INTERNATIONAL STANDARD

ISO 26782

First edition
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

Reference number
ISO 26782:2009(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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**;

b) the **INTENDED USE** of the **SPIROMETER,** including any restrictions on its use;

c) a brief description of the **SPIROMETER**, including its significant physical and performance characteristics;

d) all information necessary to operate the **SPIROMETER** in accordance with its specification;

EXAMPLE Explanations of the functions of controls, displays and signals, the sequence of operation, connection and disconnection of detachable parts and **ACCESSORIES**, and replacement of material that is consumed during operation.

e) how the **SPIROMETER** functions;

f) the information required in 5.4;

g) a description of all markings on the **SPIROMETER**;

EXAMPLE Figures, symbols, warning statements, abbreviations and indicator lights.

h) any special operating instructions;

i) any warnings and/or precautions to be taken;

j) a statement that the performance of the **SPIROMETER** can be affected by the **PATIENT** spitting or coughing into the **SPIROMETER** during expiration or by extremes of temperature, humidity and altitude if applicable;

k) if installation of the **SPIROMETER** or its parts is required, a reference to where the installation instructions are to be found (e.g. the technical description);

l) the correct method of re-assembly, if the **SPIROMETER** is intended to be dismantled by the **OPERATOR**;

m) details of the **SPIROMETER** checks that the **OPERATOR** should consider if unusual readings are obtained;

n) recommended storage conditions;

o) details of the nature and frequency of any maintenance and/or calibration needed to ensure that the **SPIROMETER** operates within the requirements specified in this International Standard;

p) details of any breathing system filter recommended;

q) information concerning the disposal of the **SPIROMETER**, its **ACCESSORIES**, detachable parts and material;

r) the date of issue of the **ACCOMPANYING DOCUMENTS**.

Check compliance by inspection.

5.5.2 Cleaning, disinfection and sterilization

For **SPIROMETER** parts or **ACCESSORIES** that can become contaminated through contact with the **PATIENT** or with body fluids or expired gases during **NORMAL USE**, the instructions for use shall contain:

a) details about cleaning and disinfection or cleaning and sterilization methods that may be used;

b) a list of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such **SPIROMETER** parts or **ACCESSORIES** can tolerate.

See also 9.1 and 9.2.

This requirement does not apply to any material, component, **ACCESSORY** or **SPIROMETER** that is marked as intended for single use unless the **MANUFACTURER** specifies that the material, component, **ACCESSORY** or **SPIROMETER** is to be cleaned and disinfected or cleaned and sterilized before use (see 9.2).

Check compliance by inspection.

5.6 Technical description

5.6.1 The technical description shall include the following:

a) specification of the signal input/output part, if applicable;

b) limits of accuracy of the measured value (see 7.1);

c) the method by which the **SPIROMETER** determines **TIME ZERO**;

d) the highest expiratory impedance and the flow at which this occurs when using the **SPIROMETER** within its **MEASUREMENT RANGE**, including any **ACCESSORIES** listed in the **ACCOMPANYING DOCUMENT.**

5.6.2 The technical description shall also include, if applicable, the following:

a) any correction factors to be applied for changes in ambient conditions;

b) a statement to the effect that the values displayed by the **SPIROMETER** are expressed as **BTPS** values or if the volumes are not expressed as **BTPS**, a warning to describe the deviation and the conditions under which the values are expressed, together with a conversion formula to change the volumes into **BTPS**.

Check compliance by inspection.

6 *Measurement range

The **MEASUREMENT RANGE** shall be from zero to at least 8 l when referenced to **BTPS** conditions.

Check compliance by inspection.

7 Performance requirements

7.1 Accuracy

The maximum permissible error for the volume reading in the **MEASUREMENT RANGE** shall be $\pm$ 3,0 % of reading or 0,05 l (whichever is greater).

This applies under the following environmental conditions:

— ambient temperature from 17 °C to 35 °C;

— relative humidity from 30 % RH to 75 % RH;

— ambient pressure from 850 hPa to 1 060 hPa.

NOTE The maximum permissible errors do not take into account the tolerances of the test apparatus.

Check compliance by the tests described in Annex B.

7.2 Recording time

While measuring **FVC**, a **SPIROMETER** shall be capable of recording volume for at least 15 s.

Check compliance by functional testing.

7.3 Graphical display aspect ratios

If graphically displayed recordings are provided, the following shall be the default aspect ratios:

a) for volume *vs*. time (1 l:1 s) maintained for at least 6 s

b) for flow *vs*. volume (2 l/s:1 l) maintained for the full volume

Check compliance by inspection.

7.4 Volume recording

FEV_1 and **FEV_6** shall be measured at 1 s and 6 s from **TIME ZERO** determined by back extrapolation.

Check compliance by the tests described in Annex B.

7.5 *Start of forced exhalation

The **SPIROMETER** shall provide a means of indicating that the start of a forced exhalation is acceptable, i.e. when back-extrapolated volume is < 0,15 l or < 5 % of the **FVC**, whichever is greater.

Check compliance by the tests described in Annex B.

