



Third Committee Draft (3CD) – Marked version

Project: Revision of R 16-1:2002 *(see BIML note on p3)*
Title: R xxx *Non-invasive non-automated sphygmomanometers*
Part 2: Test procedures

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Project Group: OIML TC 18/SC 1/p 1
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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every five years after publication by the responsible TC/SC to decide whether they should be confirmed, revised, or withdrawn.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 16-1 *Non-invasive mechanical sphygmomanometers* after the project for revision was approved at the 43rd CIML Meeting held in October 2008 in Sydney.

During this work, the convener 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 16-1 are the following:

- OIML R16-1 should be revised into three parts according to OIML B 6, and now OIML Rxxx-2 refers to *Part 1 – Test procedures*;
- “*Mechanical sphygmomanometers*” has been replaced by “*Non-automated sphygmomanometers*” to clarify the main distinction between types of sphygmomanometers. This is also an argument consistent with the new ISO/IEC standards;
- Those terms that are no longer used have been deleted;
- “A manual system for applying and releasing pressure” has been replaced by “a pneumatic system” to harmonise the term and also to allow for electro-mechanical control;
- The metrological requirements on MPEs no longer distinguish between “the first time” and “in use”, and the value has finally been set at “0.4 kPa (3 mmHg)” in consideration of recent technical developments in health care;
- In consideration of environmental and health protection, the requirement on the internal diameter of the mercury tube has been deleted to encourage the reduction of the total mercury volume;
- Parts of safety requirements are clarified in agreement with, or according to, the new ISO/IEC standards;
- Verification no longer distinguish between “initial” and “subsequent”;

The current document is the third Committee Draft (3CD). It was drawn up on the basis of the comments received from PG members on the second 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.

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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 16-1, 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 16-1:2002 (E).

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Non-invasive Non-automated Sphygmomanometers

Part 2: Test procedures

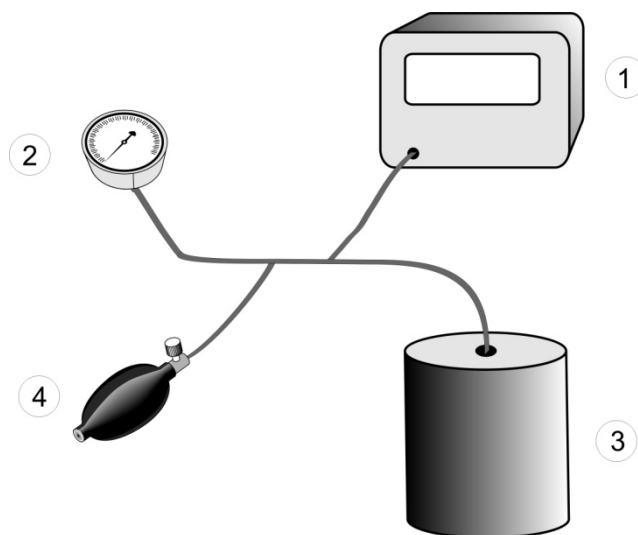
1 Test for the maximum permissible errors of the cuff pressure indication

1.1 Apparatus

- rigid metal vessel with a capacity of 500–ml \pm 25 ml;
- calibrated reference manometer with maximum permissible error within ± 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 the calibrated reference manometer by means of a T-piece connector and hoses to the pneumatic system (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 7–kPa (50–mmHg) between 0–kPa (0–mmHg) and the maximum pressure of the scale range.



- 1 - Reference manometer; 2 - ~~the device to be tested~~ 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 the influence of temperature on cuff pressure indication

2.1 Apparatus

- apparatus as specified in 1.1; plus
- a climatic chamber, ~~Non~~uniformity of temperature within ± 1 °C, ~~Instability~~ instability of temperature within ± 1 °C, ~~Non~~uniformity of relative humidity within ± 5 %, ~~Instability~~ instability of relative humidity within ± 5 %.

