

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

The European Standard EN ISO 23747:2007 has the status of a
British Standard

ICS 11.040.10

National foreword

This British Standard is the UK implementation of EN ISO 23747:2007. It supersedes BS EN 13826:2003 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/121, Anaesthetic and respiratory equipment, to Subcommittee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007)

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 (ISO 23747:2007)

Anästhesie- und Beatmungsgeräte - Spirometer für den expiratorischen Spitzenfluss zur Bewertung der Lungenfunktion bei spontan atmenden Menschen (ISO 23747:2007)

This European Standard was approved by CEN on 28 June 2007.

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Foreword

This document (EN ISO 23747:2007) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.

This document supersedes EN 13826:2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 23747:2007 has been approved by CEN as EN ISO 23747:2007 without any modifications.

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**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*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 23747 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

Introduction

The development of a standard for peak expiratory flowrate (PEF) measurement is considered important for the enhancement of the ability of clinicians to diagnose and monitor lung conditions by ensuring that all devices for such purposes meet minimum levels for safety and performance. An agreed standard means that peak expiratory flow meters (PEFM) can be tested to meet the same requirements with the latest accepted methods. Clinicians and patients can then be confident that these PEFM are fit for the purposes for which they are intended.

The American Thoracic Society has been foremost in proposing initial standards for testing PEFM [14]. They have proposed 26 waveforms for testing PEF, which are deemed suitable for checking that these PEFMs can correctly measure PEF.

The work of Miller et al. [16] first showed the problem of PEFM inaccuracy and they have recently defined the population characteristics of the PEF profile [18] and demonstrated limitations of pump systems for testing PEFM [17]. The European Respiratory Society has published a comprehensive statement on PEF [18].

This International Standard is based on the best currently available evidence concerning the methods and waveforms suited for testing PEFM [15].

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

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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 peak expiratory flow meters (PEFMs) intended for the assessment of pulmonary function in spontaneously breathing humans.

This International Standard covers all devices that measure peak expiratory flowrate in spontaneously breathing humans either as part of an integrated lung function device or as a stand-alone device.

Planning and design of products applying to this International Standard should 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 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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 14937, *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*

3 Terms and definitions

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

3.1

BTPS

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

3.2

dwelt time

DT

time for which the expiratory flowrate is in excess of 90 % of the achieved PEF (3.3)

3.3
peak expiratory flowrate
PEF

maximum flowrate measured at the mouth during an expiration delivered with maximal force starting immediately after achieving maximum lung inflation

3.4
peak expiratory flow meter
PEFM

device for measurement of peak expiratory flowrate (3.3)

3.5
rise time
RT

time taken for flowrate to rise from 10 % to 90 % of the achieved PEF (3.3)

4 General requirements

4.1 Safety for PEFMs that utilize electricity

A PEFM that utilizes electrical power shall meet the requirements of 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 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. visual acuity of 0 on the log minimum angle of resolution (log MAR) scale or 6/6 (20/20), 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. (see Clause 6).

Check compliance by inspection and functional testing.

5.2 Marking of 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 trademark and address of the manufacturer;
- c) where appropriate, an identification reference to the batch or serial number, or symbol 5.14 or 5.16 from ISO 15223-1:2007;
- 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 5.20, 5.21, 5.22, 5.23 or 5.24 from ISO 15223-1:2007;
- c) for a PEFM with an expiration date, symbol 5.12 from ISO 15223-1:2007;
- d) for a single use PEFM, the words "single use only" or "do not re-use" or symbol 5.2 from ISO 15223-1:2007;
- e) any special storage and/or handling instructions;
- f) the intended purpose of the PEFM.

Check compliance by inspection.

