INTERNATIONAL STANDARD

ISO 23747

Second edition
2015-08-01

Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

Matériel d'anesthésie et de réanimation respiratoire — Débitmètres à débit de pointe expiratoire pour l'évaluation de la fonction pulmonaire chez les êtres humains respirant spontanément

Reference number
ISO 23747:2015(E)

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This second edition cancels and replaces the first edition (ISO 23747:2007), which has been technically revised.

Introduction

The development of a standard for PEAK EXPIRATORY FLOWRATE (PEF) measurement is considered important for clinicians to use in diagnosing and monitoring lung and airway conditions by ensuring that all MEDICAL DEVICES for such purposes meet minimum levels for safety and performance. An agreed standard means that a PEAK EXPIRATORY FLOW METER (PEFM) can be tested to meet the same requirements with the latest accepted methods. Clinicians and patients can then be confident that a PEFM is fit for the purposes for which it is intended.

The American Thoracic Society has been foremost in proposing initial standards for testing a PEFM (see Reference [15]). They have proposed 26 waveforms suitable for testing PEF, which are deemed suitable for checking that a PEFM can correctly measure PEF.

The work of Miller et al. (see Reference [18]) first showed the problem of PEFM inaccuracy and they have subsequently defined the population characteristics of the PEF profile (see Reference [21]) and demonstrated limitations of pump systems for testing a PEFM (see Reference [20]). The European Respiratory Society has published a comprehensive statement on PEF (see Reference [21]).

This International Standard is based on the best currently available evidence concerning the methods and waveforms suited for testing a PEFM (see Reference [17]).

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

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans

1 Scope

This International Standard specifies requirements for a PEAK EXPIRATORY FLOW METER (PEFM) intended for the assessment of pulmonary function in spontaneously breathing humans.

This International Standard covers all MEDICAL DEVICES that measure PEAK EXPIRATORY FLOWRATE in spontaneously breathing humans either as part of an integrated lung function MEDICAL DEVICE or as a stand-alone MEDICAL DEVICE.

Planning and design of products applying to this International Standard are to consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex E.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing 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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

3 Terms and definitions

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

NOTE An alphabetized index of defined terms is found in Annex G.

3.1
BTPS
body temperature (37 °C), at the measured pressure when saturated with water vapour

3.2
DWELL TIME
DT
time for which the expiratory flowrate is in excess of 90 % of the achieved PEF

3.3
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a MEDICAL DEVICE, assembling a system, or adapting a MEDICAL DEVICE before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

Note 1 to entry: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

Note 2 to entry: For a definition of labelling, see ISO 13485:2003, definition 3.6. [11]

[SOURCE: ISO 14971:2007, definition 2.8]

3.4
MEDICAL DEVICE
any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other similar or related article, intended by the MANUFACTURER (3.3) to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of MEDICAL DEVICES,

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means.

Note 1 to entry: This definition has been developed by the Global Harmonization Task Force (GHTF). See Reference [15].

[SOURCE: ISO 13485:2003, definition 3.7]

3.5
MODEL OR TYPE REFERENCE
combination of figures, letters, or both used to identify a particular model of MEDICAL DEVICE (3.4) or accessory

[SOURCE: IEC 60601-1:2005, definition 3.66, modified: 'equipment' was replaced by 'MEDICAL DEVICE']

3.6
PEAK EXPIRATORY FLOWRATE
PEF
maximum flowrate measured at the mouth during an expiration delivered with maximal force starting immediately after achieving maximum lung inflation

3.7
PEAK EXPIRATORY FLOW METER
PEFM
MEDICAL DEVICE (3.4) for measurement of PEAK EXPIRATORY FLOWRATE (3.6)

3.8
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a MEDICAL DEVICE (3.4)

Note 1 to entry: 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 to entry: Education and training is included in "use."

[SOURCE: IEC 60601-1:2005, definition 3.101, modified: 'an ME EQUIPMENT or an ME SYSTEM' was replaced by 'a MEDICAL DEVICE'.]

3.9
RISE TIME
RT
time taken for flowrate to rise from 10 % to 90 % of the achieved PEF (3.6)

4 General requirements

4.1 Safety for a PEFM that utilizes electricity

A PEFM that utilizes electrical power shall meet the requirements of IEC 60601-1:2005+A1:2012, in addition to the requirements in this International Standard.

NOTE 1 IEC 60601–1 requires a PEFM to comply with IEC 60601–1-2 to control the risks associated with electromagnetic compatibility.

NOTE 2 IEC 60601–1 requires a PEFM to comply with IEC 60601–1-6 to control the risks associated with usability.

NOTE 3 IEC 60601–1 requires a PEFM intended for use in the home healthcare environment to comply with IEC 60601–1-11.

NOTE 4 IEC 60601–1 requires a PEFM intended for use in the emergency medical services environment to comply with IEC 60601–1-12.

Check compliance by application of the tests of IEC 60601-1:2005+A1:2012*.*

4.2 Mechanical basic safety for all PEFMS

Rough surfaces, sharp corners, and edges, which can cause injury or damage shall be avoided or covered. Particular attention shall be paid to flange or frame edges and the removal of burrs.

Check compliance by inspection.

