



First Committee Draft (1CD) – Marked version

Project: Revision of R 16-2:2002 (*see BIML note on p3*)
Title: R yyy *Non-invasive automated sphygmomanometers*
Part 2: Test procedures

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Project Group: OIML TC 18/SC 1/p 2
Convenership: P.R. China
Conveners: Ms. Can Wang

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Explanatory note

According to OIML B6 “Directives for OIML technical work”, each recommendation shall be reviewed every five years after its publication by the responsible TC/SC to decide whether it should be confirmed, revised, or withdrawn. The present (old) R16 which TC18/SC1 is responsible for was published in 2002, and it’s identified that there are a few technical conflicts between new ISO/IEC standard and OIML R16. To avoid different requirements worldwide on blood pressure instruments, the secretariat started the work on drafting R16-2 “*Non-invasive automated sphygmomanometers*” after the project of revision was approved at the 43rd CIML Meeting held in October 2008 in Sydney.

During this work, the secretariat received dozens of comments from member nations and liaisons. Therefore, we wish to express our most sincere thanks for all experts’ kindness. After arrangement, a lot of proposal has been accepted and published in this current version.

The main changes proposed to R16-2 are the following:

- OIML R16-2 should be revised into three parts according to OIML B6 with new number, and now OIML Rxxx-2 is refer to part 2 Test procedures;
- Modification of terminology as to comply with the new (2012) edition of the VIM;
- Removal of terminology not used in the document;
- Requirements for the Maximum permissible errors of the cuff pressure and environmental conditions are stated in Rxxx-1 5.1, and the requirements of storage is also changed;
- Introducing blood pressure indication repeatability requirements;
- Maximum time for which the cuff is inflated is added;
- Test for stability of the cuff pressure indication is replaced by durability;
- Requirements for alarms are removed;
- Better describe of the environmental conditions for verification. No longer distinguish between “initial” verification and “subsequent” verification;
- Updating testing methods for the maximum permissible errors of the cuff pressure indication in Test procedures;
- Testing methods for resistance to vibration and shock is prescribed for sphygmomanometers;
- Technical requirements of patient simulators are modified. Considering that patient simulators have none traceability currently, they are not used for the accuracy test as the reference standard, but only used for test of the repeatability and blood pressure measuring rang;
- Modifying test report format in Annex B.
- Making an agreement on electromagnetic compatibility test with the ISO/IEC standards;

The present document is the first Committee Draft (1CD), which was drawn up on the basis of the conclusions of comments from member nations on the Working Draft circulated since July 2011. It also had been discussed as preliminary 1CD in the TC 18/SC 1 meeting held on 22 to 26 October 2012 in Berlin.

Definitions and references related to the International vocabulary of metrology – Basic and general concepts and associated terms (VIM) have been modified according to the 2012 edition.

BIML note

The existing R 16 is published in two parts:

R 16-1 *Non-invasive mechanical sphygmomanometers*, and

R 16-2 *Non-invasive automated sphygmomanometers*.

These are being revised under two separate projects: TC 18/SC 1/p 1 and TC 18/SC 1/p 2 respectively.

The existing part numbering of R 16 is not consistent with current OIML practice. All Recommendations are now published with separate parts for the metrological and technical requirements (designated R xxx-1), test procedures (designated R xxx-2), and test report format (designated R xxx-3). To avoid confusion with the existing numbering of R 16, on completion of the two projects, the existing R 16-1 and R 16-2 will be replaced by two separate Recommendations with new numbers and each having three parts:

R xxx-1 *Non-invasive non-automated sphygmomanometers – Metrological and technical requirements*

R xxx-2 *Non-invasive non-automated sphygmomanometers – Test procedures*

R xxx-3 *Non-invasive non-automated sphygmomanometers – Test report format*

R yyy-1 *Non-invasive automated sphygmomanometers – Metrological and technical requirements*

R yyy-2 *Non-invasive automated sphygmomanometers – Test procedures*

R yyy-3 *Non-invasive automated sphygmomanometers – Test report format*

This CD has been re-numbered in line with this arrangement.

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Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States. The main categories of OIML publications are:

International Recommendations (OIML R), which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;

International Documents (OIML D), which are informative in nature and intended to improve the work of the metrological services;

International Basic Publications (OIML B), which define the operating rules of the various OIML structures and systems;

International Guides (OIML G), which are informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements are established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

International Recommendations, Documents and Guides are published in French (F) and English (E) and are subject to periodic revision.

Additionally, the OIML participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology Experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice to metrological authorities, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus they do not necessarily represent the views of the OIML.

