SLOVENSKI STANDARD
SIST EN 1060-2:2000+A1:2010

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Neinvazivni sfigmomanometri - 2. del: Dodatne zahteve za neavtomatizirane sfigmomanometre

Non-invasive sphygmomanometers - Part 2: Supplementary requirements for mechanical sphygmomanometers

Nichtinvasive Blutdruckmessgeräte - Teil 2: Ergänzende Anforderungen für mechanische Blutdruckmessgeräte

Tensiomètres non invasifs - Partie 2: Exigences complémentaires concernant les tensiomètres mécaniques

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 1060-2:1995+A1:2009) has been prepared by Technical Committee TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by May 2010, and conflicting national standards shall be withdrawn at the latest by May 2010.

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

This European Standard was approved by CEN on 30 July 1995 and includes Corrigendum 1 issued by CEN on 24 July 2002 and Amendment 1 approved by CEN on 17 October 2009.

This document supersedes EN 1060-2:1995.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩.

The modifications of the related CEN Corrigendum have been implemented at the appropriate places in the text and are indicated by the tags ⟨AC⟩ ⟨AC⟩.

⟨A1⟩ 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. ⟨A1⟩

Annexes A, B and C are given for information and do not form normative parts of this European Standard.

Attention is drawn to annex A, concerning A-deviations.

This European Standard "Non-invasive sphygmomanometers" consists of the following parts:

Part 1: General requirements

Part 2: Supplementary requirements for mechanical sphygmomanometers

Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems (in course of preparation)

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

1 Scope

This part of EN 1060, in conjunction with EN 1060-1:1995, specifies performance, efficiency and mechanical and electrical safety requirements, including test methods, for non-invasive mechanical sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

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.

〚A1〛 EN 980:2008, *Symbols for use in the labelling of medical devices* 〚A1〛

EN 1060-1:1995, *Non-invasive sphygmomanometers – Part 1: General requirements*

3 Definitions

For the purposes of this Part of EN 1060, the definitions in EN 1060-1:1995 together with the following apply,

3.1
mechanical sphygmomanometer
sphygmomanometer which uses either a mercury or an aneroid manometer or other mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff

NOTE Components of these devices are manometer, cuff, valve for deflation (often in combination with rapid exhaust valve), hand pump or electro-mechanical pump and connection hoses. These devices may also contain electro-mechanical components for pressure control.

3.2
self-linearizing deflation valve
valve for controlled linearizing exhaust of the pneumatic system during measurement

3.3
rapid exhaust valve
valve for rapidly exhausting the pneumatic system

3.4
tamper proofing
means of preventing the user gaining easy access to the measuring mechanism of the device

4 Cuff

Clause 4 of EN 1060-1:1995 shall apply.

5 Display

Clause 5 of EN 1060-1:1995 shall apply.

6 Units

Clause 6 of EN 1060-1:1995 shall apply.

7 Requirements

7.1 Performance

7.1.1 Limits of the error of the cuff pressure indication

Subclause 7.1.1 of EN 1060-1:1995 shall apply.

7.1.2 Environmental performance

7.1.2.1 Effect of storage

Subclause 7.1.2.1 of EN 1060-1:1995 shall apply.

7.1.2.2 Effect of temperature

Subclause 7.1.2.2 of EN 1060-1:1995 shall apply.

7.1.3 Pneumatic system

7.1.3.1 Air leakage

Air leakage shall not exceed a pressure drop of 4 mmHg/min (0,5 kPa/min).

Testing shall be carried out in accordance with 8.1.

7.1.3.2 Pressure reduction rate

Manually operated and self-linearizing deflation valves shall be capable of adjustment to a deflation rate of (2 to 3) mmHg/s ((0,3 to 0,4) kPa/s).

Manually operated deflation valves shall be easily adjusted to these values.

Self-linearizing valves shall be tested in accordance with 8.2.

