SLOVENSKI STANDARD
SIST EN 1060-1:2000+A2:2010

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Neinvazivni sfigmomanometri - 1. del: Splošne zahteve

Non-invasive sphygmomanometers - Part 1: General requirements

Nichtinvasive Blutdruckmeßgeräte - Teil 1: Allgemeine Anforderungen

Tensiomètres non invasifs - Partie 1: Exigences générales

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Non-invasive sphygmomanometers - Part 1: General requirements

Tensiomètres non invasifs - Partie 1: Exigences générales

Nichtinvasive Blutdruckmessgeräte - Teil 1: Allgemeine Anforderungen

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

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Foreword

This document has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

The 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 [A2] *deleted text* [A2]
[A2] Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers [A2]

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of an identical text or by endorsement, at the latest by June 2010, and conflicting national standards shall be withdrawn at the latest by June 2010.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 document includes Amendment 1, approved by CEN on 2002-04-06 and Amendment 2, approved by CEN on 2009-11-15.

This document supersedes EN 1060-1:1995.

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1] [A1] and [A2] [A2].

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(s).

For relationship with EU Directives, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of 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 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

[A2] The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. [A2]

EN 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

[A2] EN 980, *Symbols for use in the labelling of medical devices* [A2]

[A2] EN 1041, *Information supplied by the manufacturer of medical devices* [A2]

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

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 pressurised 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 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 recognised.

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);

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

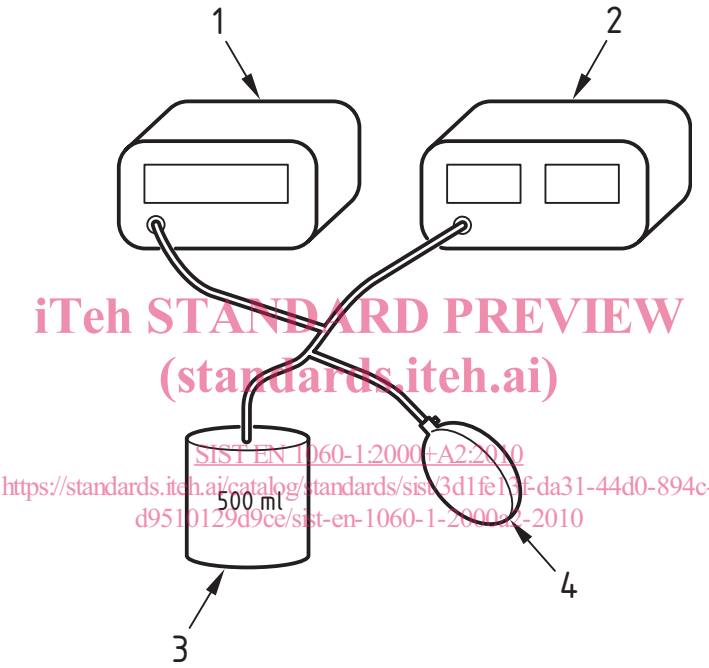
d) T-piece connectors and hoses.

8.1.2 Procedure

a) Replace the cuff of the device with the vessel (8.1.1 a)).

Connect the calibrated reference manometer (8.1.1 b)) by means of a T-piece connector and hoses (8.1.1 d)) to the pneumatic system (see figure 1). After disabling the electromechanical pump (if fitted), connect the additional pressure generator (8.1.1 c)) into the pressure system by means of another T-piece connector.

b) Carry out the test in pressure steps of not more than 50 mmHg between 0 mmHg and the maximum pressure of the scale range.



Key

1 Reference manometer (8.1.1 b))

2 Manometer of the device to be tested

3 Metal vessel (8.1.1 a))

4 Pressure generator (8.1.1 c))

Figure 1 — Test rig for determining the limits of error of the cuff pressure indication

8.1.3 Expression of results

Express the results as the difference between the indicated pressure of the manometer of the device to be tested and the corresponding reading of the reference manometer.