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.