7.1.3.3 Rapid exhaust

During the rapid exhaust of the pneumatic system, with fully opened valve the time for the pressure reduction from 260 mmHg to 15 mmHg (35 kPa to 2 kPa) shall not exceed 10 s.

Testing shall be carried out in accordance with 8.3.

7.1.4 Pressure indicating devices

7.1.4.1 Nominal range and measuring range

The nominal range shall be equal to the measuring range.

The nominal range for the cuff gauge pressure shall extend from 0 mmHg to at least 260 mmHg (0 kPa to at least 35 kPa).

7.1.4.2 Analogue indication

7.1.4.2.1 Scale

The scale shall be designed and arranged so that the measuring values can be read clearly and are easily recognised.

Testing shall be carried out by visual inspection.

7.1.4.2.2 First scale mark

The graduation shall begin with the first scale mark at 0 mmHg (0 kPa).

Testing shall be carried out by visual inspection.

7.1.4.2.3 Scale division

Scale divisions shall be either in kilopascals (kPa) or in millimetres of mercury (mmHg) as follows:

a) 0,2 kPa for a scale graduated in kPa;

b) 2 mmHg for a scale graduated in mmHg.

For a scale interval of 2 mmHg (0,2 kPa) each fifth scale mark shall be indicated by greater length and each tenth scale mark shall be numbered. An example of scale division is given in figure 1.

Testing shall be carried out by visual inspection.

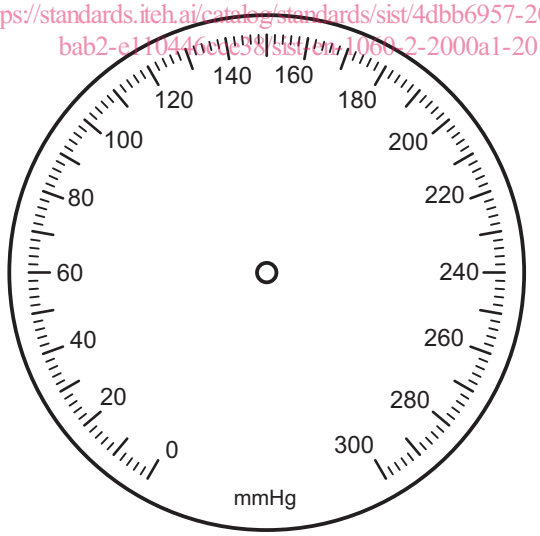

Figure 1 — Example of an aneroid manometer scale (division in mmHg without a tolerance zone at zero)

7.1.4.2.4 Scale spacing and thickness of the scale marks

The distance between adjacent scale marks shall be not less than 0,7 mm. The thickness of the scale marks shall not exceed 20 % of the smallest scale spacing.

All scale marks shall be of equal thickness.

Testing shall be carried out in accordance with **8.4**.

7.2 Safety

7.2.1 Electrical safety

Subclause 7.2.1 of EN 1060-1:1995 shall apply.

7.2.2 Resistance to vibration and shock

Subclause 7.2.2 of EN 1060-1:1995 shall apply.

7.2.3 Mechanical safety

It shall be possible to abort the blood pressure measurement at any time by activating the manual rapid exhaust valve, which shall be easily accessible.

7.2.4 Tamper proofing

Tamper proofing of the manometer shall be achieved by requiring the use of a tool or the breaking of a seal.

Testing shall be carried out by inspection.

7.3 Additional requirements for mercury manometer

7.3.1 Internal diameter of the tube containing mercury

The nominal internal diameter of the tube containing mercury shall be at least 3,5 mm. The tolerance on diameter shall not exceed ± 0,2 mm. (See also 9.3 b)).

Testing shall be carried out in accordance with 8.5.

7.3.2 Portable devices

A portable device shall be provided with an adjusting or locking mechanism to secure it in the specified position for use.

Testing shall be carried out by visual inspection.

7.3.3 Tube containing mercury and reservoir

A locking device shall be placed between the reservoir and the tube to prevent the spillage of mercury during transport.

Testing shall be carried out by visual inspection.

