Anesteesia- ja hingamisaparatuur. Tippvõimsusega mõõturid kopsutalitluse mõõtmiseks

Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 23747:2009 sisaldab Euroopa standardi EN ISO 23747:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 23747:2009 consists of the English text of the European standard EN ISO 23747:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 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 04.03.2009.	Date of Availability of the European standard text 04.03.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

Võtmesõnad: electrical medical e, measuremen, measuring instruments, medical equipment, medical sciences, medicine, metrology, radiation protection, safety, safety devices, safety engineering, safety regulations, specification (approval), specifications, spirometers, spirometry

EUROPEAN STANDARD

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EN ISO 23747

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Supersedes EN ISO 23747:2007

English Version

Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007)

Matériel d'anesthésie et de réanimation respiratoire - Débitmètres à débit de pointe expiratoire pour l'évaluation de la fonction pulmonaire chez les êtres humains respirant spontanément (ISO 23747:2007)

Anästhesie- und Beatmungsgeräte - Spirometer für den exspiratorischen Spitzenfluss zur Bewertung der Lungenfunktion bei spontan atmenden Menschen (ISO 23747:2007)

This European Standard was approved by CEN on 24 February 2009.

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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.

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Ref. No. EN ISO 23747:2009: E

Foreword

The text of ISO 23747:2007 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 23747:2009 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 September 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 23747:2007.

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 Directives.

For relationship with EC Directives, 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 23747:2007 has been approved by CEN as a EN ISO 23747:2009 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. 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. - Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	And via IEC 60601-1
4.1	12.6	And via IEC 60601-1, Clauses 4, 8
4.2	9.2	And via IEC 60601-1, Clauses 4, 5, 9, and Subclauses 8.9.1.5, 12.2, 15.2
5	5, 13.1	And via IEC 60601-1, Clauses 4, 7 and Subclauses 7.2.17, 7.9.3.1, 15.3.7,16.2
5.1 a)	10.3	And via IEC 60601-1, Subclause 7.4.3
5.1 b)	10.1, 10.2, 12.9	And via IEC 60601-1, Clause 4 and Subclauses 7.4, 7.5, 7.6, 7.8, 12.1, 12.2
5.1 c)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.1 d)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.1 e)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.2.1	13.3 (a):	This relevant Essential Requirement is not fully addressed in this European Standard
5.2.1 a)	9.1, 12.9	And via IEC 60601-1, Clauses 4, 14, 16, and Subclauses 7.4, 7.5, 7.6, 7.8, 8.2, 8.3, 8.5.2, 8.5.5, 8.6.6, 8.10.3, 8.10.4, 9,11.2.2, 11.4, 11.5, 12.2
5.2.1 b)	13.3 a)	And via IEC 60601-1, Subclause 7.2.2
5.2.1 c)	13.2, 13.3 d)	And via IEC 60601-1, Subclauses 7.2, 7.4, 7.5, 7.6

5.2.1 d)	13.6 n)	
5.2.2	7.5 (2nd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5.2.2	13.3 (f)	This relevant Essential Requirement is not fully addressed in this European Standard
5.2.2 a)	13.3 b)	And via IEC 60601-1, Subclause 7.2.2
5.2.2 b)	8.3, 8.7, 13.2, 13.3 c)	And via IEC 60601-1, Subclauses 7.2, 7.4, 7.5, 7.6, 11.6.7
5.2.2 c)	13.3 e)	
5.2.2 d)	13.2, 13.3 f)	And via IEC 60601-1, Subclauses 7.2.1, 7.4, 7.5, 7.6
5.2.2 e)	13.3 i)	And via IEC 60601-1, Subclause 7.2.17
5.2.2 f)	13.4	And via IEC 60601-1, Subclauses 7.9.2.1, 16.2
5.3	7.5 (3rd paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
5.3	13.6 a)	And via IEC 60601-1, Subclauses 7.9.1, 7.9.2, 16.2
5.3	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
5.3 c)	13.6 d)	And via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.13, 7.9.2.16, 9.8.1, 16.2
5.3 d)	13.6 b), 13.6 k)	And via IEC 60601-1, Subclauses 7.9.2.1, 7.9.2.2 ,7.9.2.9,16.2
5.3 e)	13.6 i)	
5.3 f)	7.6, 8.1, 13.6 h)	And via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.12, 7.9.2.14, 11.3, 11.6.1, 11.6.7, 11.6.8, 13.1.2, 13.2.6, 16.2
5.4 a)	9.1, 13.6 b)	And via IEC 60601-1, Clauses 4, 14, 16, and Subclauses 7.9.2.1, 7.9.2.2 ,7.9.2.9, 8.2, 8.3, 8.5.2, 8.5.5, 8.6.6, 8.10.3, 8.10.4, 9,11.2.2, 11.4, 11.5, 16.2
5.4 b)	10.1, 13.6 p)	And via IEC 60601-1, Clause 4 and Subclause 12.1
5.4 c)	10.1, 13.6 l)	And via IEC 60601-1, Clause 4 and Subclause 12.1