2.2 Procedure

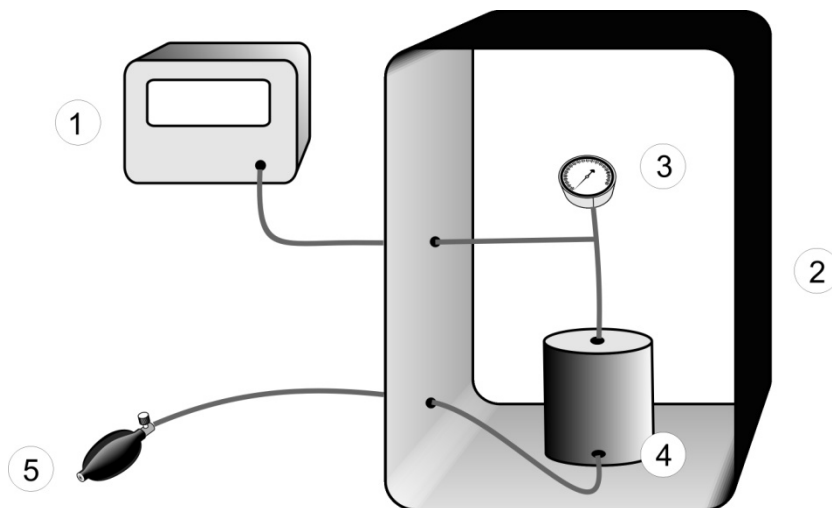
Replace the cuff with the vessel.

Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system (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~~ manometer; 2 - Climatic chamber
 3 - Manometer of the device to be ~~tested~~ 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 the maximum permissible error after storage

3.1 Apparatus

Apparatus as specified in 2.1.

3.2 Procedure

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system (see Figure 23). 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 in Rxxx-1 5.2.

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

After at least one hour at a temperature of $20\text{--}^{\circ}\text{C} \pm 5\text{--}^{\circ}\text{C}$, 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 Rxxx-1, 6.2.1, the following test shall be performed.

4.1 Apparatus

- rigid metal cylinder of an appropriate size ~~(see Rxxx-1 6.1)~~;
- pressure generator, e.g. Ball pump (hand pump) with a deflation valve;
- time measuring device with 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 $(7\text{--} \pm 2)\text{--}\%$.

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

Carry out the test over the whole measuring range at ~~at~~ least three equally spaced pressure steps (e.g. 7-- kPa (50-mmHg), 20-- kPa (150-mmHg), and 34-- kPa (250-mmHg)). Test the air leakage over a period of 5-- min and determine the measured value from this.

4.3 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 Rxxx-1, 6.2.2, the following test shall be performed.

5.1 Apparatus

- T-piece connector;
- calibrated reference manometer with signal output and maximum permissible error within $\pm 0.1\text{--}$ kPa ($\pm 0.8\text{--}$ 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 ~~intention~~[recommendation](#) is to use artificial limbs, but measurements performed with human volunteers are acceptable.

Note 2: It is ~~intended~~[recommended](#)— that the properties of the artificial limbs reflect some elastic properties of human limbs.

Because cuff deflation rate may be influenced by the way that a 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 limb circumferences for which a particular size of cuff is recommended to be used. A resetting of 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 Rxxx-1, 6.2.3, the following test shall be performed.](#)

6.1 Apparatus

- rigid metal cylinder of an appropriate size (see Rxxx-1 6.1);
- pressure generator if necessary, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connector;
- time measuring device with 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 by means of a T-piece to the pneumatic system. Inflate to the maximum pressure and open the rapid exhaust valve. Measure the time between the pressure values specified in Rxxx-1 6.2.3.

6.3 Expression of results

Express the result as the time for the pressure reduction from 35—kPa to 2—kPa (260—mmHg to 15—mmHg)

7 Test for the thickness of the scale marks and the scale spacing

[To comply with the requirement of Rxxx-1, 6.3.2.4, the following test shall be performed.](#)

7.1 Apparatus

- 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

8.1 Apparatus

- collecting vessel of an adequate size;
- calibrated reference manometer, with a nominal range up to at least 41.3_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 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

9.1 Apparatus

- pressure generator, e.g. ball pump (hand pump) with a deflation valve.
- time measuring device with 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 27_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 27_kPa (200_mmHg) mark to the 5_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 Rxxx-1, 6.5.4, the following test shall be performed.](#)

10.1 Apparatus

- rigid metal vessel, with a capacity of 500_ml \pm 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;
- time measuring device with maximum permissible error of 0.1_s.

10.2 Procedure

Replace the cuff with the vessel.

Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system. 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 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 Rxxx-1, 6.5.5, the following test shall be performed.

11.1 Apparatus

- 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 A-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 durability of markings

Check compliance by inspection and the following tests.

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

- 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;
- Adhesive labels shall not have worked loose or become curled at the edges.