7.6 *End of forced exhalation

If the **SPIROMETER** records **FVC**, it shall have a means of indicating that a satisfactory end-phase of a forced exhalation has been achieved, i.e. when the rate of change of volume is less than 0,025 l/s. See Reference [7].

Check compliance by functional testing.

7.7 Linearity

The linearity error of the **SPIROMETER**, including its **ACCESSORIES** and detachable parts, shall not exceed 3 % when measured at steps that are between 0,4 l and 0,6 l apart and span the **MEASUREMENT RANGE** of the **SPIROMETER** for the defined test profiles of Annex C.

Check compliance by the tests described in Annex B.

7.8 Repeatability

The span of the **SPIROMETER** readings within the **MEASUREMENT RANGE** at each test value shall be within 0,05 l or 3 % of the mean of the readings, whichever is greater, when measured at ambient conditions for the defined test profiles of Annex C (see B.1 in Annex A).

NOTE The tolerances do not take into account the tolerances of the test apparatus.

Check compliance by the tests described in Annex B.

7.9 Expiratory impedance

The expiratory impedance of the **SPIROMETER**, including its **ACCESSORIES** and detachable parts, shall not exceed 0,15 kPa/(l/s) for the defined test profiles listed in Table C.1 with flows up to 14 l/s.

NOTE A breathing system filter is considered an **ACCESSORY**.

Check compliance by the tests described in Annex B.

8 Constructional requirements

8.1 Effects of dropping components of a hand-held spirometer or accessory

The **HAND-HELD** components and **ACCESSORIES** of a **SPIROMETER** shall be tested by the method given in 15.3.4.1 of IEC 60601:2005. Following the test, the **SPIROMETER**, including its **ACCESSORIES** and detachable parts, shall meet the requirements of Clause 7.

NOTE Any components that become disassembled should be fitted together again following each drop.

*Check compliance by application of the tests of IEC 60601:2005, 15.3.4.1. Subsequently, ensure that the **SPIROMETER**, including its **ACCESSORIES** and detachable parts, complies with Clause 7.*

8.2 Calibration

The **SPIROMETER**, including its **ACCESSORIES**, shall be provided with a means of checking the calibration of the **SPIROMETER** using a 3 l calibration syringe with an accuracy of 0,5 % or better.

Check compliance by inspection.

8.3 Dismantling and re-assembly

If intended for dismantling by the **OPERATOR**, the **SPIROMETER** shall:

a) be designed or marked to ensure correct assembly when all the parts are mated;

b) when re-assembled, meet the requirements of Clause 7.

*Check compliance by disassembling and re-assembling the spirometer as indicated in the **ACCOMPANYING DOCUMENT**. Ensure that following re-assembly, the **SPIROMETER**, including its **ACCESSORIES** and detachable parts, complies with Clause 7.*

9 Cleaning, sterilization and disinfection

9.1 Re-usable spirometer and parts

All components specified for re-use in the **ACCOMPANYING DOCUMENTS**, and which come into contact with the **PATIENT,** shall be capable of being cleaned and disinfected or cleaned and sterilized.

*Check compliance by a review of the **ACCOMPANYING DOCUMENTS** for methods of cleaning and disinfection or cleaning and sterilization (see 5.5.2) and by inspection of the relevant validation reports.*

9.2 Spirometer and parts requiring processing before use

All components specified in the **ACCOMPANYING DOCUMENTS** to be cleaned and disinfected or cleaned and sterilized before use and which come into contact with the **PATIENT** shall be capable of being cleaned and disinfected or cleaned and sterilized.

*Check compliance by a review of the **ACCOMPANYING DOCUMENTS** for methods of cleaning and disinfection or cleaning and sterilization (see 5.5.2) and by inspection of the relevant validation reports.*

9.3 Spirometer and parts delivered sterile

SPIROMETERS or **ACCESSORIES** labelled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937.

Check compliance by inspection of the relevant validation reports.

10 Biocompatibility

SPIROMETERS and parts thereof intended to come into contact with biological tissues, cells, body fluids or breathing gases shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Check compliance by inspection of the relevant validation reports.

Annex A
(informative)

Rationale

This annex provides a rationale for certain requirements of this International Standard and is intended for those who are familiar with the subject of this International Standard but who have not participated in its development. An understanding of the reasons for these requirements is considered to be essential for their proper application and is provided to aid in the application of this International Standard. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this International Standard necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this International Standard. The numbering is, therefore, not consecutive.

1 *Scope

SPIROMETERS are used for a variety of tasks within the context of measuring lung function. This International Standard is limited to only those **SPIROMETERS** that are used for making timed measurements of forced expiratory volumes. Such **SPIROMETERS** can use one of a wide variety of transduction systems to obtain these timed volumes and this International Standard applies to all such systems. Future standards might include other types of **SPIROMETER** such as those measuring inspiratory volumes or un-timed (continuous) expiratory volumes.

This International Standard is designed to ensure these **SPIROMETERS** can record those lung function indices that are recognised to have value in **PATIENT** care. These include forced expiratory volume in 1 s (**FEV_1**), forced vital capacity (**FVC**) and forced expiratory volume in 6 s (**FEV_6**).

