Hingamisvahendid. Beebimonitorid. Erinõuded

Respiratory equipment - Infant monitors - Particular requirements

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 18778:2009 sisaldab Euroopa standardi EN ISO 18778:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 18778:2009 consists of the English text of the European standard EN ISO 18778:2009.
Standard on kinnitatud Eesti Standardikeskuse 29.05.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 29.05.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 15.04.2009.	Date of Availability of the European standard text 15.04.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad:

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18778

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Supersedes EN ISO 18778:2005

English Version

Respiratory equipment - Infant monitors - Particular requirements (ISO 18778:2005)

Matériel respiratoire - Moniteurs pour enfants - Exigences particulières (ISO 18778:2005)

Beatmungsgeräte - Überwachungsgeräte für Kleinkinder - Besondere Anforderungen (ISO 18778:2005)

This European Standard was approved by CEN on 21 March 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 18778:2009: E

Foreword

The text of ISO 18778:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 18778:2009 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18778:2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 18778:2005 has been approved by CEN as a EN ISO 18778:2009 without any modification.

Annex ZA
(Informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 – Correspondence between this International Standard and Directive 93/42/EEC Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	All	
5	All	
6	13, 13.2	
6.1	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard.
6.1 d)	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2aa)	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
6.8.2	13.6 (h)(2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
-	13.6 (q)	This relevant Essential Requirement is not addressed in this European Standard

6.3	10.2, 10.3, 12.8, 12.9	
6.8	13.1, 13.3, 13.4, 13.6	
6.101	12.9	
7	12.6	
8	12.6	
9	12.6	
10.1	5	
10.2	5	
13	12.6	
14	12.6	
15	12.6	
16	12.6, 12.7	
17	12.6	
18	12.6	
19	12.6	
20	12.6	
21	12.7	
22	12.7	
23	12.7	
24	12.7	
25	12.7	
26	12.7.2, 12.7.3	
27	12.8	
28	12.7	
29	11	
36	9.2, 12.5	
38	13	
39	9.2, 9.3, 12.6, 12.7	
40	9.2, 9.3, 12.6, 12.7	
41	9.2, 9.3, 12.6, 12.7	
42	12.7	
43	9.3, 12.7	
44.3	7.6, 12.6	
44.6	7.6, 12.6	
44.7	8.1	

44.8	7.1, 7.3, 7.5, 9.3	
45	12.7	
46	9, 10, 12.9	
47	12.5	
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
-	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
48	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
48	7.1, 7.5	
49	9.2, 12.8	
50	10	
51	10, 12.8	
52	12.1, 12.6, 12.7, 12.8	
53	5	
54	9	
55	9	
56	9	
56.3	9.1	
56.7	12.2	
57	12.6, 12.7	
58	12.6, 12.7	
101.2.1	9.2, 12.8	
101.2.3	12.8	
101.2.4	12.8	
101.2.6	12.8	
101.2.7	12.2	
101.2.8	9.3, 12.6, 12.8	
101.3	12.3, 12.8	

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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*
ce with the **accompanying documents** and able to perform according
to the manufacturer's specifications