5.3 Instructions for use

The accompanying documents shall include the following:

- a) the intended purpose of the PEFM including any restrictions for its use;
- b) 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;
- c) if the PEFM is intended to be dismantled by the user, the correct method of reassembly;
- d) details of what the user should do if unusual readings are obtained;
- e) recommended storage conditions;
- f) 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;

- g) the highest resistance to flow within the measurement range of the PEFM and the flowrate at which this occurs;
- h) details of the nature and frequency of any maintenance and/or calibration needed to ensure that the PEFM operates properly and safely;
- i) information concerning the disposal of the PEFM and its components (e.g. a battery).

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) error of the measured value (see 7.1);
- c) a statement to the effect that the values displayed by the instrument are expressed as BTPS values;
- d) any correction factors to be applied for changes in ambient conditions.

Check compliance by inspection.

6 PEFM measurement range

The marked measurement range shall be from no greater than 60 l/min (1,00 l/s) to not less than 800 l/min (13,33 l/s). The marked measurement range shall be expressed at BTPS conditions.

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 ($\pm 0,17$ l/s) or 10 % of the reading, whichever is the 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 the 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 0,35 kPa/l/min (0,006 kPa/l/s).

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 the 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 the 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 the greater.

10 Effects of dropping a hand-held PEFM

A hand-held PEFM shall meet the requirements of Clause 7.

Check compliance by the tests of Annex D.

11 Cleaning, sterilization and disinfection

11.1 Re-usable PEFM and parts

All components specified in the accompanying documents for re-use 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 documents 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

The 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

The 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 PEFMs. 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 [18]. 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 PEFMs with profiles that span the 90 % confidence limits for the defining characteristics relating to PEF measurement using just two profiles. Profile A has RT and DT at the upper 95th centile and profile B has RT and DT at the lower 5th centile and 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 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

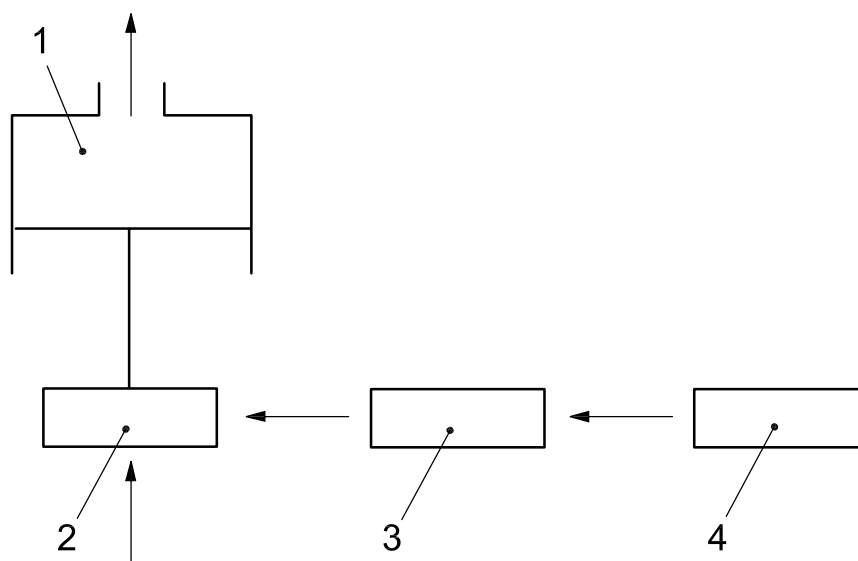
The performance of a PEFM involves three aspects:

- 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 devices 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 PEFM, a dynamic test is more appropriate than a test in 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 ^[15] and an explosive decompression apparatus ^[19] 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, are delivered without the use of an independent flow meter ^[17].

Recent developments by some pump manufacturers have overcome these restrictions and are producing pump systems that are able to deliver short RT and short DT profiles. Explosive decompression devices are able to deliver short RT and short DT profiles without any difficulty. 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 ^[20].

An explosive decompression apparatus can be one of fixed volume primed to a certain pressure that dissipates during discharge so the chamber of the apparatus returns to ambient pressure. Under these circumstances, the driving pressure declines throughout discharge so 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, recognised that recent developments in pump technology now make it possible to use some pump systems for testing frequency response.

