INTERNATIONAL STANDARD

ISO 18778

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Respiratory equipment — Infant monitors — Particular requirements

Matériel respiratoire — Moniteurs pour enfants — Exigences particulières

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 18778 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment* Subcommittee SC 3, *Lung ventilators and related equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

This International Standard specifies requirement for infant monitors (called in previous working documents “infant apnoea monitors” but with a too restrictive scope) which are used to recognize apparent life-threatening events in an infant who is asleep.

These devices are for domiciliary use only.

This International standard is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/for hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definition of Collateral Standard and Particular can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

This International Standard uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

— “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list item, note, table, figure) additional to the General Standard.

— “Amendment” means that an existing element of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: clauses, subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional Annexes are lettered AA, BB, etc.

The term “this Standard” is used to make reference to the General Standard and this Standard taken together.

Where there is no corresponding section, clause or subclause in this Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification, where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Standard.

Clauses and subclauses to which there is a rationale are marked with an throughout this International Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*). This rationale can be found in the informative Annex AA.

Respiratory equipment — Infant monitors — Particular requirements

1 * Scope

IEC 60601-1:1988, Clause 1, applies except as follows:

Amendments (add at end of 1.1):

1.1

This International Standard specifies requirements for the safety and essential performance of monitors used to detect apparent life-threatening events[1)] in sleeping or resting children under three years of age. This International Standard applies to devices used in home care applications. These monitors are generally used without continual professional supervision.

This International Standard also applies to the accessories, e.g. probes and cables necessary to apply the monitor to the **patient**.

This International Standard does not apply to monitors intended for use in health care facilities/institutions.

The requirements of this International Standard, which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995), are intended to take precedence over the corresponding general requirements.

1.4

Addition:

NOTE Planning and design of products complying with this Standard can have environmental impact during the product life cycle. Environmental aspects are addressed in Annex BB. Additional aspects of environmental impact are addressed in ISO 14971.

2 Normative references

The following referenced documents are indispensable for the application 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.

EN 71-1:1998 + A1:2001, *Safety of toys — Part 1: Mechanical and physical properties*

EN 980:2003, *Graphical symbols for use in the labelling of medical devices*

EN 1041:1998, *Information supplied by the manufacturer with medical devices*

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1) Referred to as “monitor” throughout the document.

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

IEC 60601-1:1988 + A1:1991 + A2:1995 and corrigendum 1995 mod, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety —Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60529:2001, *Degree of protection provided by enclosures (IP Code)*

IEC 60068-2-32:1975, *Environmental testing — Part 2: Tests — Test Ed: Free fall.* (A 1:1982 + A 2:1990)

IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration broad-band random (digital control) and guidance*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Methods of test for ignition temperature*

IEC 60601-2-23:1999, *Medical electrical equipment — Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment*

IEC 60601-2-27:1994, *Medical electrical equipment — Part 2-27: Particular requirements for the safety of electrocardiographic monitoring equipment*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 9919, *Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use*

ISO 15001:2003, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:1988, ISO 4135 and the following apply.

3.1
applied part
part of the monitor intended to be connected to the **patient** and which in **normal use**:

— necessarily comes into physical contact with the **patient** for the infant monitor to perform its function or

— can be brought into contact with the **patient** or

— needs to be touched by the **patient**.

3.2
expected service life
period during which the performance of the monitor or any of its components is expected to meet the requirements of this Standard when used and maintained according to the **accompanying documents**

3.3
shelf life
minimum period of time during which the monitor or any of its components may be stored in its original container under conditions in accordance with the **accompanying documents** and able to perform according to the manufacturer's specifications

4 General requirements and general requirements for tests

IEC 60601-1:1988, Clauses 3 and 4 apply, except as follows:

Additions:

3.1 * No safety hazard in normal condition and single fault condition

Add at the end of the subclause:

Function of the monitor shall be assured under single fault condition.

NOTE In order to assure function of the monitor under single fault condition, monitoring of two physiological variables is required (e.g. heat rate, oxygen saturation, respiratory rate).

4.101 Other test methods

Test methods other than those specified in this International Standard, but of equal or greater accuracy may be used to verify compliance with requirements.

