Second Committee Draft (2CD) – Marked version

Project:	Revision of R 16-1:2002 *(see BIML note on p3)*
Title:	R xxx *Non-invasive Non-automated Sphygmomanometers* *Part 1: Metrological and technical requirements*
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Explanatory note

According to OIML B6 "Directives for OIML technical work", each recommendation shall be reviewed every five years after its publication by the responsible TC/SC to decided whether it should be confirmed, revised, or withdrawn. The present (old) R16 which TC18/SC1 is responsible for was published in 2002, and it's identified that there are a few technical conflicts between new ISO/IEC standard and OIML R16. To avoid different requirements worldwide on blood pressure instruments, the secretariat started the work on drafting R16-1 *"None-invasive mechanical sphygmomanometers"* after the project of revision was approved at the 43rd CIML Meeting held in October 2008 in Sydney.

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

The main changes proposed to R16-1 are the following:

- OIML R16-1 should be revised into three parts according to OIML B6, and now OIML R16-1 is refer to part 1 Metrological and technical requirements;
- "Mechanical Sphygmomanometer" is 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 on the context are deleted;
- "A manual system for applying and releasing pressure" is replaced by "a pneumatic system" to correspond with the term and also leave some room for electro-mechanical control;
- The metrological requirements on MPE no longer distinguish between "the first time" and "in use", and the value is put at "0.4kPa(3mmHg)" finally in consideration of the recent technical developments and health care concerned;
- In consideration of environmental and health protection, the requirement on internal diameter of the mercury tube is deleted to encourage an approach to reduce 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";
- ~~Additional technical parameters of some devices in annex A are given;~~

The present document constitutes the second Committee Draft (2CD). It was drawn up on the basis of the conclusions of comments from member nations on the first Committee Draft circulated since July 2011. 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

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 xxx, 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 1: Metrological and technical requirements

~~OIML R 16-1 201X (E)~~
~~Revised English Version~~

1. Scope

This Recommendation specifies general, performance, efficiency and mechanical and electrical safety requirements, including test methods for type approval, for non-invasive, non-automated sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure. The application of the cuff is not limited to a particular extremity of the human body (e.g. the upper arm)

Included within the scope of this Recommendation are sphygmomanometers with a mechanical or integrated electro-mechanical pressure sensing element and display, used in conjunction with a stethoscope or other methods for detecting Korotkoff sounds and for cuff inflation.

~~*Note:* Luer locks shall not be used with these devices (see 7.5).~~ (Move to 6.6.5)

2. Terminology (reordered)

2.1 Non-automated sphygmomanometer (2.7 in CD1)

Sphygmomanometer which allows a trained person to use an inflatable cuff for the non-invasive measurement estimation of the arterial blood pressure by means of the cuff pressure display. (See also Note under 3.)

2.2 Non-invasive blood pressure measurement (2.3 in CD1)

Indirect measurement of the arterial blood pressure without arterial puncture.

2.3 Pneumatic system (2.4 in CD1)

System that includes all pressurized and pressure-controlling parts such as cuff, tubing, connectors, valves, transducer and pump.

2.4 Cuff (2.2 in CD1)

Component of the sphygmomanometer, comprising a bladder and a sleeve, which is wrapped around the limb of the patient.

2.5 Bladder (2.1 in CD1)

Inflatable component of the cuff.

~~**2.6 Sphygmomanometer**~~

~~Instrument used for the non-invasive measurement of the arterial blood pressure.~~

2.6 Sleeve (2.5 in CD1)

Essentially inelastic part of the cuff that encloses the bladder.

2.7 Deflation valve (2.9 in CD1)

Valve for controlled exhaust of the pneumatic system during measurement.

2.8 Auscultatory method

Technique whereby sounds (known as Korotkoff sounds) are heard over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with the systolic blood pressure and the disappearance of sounds with the diastolic blood pressure in adults. In children under age of 13, “k4” (i.e. 4th phase Korotkoff sound) may be appropriate.

2.9 Rapid exhaust valve (2.10 in CD1)

Valve for rapidly exhausting the pneumatic system.

2.10 Tamper proofing (2.11 in CD1)

Means of preventing the user from gaining easy access to the measuring mechanism of the device.

