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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.

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.