5 Classification

IEC 60601-1:1988, Clause 5 applies, except as follows:

Replacement:

5.2 Applied part classification

The monitor and its **applied parts** shall be classified as type BF or type CF.

6 Identification, marking and documents

IEC 60601-1:1988, Clause 6 applies, except as follows:

Addition:

Information and marking shall comply with EN 980 and EN 1041.

6.1 Marking on the outside of equipment or equipment parts

Replacement:

d) if the size of the monitor does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the monitor:

— the name of the manufacturer;

— a serial or lot or batch identifying number;

— symbol ISO 7000-0434 (or see Table D1, Symbol 14 in of IEC 60601-1:1988).

Additions:

aa) the manufacturer shall mark the monitor with a caution to refer the **user** or operator to the **accompanying documents** or symbol ISO 7000-0434 for the expected adverse effects on the performance of the monitor;

bb) packages for single use components shall be durably marked with the following words: “single use” or “single **patient** use” or the symbol ISO 7000-1051;

cc) on monitors intended for hospital use only, a permanent warning label to the effect that: “The device is not for use in home care environment”;

dd) the monitor and its parts shall be marked regarding their proper disposal, as adequate.

6.3 Markings of controls and instruments

Additions:

Marking of controls should be clearly legible at a distance of 1 m in a range of illumination from 100 lx to 1 500 lx by an individual with a visual acuity of 1 (corrected if necessary).

All controls which increase or decrease a function shall be marked with a legible indication to inform the operator which action(s) is (are) required to increase or decrease the controlled function.

Controls should be identified with their associated markings.

6.8 Accompanying documents

Additions:

6.8.2 * Instructions for use

Additions:

6.8.2d) Cleaning, disinfection and sterilization

— any pre-use cleaning or disinfecting procedures for the monitor and any accessories including any specific procedure(s) necessary before the monitor is transferred to another **patient**;

— methods for cleaning, disinfecting or sterilizing and the recommended frequencies;

— any limitations on the number of cleaning, disinfecting or sterilizing cycles.

6.8.2aa)

Additions:

NOTE The following requirements are grouped under an appropriate headline as they usually appear in the instructions for use. This has been done for convenience of the people involved in this. This does not mean that the required information in the instructions for use is to be presented in the order as listed below.

1) Intended use

— a statement of the intended uses (i.e. purpose) of the monitor and an explanation on how the monitor accomplishes that purpose;

— a description of the types of apparent life-threatening events that the device is intended to monitor;

— the parameters monitored by any additional modality, if applicable;

— a description of the principles of operation of the monitor;

— the type of sensors used.

2) Precautions and hazards

— precautions to minimize the risk of strangulation, accomplished by providing instructions for routing of **patient** wires and tubing in the device labelling;

— precautions to minimize hazards due to exposure to toxic materials from the monitor occasioned by abnormal conditions;

— the location of all latex-based components;

— advice of other hazards and risks associated with the monitor;

— precaution to minimize the risk due to small parts being inhaled or swallowed and due to fingers or flesh being entrapped.

3) Monitor information

— explanation of the function and meaning of each alarm and indicator provided with the monitor;

— a statement that the monitor may not be able to detect all life-threatening events.

4) Operating information

— clear, simple diagrams and illustrations of the fully-assembled and ready-to-operate monitor;

— steps required to prepare the monitor for operation;

— diagrams, illustrations or photos showing proper connection of the **patient** to the monitor and other equipment, if applicable, including alternative recommended electrode and sensor placement;

— proper connection of auxiliary devices;

— description of appropriate warm-up procedures and intervals;

— drawings or photos of all controls, alarms and indicators provided with the monitor;

— explanation of the use of the controls, alarms and indicators;

— a step-by-step procedure for checking proper functioning of all controls, indicators and alarms;

— list of error messages, if applicable, their meaning and the corrective steps that can be taken by the operator;

— a troubleshooting guide for use when there are indications of a monitor malfunction during checkout and/or operation;

— the positioning of sensors and electrodes, alternate electrode placement, preparation of electrodes and **patient** for electrode attachment, and identification of loose sensors and electrodes;

— procedures to follow in the event of a monitor **alarm condition**;

— warnings concerning the precautions necessary to avoid possible or unsafe use of the monitor;

— connection and proper use of remote alarm units, including recommended placement and the importance of the operator being able to access the **patient** as quickly as possible;

— legible reproductions of all required labels and hazard warnings on the device;

— description of the circumstances when it may be appropriate to contact the prescribing physician or health care professional;

— recommendation to the effect that the lay operator be trained in cardiopulmonary resuscitation;

— information concerning the disposal of the monitor and its components (e.g. battery).

