INTERNATIONAL RECOMMENDATION

OIML R 148-2

Edition 2020 (E)

Non-invasive non-automated sphygmomanometers

Part 2: Test procedures

Sphygmomanomètres non invasifs non automatiques

Partie 2: Procédures d'essai

OIML R 148-2 Edition 2020 (E)

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 maximum permissible errors of the cuff pressure indication under varying temperature conditions **7**
2.1 Apparatus 7
2.2 Procedure 7
2.3 Expression of results 8

3 Test for maximum permissible error of the cuff pressure indication under storage conditions **9**
3.1 Apparatus 9
3.2 Procedure 9
3.3 Expression of results 9

4 Test for air leakage of the pneumatic system **9**
4.1 Apparatus 9
4.2 Procedure 9

5 Test for pressure reduction rate for deflation valves **10**
5.1 Apparatus 10
5.2 Procedure 10
5.3 Expression of results 10

6 Test for rapid exhaust **10**
6.1 Apparatus 10
6.2 Procedure 11
6.3 Expression of results 11

7 Test for scale spacing and thickness of the scale marks **11**
7.1 Apparatus 11
7.2 Procedure 11

8 Test for security against mercury losses **11**
8.1 Apparatus 11
8.2 Procedure and evaluation 11

9 Test for the influence of the mercury stopping device **12**
9.1 Apparatus 12
9.2 Procedure and evaluation 12

10 Test for the hysteresis error of aneroid manometer **12**
10.1 Apparatus 12
10.2 Procedure 12
10.3 Expression of results 12

11 Test for durability of aneroid manometers **13**
11.1 Apparatus 13
11.2 Procedure 13
11.3 Expression of results 13

12 Test for mechanical safety 13
12.1 Resistance to vibration and shock for handheld sphygmomanometers 13
12.2 Resistance to vibration and shock for sphygmomanometers used during patient transport 14
12.3 Sphygmomanometers containing a mercury manometer 14
13 Test for durability of markings 14

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 148-2, edition 2020 (E) - was developed by 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 16-1:2002 (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 non-automated sphygmomanometers
Part 2: Test procedures

1 Test for maximum permissible errors of the cuff pressure indication

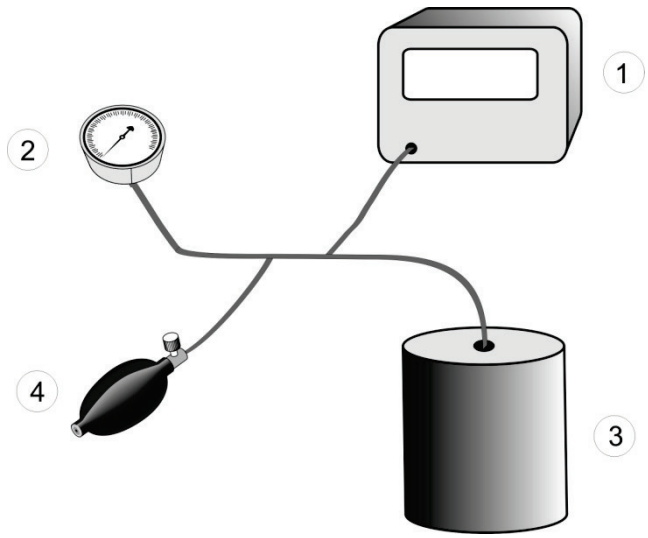
1.1 Apparatus

The apparatus consists of the following:

- rigid metal vessel with a capacity of 500 ml ± 25 ml;
- calibrated reference manometer with 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;
- hoses with an overall length of no more than 600 mm.

1.2 Procedure

Replace the cuff with the vessel. Connect both the calibrated reference manometer and the manometer of the device to be tested to the pneumatic system by means of a T-piece connector and hoses (see Figure 1). After disabling the electromechanical pump (if fitted), connect the 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 kPa (0 mmHg) and the maximum pressure of the scale range.