5 Identification, marking and documents

5.1 Marking of the scale or display

The scale or display of the PEFM shall be marked clearly and legibly as follows.

a) The scale or display shall be marked in units of litres per second or litres per minute.

b) For a PEFM with a graduated scale, the increment between adjacent graduations shall represent a difference in peak flowrate no greater than 10 l/min (0,17 l/s) at flowrates of 700 l/min (11,67 l/s) or below, and 20 l/min (0,33 l/s) at flowrates above 700 l/min (11,67 l/s). For a PEFM with a digital display, the incremental steps shall be no greater than 5 l/min or 0,08 l/s.

NOTE Litres per minute and litres per second are not exact equivalents because digital displays do not usually register to three decimal places.

c) The numbering and graduation lines on a scale or digital display shall be clearly legible with normal vision [i.e. readable by an observer with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and able to read N6 of the Jaeger test card, corrected if necessary, at a distance of 0,5 m and at an ambient luminance in the range 100 lx to 1 500 lx].

d) The numbering on a scale shall appear at intervals no greater than 50 l/min (0,83 l/s) up to 700 l/min (11,67 l/s) and 100 l/min (1,67 l/s) above 700 l/min (11,67 l/s).

e) The numbering on a scale or digital display shall not exceed the measurement range.

NOTE Clause 6 contains additional requirements.

Check compliance by inspection and functional testing.

5.2 Marking of the PEFM or packaging

5.2.1 Marking of the PEFM

The PEFM and/or its components shall be marked clearly and legibly with the following:

a) an arrow showing the direction of flow for any user-detachable components that are flow-direction-sensitive unless designed in such a way that prevents incorrect assembly;

b) the name or trade name and address of

— the MANUFACTURER, and

— where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale, to which the RESPONSIBLE ORGANIZATION can refer;

c) where appropriate, an identification reference to the batch code, preceded by the word 'LOT', or serial number, or symbol 5.1.5 or 5.1.7 from ISO 15223-1:2012;

d) indications with regard to proper disposal, as appropriate.

Check compliance by inspection.

5.2.2 Marking of the PEFM packaging

The following shall be marked on the packaging:

a) details to enable the user to identify the PEFM and the contents of the packaging;

b) for a sterile PEFM, the word "STERILE" or the appropriate symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4 or 5.2.5 from ISO 15223-1:2012;

c) for a PEFM with an expiration date, symbol 5.1.4 from ISO 15223-1:2012;

d) for a single use PEFM, the words "single use only" or "do not re-use" or symbol 5.4.2 from ISO 15223-1:2012 (for a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent for the MODEL OR TYPE REFERENCE);

e) any special storage and/or handling instructions;

f) any special operating instructions;

g) the intended purpose of the PEFM.

Check compliance by inspection.

5.3 Instructions for use

The accompanying documentations shall include the following:

a) the intended purpose of the PEFM including any restrictions on its use;

b) the name or trade name and address of

— the MANUFACTURER, and

— where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale, to which the RESPONSIBLE ORGANIZATION can refer;

c) a statement, if applicable, that the performance of the PEFM can be affected by the patient spitting or coughing into the PEFM or by extremes of temperature, humidity and altitude;

d) if the PEFM is intended to be dismantled by the user, the correct method of reassembly;

e) details of what the user should do if unusual readings are obtained;

f) recommended storage conditions;

g) details about cleaning and disinfection or cleaning and sterilization methods that can be used and a list of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that the PEFM parts can tolerate;

h) the highest resistance to flow within the measurement range of the PEFM and the flowrate at which this occurs;

i) details of the nature and frequency of any maintenance and/or calibration needed to ensure that the PEFM operates properly and safely;

j) error of the measured value (see 7.1);

k) information concerning the disposal of the PEFM and its components (e.g. a battery);

l) a unique version identifier such as the date of issue.

Check compliance by inspection.

5.4 Technical description

The technical description shall include the following:

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

b) a statement to the effect that the values displayed by the instrument are expressed as BTPS values;

c) any correction factors to be applied for changes in ambient conditions.

Check compliance by inspection.

6 PEFM measurement range

The measurement range shall, as a minimum, be marked from 60 l/min (1,00 l/s) to 800 l/min (13,33 l/s) and shall be expressed at BTPS conditions. The marked measurement range may be wider than the minimum required range.

Check compliance by inspection.

7 Performance requirements

7.1 Error of measurement

The maximum permissible error for flowrate in the measurement range shall be ±10 l/min (±0,17 l/s) or ±10 % of the reading, whichever is greater. This applies under the following environmental conditions:

— ambient temperature from 10 °C to 35 °C;

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

— altitude from 0 m to 1 400 m (atmospheric pressure range from 1 060 hPa to 850 hPa).

Check compliance by the tests of Annex B.

7.2 Linearity

The difference between the mean error at any two consecutive test flowrates (see Annex B) shall not exceed 5 % of the larger of the two test flowrates.

Under ambient conditions, the PEFM reading at any peak flowrate in the measurement range shall not vary by more than 10 l/min (0,17 l/s) or 5 % of the mean of the readings, whichever is greater.

Check compliance by the tests of Annex B.

