SLOVENSKI STANDARD
SIST EN 1060-4:2005

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Neinvazivni sfigmomanometri - 4. del: Preskusni postopki za ugotavljanje splošne točnosti sistema za avtomatizirane neinvazivne sfigmomanometre

Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

Nichtinvasive Blutdruckmessgeräte - Teil 4: Prüfverfahren zur Bestimmung der Messgenauigkeit von automatischen nichtinvasiven Blutdruckmessgeräten

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Tensiometres non invasifs - Partie 4 : Procédures pour déterminer la précision de l'ensemble du systeme des tensiometres non invasifs automatiques

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 1060-4

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Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

Tensiomètres non invasifs - Partie 4 : Procédures pour déterminer la précision de l'ensemble du système des tensiomètres non invasifs automatiques

Nichtinvasive Blutdruckmessgeräte - Teil 4: Prüfverfahren zur Bestimmung der Messgenauigkeit von automatischen nichtinvasiven Blutdruckmessgeräten

This European Standard was approved by CEN on 9 July 2004.

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Foreword

This document (EN 1060-4:2004) 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of an identical text or by endorsement, at the latest by March 2005, and conflicting national standards shall be withdrawn at the latest by March 2005.

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, see informative Annex ZA, which is an integral part of this document.

EN 1060 consists of the following Parts under the general title “Non-invasive sphygmomanometers”:

Part 1: General requirements

Part 2: Supplementary requirements for mechanical sphygmomanometers

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

Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

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Annexes A, B, C, D, E and ZA are informative.

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1 Scope

This document describes test procedures for investigations to determine the overall system accuracy of automated non-invasive sphygmomanometers, designed for the indirect measurement of blood pressure.

2 Normative references

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.

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

EN 1060-2, *Non-invasive sphygmomanometers – Part 2: Supplementary requirements for mechanical sphygmomanometers.*

EN 1060-3:1997, *Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems.*

EN ISO 14155-1, *Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003).*

EN ISO 14155-2, *Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans (ISO 14155-2:2003).*

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3 Terms and definitions

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For the purposes of this document, the terms and definitions given in EN 1060–1:1995 and EN 1060–3:1997 and the following apply.

3.1
neonatal mode
mode, specified by the manufacturer of the sphygmomanometer for the measurement of neonates/infants

3.2
paired measurements
parallel blood pressure measurements carried out by the observers and the device under test

— at the same arm at the same time or

— on opposite arms at the same time or

— at the same arm at different times or

— at one arm and another limb, at the same time or at different times.

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4 Requirements

4.1 General information on the non-invasive reference methods

The clinical investigation shall be performed in accordance with EN ISO 14155–1 and EN ISO 14155–2.

The auscultatory blood pressure measurements described shall be carried out by two observers by means of a double stethoscope. The auscultatory reference value will then be the mean value of the two values determined by the observers. The difference between both values shall not exceed 4 mmHg. Any measurements with observer-to-observer differences greater than 4 mmHg shall not be included in the data set. The number of discarded measurements shall not be greater than the number of the required valid measurements.

NOTE 1 Reading of the values on the reference manometer should be as accurate as possible. When reading the value on the reference manometer(s) the observers should avoid parallax errors. Rounding to zero and five has a negative effect on the result of the investigation. More information and recommendations are given in annex D.

The calibrated reference manometers shall comply with the requirements of EN 1060-1 to EN 1060-3 but shall not exceed error limits of 1 mmHg (0,1 kPa) with dropping cuff pressure prior to the start of the clinical investigation.

NOTE 2 The reference manometer should be calibrated before and after the clinical investigation. When the reference manometer is linked to the pneumatic system of the tested device (e.g. test method N2), an aneroid manometer should be used. Mercury manometer may alter pneumatic characteristics (resonant frequency, damping coefficient) and should not be used in this case.

4.2 General information on the invasive reference methods

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The clinical investigation shall be performed in accordance with EN ISO 14155–1 and EN ISO 14155–2.

