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BSI Group Headquarters
389 Chiswick High Road
London W4 4AL
Tel: +44 (0)20 8996 9000
Fax: +44 (0)20 8996 7400
www.bsi-global.com

Direct tel : 0208 996 7849
Direct fax: 020 8996 7249
E-mail: carla.martin@bsi-global.com

Our Ref: CH/121/3

Date: 16 January 2003

To the members of committee
CH/121 - Anaesthetic and respiratory equipment and
CH/121/3 - Lung ventilators and related equipment

Dear Member

CEN FORMAL VOTE DOCUMENT – prEN 13826 Peak expiratory flow meters

This CEN draft is circulated to CEN members for Formal Voting. As a member of CH/121 and CH/121/3**,** you are asked to advise the UK committee on the vote to be returned to CEN.

You are reminded that there is a weighted voting procedure in CEN and therefore even if the UK returns a negative vote we may still be required to publish an identical British Standard.

All votes are required to be unconditional. All comments, which should be typed, should be structured so that it is clear:

(a) to which clause each comment refers;
(b) the change(s) to the text, if any, which is(are) proposed; and
(c) the reason(s) for the comment or proposed change.

Please note that annotated text is not acceptable. Noting also that technical comments are not allowed at this stage unless being used as a justification for a negative vote. Comments should be submitted under the following three separate headings: 'Editorial'; 'Technical'; and 'Legal'. The official ISO comments table can be found in the public access area at www.iso.ch/sdis/forms under 'Template for comments and secretariat observations'. Comments in the above format may be submitted by email, on disk (preferably in MS Word) or by fax to be received by the BSI Secretary by no later **THURSDAY 13 FEBRUARY 2003.** Please note that the UK rejected the CEN enquiry text of prEN 13826 [00/560631DC] in June 2000.

Your agreement to return an affirmative vote on the draft will also be taken as authority to publish an identical British Standard. Supersession information: If you are aware of a current national standard which may be affected please notify me dircetly.

If I do not hear from you by **THURSDAY 13 FEBRUARY 2003** I shall assume that a positive vote should be returned to CEN and shall take the necessary action. Any contentious issues/comments shall be resolved with advice from the Committee Chairmen.

Yours sincerely

Carla Martin
Committee Secretary to CH/121

FINAL DRAFT
prEN 13826

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2003

ICS 11.040.10

English version

Peak expiratory flow meters

Spiromètre permettant la mesure du débit de pointe expiratoire

Spirometer für den exspiratorischen Spitzenfluss

This draft European Standard is submitted to CEN members for formal vote. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (prEN 13826:2003) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

This document is currently submitted to the Formal Vote.

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 for informative.

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].

prEN 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 60601-1:1998).

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

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).

7.4 Frequency response

When tested in accordance with annex B the difference between the indicated PEF values of the PEFM for Profiles A and B (see A 2.2, B 2.2 and Figure B1) shall for identical reference PEF not exceed 15 l/min (0,25 l/s) or 12% whichever is the greater.

NOTE The frequency response tolerances do not take into account the error limits of the test apparatus specified in annex B

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.

8.2 When tested in accordance with annex C after dismantling and reassembly in accordance with the manufacturer's instructions, the PEFM shall meet the requirements of clause 7 and its readings shall not have changed by more than 10 % or 10 l/min (0,15 l/s), whichever is the greater.

9 Effects of mechanical ageing

If the PEFM has moving parts as part of the flow sensing/indicating system then after being tested in accordance with annex C, the PEFM shall meet the requirements of clause 7 and its readings shall not have changed by more than 10 % or 10 l/min (0,15 l/s), whichever is the greater.

10 Effects of dropping hand-held PEFM

When tested in accordance with annex C, hand-held PEFM shall meet the requirements of clause 7.