This publication - reference OIML R~~16-2xxx~~, edition 201X (E) - was developed by the OIML Technical Subcommittee TC 18/SC 1 *Blood pressure instruments*. It was approved for final publication by the International Committee of Legal Metrology in 201X and supersedes OIML R 16-2:2002 (E).

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Bureau International de Métrologie Légale

11, rue Turgot - 75009 Paris - France

Telephone: 33 (0)1 48 78 12 82

Fax: 33 (0)1 42 82 17 27

E-mail: biml@oiml.org

Non-invasive automated sphygmomanometers

Part 2: Test procedures

OIML R 16-2 201X (E)

Revised English Version

1 General Test for the maximum permissible errors of the cuff pressure indication

Requirements in 5.1 shall apply.

1.1 Apparatus

- rigid metal vessel with a capacity of 500 ml $\pm 5\% \pm 25$ ml;
- calibrated reference manometer with ~~an uncertainty less than 0.1 kPa (0.8 mmHg)~~ maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors and hoses;
- climatic chamber, Non-uniformity of temperature within ± 1 °C, Instability of temperature within ± 1 °C, Non-uniformity of relative humidity within $\pm 5\%$, Instability of relative humidity within $\pm 5\%$.

1.2 Procedure

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector and hoses to the pneumatic circuit (see Figure 1). ~~After disabling the electro-mechanical pump (if fitted), connect~~ Set the automated sphygmomanometer to the test mode according to the information provided by the manufacturer. Connect the additional pressure generator into the pressure system by means of another T-piece connector. Carry out the test in pressure steps of not more than 6.7 kPa (50 mmHg) between 0.0 kPa (0 mmHg) and the maximum pressure of the scale range.¹

For each of the following combinations of temperature and humidity, place the automated sphygmomanometer for at least 3 h in the climatic chamber to allow the system to reach steady conditions:

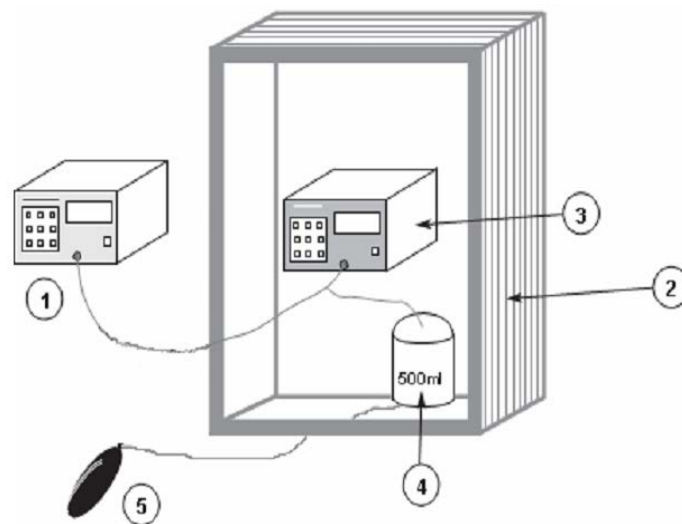
- 10 °C ambient temperature, 85% relative humidity (non-condensing);
- 20 °C ambient temperature, 85% relative humidity (non-condensing);
- 40 °C ambient temperature, 85% relative humidity (non-condensing).

At each combination of temperature and humidity switch on the automated sphygmomanometer before starting the test. Wait until the warm up time (described in the instructions for use) has elapsed, carry out the measurement and switch off the automated sphygmomanometer afterwards.

1.3 Expression of results

Express the results as the differences between the ~~indicated~~ cuff pressure indication of the ~~manometer of the device~~ automated sphygmomanometer to be tested and the corresponding readings of the reference manometer ~~(see B.2).~~

¹ In case of doubt about the linearity, spot checks should be carried out or the width of the pressure steps should be reduced, i.e., from the normally recommended 6.7 kPa (50 mmHg) to 2.7 kPa (20 mmHg). This also applies to Table 1 in Annex B-Rxxx-3.



1 - Reference manometer; 2 - Climatic chamber;

3 - Device to be tested; 4 - Metal vessel; 5 - Pressure generator

Figure 1 Measurement system for determining the error limits of the cuff pressure indication

2 Test for the blood pressure measuring range (A.15 in last version)

2.1 Apparatus

- Patient simulator for the auscultatory and/or oscillometric method, having an experimental standard deviation for the simulator of not more than 0.13 kPa (1 mmHg). The generated signal values shall be approximately: systolic: 16.0 kPa (120 mmHg); diastolic: 10.6 kPa (80 mmHg); pulse rate: 70 min⁻¹-80 min⁻¹.

