SLOVENSKI STANDARD
oSIST prEN ISO 26782:2026

01-december-2026

Anestezijska in dihalna oprema - Merilniki pretoka zraka (spirometri) za merjenje pospešenega volumna izdiha pri ljudeh (ISO/DIS 26782:2026)

Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans (ISO/DIS 26782:2026)

Anästhesie und Beatmungsgeräte - Spirometer zur Messung des zeitbezogenen forcierten Exspirationsvolumens beim Menschen (ISO/DIS 26782:2026)

Matériel d'anesthésie et de réanimation respiratoire - Spiromètres destinés au mesurage des volumes expiratoires forcés chronométrés chez les humains (ISO/DIS 26782:2026)

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ICS:

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

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DRAFT International Standard

ISO/DIS 26782

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

ICS: 11.040.10

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CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
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Foreword

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

The main changes are as follows:

— Normative references updated;

— Editorial changes made to conform with the latest ISO directives;

— Test profile C8 deleted in Table C.1 as it was unachievable and text amended to reflect that deletion;

— New requirement to conform with ISO 20417:2026 and removal of those requirements now covered by this standard; and

— Annex D on Environmental aspects has been removed as it is no longer accepted.

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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 many purposes including but not limited to:

— screening individuals at risk of lung disease;

— giving objective measures in the presence of lung disease;

— evaluating symptoms and pre-operative risk;

— recording the effect of therapeutic intervention; and

— 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 [1][2]. 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 document 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.

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The minimum safety requirements specified in this document are considered to provide a practical degree of safety in the operation of spirometers.

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The requirements are followed by specifications for the relevant tests.

Annex A contains rationale and guidance giving some explanatory notes, where appropriate, about the more important requirements is included in this document.

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

1 Scope (see Clause A.2)

This document specifies requirements for spirometers intended for the assessment of pulmonary function in humans weighing more than 10 kg.

This document applies to a spirometer that measures 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 document.

NOTE This document has been prepared to address the relevant essential principles [3] and labelling principles [4] of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex D.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

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ISO 10993-1:2025, *Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

ISO 18562-1:2024, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417:2026, *Medical devices — Information to be supplied by the manufacturer*

IEC 60601-1:2005, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012, *Amendment 1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD2:2020, *Amendment 2 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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3 Terms and definitions (see Clause A.3)

For the purposes of this document the following terms and definitions apply.

Annex E contains an alphabetized index of defined terms.

3.1
accessory, noun
item intended specifically by its *manufacturer* (3.15) to be used together with one or more *medical devices* (3.18) to specifically enable or assist those *medical devices* (3.18) to be used in accordance with their *intended use* (3.13)

Note 1 to entry: An *accessory* (3.1) is typically a consumable or separate item for use with one or more *medical devices* (3.18).

Note 2 to entry: Some authorities having jurisdiction consider an *accessory* (3.1) to be a *medical device* (3.18).

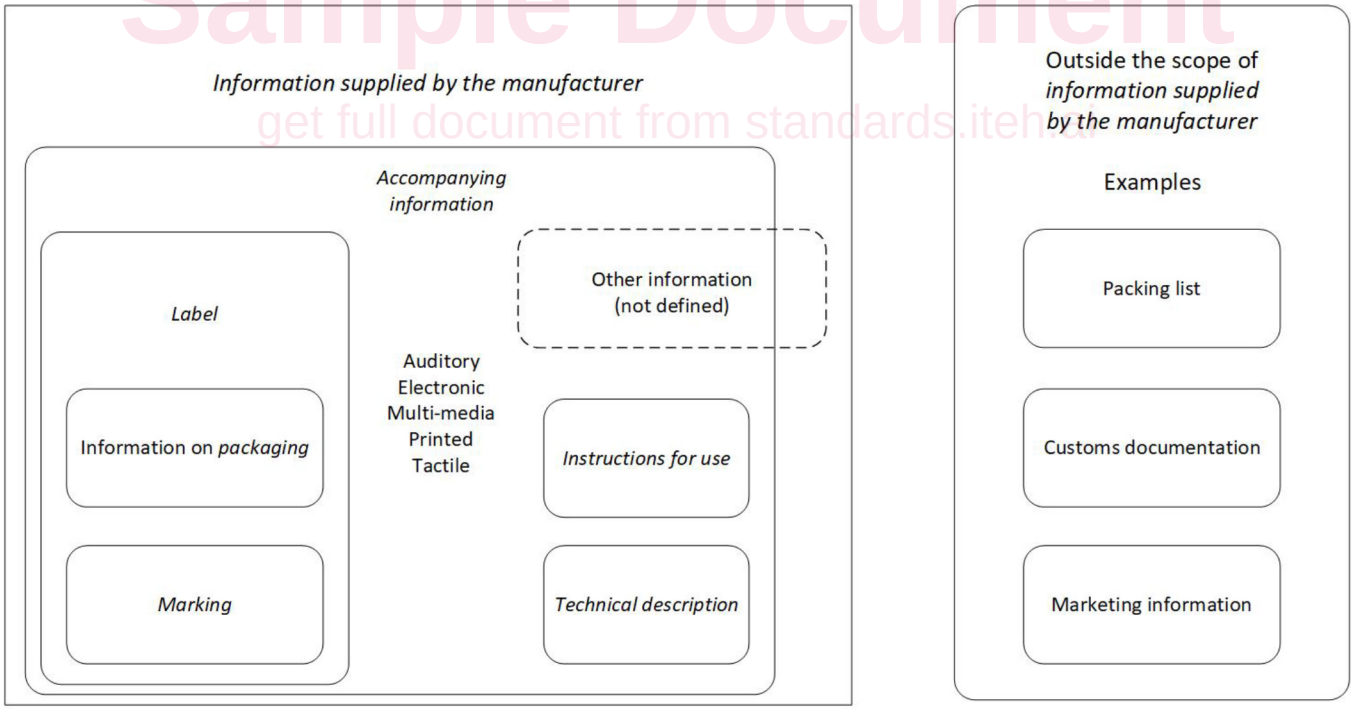
Note 3 to entry: Some authorities having jurisdiction have a different definition of *accessory* (3.1).

