SLOVENSKI STANDARD
SIST EN 1060-2:2000

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

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

Nichtinvasive Blutdruckmeßgeräte - Teil 2: Ergänzende Anforderungen für mechanische Blutdruckmeßgeräte

Tensiometres non invasifs - Partie 2: Exigences complémentaires concernant les tensiometres mécaniques

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English version

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

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

Nichtinvasive Blutdruckmeßgeräte - Teil 2: Ergänzende Anforderungen für mechanische Blutdruckmeßgeräte

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Standard has been prepared by Technical Committee TC 205 "Non-active medical devices" of which the Secretariat 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of an identical text or by endorsement, at the latest by June 1996, and conflicting national standards shall be withdrawn at the latest by June 1996.

This European Standard has been prepared under a mandate given to CEN by the Commission of the European Communities and the European Free Trade Association, and supports essential requirements of EC Directive(s). For relationship with EU Directives, see informative annex C, which is an integral part of this standard.

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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the 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.

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

EN 980[1)] Terminology, symbols and information provided with medical devices; Graphical symbols for use in the labelling of medical devices

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.

[1)] In preparation

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 recognized.

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.

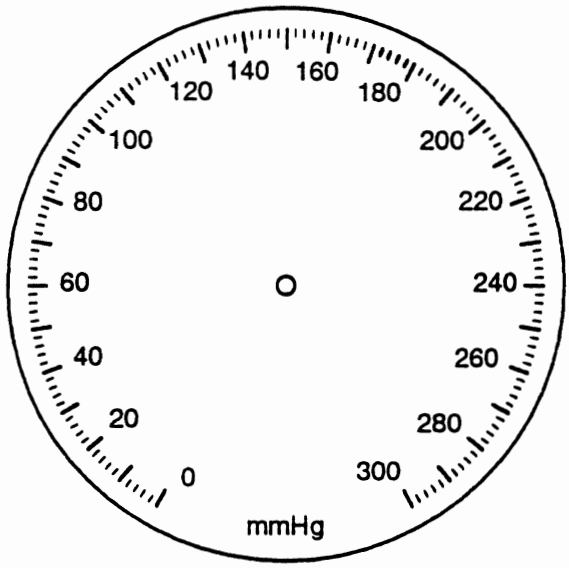

Figure 1: Example of an aneroid manometer scale (division in mmHg without a tolerance zone at zero)

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 9.3b)).

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 the 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*