7.3 Resistance to flow

The resistance to flow across the measurement range of the PEFM shall not exceed 0,36 kPa/l/s (0,006 kPa/l/min).

Check compliance by the tests of Annex B.

7.4 Frequency response

The difference between the indicated PEF value of the PEFM for profiles A and B (see B.2.1, C.2.1, C.2.2, and Figure C.1) shall, for an identical reference PEF, not exceed 15 l/min (0,25 l/s), or 12 %, whichever is greater.

Check compliance by the tests of Annex C.

8 Dismantling and reassembly

8.1 If intended for dismantling by the user, the PEFM shall be designed or marked to indicate correct reassembly when all parts are mated.

Check compliance by inspection.

8.2 After dismantling and reassembly in accordance with the instructions for use, the PEFM shall meet the requirements of Clause 7 and its readings shall not have changed by more than 10 % or 10 l/min (0,17 l/s), whichever is greater.

Check compliance by the tests of Annex D.

9 Effects of mechanical ageing

If the PEFM has moving parts as part of the flowrate sensing/indicating means, then after being tested in accordance with Annex D, the PEFM shall meet the requirements of Clause 7 and its readings shall not have changed by more than 10 % or 10 l/min (0,17 l/s), whichever is greater.

10 Effects of dropping a hand-held PEFM

A hand-held PEFM shall meet the requirements of Clause 7 and its readings shall not have changed by more than 10 % or 10 l/min (0,17 l/s), whichever is greater, following the 1 m drop test of IEC 60601-1:2005 + A1:2012, 15.3.4.1.

Check compliance by the tests of Annex D.

11 Cleaning, sterilization, and disinfection

11.1 Reusable PEFM and parts

All components specified in the accompanying documentations for reuse and which come into contact with the patient or breathing gases shall be capable of being cleaned and disinfected or cleaned and sterilized.

Compliance is checked by a review of the accompanying documentations for methods of cleaning and disinfection or cleaning and sterilization [see 5.3, f)] and by inspection of the relevant validation reports.

11.2 PEFM and parts delivered sterile

A PEFM or accessories labelled "sterile" shall have been sterilized using an appropriate, validated method as described in ISO 14937.

Compliance is checked by inspection of the relevant validation reports.

12 Compatibility with substances

A PEFM and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the PEFM or its components during operation, including routine inspection and adjustments by the user, in accordance with the instructions for use.

Particular attention should be paid to the toxicity of materials and their compatibility with substances and gases with which they come into contact during use, including routine inspection and adjustments by the user, in accordance with the instructions for use.

Compliance is checked by inspection of the relevant validation reports.

13 Biocompatibility

A PEFM 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.

Compliance is checked by inspection of the relevant validation reports.

Annex A
(informative)

Rationale for tests and examples of test apparatus

A.1 Test Profiles

See also Annexes B and C. The reason for using test profiles is to ensure that a PEFM can record the PEF accurately for a defined group of patients who are likely to use these instruments (the intended patient population). The 26 ATS profiles were chosen to be "representative" profiles that should be used to test a PEFM. However, there is no evidence supplied with these profiles to show that they truly reflect the range of PEFM characteristics found in the intended patient population. The RT and DT characteristics for PEFS in a large population of normal subjects and patients with airflow limitation have been published [21]. For the whole population of 912 subjects (normal and those with airflow limitation) the centiles for RT and DT are shown in Table A.1.

Table A.1 — Centiles for RT and DT

Values in milliseconds

Centile	RT	DT
2,5 th	24	11
5 th	29	14
50 th	62	35
95 th	128	106
97,5 th	155	138

From these data it was evident that the 26 ATS profiles do not cover the full range of PEF characteristics in the intended patient population and there can be some redundancy when testing with all 26. This International Standard tests a PEFM with profiles that span the 90 % confidence limits for the defining characteristics relating to PEF measurement using just two profiles. Profile A (Figure C.1) has RT and DT at the upper 95th centile and profile B has RT and DT at the lower 5th centile so they cover 90 % of the intended patient population characteristics.

Where possible, this International Standard takes steps to reduce the number of individual tests required to ensure that the PEFM has been adequately tested.

The profiles have been derived from a single subject's recorded flowrate time profile. The segment from the start of the blow (start of expiration) to PEF is adjusted in the time domain to derive the desired RT, and the segment after PEF is then similarly adjusted to give the desired DT. If the resulting profile lasts longer than 0,8 s, the flowrate is linearly reduced to zero flowrate at 1,0 s. Since the shape of the profile at this point is not relevant to measuring PEF, the profiles are capped at 1 000 data points at 1 ms intervals.

Profile A has RT and DT at the upper 95th centile for a population including normal subjects and patients with airflow limitation. Profile B has RT and DT at the 5th centile for such a population. The range of RT and DT specified allows for possible error in producing output profiles with these shapes.

