SLOVENSKI STANDARD
SIST EN ISO 26782:2009

01-november-2009

Anestezijska in dihalna oprema - Merilniki pretoka zraka (spirometri) za merjenje pospešenega volumna izdiha pri ljudeh (ISO 26782:2009)

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

Anästhesie- und Beatmungsgeräte - Spirometer zur Messung des zeitbezogenen forcierten Exspirationsvolumens beim Menschen (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)

Ta slovenski standard je istoveten z: **EN ISO 26782:2009**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

SIST EN ISO 26782:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 26782

July 2009

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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)

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

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

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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of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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.

INTERNATIONAL STANDARD

ISO 26782

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2009-07-15

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

Matériel d'anesthésie et de réanimation respiratoire — Spiromètres destinés au mesurage des volumes expiratoires forcés chronométrés chez les humains

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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.

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 26782 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

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 (*).