7.3.4 Stopping device in the tube containing mercury and reservoir

A stopping device shall be incorporated in the reservoir and the tube, which shall prevent the mercury from being spilled during transport and use. The delay in the setting of the mercury column due to the stopping device shall not exceed 1,5 s for the flow of mercury from 200 mmHg to 50 mmHg (from 25 kPa to 5 kPa) when the pressure in the system drops rapidly from 200 mmHg to 0 mmHg (from 25 kPa to 0 kPa).

Testing shall be carried out in accordance with 8.6 and 8.7.

7.3.5 Quality of the mercury

The mercury shall have a purity of not less than 99,99 % according to the declaration of the supplier of the mercury.

7.3.6 Gauge

The scale marks shall be inscribed on the tube containing mercury.

If numbered at each fifth scale mark, the numbering shall be alternately on the right and left-hand side of, and adjacent to, the tube.

Testing shall be carried out by visual inspection.

7.4 Additional requirements for aneroid manometer

7.4.1 Scale mark at zero

If a tolerance zone is shown at zero it shall not exceed ± 3 mmHg (± 0,4 kPa) and shall be clearly marked.

A scale mark at zero shall be indicated.

NOTE Graduations within the tolerance zone are optional.

Testing shall be carried out by visual inspection.

7.4.2 Zero

The movement of the elastic sensing element including the pointer shall not be obstructed within 6 mmHg (0,8 kPa) below zero.

Neither the dial nor the pointer shall be adjustable by the user.

Testing shall be carried out by visual inspection.

7.4.3 Pointer

The pointer shall cover between 1/3 and 2/3 of the length of the shortest scale mark of the scale. At the place of indication it shall be not thicker than the scale mark. The distance between pointer and dial shall not exceed 2 mm.

Testing shall be carried out by visual inspection.

7.4.4 Hysteresis error

The hysteresis error throughout the pressure range shall be within the range 0 mmHg to 4 mmHg (0 kPa to 0,5 kPa).

Testing shall be carried out in accordance with **8.8**.

7.4.5 Construction and materials

The construction of the aneroid manometer and the material for the elastic sensing elements shall ensure an adequate stability of the measurement. The elastic sensing elements shall be aged with respect to pressure and temperature.

The difference in the pressure indication of the aneroid manometer before and after 10 000 alternating pressure cycles shall be not more than 3 mmHg (0,4 kPa) throughout the pressure range.

Testing shall be carried out in accordance with **8.9**.

8 Test methods

8.1 Method of test for air leakage of the pneumatic system

8.1.1 Apparatus

8.1.1.1 Rigid metal cylinder

8.1.1.2 Pressure generator, e.g. ball pump (hand pump) with a deflation valve.

8.1.1.3 Time measuring device, e.g. stopwatch

8.1.2 Procedure

Wrap the cuff around the cylinder (8.1.1.1) of an appropriate size (see clause 4).

NOTE Electro-mechanical pumps which are part of the device may be used for the test.

Carry out the test over the whole measuring range at at least five equally spaced pressure steps (e.g. 50 mmHg, 100 mmHg, 150 mmHg, 200 mmHg and 250 mmHg). Test the air leakage over a period of 5 min (8.1.1.3), and determine the measured value from this. Wait at least 60 s before reading each value.

8.1.3 Expression of results

Express the air leakages as the rate of the pressure reduction per minute.

8.2 Method of test for pressure reduction rate for self-linearizing valves

8.2.1 Apparatus

8.2.1.1 T-piece connector

8.2.1.2 Calibrated reference manometer, with signal output and an error less than 0.8 mmHg (0,1 kPa).

8.2.1.3 Artificial limbs

NOTE The intention is to use artificial limbs, but as these are still under consideration, measurements performed with human volunteers are acceptable.

8.2.1.4 Recording unit

8.2.2 Procedure

Measure the pressure reduction rate either on human limbs or artificial limbs (8.2.1.3).

NOTE It is intended that the properties of the artificial limbs reflect some elastic properties of human limbs.