A.2 Performance

A.2.1 General

The performance of a PEFM involves three aspects:

— error, linearity and repeatability;

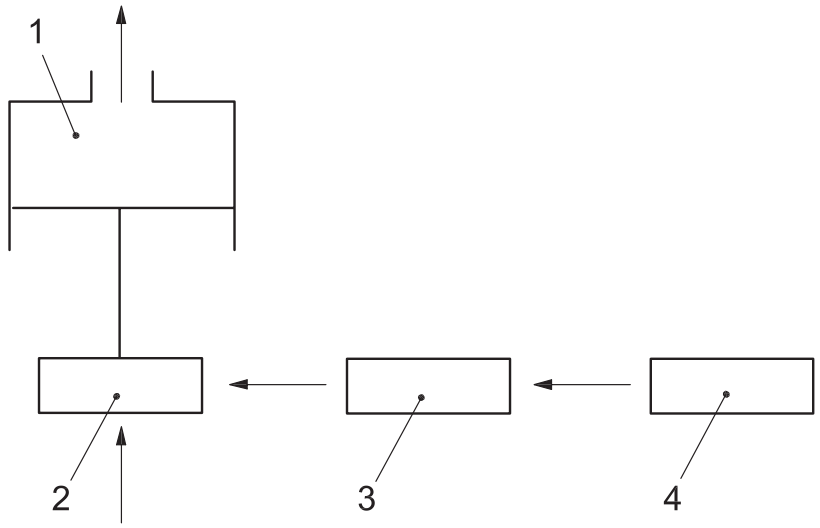
— frequency response;

— resistance.

A.2.2 Error, linearity, and repeatability

Error, linearity, and repeatability can be tested using a simple profile that has an RT and DT at the upper 95th centile. Pump systems can produce such a profile very accurately. Profile A is such a profile, i.e. smooth and without artefact.

An apparatus suitable for this purpose (see Figure A.1) could be a mechanical syringe or piston pump. This type of apparatus can be manufactured with sufficient accuracy that can be verified by independent measurement. The motor and drive to the piston should be sufficient to deliver a PEF of 720 l/min (12,00 l/s) within 50 ms. The motor should incorporate an independent means for verifying its position, for example by the use of an optical shaft encoder or similar apparatus. The seal to the piston should allow a chamber pressure of 8 kPa with a leak of less than 3 l/min. Such equipment should not be used to deliver profiles with a short RT or a short DT since complex interactions within the chamber affect the true output flowrate.



Key

1 syringe or piston pump
2 motor
3 profile
4 computer

Figure A.1 — Schematic diagram of test apparatus

A.2.3 Frequency response

The frequency response is more difficult to test since many PEFMS do not have an analogue waveform output for recording. For a PEFM to have adequate frequency response, it should be able to record a given PEF to the same parameters whether it is from a profile with a short RT and a long DT (profile A)

or from a profile with a short RT and a short DT (profile B). It is thus proposed that this aspect of PEFM performance be tested using profiles A and B at the same delivered flowrate, and the readings from the PEFM be compared. They should agree within the accuracy limits in this International Standard.

A.2.4 Resistance

For reflecting the real use of a PEFM, a dynamic test is more appropriate than a test using steady flow conditions. A concurrent test of linearity, accuracy, and repeatability using profile A and the test method described in Annex B is utilized. Under these conditions, all aspects of the profile's delivery can be ensured so that the resistance can be accurately determined across the measurement range of the PEFM.

A.3 Apparatus

Pump systems of differing design (see Reference [17]) and an explosive decompression apparatus (see Reference [22]) have all been proposed for the testing of a PEFM. Pump systems have the advantage that their output can be traced back to a standard. The relevant components such as the piston, the chamber drive mechanism, and the performance of the motor can all be verified. The timing of movement, which relates to the accuracy of oscillations and the pump position in relation to time, can be checked by optical shaft encoders. Pump systems have been used to test PEFMS with a wide range of profiles but until recently, their output did not accurately follow the input when profiles with a short DT and, to a lesser extent, a short RT, were delivered without the use of an independent flowmeter (see Reference [20]).

Recent developments by some pump manufacturers [1)] have overcome these restrictions and are producing pump systems that are able to deliver short RT and short DT profiles. Explosive decompression equipment is able to deliver short RT and short DT profiles. One limitation in this context is that their output cannot be traced back to a standard without the use of an independent flow meter. However, for testing frequency response, it is not necessary for the output of this type of apparatus to be accurately calibrated; the only requirement is that the output is the same for the two types of profile. An explosive decompression apparatus fitted with a fast response solenoid whose position can be varied in real time can deliver the same output to a given PEFM if the discharge pressure and solenoid opening aperture are kept the same. An independent flow meter with adequate frequency response of its analogue waveform output is needed only to verify that the shape of the profiles delivered by the apparatus matches that required. The frequency response of such flow meters, which have a continuous waveform output, can be checked independently using a step test (see Reference [23]).

An explosive decompression apparatus can be one of fixed volume primed to a certain pressure that dissipates during discharge so that the chamber of the apparatus returns to ambient pressure. Under these circumstances, the driving pressure declines throughout discharge so that the DT of the delivered profile will differ from the input signal to the solenoid. The relationship between decay in pressure and its effect on DT can be determined. The input signal to the solenoid is then adjusted so that the desired RT and DT are achieved. An alternative is to have a much larger chamber or reservoir at the desired driving pressure and have a fast response compressor to maintain this pressure through the opening cycle of the solenoid.