5) Operator maintenance instructions

— methods and materials for cleaning, disinfecting or sterilizing the monitor;

— schedule of operator-initiated maintenance including any specific procedure(s) necessary before the monitor is transferred to another **patient**;

— battery care and maintenance procedures, including instructions for recharging or replacement;

— description of periodic visual safety inspections that should be performed by the operator.

6) Patient information

— clinical circumstances that might require sensor adjustment or checking for proper operation;

— circumstances related to the use of the monitor which could cause a hazardous situation (e.g. bio-incompatibility, chemical, or thermal injury);

— instructions for preventing injury reactions, e.g. periodically repositioning electrodes.

7) Operating environment information

— the ranges of temperature, atmospheric pressure and humidity for operation and for storage;

— the time from switching “ON” to obtaining specified operating performance;

— description of known or recognizable conditions of the environment which can affect the safe and effective operation of the monitor, including the following items:

  a) facility information, including a description of what should be expected if electricity to the monitor is lost;

  b) effects of lint, dust, sun, artificial light, heat or humidity;

  c) effects and possible sources of electromagnetic (conducted and radiated) interference;

  d) effects and causes of electrostatic discharge;

  e) list of other devices that pose potential electrical problems;

  f) effects of fluctuation(s) in electrical supply mains or battery voltage;

  g) description of conditions of the sensors and electrodes, such as loosened electrodes, that can cause environmental effects to be more pronounced;

  h) other sources of interference;

  i) steps that can be taken by the operator to identify and resolve environmental interference.

8) Service information

— the recommended methods and frequency of routine inspection, testing, calibration, repair and periodic service;

— a list of facilities that provide service, and their locations;

— **expected service life** of the monitor;

— **shelf life** and **expected service life** of sensors;

— information concerning the disposal of the monitor or components thereof.

6.8.3 Technical description

Additions:

aa) the technical description shall include the following:

— equipment specifications, including signal processing functions, algorithms and averaging times for monitor functions that are applicable to the operation and use of the device;

— a statement as to whether or not pacemaker pulse rejection and defibrillator protection are included;

— a description of equipment required for monitor use and any specifications necessary for electrodes, sensors, leads, cables, tubing, batteries and any other accessories;

— step-by-step procedures to prepare the monitor for initial and subsequent use;

— if a manual sensitivity control is provided, instructions as to when to use manual sensitivity and how to adjust the control for optimal signal detection;

— step-by-step procedures recommended for determining whether the monitor is susceptible to the levels of electromagnetic interference occurring at the use location, a recommendation to repeat the testing periodically, and recommended action to take if the monitor fails the test;

— precautions and a schedule of maintenance and calibrations necessary.

6.101 Legibility

Safety indications shall be legible and correctly perceived by an individual with a visual acuity of 1 (corrected if necessary) from a distance of 1 m at a range of illumination of 100 lx to 1 500 lx, when viewing the information, markings, etc. perpendicular to and including 15° above, below, left and right of the normal line of sight of the operator.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies, except as follows:

10.1 Transport and storage

Replacement:

The monitor (not including the battery) shall be capable, while packed for transport and storage, of being exposed to an environmental temperature range of − 40°C to + 70°C and at relative humidity up to 95 %, non-condensing.

After such an exposure, the monitor shall meet the requirements of this International Standard and shall remain operational.

10.2.1 Environment

Replacements:

a) an ambient temperature range of + 5 °C to + 40 °C;

b) a relative humidity range of 15 % to 95 %, non-condensing.

10.2.2 * Power supply

When mains-powered, the monitor shall operate within specification (± 20 % nominal).

Addition:

10.3 Disposal

Consideration should be given to the disposal of packaging wastes.

11 Not used

IEC 60601-1:1988, Clause 11 applies.