5.4 d)	10.1, 13.6 l)	And via IEC 60601-1, Clause 4 and Subclause 12.1
6	10.1, 10.2	And via IEC 60601-1, Clause 4 and Subclauses 12.1, 12.2
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
7	3, 10.1	And via IEC 60601-1, Clause 4 and Subclauses 11.1, 12.1
8	4, 9.2, 10.1	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.1, 12.2, 15.2
9	4, 9.2, 10.1	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.1, 12.2, 15.2
10	4, 9.2	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.2, 15.2
11.1	4, 7.3, 8.1, 8.5	And via IEC 60601-1, Clauses 4, 15 and Subclauses 7.9, 11.2, 11.4, 11.5, 11.6, 11.7, 16.2
11.2	8.4	And via IEC 60601-1, Subclause 11.6.7
12	4, 7.1, 7.3, 7.5	And via IEC 60601-1, Clauses 4, 9, 15, and Subclauses 7.9, 11.2, 11.3, 11.4, 11.5, 11.6, 11.7, 13.1.2, 13.2.6, 15.2
13	7.1	And via IEC 60601-1, Clause 9,and Subclauses 11.2, 11.3, 11.4, 11.5, 11.6.8, 11.7, 15.2
12, 13	7.5 (1st paragraph)	This relevant Essential Requirement is not fully addressed in this European Standard
—	7.2	Via IEC 60601-1, Subclauses 11.6.6, 11.6.7, 11.7, 15.3.7, 16.2
—	9.3	Via IEC 60601-1, Clause 4, and Subclauses 8.11.6, 11.2, 11.3, 11.4, 11.5, 13.1.2, 15.4.3.5
—	11.3.1	Via IEC 60601-1, Clauses 4, 10, and Subclause 12.4.5.1
—	12.5	Via IEC 60601-1, Clauses 4, 17
—	12.7.1	Via IEC 60601-1, Clauses 4, 9, and Subclause 15.3
—	12.7.2	Via IEC 60601-1, Clause 4 and Subclause 9.6
—	12.7.3	Via IEC 60601-1, Clause 4 and Subclause 9.6

—	12.7.4	Via IEC 60601-1, Clause 4, and Subclauses 8.10.3, 8.10.4, 8.11
—	12.7.5	Via IEC 60601-1, Clause 4, and Subclauses 8.11.4, 11.1, 15.4.1, 16.9.1, 16.9.2.1
—	12.8.2	Via IEC 60601-1, Clause 4, and Subclauses 7.8, 12.3, 12.4
—	13.3 m)	Via IEC 60601-1, Subclauses 6.4, 7.2.17
—	13.5	Via IEC 60601-1, Subclauses 7.2.2, 7.2.4
—	13.6 c)	Via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.14, 16.2
—	13.6 f)	Via IEC 60601-1, Subclause 7.9.2.2
a The following comments relating to clauses and subclauses of IEC 60601-1:2005 describe the consequences of the general normative reference to IEC 60601-1:2005 made in the requirement 4.1 of the present standard.		

Warning – Other requirements and other EU Directives may be applicable to the products falling within the scope of this International standard.

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Introduction

The development of a standard for peak expiratory flowrate (PEF) measurement is considered important for the enhancement of the ability of clinicians to diagnose and monitor lung conditions by ensuring that all devices for such purposes meet minimum levels for safety and performance. An agreed standard means that peak expiratory flow meters (PEFM) can be tested to meet the same requirements with the latest accepted methods. Clinicians and patients can then be confident that these PEFM are fit for the purposes for which they are intended.

The American Thoracic Society has been foremost in proposing initial standards for testing PEFM [14]. They have proposed 26 waveforms for testing PEF, which are deemed suitable for checking that these PEFMs can correctly measure PEF.

The work of Miller et al. [16] first showed the problem of PEFM inaccuracy and they have recently defined the population characteristics of the PEF profile [18] and demonstrated limitations of pump systems for testing PEFM [17]. The European Respiratory Society has published a comprehensive statement on PEF [18].

This International Standard is based on the best currently available evidence concerning the methods and waveforms suited for testing PEFM [15].

Throughout this International Standard, text for which a rationale is provided in Annex A, is indicated by an asterisk (*).

Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

1 Scope

This International Standard specifies requirements for peak expiratory flow meters (PEFMs) intended for the assessment of pulmonary function in spontaneously breathing humans.

This International Standard covers all devices that measure peak expiratory flowrate in spontaneously breathing humans either as part of an integrated lung function device or as a stand-alone device.

Planning and design of products applying to this International Standard should consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex E.

NOTE 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.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:2007, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

For the purposes of this document the following terms and definitions apply.

3.1
BTPS
body temperature (37 °C), at the measured pressure when saturated with water vapour

3.2
dwell time
DT
time for which the expiratory flowrate is in excess of 90 % of the achieved PEF (3.3)