INTERNATIONAL RECOMMENDATION

OIML R 149-2

Edition 2020 (E)

Non-invasive automated sphygmomanometers

Part 2: Test procedures

Sphygmomanomètres non invasifs automatiques

Partie 2: Procédures d'essai

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Contents

Foreword **5**

1 Test for maximum permissible errors of the cuff pressure indication **6**
1.1 Apparatus 6
1.2 Procedure 6
1.3 Expression of results 7

2 Test for blood pressure measurement range **7**
2.1 Apparatus 7
2.2 Procedure and evaluation 7

3 Test for repeatability of blood pressure indication **8**
3.1 Apparatus 8
3.2 Procedure 8
3.3 Expression of results 8

4 Test for effect of voltage variations of the power source **9**
4.1 Internal electrical power source 9
4.2 External electrical power source - alternating current 9
4.3 External electrical power source - direct current 10
4.4 Voltage variations of the external electrical power source - alternating current 11
4.5 Voltage variations of the external electrical power source - direct current 11

5 Test for air leakage of the pneumatic system **12**
5.1 Apparatus 12
5.2 Procedure 12
5.3 Expression of results 12

6 Test for pressure reduction rate of devices using the auscultatory method **12**
6.1 Apparatus 12
6.2 Procedure 13
6.3 Expression of results 13

7 Test for rapid exhaust **13**
7.1 Apparatus 13
7.2 Procedure 13
7.3 Expression of results 14

8 Test for zero adjustment of a measuring system **14**
8.1 Apparatus 14
8.2 Procedure and evaluation 14
8.3 Expression of results 15

9 Test for instrumental drift of the cuff pressure indication **15**
9.1 General 15
9.2 Apparatus 15
9.3 Procedure and evaluation 15

10 Test for maximum time for which the cuff is inflated **15**
10.1 Apparatus 15
10.2 Procedure and evaluation 16

11 Test for durability **16**
11.1 Apparatus 16
11.2 Procedure 16
11.3 Expression of results 16

12 Test for signal input and output ports 17
12.1 Apparatus 17
12.2 Procedure 17
12.3 Evaluation 17

13 Test for cuff pressure deflation following an aborted measurement 17
13.1 Apparatus 17
13.2 Procedure and evaluation 17

14 Test for resistance to vibration and shock 18
14.1 Apparatus 18
14.2 Procedure 18
14.3 Evaluation 18

15 Test for durability of markings 19

Foreword

The International Organisation of Legal Metrology (OIML) is a worldwide, intergovernmental organisation whose primary aim is to harmonise the regulations and metrological controls applied by the national metrological services, or related organisations, 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. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and which are intended to harmonise and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.

OIML Draft Recommendations, Documents and Guides are developed by Project Groups linked to Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been 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, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML participates in Joint Committees with other Institutions for the development of **Vocabularies (OIML V)** and **Joint Guides (G)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, 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 149-2, edition 2020 (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 2020 and supersedes OIML R 16-2:2002 (E).

OIML Publications may be downloaded from the OIML website in the form of PDF files. Additional information on OIML Publications may be obtained from the Organisation'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
Internet: www.oiml.org

Non-invasive automated sphygmomanometers
Part 2: Test procedures

1 Test for maximum permissible errors of the cuff pressure indication

1.1 Apparatus

The apparatus consists of the following:

- rigid metal vessel with a capacity of 500 ml ± 25 ml;
- calibrated reference manometer with a 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 with an overall length of no more than 600 mm;
- climatic chamber, non-uniformity of temperature within ±1 °C, instability of temperature within ±1 °C, non-uniformity of relative humidity within ±5 %, instability of relative humidity within ±5 %.

1.2 Procedure

Replace the cuff with the vessel. Connect both the calibrated reference manometer and the manometer of the device to be tested by means of a T-piece connector and hoses to the pneumatic system (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]

a) Under ambient conditions

For each of the following combinations of temperature and humidity, place the automated sphygmomanometer in the climatic chamber for at least 3 h 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.