$FEF_{25–75\ \%}$ can be calculated from a volume/time trace of a maximum forced exhalation. It is the slope of the line joining the volume when 25 % and 75 % of the **FVC** had been exhaled. It has the units of flow (litres per second) but it is not necessary for the **SPIROMETERS** to record flow as the primary signal in order to calculate this spirometric index. $FEF_{25–75\ \%}$ is not included in this International Standard as an index to be tested. It is not recommended for use in clinical practice, as it is not as repeatable within individuals because its magnitude changes substantially with relatively small changes in **FVC** and its normal values vary widely within the population. A **SPIROMETER** meeting this International Standard for accuracy of volumes across its range should be accurate to derive $FEF_{25–75\ \%}$ should it be required.

No flow measurements are included in this International Standard. ISO 23747 [4] covers devices for measuring peak expiratory flow (PEF) and a device meeting these requirements should be adequate to record other instantaneous flows during a forced exhalation if they are needed.

3.12 *Model or type reference

The **MODEL OR TYPE REFERENCE** is intended to establish the relationship of the **SPIROMETER** to commercial and technical publications, to **ACCOMPANYING DOCUMENTS** and between separable parts of the **SPIROMETER**. It is also important for identifying the **SPIROMETER** or **ACCESSORIES** in case of a safety alert or other required corrective action.

3.18 *Time zero

Figure A.1 shows an example of the method of determining **TIME ZERO**. The first 0,2 s of a blow ultimately achieving an FVC of 5,9 l shows how the back extrapolation method is undertaken. At the point of peak expiratory flow (PEF), a tangent is drawn with a slope equal to PEF and its intersection on the abscissa defines the **TIME ZERO**. V_E is the back extrapolated volume which is the volume of gas that has already been exhaled at the point of **TIME ZERO** as defined by back extrapolation. The method to determine the time elapsed by **TIME ZERO,** t_0, is given by Equation A.1.

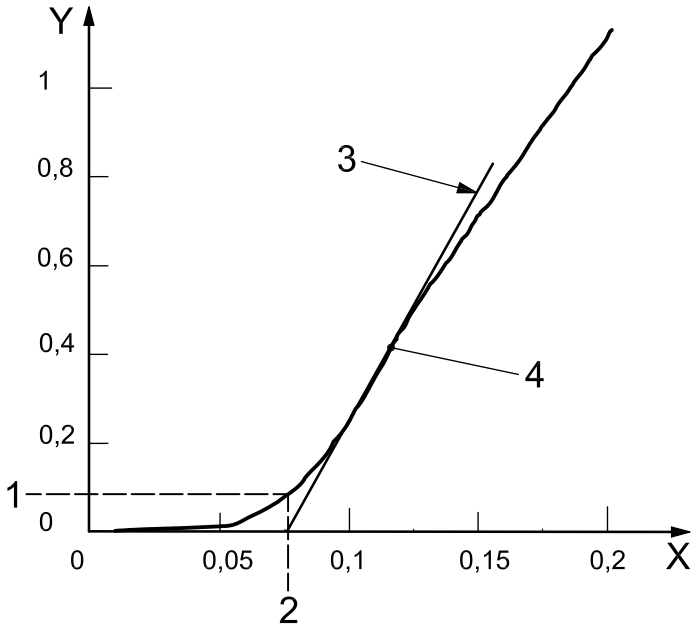
$$t_0 = t_{PEF} - (V_{PEF}/PEF) \quad (A.1)$$

where

PEF is the the peak expiratory flow;

t_{PEF} is the the elapsed time at PEF;

V_{PEF} is the the expired volume at PEF.



Key

X t (s)

Y V (l)

1 V_E = 0,084 l

2 t_0 = 0,75 s

3 tangent drawn through point of PEF with a slope equal to PEF

4 PEF = 10,8 l/s at 0,114 s

Figure A.1 — Example of time zero determination

6 *Measurement range

The volume range for which **SPIROMETERS** are required to operate is from 0 l to 8 l. Very few humans have an **FVC** in excess of 8 l. When spirometry is recorded according to ATS/ERS standards, the lowest **FEV_1** values recorded in adults (1st centile value) who are able to attend for lung function testing is about 0,4 l (M.R. Miller personal communication). **SPIROMETERS** need to be able to accurately record volumes below this level so that back extrapolation procedures are correct. This International Standard does not test volume accuracy below 0,2 l since few **PATIENTS** have valid measurements of FEV_1, FEV_6 or FVC values in this range.

7.5 *Start of forced exhalation

The most demanding aspect of spirometry with regard to frequency response characteristics is the ability of a **SPIROMETER** to detect a satisfactory start of test. Overall, for the indices **FVC** and **FEV_t** included in this International Standard, the frequency response characteristics required are that the signal amplitude be flat (< 10 % deviation) up to 5 Hz.