3. Description of the category of instrument

The basic components of a sphygmomanometer are a cuff that can be wrapped around a patient’s limb, a pneumatic system for applying and releasing pressure in the bladder, and a means of measuring and displaying the instantaneous pressure in the bladder.

Non-automated sphygmomanometers typically use either a mercury or an aneroid manometer or another mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff.

Note: Components of these devices are manometer, cuff, valve for deflation (often in combination with rapid exhaust valve), hand pump or electromechanical pump and connection hoses. These devices may also contain electro-mechanical components for pressure control.

4. Units of measurement

The blood pressure shall be indicated either in kilopascal (kPa) or in millimeter of mercury (mmHg).

5. Metrological requirements

~~**5.1 Maximum permissible errors of the cuff pressure indication**~~

~~*5.1.1 Under ambient conditions*~~

~~For any set of conditions within the ambient temperature range of 15℃ to 25℃ and the relative humidity range of **15**% to 85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be **±0.4kPa (±3 mmHg)**for sphygmomanometers.~~

~~Testing shall be carried out in accordance with **A.1**.~~

5.1 Maximum permissible errors of the cuff pressure indication under ambient conditions

For any set of conditions within the ambient temperature range of 15℃ to 25℃ and the relative humidity range of 15% to 85% for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ±0.4 kPa (±3 mmHg)for sphygmomanometers.

~~Testing shall be carried out in accordance with A.1.~~

~~*5.1.2 Under storage conditions*~~

~~The sphygmomanometer shall maintain the maximum permissible error requirements for the measurement of the cuff air pressure specified in this Recommendation (5.1.1) after storage for 24 h at a temperature of -20℃ and for 24 h at a temperature of 70℃ and a relative humidity of 85% (non-condensing). **The test shall be performed with the unpacked sphygmomanometer.**~~

~~Testing shall be carried out in accordance with A.3.~~

5.2 Maximum permissible errors of the cuff pressure indication under storage conditions

The sphygmomanometer without electronic components shall maintain the maximum permissible error requirements for the measurement of the cuff pressure specified in this Recommendation (5.1) after storage for 24 h at a temperature of -20℃ and for 24 h at a temperature of 70℃ and a relative humidity of 85% (non-condensing).

The sphygmomanometer with electronic components shall maintain the maximum permissible error requirements for the measurement of the cuff pressure specified in this Recommendation (5.1) after storage for 24 h at a temperature of -5 °C and for 24 h at a temperature of 50 °C and a relative humidity of 85% (non-condensing).

The test shall be performed with the unpacked sphygmomanometer. ~~Testing shall be carried out in accordance with A.3.~~

~~*5.1.3 Under varying temperature conditions*~~

~~For the ambient temperature range of 10℃ to 40℃ and the relative humidity of 85% (non-condensing), the difference **between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.4) at the relevant temperature value**~~

~~shall not exceed **±0.4kPa (±3 mmHg)**.~~

~~Testing shall be carried out in accordance with A.2.~~

5.3 Maximum permissible errors of the cuff pressure indication under varying temperature conditions

For the ambient temperature range of 10℃ to 40℃ and the relative humidity of 85% (non-condensing), the difference between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.4) at the relevant temperature value shall not exceed ±0.4 kPa (±3 mmHg) or ±2 % of the reading, whichever is greater.

~~Testing shall be carried out in accordance with A.2.~~

Note：The requirement of this subclause does not apply to mercury manometers.

6. Technical requirements

6.1 Technical requirements for the cuff and bladder

The cuff shall contain a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents (see 7.5).

The bladder length should be approximately 0,80 x the circumference of the limb at the midpoint of the intended range of the cuff. The width of the bladder should be at least 0,40 x the circumference of the limb at the midpoint of the intended range of the cuff.

***Note:* These recommended dimensions are subject to ongoing consideration.**

6.2 Technical requirements for the pneumatic system

6.2.1 Air leakage

Air leakage shall not exceed a pressure drop of 0.5 kPa/min (4 mmHg/min).