b) Under storage conditions

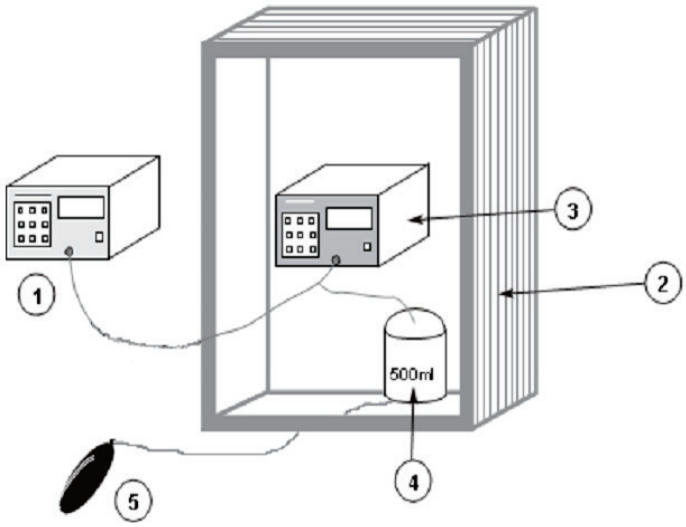
Testing shall be carried out a) under ambient conditions after the test sample has been placed unpacked for 24 h at a temperature of –5 °C and immediately afterwards for 24 h at a temperature of 50 °C in a climatic chamber. Any abnormal status shall be recorded during the testing.

[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 R 149-3.

Note: Integrated multi-parameter monitors may contain components which may be damaged during storage. The general temperature range has therefore been reduced compared to the requirements in R 149-1, 5.1. For simplification, testing can also be carried out at a temperature of 20 °C ± 5 °C and at ambient humidity.

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 – 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 blood pressure measurement range

To comply with the requirement of R 149-1, 5.4, the following test shall be performed.

2.1 Apparatus

The apparatus consists of the following:

- Patient simulator for the auscultatory and/or oscillometric method, having an experimental standard deviation for the repeatability 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} to 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 repeatability of blood pressure indication

To comply with the requirement of R 149-1, 5.5, the following test shall be performed.

3.1 Apparatus

The apparatus consists of the following:

- Patient simulator for the auscultatory and/or oscillometric method, having an experimental standard deviation for the repeatability 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} to 80 min^{-1}.

3.2 Procedure

Connect the automated sphygmomanometer with the cuff and the patient simulator, which is set to the target systolic and diastolic blood pressure values (see Figure 2).

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

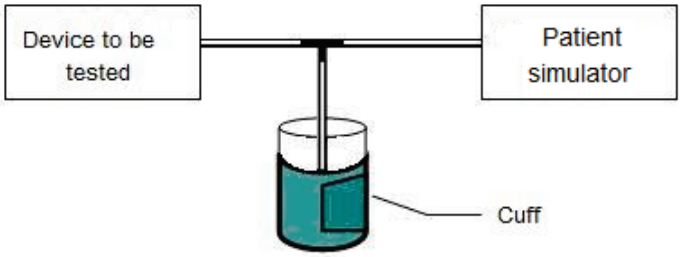


Figure 2 – Setup to test the repeatability of the blood pressure indication

Note 1: If the device is being tested for adult blood pressure measurement, the pulse rate is set at 80 min^{-1}.

Note 2: If the device is being tested for neonatal/infant blood pressure measurement, the pulse rate is set at 120 min^{-1}.

3.3 Expression of results

The repeatability of a blood pressure indication is calculated as follows:

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

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

$L_{\mathrm{S(D)}i}$ being the displayed systolic (or diastolic) blood pressure at the ith measurement of the device under test;

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

n number of measurements.

4 Test for effect of voltage variations of the power source

To comply with the requirement of R 149-1, 6.3, the following test shall be performed.

4.1 Internal electrical power source

4.1.1 Apparatus

The apparatus consists of the following:

- adjustable direct current voltage supply;
- voltmeter with a maximum permissible error within 0.5 % of the measured value;
- calibrated reference manometer with a maximum permissible error within ±0.1 kPa (±0.8 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 °C ± 5 °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 the nominal voltage.

4.2 External electrical power source - alternating current

4.2.1 Apparatus

The apparatus consists of the following:

- adjustable alternating current voltage supply;
- voltmeter with a maximum permissible error within 0.5 % of the measured value;
- calibrated reference manometer with a 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 °C ± 5 °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 may be carried out at only one cuff pressure within the range 6.7 kPa to 33.3 kPa (50 mmHg to 250 mmHg).

Note: The maximum rated voltage is declared by the manufacturer as well as the minimum 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 4.1.1.

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 °C ± 5 °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 the range 6.7 kPa to 33.3 kPa (50 mmHg to 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 4.2.1.

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.

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 °C ± 5 °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 the range 6.7 kPa to 33.3 kPa (50 mmHg to 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 4.1.1.

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.

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 °C ± 5 °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 the range 6.7 kPa to 33.3 kPa (50 mmHg to 250 mmHg).

4.5.3 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.

5 Test for air leakage of the pneumatic system

To comply with the requirement of R 149-1, 6.4.1, the following test shall be performed.

