



Second Committee Draft (2CD) – 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

Date: 27 September 2019
Document number: TC18_SC1_P2_N018
Supersedes document: TC18_SC1_P2_N012

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

Circulated to P- and O-members and liaison international bodies and external organizations for:

☐ ☐ Discussion at (date and place of meeting):

☐ ☐ Comments by:

☐ ☒ Vote (P-members only) and comments by: **27 December 2019**

Explanatory note

According to OIML B 6 *Directives for OIML technical work*, OIML publications shall be reviewed every five years after publication by the responsible TC/SC to decide whether they should be confirmed, revised, or withdrawn. The current (old) R 16, which TC 18/SC 1 is responsible for, was published in 2002, and it has been identified that there are a few technical conflicts between the new ISO/IEC standard and OIML R 16. To avoid different requirements worldwide on blood pressure instruments, the convener started the work on drafting R 16-2 *Non-invasive automated sphygmomanometers* after the project for revision was approved at the 43rd CIML Meeting held in October 2008 in Sydney.

During this work, the secretariat received dozens of comments from the Project Group's members and liaisons. Therefore, we wish to express our most sincere thanks for all experts' kindness. Many of these proposals have been accepted and published in this current version.

The main changes proposed to R 16-2 are the following:

- OIML R 16-2 should be revised into three parts according to OIML B 6, and now OIML R 16-2 refers 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 MPEs of cuff pressure and environmental conditions are stated in R 16-2 5.1, and the requirements for storage have also been changed;
- Introducing blood pressure indication repeatability requirements;
- Maximum time for which the cuff is inflated has been added;
- Test for stability of the cuff pressure indication has been replaced by durability;
- Requirements for alarms have been removed;
- Better description of the environmental conditions for verification. There is no longer a distinction between “initial” verification and “subsequent” verification;
- The testing methods for maximum permissible errors of the cuff pressure indication have been updated in the test procedures;
- Testing methods for resistance to vibration and shock are prescribed for sphygmomanometers;
- Technical requirements for patient simulators have been modified. Considering that patient simulators currently have no traceability, they are not used as the reference standard for the accuracy test, but only used for testing the repeatability and blood pressure measuring range;
- Modified test report format.
- Harmonisation of electromagnetic compatibility test with the ISO/IEC standards.

The current document is the second Committee Draft (2CD), which was drawn up on the basis of the comments received from PG members on the first Committee Draft circulated in December 2018.

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.

Contents

<u>Foreword</u>	5
<u>1 Test for the maximum permissible errors of the cuff pressure indication</u>	6
<u>2 Test for the blood pressure measuring range</u>	7
<u>3 Test for the repeatability of blood pressure indication</u>	7
<u>4 Test for the effect of voltage variations of the power source on the cuff pressure indication</u>	8
<u>5 Test for air leakage of the pneumatic system</u>	10
<u>6 Test for the pressure reducing rate of devices using the auscultatory method</u>	11
<u>7 Test for the rapid exhaust</u>	12
<u>8 Test for the zero adjustment of a measuring system</u>	12
<u>9 Test for the instrumental drift of the cuff pressure indication</u>	13
<u>10 Test for the maximum time for which the cuff is inflated</u>	13
<u>11 Test for the durability</u>	14
<u>12 Test for the signal input and output ports</u>	14
<u>13 Test for the cuff pressure deflation following an aborted measurement</u>	15
<u>14 Test for the resistance to vibration and shock</u>	15
<u>Foreword</u>	4
<u>1 Test for the maximum permissible errors of the cuff pressure indication</u>	5
<u>2 Test for the blood pressure measuring range</u>	6
<u>3 Test for the repeatability of blood pressure indication</u>	6
<u>4 Test for the effect of voltage variations of the power source on the cuff pressure indication</u>	7
<u>5 Test for air leakage of the pneumatic system</u>	9
<u>6 Test for the pressure reducing rate of devices using the auscultatory method</u>	10
<u>7 Test for the rapid exhaust</u>	10
<u>8 Test for the zero adjustment of a measuring system</u>	11
<u>9 Test for the instrumental drift of the cuff pressure indication</u>	12
<u>10 Test for the maximum time for which the cuff is inflated</u>	12
<u>11 Test for the durability</u>	13
<u>12 Test for the signal input and output ports</u>	13
<u>13 Test for the cuff pressure deflation following an aborted measurement</u>	14
<u>14 Test for the resistance to vibration and shock</u>	14

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 Ryyy, 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).