The invasive blood pressure measuring system consisting of catheter, pressure transducer, monitor and recording device shall be statically calibrated so that the indicated values do not deviate from the values indicated by the reference manometer (see 4.5.1.1 a) by more than ± 2 mmHg. Prior to and after each series of measurements the resonant frequency and damping coefficient of the system shall be determined [1].

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Except for devices measuring in the neonatal mode, the comparison shall be carried out by invasive and non-invasive blood pressure measurement on the same arm. The simultaneous measurement on opposite arms is permissible if no lateral difference has been determined by additional measurements.

NOTE Intra-arterial methods are invasive and should not be used for patients or subjects solely for the purpose of validating instrument performance, but conducted on clinical patients in whom an intra-arterial line has already been placed for reasons other than sphygmomanometer verification.

4.3 Selection of clinical test method

The selection of the clinical test method is dependent on the measurement technique, the application of the sphygmomanometers to be tested and the intended application of the device and shall be in accordance with Table 1.

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Table 1 — Matrix for the selection of the clinical test method

Reference method	Measurement technique of the device to be tested	Clinical test method as a function of application			
		adults	neonatal mode	ergo.[a]	ABPM[b]
Auscultatory measurement at the upper arm	Continuous pressure drop or pressure drop in steps (upper arm measurement)				
	≤ 3 mmHg/s or ≤ 3 mmHg/pulse[c]	N1/N2/N3	-	N4	N5/N6
	> 3 mmHg/s or > 3 mmHg/pulse[c]	N2/N3	-	-	N6
	Measurement on other sites than the upper arm	N2/N3			
	Measurement during inflation phase	N2/N3	-	-	N6
Invasive measurement	Measurement during the pressure drop or the inflation phase	I 1	I 2	-	-

a Ergometry (measurement under physical load)

b Ambulatory blood pressure measurement

c For devices adapting to the pulse rate

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4.4 Application of test method

4.4.1 Non-invasive reference measurement

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4.4.1.1 Simultaneous blood pressure measurement on the same upper arm; also under physical load and ambulatory

The test methods (N1, N4, N5) for the simultaneous blood pressure measurement on the same upper arm are suitable for sphygmomanometers operating

— with continuous pressure drop (rate of pressure drop ≤ 3 mmHg/s) and/or

— with pressure drop in steps (rate of pressure drop per step ≤ 3 mmHg) and/or

— with a pulse-controlled pressure drop (rate of pressure drop ≤ 3 mmHg per pulse)

These values apply for the range of the systolic and diastolic blood pressures.

4.4.1.2 Simultaneous blood pressure measurement on opposite arms

The test methods (N2 and N6) for the simultaneous blood pressure measurement are suitable for sphygmomanometers operating

— with continuous pressure drop and/or

— with pressure drop in steps and/or

— with a pulse-controlled pressure drop.

This test method is also suitable for sphygmomanometers measuring during the inflation phase or measuring on other sites then upper arm.

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4.4.1.3 Sequential blood pressure measurement

The test methods (N3) for sequential blood pressure measurement are suitable for sphygmomanometers operating

— with continuous pressure drop and/or

— with pressure drop in steps and/or

— with a pulse-controlled pressure drop and/or

— measuring on other sites than the upper arm.

This test method is also suitable for sphygmomanometers measuring during the inflation phase.

4.4.2 Invasive reference measurement

The test method (I1) is suitable for sphygmomanometers for measurement on adults.

The test method (I2) is suitable for sphygmomanometers for measurement on neonates and infants.

4.5 Test equipment

4.5.1 Non-invasive reference measurement

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4.5.1.1 Simultaneous blood pressure measurement; also under physical load and ambulatory

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a) calibrated reference manometer(s) with error limit(s) of 1 mmHg (0,1 kPa);

b) T-piece;

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c) hose;

d) double stethoscope.

