SLOVENSKI STANDARD

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Merilniki maksimalnega pretoka zraka med izdihom

Peak expiratory flow meters

Spirometer für den exspiratorischen Spitzenfluss

Spirometre permettant la mesure du débit de pointe expiratoire

Ta slovenski standard je istoveten z: EN 13826:2003

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Spiromètre permettant la mesure du débit de pointe expiratoire

Spirometer für den exspiratorischen Spitzenfluss

This European Standard was approved by CEN on 21 April 2003.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN 13826:2003) has been prepared by 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of an identical text or by endorsement, at the latest by December 2003, and conflicting national standards shall be withdrawn at the latest by December 2003.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.

Annexes A, B and C are normative and form part of this European Standard.

Annexes D and ZA are informative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

The development of a standard for peak expiratory flow (PEF) measurement is considered essential to enhance 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 standards with the latest accepted methods. Clinicians and patients can then be confident that these PEFM are fit for the purpose.

The American Thoracic Society has been foremost in proposing initial standards for testing PEFM [1]. They have proposed 26 waveforms for testing PEF that are deemed representative signals to check that these PEFM can correctly measure PEF.

The work of Miller et al [2] first showed the problem of PEFM inaccuracy and they have recently defined the population characteristics of the PEF profile [3] and demonstrated the limitations of pump systems for testing PEFM [4]. The European Respiratory Society has published a comprehensive statement on PEF [5].

EN 13826 is based on the best currently available evidence concerning the methods and signals suited for the purpose of testing PEFM [2]. This standard is applicable to devices that are designed either to measure PEF, or to record many other indices of lung function in addition to PEF.

1 Scope

This European Standard specifies requirements for peak expiratory flow meters (PEFM) intended for the assessment of pulmonary function in spontaneously breathing humans.

This European Standard covers all devices that measure peak expiratory flow either as part of an integrated lung function device or as a stand-alone device.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 60601-1:1990, Medical electrical equipment. Part 1: General requirements for safety (IEC 60601-1:1988).

EN 980:1996, Graphical symbols for use in the labelling of medical devices.

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply:

3.1
measurement range
set of values of measurands for which the error of a measuring instrument is intended to lie within specified limits

3.2
peak expiratory flow meter
device for measurement of peak expiratory flow

NOTE The abbreviation PEFM is used throughout the document.

3.3
peak expiratory flow
maximum flow measured at the mouth during an expiration delivered with maximal force starting immediately after achieving maximum lung inflation

NOTE The abbreviation PEF is used throughout the document.

3.4
BTPS
body temperature (37 °C), at the measured pressure and saturated with water vapour

NOTE: BTPS is the abbreviation for Body Temperature, Pressure and Saturated water vapour.

3.5
dwell time
time for which flow is in excess of 90% of the achieved PEF

NOTE The abbreviation DT is used throughout this standard.

3.6
rise time
time taken for flow to rise from 10% to 90% of the achieved PEF

NOTE The abbreviation RT is used throughout this standard.

4 General requirements

4.1 Electrical safety

PEFM that are defined as Medical Electrical Equipment (see sub-clause 2.2.15 of EN 60601-1:1990) shall, in addition to the requirements in this European Standard, meet the applicable requirements in EN 60601-1 and amendments 1 and 2.

The environmental conditions given in clause 7.1 of this European Standard replace those given in sub-clause 10.2.1 of EN 60601-1:1990

4.2 Mechanical safety

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

Compliance is checked by inspection.

5 Identification, marking and documents

5.1 Marking of the scale or display

The scale or display of the PEFM shall be clearly and legibly marked with the following:

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

b) for PEFM with a graduated scale the increment between any two adjacent graduation lines shall represent a difference in peak flow no greater than 10 l/min (0,15 l/s) at flows of 700 l/min (11 l/s) or below, and 20 l/min (0,3 l/s) at flows above 700 l/min (11l/s). For PEFM with a digital display the incremental step shall be no greater than 5 l/min or 0,02 l/s.

NOTE 5 l/min and 0,02 l/s 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. a visual acuity of 1, corrected if necessary, at a distance of 0,5 m and at an ambient illuminance in the range 100 Lx to 1500 Lx);

d) the numbering on a scale shall appear at intervals no greater than 50 l/min (1,0l/s) up to 700 l/min (11,0 l/s) and 100 l/min (1,7 l/s) thereafter;

e) the numbering on a scale or digital display shall not exceed the measurement range. (see clause 6).

5.2 Marking of PEFM or packaging

5.2.1 Marking of the PEFM

The PEFM and/or its components shall be clearly and legibly marked 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, either the serial number or batch code preceded by the symbol for “BATCH CODE”(see symbol 4.3 of EN 980:1996).

5.2.2 Marking of the 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) if appropriate, the symbol for “STERILE” (see symbols 4.6, 4.7 and 4.10 in EN 980:1996);

c) if appropriate, the symbol for “USE BY” (see symbol 4.2 in EN 980:1996);

d) if appropriate, an indication that the PEFM is for single patient use;

e) any special storage and/or handling instructions;

f) the intended purpose of the PEFM.

5.3 Accompanying documents

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 during expiration 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) methods of cleaning, disinfection and sterilization, if appropriate;

g) the highest resistance to flow within the measurement range of the PEFM and the flow 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.

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.

6 PEFM measurement ranges

The range shall be from no greater than 60 l/min (1,0 l/s) to not less than 800 l/min (13,3 l/s) and expressed at BTPS conditions.

7 Performance requirements

7.1 Error of measurement

When tested in accordance with annex A, the maximum permissible error for flow in the measurement range shall be:

± 10 l/min (± 0,15 l/s) or 10 % of the reading whichever is the greater. This applies under the following environmental conditions:

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

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

— altitude range from 0 m to 1 400 m (atmospheric pressure range from 1060 hPa to 850 hPa.

NOTE The maximum permissible error values do not take into account the error limits of the test apparatus specified in annex A.

7.2 Linearity

When tested in accordance with annex A, the difference between the mean error at any two consecutive test flows (see annex A) shall not exceed 5 % of the larger of the two test flows.

NOTE The linearity tolerances do not take into account the error limits of the test apparatus specified in annex A

When tested in accordance with annex A and under ambient conditions, the span of the PEFM readings at any set peak flow in the measurement range shall not vary by more than 10 l/min (0,15 l/s) or 5 % of the mean of the readings, whichever is the greater.

NOTE The repeatability tolerances do not take into account the tolerances of the test apparatus specified in annex A.

7.3 Resistance to flow

When tested in accordance with annex A the resistance to flow across the measurement range of the PEFM shall not exceed 0,35 kPa/l/s (0,006 kPa/l/min).