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OIML TC 18/SC1 Project p1 Revision of "None-invasive mechanical sphygmomanometers", OIML R16-1 Secretariat: Mr. Cui Qiming - P.R.CHINA		Circulated to P- and O- members and liaison international bodies and external organizations for: ☐ Discussion at (date and place for meeting): …… ☑ Comments by 30 September 2010 ☐ Vote (P-member only) and comments

Title of the CD (English):

Non-invasive Non-automated Sphygmomanometers

Original version in English

Participating Nations:

AUSTRIA, BRAZIL, CZECH REPUBLIC, GERMANY, JAPAN, P.R. CHINA
POLAND, SERBIA, SLOVAKIA, SLOVENIA, UNITED STATES

Observing Nations:

AUSTRALIA, BULGARIA, CANADA, FINLAND, INDONESIA, NETHERLANDS
RUSSIAN FEDERATION, SPAIN, SRI LANKA, SWITZERLAND

Liaisons:

IEC, International Electro-technical Commission
WHO, World Health Organization

Explanatory note

According to OIML B06 "Directive for The 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every five years after its publication by the responsible TC/SC to decided whether it should be confirmed, revised, or withdrawn.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 on October 2008 in Sydney (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:

- "Mechanical Sphygmomanometer" is replaced by "Non-automated Sphygmomanometers" to clarify the important differ between OIML R16-1 and -2. 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 first Committee Draft (1CD). It was drawn up on the basis of the conclusions of comments from member nations on the Working Draft circulated since July 8, 2009.

Definitions and references related to the International vocabulary of metrology – Basic and general concepts and associated terms (VIM) have been modified according to the 2007 edition.

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 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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Bureau International de Métrologie Légale
11, rue Turgot - 75009 Paris - France
Telephone: 33 (0)1 48 78 12 82
Fax: 33 (0)1 42 82 17 27
E-mail: biml@oiml.org

Non-invasive Non-automated Sphygmomanometers

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).

2. Terminology

2.1 Bladder

Inflatable component of the cuff.

2.2 Cuff

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

2.3 Non-invasive blood pressure measurement

Indirect measurement of the arterial blood pressure without arterial puncture.

2.4 Pneumatic system

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

2.5 Sleeve

Essentially inelastic part of the cuff that encloses the bladder.

2.6 Sphygmomanometer

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

2.7 Non-automated sphygmomanometer

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 pressure display of a cuff manometer.** (See also Note under 3.)

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 Deflation valve

Valve for controlled exhaust of the pneumatic system during measurement.

2.10 Rapid exhaust valve

Valve for rapidly exhausting the pneumatic system.

2.11 Tamper proofing

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.

Mechanical 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 kilo-Pascal (kPa) or in millimeters 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**.

5.1.2 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.

5.1.3 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.

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.

6.2.3 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 10s.

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 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).

Testing shall be carried out by visual inspection.

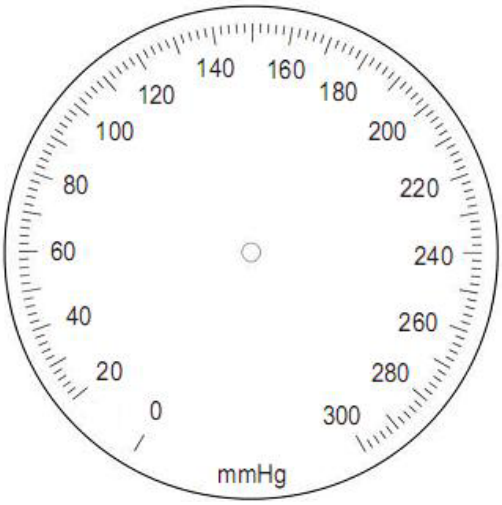


Figure 1 Example of an aneroid manometer scale

(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.

6.4 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.

6.4.2 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.

6.4.3 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.9 and A.10.

6.4.4 Quality of the mercury

6.4.4.1 The mercury shall have a purity of not less than 99.99 % according to the declaration of the supplier of the mercury.

6.4.4.2 The mercury shall exhibit a clean meniscus and shall not contain air bubbles.

6.4.5 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 the range 0 kPa to 0.5 kPa (0 mmHg to 4 mmHg). Testing shall be carried out in accordance with A.11.

6.5.5 Construction and materials

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.12.