Note 4 to entry: In general, spare parts are not considered *accessories* (3.1).

[SOURCE: IEC 60050-880,[5] 880-08-04]

3.2
accompanying information, noun
DEPRECATED: accompanying documents
DEPRECATED: accompanying documentation
information supplied by the *manufacturer* (3.15) with or *marked* (3.16) on a *medical device* (3.18) or *accessory* (3.1) for the *user* (3.30) or the *responsible organization* (3.23), particularly regarding safe use

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NOTE 1 The *label* can include the information on the *packaging* of the *medical device* or *accessory*.
NOTE 2 *e-documentation* can include any or all types of *information supplied by the manufacturer* partially or entirely.
NOTE 3 Marketing information is also known as promotional material.
NOTE 4: Other information can include quick reference guide, *symbol* glossary, summaries, *advisory notices*, *cybersecurity* communication.

Note 1 to entry: The *accompanying information* (3.2) is regarded as part of the *medical device* (3.18) or *accessory* (3.1).

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Note 2 to entry: The *accompanying information* (3.2) can consist of the label, *marking* (3.16), *instructions for use* (3.14), *technical description* (3.27), information shown on the packaging or graphical *user* (3.30) interface (GUI), installation manual, quick reference guide, etc. and can address the installation, use, *processing* (3.21), maintenance and disposal of the *medical device* (3.18) or *accessory* (3.1).

Note 3 to entry: *Accompanying information* (3.2) is not necessarily a written or printed document but can involve auditory, visual or tactile materials and multiple media types (e.g. CD-ROM, DVD-ROM, USB stick, website).

Note 4 to entry: *Medical devices* and *accessories* (3.1) that can be used safely without *accompanying information* (3.2) are exempted from having *accompanying information* (3.2) by some authorities having jurisdiction.

[SOURCE: IEC 60050-880,[5] 880-10-01]

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

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

[SOURCE: IEC 60050-880,[5] 880-20-02]

3.5
conformity, noun
DEPRECATED: conformance
DEPRECATED: compliance
fulfilment of a requirement

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Note 1 to entry: In English the word "*conformance* (3.5)" is synonymous but deprecated. In French the word "*compliance* (3.5)" is synonymous but deprecated.

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[SOURCE: IEC 60050-880,[5] 880-14-07]

3.6
expected lifetime, noun
expected service life, noun
period specified by the *manufacturer* (3.15) during which the product is expected to maintain basic safety and essential performance

Note 1 to entry: Maintenance, repairs or upgrades (e.g. safety or security modifications) can be necessary during the *expected lifetime* (3.6).

Note 2 to entry: Some products have an absolute *expected lifetime* (3.6) (e.g. 5 years) and some have an *expected lifetime* (3.6) based on the number of uses or cycles (e.g. 15 uses) or duration of use, whereas other products (e.g. software) have a relative *expected lifetime* (3.6) (e.g. the time between two major releases).

Note 3 to entry: The *expected lifetime* (3.6) can be related to:

— healthcare products whose performance, physical, chemical or functional properties can be altered or compromised over a stated time interval;

— the period over which sterility is assured;

— in vitro diagnostic (IVD) reagents, calibrators and controls, when stored, transported and used in accordance with conditions specified in the information supplied by the *manufacturer* (3.15); and

— measuring instruments or measuring systems after calibration.

Note 4 to entry: The *expected lifetime* (3.6) of an in vitro diagnostic (IVD) reagent or measuring system is normally quantified in terms of:

— a time interval over which a measured property changes by a stated amount; or

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— the change of a property under specified conditions.

[SOURCE: IEC 60050-880,[5] 880-17-07]

3.7
forced expiratory volume, noun
FEV, noun
expiratory volume of a *patient* (3.22) under forced conditions

3.8
forced expiratory volume after time t, noun
FEV_t, noun
, noun
$FEV_{0,025}$, noun
FEV_1, noun
FEV_6, noun
expiratory volume of a *patient* (3.22) under forced conditions at time t in seconds, measured from *time zero* (3.28)

3.9
forced vital capacity, noun
FVC, noun
maximal volume of air exhaled with a continuous maximum forced expiratory effort from the point of maximal inspiration

3.10
gas pathway
interior surfaces over which respiratory gases or liquids pass that can be inspired

EXAMPLE 1 The ventilator breathing system, inlet filter, gas mixer, blower and internal piping.

EXAMPLE 2 Enclosed chamber of an incubator including the mattress or the inner surface of an oxygen hood.

EXAMPLE 3 The inner surfaces of breathing tubes, tracheal tubes or masks and mouthpieces.

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Note 1 to entry: The *gas pathway* (3.10) is bounded by the fluid ports through which gases or liquids enter the *medical device* (3.18) or *accessory* (3.1). This can include the *patient* (3.22) interface or the interior surfaces of enclosures that are in contact with gases or liquids that can be inspired.

Note 2 to entry: The *gas pathway* (3.10) can include some surfaces in the expiratory pathway.

Note 3 to entry: The fluids from a *gas pathway* (3.10) can be ingested.

[SOURCE: IEC 60050-880,[5] 880-08-14]

3.11
hand-held, adj
intended to be supported by the hand once installed and placed into service

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