2.2 Procedure and evaluation

Adjust the patient simulator to generate signals in such a way that the automated sphygmomanometer displays diastolic blood pressure values of 2.7kPa (20mmHg) or less and systolic blood pressure values of 14.7kPa (110mmHg) or more in neonatal mode and diastolic blood pressure values of 5.3 kPa (40 mmHg) or less and systolic blood pressure values of 30.7kPa (230mmHg) or more otherwise.

Check by visual inspection.

3 Test for the repeatability of blood pressure indication (A.16 in last version)

3.1 Apparatus

- Patient simulator for the auscultatory and/or oscillometric method, having an experimental standard deviation for the simulator of not more than 0.13 kPa (1mmHg). The generated signal values shall be approximately: systolic: 16.0 kPa (120 mmHg); diastolic: 10.7 kPa (80 mmHg); pulse rate: 70 min⁻¹-80 min⁻¹.

3.2 Procedure

Connect, as shown in the figure, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values.

Perform 20 consecutive measurements at 10 °C~40 °C and any relative humidity in the range between 15 % and 85 %.

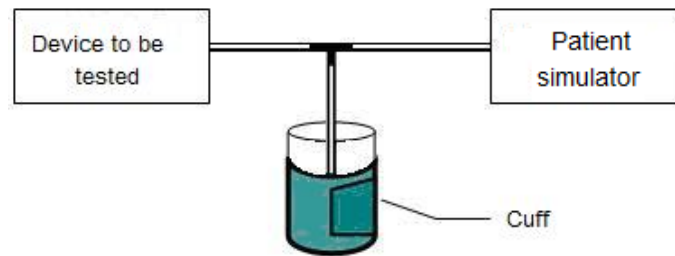


Figure 2 Setup to test the repeatability of the blood pressure indication

Note 1: The device to be tested for adult blood pressure measurement: pulse rate set at 80 min⁻¹.

Note 2: The device to be tested for neonatal/infant blood pressure measurement: pulse rate set at 120min⁻¹.

3.3 Expression of results

The repeatability of blood pressure indication is calculated as follows:

$$r_{S(D)} = \sqrt{\frac{\sum_{i=1}^n (\bar{L}_{S(D)} - L_{S(D)_i})^2}{n-1}}$$

$r_{S(D)}$ being the display value repeatability of systolic (or diastolic) blood pressure;

$L_{S(D)_i}$ being the systolic (or diastolic) blood pressure at the i^{th} measurement;

$\bar{L}_{S(D)}$ being the mean of systolic (or diastolic) blood pressure.

n being times of measurement

4 Test for the effect of voltage variations of the power source on the cuff pressure indication

4.1 Internal electrical power source

4.1.1 Apparatus

- adjustable direct current voltage supply;
- voltmeter with ~~an uncertainty of less than~~ maximum permissible error within 0.5 % of the measured value;
- calibrated reference manometer with ~~an uncertainty of less than~~ maximum permissible error within ± 0.1 kPa (± 0.8 mmHg).

4.1.2 Procedure

Replace the internal electrical power source of the ~~blood pressure measuring system~~ automated sphygmomanometer with a DC voltage supply having an impedance which is equivalent to the impedance of the internal electrical power source specified by the manufacturer. Measure the variation in applied DC voltage supply with a voltmeter. Test the ~~blood pressure measuring system~~ automated sphygmomanometer by altering the DC voltage supply in steps of 0.1 V and determine the lowest voltage limit at which the cuff pressure ~~reading indication~~ is still displayed.

Carry out this test with the maximum permissible impedance of the internal electrical power source.

Carry out the test ~~according to the procedure specified in A.1~~ for the maximum permissible errors of the cuff pressure indication but only at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at ambient humidity, and at the lowest voltage limit ~~described above~~ increased by 0.1 V and also at the nominal voltage.

4.1.3 Expression of results

Express the results as the difference between the cuff pressure indication of the ~~blood pressure measuring~~

~~system~~ automated sphygmomanometer to be tested and ~~that the~~ corresponding readings of the reference manometer at the lowest voltage limit increased by 0.1 V and at nominal voltage.

4.2 External electrical power source - alternating current

4.2.1 Apparatus

- adjustable alternating current voltage supply;
- voltmeter with ~~an uncertainty of less than~~ maximum permissible error within 0.5 % of the measured value;
- calibrated reference manometer with ~~an uncertainty of less than~~ maximum permissible error within ± 0.1 kPa (± 0.8 mmHg).

4.2.2 Procedure

Connect the ~~blood pressure measuring system~~ automated sphygmomanometer to the adjustable alternating current voltage supply. Measure the variation in AC voltage supply with the voltmeter.

Carry out the test ~~according to the procedure specified in A.21~~ for the maximum permissible errors of the cuff pressure indication but only at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at ambient humidity at:

- the maximum rated voltage, declared by the manufacturer;
- the mean value of the maximum and minimum rated voltage, declared by the manufacturer;
- the minimum rated voltage, declared by the manufacturer.