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)

6.6.1.2 Non-automated sphygmomanometers for 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 60068-2-27:1987
- 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: 1993
- 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 5.1.1

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.

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/m3) 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.

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.

7. Metrological controls

Regional or national regulations may prescribe type approval, initial and/or periodic 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. A test report shall be prepared according to Annex B.

7.2 Verification

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.

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

• **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).

The following additional markings are required for mercury manometers:

- symbol for “see instructions for use”;
- indication of the internal nominal diameter and the tolerance of the tube containing mercury (see 6.4.1).

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 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;
- internal nominal diameter and tolerance of the tube containing mercury; and
- detailed instructions for the safe handling of mercury (see Annex C).

Annex A

Test procedures

(Mandatory)

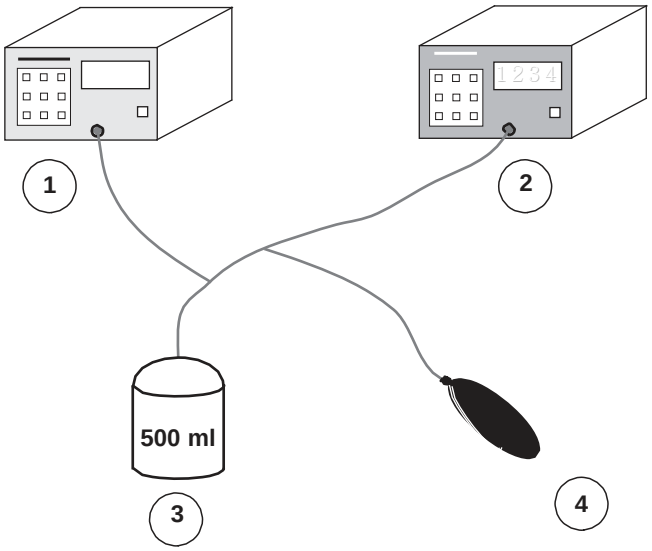
A.1 Method of test for the maximum permissible errors of the cuff pressure indication

A.1.1 Apparatus

- rigid metal vessel with a capacity of 500 ml ±5%;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors
- **Low-elastic rubber hoses with overall length no more than 600 mm**

A.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 2). 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 - Manometer of the device to be tested;
3 - Metal vessel; 4 - Pressure generator

Figure 2 Measurement system for determining the limits of error of the cuff pressure indication

A.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 (see B.2).

A.2 Method of test for the influence of temperature on cuff pressure indication

A.2.1 Apparatus

- apparatus as specified in A.1.1; plus
- a climatic chamber. **(Accuracy of temperature less then ±1°C and humity less than ±5%)**

A.2.2 Procedure

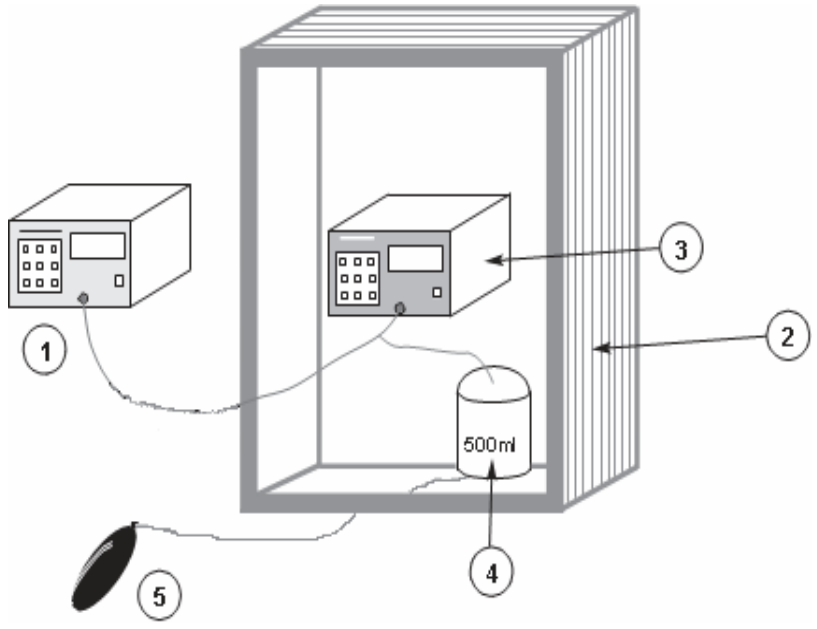
Replace the cuff with the vessel.

Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system (see Figure 3). 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℃ ambient temperature, 85 % relative humidity (non-condensing);
- 20℃ ambient temperature, 85 % relative humidity (non-condensing);
- 40℃ ambient temperature, 85 % relative humidity (non-condensing).

Carry out the test of the cuff pressure indication as described in A.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 3 Measurement system for determining the influence of temperature

A.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 (see B.4) at the relevant

temperature value.

A.3 Method of test for the maximum permissible error after storage

A.3.1 Apparatus

Apparatus as specified in A.1.1.

A.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 3). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pneumatic system by means of another T-piece connector. Store the instrument under test for 24 h at a temperature of -20℃ and subsequently for 24 h at a temperature of 70℃ and a relative humidity of 85 % (no condensing).

Note: This is one test and not two separate tests.

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.

A.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 (see B.3).

A.4 Method of test for air leakage of the pneumatic system

A.4.1 Apparatus

- rigid metal cylinder of an appropriate size (see 6.1);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- time measuring device with **minimum resolution of 0.1s**

A.4.2 Procedure

Wrap the cuff around the cylinder.

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 five equally spaced pressure steps (e.g. 7 kPa (50 mmHg), 13 kPa (100 mmHg), 20 kPa (150 mmHg), 27 kPa (200 mmHg) and 34 kPa (250 mmHg)). Test the air leakage over a period of 5 min and determine the measured value from this.

A.4.3 Expression of results

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

A.5 Method of test for pressure reduction rate for deflation valves

A.5.1 Apparatus

- T-piece connector;
- calibrated reference manometer with signal output and an uncertainty less than 0.1 kPa (0.8 mmHg);
- artificial limbs (see Notes under A.5.2);
- recording unit.

A.5.2 Procedure

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

Note 1: The intention is to use artificial limbs, but as these are still under consideration, measurements performed with human volunteers are acceptable.

Note 2: It is intended 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.

A.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.

A.6 Method of test for the rapid exhaust valve

A.6.1 Apparatus

- rigid metal cylinder of an appropriate size (see 6.1);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connector;
- time measuring device with **minimum resolution of 0.1s**

A.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.

A.6.3 Expression of results

Measure the time between the pressure values specified in 6.2.3.

A.7 Method of test for the thickness of the scale marks and the scale spacing

A.7.1 Apparatus

- scaled magnifying lens or similar device.

A.7.2 Procedure

Determine the thickness of the scale marks and the scale spacing using the scaled magnifying lens.

A.8 Method of test for the internal diameter of the mercury tube

A.8.1 Apparatus

- limit plug gauges or similar devices, with a tolerance less than 0.05 mm.

A.8.2 Procedure

Test the nominal internal diameter of the tube at each end by using the limit plug gauge.

A.9 Method of test for security against mercury losses

A.9.1 Apparatus

- collecting vessel of an adequate size;
- calibrated reference manometer, with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connector;
- pressure generator, e.g. ball pump (hand pump) with a deflation valve.

A.9.2 Procedure

- collecting vessel of an adequate size;
- **alternative** manometer, with an uncertainty **less than 1mmHg**;
- T-piece connector;
- pressure generator, e.g. ball pump (hand pump) with a deflation valve.
- **time measuring device with minimum resolution of 0.1s**

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.

A.10 Method of test for the influence of the mercury stopping device

A.10.1 Apparatus

- pressure generator, e.g. ball pump (hand pump) with a deflation valve.
- time measuring device **with minimum resolution of 0.1s**

A.10.2 Procedure

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.

A.11 Method of test for the hysteresis error of the aneroid manometer

A.11.1 Apparatus

- rigid metal vessel, with a capacity of 500 ml ±5 %;
- calibrated reference manometer, with an uncertainty less than 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 minimum resolution of 0.1s**

A.11.2 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.

Disconnect the calibrated reference manometer during the 5 min at maximum pressure.

A.11.3 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.

A.12 Method of test for the construction

A.12.1 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.

A.12.2 Procedure

Carry out the procedure specified in A.1.

Connect the aneroid manometer directly to the alternating pressure generator and perform 10 000 alternating pressure cycles.

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.

A.12.3 Expression of results

Express the results as the **changes** between the indicated values on the manometer at the same test pressure steps before and after the stress test.