7.6 *End of forced exhalation

FVC is recorded from the terminal phase of the spirogram. In most **PATIENTS**, this looks like a plateau on the volume-time trace and ATS/ERS suggests that a satisfactory plateau phase has been achieved if the incremental increase in volume in the last second is 0,025 l or less. See Reference [6]. ATS/ERS encourage **PATIENTS** to achieve this goal of a satisfactory plateau in order to ensure that the largest FVC value is achieved during the test sessions. Once a satisfactory plateau has been achieved, many **PATIENTS** can still continue to exhale beyond this point and should be encouraged to do so. However, some **PATIENTS**, usually young in age, have their FVC limited by their chest wall and the blow stops abruptly in a repeatable way and they will never be able to achieve the criterion of a satisfactory plateau.

The point at the end of the blow which defines the FVC value is when the volume that has been exhaled in the preceding 1 s falls below the minimum detectable level for the **SPIROMETER**.

The **OPERATOR** can decide the **FVC** blow is finished when one the following occurs:

a) the **PATIENT** stops blowing;

b) the **PATIENT** is in distress;

c) the recording exceeds 15 s;

NOTE Longer exhalations are possible in some **PATIENTS**.

d) the volume change in the preceding 1 s is less than the minimum detectable for a **SPIROMETER** or 0,025 l.

For the purposes of this International Standard, some spirograms do not achieve the required plateau and for those that do have a plateau, the spirogram does not have a further surge or increase in flow after this point.

B.1 *Principle

The 24 ATS profiles that were recommended for testing the accuracy of **SPIROMETERS** were real human exhalations that were arbitrarily deemed to cover the range of forced exhalation seen in clinical practice. This assertion has never been verified. The profiles were presented as volume increments at only 10 ms intervals, which mean that many pump systems deliver jerky profiles that need smoothing, since most pumps can deliver test profiles with higher frequency content than this. There appears to be considerable redundancy in the 24 profiles since many do not significantly test key aspects of spirometry.

The approach for this International Standard is to consider the key aspects of the spirometry waveforms. These aspects are then tested across a range of volumes and speeds of delivery that are known to cover the range seen in the **PATIENTS**. The proposal is to use exponential defined test profiles with different time constants and volumes and different start and finish characteristics to encompass the range produced by the **PATIENT** population. Defined test profiles A and B are used in ISO 23747 [4] which covers forced expiratory flows. To avoid any confusion, the defined test profiles used here for timed volume measurements are referred to as defined test profile C subscripted numerically from 1 to 13. These defined test profiles are described in detail in Annex C.

The use of exponentials is desirable as they approximate the main characteristics of human expiratory volume-time profiles, are free from artefact and are mathematically described. During forced exhalations, the waveform to capture is the volume change due to lung deflation and potential noise on this signal comes from the larynx and airways as sound. The potential effect that this can have on **SPIROMETER** recordings is tested for separately in this International Standard. A cough can produce significant volume deflections that are recorded as volume changes. It is an **OPERATOR** decision as to how a cough impacts the recording of the indices relevant to this International Standard, so the effect of these is not included in this International Standard.

Annex C *Defined test profiles

This International Standard uses defined test profiles derived from exponential curves of volume as a function of time which are derived from Equation (C.1).

To obtain defined test profiles that encompass the characteristics seen in the population of **PATIENTS**, the values for total volume (vital capacity), VC, are varied from 1,0 l to 8,0 l, and the values for the exponential time constant, τ, are varied from 0,5 s to 2,5 s. These profiles are then modified in two ways.

Firstly, a start section is added to the profile to mimic the progressive rise up to the maximum flow seen in humans. This is either a fast start at the lower 90 % confidence limit or a slow start with the rise time at the upper 90 % confidence limit of the rise time to peak expiratory flow (PEF). This aspect determines the back extrapolated volume and definition of the **TIME ZERO** that is essential for the correct identification of $\mathbf{FEV}_1$ and $\mathbf{FEV}_6$. If this part of the blow is not recorded and handled properly, these timed volumes will be incorrect. A **SPIROMETER** needs adequate frequency response characteristics to be able to handle this part of the blow and correctly calculate the back extrapolated volume.

Secondly, the end of the blow is modified to simulate either a prolonged finish, such as can be seen in **PATIENTS** with airflow limitation, or an abrupt finish, which can be seen in young **PATIENTS** whose chest wall limits their expiration at residual volume. The prolonged finish is achieved by continuing the flow signal at a constant flow of 0,025 l/s for over 6 s once the satisfactory plateau criterion of 0,025 l in the preceding 1 s is first met.

These end sections test whether the **SPIROMETER** is able to handle the known flows seen in humans. See Reference [3] and still correctly identify **FVC** (the total expired volume). Examples of abrupt and prolonged finishes to the forced exhalation are shown in Figure C.1 and Figure C.2. All these defined test profiles, including the starting and ending sections, are mathematically defined. A **SPIROMETER** can then be tested with a panel of these defined test profiles to cover the attributes required.

Table C.1 presents 13 defined test profiles that are considered to be representative of **PATIENTS**. Bench testing a **SPIROMETER** to these defined test profiles is considered more effective than human testing for the purposes of determining the accuracy of a **SPIROMETER**.