Annex A
(normative)

Method of determining error, repeatability and resistance to flow of peak expiratory flow meter output

A.1 Principle

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

A.2 Apparatus

A.2.1 An air flow source capable of producing a peak flow accurate to within ± 3 % of maximum flow or ± 3 l/min, a repeatability tolerance within ± 2 % or 3 l/min (0,05 l/s) whichever is the greater, and a linearity tolerance not exceeding ± 2 % when producing flow profile A (see A.2.2).

A.2.2 Profile A: Having a RT between 120 ms and 140 ms and a DT between 100 ms and 120 ms.

A.2.3 Rigid, smooth-bore coupling of not more than 100 mm in length.

A.3 Procedure

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

A.3.2 Connect the air flow source to the outside of the PEFM mouthpiece using the rigid coupling, ensuring that the PEFM is orientated in accordance with the manufacturer's instructions.

A.3.3 Prepare the PEFM for use according to the manufacturer's instructions.

A.3.4 Using profile A (see Figure B.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 (1,7 l/s; 2,5 l/s; 3,3 l/s; 5,0 l/s; 7,5 l/s; 10,0 l/s; 12,0 l/s and at 2,5 l/s intervals thereafter.)

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

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

A.3.6 Repeat A.3.3 and A.3.4 five times at 300 l/min and 600 l/min (5,0 l/s and 10,0 l/s) but this time discharge gas at a temperature of 34 °C ± 2 °C and a relative humidity above 90 %.

A.4 Calculations

If the manufacturer indicates that the output of the PEFM is known to vary according to ambient conditions and/or the characteristics of the gas flowing through it, then all results from the PEFM shall be adjusted with appropriate correction factors given by the manufacturer (with removal of BTPS correction for tests in A 3.4, where appropriate) to account for the set of ambient conditions and different test gas conditions in A.3.4 and A.3.6.

A.4.1 Error of measurement

Calculate the error of the PEFM for each reference peak flow n, which is expressed as the error e_n from the following equation:

$$e_n = \overline{Q}_n - Q_{ref,\,n} \qquad \text{(A.1)}$$

with

$\overline{Q}_n$ = mean of 5 recorded PEF for reference flow n;

$Q_{ref,n}$ = reference PEF for flow n.

A.4.2 Output repeatability

Calculate the span s_n of PEFM readings for each reference peak flow n from the following equation:

$$s_n = Q_{max,n} - Q_{min,n} \qquad \text{(A.2)}$$

with

$Q_{max,n}$ = maximum PEFM reading for reference flow n;

$Q_{min,n}$ = minimum PEFM reading for reference flow n.

A.4.3 Resistance to flow

Calculate the resistance R to flow for each of the reference flows n from the following equation:

$$R_n = P_n / Q_{ref,n} \qquad \text{(A.3)}$$

with

P_n = peak pressure for reference flow n;

$Q_{ref,n}$ = reference flow for flow n.

A.4.4 Linearity

Calculate the difference d (in %) for each of the reference flows Q_{refn} from the following equation:

$$\text{if } \overline{Q}_{n+1} \geq \overline{Q}_n: \quad d = \frac{(e_n - e_{n+1}) \times 100}{\overline{Q}_{n+1}}$$

$$\text{if } \overline{Q}_{n+1} \leq \overline{Q}_n: \quad d = \frac{(e_n - e_{n+1}) \times 100}{\overline{Q}_n} \qquad \text{(A.4)}$$

with

e_n = error of the PEFM at peak flow n;

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

$\overline{Q}_n$ = mean of 5 recorded PEF for reference flow n;

$\overline{Q}_{n+1}$ = mean of 5 recorded PEF for reference flow one increment above reference flow n.

A.5 Test report

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

For the data from A.3.4 and A.3.5:

a) the 5 readings for each of the flows tested;

b) the span of these 5 readings (repeatability);

c) the error for each of the 5 readings for each flow tested and their mean (accuracy);

d) the error for each of the 5 readings expressed as a percentage of the reference flow for each of the flows tested, and their mean (accuracy);

e) the difference % (linearity) for each pair of consecutive flows tested (A.3.4) across the measurement range;

f) the peak pressure reading in kPa, and the derived resistance, at each of the flows tested (resistance).