Express the results as the differences between the indicated values on the manometer at the same test pressure steps before and after the stress test.

Annex B

Test Report Format

(Mandatory for application within the

OIML Certificate System for Measuring Instruments)

Explanatory notes on the test report format

i) General

This Test report format, which is informative with regard to the implementation of OIML Recommendation R 16-1 in national regulations, presents a standardized format for the results of the various tests and examinations to which a type of sphygmomanometer shall be submitted with a view to its approval as well as for the results of verification tests. The tests are listed in Annex A of this International Recommendation.

It is recommended that all metrology services or laboratories evaluating types of sphygmomanometers according to OIML R 16-1 or to national or regional regulations based on OIML R 16-1 use this Test report format, directly or after translation into a language other than English or French.

It is also recommended that this Test report format in English or in French (or in both languages) be transmitted by the country performing these tests to the relevant authorities of another country, under bi- or multi-lateral cooperation agreements.

In the framework of the OIML Certificate System for Measuring Instruments, use of the Test report format is mandatory.

ii) Page numbering and the use of report page formats

In addition to the sequential numbering at the bottom of each page, a space has been left at the top of each page (starting on page 18) for numbering the pages of reports established following this model. In particular, each test is reported individually on a separate page following the relevant format. For a given report, it is advisable to complete the sequential numbering of each page by indicating the total number of pages in the report.

Where required, pressure values in the Tables can be replaced by values expressed in kPa.

Where required, these forms can be copied and used several times in cases where the test in question has to be repeated under varying conditions.

iii) Definitions and formula

For the purposes of this test report format, the following definitions and formula, taken from the International Vocabulary of Basic and General Terms in Metrology **(VIM, 1993 edition)** are used.

Non-invasive Non-automated Sphygmomanometers

OIML R 16 — 1 Edition 2002 (E)

TEST REPORT

TYPE APPROVAL TEST REPORT ☐
VERIFICATION TEST REPORT ☐
(For verification purposes tick those fields which are appropriate for verification according to your national regulations or which are listed in B.1.2 under the heading: Summary of test results for verification.)

Number of report: .....

Object:.....

Type: .....

Serial number: .....

Manufacturer's name and address: .....

.....

.....

Customer's name and address:.....

.....

.....

Date of receipt: .....

Date/period of measurement: ....

Date of report: ..... Number of pages: ....

Issuing Institute's name and address: ....

.....

.....

Characteristic values (principle of measurement, measuring unit,

measuring range, range of display):.....

.....

Additional devices (printer, interface etc.): .....

.....

Reference manometer (serial number, uncertainty, calibration certificate): .....

....

Stamp/signature:

B.1 Test review

B.1.1 Summary of test results for type approval

Clause	Subject	Maximum deviation	Maximum permissible error	Passed	Failed
B.2	Cuff pressure indication				
B.3	Effect of storage on cuff pressure indication				
B.4	Effect of temperature on cuff pressure indication				
B.5	Air leakage rate of the pneumatic system				
B.6	Pressure reduction rate for deflation valves				
B.7	Rapid exhaust valve				
B.8	Resistance to vibration and shock				
B.9	Electrical safety				
B.10	Pressure indicating device				
B.10.1	Nominal range and measuring range				
B.10.2	Analogue indication - Scale				
B.10.3	Analogue indication - First scale mark				
B.10.4	Analogue indication - Scale interval				
B.10.5	Scale spacing and thickness of scale marks				
B.11	Additional technical requirements for mercury manometers				
B.11.1	Internal diameter of the tube containing mercury				
B.11.2	Portable devices				
B.11.3	Device to prevent mercury from being spilled (use/transport)				
B.11.4	Performance of this device				
B.11.5	Quality of the mercury				
B.11.6	Graduation of the mercury tube				
B.12	Additional requirements for aneroid manometer				
B.12.1	Scale mark at zero				
B.12.2	Zero				

B.12.3.1	Pointer length				
B.12.3.2	Pointer thickness				
B.12.4	Hysteresis error				
B.12.5	Construction and materials				
B.13	Tamper proofing				

B.1.2 Summary of test results for verification

Clause	Subject	Maximum deviation	Maximum permissible error	Passed	Failed
B.2	Cuff pressure indication				
B.5	Air leakage rate of the pneumatic system				
B.7	Rapid exhaust valve				
B.9	Electrical safety				
B.11.4	Performance of the device to prevent mercury from being spilled (use/transport)				
B.11.5	Quality of the mercury				
B.12.4	Hysteresis error				
B.13	Tamper proofing				

Note 1: The sequence of the different tests is arbitrary; it follows the sequence of the different clauses in the text. The sequence of testing is at the discretion of the person conducting the tests.

