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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 (*).

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)

3 Terms and definitions

For the purposes of this document the following terms and definitions apply. For convenience, the sources of all defined terms used in this International Standard are given in the Alphabetical Index.

3.1
accessory
additional part for use with **SPIROMETER** in order to:
— achieve the **INTENDED USE**,
— adapt it to some special use,
— facilitate its use,
— enable its functions to be integrated with those of other equipment

NOTE Adapted from IEC 60601-1:2005, definition 3.3.

3.2
accompanying document
document accompanying a **SPIROMETER** or **ACCESSORY** and containing information for those accountable for the installation, use and maintenance of the **SPIROMETER** or **ACCESSORY**, the **OPERATOR** or the **RESPONSIBLE ORGANIZATION**, particularly regarding safety

NOTE Adapted from ISO 14971:2007, definition 2.1.

3.3
body temperature and pressure saturated
BTPS
body temperature (37 °C), at the ambient pressure and saturated with water vapour

3.4
clearly legible
capable of being read by a person with normal vision

[IEC 60601-1:2005, definition 3.15]

3.5
expected service life
maximum period of useful life as defined by the **MANUFACTURER**

[IEC 60601-1:2005, definition 3.28]

3.6
forced expiratory volume after time t
FEV$_t$
expiratory volume of a **PATIENT** under forced conditions at time t in seconds, measured from **TIME ZERO**

3.7
forced vital capacity
FVC
maximal volume of air exhaled with a continuous maximum forced expiratory effort from the point of maximal inspiration

3.8
hand-held
term referring to equipment intended to be supported by the hand during **NORMAL USE**

NOTE Adapted from IEC 60601-1:2005, definition 3.37.

3.9
intended use
use of a product, process or service in accordance with the specifications, instructions and information provided by the **MANUFACTURER**

NOTE **INTENDED USE** is not to be confused with **NORMAL USE**. While both include the concept of use as intended by the **MANUFACTURER**, **INTENDED USE** focuses on the medical purpose while **NORMAL USE** incorporates not only the medical purpose, but also maintenance, service, transport, etc.

[IEC 60601-1:2005, definition 3.44]

3.10
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of **SPIROMETER**, or adapting **SPIROMETER**, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 [1] defines “labelling” as written, printed or graphic matter

— affixed to a medical device or any of its containers or wrappers or

— accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents. In this International Standard, that material is described as markings and the **ACCOMPANYING DOCUMENT**.

NOTE 2 “Adapting” includes making substantial modifications to a **SPIROMETER** already in use.

NOTE 3 In some jurisdictions, the **RESPONSIBLE ORGANIZATION** can be considered a **MANUFACTURER** when involved in the activities described.

NOTE 4 Adapted from IEC 60601-1:2005, definition 3.55.

3.11
measurement range
set of values of measurands for which the error of a measuring instrument is intended to lie within specified limits

3.12
***model or type reference**
combination of figures, letters or both used to identify a particular model of **SPIROMETER** or **ACCESSORY**

NOTE Adapted from IEC 60601-1:2005, definition 3.66.

3.13
normal use
operation, including routine inspection and adjustments by any **OPERATOR**, and stand-by, according to the instruction for use

NOTE **NORMAL USE** should not be confused with **INTENDED USE**. While both include the concept of use as intended by the **MANUFACTURER, INTENDED USE** focuses on the medical purpose while **NORMAL USE** incorporates not only the medical purpose, but also maintenance, service, transport, etc.

[IEC 60601-1:2005, definition 3.71]

3.14
operator
person handling equipment

[IEC 60601-1:2005, definition 3.73]

3.15
patient
living being (person or animal) undergoing a medical, surgical or dental procedure

[IEC 60601-1:2005, definition 3.76]

3.16
responsible organization
entity accountable for the use and maintenance of a **SPIROMETER**

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the **PATIENT**, **OPERATOR** and **RESPONSIBLE ORGANIZATION** can be one and the same person.

NOTE 2 Education and training is included in "use."

NOTE 3 Adapted from IEC 60601-1:2005, definition 3.101.

3.17
spirometer
device for recording forced expiratory volume over a period of time

3.18
***time zero**
point of intersection on the time axis of a line drawn on the volume time trace through the point of peak expiratory flow (PEF) with a slope equal to peak expiratory flow

3.19
tool
extra-corporeal object that can be used to secure or release fasteners or to make adjustments

NOTE Coins and keys are considered **TOOLS** within the context of this International Standard.

[IEC 60601-1:2005, definition 3.127]

4 General requirements

4.1 Electrical safety

SPIROMETERS that utilize electrical power shall meet the applicable requirements in IEC 60601-1, in addition to the requirements in this International Standard.