12 Not used

IEC 60601-1:1988, Clause 12 applies.

13 General

IEC 60601-1:1988, Clause 13 applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies.

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

17 Separation

IEC 60601-1:1988, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies.

20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies.

21 Mechanical strength

IEC 60601-1:1988, Clause 21 applies, except as follows:

21.6 Portable and mobile equipment

Addition:

The monitor is considered to be a portable and mobile piece of equipment and shall be capable of withstanding the stresses caused by rough handling.

Compliance is checked by the tests a) and b) of IEC 60601-1:1988, and its amendments and the following additional tests:

c) mechanical shock

Test the monitor according to IEC 60068-2-32 shock test (free fall) with the following severity levels:

— height: 0,5 m;

— number of falls: 2 falls on each face.

After each of these tests, the monitor shall perform within the manufacturer's specifications and meet the requirements of this International Standard:

d) vibration resistance;

Test the monitor according to IEC 60068-2-64 broad-band random vibration test with the following severity levels:

- frequency range: 10 Hz to 150 Hz;
- acceleration spectral density: 1 $(m/s^2)^2/Hz$ (g^2/Hz) from 10 Hz to 12 Hz, decreasing at a rate of 3 dB per octave from 12 Hz to 150 Hz;
- duration: 30 min on each orthogonal axis.

During each of these tests, visually inspect the monitor. After each of these tests, the monitor shall perform within the manufacturer's specification and meet the requirements of this International Standard.

22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23 applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.

26 Vibration and noise

IEC 60601-1:1988, Clause 26 applies.

27 Pneumatic and hydraulic power

IEC 60601-1:1988, Clause 27 applies.

28 Suspended masses

IEC 60601-1:1988, Clause 28 applies.

29 X-Radiation

IEC 60601-1:1988, Clause 29 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

IEC 60601-1:1988, Clause 30 applies.

31 Microwave radiation

IEC 60601-1:1988, Clause 31 applies.

32 Light radiation (including lasers)

IEC 60601-1:1988, Clause 32 applies.

33 Infrared radiation

IEC 60601-1:1988, Clause 33 applies.

34 Ultraviolet energy

IEC 60601-1:1988, Clause 34 applies.

35 Acoustical energy (including ultrasonics)

IEC 60601-1:1988, Clause 35 applies.

36 * Electromagnetic Compatibility

IEC 60601-1:1988, Clause 36 applies, except as follows:

Addition:

The monitor shall be subjected to those tests and those test levels as specified in IEC 60601-1-2 for devices specified as life-supporting equipment and systems.

NOTE Although the monitor itself is not life-supporting equipment and system, it was considered necessary to apply the same requirement as for life-supporting equipment and systems (see also AA.3.1).

37 Locations and basic requirements

IEC 60601-1:1988, Clause 37 applies.

38 Marking and accompanying documents

IEC 60601-1:1988, clause 38 applies.

39 Common requirements for category AP and category APG equipment

IEC 60601-1:1988, Clause 39 applies.

40 Requirements and tests for category AP equipment, parts and components thereof

IEC 60601-1:1988, Clause 40 applies.

41 Requirements and tests for category APG equipment, parts and components thereof

IEC 60601-1:1988, Clause 41 applies.

42 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies, except as follows:

Addition:

NOTE For sensor temperature, see Subclause 101.1 of this International Standard.

43 * Fire prevention

IEC 60601-1:1988, Clause 43 applies, except as follows:

43.2 Oxygen enriched atmospheres

Replacement:

In order to reduce the risk of fire to **patients**, other persons or the surroundings, ignitable material, under normal and single fault condition, shall not at the same time be subjected to conditions in which:

— the temperature of the material is raised to its minimum ignition temperature;

— an oxidant is present.

The minimum ignition temperature is determined in accordance with IEC 60079-4, using the oxidizing conditions present under normal and single fault conditions.

Compliance is checked by determining the temperature the material is raised to under normal and single fault conditions.

If sparking can occur under normal or single fault condition(s), the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal condition(s) with a single fault.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

IEC 60601-1:1988, Clause 44 applies, except as follows:

44.3 Spillage

Amendment:

The monitor and its components shall be so constructed that spillage does not wet component parts which, when wetted, can cause a safety hazard.