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 $\pm 3\%$ of maximum flowrate or ± 3 l/min, a repeatability tolerance within $\pm 2\%$ or 3 l/min (0,05 l/s) whichever is the greater, and a linearity tolerance not exceeding $\pm 2\%$ 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 \pm 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 Equation B.1:

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

where

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

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

B.4.3 Output repeatability

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

$$s_n = q_{\text{max},n} - q_{\text{min},n} \quad (\text{B.2})$$

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 Equation B.3:

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

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 Equations:

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

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

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.

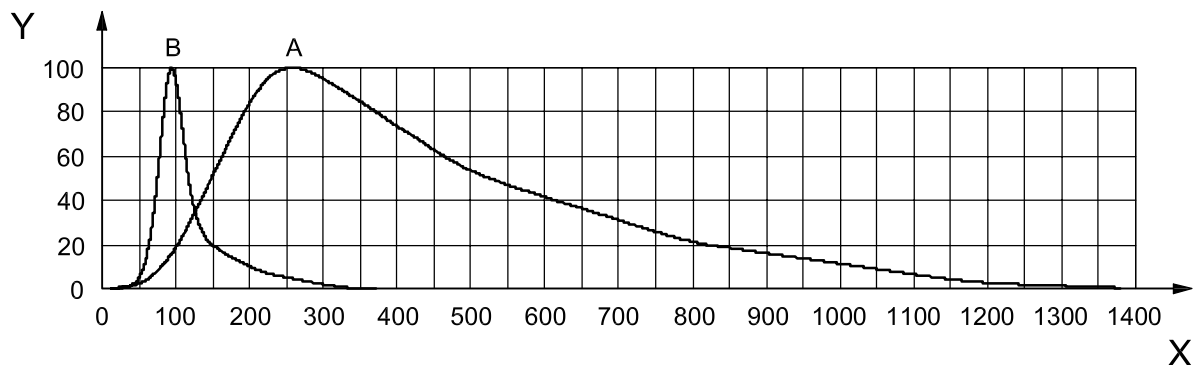
Annex C (normative)

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 Society¹⁾.

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 $\pm 3\%$. 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.

1) <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 effects of dismantling, ageing and dropping

D.1 Principle

To assess the effects of:

- a) dismantling and reassembling PEFM;
- b) mechanical ageing, by simulating two years of usage;
- c) dropping hand-held devices.

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 % \pm 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 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 and re-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 hand-held PEFMs

Drop the hand-held PEFM in accordance with the test described in IEC 60601-1:2005, Subclause 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 difference before and after dismantling and re-assembling, mechanical ageing or dropping using Equation D.1:

$$d_n = \frac{q_{\text{post}} - q_{\text{pre}}}{q_T} \text{ change to } q_{\text{post } n} - \frac{q_{\text{pre } n}}{q_{\text{ref } n}} \quad (\text{D.1})$$

where

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

$q_{\text{pre } n}$ is the pre (dismantling/ageing/dropping) reading for reference flowrate n ;

$q_{\text{ref } n}$ is the reference value for 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
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 principals

This International Standard has been prepared to support the essential principles of safety and performance of peak expiratory flow meters as medical devices 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 — Correspondence between this International Standard and the essential principles

