for use, a description how to connect and test the connection of a *distributed alarm system,* if provided	7.8.2 b)
Lay operator instructions for use, a description of a means to determine the operation time of the *internal electrical power source*	7.8.2 a)
Lay operator instructions for use, method by which switchover to and operation from the *internal electrical power supply* can be functionally tested to determine if operating correctly	7.7 a) 2)
Lay operator instructions for use, method by which the assembled sensors and related *accessories* can be functionally tested to determine if operating correctly	7.7 a) 1)
Lay operator instructions for use, the *procedure* by which the functional testing required in 15.3 are performed	15.3 d)
Means for detecting *apnoea*	12.3.3 b)

Table C.3 *(continued)*

Description of requirement	Subclause
Method for determining the type of *apnoea*, if applicable	12.3.3 b) 1)
Minimum time between complete loss of the *internal electrical power source* and the start of the *low priority* impending *internal electrical power source* failure *alarm condition*	11.5.2 g) 4) i)
Minimum time between complete loss of the *internal electrical power source* and the *medium priority* impending internal electrical power source failure *alarm condition*	11.5.2 g) 4) ii)
Model or type reference of any required *accessories* or test equipment needed to perform the functional testing required in 15.3	15.3 c)
Obstructive sleep apnoea warning, if applicable	7.6 b)
Operational time of the *infant cardiorespiratory monitor* when powered from a fully charged internal electrical power source	11.5.2 g) 1)
Positioning of sensors, if applicable	7.11
Procedures for *cleaning*, *disinfection* or *sterilization* and the recommended frequencies	7.9 b)
Requirements of ISO 20417	7.2
Separate *instructions for use* for the *lay operator* and *healthcare professional operator*	7.5 a)

C.5 *Accompanying documents, technical description*

Additional requirements for information to be included in the *technical description* of an *infant cardiorespiratory monitor* or its parts are found in Table C.4.

Table C.4 — *Technical description*

Description of requirement	Subclause
Description of a method for checking the proper functioning of the *alarm system* for each of the *alarm conditions* specified in this document	7.12 a)
Measurement uncertainty of each disclosed tolerance	5.2 d)
Requirements of ISO 20417	7.2
Which checks of the proper functioning of the *alarm system* for each of the *alarm conditions* specified in this document are performed automatically	7.12 b)

Annex D
(informative)

Symbols on *marking*

Annex D of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies, with the following additions:

Table D.1 — Additional *symbols* on *marking*

No	*Symbol*	Reference	Title and description
1		IEC 60878:2015[5] *Symbol* 7.3.1-1 IEC 62570:2014	MR Safe To identify an item which poses no unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. NOTE When color reproduction is not practical, the *symbol* can be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.
2		IEC 60878:2015[5] *Symbol* 7.3.1-2 IEC 62570:2014	MR Safe Alternative graphical *symbol* representation. Same meaning as IEC 62570-7.3.1-1.
3		IEC 60878:2015[5] *Symbol* 7.3.2 IEC 62570:2014	MR Conditional To identify an item which poses no unacceptable *risks* within defined conditions to the *patient*, medical staff or other persons within the MR environment. NOTE 1 When color reproduction is not practical, the *symbol* can be printed in black and white. The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. NOTE 2 The MR Conditional *symbol* can be supplemented by supplementary *marking* that describes the conditions for which the item has been demonstrated to be MR Conditional.
4		IEC 60878:2015[5] *Symbol* 7.3.3 IEC 62570:2014	MR Unsafe To identify an item which poses unacceptable *risks* to the *patient*, medical staff or other persons within the MR environment. NOTE When color reproduction is not practical, the *symbol* can be printed in black and white. The use of the colored version is strongly encouraged for the added visibility and information provided by the color.

Annex E
(informative)

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

Annex E of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex F
(informative)

Suitable measuring supply circuits

Annex F of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex G
(informative)

Protection against *hazards* of ignition of flammable anaesthetic mixtures

Annex G of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex H
(informative)

PEMS structure, *PEMS development life-cycle* and documentation

Annex H of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex I
(informative)

ME systems aspects

Annex I of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex J
(informative)

Survey of insulation paths

Annex J of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex K
(informative)

Simplified *patient leakage current* diagrams

Annex K of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex L
(informative)

Insulated winding wires for use without interleaved insulation

Annex L of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex M
(informative)

Reduction of pollution degrees

Annex M of IEC 60601-1:2005+AMD1:2012+AMD2:2020 applies.

Annex N
(informative)

Data interface requirements

N.1 Background and purpose

Heightened interest in the monitoring of the *infant cardiorespiratory monitor* in the *home healthcare environment*, as well as accountability and responsiveness of the parties involved has become evident on an international scale. Consequently, *patients*, caregivers, clinicians, service providers, and payers have begun the systematic definition and collection of information with regard to monitoring the performance of this type of *infant cardiorespiratory monitor*. This trend is also driven by an enhanced data infrastructure. In order to establish a common definition for monitoring the performance of *infant cardiorespiratory monitors*, explicit criteria need be applied to choosing and defining parameters. This framework is intended to inform about a common definition of parameters for *infant cardiorespiratory monitors* in the *home healthcare environment*. The selection is based on some agreement about what is to be monitored, and for what purpose.

