INTERNATIONAL RECOMMENDATION

OIML R 148-1

Edition 2020 (E)

Non-invasive non-automated sphygmomanometers

Part 1: Metrological and technical requirements

Sphygmomanomètres non invasifs non automatiques

Partie 1: Exigences métrologiques et techniques

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

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Foreword

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This publication - reference OIML R 148-1, edition 2020 (E) - was developed by OIML Technical Subcommittee TC 18/SC 1 *Blood pressure instruments*. It was approved for final publication by the International Committee of Legal Metrology in 2020 and supersedes OIML R 16-1:2002 (E).

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Non-invasive non-automated sphygmomanometers
Part 1: Metrological and technical requirements

1 Scope

This Recommendation specifies general, performance, efficiency and mechanical 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.

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

2 Terminology

2.1 auscultatory method

method whereby sounds (known as Korotkoff sounds) are heard or detected (e.g. by a microphone) 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

2.2 bladder

inflatable component of the cuff

2.3 cuff

component of the non-invasive non-automated sphygmomanometer, comprising a bladder and a sleeve, which is wrapped around the limb of the patient

Note: A cuff might comprise a bladder and an inelastic part that encloses the bladder, or have an integral bladder (i.e. the cuff including the bladder are fixed together or are one piece).

2.4 deflation valve

valve for controlled exhaust of the pneumatic system during measurement

2.5 diastolic blood pressure (value)

minimum value of the arterial blood pressure as a result of relaxation of the systemic ventricle

Note: Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

2.6 manometer

instrument used to measure and display pressure

2.7 non-invasive non-automated sphygmomanometer

medical measuring instrument used by a trained person for the non-invasive measurement of the arterial blood pressure by utilising an inflatable cuff with a display and used in conjunction with a stethoscope or any other manual methods for estimating blood pressure. Hereafter called sphygmomanometer in this Recommendation

2.8 non-invasive blood pressure measurement

indirect measurement of the arterial blood pressure without arterial puncture

2.9 pneumatic system

system that includes all pressurised and pressure-controlling parts such as cuff, tubing, connectors, valves, transducer and pump

2.10 rapid exhaust valve

valve for rapidly exhausting the pneumatic system

2.11 sleeve

essentially inelastic part of the cuff that encloses the bladder

2.12 systolic blood pressure (value)

maximum value of the arterial blood pressure as a result of the contraction of the systemic ventricle

Note: Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

2.13 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 manometer for measuring and displaying pressure in the bladder and a pneumatic system for applying and releasing pressure in the bladder.

The pneumatic system includes a cuff that can be wrapped around a patient's limb, tubing, connectors, a valve for deflation (often in combination with rapid exhaust valve), transducers and a hand pump or electromechanical pump. For pressure control, electro-mechanical components may be used.

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.

4 Units of measurement

The units used to indicate blood pressure shall be either the kilopascal (kPa) or the millimetre of mercury (mmHg).

5 Metrological requirements

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

For any set of conditions within an ambient temperature range from 15 °C to 25 °C and a relative humidity range from 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.

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

Sphygmomanometers without electronic components shall maintain the maximum permissible error requirements for the measurement of the cuff pressure specified in 5.1 after storage for 24 h at a low temperature of −20 °C, followed by additional storage for 24 h at a high temperature of 70 °C and at a relative humidity of 85 % (non-condensing).

Sphygmomanometers with electronic components shall maintain the maximum permissible error requirements for the measurement of the cuff pressure specified in 5.1 after storage for 24 h at a low temperature of −5 °C, followed by additional storage for 24 h at a high temperature of 50 °C and at a relative humidity of 85 % (non-condensing).

The storage shall occur with the sphygmomanometers unpacked.

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

For an ambient temperature range from 10 °C to 40 °C and a 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 at the relevant temperature value shall not exceed ±0.4 kPa (±3 mmHg) or ±2 % of the reading, whichever is greater.

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 7.4.2).

The bladder length should be approximately 0.80 × 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 × the circumference of the limb at the midpoint of the intended range of the cuff.

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).

6.2.2 Pressure reduction rate

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

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

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 34.7 kPa to 2.0 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s.

6.3 Technical requirements for the pressure indicating devices

6.3.1 Nominal range and measurement range

The nominal range shall be equal to the measurement range.

The nominal range for the cuff pressure indication shall extend from 0 kPa to at least 34.7 kPa (0 mmHg to at least 260 mmHg).

The nominal range for the cuff pressure measurement shall be disclosed in the accompanying document. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range.

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 recognised.

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.

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

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

Testing shall be carried out by visual inspection.

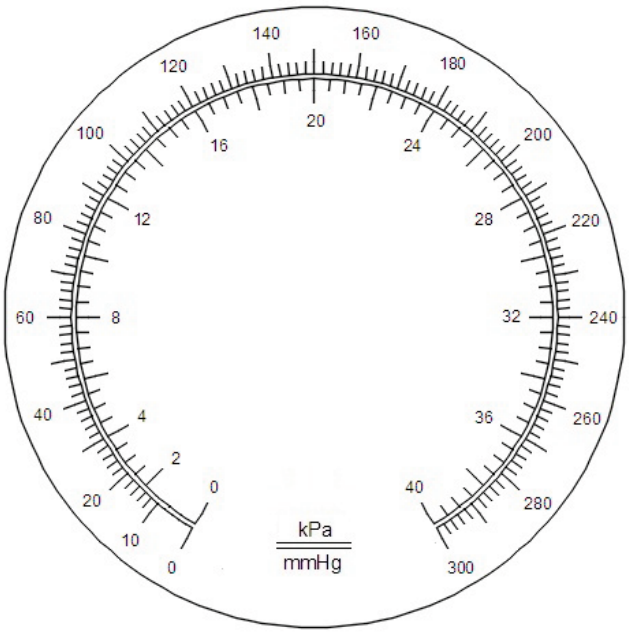

Figure 1 - Example of an aneroid manometer scale

(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.