~~Testing shall be carried out in accordance with A.4.~~

~~*6.2.2 Pressure reduction rate*~~

~~**The pneumatic system** deflation valves shall be capable of adjustment to a deflation rate from 0.3kPa/s to 0.4kPa/s (2mmHg/s to 3mmHg/s).~~

~~**The pneumatic system** deflation valves shall be easily adjusted to these values.~~

~~Deflation valves shall be tested in accordance with A.5.~~

6.2.2 Pressure reduction rate

The deflation valves in the pneumatic system shall be capable of adjustment to a deflation rate from 0.3kPa/s to 0.4kPa/s (2mmHg/s to 3mmHg/s).

The deflation valves in the pneumatic system shall be easily adjusted to these values.

~~Deflation valves shall be tested in accordance with A.5.~~

6.2.3 Rapid exhaust

During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s.
~~Testing shall be carried out in accordance with A.6.~~

6.3 Technical requirements for the pressure indicating devices

6.3.1 Nominal range and measuring range

The nominal range shall be equal to the measuring range.
The nominal range for the cuff ~~gauge~~ pressure indication shall extend from 0 kPa to at least 35 kPa (0 mmHg to at least 260 mmHg).

6.3.2 Analogue indication

6.3.2.1 Scale
The scale shall be designed and arranged so that the measuring values can be read clearly and are easily recognized.
Testing shall be carried out by visual inspection.

6.3.2.2 First scale mark
The graduation shall begin with the first scale mark at 0 kPa (0 mmHg).
Testing shall be carried out by visual inspection.

6.3.2.3 Scale interval
The scale interval shall be:

- 0.5 kPa for a scale graduated in kPa;
- 2 mmHg for a scale graduated in mmHg.

~~Each **second** scale mark shall be indicated by greater length and each **fourth** scale mark shall be numbered. An example of a scale in mmHg is given in Figure 1.~~

~~**Where the sphygmomanometer uses a manometer with elastic or electro-mechanical sensing elements, no scale mark is needed within the range of 0-2kPa (0-20 mmHg).**~~

In the case for a scale graduated in kPa: Each second scale mark shall be indicated by greater length and each fourth scale mark shall be numbered. In the case for a scale graduated in mmHg: Each fifth scale mark shall be indicated by greater length and each tenth scale mark shall be numbered. An example of a scale in mmHg is given in Figure 1.

For sphygmomanometer with a manometer with elastic or electro-mechanical sensing elements, no graduation is needed within the range of > 0 kPa to < 2 kPa (> 0 mmHg to < 15 mmHg).

Testing shall be carried out by visual inspection.

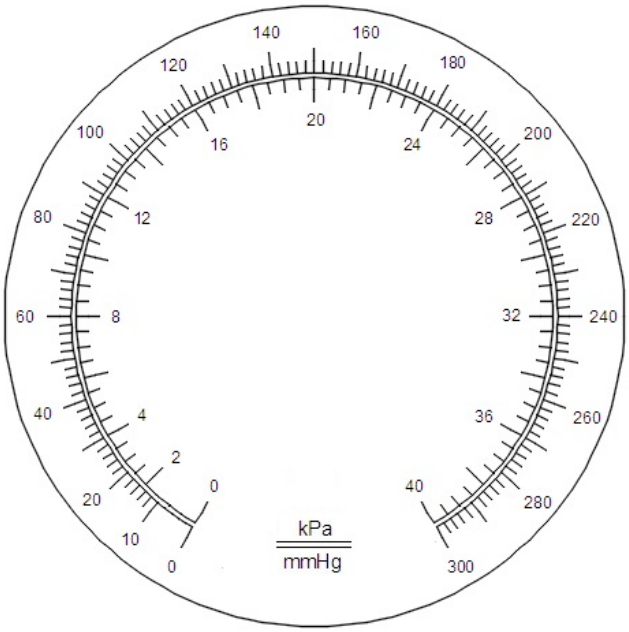

Figure 1 Example of an aneroid manometer scale

(division in mmHg without a tolerance zone at zero)

6.3.2.4 Scale spacing and thickness of the scale marks

The distance between adjacent scale marks shall be not less than 1.0 mm. The thickness of the scale marks shall not exceed 20% of the smallest scale spacing.