It is important to note that any data collection needs to be carried out according to privacy and confidentiality legislation and ethical principles.

A harmonized effort to develop internationally accepted therapy indicators for *infant cardiorespiratory monitors* in the *home healthcare environment* not only fosters increasingly robust cross-national analyses, but can also facilitate the development of comparable data that can be used as a basis for the setting of international benchmarks.

The standardization of data available from *infant cardiorespiratory monitors* in the *home healthcare environment* is intended to help to eliminate the current shortcomings and contribute significantly to the improvement of the monitoring. This approach seeks to provide a definition that can used across *infant cardiorespiratory monitors* for providing monitoring data independent of the *infant cardiorespiratory monitor manufacturer* or what mechanisms are used to transport the data, either locally or remotely to a *healthcare professional operator*. This approach ensures comparability between data regardless of the transport mechanism chosen to be most appropriate for a *patient* situation. It also provides for flexible and cost-effective integration into disparate equipment that *healthcare professional operators* can use for *patient* data management. This approach also maintains comparability between data while allowing advancement in data transport technology to provide solutions that better meet the needs of *patients*, caregivers, clinicians, service providers and payers. As such, the definition of specific equipment communication interface hardware or software considerations such as protocols or transport mediums is outside of the scope of this document.

The following levels of data are defined:

— **Equipment identification:** Information identifying the *infant cardiorespiratory monitor*

— **Usage monitoring:** Data providing monitoring of the use

— **Settings *of the infant cardiorespiratory monitor*:** Settings relating to monitoring of *patient*

— ***Infant cardiorespiratory monitor alarm limits*:** Settings relating to *alarm limits*

— **Event information:** Information provided about events related to the usage of the *infant cardiorespiratory monitor*

— **Service monitoring:** Indicators relating to preventative or corrective maintenance of the *infant cardiorespiratory monitor* and its *accessories*

All *infant cardiorespiratory monitors* should provide the information to enable identification of the *infant cardiorespiratory monitor*. Implementation of any further data levels is optional.

Information identifying pressure units used in the data set should also be provided.

N.2 Data definition

Table N.1 defines *infant cardiorespiratory monitor* identification data.

Table N.1 — Equipment Identification

Parameter	Description	Type
Equipment *manufacturer*	Identification of the *manufacturer* of the equipment	Text string
Equipment model	Identification of the product or model number of the equipment	Text string
Equipment serial number	Identification number of the equipment	Text string
Equipment software version	Identification of the software version(s) implemented in the equipment	Text string
NOTE More than one software version can need to be communicated from the equipment.		

Table N.2 defines data required for usage monitoring.

A set of measured and calculated values should be provided for each monitoring session, where a monitoring session is any period of time the *infant cardiorespiratory monitor* is monitoring the *patient.*

Table N.2 — Usage monitoring

Parameter	Description	Type
Monitoring start date/time	The current UTC (Coordinated Universal Time) date and time when the usage session was started	ISO 8601-1 Date Time (YYYY-MM-DDThh:mm:ss)
Monitoring stop date/time	The current UTC date and time when the usage session was stopped	ISO 8601-1 Date Time (YYYY-MM-DDThh:mm:ss)
Hours of monitoring	Number of hours the equipment is powered on and monitoring the *patient*	Value: (h)
Hours of *patient* use	Number of hours the equipment is monitoring the *patient*	Value: (h)

Table N.3 defines applicable *infant cardiorespiratory monitor* usage information.

Table N.3 — Event information

Parameter	Description	Type
Power supply source	Current source of electrical power 1 = external AC *supply mains* 2 = *internal electrical power source* 3 = external DC *supply mains*	Mode in use: (1, 2, 3)
Alarm signal inactive state present	List of text strings (*alarm off, alarm paused, audio off, audio paused, acknowledged*)	List of text strings
Active *alarm condition*	Currently active *alarm conditions*	List of text strings (*manufacturer*-defined)

Table N.3 *(continued)*

Parameter	Description	Type
Access mode	Current access mode of the *infant cardiorespiratory monitor* 1 = *lay operator* 2 = *healthcare professional operator* 3 = *responsible organization*	Mode in use: (1, 2, 3)

Table N.4 defines applicable service and maintenance parameters.

Table N.4 — Service monitoring

Parameter	Description	Type
Maintenance needed	A *manufacturer*-specific list of any items requiring maintenance	List of text strings (*manufacturer*-defined)
Infant cardiorespiratory monitor service indicator	An indication that service is required	Text string: (*manufacturer*-defined)
Hours of monitoring	Number of hours the equipment is powered on and monitoring the *patient*	Value: (h)