Clause(s)/sub-clause(s) of this International Standard	Corresponding essential principle of ISO/TR 16142:2006	Qualifying remarks/Notes
all	A.1, A.2, A.3	And via IEC 60601-1:2005
8, 9, 10, 11, 12	A.4	And via IEC 60601-1:2005, Clauses 4, 15 and Subclause 7.9
5	A.5	And via IEC 60601-1:2005, Clause 4, and Subclauses 7.2.17, 7.9.3.1, 15.3.7, 16.2
—	A.6	And via IEC 60601-1:2005, Subclause 4.2
12, 13	A.7.1	And via IEC 60601-1:2005, Clause 9, and Subclauses 11.2, 11.3, 11.4, 11.5, 11.6.8, 11.7, 15.2
—	A.7.2	And via IEC 60601-1:2005, Subclauses 11.6.6, 11.6.7, 11.7, 15.3.7, 16.2
11, 12	A.7.3	And via IEC 60601-1:2005, Clause 4, and Subclauses 11.2, 11.4, 11.5, 11.6, 11.7
—	A.7.4	
12	A.7.5	And via IEC 60601-1:2005, Subclauses 11.3, 11.6.8, 13.1.2, 13.2.6
5.3 f)	A.7.6	And via IEC 60601-1:2005, Subclauses 11.3, 11.6.8, 13.1.2, 13.2.6
5.3 f), 11.1	A.8.1	And via IEC 60601-1:2005, Subclauses 11.6.1, 11.6.7, 11.6.8, 16.2
—	A.8.1.1	
—	A.8.1.2	
5.2.2 b)	A.8.2	And via IEC 60601-1:2005, Subclause 11.6.7
11.2	A.8.3	And via IEC 60601-1:2005, Subclause 11.6.7
11.1	A.8.4	And via IEC 60601-1:2005, Subclause 11.6.7
—	A.8.5	And via IEC 60601-1:2005, Subclause 11.6.7
5.2.2 b)	A.8.6	And via IEC 60601-1:2005, and Subclause 7.2.17
5.2.1 a), 5.4 a)	A.9.1	And via IEC 60601-1:2005, Clauses 4, 14, 16, and Subclauses 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
4.2, 8, 9, 10	A.9.2	And via IEC 60601-1:2005, Clauses 4, 5, 9, and Subclauses 8.9.1.5, 12.2, 15.2
—	A.9.3	And via IEC 60601-1:2005, Clause 4, and Subclauses 8.11.6, 11.2, 11.3, 11.4, 11.5, 13.1.2, 15.4.3.5
5.1 b), 5.4 b), 5.4 c), 5.4 d), 6, 7, 8, 9	A.10.1	And via IEC 60601-1:2005, Clause 4 and Subclause 12.1
5.1 b), 6	A.10.2	And via IEC 60601-1:2005, Clause 4 and Subclause 12.2
5.1 a)	A.10.3	And via IEC 60601-1:2005, Subclause 7.4.3
—	A.11.1	And via IEC 60601-1:2005, Clauses, 4, 10, 17, and Subclause 12.4.5
—	A.11.2.1	And via IEC 60601-1:2005, Clauses, 4, 10, and Subclause 12.4
—	A.11.2.2	And via IEC 60601-1:2005, Clauses 4, 12

Table F.1 (continued)

Clause(s)/sub-clause(s) of this International Standard	Corresponding essential principle of ISO/TR 16142:2006	Qualifying remarks/Notes
—	A.11.3	Via IEC 60601-1:2005, Clauses 4, 10, and Subclause 12.4.5.1
—	A.11.4	Via IEC 60601-1:2005, Clause 4, and Subclauses 7.9.2.1, 7.9.2.2
—	A.11.5.1	Via IEC 60601-1:2005, Clause 4, and Subclauses 10.1.2, 12.4
—	A.11.5.2	Via IEC 60601-1:2005, Clause 4, and Subclauses 10.1.2, 12.4
—	A.11.5.3	Via IEC 60601-1:2005, Clause 4, and Subclauses 10.1.2, 12.4
—	A.12.1	Via IEC 60601-1:2005, Clauses 4, 14
—	A.12.2	
—	A.12.3	Via IEC 60601-1:2005, Clause 4, and Subclauses 7.8, 12.3
—	A.12.4	Via IEC 60601-1:2005, Clause 4, and Subclauses 7.8, 12.3
—	A.12.5	Via IEC 60601-1:2005, Clauses 4, 17
4.1	A.12.6	And via IEC 60601-1:2005, Clauses 4, 8
—	A.12.7.1	Via IEC 60601-1:2005, Clauses 4, 9, and Subclause 15.3
—	A.12.7.2	Via IEC 60601-1:2005, Clause 4 and Subclause 9.6
—	A.12.7.3	Via IEC 60601-1:2005, Clause 4 and Subclause 9.6
—	A.12.7.4	Via IEC 60601-1:2005, Clause 4, and Subclauses 8.10.3, 8.10.4, 8.11
—	A.12.7.5	Via IEC 60601-1:2005, Clause 4, and Subclauses 8.11.4, 11.1, 15.4.1, 16.9.1, 16.9.2.1
—	A.12.8.1	Via IEC 60601-1:2005, Clause 4, and Subclauses 12.1, 12.4
—	A.12.8.2	Via IEC 60601-1:2005, Clause 4, and Subclauses 7.8, 12.3, 12.4
5.1 b), 5.1 c), 5.1 d), 5.1 e), 5.2.1 a)	A.12.8.3	And via IEC 60601-1:2005, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5, 5.3 b)	A.13.1	And via IEC 60601-1:2005, Clause 7 and Subclause 16.2
7	A.14.1	And via IEC 60601-1:2005, Clause 4 and Subclause 11.1