OIML Publications may be downloaded from the OIML web site in the form of PDF files. Additional information on OIML Publications may be obtained from the Organization's headquarters:

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

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

1.1 Apparatus

- rigid metal vessel with a capacity of 500 ml \pm 25 ml;
- calibrated reference manometer with maximum permissible error within \pm 0.1 kPa (\pm 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 \pm 1 °C, ~~Instability~~ instability of temperature within \pm 1 °C, ~~Non~~uniformity of relative humidity within \pm 5 %, ~~Instability~~ 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). 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:

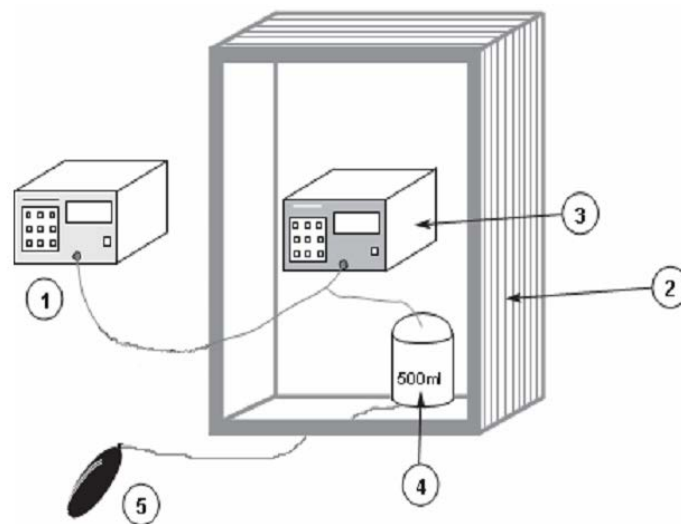
- 10 °C ambient temperature, 85 % relative humidity (non-condensing);
- 20 °C ambient temperature, 85 % relative humidity (non-condensing);
- 40 °C ambient temperature, 85 % relative humidity (non-condensing).

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 cuff pressure indication of the automated sphygmomanometer to be tested and the corresponding readings of the reference manometer.

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 Ryy-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

2.1 Apparatus

- Patient simulator for the auscultatory and/or oscillometric method, having an experimental standard deviation for the [repeatability simulator](#) of not more than 0.13 kPa (1 mmHg). The generated signal values shall be approximately: systolic: 16.0 kPa (120 mmHg); diastolic: 10.7 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 2.7 kPa (20 mmHg) or less and systolic blood pressure values of 14.7 kPa (110 mmHg) or more in neonatal mode and diastolic blood pressure values of 5.3 kPa (40 mmHg) or less and systolic blood pressure values of 30.7 kPa (230 mmHg) or more otherwise. Check by visual inspection.

3 Test for the repeatability of blood pressure indication

3.1 Apparatus

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

3.2 Procedure

Connect, as shown in the figure [2](#), 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 [any temperature in the range](#) 10 °C ~ 40 °C and [for](#) any relative humidity in the range [between](#) 15 % [and](#) 85 %.

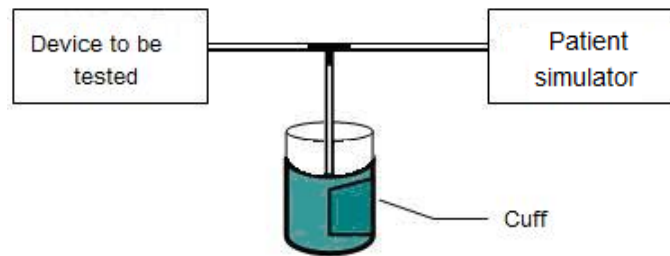


Figure 2 Setup to test the repeatability of the blood pressure indication

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 120 min^{-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 [of the device under test](#);

$L_{S(D)i}$ being the [displayed](#) systolic (or diastolic) blood pressure at the i^{th} measurement [of the device under test](#);

$\bar{L}_{S(D)}$ being the [displayed](#) mean of systolic (or diastolic) blood pressure [of the device under test](#);

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 maximum permissible error within 0.5% of the measured value;
- calibrated reference manometer with maximum permissible error within $\pm 0.1 \text{ kPa}$ ($\pm 0.8 \text{ mmHg}$).

4.1.2 Procedure

Replace the internal electrical power source of the 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 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 indication is still displayed.

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

Carry out the 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 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 automated

sphygmomanometer to be tested and 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 maximum permissible error within 0.5 % of the measured value;
- calibrated reference manometer with maximum permissible error within ± 0.1 kPa (± 0.8 mmHg).

4.2.2 Procedure

Connect the automated sphygmomanometer to the adjustable alternating current voltage supply. Measure the variation in AC voltage supply with the voltmeter.

Carry out the 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 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~~ may be carried out at only ~~at~~ one cuff pressure ~~point~~ within the range 6.7 kPa ~~~~~ 33.3 kPa (50 mmHg ~~~~~ 250 mmHg).

Note: The maximum rated voltage is declared by the manufacturer as well as the minimum rated voltage. ~~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 automated sphygmomanometer to be tested and the corresponding readings of the reference manometer.

4.3 External electrical power source - direct current

4.3.1 Apparatus

Use the apparatus listed in 3.1.1.

4.3.2 Procedure

Connect the automated sphygmomanometer to the DC voltage supply. Control the DC voltage supply by reference to a voltmeter.

Carry out the 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 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 6.7 kPa ~~~~~ 33.3 kPa (50 mmHg ~~~~~ 250 mmHg).

4.3.3 Expression of results

Express the results as the difference between the cuff pressure indication of the automated sphygmomanometer to be tested and 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 3.2.1.