If profiles A and B are discharged from an explosive decompression apparatus with identical driving pressure at peak flowrate, then the recordings from the PEFM for these two profiles can be compared. If the difference is greater than that allowed in this International Standard, then the frequency response characteristics of the PEFM are inadequate.

Whilst the exact apparatus used to test a PEFM is not defined by this International Standard, it is suggested that one test method is to use a pump apparatus to undertake testing in Annex B and an adapted explosive decompression apparatus for the tests in Annex C. It is, however, recognized that recent developments in pump technology now make it possible to use some pump systems for testing frequency response.

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1) Suitable test equipment is commercially available: The Series 1120 flow / volume simulator from Hans Rudolph, Inc., http://www.rudolphkc.com/ or the pulmonary waveform generator from Piston Medical, http://www.pistonmedical.com/. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

Annex B
(normative)

Determination of error, repeatability, and resistance to PEFM output

B.1 Principle

A waveform of known peak flowrate is discharged through the PEFM and the output compared with the set reference peak flowrate.

B.2 Apparatus

B.2.1 **An air flow source**, capable of producing a peak flowrate accurate to within ±3 % of maximum flowrate or ±3 l/min, a repeatability tolerance within ±2 % or ±3 l/min (0,05 l/s) whichever is greater, and a linearity tolerance not exceeding ±2 % when producing flowrate profile A, having an RT between 120 ms and 140 ms and a DT between 100 ms and 120 ms. (see Figure C.1).

B.2.2 **Rigid, smoothbore coupling**, not more than 100 mm in length.

B.3 Procedure

B.3.1 *Carry out the procedure with the apparatus equilibrated to ambient conditions within the temperature range 15 °C to 25 °C using gas delivered at the same ambient temperature.*

B.3.2 *Connect the airflow source (B.2.1) to the outside of the PEFM mouthpiece using the rigid coupling (B.2.2), ensuring that the PEFM is orientated in accordance with the instructions for use.*

B.3.3 *Prepare the PEFM for use according to the instructions for use.*

B.3.4 *Using profile A (see Figure C.1) discharge gas at the chosen ambient conditions, through the PEFM and record the PEF and peak pressure at 100 l/min, 150 l/min, 200 l/min, 300 l/min, 450 l/min, 600 l/min, 720 l/min and at 150 l/min intervals thereafter (1,67 l/s; 2,50 l/s; 3,33 l/s; 5,00 l/s; 7,50 l/s; 10,00 l/s; 12,00 l/s and at 2,50 l/s intervals thereafter) up to the maximum indicated peak flowrate.*

B.3.5 *Repeat B.3.3 and B.3.4 four more times (i.e. a total of five times), at each flowrate.*

NOTE Step B.3.5 can be carried out during B.3.4 for each waveform.

B.3.6 *Repeat steps B.3.3 and B.3.4 five times at 300 l/min and 600 l/min (5,00 l/s and 10,00 l/s), but this time using gas at a temperature of 34 °C ± 2 °C and a relative humidity above 90 % with air conditions at BTPS.*

B.4 Calculations

B.4.1 General

If the technical description includes a warning that the output of the PEFM is known to vary with changes in ambient conditions and/or the characteristics of the gas flowing through it, adjust all results using the appropriate correction factors indicated in the technical description (with removal of BTPS correction

for tests in B.3.4, where appropriate) to account for the set of ambient conditions and the different test gas conditions in B.3.4 and B.3.6.

B.4.2 Error of measurement

Calculate the error of the PEFM for each reference peak flowrate, n, which is expressed as the error, e_n, from Formula (B.1):

$$e_n = \bar{q}_n - q_{\text{ref},n} \tag{B.1}$$

where

$\bar{q}_n$ is the mean of five recorded PEF for reference flowrate n;

$q_{\text{ref},n}$ is the reference PEF for flowrate n.

B.4.3 Output reading repeatability

Calculate the span, s_n, of PEFM readings for each reference peak flowrate, n, using Formula (B.2):

$$s_n = q_{max,n} - q_{min,n} \tag{B.2}$$

where

$q_{\text{max},n}$ is the maximum PEFM reading for reference flowrate n;

$q_{\text{min},n}$ is the minimum PEFM reading for reference flowrate n.

B.4.4 Resistance to flow

Calculate the resistance, R, to flow for each reference flowrate, n, using Formula (B.3):

$$R_n = p_n / q_{\text{ref},n} \tag{B.3}$$

where

p_n is the peak pressure for reference flowrate n;

$q_{\text{ref},n}$ is the reference flowrate for flowrate n.

B.4.5 Linearity

Calculate the difference, d, (in %) for each of the reference flowrates, $q_{\text{ref},n}$, using one of the B.4 formulae:

$$\text{if } \bar{q}_{n+1} \text{ W } \bar{q}_n\text{:} \quad d = \frac{(e_n - e_{n+1}) \times 100}{\bar{q}_{n+1}} \tag{B.4 a}$$

$$\text{if } \bar{q}_{n+1} \cup \bar{q}_n: \quad d = \frac{(e_n - e_{n+1}) \times 100}{\bar{q}_n} \qquad \text{(B.4 b)}$$

where

e_n is the error of the PEFM at peak flowrate n;

e_{n+1} is the error of the PEFM at peak flowrate one increment above peak flowrate n;

$\bar{q}_n$ is the mean of five recorded PEFS for reference flowrate n;

$\bar{q}_{n+1}$ is the mean of five recorded PEFS for a reference flowrate one increment above reference flowrate n.