1 – Reference manometer; 2 – Manometer of the device to be tested;
3 – Metal vessel; 4 – Pressure generator

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

1.3 Expression of results

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer.

2 Test for maximum permissible errors of the cuff pressure indication under varying temperature conditions

2.1 Apparatus

The apparatus consists of the following:

- apparatus as specified in 1.1; plus
- a 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 %.

2.2 Procedure

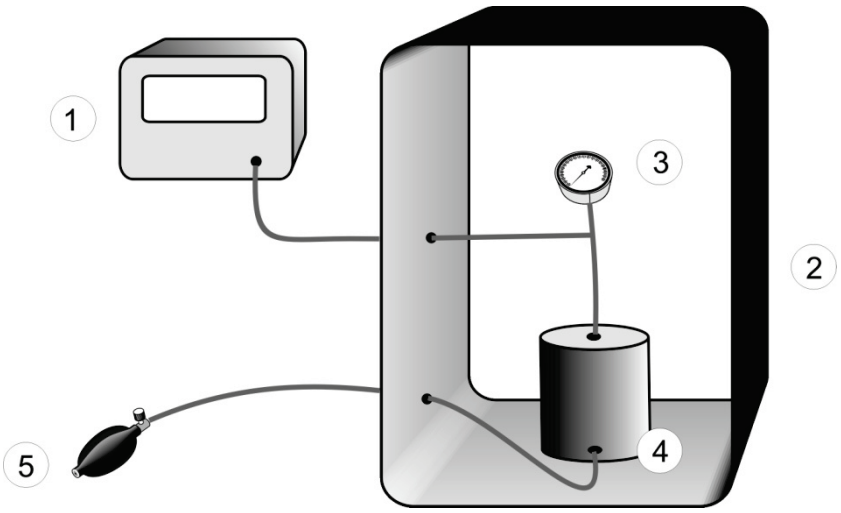
Replace the cuff with the vessel.

Connect both the calibrated reference manometer and the manometer of the device to be tested to the pneumatic system by means of a T-piece connector (see Figure 2). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pneumatic system by means of another T-piece connector.

For each of the following combinations of temperature and humidity, condition the device for at least 3 h in the climatic chamber to allow the device 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).

Carry out the test of the cuff pressure indication as described in 1.2 for each of the combinations of temperature and humidity mentioned above.



1 – Reference manometer;2 – Climatic chamber
3 – Manometer of the device to be tested;4 – Metal vessel
5 – Pressure generator

Figure 2 - Measurement system for determining the influence of temperature

2.3 Expression of results

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer at the relevant temperature value.

3 Test for maximum permissible error of the cuff pressure indication under storage conditions

3.1 Apparatus

The apparatus is as specified in 2.1.

3.2 Procedure

Replace the cuff with the vessel. Connect both the calibrated reference manometer and the manometer of the device to be tested to the pneumatic system by means of a T-piece connector (see Figure 2). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pneumatic system by means of another T-piece connector. Unpack the non-automated sphygmomanometer and store the instrument under test conditions specified in R 148-1, 5.2.

Note: This is one procedure and not two separate ones.

After at least one hour at a temperature of 20 °C ± 5 °C and 60 % relative humidity, carry out the test according the procedure in 1.2.

3.3 Expression of results

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer.

4 Test for air leakage of the pneumatic system

To comply with the requirement of R 148-1, 6.2.1, the following test shall be performed.

4.1 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;
- time measuring device with a maximum permissible error of 0.1 s.

4.2 Procedure

Wrap the cuff around the cylinder of an appropriate size, such that the internal circumference of the applied cuff exceeds the circumference cylinder by (7 ± 2) %.

Note: Electro-mechanical pumps which are part of the device may be used for the test.

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)). Test the air leakage over a period of 5 min and determine the measured value from this.

4.2.1 Expression of results

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

5 Test for pressure reduction rate for deflation valves

To comply with the requirement of R 148-1, 6.2.2, the following test shall be performed.

