ANESTEESIA- JA HINGAMISAPARATUUR. VÄLJAHINGAMISE TIPPVOO MÕÕTURID SPONTAANSELT HINGAVA PATSIENDI KOPSUFUNKTSIOONI HINDAMISEKS

Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 23747:2015 sisaldab Euroopa standardi EN ISO 23747:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 23747:2015 consists of the English text of the European standard EN ISO 23747:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 19.08.2015.	Date of Availability of the European standard is 19.08.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 23747

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Supersedes EN ISO 23747:2009

English Version

Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2015)

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 23747:2015)

Anästhesie- und Beatmungsgeräte - Spirometer für den exspiratorischen Spitzenfluss zur Bewertung der Lungenfunktion bei spontan atmenden Menschen (ISO 23747:2015)

This European Standard was approved by CEN on 13 June 2015.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 23747:2015 E

European foreword

This document (EN ISO 23747:2015) has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” in collaboration with 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 February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

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 23747:2009.

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 EU Directive(s).

For relationship with EU Directive(s), 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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 23747:2015 has been approved by CEN as EN ISO 23747:2015 without any modification.

Annex ZA
(informative)

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

By agreement between ISO and CEN, this CEN annex is included in the DIS and the FDIS but will not appear in the published ISO document.

This Document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this document 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 document given in Table ZA.1, within the limits of the scope of this document, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this Document and Directive 93/42/EEC

Corresponding essential requirement of Directive 93/42/EEC	Clause/subclause of this Document	Qualifying remarks/notes
7.1	12, 13	The part of ER 7.1 relating to biophysical or modelling research is not addressed.
7.2	—	This relevant ER is not covered by this standard.
7.3	11, 12	
7.5	12	The parts of ER 7.5 relating to phthalates are not addressed.
7.6	—	This relevant ER is not covered by this standard.
8.1	5.3 f), 11.1	
8.3	—	This relevant ER is not covered by this standard.
8.4	11.2	
8.5	—	This relevant ER is not covered by this standard.
8.6	—	This relevant ER is not covered by this standard.
8.7	—	This relevant ER is not covered by this standard.
9.1	5.2.1 a), 5.4 a)	
9.2	4.1, 4.2, 8, 9, 10	

Corresponding essential requirement of Directive 93/42/EEC	Clause/subclause of this Document	Qualifying remarks/notes
9.3	—	This relevant ER is not covered by this standard.
10.1	5.1 b), 5.4 b), 5.4 c), 5.4 d), 6, 7, 8, 9	
10.2	5.1 b), 6	
10.3	5.1 a)	
12.6	4.1	
12.7.1	—	This relevant ER is not covered by this standard.
12.7.2	—	This relevant ER is not covered by this standard.
12.7.3	—	This relevant ER is not covered by this standard.
12.7.4	—	This relevant ER is not covered by this standard.
12.7.5	—	This relevant ER is not covered by this standard.
12.9	5.1 b), 5.1 c), 5.1 d), 5.1 e), 5.2.1 a)	
13.1	5	
13.2	5.2.1 c), 5.2.2 b), 5.2.2 c)	
13.3 a)	5.2.1 b)	
13.3 b)	5.2.2 a)	
13.3 c)	5.2.2 b)	
13.3 d)	5.2.1 c)	
13.3 e)	5.2.2 c)	
13.3 f)	5.2.2 d)	
13.3 i)	5.2.2 e)	
13.3 j)	5.2.2 f)	
13.3 k)	—	This relevant ER is not covered by this standard.
13.3 l)	—	This relevant ER is not covered by this standard.
13.3 m)	5.2.2 b)	
13.4	5.2.2 f), 5.3 a)	
13.5	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 a]	5.3 b)	
13.6 a) [13.3 b]	—	This relevant ER is not covered by this standard.

Corresponding essential requirement of Directive 93/42/EEC	Clause/subclause of this Document	Qualifying remarks/notes
13.6 a) [13.3 c]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 f]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 i]	5.3 e)	
13.6 a) [13.3 j]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 k]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 l]	—	This relevant ER is not covered by this standard.
13.6 a) [13.3 m]	—	This relevant ER is not covered by this standard.
13.6 b)	—	This relevant ER is not covered by this standard.
13.6 c)	—	This relevant ER is not covered by this standard.
13.6 d)	5.3 b), 5.3 c), 5.3 d), 5.3 f), 5.3 h)	
13.6 h)	5.3 f)	The part of ER 13.6 h) relating to single use is not addressed.
13.6 i)	—	This relevant ER is not covered by this standard.
13.6 k)	5.3 d)	
13.6 l)	—	This relevant ER is not covered by this standard.
13.6 n)	5.3 i)	
13.6 p)	5.3 j)	
13.6 q)	5.3 l)	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this International Standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 3 of amended Directive 93/42/EEC)

EHSR of 2006/42/EC	Clause(s)/sub-clause(s) of this EN	Qualifying remarks/Notes
1.1.4	–	This relevant EHSR is not covered by this standard.
1.2.2	–	This relevant EHSR is not covered by this standard.
1.5.4	–	This relevant EHSR is not covered by this standard.
3.6.2	–	This relevant EHSR is not covered by this standard.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This second edition cancels and replaces the first edition (ISO 23747:2007), which has been technically revised.

Introduction

The development of a standard for PEAK EXPIRATORY FLOWRATE (PEF) measurement is considered important for clinicians to use in diagnosing and monitoring lung and airway conditions by ensuring that all MEDICAL DEVICES for such purposes meet minimum levels for safety and performance. An agreed standard means that a PEAK EXPIRATORY FLOW METER (PEFM) can be tested to meet the same requirements with the latest accepted methods. Clinicians and patients can then be confident that a PEFM is fit for the purposes for which it is intended.

The American Thoracic Society has been foremost in proposing initial standards for testing a PEFM (see Reference [15]). They have proposed 26 waveforms suitable for testing PEF, which are deemed suitable for checking that a PEFM can correctly measure PEF.

The work of Miller et al. (see Reference [18]) first showed the problem of PEFM inaccuracy and they have subsequently defined the population characteristics of the PEF profile (see Reference [21]) and demonstrated limitations of pump systems for testing a PEFM (see Reference [20]). The European Respiratory Society has published a comprehensive statement on PEF (see Reference [21]).

This International Standard is based on the best currently available evidence concerning the methods and waveforms suited for testing a PEFM (see Reference [17]).

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

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

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 a PEAK EXPIRATORY FLOW METER (PEFM) intended for the assessment of pulmonary function in spontaneously breathing humans.

This International Standard covers all MEDICAL DEVICES that measure PEAK EXPIRATORY FLOWRATE in spontaneously breathing humans either as part of an integrated lung function MEDICAL DEVICE or as a stand-alone MEDICAL DEVICE.

Planning and design of products applying to this International Standard are to 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14937:2009, *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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1:2005+A1:2012, *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.

NOTE An alphabetized index of defined terms is found in Annex G.

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