For the data from A.3.6:

g) the 5 readings for each of the 2 flows tested;

h) The error for each of the 5 readings for the 2 test flows and their mean.

A.6 Pass/ fail criteria

Any error of PEFM reading shall be less than the sum of the stated permissible errors in this European Standard and the known error of the test apparatus (which shall be equal or less than that stated in A.2).

Annex B
(normative)

Method of determining frequency response

B.1 Principle

Two specially chosen artificial profiles (see Figure B.1) are delivered to PEFM to determine their frequency response.

NOTE Many PEFM do not give an analogue output signal to allow frequency response to be measured by spectral analysis. It is therefore necessary to check that PEFM accurately read PEF from flow profiles that span the range of frequency content found in the client population who use these PEFM. These two artificial profiles are chosen to span the 90% confidence limits for the RT and DT for PEF.

B.2 Apparatus

B.2.1 An air flow source capable of delivering profile A given in A.2.2 and profile B given in B.2.2 with a flow reproducibility of ± 3 %. (see also Figure B.1).

(See annex D for an example of such an airflow source).

B.2.2 Profile B: Having a RT of between 24 ms and 36 ms and a DT of between 12 ms and 18 ms.

B.2.3 A rigid, smooth-bore coupling of no more than 100 mm in length if required.

B.3 Procedure

B 3.1 Using the mouthpiece and rigid, smooth-bore coupling, if required, attach the PEFM to the airflow source.

B.3.2 Measure, five times, the PEFM reading at three different flows using profile A and B.

NOTE These flows should be at 25 %, 50 % and 75 % of the top of the measurement range.