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Annex ZA (informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and EU Directives

Clause(s)/Subclause(s) of this International Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments ^a
All	1, 2, 3	And via IEC 60601-1
4.1	12.6	And via IEC 60601-1, Clauses 4, 8
4.2	9.2	And via IEC 60601-1, Clauses 4, 5, 9, and Subclauses 8.9.1.5, 12.2, 15.2
5	5, 13.1	And via IEC 60601-1, Clauses 4, 7 and Subclauses 7.2.17, 7.9.3.1, 15.3.7, 16.2
5.1 a)	10.3	And via IEC 60601-1, Subclause 7.4.3
5.1 b)	10.1, 10.2, 12.9	And via IEC 60601-1, Clause 4 and Subclauses 7.4, 7.5, 7.6, 7.8, 12.1, 12.2
5.1 c)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.1 d)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.1 e)	12.9	And via IEC 60601-1, Clause 4, and Subclauses 7.4, 7.5, 7.6, 7.8, 12.2
5.2.1 a)	9.1, 12.9	And via IEC 60601-1, Clauses 4, 14, 16, and Subclauses 7.4, 7.5, 7.6, 7.8, 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, 12.2
5.2.1 b)	13.3 a)	And via IEC 60601-1, Subclause 7.2.2
5.2.1 c)	13.2, 13.3 d)	And via IEC 60601-1, Subclauses 7.2, 7.4, 7.5, 7.6
5.2.1 d)	13.6 n)	
5.2.2 a)	13.3 b)	And via IEC 60601-1, Subclause 7.2.2
5.2.2 b)	8.3, 8.7, 13.2, 13.3 c)	And via IEC 60601-1, Subclauses 7.2, 7.4, 7.5, 7.6, 11.6.7