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 shall be clearly legible.

Testing shall be carried out by visual inspection.

6.4 Additional technical requirements for mercury manometers

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 26.6 kPa to 0 kPa (from 200 mmHg to 0 mmHg), the time taken for the mercury column to fall from 26.6 kPa to 5.3 kPa (from 200 mmHg to 40 mmHg) shall not exceed 1.5 s. This time is known as the "exhaust time".

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 ±0.4 kPa (±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.

6.5.4 Hysteresis error

The hysteresis error throughout the pressure range shall not exceed the range 0 kPa to 0.5 kPa (0 mmHg to 4 mmHg).

6.5.5 Durability of the manometer

The construction of the 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 from 3 kPa (20 mmHg) to full scale, the change in the pressure indication shall be not more than 0.4 kPa (3 mmHg).

6.6 Safety requirements

6.6.1 Mechanical safety

6.6.1.1 Resistance to vibration and shock for handheld sphygmomanometers

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 sphygmomanometers and mercury manometers are exempt from the requirements of this subclause.

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

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

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

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

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.

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

6.6.1.3 Sphygmomanometers containing a mercury manometer

A sphygmomanometer containing a mercury manometer shall not leak mercury following a free fall from a distance, d = 1 m.

After testing, the device shall comply with the requirements of 5.1 at a temperature of 20 °C ± 5 °C and ambient humidity.

6.6.2 Aborting a measurement

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

6.6.3 Unauthorised access and tamper proofing

Means shall be provided to prevent tampering or unauthorised access:

- for all sphygmomanometers, any adjustment or function that affects accuracy;
- for mercury sphygmomanometers, the separation of reservoir and scale.

Example: Requiring a tool for opening or breaking a seal.

It shall be clear to an operator if tampering or unauthorised 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 sphygmomanometer to intervascular fluid systems as air might inadvertently be pumped into a blood vessel.

Note: There is more information about "Small-bore connectors for liquids and gases in healthcare applications" in ISO 80369-1:2018 *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements* and IEC 80369-5:2016 *Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications*.

6.7 Durability of markings

The markings shall be removable only with a tool or by appreciable force and shall be sufficiently durable to remain clearly legible during the expected service life of the sphygmomanometer. In considering the durability of the markings, the effect of normal use shall be taken into account.

7 Metrological controls

Regional or national regulations may prescribe type approval, initial and/or subsequent verification for sphygmomanometers. These metrological controls shall meet the conditions in 7.1–7.5.

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 OIML R 148-2. A test report shall be prepared according to OIML R 148-3.

7.2 Verification

After type approval has been granted, verification shall be carried out before the 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 from 15 °C to 25 °C and the relative humidity range from 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 the requirements of 5.1 and 6.2.1 shall be fulfilled.

7.3 Sealing

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

- 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

7.4.1 Markings required on the indicating device

The indicating device of the sphygmomanometer shall be marked with the following information:

- name and/or trademark of the manufacturer;
- type of sphygmomanometer;
- units of measurement (kPa and/or mmHg), positioned close to the displayed values;
- measurement range;
- type approval number (if applicable);
- serial number;
- year of fabrication;
- country of origin;
- information on the mercury content (required for mercury manometers).

7.4.2 Markings required on the cuff

The cuff of the sphygmomanometer shall be marked with the following information:

- limb circumference for which it is appropriate;
- marking of the limb circumference indication range;
- centre of the bladder, indicating the correct position for the cuff over the artery.

Testing shall be carried out by visual inspection.

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 148, 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);
- methods for cleaning reusable cuffs;

- if the bladder is removable, the method for ensuring the correct repositioning of the bladder in the cuff;
- nature and frequency of the maintenance required to ensure that the device operates correctly and safely at all times;
- disclosure that applicable national or regional metrological laws and regulations shall be considered;
- detailed instructions for the safe handling of mercury (see Annex A);
- list of all components belonging to the pressure measuring system, including accessories;
- remarks on the environmental or operational factors which may affect the performance (e.g. electromagnetic fields, arrythmia);
- specification of the rated voltage, if applicable;
- specification of the intended power source, if applicable;
- measurement range;
- operating and storage temperature, and humidity ranges;
- warm-up time, if applicable;
- description of all symbols, abbreviations and error codes used on the instrument; and
- name and address of manufacturer.

Testing shall be carried out by visual inspection.

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. made 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 vapour 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, latex gloves should be worn. Prolonged inhalation of mercury vapour should be avoided and an open vacuum system should not be used to aid collection.

Any small droplets of spilt mercury should be collected into one globule and immediately transferred into a container, which should then be sealed.

After removal of as much of the mercury as practicable, the contaminated surfaces should be treated with a wash composed of equal parts of calcium hydroxide and powdered sulphur mixed with water to form a thin paste. This paste should be applied to all the contaminated surfaces and allowed to dry. After 24 h, the paste should be removed and the surfaces washed with clean water. The area should be dried and ventilated.

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.