Note 2: To be considered as approved or verified, an instrument must have successfully passed all the applicable tests.

B.2 Maximum permissible errors of the cuff pressure indication

For the limits of temperature and humidity see 5.1.1: the temperature should be between 15℃ and 25℃, the relative humidity should be between 20% and 85%.

To find out the error of the cuff pressure indication proceed as follows (up and down runs) at three different temperatures: e.g. 15℃ and 20% relative humidity, 20℃ and 60% relative humidity and 25℃ and 85% relative humidity.

Table 1 Example: Temperature 20℃ and…% relative humidity

1	2	3	4	5	6	7	8	9	10	11
pressure	1st reading		2nd reading		mean		deviation		hysteresis	
mmHg	up	down	up	down	up	down	up	down	1st reading	2nd reading
0	2	0	0	4	1	2	1	2	2	4
50	52	54	54	54	53	54	3	4	2	0
100	106	100	104	104	105	102	5	2	6	0
150										
200										
250										

maximum deviation: 5 mmHg maximum hysteresis: 6 mmHg

Column 1 = values measured by the reference manometer

Column 2, 3, 4 and 5 = results of the measurement of the instrument under test

Column 6 = (column 2 + column 4) / 2

Column 7 = (column 3 + column 5) / 2

Column 8 = column 6 - column 1

Column 9 = column 7 - column 1

Column 10 = abs (column 2 - column 3)

Column 11 = abs (column 4 - column 5)

Table 2: Temperature 20℃ and…% relative humidity

pressure	1st reading		2nd reading		mean		deviation		hysteresis	
mmHg	up	down	up	down	up		up	down	up	down
0										
50										
100										
150										
200										
300 or max										

Maximum deviation: ..... Maximum hysteresis: .....

Note 1: The hysteresis error is the difference between the indications of the instrument when the same pressure is reached by increasing or decreasing the pressure.

Note 2: The time between up and down run should not be less than 5 minutes at the maximum pressure (see A.11.2). A time difference from the first run to the second run of one hour is recommended.

Is the maximum deviation of all of the readings of the instrument under test and of the reference manometer less than or equal to **±0.4 kPa (±3 mmHg) or ±0.5 kPa (±4 mmHg)** (see 5.1.1)?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.3 Effect of storage on cuff pressure indication

Refer to 5.1.2. Determine the error after the storage for 24 h at a temperature of -20℃ and for 24 h at a temperature of 70℃ and a relative humidity of 85% (refer to Note 1 below).

Note 1: The measurements are to be performed before and after applying the test conditions, respectively:

- First measurement at 20℃ and 60% relative humidity before the test (refer to Table 2);

• Storage of the instrument under test for 24 hours at -20℃ and 85% relative humidity, immediately followed by storage of the instrument under test for 24 hours at 70℃ and 85% relative humidity;

• Second measurement at 20℃ and 60% relative humidity after the test.

The percentages for the relative humidity are arbitrary. The first measurement gives the reference values.

Each measurement requires two readings. Calculate the deviation of the mean of the two readings after storage in Table 3 from the mean calculated in Table 2. The result should be within the error limits mentioned below.

Note 2: These conditions apply for **non-auotomated** blood pressure measuring instruments only.

Table 3 Measurement at 20℃ and 60% relative humidity after storage at -20℃ and 70℃

pressure mmHg	1st reading after storage		2nd reading after storage		mean		deviation between the mean after storage and Table 2	
	up	down	up	down	up	down	up	down
0								
50								
100								
150								
200								
250								
300 or max								

Maximum deviation: .....

Is the maximum deviation of the cuff pressure indication (mean value), after storage at -20℃ and 70℃, less than or equal to **±0.4 kPa (±3 mmHg) or ±0.5 kPa (±4 mmHg)** compared to the mean values at 20℃ and 60% relative humidity before storage?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.4 Effect of temperature on cuff pressure indication

Refer to 5.1.3.