5.1 Apparatus

The apparatus consists of the following:

- T-piece connector;
- calibrated reference manometer with signal output and maximum permissible error within ±0.1 kPa (±0.8 mmHg);
- artificial limbs (see notes under 5.2);
- recording unit, which can record the output of the calibrated reference manometer, giving deflation rate in kPa/s or mmHg/s.

5.2 Procedure

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

Note 1: The recommendation is to use artificial limbs, but measurements performed with human volunteers are acceptable.

Note 2: It is recommended that the properties of the artificial limbs reflect some elastic properties of human limbs.

Because the cuff deflation rate may be influenced by the way in which the cuff is applied, the cuff should be applied and removed for each of at least ten repeated measurements, on at least two different limb sizes. These two limb sizes should be equal to the upper and lower limits of the limb circumferences for which a particular size of cuff is recommended to be used. Resetting the deflation valve is permitted during the test.

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

Plot the pressure reduction in the form of a pressure curve as a function of time.

5.3 Expression of results

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

6 Test for rapid exhaust

To comply with the requirement of R 148-1, 6.2.3, the following test shall be performed.

6.1 Apparatus

The apparatus consists of the following:

- rigid metal cylinder of an appropriate size (see R 148-1, 6.1);
- pressure generator if necessary, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connector;
- time measuring device with a maximum permissible error of 0.1 s.

6.2 Procedure

Carry out the test with the vessel in place of the cuff.

Connect the calibrated reference manometer to the pneumatic system by means of a T-piece connector. Inflate to the maximum pressure and open the rapid exhaust valve. Measure the time between the pressure values specified in R 148-1, 6.2.3.

6.3 Expression of results

Express the result as the time for the pressure reduction from 34.7 kPa to 2.0 kPa (260 mmHg to 15 mmHg).

7 Test for scale spacing and thickness of the scale marks

To comply with the requirement of R 148-1, 6.3.2.4, the following test shall be performed.

7.1 Apparatus

The apparatus consists of the following:

- scaled magnifying lens or similar device.

7.2 Procedure

Determine the thickness of the scale marks and the scale spacing in at least three different areas of the scale using the scaled magnifying lens.

8 Test for security against mercury losses

To comply with the requirement of R 148-1, 6.4.2, the following test shall be performed.

8.1 Apparatus

The apparatus consists of the following:

- collecting vessel of an adequate size;
- calibrated reference manometer, with a nominal range up to at least 53.2 kPa (400 mmHg) and maximum permissible error within ±0.13 kPa (±1.0 mmHg);
- T-piece connector;
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- time measuring device with a maximum permissible error of 0.1 s.

8.2 Procedure and evaluation

Place the sphygmomanometer to be tested in the collecting vessel. Connect the pressure generator and a T-piece connector attached to a calibrated reference manometer directly to the hose leading to the mercury reservoir. Use the pressure generator to raise the pressure in the manometer to 13.3 kPa (100 mmHg) greater than the maximum indicated scale reading on the test manometer. Maintain this pressure for 5 s and then release the pressure in the system.

Check that no mercury has spilled.

9 Test for the influence of the mercury stopping device

To comply with the requirement of R 148-1, 6.4.2, the following test shall be performed.

9.1 Apparatus

The apparatus consists of the following:

- pressure generator, e.g. ball pump (hand pump) with a deflation valve.
- time measuring device with a maximum permissible error of 0.1 s

9.2 Procedure and evaluation

Connect the pressure generator directly to the hose leading to the mercury reservoir, i.e. without connecting a cuff. When a gauge pressure of more than 26.6 kPa (200 mmHg) has been reached, occlude the tube and remove the pressure generator.

After removing the occlusion from the tube, measure the time taken for the mercury column to fall from the 26.6 kPa (200 mmHg) mark to the 5.3 kPa (40 mmHg) mark.

Check that the exhaust time does not exceed 1.5 s.