All scale marks shall be of equal thickness.

~~Testing shall be carried out in accordance with A.7.~~

6.3.3 Digital indication

The digital scale interval shall be 0.1 kPa (1 mmHg).

If the measured value of a parameter is to be indicated on more than one display, all the displays shall indicate the same numerical value.

Measured numerical values on the display(s), and the symbols defining the units of measurement shall be arranged in such a way so as to avoid misinterpretation.

Numbers and characters should be clearly legible.

Testing shall be carried out by visual inspection.

6.4 Additional technical requirements for mercury manometers

~~*6.4.1 Internal diameter of the tube containing mercury*~~

~~The tolerance on diameter shall not exceed ±0.2 mm (see also 7.4).~~

~~Testing shall be carried out in accordance with A.8.~~

6.4.1 Portable devices

A portable device shall be provided with an adjusting or locking mechanism to secure it in the specified position of use.

Testing shall be carried out by visual inspection.

6.4.2 Devices to prevent mercury from being spilled during use and transport

A device shall be placed in the tube to prevent mercury from being spilled during use and transport (for example: stopping device, locking device, etc.). This device shall be such that when the pressure in the system drops rapidly from 27 kPa to 0 kPa (from 200 mmHg to 0 mmHg), the time taken for the mercury column to fall from 27 kPa to 5 kPa (from 200 mmHg to 40 mmHg) shall not exceed 1.5 s. This time is known as the “exhaust time”.
~~Testing shall be carried out in accordance with A.8 and A.9.~~

6.4.3 Quality of the mercury

6.4.3.1 The mercury shall have a purity of not less than 99.99 % according to the declaration of the supplier of the mercury.
6.4.3.2 The mercury shall exhibit a clean meniscus and shall not contain air bubbles.

6.4.4 Graduation of the mercury tube

Graduations shall be permanently marked on the tube containing mercury. If numbered at each fifth scale mark, the numbering shall be alternately on the right- and left-hand side of, and adjacent to, the tube.
Testing shall be carried out by visual inspection.

6.5 Additional technical requirements for aneroid manometers

6.5.1 Scale mark at zero

If a tolerance zone is shown at zero it shall not exceed ±0.4kPa (±3 mmHg) and shall be clearly marked.

A scale mark at zero shall be indicated.
Note: Graduations within the tolerance zone are optional.
Testing shall be carried out by visual inspection.

6.5.2 Zero

The movement of the elastic sensing element including the pointer shall not be obstructed within 0.8 kPa (6 mmHg) below zero.
Neither the dial nor the pointer shall be adjustable by the user.
Testing shall be carried out by visual inspection.

6.5.3 Pointer

The pointer shall cover between 1/3 and 2/3 of the length of the shortest scale mark of the scale. At the place of indication it shall be not thicker than the scale mark. The distance between the pointer and the dial shall not exceed 2 mm.
Testing shall be carried out by visual inspection.

6.5.4 Hysteresis error

The hysteresis error throughout the pressure range shall ~~be within~~ not exceed the range 0 kPa to 0.5 kPa (0 mmHg to 4 mmHg). ~~Testing shall be carried out in accordance with A.10.~~

6.5.5 ~~Construction and materials~~ Durability of manometer

The construction of the ~~cuff~~ manometer and the material for the elastic sensing elements shall ensure an adequate stability of the measurement. When elastic sensing elements are used, they shall be aged with respect to pressure and temperature. After 10 000 alternating pressure cycles the change in the pressure indication ~~of the cuff manometer~~ shall be not more than 0.4 kPa (3 mmHg) throughout the pressure range. ~~Testing shall be carried out in accordance with A.11.~~

6.6 Safety requirements

6.6.1 Mechanical safety

~~6.6.1.1 Resistance to vibration and shock~~

~~The sphygmomanometer shall comply with the relevant paragraphs of International Document OIML D 11 (e.g. sub-clause A.2.2 of the 1994 edition for mechanical shock).~~

~~After testing, the device shall comply with the requirements of 5.1.1 (of this Recommendation)~~

6.6.1.1 Resistance to shock for handheld sphygmomanometer

Non-automated sphygmomanometers or their parts shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling.