5.1 Apparatus

The apparatus consists of the following:

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

5.3 Expression of results

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

6 Test for pressure reduction rate of devices using the auscultatory method

To comply with the requirement of R 149-1, 6.4.2, the following test shall be performed.

6.1 Apparatus

The apparatus consists of the following:

- T-piece connectors;
- calibrated reference manometer with a signal output port and a 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 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 the limb circumferences with which a particular cuff size is recommended for use.

Note 3: It is 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 in which 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 rapid exhaust

To comply with the requirement of R 149-1, 6.4.3, the following test shall be performed.

7.1 Apparatus

The apparatus consists of the following:

- two rigid vessels with capacities of 100 ml ± 5 ml and 500 ml ± 25 ml, respectively;
- calibrated reference manometer with a 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 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 R 149-1, 6.4.3, wait 60 s and activate the rapid exhaust valve.

Measure the time between the pressure values specified in R 149-1, 6.4.3 using the stopwatch.

7.3 Expression of results

Express the results as the measured exhaust time.

8 Test for zero adjustment of a measuring system

To comply with the requirement of R 149-1, 6.4.4, the following test shall be performed.

8.1 Apparatus

The apparatus consists of the following:

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

8.2 Procedure and evaluation

If, for 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:

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 d) and f).

9 Test for instrumental drift of the cuff pressure indication

To comply with the requirement of R 149-1, 6.4.4, the following test shall be performed.

9.1 General

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

9.2 Apparatus

The apparatus consists of the following:

- rigid vessel with a capacity of 500 ml ± 25 ml;
- calibrated reference manometer with a maximum permissible error within ±0.1 kPa (±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 determine the time, *t*, until the automated sphygmomanometer has switched off automatically.

Switch on the automated sphygmomanometer and set it to the test mode. Apply a pressure of 6.7 kPa (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 °C ± 5 °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 maximum time for which the cuff is inflated

To comply with the requirement of R 149-1, 6.4.6, the following test shall be performed.

10.1 Apparatus

The apparatus consists of the following:

- 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 a blood pressure measurement and the stopwatch. Extend the blood pressure measurement as long as possible. Examples (for automated sphygmomanometer measuring during cuff deflation) of 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 R 149-1 6.4.6.

11 Test for durability

To comply with the requirement of R 149-1, 6.6, the following test shall be performed.

11.1 Apparatus

The apparatus consists of the following:

- rigid metal vessel with a capacity of 500 ml ± 25 ml;
- calibrated reference manometer with a 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 for the maximum permissible errors of the cuff pressure indication but only at a temperature of 20 °C ± 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 results 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 signal input and output ports

To comply with the requirement of R 149-1, 6.8, the following test shall be performed.

12.1 Apparatus

The apparatus consists of the following:

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

a) raise the pressure to 13.3 kPa (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.

12.3 Evaluation

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

13 Test for cuff pressure deflation following an aborted measurement

To comply with the requirement of R 149-1, 6.9.1, the following test shall be performed.

13.1 Apparatus

The apparatus consists of the following:

- 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 resistance to vibration and shock

To comply with the requirement of R 149-1, 6.10, the following test shall be performed.

14.1 Apparatus

The apparatus consists of the following:

- shaker.

14.2 Procedure

Compliance is checked by the following tests:

a) Shock test in accordance with IEC 60068-2-27:2008 *Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock* using the conditions of test type 1 or 2:

Note 1: This represents IEC TR 60721-4-7 *Classification of environmental conditions - Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 - Portable and non-stationary use*, Class 7M2.

1) Test type: Type 1:
   - peak acceleration: 150 m/s^2 (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/s^2 (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 *Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance* using the following conditions:

Note 2: This represents IEC TR 60721-4-7 *Classification of environmental conditions - Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 - Portable and non-stationary use*, Classes 7M1 and 7M2

1) Acceleration amplitude:
   - 10 Hz to 100 Hz: 1.0 (m/s^2)^2/Hz;
   - 100 Hz to 200 Hz: –3 dB/octave;
   - 200 Hz to 2 000 Hz: 0.5 (m/s^2)^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 R 149-1, 5.1 but only at a temperature of 20 °C ± 5 °C and at ambient humidity.

15 Test for durability of markings

To comply with the requirement of R 149-1, 6.11, the following test shall be performed.

Check compliance by inspection and the following tests.

After all the other tests of this document have been performed:

a) markings are rubbed by hand, without undue pressure, first for 15 s with a cloth soaked with distilled water, then for 15 s with a cloth soaked with methylated spirits and then for 15 s with a cloth soaked with isopropyl alcohol;

b) adhesive labels shall not have worked loose or become curled at the edges.