Testing can be carried out only at one cuff pressure point within 6.7kPa~33.3kPa(50mmHg~250mmHg).

Note: The maximum rated voltage is declared by the manufacturer as well as the minimum rated voltage(see 7.5). When the rated voltage is not described with a range but only one nominal value, it means that the minimum rated voltage equals to the maximum rated voltage.

4.2.3 Expression of results

Express the results as the difference between the cuff pressure indication of the ~~blood pressure measuring system~~ automated sphygmomanometer to be tested and ~~that the~~ corresponding readings of the reference manometer.

4.3 External electrical power source - direct current

4.3.1 Apparatus

Use the apparatus listed in ~~A.3.1.1~~.

4.3.2 Procedure

Connect the ~~blood pressure measuring system~~ automated sphygmomanometer to the DC voltage supply. Control the DC voltage supply by reference to a voltmeter.

Carry out the test ~~according to the procedure specified in A.21~~ for the maximum permissible errors of the cuff pressure indication but only at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at ambient humidity at:

- the maximum rated voltage, declared by the manufacturer ~~increased by 10%~~;
- the mean value of the maximum and minimum rated voltage, declared by the manufacturer;
- the minimum rated voltage, declared by the manufacturer ~~decreased by 10%~~.

Testing can be carried out only at one cuff pressure point within 6.7kPa~33.3kPa(50mmHg~250mmHg).

4.3.3 Expression of results

Express the results as the difference between the cuff pressure indication of the ~~blood pressure measuring system~~ automated sphygmomanometer to be tested and ~~that the~~ corresponding readings of the reference manometer.

4.4 Voltage variations of the external electrical power source - alternating current

4.4.1 Apparatus

Use the apparatus listed in [A.3.2.1](#).

4.4.2 Procedure

Connect the ~~blood pressure measuring system~~ automated sphygmomanometer to the AC voltage supply. Measure the variation in the AC voltage supply with the voltmeter. Test the ~~blood pressure measuring system~~ automated sphygmomanometer by altering the AC voltage supply in steps of 5 V and determine the lowest voltage limit at which the cuff pressure ~~reading indication~~ is displayed.

Note: Outside the working range specified by the manufacturer, no cuff pressure indication shall be displayed.

Carry out the test ~~according to the procedure specified in A.21~~ for the maximum permissible errors of the cuff pressure indication but only at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at ambient humidity at the lowest voltage limit increased by 5 V ~~and also at the rated voltage~~.

Testing can be carried out only at one cuff pressure point within 6.7kPa~33.3kPa(50mmHg~250mmHg).

4.4.3 Expression of results

Express the results as the difference between the cuff pressure indication of the ~~blood pressure measuring system~~ automated sphygmomanometer to be tested and ~~that the~~ corresponding readings of the reference manometer at the lowest voltage limit increased by 5 V.

4.5 Voltage variations of the external electrical power source - direct current

4.5.1 Apparatus

Use the apparatus listed in [A.3.1.1](#).

4.5.2 Procedure

Connect the ~~blood pressure measuring system~~ automated sphygmomanometer to the DC voltage supply. Measure the variation in the DC voltage supply with the voltmeter.

Test the ~~blood pressure measuring system~~ automated sphygmomanometer by altering the DC voltage supply in steps of 0.1 V and determine the lowest voltage limit at which the cuff pressure ~~reading indication~~ is displayed.

Note: Outside the working range specified by the manufacturer, no cuff pressure indication shall be displayed.

Carry out the test ~~according to the procedure specified in A.21~~ for the maximum permissible errors of the cuff pressure indication but only at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at ambient humidity at the lowest voltage limit increased by 0.1 V.

Testing can be carried out only at one cuff pressure point within 6.7kPa~33.3kPa(50mmHg~250mmHg).

4.5.3 Expression of results

Express the results as the difference between the cuff pressure indication of ~~blood pressure measuring system~~ automated sphygmomanometer to be tested and ~~that the~~ corresponding readings of the reference manometer at the lowest voltage limit increased by 0.1 V.

~~A.5 Test methods for the effect of voltage variations of the power source on the result of the blood pressure measurement~~

~~A.5.1 Internal electrical power source~~

~~A.5.1.1 Apparatus~~

- ~~• adjustable direct current voltage supply;~~
- ~~• voltmeter with an uncertainty less than 0.5% of the measured value;~~

Suggested Revision 21*(Original)*

- ~~patient simulator~~ (see 2.15) for the auscultatory and/or oscillometric method, having additional deviations originating from the simulator of not more than 0.27 kPa (2 mmHg) for the mean value of the measurements and generating signals for blood pressure values of approximately: systolic: 16 kPa (120 mmHg); diastolic: 11 kPa (80 mmHg); pulse rate: $70 \text{ min}^{-1} - 80 \text{ min}^{-1}$.