Annex B
(normative)

Testing accuracy, linearity and impedance of spirometers

B.1 *Principle

Exponential volume time profiles are discharged to the **SPIROMETER** from an air source capable of producing the defined test profiles. These defined test profiles (see Table C.1) are adjusted for their size and time constant to vary the range of flow and volume to ensure the **SPIROMETER** can accurately record a **PATIENT'S** blow.

Two additional aspects of the defined test profile are important and are varied.

a) The beginning of the defined test profile starts in a manner similar to that seen in **PATIENTS** and is varied to give a test of the **SPIROMETER'S** ability to perform a correct back extrapolation procedure.

b) The end of the defined test profile is varied to cover three possible ends that are encountered as indicated in Figure C.1:

   — an abrupt decrease in flow with regard to volume as seen in young **PATIENTS** whose blow is limited by their chest wall (C1);

   — a slow smooth finish (C2);

   — a prolonged finish (C12).

B.2 Apparatus

B.2.1 ***AN AIRFLOW SOURCE****, capable of delivering defined test profile C with variations for volume, start of test, end of test and speed of delivery, with a reproducibility for the delivered volumes* ***FEV$_1$****,* ***FEV$_6$*** *and* ***FVC*** *of ± 10 ml or ± 0,5 % whichever is greater, when discharging to ambient air.*

B.2.2 ***A RIGID SMOOTHBORE COUPLING****, no more than 100 mm in length, with side-port-coupling flush to the inner wall.*

B.2.3 ***A CALIBRATED PRESSURE TRANSDUCER, MEASUREMENT RANGE*** *0 kPa to 3 kPa, with a flat frequency response (± 3 dB) up to 30 Hz.*

B.2.4 ***AN ENVIRONMENTAL CHAMBER****, for control of ambient temperature at 17 °C and at 35 °C.*

B.2.5 ***AN ENVIRONMENTAL CHAMBER****, for control of ambient pressure at 850 hPa and at 1 060 hPa.*

B.3 Procedure

a) Acclimatise the test apparatus and the ***SPIROMETER****, including its* ***ACCESSORIES*** *and detachable parts, at an ambient temperature, pressure and relative humidity within the range specified in 7.1.*

b) Using a mouthpiece (and air filter if required) and a rigid smoothbore coupling, connect the ***SPIROMETER*** *to the air source.*

c) *Discharge defined test profiles C1 to C11 with ambient air to the* ***SPIROMETER*** *and measure* $\mathbf{FEV_1}$, $\mathbf{FEV_6}$ *and* ***FVC*** *(if appropriate) three times for each defined test profile.*

d) *Record the pressure throughout each defined test profile with and without the* ***SPIROMETER****, including its* ***ACCESSORIES*** *and detachable parts, attached. Measure the peak impedance once the 1,0 l volume has been discharged.*

e) *Discharge defined test profiles C12 and C13 with gas at a temperature of 34 °C* $\pm$ *2 °C and a relative humidity above 90 % to the* ***SPIROMETER****, including its* ***ACCESSORIES*** *and detachable parts, and measure* $\mathbf{FEV_1}$, $\mathbf{FEV_6}$ *and* ***FVC*** *three times (if appropriate) for each defined test profile.*

B.4 Calculations

B.4.1 General

If the **ACCOMPANYING DOCUMENT** indicates that the output of the **SPIROMETER** is known to vary according to ambient conditions or the characteristics of the gas flowing through it, then all results for the **SPIROMETER** are adjusted with the appropriate correction factors [with the removal of **BTPS** correction for tests in B.3 c) where appropriate] to account for the set of ambient conditions and different test gas conditions when testing as in B.3 e).

B.4.2 Accuracy

Calculate the mean error, V_{err}, of the **SPIROMETER** for each reference value for $\mathbf{FEV_1}$, $\mathbf{FEV_6}$ and **FVC** (where appropriate) using Equation B.1.

$$V_{\text{err}} = \frac{1}{3} \times \left(\sum_{i=1}^{3} V_i\right) - V_{\text{ref}} \tag{B.1}$$

where

V_i is a measured volume;

V_{ref} is the reference value for the defined test profile taken from Table C.1, as appropriate.

B.4.3 Repeatability

Calculate the span, V_{span}, of the readings for each set of three measurements of $\mathbf{FEV_1}$, $\mathbf{FEV_6}$ and **FVC** (where appropriate) using Equation B.2.

$$V_{\text{span}} = V_{\text{max}} - V_{\text{min}} \tag{B.2}$$

where

V_{max} is the maximum measured value;

V_{min} is the minimum measured value.

B.4.4 Pneumatic impedance to flow

Calculate the pneumatic expiratory impedance, Z_S, of the **SPIROMETER** using Equation B.3. Repeat for each combination of **ACCESSORIES** and detachable parts disclosed in the **ACCOMPANYING DOCUMENTS** (see 7.9).

$$Z_S = Z_T - Z_A \tag{B.3}$$

where

Z_T is the total flow impedance for the system;

Z_A is the flow impedance caused by the test apparatus (without the **spirometer** under test).

