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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 (*).

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
dwell 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 (± 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.