Compliance is checked by the test described in 44.3 of IEC 60601-1:1988.

44.6 Ingress of liquids

Amendment:

The enclosures of the monitor and its components shall be classified as drip-proof equipment in accordance with IEC 60529.

Compliance is checked by the tests of IEC 60529. Following each of these tests visually inspect the monitor and perform a functional test.

44.7 Cleaning, sterilization or disinfection

Amendment:

All components not specified by the manufacturer as for single **patient** use, which come into contact with the **patient**, shall be capable of being sterilized or disinfected.

*Compliance is checked by a review of the **accompanying documents** for methods of sterilization or disinfection and by inspection of the relevant validation reports.*

44.8 Compatibility with substances used with the equipment

Addition:

The monitor shall comply with ISO 15001.

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45 applies.

46 Human errors

IEC 60601-1:1988, Clause 46 applies, except as follows:

Addition:

NOTE Attention is drawn to IEC 60601-1-6 [1].

47 Electrostatic charges

IEC 60601-1:1988, Clause 47 applies.

48 Biocompatibility

IEC 60601-1:1988, Clause 48 applies.

49 Interruption of the power supply

IEC 60601-1:1988, Clause 49 applies, except as follows:

Addition:

49.101 Backup power

All mains-powered monitors intended for use in the home shall have a battery power backup. Unless the over-current protection has activated the battery, power backup shall automatically be activated when the mains power is outside the range specified by the manufacturer.

The monitor shall be fully operational within 5 s of the battery backup power being activated.

The battery shall have sufficient capacity, when fully charged, to supply power for normal operation for at least 8 h.

50 Accuracy of operating data

IEC 60601-1:1988, Clause 50 applies.

51 Protection against hazardous output

IEC 60601-1:1988, Clause 51 applies, except as follows:

Addition:

51.101 * Measurement accuracy

The accuracy of parameters for detecting life-threatening events, including the drift due to environmental effects or time, shall be as specified by the manufacturer in the instructions for use.

NOTE For other physiological variables monitored, see accuracy requirements of the appropriate standards (see 101.1).

Compliance is checked by measurement of the time from the start of the simulation of the life-threatening event until activation of the alarm function for each variable monitored.

52 Abnormal operation and fault conditions

IEC 60601-1:1988, Clause 52 applies.

53 Environmental tests

IEC 60601-1:1988, Clause 53 applies.

54 General

IEC 60601-1:1988, Clause 54 applies.

55 Enclosures and covers

IEC 60601-1:1988, Clause 55 applies.

56 Components and general assembly

IEC 60601-1:1988, Clause 56 applies, except as follows:

56.7 Batteries

Addition to c):

Means shall be provided to determine the state of the battery power supply.

56.10 Actuating parts of controls

Addition to b):

— controls of monitors intended for home use shall be protected from inadvertent changes or adjustment;

— operator-adjustable-controls used for calibration shall include a means to prevent unintentional changes from the intended position.

57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57 applies.

58 Protective earthing – Terminals and connections

IEC 60601-1:1988, Clause 58 applies.

59 Construction and layout

IEC 60601-1:1988, Clause 59 applies, except as follows:

59.3 Excessive current and voltage protection

Addition:

All mains-powered monitors shall be provided with an over-current protection.

An auditory **alarm signal** shall be activated when the over-current protection device is activated and the monitor is not functioning as specified for normal use.

This auditory **alarm signal** shall be capable of sounding for at least 15 min.

101 Additional requirements

101.1 General requirements

The monitoring of physiological variables shall comply with the requirements of the appropriate standards in addition to those specified in this International Standard (see also 3.1):

ECG monitoring functions shall comply with IEC 60601-2-27.

Transcutaneous monitoring shall comply with IEC 60601-2-23.

Pulse oximetry functions shall comply with ISO 9919.

A self-test shall be included in the monitor, for confirmation by the operator, to operate or exercise all visual and auditory **alarm signals** and status indicators each time the monitor is turned on.

101.2 Constructional requirements

101.2.1 Protection against strangulation

Provision shall be made in routing, retention devices, or other means to minimize the risk of strangulation of the **patient** by wires or tubing.