B.4.5 Linearity

Use the calculated mean error (see B.4.2) for each of the n designated defined test profile volumes used for testing linearity that are between 0,4 l and 0,6 l apart and span the **MEASUREMENT RANGE** of the **SPIROMETER**. Calculate the percentage difference, ϵ, for each pair of adjacent volume values using Equation B.4.

$$\epsilon_n = \frac{(V_{\mathrm{err}_n} - V_{\mathrm{err}_{n+1}}) \times 100}{0{,}5 \times (V_{\mathrm{ref}_n} + V_{\mathrm{ref}_{n+1}})} \tag{B.4}$$

where

V_{err_n} is calculated using Equation (B.1) for the nth defined test profile;

n is the index for the defined test profile (1 to 15);

V_{ref_n} is the reference value for the nth defined test profile taken from Table C.1, as appropriate.

B.5 Test Report

B.5.1 *Create a test report that includes a reference to the site, date, time, ambient conditions and the apparatus used for this test from the data obtained according to B.3 c) and B.3 d) and the following:*

*a) the three readings for each of **FEV$_1$**, **FEV$_6$** and **FVC** (where appropriate) for each defined test profile and the mean of the three readings;*

b) the span of these three readings;

c) the error for each of the three readings and the mean of these three errors;

d) the error for each of the three readings expressed as a percentage of the reference volume and the mean of these percentage errors;

e) the difference, ϵ, for each pair of consecutive volumes (V_n) used for testing linearity;

f) the peak pressure recorded in kilopascals for each of the three tests of each defined test profile recorded once 1 l had been discharged together with the flow at the time of this peak pressure and the derived impedance in kilopascals/(litres per second);

g) the mean impedance from f) for each of the defined test profiles tested.

B.5.2 *From the data obtained according to B.3 e);*

a) the three readings for each of ***FEV_1***, ***FEV_6*** *and* ***FVC*** *(where appropriate) for each defined test profile and the mean of the three readings;*

b) the error for each of the three readings and the mean of these three errors.

B.6 Acceptance criteria

Verify that the maximum permissible error of volume reading is less than $\pm$ 3,0 % of reading or 0,05 l (whichever is greater) plus the known error of the test apparatus (see B.2).

Verify that the error of any measurement is less than the sum of the stated permissible errors in this International Standard.

Verify that each of the 15 different linearity calculations, ϵ_n, does not exceed 3 %.

Verify that no more than 3 of the 30 volume mean error calculations exceed the requirement of 7.1.

Verify that each of the repeatability of the span of calculations for each of the 24 volumes tested under B.3 c) does not exceed the requirement of 7.8.

Verify that the impedance of the ***SPIROMETER****, including its* ***ACCESSORIES*** *and detachable parts, does not exceed the requirement of 7.9.*

Annex C
(normative)

* Defined test profiles

Table C.1 contains the mathematical descriptions of the ten defined test profiles used for testing **SPIROMETER** performance in Annex B.

The defined test profiles are derived from exponential curves of volume, V, as a function of time using Equation (C.1):

$$V = \textbf{FVC} \times [1 - e^{(-t/\tau)}] \quad \text{(C.1)}$$

where

FVC (total forced vital capacity) is the total volume exhaled;

t is the time;

τ is an exponential time constant.

Added to this is either the fast or slow start section as indicated in Table C.1.

To these defined test profiles are added the finish as follows:

a) the prolonged finish is achieved by superimposing the flow signal using sine waves of varying amplitudes from 0 % to 97 % of the flow values starting when flow is below a certain threshold;

b) for an early finish this threshold is 0,75 l/s and for a late finish this threshold is below 0,25 l/s;

c) the sine wave can have either a low frequency (0,5 Hz) or a higher frequency (up to 2 Hz).

Example flow-volume spirograms for three of the defined test profiles are shown in Figure C.1 and Figure C.2.

Table C.1 — Spirometer defined test profiles

Defined test profile	**Exp volume**[a] l	**Time constant**[b] τ s^{-1}	**Start**[c]	**Ending**[d]	**FEV**$_1$ l	**FEV**$_6$ l	**FVC**[e] l	**FEV**$_{0,025}$[f] l	**PEF** l/s	**FET**[g] s	V_E[h] **ml**	t_R[i] **ms**
C1	7,0	1,00	Slow	Abrupt	4,894	7,120	7,120	—	6,986	2,658	112	114
C2	5,0	1,00	Fast	Smooth	3,272	5,168	5,179	5,128	4,990	8,586	23	38
C3	5,0	1,50	Fast	Smooth	2,489	5,027	5,119	5,037	3,329	12,236	16	38
C4	5,0	1,00	Slow	Smooth	4,090	6,636	6,652	6,601	4,990	9,120	252	340
C5	7,0	0,75	Slow	Smooth	5,889	8,025	8,027	7,992	9,308	7,056	150	114
C6	0,5	0,50	Slow	Smooth	0,526	0,609	0,609	0,589	0,996	3,654	16	114
C7	3,0	2,00	Slow	Abrupt	1,242	1,769	1,769	—	1,499	1,812	24	114
C8	0,5	1,50	Slow	Smooth	0,260	0,527	0,535	0,453	0,333	8,916	5	114
C9	4,0	1,50	Fast	Smooth	1,991	4,021	4,095	4,013	2,663	12,402	12	38
C10	6,0	0,75	Fast	Prolonged	4,627	6,311	6,438	6,252	7,979	12,810	37	38
C11	4,0	0,50	Bad	Smooth	5,588	6,639	6,639	6,619	7,968	5,094	402	340
C12	3,0	1,00	Slow	Prolonged	2,097	3,333	3,480	3,279	2,994	14,210	48	114
C13	4,0	2,50	Slow	Abrupt	1,374	2,406	2,406	—	1,599	2,320	26	114