Wall mounted non-automated sphygmomanometers and mecury manometers are exempt from the requirements of this subclause.

The non-automated sphygmomanometer shall function normally following a free fall from a distance d=25 cm.

A non-automated sphygmomanometer that is marked 'Shock Resistant' shall function normally following a free fall from a distance d=1 m.

Allow the non-automated sphygmomanometer to fall freely 6 times (once on each side) from a height of distance d 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.

After testing, the device shall comply with the requirements of 5.1.

6.6.1.2 Non-automated sphygmomanometers used during patient transport

Non-automated sphygmomanometers or their parts, intended for use during patient transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping, and rough handling.

a) Shock ~~according to IEC 60068-2-27~~:

- Peak acceleration: 1 000 m/s^2 (10^2 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~~:

- Frequency range: 10 Hz to 2000 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 2000 Hz: 1.0 (m/s^2)^2/Hz
- Duration: 30 min per each perpendicular axis (3 total)

~~After the test, check that the non-automated sphygmomanometer functions normally by performing the tests in A.1.~~
After testing, the device shall comply with the requirements of 5.1.

6.6.1.3 Non-automated sphygmomanometers containing a mercury manometer
A non-automated sphygmomanometer containing a mercury manometer shall not leak mercury following a free fall from a distance d=1 m ~~in a condition of normal use~~ under conditions of packed.
~~Check compliance by the following test.~~
Allow the non-automated sphygmomanometer to fall freely 6 times (once on each side) from a height of distance d 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 non-automated sphygmomanometer under test fail ~~this test~~.
After the test, visually inspect to check that there is no leakage of mercury from the manometer of the non-automated sphygmomanometer.
After testing, the device shall comply with the requirements of 5.1.

6.6.2 Abort a measurement

It shall be possible to abort the blood pressure measurement at any time by activating the manual rapid exhaust valve, which shall be easily accessible.

6.6.3 Tamper proofing

Means shall be provided to prevent tampering or unauthorized access:
- for all non-automated sphygmomanometers, any adjustment or function that affects accuracy;
- for mercury non-automated sphygmomanometers, the separation of reservoir and scale.

EXAMPLE: Requiring a tool for opening or seal breakage.
It shall be clear to an operator if tampering or unauthorized access has occurred.

6.6.4 Electrical safety

Regional or national regulations may specify electrical safety requirements.

6.6.5 Tubing connectors

Luer lock and Luer slip connectors shall not be used on non-automated sphygomanometers so as to avoid any risk of connecting the output of the non-automated sphygmomanometer to intervascular fluid systems as air might inadvertently be pumped into a blood vessel.

7. Metrological controls

Regional or national regulations may prescribe type approval, initial and/or ~~periodic~~ subsequent verification for noninvasive sphygmomanometers. These controls shall meet the following conditions.

7.1 Type approval

At least three samples of a new type of sphygmomanometer shall be tested.
The tests to verify conformity to metrological and technical requirements shall be carried out according to ~~Annex A~~OIML R16-2. A test report shall be prepared according to ~~Annex B~~OIML R16-3.

7.2 Verification

After type approval has been granted, verification shall be carried out before the non-automated sphygmomanometer is put into use and during its lifetime. At verification, testing can be conducted at any set of climatic conditions within the temperature range of 15 °C to 25 °C and the relative humidity range of 15 % to 85 %. A climatic chamber is not required.

~~Each instrument of an approved type of sphygmomanometer **shall be verified periodically in accordance with applicable metrological laws and regulations of a member state** or after repair. At least 5.1.1 shall be fulfilled and tests must be carried out according to A.1.~~
Each instrument of an approved type of non-automated sphygmomanometer shall be verified periodically in accordance with applicable metrological laws and regulations of a member state, or after repair. At least the requirements of 5.1 and 6.2.1 shall be fulfilled.
~~Testing shall be carried out according to A.1 and A.4.~~

7.3 Sealing

7.3.1 Control marks will be put on lead seals for which corresponding punched screws shall be attached whenever necessary. These seals shall prevent, without destruction of the control marks:

- in the case of mercury manometers: the separation of reservoir and scale;
- in the case of all other manometers: the opening of the casing.