Note 1: For a type approval test report testing has to be carried out also at 10℃ and 40℃ (see A.2.2).

Note 2: Take the first mean of the readings of the measuring instrument before storage as reference value (Table 2) and calculate the deviation of the mean of the values measured after storage (mean values here in Table 4) from the mean values of Table 2. The result should be within the error limits mentioned below.

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.

Table 4 Temperature 10℃ and 85% relative humidity

pressure mmHg	1st reading		2nd reading		mean		deviation from Table 2	
	up	down	up	down	up	down	up	down
0								
50								
100								
150								
200								
250								
300 or max								

Maximum deviation: .....

Table 5 Temperature 40℃ and 85% relative humidity

pressure mmHg	1st reading		2nd reading		mean		deviation from Table 2	
	up	down	up	down	up	down	up	down
0								
50								
100								
150								
200								
250								
300 or max								

Maximum deviation: .....

Is the maximum **difference 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** less than or equal to **±0.4kPa (±3 mmHg)**.

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.5 Air leakage rate of the pneumatic system

Carry out the test over the whole measuring range at five equally spaced pressure steps at least (e.g. 7 kPa (50 mmHg), 13 kPa (100 mmHg), 20 kPa (150 mmHg), 27 kPa (200 mmHg) and 33 kPa (250 mmHg)). Test the air leakage rate over a period of 5 min (see A.4.2), and determine the measured

value from this.

Table 6

pressure	first reading	reading after 5 min	difference between the readings
50mmHg			
100mmHg			
150mmHg			
200mmHg			
250mmHg			

Does the **pressure drop** over a period of 5 minutes correspond to **an air leakage rate** less than or equal to 0.5 kPa/min (4 mmHg/min)?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.6 Pressure reduction rate for deflation valves

The pneumatic system deflation valves shall be capable of adjustment to a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s)? **The pneumatic system** deflation valves shall be easily adjusted to these values.

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.7 Rapid exhaust valve

Testing shall be carried out in accordance with 6.2.3 and A.6.

Time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg):

t_{Re} = s,

Is t_{Re} less than **or equal to** 10s?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.8 Mechanical safety

B.8.1 Resistance to vibration and shock

Refer to **6.6.1.1** the mechanical conditions can be found in OIML D 11 (for example clause A.2.2 of the 1994 edition).

B.8.2 Non-automated sphygmomanometers for transport

The mechanical conditions can be found in 6.6.1.2.

B.8.3 Non-automated sphygmomanometers containing a mercury manometer

The mechanical conditions can be found in 6.6.1.3.

Does the instrument comply with 5.1.1 of this Recommendation after the vibration and shock test?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.9 Electrical safety (This test is optional within the OIML Certificate System)

If the instrument is equipped with electrical devices, do these devices comply with regional and national safety regulations?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.10 Pressure indicating devices

All the tests can be carried out by visual inspection.

For reference see: Scale readable: 6.3.2.1

First scale mark: 6.3.2.2

Scale interval: 6.3.2.3

Scale spacing and thickness of scale marks: 6.3.2.4

B.10.1 Nominal range and measuring range

Does the nominal range extend from 0 kPa to at least 35 kPa (0 mmHg to at least 260 mmHg)?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.10.2 Analogue indication - Scale

Is the scale clearly readable?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.10.3 Analogue indication - First scale mark

Is there a scale mark at 0 kPa (0 mmHg)?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.10.4 Analogue indication - Scale interval

Is the scale interval 0.2 kPa or 2 mmHg for a scale graduated in kPa or mmHg, respectively?

yes ☐	→	passed ☐	
no ☐	→	failed ☐	

B.10.5 Analogue indication - Scale spacing and thickness of scale marks

Is the distance between adjacent scale marks not less than 1.0 mm and does the thickness of the scale marks not exceed 20 % of the smallest scale spacing?

yes ☐	→	passed ☐	
no ☐	→	failed ☐	

Are the scale marks of equal thickness?

yes ☐	→	passed ☐	
no ☐	→	failed ☐	

B.11 Additional technical requirements for mercury manometers

B.11.1 Internal diameter of the tube containing mercury

Is the nominal internal diameter of the mercury tube at least 3.5 mm $\pm$ 0.2 mm?

yes ☐	→	passed ☐	
no ☐	→	failed ☐	

For reference see 6.4.1.