101.2.2 Protection against inhalation and ingestion of parts

Any part that is not intended to be detached shall conform to one of the following:

a) the part shall be so embedded that an infant cannot grip it with teeth or fingers;

b) the part shall not become detached when tested in accordance with 8.3 and 8.4 of EN 71-1:1998/A1:2001;

c) any parts that become detached in accordance with 8.3 and 8.4 of EN 71-1:1998/A1:2001 shall not fit wholly within the small parts cylinder specified in 8.2 of EN 71-1:1998/A1:2001.

101.2.3 Protection against entrapment of fingers or flesh

There shall be no accessible open-ended tubes, projections, holes, loose washers, speed fixings, nuts or crevices in which an infant's finger or flesh could become trapped.

To avoid entrapment of fingers, there shall be no accessible openings with a width greater than 5 mm and less than 12 mm, unless the depth of penetration is less than 10 mm.

Where mesh is used, to avoid the creation of trapping hazards due to the flexibility of the mesh material, the mesh shall resist penetration by a 7 mm diameter test probe under a specified force of 30 N.

101.2.4 Protective incompatibility of connector

Monitor connectors, including those on wires and tubing, shall be designed in such a way that insertion into a receptacle other than one for which they are intended or into a receptacle using an improper orientation is not possible.

101.2.5 Low battery alarm

Monitors intended for use in the home shall have an auditory and visual low battery alarm that activates at least 15 min before the battery has insufficient charge remaining to supply power for monitor operation.

Audio-pausing for the auditory low battery **alarm signal** shall be provided but the visual low battery **alarm signal** shall remain activated until the battery is depleted.

101.2.6 Battery compartments

Battery compartments should be designed to prevent the risk of accidentally short-circuiting the battery.

If a **safety hazard** or monitor malfunction could result from incorrect connection or replacement of a battery, the monitor shall be designed to prevent incorrect polarity of connection.

101.2.7 Electrical power indicators

A visual indicator shall be provided to indicate that the monitor is energized.

Such an indicator shall be located conspicuously on the monitor and shall distinguish between battery power and mains-power sources when both sources are provided.

If the monitor incorporates a means for battery charging, a visual indication that the battery is charging shall be provided.

101.3 Alarms

101.3.1 Functional requirements

101.3.1.1 Apparent life-threatening event alarm

If the monitor is provided with a function to measure the duration of an apparent life-threatening event (ALTE), an alarm function with a visual and auditory signal shall be activated within 2 s of the duration of the ALTE exceeding the set value.

The **alarm signal** generation delay of an ALTE shall be pre-set if not, operator adjustable-settings other than 20 s shall require the use of a tool or special authorized procedures to change those settings from 20 s

A visual indication shall be provided to indicate that the setting has been changed from 20 s.

The **alarm signal** generation delay of an ALTE shall be indicated continuously or on operator demand.

101.3.1.2 Sensor fault alarm

The monitor shall be provided with a sensor fault alarm function with a visual and auditory signal to indicate when the sensor signal is outside the range of values specified for proper function by the manufacturer.

101.3.2 Alarm signal requirements

101.3.2.1 General alarm signal requirements

Reset controls for **alarm signals** shall function such that neither continuous activation nor failure of the reset control will permanently disable the **alarm signal**.

101.3.2.2 Visual signals

Red shall be used for visual **alarm signals** only.

Green shall be used for visual status indicators only.

Visual **alarm signals** and status indicators shall be legible at a distance of 1 m, when viewed by an individual with visual acuity of 1 (corrected if necessary), under conditions having a range of illumination from 100 lx to 1 500 lx.

Visual **alarm signals** shall continue to be activated until they are manually reset, even if the condition generating the alarm resolves.

101.3.2.3 Auditory signals

Auditory **alarm signals**, which indicate the need for immediate attention to the **patient**, shall be distinct from other types of auditory indicators.

Sound level measured at a distance of 1 m should be at least 75 dB (A-weighted) for home monitors and 70 dB (A-weighted) for hospital monitors.

Permanently disabling of auditory **alarm signals** shall not be provided.

Except in the case of the low battery alarm, the activation of an **audio-pause** state of any auditory **alarm signal** shall not exceed 2 min. This activation shall be accompanied by a visual indication of **audio-pause**.