(Revised)

- The technical requirements for stability of patient simulator (see 2.15) for the auscultatory and/or oscillometric method, having additional deviations originating from the simulator of not more than 0.27 kPa (2 mmHg) for the mean value of the measurements and generating signals for blood pressure values of approximately: systolic: 16 kPa (120 mmHg); diastolic: 11 kPa (80 mmHg); pulse rate: $70 \text{ min}^{-1} - 80 \text{ min}^{-1}$.

Note:

- ~~Term 2.15 has emphasized the function of the simulator for the stability evaluation without giving the corresponding technical requirements.~~
- ~~The concept of additional deviations is not appropriate. How can the deviation be determined since there is no "standard blood pressure value"?~~

A.5.1.2 Procedure

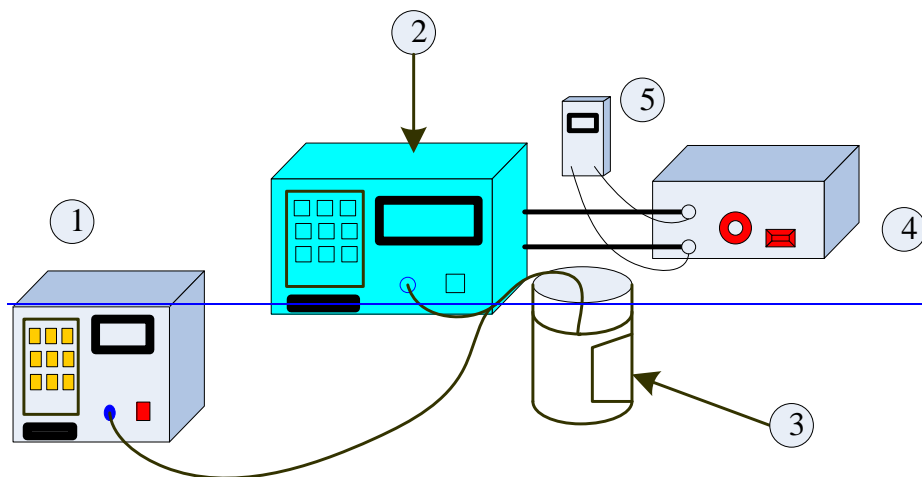
Replace the internal electrical power source of the blood pressure measuring system by a DC voltage supply having an impedance which is equivalent to the impedance of the internal electrical power source specified by the manufacturer. Devices intended to be used with consumer batteries shall be tested with an impedance of less than 1Ω .

Control the DC voltage supply by reference to the voltmeter.

Connect the blood pressure measuring system to the patient simulator. Carry out the test at the maximum permissible impedance of the internal electrical power source. Carry out 20 simulated blood pressure measurements at the lowest voltage limit as determined in A.4.1.2 increased by 0.1 V and at nominal voltage.

Suggested Revision 1*(Addition)*

Specified measuring system is displayed in Figure 3.



1— Patient Simulator; 2— Device to be tested;
3— Cuff; 4— DC voltage supply; 5— voltmeter

Figure 3 Measurement system for determining the influence of voltage

A.5.1.3 Expression of results

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.

A.5.2 External electrical power source alternating current

A.5.2.1 Apparatus

- adjustable alternating current voltage supply;
- voltmeter with an uncertainty less than 0.5% of the measured value;
- patient simulator as described in A.5.1.1.

A.5.2.2 Procedure

Connect the blood pressure measuring system to the AC voltage supply. Control the AC voltage supply by reference to the voltmeter. Connect the blood pressure measuring system to the simulator.

Carry out 20 simulated blood pressure measurements each at:

- the maximum rated voltage, declared by the manufacturer, increased by 10%;
- the mean value of the maximum and minimum rated voltage, declared by the manufacturer;
- the minimum rated voltage, declared by the manufacturer, decreased by 10%.

A.5.2.3 Expression of results

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.

A.5.3 External electrical power source direct current

A.5.3.1 Apparatus

- adjustable direct current voltage supply;

- ~~voltmeter with an uncertainty less than 0.5 % of the measured value;~~
- ~~patient simulator as described in A.5.1.1.~~

~~A.5.3.2 Procedure~~

~~Connect the blood pressure measuring system to the DC voltage supply. Control the DC voltage supply by reference to the voltmeter. Connect the blood pressure measuring system to the simulator.~~

~~Carry out 20 simulated blood pressure measurements each at:~~

- ~~the maximum rated voltage, declared by the manufacturer, increased by 10%;~~
- ~~the mean value of the maximum and minimum rated voltage, declared by the manufacturer;~~
- ~~the minimum rated voltage declared by the manufacturer, decreased by 10%.~~

~~A.5.3.3 Expression of results~~

~~Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.~~

5 Test for air leakage of the pneumatic system

5.1 Apparatus

- rigid metal cylinder of an appropriate size;
- pressure generator, e.g. ball pump (hand pump) with deflation valve;
- stopwatch.