10 Test for the hysteresis error of aneroid manometer

To comply with the requirement of R 148-1, 6.5.4, the following test shall be performed.

10.1 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;
- time measuring device with a maximum permissible error of 0.1 s.

10.2 Procedure

Replace the cuff with the vessel.

Connect the calibrated reference manometer to the pneumatic system by means of a T-piece connector. After disabling the electromechanical pump (if fitted), connect the additional pressure generator into the pneumatic system by means of another T-piece connector.

Test the device with increasing pressure steps of not more than 6.7 kPa (50 mmHg) to the scale maximum, at which point hold the pressure for 5 min and then decrease it by the same steps. Do not tap on the manometer housing to reduce the friction to move the pointer.

Disconnect the calibrated reference manometer during the 5 min at maximum pressure, if it has elastic sensing elements.

10.3 Expression of results

Express the results as the difference between the indicated values on the manometer at the same test pressure steps when increasing the pressure and when decreasing the pressure.

11 Test for durability of aneroid manometers

To comply with the requirement of R 148-1, 6.5.5, the following test shall be performed.

11.1 Apparatus

The apparatus consists of the following:

- alternating pressure generator, which generates a sinusoidal pressure variation between 3 kPa and 30 kPa (20 mmHg and 220 mmHg) at a maximum rate of 60 cycles per minute.

11.2 Procedure

Carry out the procedure specified in 1.

Connect the aneroid manometer directly to the alternating pressure generator and perform 10 000 alternating pressure cycles. A full-scale cycle is a pressure change from 20 mmHg to full scale, and then back to 20 mmHg.

One hour after the stress test, carry out the procedure as specified in 1 at the same test pressure levels as before the stress test.

11.3 Expression of results

Express the results as the changes, Δ_{physt}, between the indicated values on the manometer at the same test pressure steps on deflation, p_{down}, and on inflation, p_{up}, using the equation $\Delta_{\text{physt}} = p_{\text{down}} - p_{\text{up}}$.

12 Test for mechanical safety

To comply with the requirement of R 148-1, 6.6.1, the following test shall be performed.

12.1 Resistance to vibration and shock for handheld sphygmomanometers

Sphygmomanometers shall function normally following a free fall from a distance d = 25 cm.

A sphygmomanometer that is marked “Shock Resistant” shall function normally following a free fall from a distance d = 1 m.

Allow the sphygmomanometer to fall freely six times (once on each side) from a height of distance d = 1 m onto a 50 mm ± 5 mm thick hardwood (hardwood density > 600 kg/m^3) board lying flat on a concrete or a similar rigid base.

12.2 Resistance to vibration and shock for sphygmomanometers used during patient transport

a) Shock:

- peak acceleration: 1 000 m/s^2 (10^2 g);
- duration: 6 ms;
- pulse shape: Half sine;
- number of shocks: three shocks per direction per axis (18 total).

b) Broad-band random vibration:

- frequency range: 10 Hz to 2 000 Hz;
- resolution: 10 Hz;
- acceleration amplitude:

  10 Hz to 100 Hz: 5.0 (m/s^2)^2/Hz;

  100 Hz to 200 Hz: -7 db/octave;

  200 Hz to 2 000 Hz: 1.0 (m/s^2)^2/Hz;
- duration: 30 min on each perpendicular axis (three total).

12.3 Sphygmomanometers containing a mercury manometer

Allow the sphygmomanometer to fall freely six times (once on each side) from a height of distance d = 1 m onto a 50 mm ± 5 mm thick hardwood (hardwood density > 600 kg/m^3) board lying flat on a concrete or a similar rigid base. Care should be taken while testing to ensure that there is no escape of mercury into the environment should the sphygmomanometer under test fail. After the test, visually inspect to check that there is no leakage of mercury from the manometer of the sphygmomanometer.

13 Test for durability of markings

To comply with the requirement of R 148-1, 6.7, the following test shall be performed.

Check compliance by inspection and the following tests.

After all the other tests of this Recommendation 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.