B.4 Calculations for frequency response

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

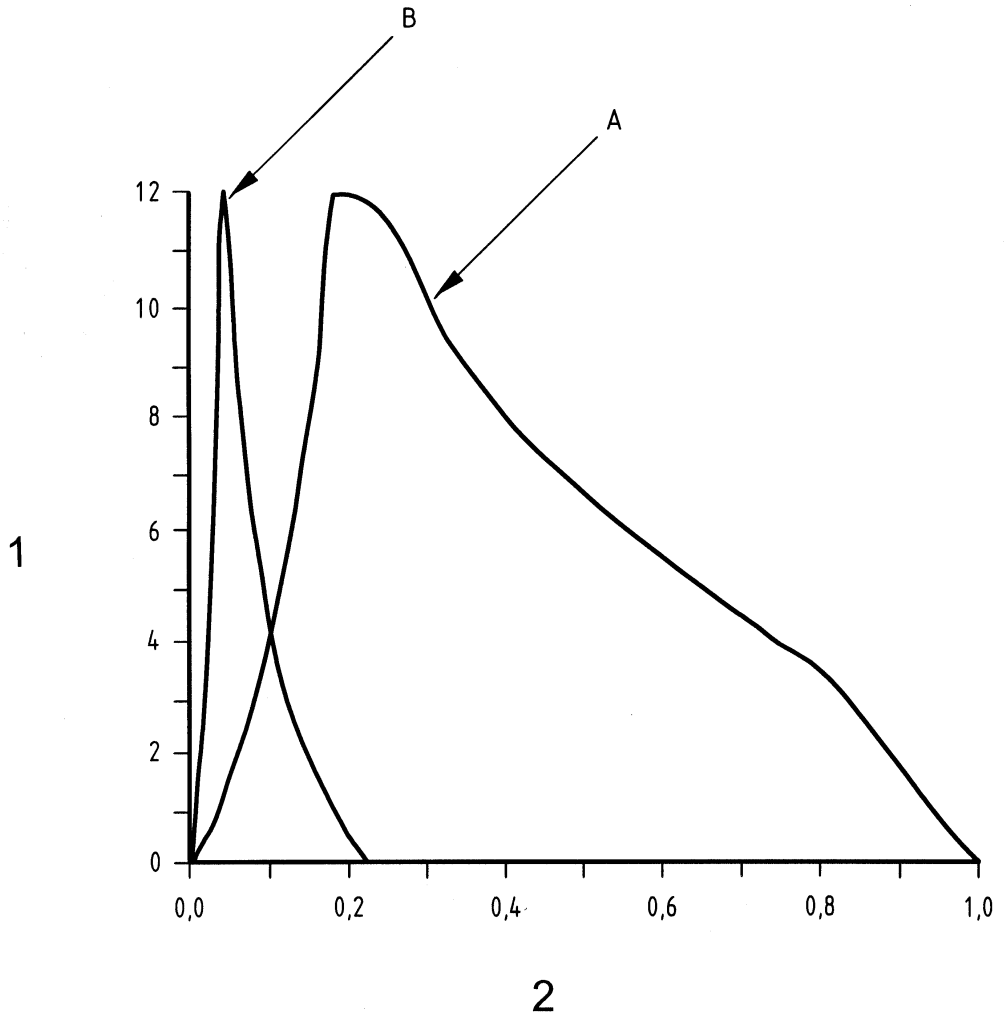
B.5 Test report

The report shall include for each of the three flows:

a) the mean of the readings, for profile A and B;

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

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



Key:

A Profile A
B Profile B
1 Flow in l/s
2 Time in s

Figure B.1 — Examples of flow time plots of Profiles A and B

NOTE Profiles are available in digital format from the European Respiratory Society.

B.6 Pass/ fail criteria

Any error of PEFM reading shall be less than the sum of the stated permissible errors in this European Standard and the known error of the test apparatus (which shall be equal to or less than that stated in B.2).

Annex C
(normative)

Test methods for determining the effects of dismantling, ageing and dropping

C.1 Principle

To assess the effects of: (1) dismantling and reassembling PEFM; (2) mechanical ageing, by simulating 2 years usage and; (3) dropping hand-held devices

C.2 Apparatus

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

C.2.2 A rigid smooth-bore coupling of no more than 100 mm in length, if required.

C.3 Procedures

C.3.1 Procedure for testing PEFM that may 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 in annex A and annex B. Calculate the effects of dismantling and re-assembly in accordance with C.4

C.3.2 Procedure for testing the effects of mechanical ageing

C.3.2.1 Using the mouthpiece and rigid, smooth-bore coupling, if required, attach the PEFM at its recommended working orientation to the outlet of the test apparatus. Ensure that the peak flow from the airflow source does not exceed the measurement range of the PEFM.

C.3.2.2 Prepare the PEFM according to the manufacturer’s instructions.

C.3.2.3 Actuate the airflow source.

C.3.2.4 Repeat C.3.2.2 and C.3.2.3 2 000 times.

C.3.2.5 Carry out the procedures in annex A and annex B after a period of at least 1 h after the last repeat of C.3.2.4. Calculate the effects of mechanical ageing in accordance with C.4

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

Drop the hand-held PEFM in accordance with the test given in clause 21.5 of EN 60601-1:1990 and then carry out the procedures in annex A and annex B. Calculate the effects of dropping in accordance with C.4

C.4 Calculation of effects

Calculate the difference before and after dismantling and re-assembling, mechanical ageing or dropping using the formula:

$$d_n = \frac{Q_{post} - Q_{pre}}{Q_T} \text{ change to } Q_{post,n} - Q_{pre,n} \div Q_{ref,n} \quad \text{(C.1)}$$

with

$Q_{post\ n}$= post (dismantling/ageing/dropping) reading for reference

Flow n;

$Q_{pre\ n}$ = pre (dismantling/ageing/dropping) reading for reference

flow n;

$Q_{ref\ n}$ = reference value for flow n;

C.5 Test report

The report shall include the following information:

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

b) the mean PEF readings at each flow (as tested in annex A) before and after dismantling, ageing and dropping, their difference and that difference expressed as a % of the reference flow;

c) reference to this test method.

