INTERNATIONAL STANDARD

ISO 18778

First edition
2005-02-15

Respiratory equipment — Infant monitors — Particular requirements

Matériel respiratoire — Moniteurs pour enfants — Exigences particulières

Reference number
ISO 18778:2005(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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*

---

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