B.11.2 Portable devices

Does the portable device have an adjusting or locking mechanism to secure it in a specified position of use?

yes ☐	→	passed ☐	
no ☐	→	failed ☐	

For reference see 6.4.2.

B.11.3 Device to prevent mercury from being spilled during use and transport

Does the tube have a device to prevent the mercury from being spilled during transport and use and is this device efficient?

yes ☐	→	passed ☐	
no ☐	→	failed ☐	

For reference see 6.4.3.

B.11.4 Influence of the device to prevent mercury from being spilled during use and transport

Does the delay in the setting of the mercury column due to this device **is less than or equal to** 1.5 s for the flow of the mercury from 27 kPa to 5 kPa (from 200 mmHg to 40 mmHg) when the pressure in the system drops rapidly from 27 kPa to 0 kPa (from 200 mmHg to 0 mmHg)?

yes ☐	→	passed ☐
no ☐	→	failed ☐

For reference see 6.4.3.

B.11.5 Quality of the mercury

For type approval only:

Does the supplier confirm that the purity of the mercury is not less than 99.99 %?

yes ☐	→	passed ☐
no ☐	→	failed ☐

For reference see 6.4.4.1

For type approval and for verification:

Does a visual inspection show a clean meniscus and no bubbles of air?

yes ☐	→	passed ☐
no ☐	→	failed ☐

For reference see 6.4.4.2.

B.11.6 Graduation of the mercury tube

Are the graduations permanently marked on the tube containing mercury?

yes ☐	→	passed ☐
no ☐	→	failed ☐

For reference see 6.4.5.

Note: Numbered at each fifth scale mark, the numbering shall be alternately on the right-hand and left-hand side of, and adjacent to, the tube.

All the tests can be carried out by visual inspection.

B.12 Additional requirements for aneroid manometers

B.12.1 Scale mark at zero

If a tolerance zone is shown at zero, is it smaller than **±0.4kPa (±3 mmHg)**?

yes ☐	→	passed ☐
no ☐	→	failed ☐

For reference see 6.5.1.

Note: Graduations within the tolerance zone are optional.

B.12.2 Zero

Is the movement of the elastic sensing element including the pointer **unobstructed** within 0.8 kPa (6 mmHg) below zero?

yes ☐	→	passed ☐
no ☐	→	failed ☐

For reference see 6.5.2.

Note: Neither the dial nor the pointer shall be adjustable by the user.

B.12.3 Pointer

For reference see 6.5.3.

All the tests can be carried out by visual inspection.

B.12.3.1 Pointer length

Does the pointer cover between 1/3 and 2/3 of the length of the shortest scale mark of the scale?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.12.3.2 Pointer thickness

Is the pointer thicker than the scale mark at the place of indication and does the distance between the pointer and the dial **is less than or equal to** 2 mm?

yes ☐	→	passed ☐
no ☐	→	failed ☐

B.12.4 Hysteresis error

Is the maximum hysteresis error throughout the pressure range less than or equal to 0.4 kPa (3 mmHg) according to Table 2?

yes ☐	→	passed ☐
no ☐	→	failed ☐

Note: The purpose of this test is to determine if the elastic sensing element has been exposed to a tension within the elastic range (i.e. the “Hooke’s” range) or not throughout the whole pressure range.

For reference see 6.5.4. The test should be carried out according to A.11.

B.12.5 Construction and materials

Is the difference in the pressure indication of the aneroid manometer after 10 000 alternating pressure cycles more than **±0.4kPa (±3 mmHg)**at any point within the pressure range?

yes ☐	→	passed ☐
no ☐	→	failed ☐

For reference see 6.5.5. The test should be carried out according to A.12. The pressure test has to be performed according to B.2.

Note: The construction of the aneroid manometer and the material for the elastic sensing elements shall ensure an adequate stability of the measurement. The elastic sensing elements shall be aged with respect to pressure and temperature.

B.13 Tamper proofing

Tamper proofing of the manometer shall be achieved by requiring the use of a tool.

Is the manometer tamper proof?

yes ☐	→	passed ☐
no ☐	→	failed ☐

For reference see 6.6.3.

Tests should be done by an appropriate inspection.

Annex C

Advice to be included in the instructions accompanying a sphygmomanometer using a mercury manometer (Informative)

C.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.

C.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¡ã 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.

C.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.

C.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.