5.2 Procedure

If because of technical reasons, the test as described in this subclause cannot be performed, use an alternative test procedure specified by the manufacturer.

~~Carry~~ Testing shall be carried out ~~the test~~ at ~~constant temperature in the range 15°C to 25°C~~ environmental conditions (see 5.1).

Before beginning the test, allow the ~~blood pressure measuring system~~ automated sphygmomanometer to reach working temperature.

Wrap the cuff around the cylinder (see 6.2) such that, for devices measuring at the upper arm and the thigh, the circumference of the applied cuff does not exceed that of the cylinder by more than 7%.

Note 1: Electro-mechanical pumps which are a part of the system may be used for the test. Valves which are permanently opened may be disconnected for the test.

Note 2: For this test no calibrated reference manometer is required because the cuff pressure display of the unit under test can be used when the error of the cuff pressure indication is considered. The advantage of this test is that the unit under test is in its original configuration. Additional connections can increase the leakage. Carry out the test over the whole measuring range at at least ~~five~~ three equally spaced pressure steps (e.g. 6.7 kPa (50 mmHg), ~~13 kPa (100 mmHg)~~, 20.0 kPa (150 mmHg), ~~27 kPa (200 mmHg)~~ and ~~34~~ 33.3 kPa (250 mmHg)). Because the thermodynamic equilibrium is influenced by decreasing or increasing the pressure when changing to the next pressure step, wait at least 60 s before reading the values. Test the air leakage over a period of 5 minutes and determine the measured value from this.

5.3 Expression of results

Express the air leakage as the rate of pressure loss per minute.

6 ~~Method of~~ Test for the pressure ~~reduction-reducing~~ rate of devices using the auscultatory method

6.1 Apparatus

- T-piece connectors;
- calibrated reference manometer with signal output port and ~~an uncertainty less than~~ maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- artificial or human limbs (see Notes under **A.7.5.2**);
- recording unit.

6.2 Procedure

Measure the pressure reduction rate either on human subjects or artificial limbs.

Note 1: The intention is to use artificial limbs, but ~~as these are still under consideration~~, measurements performed with human volunteers are acceptable.

Note 2: Two limb sizes should be used, being equal to the upper and lower limits of limb circumferences with which a particular size of cuff is recommended for use.

Note 3: It is intended that the characteristics of the artificial limbs reflect some elastic characteristics of human limbs.

Because the cuff deflation rate may be influenced by the way that a cuff is applied, apply and remove the cuff for each of at least ten repeated measurements on at least two different limb sizes. The deflation may be reset.

Connect the calibrated reference manometer to the cuff by means of a T-piece. Connect the output part of the calibrated reference manometer to the recording unit.

6.3 Expression of results

Determine the rate of pressure reduction (e.g. by graphical evaluation and drawing tangents) at the pressure values 8.0 kPa (60 mmHg), 16.0 kPa (120 mmHg) and 24.0 kPa (180 mmHg). Calculate the pressure reduction rate as the mean value calculated separately for the pressure values 8.0 kPa (60 mmHg), 16.0 kPa (120 mmHg) and 24.0 kPa (180 mmHg) and for the various limb circumferences.

If the pressure reduction ~~rates are~~ rate is dependent on the pulse, record the pulse rate. In this case, express the result as ~~pressure reduction~~ cuff deflation rate per pulse.

7 Test for the rapid exhaust ~~valve~~

7.1 Apparatus

- two rigid vessels with capacities of 100 ml ± 5 ml and 500 ml ± 25 ml, respectively;
- calibrated reference manometer with ~~an uncertainty less than~~ maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- pressure generator;
- T-piece connector;
- stopwatch.

7.2 Procedure

Carry out the test with the 500 ml vessel in place of the cuff. For ~~blood pressure measuring systems automated sphygmomanometers~~ having the capability of measuring in a neonatal/infant mode and for devices measuring at the wrist, carry out the test with the 100 ml vessel in place of the cuff.

Connect the calibrated reference manometer by means of a T-piece to the pneumatic system.

Inflate at least to the ~~maximum~~ initial pressure given in **Rxxx-I** 6.4.3, wait 60 s and activate the rapid exhaust valve.