Check compliance by application of the tests of IEC 60601-1.

4.2 Mechanical safety

Spirometers shall comply with IEC 60601-1:2005, Clause 9.

Check compliance by inspection.

5 Identification, marking and documents

5.1 Marking of the scale or display

The scale or display of a **SPIROMETER** shall be marked as follows.

a) The scale or display shall be in units of litres.

b) The numbering on a scale or digital display shall not exceed the **MEASUREMENT RANGE**.

c) For **SPIROMETERS** with volume traces as the primary output, the increment between any two adjacent graduation lines shall represent a difference in volume no greater than 0,1 l and the numbering on a scale shall appear at intervals no greater than 1,0 l.

d) For **SPIROMETERS** with a digital display the incremental step shall be no greater than 0,01 l.

Check compliance by inspection.

5.2 Legibility of markings

The markings required by 5.1 and 5.4 shall be **CLEARLY LEGIBLE** under the following conditions:

a) for warning statements, instructive statements, safety signs and drawings on the outside of the **SPIROMETER**, from the intended position of the person performing the related function;

b) for markings on the inside of the **SPIROMETER** or **SPIROMETER** parts, from the intended position of the person performing the related function.

*Check compliance for a **CLEARLY LEGIBLE** marking by the following test.*

1) *Position the **SPIROMETER** or its part so that the viewpoint is the intended position of the **OPERATOR**; or the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.*

2) *Ensure that the ambient illuminance is the least favourable level in the range of 100 lx to 1 500 lx.*

3) *Ensure that the observer has a visual acuity of 0 on the log minimum angle of resolution (log MAR) scale or 6/6 (20/20), corrected if necessary.*

4) *The observer correctly reads the marking from the viewpoint.*

5.3 Durability of markings

The markings required by 5.1 and 5.4 shall be removable only with a **TOOL** or by appreciable force and shall be sufficiently durable to remain **CLEARLY LEGIBLE** during the **EXPECTED SERVICE LIFE** of the **SPIROMETER**. In considering the durability of the markings, the effect of **NORMAL USE** shall be taken into account.

NOTE Recordings or paper output chards are not considered markings.

Check compliance by inspection and the following tests.

After all the other tests of this document have been performed:

a) rub markings by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirits and then for 15 s with a cloth rag soaked with isopropyl alcohol;

b) test the legibility of markings to the requirements of 5.2;

c) ensure that adhesive labels have not worked loose or become curled at the edges.

5.4 Marking of the spirometer or its packaging

5.4.1 The **SPIROMETER** and, where physically possible, its **ACCESSORIES** shall be marked with the following:

a) a symbol showing the direction of flow for any **OPERATOR**-detachable components that are flow-direction sensitive unless designed in such a way as to prevent incorrect use or assembly;

b) the name and address or trademark and address of the **MANUFACTURER**;

c) **MODEL OR TYPE REFERENCE;**

d) where appropriate, an identification reference to the batch or serial number, or symbol 5.14 or 5.16 from ISO 15223-1:2007;

e) method of disposal, as appropriate;

f) for a **SPIROMETER** with an expiration date, symbol 5.12 from ISO 15223-1:2007, or if not practicable, an expiration date may be marked on the packaging.

5.4.2 The packaging of a **SPIROMETER**, an **ACCESSORY** or their components shall be marked with the following:

a) details to enable the **RESPONSIBLE ORGANIZATION** to identify the contents of the packaging;

b) the **INTENDED USE** of the **SPIROMETER** or **ACCESSORY**;

c) for a **SPIROMETER** or **ACCESSORY** with an expiration date, symbol 5.12 from ISO 15223-1:2007;

d) for a single **PATIENT** use **ACCESSORY** the words “single patient use”;

e) for a single use **SPIROMETER, ACCESSORY** or component, the words “single use only” or “do not re-use” or symbol 5.2 from ISO 15223-1:2007;

f) any special storage and/or handling instructions;

g) any special operating instructions;

h) any warnings and/or precautions to take;

i) for a sterile **SPIROMETER, ACCESSORY** or component, the word “STERILE” or symbol 5.20, 5.21, 5.22, 5.23 or 5.24 (as appropriate) from ISO 15223-1:2007.

Check compliance by inspection.

5.5 Instructions for use

5.5.1 General

The **ACCOMPANYING DOCUMENTS** shall include the following:

a) identity of the **SPIROMETER** by inclusion of the following:

— name or trade-name of the **MANUFACTURER**, and an address to which the **RESPONSIBLE ORGANIZATION** can refer;

NOTE In some countries, the name and address of a local authorized representative is required, where the **MANUFACTURER** does not have a local registered place of business.

— **MODEL OR TYPE REFERENCE**;