4.5.1.2 Opposite arm or sequential blood pressure measurement; also ambulatory

a) calibrated reference manometer(s) with error limit(s) of 1 mmHg (0,1 kPa)

b) double stethoscope and for method N2 additionally two stethoscopes;

c) cuff(s).

4.5.2 Invasive blood pressure measurement

a) calibrated reference manometer with error limit of 1 mmHg (0,1 kPa);

b) invasive blood pressure measuring system;

c) device for the recording of the invasive blood pressure.

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4.6 Subjects

4.6.1 General

The selection of the subjects and their number depends on the intended purpose (In accordance with the information given in the instructions for use and/or the instructions on the device) of the device to be tested.

Limits of application stated in the users manual shall be taken into account, e.g. concerning arrhythmia (see also 4.8).

If no special purpose is intended, e.g. measurement during pregnancy, the following applies only for adults and children:

— at least 40 % shall be male and at least 40 % shall be female;

— between 50 % and 75 % shall be older than 50 years;

— between 50 % and 75 % shall have a circumference of the arm, which lies within the upper half of the specified range of use of the cuff (if applicable);

— between 50 % and 75 % shall have a circumference of the wrist, which lies within the upper half of the specified range of use of the cuff (if applicable);

— at least 10 % below 110 mmHg systolic blood pressure;

— at least 10 % above 160 mm Hg systolic blood pressure;

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— at least 10 % below 70 mmHg diastolic blood pressure;

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— at least 10 % above 100 mm Hg diastolic blood pressure.

The different blood pressure groups (see above) shall be classified in accordance with the first valid blood pressure reference measurements.

4.6.2 Non-invasive reference measurement

4.6.2.1 General

A minimum of 3 measurements shall be carried out on each of at least 85 subjects.

4.6.2.2 Additional requirements for sphygmomanometers measuring under physical load

At least 6 paired measurements shall be carried out on each of at least 85 subjects. As much as possible, female and male subjects shall be evenly distributed while at most 25 % shall originate from the field of sports medicine. The different blood pressure groups (see 4.6.1) shall be classified in accordance with the first valid blood pressure reference measurements at rest.

4.6.2.3 Additional requirements for ambulatory sphygmomanometers

At least 6 paired measurements shall be carried out on each of at least 85 subjects. The different blood pressure groups (see 4.6.1) shall be classified in accordance with the first valid blood pressure reference measurements at rest.

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4.6.3 Invasive reference measurement

4.6.3.1 Adults

The measurements shall be carried out on at least 15 subjects, with a minimum of 150 paired observations. A minimum of five and a maximum of ten paired measurements per subject shall be made. The measurements shall be carried out with as even as possible a distribution of male and female normotensive and hypertensive subjects.

4.6.3.2 Neonates and infants

For devices measuring in the neonatal mode, at least 15 neonate/infant subjects are required, with a minimum of 100 paired observations (see Table 2). A minimum of five and a maximum of ten paired measurements per subject shall be made.

Table 2 — Distribution of subjects

Body weight g	Subjects
< 1000	at least 3
≥ 1000 ≤ 2000	at least 3
≥ 2000	at least 3

4.7 Cuff size

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The cuff of the sphygmomanometer to be tested shall be selected and applied in accordance with the recommendations of the manufacturer (see 9.2 of EN 1060-1:1995).

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The measurement shall cover all cuff sizes and applications in accordance with the intended use described in the accompanying document.

4.8 Procedure

The investigation shall be carried out under normal conditions which shall be within the specifications given by the manufacturer in the instructions for use. References in the instructions for use to limitations of the application shall be taken into account.

The blood pressure values shall be measured carefully without interruption of the measuring series for each subject, if possible.

NOTE An initial measurement should be taken. It should not be included in the evaluation (see annex A).

4.9 Evaluation of results

4.9.1 General

The results of the evaluation of all measurements shall be within the limits determined in 7.9 of EN 1060-3:1997.

The first 3 valid paired measurements shall be used for the evaluation.