Anesteesia- ja hingamisseadmed. Spiromeetrid forsseeritud ekspiratoorsete mahtude mõõtmiseks inimestel

Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 26782:2009 sisaldab Euroopa standardi EN ISO 26782:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 26782:2009 consists of the English text of the European standard EN ISO 26782:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.09.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.09.2009 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 15.07.2009.	Date of Availability of the European standard text 15.07.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.10

EUROPEAN STANDARD

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English Version

Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans (ISO 26782:2009)

Matériel d'anesthésie et de réanimation respiratoire - Spiromètres destinés au mesurage des volumes expiratoires forcés chronométrés chez les humains (ISO 26782:2009)

Anästhesie- und Beatmungsgeräte - Spirometer zur Messung des zeitbezogenen forcierten Exspirationsvolumens beim Menschen (ISO 26782:2009)

This European Standard was approved by CEN on 17 June 2009.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 26782:2009: E

Foreword

This document (EN ISO 26782:2009) 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 January 2010, 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 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 26782:2009 has been approved by CEN as a EN ISO 26782:2009 without any modification.

Annex ZA
(informative)

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

This standard 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 29 March 2007 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

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 standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
All	1, 2, 3	
4.1	12.6, 13.1, 13.2, 13.6 f)	And via IEC 60601-1
4.2	9.2	
5	13.1	And via IEC 60601-1
5.1	10.1, 10.3	And via IEC 60601-1
5.2	4, 10.2	And via IEC 60601-1
5.3	4	And via IEC 60601-1
5.4	13	
5.4.1 a)	13.6 d)	
5.4.1 b)	13.3 a)	
5.4.1 c)	13.3 b), o)	
5.4.1 d)	13.3 d)	
5.4.1 e)	13.6 n)	
5.4.1 f)	13.3 e)	
5.4.2 a)	13.3 b)	
5.4.2 b)	13.4	
5.4.2 c)	13.2, 13.3 e)	
5.4.2 d)	13.3 f)	
5.4.2 e)	13.3 f)	
5.4.2 f)	5, 13.3 i)	And via IEC 60601-1
5.4.2 g)	13.3 j)	
5.4.2 h)	13.3 k)	
5.4.2 i)	8.7, 13.2, 13.3 m)	
5.5.1	9.1	And via IEC 60601-1

Table ZA.1 *(continued)*

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
5.5.1 a)	13.6 a)	
5.5.1 b)	13.4	
5.5.1 c), d), e)	13.6 b)	
5.5.1 f)	13.6 a)	
5.5.1 h)	13.6 a)	
5.5.1 i)	13.6 a), b), n)	
5.5.1 j)	13.6 b), d)	
5.5.1 k)	13.6 c)	
5.5.1 l)	13.6 i)	
5.5.1 m)	13.6 k)	
5.5.1 n)	13.3 i)	
5.5.1 o)	13.6 d)	
5.5.1 p)	13.6 c)	
5.5.1 q)	13.3 k), 13.6 n)	
5.5.1 r)	13.6 q)	
5.5.2	13.6 g), h)	
6	10.1	And via IEC 60601-1
7	10.2	And via IEC 60601-1
7	10.3	And via IEC 60601-1
7.1	4, 10.1	And via IEC 60601-1
8	4	And via IEC 60601-1
8.2	4, 9.2	And via IEC 60601-1
9.1, 9.2	8.1, 8.5	And via IEC 60601-1
9.3	7.3, 8.4	And via IEC 60601-1
10	7.1	And via IEC 60601-1
10	7.2	And via IEC 60601-1
10	7.3	And via IEC 60601-1
Annex C	6 a)	
-	6, 7.5, 7.6, 9.3, 11.3.1, 12.2, 12.5, 12.7.1, 12.7.2, 12.7.3, 12.7.4, 12.7.5	Via IEC 60601-1
NOTE	ERs 13.3 a) and 13.6 h) are not fully addressed.	

WARNING — Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

Contents

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Introduction

A **spirometer** is a medical device that records physiological lung ventilation volumes within the range of the vital capacity.

The timed volumes that a **PATIENT** is able to expel after a maximal inspiration give a reliable method of assessing lung function. These spirometric assessments are used, for example, to screen individuals at risk of lung disease, to give objective measures in the presence of lung disease, to evaluate symptoms and pre-operative risk and to record the effect of therapeutic intervention. A **SPIROMETER** can also be used in evaluating pulmonary disability, public health and clinical trials.

The American Thoracic Society (ATS) and the European Respiratory Society (ERS) have been instrumental in developing recommendations for the standardization of lung function testing, including guidelines for spirometry [6], [7]. There is however no recognised international or national standard for **SPIROMETERS** with reliance for accuracy, repeatability, etc. based on objective test methodology and on meeting defined tolerances when tested with a carefully selected set of defined test profiles such as those published by the ATS.

This International Standard addresses this problem by developing a standard for a **SPIROMETER** to give the clinician the confidence that any **SPIROMETER** used meets agreed standards of accuracy, repeatability, electrical safety, etc.

The minimum safety requirements specified in this particular International Standard are considered to provide a practical degree of safety in the operation of **SPIROMETERS**.

The requirements are followed by specifications for the relevant tests.

A “rationale and guidance” section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex A. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this International Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this International Standard.

In this document, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— *description of type of document change, and test methods: italic type;*

— **TERMS DEFINED IN THIS DOCUMENT: SMALL CAPITALS.**

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

Anaesthetic and respiratory equipment — Spirometers intended for the measurement of time forced expired volumes in humans

1 *Scope

This International Standard specifies requirements for **SPIROMETERS** intended for the assessment of pulmonary function in humans weighing more than 10 kg.

This International Standard applies to a **SPIROMETER** that measure timed forced expired volumes, either as part of an integrated lung function device or as a stand-alone device, irrespective of the measuring method employed.

Devices intended for continuously monitoring **PATIENTS** are outside the scope of this International Standard.

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 10933-1[1)], *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14937[2)], *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*

1) To be published. (Revision of ISO 10993-1:2003)

2) To be published. (Revision of ISO 14937:2000)