B.5 Test report

The test report shall include a reference to this test and the following information:

a) For the data from B.3.4 and B.3.5:

1) the five readings for each of the flowrates tested;

2) the span of these five readings (repeatability);

3) the error for each of the five readings for each flowrate tested and their mean (accuracy);

4) the error for each of the five readings expressed as a percentage of the reference flowrate for each of the flowrates tested, and their mean (accuracy);

5) the difference in percent (linearity) for each pair of consecutive flowrates tested (B.3.4) across the measurement range;

6) the peak pressure reading in kilopascals, and the derived resistance, at each of the flowrates tested (resistance);

b) For the data from B.3.6:

1) the five readings for each of the two flowrates tested;

2) the error for each of the five readings for the two test flowrates and their mean (accuracy).

B.6 Pass/fail criteria

Consider any deviation of the PEFM reading less than the sum of the stated permissible errors in this International Standard and the known error of the test apparatus (which is required to be equal to or less than that stated in B.2) as a pass.

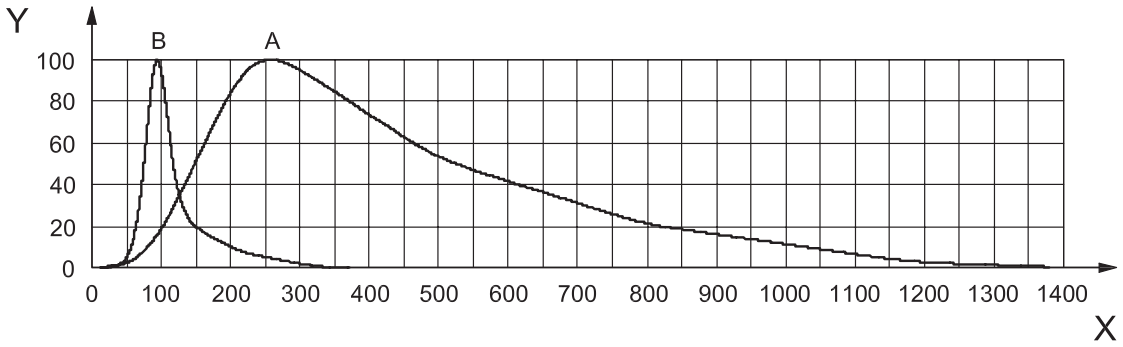
Annex C
(normative)

Determination of frequency response

C.1 Principle

Two specially chosen artificial profiles (see Figure C.1) are delivered to the PEFM to determine its frequency response.

NOTE Many PEFMS do not have a signal input/output part that gives an analogue waveform signal to allow the frequency response to be measured by spectral analysis. It is therefore necessary to check that a PEFM accurately reads PEFS from flowrate profiles that span the range of frequencies found in the intended patient population. These two artificial profiles are chosen to span the 90 % confidence limits for the RT and DT for PEF.



Key

X time in milliseconds
Y confidence limit as a percentage
A profile A flowrate
B profile B flowrate

NOTE Profiles are available in digital format from the European Respiratory Society[2)]

Figure C.1 — Examples of flowrate versus time plot for profiles A and B

C.2 * Apparatus

C.2.1 An airflow source, capable of delivering profile A (see B.2.1) and profile B (see C.2.2) with a flowrate reproducibility of ±3 %. See Figure C.1. See also Annex A for a description of such an apparatus.

C.2.2 Profile B, having an RT of between 24 ms and 36 ms and a DT of between 12 ms and 18 ms.

C.2.3 A rigid, smoothbore coupling, not more than 100 mm in length, if required.

2) http://www.ersnet.org

C.3 Procedure

C.3.1 *Using the mouthpiece and rigid, smoothbore coupling (C.2.3), if required, attach the PEFM to the airflow source (C.2.1).*

C.3.2 *Measure the PEF at three different flowrates (approximately 25 %, 50 %, and 75 % of the top of the measurement range) using profiles A (B.2.1) and B (C.2.2) five times.*

C.4 Calculations for frequency response

Calculate at each flowrate, the mean difference in reading between profiles A and B and express this as a percentage of the reading for profile A.

C.5 Test report

The test report shall include the following information for each of the three flowrates:

a) the mean of the readings for profiles A and B;

b) the difference between the mean readings for profile A and profile B;

c) the difference expressed as a percentage of the reading for profile A.

C.6 Pass/fail criteria

Consider any deviation of the PEFM reading less than the sum of the stated permissible errors in this International Standard and the known error of the test apparatus (which is required to be equal to or less than that stated in B.2) as a pass.

Annex D
(normative)

Test methods for determination of the effectsof dismantling, ageing and dropping

D.1 Principle

To assess the effects of:

a) dismantling and reassembling a PEFM;

b) mechanical ageing, by simulating two years of usage;

c) dropping a hand-held PEFM.