Clause(s)/Subclause(s) of this International Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments ^a
5.2.2 c)	13.3 e)	
5.2.2 d)	13.2, 13.3 f)	And via IEC 60601-1, Subclauses 7.2.1, 7.4, 7.5, 7.6
5.2.2 e)	13.3 i)	And via IEC 60601-1, Subclause 7.2.17
5.2.2 f)	13.4	And via IEC 60601-1, Subclauses 7.9.2.1, 16.2
5.3	13.6 a)	And via IEC 60601-1, Subclauses 7.9.1, 7.9.2, 16.2
5.3 b)	13.1, 13.3 i), 13.3 j), 13.3 k)	And via IEC 60601-1, Clause 7 and Subclause 16.2
5.3 c)	13.6 d)	And via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.13, 7.9.2.16, 9.8.1, 16.2
5.3 d)	13.6 b), 13.6 k)	And via IEC 60601-1, Subclauses 7.9.2.1, 7.9.2.2, 7.9.2.9, 16.2
5.3 e)	13.6 i)	
5.3 f)	7.6, 8.1, 13.6 h)	And via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.12, 7.9.2.14, 11.3, 11.6.1, 11.6.7, 11.6.8, 13.1.2, 13.2.6, 16.2
5.4 a)	9.1, 13.6 b)	And via IEC 60601-1, Clauses 4, 14, 16, and Subclauses 7.9.2.1, 7.9.2.2, 7.9.2.9, 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, 16.2
5.4 b)	10.1, 13.6 p)	And via IEC 60601-1, Clause 4 and Subclause 12.1
5.4 c)	10.1, 13.6 l)	And via IEC 60601-1, Clause 4 and Subclause 12.1
5.4 d)	10.1, 13.6 l)	And via IEC 60601-1, Clause 4 and Subclause 12.1
6	10.1, 10.2	And via IEC 60601-1, Clause 4 and Subclauses 12.1, 12.2
7	3, 10.1	And via IEC 60601-1, Clause 4 and Subclauses 11.1, 12.1
8	4, 9.2, 10.1	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.1, 12.2, 15.2
9	4, 9.2, 10.1	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.1, 12.2, 15.2

Clause(s)/Subclause(s) of this International Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments ^a
10	4, 9.2	And via IEC 60601-1, Clauses 4, 5, 9, 15 and Subclauses 7.9, 8.9.1.5, 12.2, 15.2
11.1	4, 7.3, 8.1, 8.5	And via IEC 60601-1, Clauses 4, 15 and Subclauses 7.9, 11.2, 11.4, 11.5, 11.6, 11.7, 16.2
11.2	8.4	And via IEC 60601-1, Subclause 11.6.7
12	4, 7.1, 7.3, 7.5	And via IEC 60601-1, Clauses 4, 9, 15, and Subclauses 7.9, 11.2, 11.3, 11.4, 11.5, 11.6, 11.7, 13.1.2, 13.2.6, 15.2
13	7.1	And via IEC 60601-1, Clause 9, and Subclauses 11.2, 11.3, 11.4, 11.5, 11.6.8, 11.7, 15.2
—	7.2	Via IEC 60601-1, Subclauses 11.6.6, 11.6.7, 11.7, 15.3.7, 16.2
—	9.3	Via IEC 60601-1, Clause 4, and Subclauses 8.11.6, 11.2, 11.3, 11.4, 11.5, 13.1.2, 15.4.3.5
—	11.3.1	Via IEC 60601-1, Clauses 4, 10, and Subclause 12.4.5.1
—	12.5	Via IEC 60601-1, Clauses 4, 17
—	12.7.1	Via IEC 60601-1, Clauses 4, 9, and Subclause 15.3
—	12.7.2	Via IEC 60601-1, Clause 4 and Subclause 9.6
—	12.7.3	Via IEC 60601-1, Clause 4 and Subclause 9.6
—	12.7.4	Via IEC 60601-1, Clause 4, and Subclauses 8.10.3, 8.10.4, 8.11
—	12.7.5	Via IEC 60601-1, Clause 4, and Subclauses 8.11.4, 11.1, 15.4.1, 16.9.1, 16.9.2.1
—	12.8.2	Via IEC 60601-1, Clause 4, and Subclauses 7.8, 12.3, 12.4
—	13.3 m)	Via IEC 60601-1, Subclauses 6.4, 7.2.17
—	13.5	Via IEC 60601-1, Subclauses 7.2.2, 7.2.4
—	13.6 c)	Via IEC 60601-1, Subclauses 7.9.2.6, 7.9.2.8, 7.9.2.9, 7.9.2.14, 16.2
—	13.6 f)	Via IEC 60601-1, Subclause 7.9.2.2
<p>^a The following comments relating to clauses and subclauses of IEC 60601-1:2005 describe the consequences of the general normative reference to IEC 60601-1:2005 made in the requirement 4.1 of the present standard.</p>		

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