4.4.2 Procedure

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

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

Carry out the 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 at the lowest voltage limit increased by 5 V.

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

4.4.3 Expression of results

Express the results as the difference between the cuff pressure indication of the automated sphygmomanometer to be tested and 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 3.1.1.

4.5.2 Procedure

Connect the automated sphygmomanometer to the DC voltage supply. Measure the variation in the DC voltage supply with the voltmeter.

Test the 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 indication is displayed.

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

Carry out the 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 at the lowest voltage limit increased by 0.1 V.

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

4.5.3 Expression of results

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

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

Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min). Check compliance by means of the following test. If, because of technical reasons, the test as described in this subclause cannot be performed, use an alternative test procedure specified by the manufacturer.

Testing shall be carried out at environmental conditions.

Before beginning the test, allow the automated sphygmomanometer to reach working temperature. Wrap the cuff around the cylinder 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%.

Carry out the test over the whole measuring range at at least three equally spaced pressure steps (e.g. 6.7 kPa (50 mmHg), 20.0 kPa (150 mmHg), and 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.

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 three equally spaced pressure steps (e.g. 6.7 kPa (50 mmHg), 20.0 kPa (150 mmHg), and 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 Test for the pressure reducing rate of devices using the auscultatory method

6.1 Apparatus

- T-piece connectors;
- calibrated reference manometer with signal output port and maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- artificial or human limbs (see Notes under 5.2);
- recording unit.

6.2 Procedure

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

Note 1: The ~~intention recommendation~~ is to use artificial limbs, but 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 size is recommended for use.

Note 3: It is ~~intended recommended~~ 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 rate is dependent on the pulse, record the pulse rate. In this case, express the result as cuff deflation rate per pulse.

7 Test for the rapid exhaust

7.1 Apparatus

- two rigid vessels with capacities of 100 ml \pm 5 ml and 500 ml \pm 25 ml, respectively;
- calibrated reference manometer with maximum permissible error within \pm 0.1 kPa (\pm 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 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 initial pressure given in **Ryyy-1** 6.4.3, wait 60 s and activate the rapid exhaust valve.

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

7.3 Expression of results

Express the results as the measured exhaust times.

8 Test for the zero adjustment of a measuring system

8.1 Apparatus

- rigid vessel with a capacity of 500 ml \pm 25 ml;
- calibrated reference manometer with maximum permissible error within \pm 0.1 kPa (\pm 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 automated sphygmomanometer to reach working temperature.

Set up the 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:

- Perform a regular adjustment to zero on the automated sphygmomanometer;
- 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);
- Apply a pressure of +0.8 ~~–~~ kPa (+6.0 ~~–~~ mmHg) while performing another adjustment to zero;
- 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);
- Apply a pressure of ~~–~~0.8 ~~–~~ kPa (~~–~~6.0 ~~–~~ mmHg) while performing another adjustment to zero;
- 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 for the instrumental drift of the cuff pressure indication

9.1 General

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

9.2 Apparatus

- rigid vessel with a capacity of 500 ~~–~~ ml \pm ~~–~~ 25 ml;
- calibrated reference manometer with maximum permissible error within \pm ~~–~~ 0.1 ~~–~~ kPa (\pm ~~–~~ 0.8 ~~–~~ mmHg);
- stopwatch;
- T-piece connectors;
- patient simulator as described in 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 automated sphygmomanometer to reach operating temperature as described in the instructions for use.

Perform one blood pressure measurement, then ~~wait~~ determine the time(t) 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 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

Apply the automated sphygmomanometer to a human or connect it to the patient simulator. [Simultaneously Start-start](#) a blood pressure measurement and the stopwatch. Extend the blood pressure measurement as long as possible. Examples (for automated sphygmomanometer measuring 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 [Ryyy-1](#) 6.4.6.

11 Test for the durability

11.1 Apparatus

- rigid metal vessel with a capacity of 500-ml \pm 25 ml;
- calibrated reference manometer with maximum permissible error within \pm 0.1 kPa (\pm 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 for the maximum permissible errors of the cuff pressure indication but only at a temperature of 20 °C \pm 5 °C and at ambient humidity prior to prolonged usage.

Perform 10,000 simulated measurement cycles with the complete 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 for the signal input and output ports

~~12.1~~ [To comply with the requirement of Ryyy-1, 6.8, the following test shall be performed.](#)

~~12.2~~12.1 Apparatus

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

~~12.3~~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.

- a) Raise the pressure to 13.3kPa~~—~~(100~~—~~mmHg) and record the displayed value.
- b) Repeat a) whilst short circuiting all contacts of the signal input/output ports belonging to the automated sphygmomanometer.
- c) Repeat a) whilst applying the maximum voltage specified by the manufacturer to each contact belonging to the automated sphygmomanometer.

~~12.4~~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

To comply with the requirement of Ryyy-1, 6.9.1, the following test shall be performed.

13.1 Apparatus

- patient simulator or human subject.

13.2 Procedure and evaluation

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 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~~three 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~~three 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 Ryyy-1 5.1 but only at a temperature of 20 °C₋₅ °C₊₅ and at ambient humidity.