D.2 Apparatus

D.2.1 An airflow source, that supplies, at ambient conditions, a profile with an RT of 24 ms to 36 ms and a DT of no more than 140 ms at a flowrate of 90 % ± 5 % at the maximum of the measurement range of the PEFM.

D.2.2 A rigid smoothbore coupling, of not more than 100 mm in length, if required.

D.3 Procedures

D.3.1 Procedure for testing a PEFM that can be dismantled and re-assembled by the user

Dismantle and re-assemble the PEFM (if applicable) according to the manufacturer's instructions and then carry out the procedures described in Annex B and Annex C. Calculate the effects of dismantling andre-assembly in accordance with D.4.

D.3.2 Procedure for testing the effects of mechanical ageing

Carry out the following steps.

a) *Using the mouthpiece and rigid, smoothbore coupling (D.2.2), if required, attach the PEFM, at its recommended working orientation, to the outlet of the test apparatus. Ensure that the peak flowrate from the airflow source (D.2.1) does not exceed the measurement range of the PEFM.*

b) *Prepare the PEFM according to the instructions for use.*

c) *Actuate the airflow source (D.2.1).*

d) *Repeat D.3.2 b) and D.3.2 c) 2 000 times.*

e) *Carry out the procedures described in Annex B and Annex C after a period of at least 1 h after the last repeat of D.3.2 d). Calculate the effects of mechanical ageing in accordance with D.4.*

D.3.3 Procedure for testing the effects of dropping a hand-held PEFM

Drop the hand-held PEFM in accordance with the test described in IEC 60601-1:2005+A1, *15.3.4.1, and then carry out the procedures described in Annex B and Annex C. Calculate the effects of dropping in accordance with D.4.*

D.4 Calculation of effects

Calculate the percentage difference, $d_{n\%}$, before and after dismantling and re-assembling, mechanical ageing or dropping using Equation D.1:

$$d_{n\%} = \frac{q_{\text{post } n} - q_{\text{pre } n}}{q_{\text{pre } n}} \times 100 \quad \text{(D.1)}$$

where

$q_{\text{post } n}$ = post (dismantling/ageing/dropping) reading for reference flowrate n;

$q_{\text{pre } n}$ = pre (dismantling/ageing/dropping) reading for reference flowrate n.

D.5 Test report

The test report shall include the following information:

a) the information listed in B.5 and C.5;

b) the mean PEF readings at each flowrate (as tested in Annex B) before and after dismantling, ageing and dropping, their difference and that difference expressed as a percentage of the reference flowrate;

c) reference to this test method.

Annex E
(informative)

Environmental aspects

The environmental impact generated by PEAK EXPIRATORY FLOW METERS performing an analysis of respiratory gases is mainly isolated to the following occurrences:

— impact at local environment during operation, including routine inspection and adjustments by the user, 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 during different stages of the life span of the PEAK EXPIRATORY FLOW METERS.

Table E.1 shows a mapping of the life cycle of PEAK EXPIRATORY FLOW METERS in terms of the environment.

Table E.1 — Environmental aspects addressed by (sub)clauses of this 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 (sub)clause			
1	Resource use	1	1	1 5.3 11	1 5.2.1 5.3
2	Energy consumption	1	1	1 11	—
3	Emission to air	1	1	1 4.1 5.3 11	1 5.2.1 5.3
4	Emission to water	1	1	1 4.1 5.3 11	1 5.2.1 5.3 11
5	Waste	1	1	1 4.1 5.3 11	1 5.2.1 5.3 11

Table E.1 *(continued)*

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 (sub)clause			
6	Noise	—	—	1 4.1	—
7	Migration of hazardous substances	1	—	1 4.1 5.3 11 12	1 5.2.1 5.3 11
8	Impacts on soil	—	—	5.3 11 12	1 5.2.1 5.3 11
9	Risks to the environment from accidents or misuse	1	—	1 4.1 5.3 11 12	1 5.3 11

Annex F
(informative)

Reference to the Essential Principles

This International Standard has been prepared to support the essential principles of safety and performance of a PEAK EXPIRATORY FLOW METER as a MEDICAL DEVICE in accordance with ISO/TR 16142. 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 F.1 maps the clauses and subclauses of this document with the essential principles of ISO/TR 16142:2006.

NOTE When an essential principle does not appear in Table F.1, it means that it is not addressed by this document.

Table F.1 — Correspondence between this International Standard and the essential principles (1 of 3)