7.3.2 If the construction of the instrument guarantees security against any interference, the metrological control marks or the security marks may be attached in form of labels.

7.3.3 All seals shall be accessible without using a tool.

7.4 Marking of the device

The device shall be marked with the following information:

- name and/or trademark of manufacturer;
- serial number and year of fabrication;
- measuring unit;
- type approval number (if applicable);
- on the cuff an indication of the correct positioning for the cuff over the artery;
- on the cuff an indication of the limb circumference for which it is appropriate (see 6.1);
- information for containing mercury are required for mercury manometers.

7.5 Manufacturer’s information

Information supplied by the manufacturer shall comply with the specifications and requirements given in this Recommendation.

The manufacturer’s instruction manual shall contain the following information:

- reference to OIML R 16~~-1~~, including the complete title;
- explanation of the operating procedures which are important for correct application (such as the selection of the appropriate cuff size, positioning of the cuff at the heart level and adjustment of the pressure reduction rate);
- ~~a warning to users of equipment intended for use in environments employing intervascular fluid systems not to connect the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used;~~

- methods for cleaning reusable cuffs;
- nature and frequency of the maintenance required to ensure that the device operates correctly and safely at all times; ~~it is recommended that the performance should be checked at least every 2 years and after maintenance and repair, by re-verifying at least the requirements in 5.1.1, 6.2.1 (testing at least at 7 kPa (50 mmHg) and 27 kPa (200 mmHg)) and 6.4.4;~~ a disclosure that applicable national or regional metrological laws and regulations have to be taken into account;
- detailed instructions for the safe handling of mercury (see Annex ~~C~~A).

Annex A: Advice to be included in the instructions accompanying a sphygmomanometer using a mercury manometer

(Informative)

A.1. Guidelines and precautions

A mercury-type sphygmomanometer should be handled with care. In particular, care should be taken to avoid dropping the instrument or treating it in any way that could result in damage to the manometer. Regular checks should be made to ensure that there are no leaks from the inflation system and to ensure that the manometer has not been damaged so as to cause a loss of mercury.

A.2. Health and safety when handling mercury

Exposure to mercury can have serious toxicological effects; absorption of mercury results in neuropsychiatric disorders and, in extreme cases, of nephrosis. Therefore precautions should be taken when carrying out any maintenance to a mercury-type sphygmomanometer.

When cleaning or repairing the instrument, it should be placed on a tray having a smooth, impervious surface which slopes away from the operator at about 10° to the horizontal, with a water-filled trough at the rear. Suitable gloves (e.g. of latex) should be worn to avoid direct skin contact. Work should be carried out in a well-ventilated area, and ingestion and inhalation of the vapor should be avoided.

For more extensive repairs, the instrument should be securely packed with adequate padding, sealed in a plastic bag or container, and returned to a specialist repairer. It is essential that a high standard of occupational hygiene is maintained in premises where mercury-containing instruments are repaired. Chronic mercury absorption is known to have occurred in individuals repairing sphygmomanometers.

A.3. Mercury spillage

When dealing with a mercury spillage, wear latex gloves. Avoid prolonged inhalation of mercury vapor. Do not use an open vacuum system to aid collection.

Collect all the small droplets of split mercury into one globule and immediately transfer all the mercury into a container, which should then be sealed.

After removal of as much of the mercury as practicable, treat the contaminated surfaces with a wash composed of equal parts of calcium hydroxide and powdered sulfur mixed with water to form a thin paste. Apply this paste to all the contaminated surfaces and allow to dry. After 24 h, remove the paste and wash

the surfaces with clean water. Allow to dry and ventilate the area.

A.4. Cleaning the manometer tube

To obtain the best results from a mercury-type sphygmomanometer, the manometer tube should be cleaned at regular intervals (e.g. under the recommended maintenance schedule). This will ensure that the mercury can move up and down the tube freely, and respond quickly to changes in pressure in the cuff.

During cleaning, care should be taken to avoid the contamination of clothing. Any material contaminated with mercury should be sealed in a plastic bag before disposal in a refuse receptacle.