Annex D
(informative)

Rationale for tests and examples of test apparatus

D.1 Introduction

The reason for using test profiles is to ensure that PEFM can record PEF accurately for a defined group of people who are likely to use these instruments (the client population). The 26 ATS profiles were chosen to be 'representative' profiles that should be used to test PEFM. However, there is no evidence supplied with these profiles that they truly reflect the range of PEFM characteristics found in the client population. The RT and DT characteristics for PEF in a large population of normal subjects and patients with airflow limitation have now been published [3]. For the whole population of 912 subjects (normal and those with airflow limitation) the centiles for RT and DT are as in Table D.1.

Table D.1 — Centiles for RT and DT

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

From these data it was evident that the 26 ATS profiles do not cover the full range of PEF characteristics in the client population and there may be some redundancy when testing with all 26. This standard proposes to test meters 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 cover 90% of the population characteristics.

Wherever possible the proposed standard has taken steps to reduce the number of individual tests required to ensure that the PEFM has been adequately tested. This may be revised in the light of future knowledge and experience.

The profiles have been derived from a single subject's recorded flow 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 flow is linearly reduced to zero flow at 1.0 s. Since the shape of the profile at this point is not material for 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 is to allow for possible error in producing output profiles with these shapes.

D.2 General

The performance of PEFM involves three aspects:

— error, linearity, and repeatability;

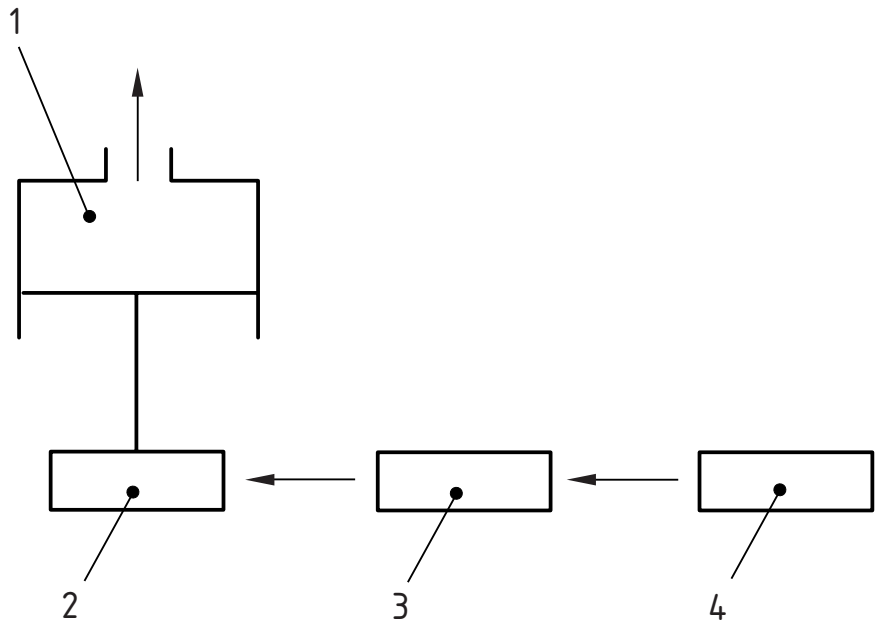
— frequency response;

— resistance.

D.2.1 Error, linearity, and repeatability

These aspects can be tested with a simple and undemanding profile that has a RT and DT at the upper 95th centile. Pump systems can produce such a profile very accurately. Profile A is such a profile that is smooth and without artefact.

A device suitable for this purpose (see Figure D.1) could be a mechanical syringe or piston pump device. This type of device 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 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 device. 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 short RT or short DT since complex interactions within the chamber affect the true output flow.



Key

1 Syringe or piston pump
2 Motor
3 Profile
4 Computer

Figure D.1 — Schematic diagram of test apparatus

D.2.2 Frequency response

The frequency response is more difficult to test since many PEFM do not have an analogue output to record. For a PEFM to have adequate frequency response it should be able to record a given PEF the same whether it is from a profile with slow RT and long DT (Profile A) or from a profile with a short RT and short DT (Profile B). It is thus proposed that this aspect of PEFM performance is tested using profiles A and B at the same delivered flow and compare the readings from the PEFM. They should agree within the accuracy limits set in this European Standard.