Measure the time between the pressure values specified in **Rxxx-1** 6.4.3 using the stopwatch.

7.3 Expression of results

Express the results as the measured exhaust times.

8 Test **method** for the zero **setting** adjustment of a measuring system

8.1 Apparatus

- rigid vessel with a capacity of 500 ml ± 25 ml;
- calibrated reference manometer with ~~an uncertainty less than~~ maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- electro-mechanical pressure/suction pump;
- pressure generator, e.g. ball pump (hand pump) with deflation valve;
- T-piece connectors;
- hoses.

8.2 Procedure and evaluation

If, because of technical reasons, the test as described in this subclause cannot be performed, use an alternative test procedure specified by the manufacturer.

To test the function of the zero **adjustment**, apply a pressure of +0.8 kPa (+6 mmHg) and subsequently -0.8 kPa (-6 mmHg) to the pneumatic system and initiate a zero setting of the device.

Ensure that all displayed pressure values have a systematic error of -0.8 kPa (-6 mmHg) and +0.8 kPa (+6 mmHg), respectively.

Before beginning the test, allow the ~~blood pressure measuring system~~ automated sphygmomanometer to reach working temperature.

Set up the ~~blood pressure measuring system~~ automated sphygmomanometer to be tested as follows:

- replace the cuff with the 500 ml vessel;
- insert the calibrated reference manometer into the pneumatic system by means of a T-piece connector;
- insert the pressure/suction pump into the pneumatic system by means of a T-piece connector;
- insert the pressure generator into the pneumatic system by means of a T-piece connector.

Note: If convenient, one adjustable pump may be used in place of the pressure/suction pump and pressure generator to generate the pressures.

Proceed in the following way:

- a) Perform a regular adjustment to zero on the automated sphygmomanometer;
- b) Raise the pressure to 13.0 kPa (or 100 mmHg) and record the indication of the automated sphygmomanometer (e.g. 12.9 kPa or 99 mmHg);
- c) Apply a pressure of +0.8 kPa (+6.0 mmHg) while performing another adjustment to zero;
- d) Raise the pressure to 13.0 kPa (or 100 mmHg) and record the indication of the automated sphygmomanometer. It shall be 0.8 kPa (6 mmHg) below the value recorded at b) (e.g. 12.1 kPa or 93 mmHg);
- e) Apply a pressure of -0.8 kPa (-6.0 mmHg) while performing another adjustment to zero;
- f) Raise the pressure to 13.0 kPa (or 100 mmHg) and record the indication of the automated sphygmomanometer. It shall be 0.8 kPa (6 mmHg) above the value recorded at b) (e.g. 13.7 kPa or 105 mmHg).

8.3 Expression of results

Express the results as shown in the d) and f).

9 Test ~~method~~ for the **instrumental** drift of the cuff pressure indication

9.1 General

This test applies for devices performing zero ~~setting~~ adjustment only immediately after switching on.

9.2 Apparatus

- rigid vessel with a capacity of 500 ml ± 25 ml;
- calibrated reference manometer with ~~an uncertainty less than~~ maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- stopwatch;
- T-piece connectors;
- patient simulator as described in **A.13.1**.

9.3 Procedure and evaluation

Replace the cuff with the 500 ml vessel. Insert the calibrated reference manometer and the patient simulator into the pneumatic circuit by means of T-piece connectors.

Before beginning the test, allow the ~~blood pressure measuring system~~ automated sphygmomanometer to reach operating temperature as described in the instructions for use.

~~Test the stability of the cuff pressure indication after the zero setting at a pressure value of 7 kPa (50 mmHg) according to the procedure specified in A.2.~~

~~Under the same environmental conditions determine the time (t1) until the change of the cuff pressure indication exceeds 0.1 kPa (1 mmHg). Switch off the device and switch on afterwards.~~ Perform one blood pressure measurement, then wait until the automated sphygmomanometer has switched off automatically and determine this time (t).

Switch on the automated sphygmomanometer and set it to the test mode. Apply a pressure of 6.7 kPa (or 50 mmHg) according the procedure specified in ~~A.4~~ test for the maximum permissible errors of the cuff pressure indication but only at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at ambient humidity and start the stopwatch. Determine the change of the cuff pressure indication during the time (t). Check that it does not exceed 0.1 kPa or 1 mmHg.

10 Test for the maximum time for which the cuff is inflated

10.1 Apparatus

- patient simulator or human subject
- stopwatch.

