SLOVENSKI STANDARD
SIST EN 1060-3:2000

01-januar-2000

Neinvazivni sfigmomanometri - 3. del: Dodatne zahteve za elektromehanske sisteme za merjenje krvnega tlaka

Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

Nichtinvasive Blutdruckmeßgeräte - Teil 3: Ergänzende Anforderungen für elektromechanische Blutdruckmeßsysteme

Tensiometres non invasifs - Partie 3: Exigences complémentaires concernant les systemes électromécaniques de mesure de la pression sanguine

Ta slovenski standard je istoveten z: **EN 1060-3:1997**

ICS:

11.040.55	Diagnostiļ na oprema	Diagnostic equipment

SIST EN 1060-3:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1060-3

February 1997

ICS 11.040.50

Descriptors: medical equipment, electromedical apparatus, measuring instruments, pressure, blood, definitions, specifications, performance evaluation, safety, tests, routine verification, technical notices, marking

English version

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CEN

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

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Ref. No. EN 1060-3:1997 E

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which 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of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

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 Directive(s), see informative Annex ZA, which is an integral part of this standard.

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

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

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.

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

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

1 Scope

This Part of EN 1060 specifies performance, efficiency and safety requirements for electro-mechanical blood pressure measuring systems that, by means of an inflatable cuff are used for non-invasive measurements of arterial blood pressure at the upper arm, the wrist and the thigh. It also specifies requirements for their accessories and gives test methods.

This Part of EN 1060 applies to electro-mechanical blood pressure measuring systems in which the cuff pressure is measured electronically, but in which the blood pressure can be determined either manually with the aid of a stethoscope or automatically.

Additional safety requirements for automatic cycling indirect blood pressure monitoring equipment are specified in EN 60601-2-30: 1995.

This Part of EN 1060 is to be used in conjunction with EN 1060-1.

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 475	Medical devices - Electrically generated alarm signals
EN 1060-1: 1995	Non-invasive sphygmomanometers - Part 1: General requirements
EN 1060-2: 1995	Non-invasive sphygmomanometers - Part 2: Supplementary requirements for mechanical sphygmomanometers
EN 60601-1: 1990	Medical electrical equipment - Part 1: General requirements for safety
EN 60601-1-2: 1993	Medical electrical equipment - Part 1: General requirements for safety; Collateral Standard - Electromagnetic compatibility - Requirements and tests

EN 60601-2-30: 1995 Medical electrical equipment -
Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment.

3 Definitions

For the purposes of this European Standard, the definitions in EN 1060-1: 1995, EN 1060-2: 1995, EN 60601-1: 1990 and EN 60601-2-30: 1995 apply, together with the following:

3.1 auscultatory method: Technique whereby sounds (known as Korotkov sounds) are heard over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with systolic and the disappearance of sounds with diastolic blood pressure.

3.2 electro-mechanical blood pressure measuring system: System that consists of:

a) at least one cuff, which is connected to the pneumatic system;

b) at least one electro-mechanical transducer to measure cuff pressure;

c) at least one measured value display;

d) if needed, signal inputs and outputs.

3.3 electro-mechanical pressure transducer: Component that transforms pressure signals into electrical signals.

3.4 oscillometric method: Method wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced.

NOTE: During the inflation and deflation of the cuff small pressure changes (oscillations) occur in the cuff as a result of the arterial blood pressure pulses.

These oscillations, which first increase and then decrease, are detected and stored together with the corresponding cuff pressure values in the measurement system. With these stored values the systolic, diastolic and mean arterial blood pressure values can be mathematically derived using an appropriate algorithm. It is possible to carry out the measurement during the inflation phase.

3.5 zero setting: Procedure that corrects a deviation of the pressure reading to 0 mmHg at atmospheric pressure (gauge pressure: 0 mmHg).

3.6 patient simulator: Device for simulating the oscillometric cuff pulses and/or auscultatory sounds during inflation and deflation.

NOTE: This device is not used for testing accuracy but is required in assessing stability of performance.

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 General

Equipment or parts thereof, using materials or having forms of construction different from those detailed in this Part of EN 1060, shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained.

7.2 Limits of the error of the cuff pressure indication

7.1.1 of EN 1060-1: 1995 shall apply.

7.3 Effect of voltage variations of the power source variations

7.3.1 *Internal electrical power source*

a) Blood pressure measuring systems in which the cuff pressure is generated by an electrical pump shall comply with 56.7 of EN 60601-2-30: 1995;

b) Changes of the voltage within the working range determined in **8.2.1** shall not influence the cuff pressure reading and the result of the blood pressure measurement;

c) Outside of the working range, no cuff pressure reading and no result of the blood pressure measurement shall be displayed.

Testing shall be carried out in accordance with **8.2.1** and **8.3.1**.

7.3.2 *External electrical power source*

a) Blood pressure measuring systems in which the cuff pressure is generated by an electrical pump shall comply with 49.3 and 49.101 of EN 60601-2-30: 1995;

b) Changes of the voltage within the working range specified by the manufacturer (see 9.2) shall not influence the cuff pressure reading and the result of the blood pressure measurement.