Auditory **alarm signals** may automatically reset if the condition generating the alarm resolves.

101.3.3 * Remote alarms

101.3.3.1

If provided, the remote alarm unit shall not cause a **safety hazard** to the **patient** under **normal condition** and under single fault condition.

NOTE The remote alarm unit should function under **single fault condition** (see 3.1).

101.3.3.2

If provided, the remote alarm unit shall give a visual and auditory **alarm signal** when an alarm function at the site of the **patient** has been activated and when the unit is unable to detect a signal from the monitor.

101.3.3.3

Using a remote alarm unit shall not disable the alarm functions at the monitor.

101.3.3.4

If provided, the remote alarm unit shall give a visual and auditory **alarm signal** when the driving power of the remote alarm is outside the range specified by the manufacturer.

101.3.3.5

If the remote alarm is battery operated, the remote alarm unit shall have auditory and visual low battery alarms that activate at least 15 min before the battery has insufficient charge remaining to supply power for normal operation of the remote alarm unit.

These low battery alarms shall remain activated until the battery is depleted.

The low battery alarm shall have a means for **audio-pause** of the auditory low battery **alarm signal** but not for inactivating the visual low battery signal.

101.3.3.6

If the remote alarm unit is mains-power operated, a battery backup that is automatically activateds within 5 s of the line power being outside the range of supply power as specified by the manufacturer shall be provided.

Annexes

IEC 60601-1:1988, Appendices apply, except as follows:

Addition:

The following Annexes are added:

Annex AA
(informative)

Rationale

AA.0 General

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

The clauses in this Annex have been so numbered to correspond to the clauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

AA.1 Scope

A variety of causes may create a Life-Threatening Event (LTE) in an infant who is asleep. Apnoea is often regarded as the most common but other pathophysiological abnormalities affecting not only respiration but in addition the nervous and cardiovascular systems may also be implicated. Furthermore, external physical conditions may be involved, e.g. respiratory obstruction and temperature changes. Any LTE can potentially progress rapidly to the so-called Sudden Infant Death Syndrome (SIDS).

Monitors designed to recognize Apparent LTE (ALTE) have been used for many years, usually based on the detection of changes in the respiratory rate, so-called apnoea monitors. It is recognized in this International Standard that a variety of physiological or physical changes may be assessed in order to indicate an ALTE, not necessarily by distinguishing apnoea.

As these monitors are most frequently used in the home environment, without the presence of medically skilled personnel, monitoring of the physiological variables of the infant and the necessary alarms reduce the risk of SIDS.

Safety and essential performance considerations with regard to the accuracy of measurement, alarm functions, electrical safety, uninterrupted availability of the monitoring in the environment in which the monitor is used and the safety of connections for sensors and other accessories led to this standard.

AA.3.1 General requirements

In the clinical environment, multiple monitoring systems to detect ALTE are available. This is not so in the home where a single infant monitor is used.

However, the widespread use of these monitors, by parents who are clearly extremely anxious about the well-being of their infant during sleep, indicate that these operators have an implicit trust in the equipment. Therefore the Committee agreed that an essential performance requirement of this monitor should be normal operation under a single-fault condition.

AA.6.8.2 Instructions for use

The instructions for use for lay persons in the home environment should be essentially simple in language, style and design, with the inclusion of ample illustrations, diagrams and functional sketches. The operating information (6.8.2.4) includes the minimum directions to be supplied. Nevertheless, the manufacturer is encouraged to broaden this schedule to include any additional pertinent advice. In particular, it is strongly recommended that the operator is made fully aware of the fact that the use of an ALTE monitor does not guarantee prevention of SIDS; it is only a tool for the parents to indicate an ALTE.

AA.10.2.2 Due to the fact that a mains power supply system in a home is expected to have greater variations than in a hospital, a monitor in homecare use shall, when mains-powered, operate within specifications, under mains-power variations of ± 20 % from the nominal voltage.

AA.36 Electromagnetic compatibility

Infant monitors are not strictly considered as life-supporting devices, in the sense of electromagnetic compatibility requirements, because they do not maintain life.

AA.43 Fire prevention

Reports of fire caused by medical electrical equipment are unusual. However, when such fires occur they can have tragic consequences.