10.2 Procedure and evaluation

~~Carry out~~ Apply the ~~testing of the signal processing by means of~~ automated sphygmomanometer to a human or connect it to the patient simulator. ~~For each of the following combinations of temperature and humidity, place~~ Start a blood pressure measurement and the stopwatch. Extend the blood pressure measurement as long as possible. Examples (for automated sphygmomanometer measuring ~~system for at least 3 h in the climatic chamber to allow the system to reach steady conditions~~ during cuff deflation) how this can be achieved are:

- by moving the limb, which causes the cuff deflation to halt or re-inflate,
- by manually blocking the deflation valve.

Measure the time until the cuff pressure drops below the pressure value specified in **Rxxx-1** 6.4.6.

11 ~~Test method for the stability of cuff pressure indication following prolonged usage~~ Test for the durability

11.1 Apparatus

- rigid metal vessel with a capacity of 500 ml ± 25 ml;
- calibrated reference manometer with maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors and hoses.

11.2 Procedure

Carry out the test ~~according to the procedure specified in A.21~~ for the maximum permissible errors of the cuff pressure indication but only at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at ambient humidity prior to prolonged usage.

Perform 10,000 simulated measurement cycles with the complete ~~blood pressure measurement system~~ automated sphygmomanometer at which at least the following cuff pressure values shall be reached:

- adult mode: 20.0 kPa (150 mmHg);
- neonatal/infant mode: 10.0 kPa (75 mmHg).

Note 1: For devices which measure with the auscultatory and oscillometric method this test should be carried out for both modes.

Note 2: For devices which measure in both modes (adult and neonatal/infant) the test should be carried out in both modes.

11.3 Expression of results

Express the result as the difference between the cuff pressure indication before and after 10,000 simulated blood pressure measurement cycles at the same test pressure and under the same environmental conditions.

12 ~~Test method for the effect of external voltages and abnormal connections to the signal input/output ports~~ Test for the signal input and output ports

12.1 Apparatus

- rigid vessel with a capacity of 500 ml ± 25 ml;
- calibrated reference manometer with ~~an uncertainty less than~~ maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- T-piece connectors;
- pressure generator, e.g. ball pump (hand pump) with deflation valve.

12.2 Procedure

Replace the cuff with the 500 ml vessel, insert the calibrated reference manometer into the pneumatic system by means of a T-piece and proceed as follows.

- Raise the pressure to 13.3 kPa (100 mmHg) and record the displayed value.
- Repeat a) whilst short circuiting all contacts of the signal input/output ports belonging to the ~~noninvasive blood pressure measuring system~~ automated sphygmomanometer.
- Repeat a) whilst applying the maximum voltage specified by the manufacturer (~~see 7.5~~) to each contact belonging to the ~~non-invasive blood pressure measuring system~~ automated sphygmomanometer.

12.3 Evaluation

Compare the indicated value under a) with the indicated values under b) and c).

13 Test for the cuff pressure deflation following an aborted measurement

13.1 Apparatus

- ~~calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);~~
- ~~T piece connectors.~~
- patient simulator or human subject.

13.2 Procedure and evaluation

~~Insert the calibrated reference manometer into the pneumatic system by means of a T piece.~~

Apply the automated sphygmomanometer to a human or connect it to the patient simulator. Start a blood pressure measurement. Abort the measurement during inflation. Start another measurement and abort it during the pressure reduction. If interval measurements are possible repeat the test in this mode.

Check by visual inspection whether the rapid exhaust ~~(6.4.3)~~ is activated.

14 Test for the resistance to vibration and shock

14.1 Apparatus

- shaker

14.2 Procedure

Compliance is checked by the following tests:

a) Shock test in accordance with IEC 60068-2-27:2008 using the conditions of test type 1 or 2:

Note 1: This represents IEC TR 60721-4-7, Class 7M2.

1) test type: Type 1:

- peak acceleration: 150 m/s² (15 g);
- duration: 11 ms;
- pulse shape: half sine;
- number of shocks: 3 shocks per direction per axis (18 total).

2) test type: Type 2:

- peak acceleration: 300 m/s² (30 g);
- duration: 6 ms;
- pulse shape: half sine;
- number of shocks: 3 shocks per direction per axis (18 total).

b) Broad-band random vibration according to IEC 60068-2-64:2008 using the following conditions:

Note 2: This represents IEC TR 60721-4-7, Classes 7M1 and 7M2

1) acceleration amplitude:

- 10 Hz to 100 Hz: 1.0 (m/s²)²/Hz;
- 100 Hz to 200 Hz: –3 dB/octave;
- 200 Hz to 2 000 Hz: 0.5 (m/s²)²/Hz;

2) duration: 30 min per each perpendicular axis (3 total).

14.3 Evaluation

After this test the automated sphygmomanometer shall comply with the requirements of ~~Rxxx-1~~ 5.1 but only at a temperature of 20 °C ± 5 °C and at ambient humidity.