Corresponding essential principle of ISO/TR 16142:2006	Clause(s)/sub-clause(s) of this International Standard	Qualifying remarks/Notes
A.1, A.2, A.3	all	And via IEC 60601–1:2005+A1:2012
A.4	8, 9, 10, 11, 12	And via IEC 60601–1:2005+A1:2012, Clauses 4, 15 and 7.9
A.5	5	And via IEC 60601–1:2005+A1:2012, Clause 4, and 7.2.17, 7.9.3.1, 15.3.7, 16.2
A.6	—	And via IEC 60601–1:2005+A1:2012, 4.2
A.7.1	12, 13	And via IEC 60601–1:2005+A1:2012, Clause 9, and 11.2, 11.3, 11.4, 11.5, 11.6.8, 11.7, 15.2
A.7.2	—	And via IEC 60601–1:2005+A1:2012, 11.6.6, 11.6.7, 11.7, 15.3.7, 16.2
A.7.3	11, 12	And via IEC 60601–1:2005+A1:2012, Clause 4, and 11.2, 11.4, 11.5, 11.6, 11.7
A.7.5	12	And via IEC 60601–1:2005+A1:2012, 11.3, 11.6.8, 13.1.2, 13.2.6
A.7.6	—	Via IEC 60601–1:2005+A1:2012, 11.3, 11.6.8, 13.1.2, 13.2.6
A.8.1	5.3 f), 11.1	And via IEC 60601–1:2005+A1:2012, 11.6.1, 11.6.7, 11.6.8, 16.2
A.8.3	11.2	And via IEC 60601–1:2005+A1:2012, 11.6.7
A.8.4	11.1	And via IEC 60601–1:2005+A1:2012, 11.6.7
A.8.5	—	And via IEC 60601–1:2005+A1:2012, 11.6.7
A.8.6	5.2.2 b)	And via IEC 60601–1:2005+A1:2012, and 7.2.17
A.9.1	5.2.1 a), 5.4 a)	And via IEC 60601–1:2005+A1:2012, Clauses 4, 14, 16, and 8.2, 8.3, 8.5.2, 8.5.5, 8.6.6, 8.10.3, 8.10.4, 9,11.2.2, 11.4, 11.5
A.9.2	4.1, 4.2, 8, 9, 10	And via IEC 60601–1:2005+A1:2012, Clauses 4, 5, 9, and 8.9.1.5, 12.2, 15.2
A.9.3	—	And via IEC 60601–1:2005+A1:2012, Clause 4, and 8.11.6, 11.2, 11.3, 11.4, 11.5, 13.1.2, 15.4.3.5

Table F.1 — (2 of 3)

Corresponding essential principle of ISO/TR 16142:2006	Clause(s)/sub-clause(s) of this International Standard	Qualifying remarks/Notes
A.10.1	5.1 b), 5.4 b), 5.4 c), 5.4 d), 6, 7, 8, 9	And via IEC 60601–1:2005+A1:2012, Clause 4 and 12.1
A.10.2	5.1 b), 6	And via IEC 60601–1:2005+A1:2012, Clause 4 and 12.2
A.10.3	5.1 a)	And via IEC 60601–1:2005+A1:2012, 7.4.3
A.11.1	—	Via IEC 60601–1:2005+A1:2012, Clauses, 4, 10, 17, and 12.4.5
A.11.2.1	—	Via IEC 60601–1:2005+A1:2012, Clauses, 4, 10, and 12.4
A.11.2.2	—	Via IEC 60601–1:2005+A1:2012, Clauses 4, 12
A.11.3	—	Via IEC 60601–1:2005+A1:2012, Clauses 4, 10, and 12.4.5.1
A.11.4	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 7.9.2.1, 7.9.2.2
A.11.5.1	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 10.1.2, 12.4
A.11.5.2	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 10.1.2, 12.4
A.11.5.3	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 10.1.2, 12.4
A.12.1	—	Via IEC 60601–1:2005+A1:2012, Clauses 4, 14
A.12.3	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 7.8, 12.3
A.12.4	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 7.8, 12.3
A.12.5	—	Via IEC 60601–1:2005+A1:2012, Clauses 4, 17
A.12.6	4.1	And via IEC 60601–1:2005+A1:2012, Clauses 4, 8
A.12.7.1	—	Via IEC 60601–1:2005+A1:2012, Clauses 4, 9, and 15.3
A.12.7.2	—	Via IEC 60601–1:2005+A1:2012, Clause 4 and 9.6
A.12.7.3	—	Via IEC 60601–1:2005+A1:2012, Clause 4 and 9.6
A.12.7.4	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 8.10.3, 8.10.4, 8.11
A.12.7.5	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 8.11.4, 11.1, 15.4.1, 16.9.1, 16.9.2.1

Table F.1 — (3 of 3)

A.12.8.1	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 12.1, 12.4
A.12.8.2	—	Via IEC 60601–1:2005+A1:2012, Clause 4, and 7.8, 12.3, 12.4
A.12.8.3	5.1 b), 5.1 c), 5.1 d), 5.1 e), 5.2.1 a)	And via IEC 60601–1:2005+A1:2012, Clause 4, and 7.4, 7.5, 7.6, 7.8, 12.2
A.13.1	5, 5.3 b)	And via IEC 60601–1:2005+A1:2012, Clause 7 and 16.2
A.14.1	7	And via IEC 60601–1:2005+A1:2012, Clause 4 and 11.1

Annex G
(informative)

Terminology — Alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP) provides access to terms and definitions. [3)]

Term	Source
BTPS	3.1
DWELL TIME	3.2
MANUFACTURER	3.3
MEDICAL DEVICE	3.4
MODEL OR TYPE REFERENCE	3.5
PEAK EXPIRATORY FLOWRATE	3.6
PEAK EXPIRATORY FLOW METER	3.7
PEF	3.6
PEFM	3.7
RESPONSIBLE ORGANIZATION	3.8
RISE TIME	3.9

3) Available at: https://www.iso.org/obp/ui/#home

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