The risk of fire is fundamentally determined by the three elements which are necessary in order to start a fire:

— ignitable material (fuel);

— temperature equal to or above the minimum ignition temperature of the material or sparks with energy dissipation equal to or above the minimum ignition energy of the materials;

— an oxidant.

Therefore, following the basic safety concepts of the General Standard, the objective in the design of the equipment shall be to ensure that under both normal and single fault conditions, and under the oxidising conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur, provided it is self-limiting so that no **safety hazard** is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in the published literature, although normally only in ambient air and 100 % oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of the oxidant present. If ignition temperatures for other materials or oxygen concentrations are required, these may be determined using the methods and apparatus described in IEC 60079-4.

In considering the ignitable materials, particular attention should be paid to materials that may accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The effect of sparks in environments containing oxidants is quite different from that in explosive gas mixtures. Spark energy is the most potent form of energy in igniting explosive gas mixtures whilst in environments containing oxidants thermal energy is more fundamental. It is possible that at higher power levels sufficient

spark energy can be dissipated in the interface between sparking conductors or their surroundings so that sustained burning occurs but there is at present no documented evidence as to the power level at which this might occur for different materials and environments. Where the potential spark power dissipation deviates from the well established safe practice therefore, specific spark tests should be conducted simulating the most unfavourable environment that can be reasonably foreseen.

The accumulating materials mentioned above are particularly susceptible to ignition by spark energy because of their low ignition temperatures and very low thermal capacity coupled with poor conductance.

In certain standards currently in use, the requirements to minimize fire risk are based on limitation of temperature and electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen, which is given in the American NFPA publication 53 M [3] as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical equipment with oxygen enriched atmospheres.

The origin of the electrical energy values that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from accepted working practices or from tests performed in other environments. Simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any “fuel” present.

It is therefore now generally accepted that there are no single or universally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances whilst not being unduly restrictive. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under single fault conditions, in a typical electrical circuit, the possible number of failure modes is very high. In this case, full assurance of safety may only be possible with the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions, and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under single fault condition.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under single fault condition.

The particular combination of material, oxidant and temperature determines whether a fire will occur, not a single value of any one of these variables.

AA.101.3.3 Remote alarms

Parents using these monitors in the home may rely on a remote alarm to alert them to an ALTE. They will have the same tacit trust in this indicator as they would in the one integral to the monitor (see AA.3.1). Again therefore, the Committee agreed that under single-fault conditions the remote alarm should continue to function normally.

Annex BB
(informative)

Environmental aspects

The environmental impact generated by an Infant monitor is mainly restricted to the following occurrences:

— impact at local environment during normal use;

— use, cleaning and disposal of consumables during testing and normal use;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the life cycle of the Infant monitor.

See Table BB.1 for a mapping of the life cycle of an Infant monitor related to aspects of the environment.

Table BB.1 — Environmental aspects addressed by clauses of this standard

Environmental aspects (Inputs and outputs)		**Product Life Cycle**			
		Production and preproduction Stage A	**Distribution** (including packaging) Stage B	**Use** Stage C	**End of life** Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
1	Resource use	1.2	1.2	1.2	1.2
2	Energy consumption	1.2	1.2	1.2 42	—
3	Emission to air	1.2	1.2	1.2 6.8.2.8 36 42 43 44 45 56.7	1.2
4	Emission to water	1.2	1.2	1.2 44	1.2
5	Waste	1.2	1.2 10.1	1.2 6.1 6.8.2 44 56.7	1.2 6.1 6.8.2

Table BB.1 (*continued*)

Environmental aspects (Inputs and outputs)		**Product Life Cycle**			
		Production and preproduction Stage A	**Distribution** (including packaging) Stage B	**Use** Stage C	**End of life** Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
6	Noise	—	—	1.2 35 101.3	—
7	Migration of hazardous substances	1.2	—	1.2 6.1 6.8.2 25 44 45 48 56.7	1.2
8	Impacts on soil	—	—	—	1.2 6.8.2
9	Risks to the environment from accidents or misuse	1.2	—	1.2 6.8.2 44 45 56 101.2 101.3	1.2

Annex CC
(informative)

Index of defined terms

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