D.2.3 Resistance

The PEFM resistance should be tested dynamically and not under steady flow conditions. It is proposed that this is tested at the same time as linearity, accuracy and repeatability using profile A and the test method described in annex A. It is known that under these conditions all aspects of the profile's delivery can be assured and so the resistance can be accurately determined across the measurement range of the PEFM.

D.3 Apparatus

Pump systems of differing design [6] and an explosive decompression device [7] have all been proposed for the purpose of testing PEFM. Pump systems have the advantage of being constructed such that their output can be traced back as 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 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 PEFM with a wide range of profiles but their output does not accurately follow the input when profiles with short DT, and to a lesser extent short RT, are delivered [4]. One suggested way to overcome these limitations is to use a flow meter to verify the output and iteratively adjust the input until the output matches that desired [6]. This process has to be undertaken for each PEFM independently since their complex impedance is the major factor that alters the pump's output. Furthermore, this process introduces a flow meter into the standard that may have its own inaccuracies and problems. This European Standard suggests that pumps should be restricted to deliver profiles with long RT and DT so the achieved flow can be a traceable standard. This type of system can test for linearity, accuracy, and repeatability and as part of testing resistance.

For testing frequency response 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 device to be accurately calibrated, the only requirement is that the output is exactly the same for two types of profile. An explosive decompression device fitted with a fast response solenoid whose position can be varied in real time can deliver the same output to a given device if the discharge pressure and solenoid opening aperture are kept the same. An independent analogue flow meter with adequate frequency response is needed only to verify that the shape of the profiles delivered by the device matches that required. The frequency response of such flow meters, which have a continuous analogue output, can be checked independently using a step test [8].

An explosive decompression device can be one of fixed volume primed to a certain pressure and then this is dissipated during discharge so the chamber of the device reverts back to ambient pressure [9]. Under these circumstances the driving pressure declines throughout and so the DT of the delivered profile will differ from the input signal to the solenoid due to the decay in driving pressure. The relationship between decay in pressure and its effect on DT can be determined. The input signal to the solenoid is then adjusted so 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 profile A and B are discharged from an explosive decompression device with identical driving pressure at peak flow then the recordings from the PEFM for these two profiles can be compared. If the difference is greater than that allowed in this European Standard then the frequency response characteristics of the PEFM are inadequate.

Whilst the exact device used to test PEFM is not defined by this European Standard it is proposed that one way to test for this European Standard is to use a pump system to undertake testing in annex A and an adapted explosive decompression device for the tests in annex B.

Annex ZA
(informative)

Clauses of this European Standard addressing Essential Requirements or other provisions of EU Directives

This European standard 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 93/42/EEC.

WARNING —Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of the EU Directive.

Compliance with the clauses of this European Standard provides one means of conforming with the specific Essential Requirements of the Directive concerned and associated EFTA regulations.

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

Clause/sub-clause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
4.1	12.6	
5	5,13	
5.1a	10.3,	
5.1b	10.2, 12.9	
5.1c	12.9	
5.1d	12.9	
5.1e	12.9	
5.2.1a	2, 12.9	
5.2.1b	13.3	
5.2.1c	13.2, 13.3d	
5.2.2a	13.3b	
5.2.2b	13.2, 13.3c	
5.2.2c	13.3e	
5.2.2d	13.2, 13.3f	
5.2.2e	13.3i	
5.2.2f	13.3j	
5.2.2g	13.3k	
5.2.2h	, 13.3m, 13.6h	
5.2.2i	13.4	
5.3	13.6a	
5.3b	13.1, 13.3l), 13.3j), 13.3k)	
5.3d	13.6b, 13.6k	
5.3f	7.6, 8.1, 13.6h	
5.4a	9.1	
5.4b	10.1, 13.6p	
6	10.2	
7	10.1	
8	10.1	
9	10.1, 9.2	
10	9.2	

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