a Exp volume is the volume for the single exponential.

b Time constant used for the single exponential.

c Starts used for defined test profile: fast, slow or bad start.

d Endings used for defined test profile: abrupt, smooth or prolonged.

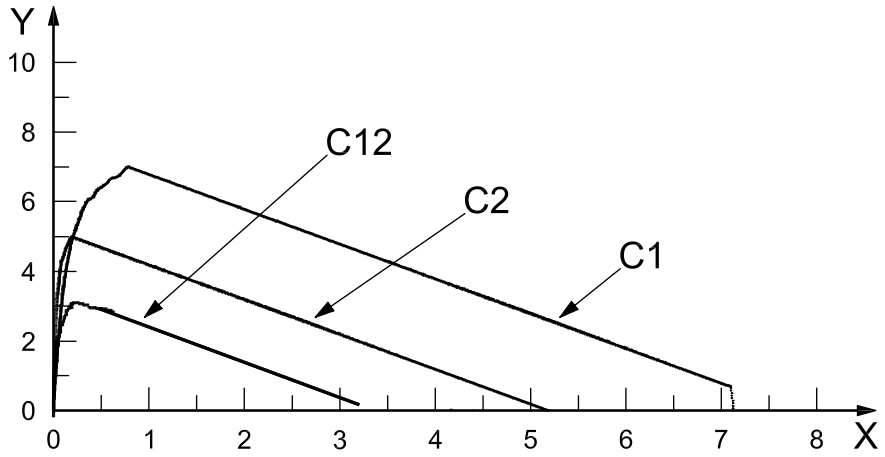
e **FVC** (total forced vital capacity) or total volume exhaled.

f **FEV** when the 0,025 l change in volume in the previous 1 s first occurred.

g Forced expiratory time (FET), the total time of the defined test profile.

h V_E, the back extrapolated volume, from method used to determine **time zero**.

i Rise time from 10 % of peak expiratory flow to 90 % of peak expiratory flow.



Key

X volume in litres

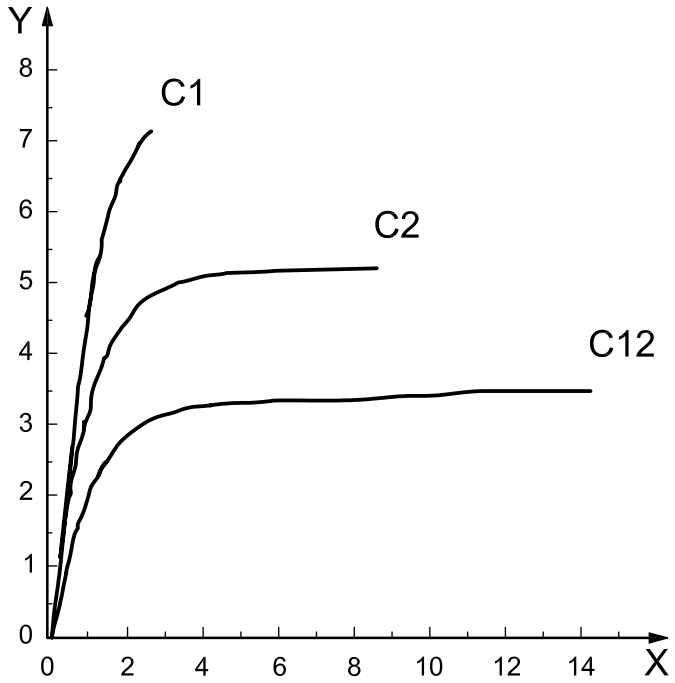
Y flow in litres per second

C1 flow-volume spirogram for defined test profile C1 (slow start, abrupt finish)

C2 flow-volume spirogram for defined test profile C2 (fast start, smooth finish)

C12 flow-volume spirogram for defined test profile C12 (fast start, early starting of prolonged finish)

Figure C.1 — Flow-volume spirograms for defined test profiles C1, C2 and C12 of Table C.1



Key

X time in seconds

Y volume in litres

C1 volume as a function of time for defined test profile C1 (slow start, abrupt finish)

C2 volume as a function of time for defined test profile C2 (fast start, smooth finish)

C12 volume as a function of time for defined test profile C12 (fast start, early starting of prolonged finish)

Figure C.2 — Spirograms (volume as a function of time) for defined test profiles C1, C2 and C12 of Table C.1

Annex D
(informative)

Environmental aspects

The environmental impact generated by a **SPIROMETER** measuring the exhaled volume of **PATIENTS** is mainly isolated to the following occurrences:

— impact at local environment during operation, including routine inspection and adjustments by the **OPERATOR**, according to the instructions for use or routine procedures;

— use, cleaning and disposal of consumables during operation, including routine inspection and adjustments by the user, according to the instructions for use or routine procedures;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this International Standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the **SPIROMETER'S** life cycle.

