SLOVENSKI STANDARD
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Neinvazivni sfigmomanometri - 1. del: Splošne zahteve

Non-invasive sphygmomanometers - Part 1: General requirements

Nichtinvasive Blutdruckmeßgeräte - Teil 1: Allgemeine Anforderungen

Tensiometres non invasifs - Partie 1: Exigences générales

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English version

Non-invasive sphygmomanometers - Part 1: General requirements

Tensiomètres non invasifs - Partie 1: Exigences générales

Nichtinvasive Blutdruckmeßgeräte - Teil 1: Allgemeine Anforderungen

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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 the Technical Committee TC 205 "Non-active medical devices" of which the Secretariat is held by BSI.

The European Standard "non-invasive sphygmomanometers" consist 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)

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of an identical text or by endorsement, at the latest by May 1996, and conflicting national standards shall be withdrawn at the latest by May 1996.

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 EC Directive(s).

For relationship with EU Directives, see informative annex A, which is an integral part of this standard.

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 this European Standard specifies general requirements for non-invasive sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

It specifies performance, efficiency, mechanical and electrical safety requirements for these devices and gives test methods.

> NOTE: This standard recommends that Luer lock connectors should not be used with these devices.

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 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 60601-1: 1988	Medical electrical equipment - Part 1: General requirements for safety
EN 980[1)]	Terminology, symbols and information provided with medical devices; Graphical symbols for use in the labelling of medical devices
EN 1041[1)]	Terminology, symbols and information provided with medical devices; Information supplied by the manufacturer with medical devices

3 Definitions

For the purposes of this Part of EN 1060, the following definitions apply.

3.1 bladder: Inflatable component of the cuff.

3.2 blood pressure: Pressure in the arterial system of the body.

[1)] In preparation.

3.3 cuff: Component of the sphygmomanometer, usually comprising a bladder and a sleeve, that is wrapped around the limb of the patient.

3.4 diastolic blood pressure (value): Minimum value of the arterial blood pressure as a result of relaxation of the left ventricle.

NOTE: Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

3.5 mean arterial blood pressure (value): Value of the integral of one cycle of the blood pressure curve divided by the time of one heart beat period.

NOTE: Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

3.6 non-invasive blood pressure measurement: Indirect measurement of the arterial blood pressure without arterial puncture.

3.7 pneumatic system: System that includes all pressurized and pressure-controlling parts such as cuff, tubing, connectors, valves, transducer and pump.

3.8 sleeve: Essentially inelastic part of the cuff that encloses the bladder.

3.9 sphygmomanometer: Instrument used for the non-invasive measurement of the arterial blood pressure.

3.10 systolic blood pressure (value): Maximum value of the arterial blood pressure as a result of the contraction of the left ventricle.

NOTE: Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

4 Cuff

The cuff shall contain a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents (see 9.2).

NOTE: The optimum bladder size is one with dimensions such that its width is 40 % of the limb circumference at the centre of the range for each cuff size and that its length is 80 % to 100 % of the limb circumference at the centre of the range for each cuff size. Use of the wrong size can affect the accuracy of the measurement. These recommended dimensions are subject to ongoing consideration.

5 Display

The display shall be designed and arranged so that the information including measuring values can be read and easily recognized.

Testing shall be carried out by visual inspection.

If abbreviations are used on the display they shall be as follows:

"S" or "SYS": systolic blood pressure (value);

"D" or "DIA": diastolic blood pressure (value);

"M" or "MAP": mean arterial blood pressure (value).

Single letter abbreviations shall be positioned in such a way to avoid confusion with SI units.

6 Units

The blood pressure shall be indicated in either millimetres of mercury (mmHg) or kilopascals (kPa).

7 Requirements

7.1 Performance

7.1.1 *Limits of the error of the cuff pressure indication*

At any single condition within the ambient temperature range of 15 °C to 25 °C and the relative humidity range of 20 % to 85 %, both for increasing and for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the scale range shall be ± 3 mmHg (± 0,4 kPa).

Testing shall be carried out in accordance with 8.1.

7.1.2 *Environmental performance*

7.1.2.1 *Effect of storage*

The sphygmomanometer shall maintain the requirements specified in this standard after storage for 24 h at a temperature of -20 °C and for 24 h at a temperature of 70 °C and a relative humidity of 85 % (non-condensing).

Testing shall be carried out in accordance with 8.1 at environmental conditions described in 7.1.1 after the test sample has been placed for 24 h at a temperature of -20 °C and immediately afterwards for 24 h at a temperature of 70 °C in a climatic chamber.

7.1.2.2 *Effect of temperature*

For the ambient temperature range of 10 °C to 40 °C and the relative humidity of 85 % (non-condensing), the difference of the cuff pressure indication of the sphygmomanometer shall not exceed 3 mmHg (0,4 kPa).

Testing shall be carried out in accordance with 8.2.

7.2 Safety

7.2.1 *Electrical safety*

Electro-mechanical sphygmomanometers shall comply with EN 60601-1: 1988.

7.2.2 *Resistance to vibration and shock*

The sphygmomanometer shall comply with subclause 21.6 of EN 60601-1: 1988.

After testing, the device shall comply with 7.1.1.

8 Test methods

8.1 Method of test for the limits of error of the cuff pressure indication

8.1.1 *Apparatus*

a) rigid metal vessel with a capacity of 500 ml ± 5 %;

b) calibrated reference manometer with an error less than 0,8 mmHg (0,1 kPa);