Testing shall be carried out in accordance with **8.2.2** and **8.3.2** (alternating current) or **8.2.3** and **8.3.3** (direct current).

c) Incorrect values resulting from voltage variations outside the limits given in **7.3.2** b) shall not be displayed.

Testing shall be carried out in accordance with **8.2.4** (alternating current) or **8.2.5** (direct current).

7.4 Pneumatic system

7.4.1 *Air leakage*

Air leakage shall not exceed a pressure drop of 6 mmHg/min (0,8 kPa/min).

For those devices in which the blood pressure is determined manually with the aid of a stethoscope the air leakage shall not exceed a pressure drop of 4 mmHg/min (0,5 kPa/min). Testing shall be carried out in accordance with **8.4**.

7.4.2 *Pressure reducing system for devices using the auscultatory method*

The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 2 mmHg/s to 3 mmHg/s (0,3 kPa/s to 0,4 kPa/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of between 2 mmHg/pulse and 3 mmHg/pulse (0,3 kPa/pulse and 0,4 kPa/pulse) shall be maintained.

NOTE: Manually operated deflation valves should be easily adjustable to these values.

Testing shall be carried out in accordance with **8.5**.

7.4.3 *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 (34,7 kPa to 2,0 kPa) shall not exceed 10 s.

For blood pressure measuring systems having the capability to measure in a neonatal/infant mode, the time for the pressure reduction from 150 mmHg to 5 mmHg (20,0 kPa to 0,7 kPa) during the rapid exhaust of the pneumatic system with fully opened valve shall not exceed 5 s.

Testing shall be carried out in accordance with **8.6**.

7.4.4 *Zero setting*

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0 mmHg (0 kPa) shall exist and be displayed thereafter.

Devices performing zero setting only immediately after switching on, shall switch off automatically before the drift of the pressure transducer and the analog signal processing exceeds 1 mmHg (0,1 kPa).

Testing shall be carried out in accordance with **8.7** and **8.8**.

7.5 Environmental performance

7.5.1 *Storage*

Blood pressure measuring systems shall maintain the requirements specified in this Part of EN 1060 after storage for 24 h at a temperature of - 5 °C and for 24 h at a temperature of + 50 °C and a Relative Humidity of 85 % (non-condensing).

Testing shall be carried out at environmental conditions (see subclause 7.1.1 of EN 1060-1: 1995) in accordance with 8.1 of EN 1060-1: 1995 after the test sample has been placed for 24 h at a temperature of - 5 °C and immediately afterwards for 24 h at a temperature of + 50 °C in a climatic chamber.

NOTE: Integrated multiparameter monitors may contain components which can be damaged during storage. The general temperature range in EN 1060-1: 1995 has therefore been reduced.

7.5.2 ***Temperature, relative humidity***

7.1.2.2 of EN 1060-1: 1995 shall apply.

The signal processing for the determination of the blood pressure values shall not be influenced within the range of temperature and Relative Humidity specified in 7.1.2.2 of EN 1060-1: 1995.

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

7.5.3 ***Electromagnetic compatibility***

Either:

a) Electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement, or;

b) if electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance.

Testing shall be carried out in accordance with EN 60601-1-2: 1993.

7.6 Stability of the cuff pressure indication

The change of the cuff pressure indication shall not be more than 3 mmHg (0,4 kPa) throughout the pressure range after 10 000 simulated measurement cycles.

Testing shall be carried out in accordance with **8.10**.

7.7 Pressure indicating device

7.7.1 *Nominal range and measuring range*

The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of blood pressure measurement results outside the nominal range of cuff pressure shall be clearly indicated as out of range.

Testing shall be carried out by visual inspection.

7.7.2 *Digital indication*

The numerical step shall be 1 mmHg (0,1 kPa).

Numbers shall be clearly legible in accordance with clause 6 of EN 60601-1: 1990.

If the measured value of a parameter is to be indicated on more than one display, all the displays shall indicate the same numerical value.

Measured, numerical values on the display(s), and the symbols defining the units of measurement shall be arranged in such a way so as to avoid misinterpretation.

Testing shall be carried out by visual inspection.

7.8 Signal input and output parts

The construction of the signal input and output parts (excluding internal interfaces, e.g. microphone signal input) relevant to the non-invasive blood pressure measurement shall ensure that incorrectly fitted or defective accessories shall not result in erroneous indication of cuff pressure or erroneous indication of blood pressure.

Testing shall be carried out in accordance with **8.11**.

7.9 Overall system accuracy

Except for short term automatic mode (see 2.102 of EN 60601-2-30: 1995) and devices in which blood pressure is determined manually with the aid of a stethoscope, the following overall system accuracy values shall apply:

a) maximum mean error of measurement: ± 5 mmHg (± 0,7 kPa);

b) maximum experimental standard deviation: 8 mmHg (1,1 kPa).