See Table D.1 for a mapping of the life cycle of a **SPIROMETER** to aspects of the environment.

Table D.1 — Environmental aspects addressed by clauses of this International Standard

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in subclause			
1	Resource use	4.1	4.1	4.1	4.1
2	Energy consumption	4.1	4.1	4.1	4.1
3	Emission to air	4.1	4.1	4.1	4.1, 5.4.1 e), 5.4.2 b), 5.5.1 q)
4	Emission to water	4.1	4.1	4.1	4.1, 5.4.1 e), 5.4.2 b), 5.5.1 q)
5	Waste	4.1	4.1, 5.4.1 e)	4.1	4.1, 5.4.1 e), 5.4.2 h), 5.5.1 q)
6	Noise	4.1	4.1	4.1	4.1
7	Migration of hazardous substances	4.1	4.1	4.1	4.1, 5.4.1 e), 5.4.2 h), 5.5.1 q)
8	Impacts on soil	4.1	4.1	4.1	4.1, 5.4.1 e), 5.4.2 h), 5.5.1 q)
9	Risks to the environment from accidents or misuse	4.1	4.1	4.1	4.1, 5.4.2 b), 5.5.1 q)

Annex E
(informative)

Reference to the essential principals

This International Standard has been prepared to support the essential principles of safety and performance of **SPIROMETERS** as medical devices according to ISO/TR 16142[3]. This International Standard is intended to be acceptable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible.

Table E.1 — Correspondence between the essential principles and this International Standard

Essential principal	Corresponding clause/subclause of this International Standard	Comments
1	All	
2	All	
3	All	
4	5.2, 5.3, 7.1, 8.1, 8.2	And via IEC 60601-1
5	5.4.1 f)	And via IEC 60601-1
6	—	Via IEC 60601-1
7.1	10	And via IEC 60601-1
7.2	10	And via IEC 60601-1
7.3	9.3, 10	And via IEC 60601-1
7.4	—	
7.5	—	Via IEC 60601-1
7.6	—	Via IEC 60601-1
8.1	9.1, 9.2	And via IEC 60601-1
8.1.1	—	
8.1.2	—	
8.2	—	
8.3	9.3	
8.4	9.3	
8.5	9.1, 9.2	
8.6	5.4.2 i)	
9.1	5.5.1	And via IEC 60601-1
9.2	4.2, 8.2	And via IEC 60601-1
9.3	—	Via IEC 60601-1
10.1	5.1, 6, 7	And via IEC 60601-1

Table E.1 (*continued*)

Essential principal	Corresponding clause/subclause of this International Standard	Comments
10.2	5.1, 5.2, 6, 7	And via IEC 60601-1
10.3	5.1, 7	And via IEC 60601-1
11.1.1	—	
11.2.1	—	
11.2.2	—	
11.3.1	—	Via IEC 60601-1
11.4.1	—	
11.5.1	—	
11.5.2	—	
11.5.3	—	
12.1	—	
12.2	—	Via IEC 60601-1
12.3	—	
12.4	—	
12.5	—	Via IEC 60601-1
12.6	4.1	And via IEC 60601-1
12.7.1	—	Via IEC 60601-1
12.7.2	—	Via IEC 60601-1
12.7.3	—	Via IEC 60601-1
12.7.4	—	Via IEC 60601-1
12.7.5	—	Via IEC 60601-1
12.8.1	—	
12.8.2	—	
12.8.3	—	
13.1	5	And via IEC 60601-1
14.1	Annex C	

Bibliography

[1] ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

[2] ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

[3] ISO/TR 16142, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[4] ISO 23747, *Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans*

[5] PD 6461-1, *General metrology. Basic and general terms (VIM)*

[6] American Thoracic Society, *Standardization of 1994 update ATS statement*, Am J Respir Crit Care Med, **152**, pp 1107–1136, 1995

[7] MILLER, M.R., et al., *Standardisation of spirometry*, Eur Respir J, **26**, pp 319-338, 2005

[8] MILLER, M.R., et al., *General considerations for lung function testing*, Eur Respir J, **26**, pp 153-161, 2005

[9] MILLER, M.R., et al., *The rise and dwell time for peak expiratory flow in patients with and without airflow limitation,* Am J Respir Crit Care Med, **158**, pp 23-27, 1998

Alphabetized index of defined terms used in this International Standard

ICS 11.040.10

Price based on 27 pages