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Non-invasive automated sphygmomanometers

Part 1: Metrological and technical requirements

Sphygmomanomètres non invasifs automatiques

Partie 1: Exigences métrologiques et techniques

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

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

1 Scope

This Recommendation specifies general, performance, efficiency and mechanical safety requirements for non-invasive automated sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

This Recommendation only applies to devices measuring at the arm, the wrist or the thigh.

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 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 mean arterial blood pressure (value)

value of the integral of one cycle of the blood pressure curve divided by the time of one heart beat period

Note: Because of hydrostatic effects, this value should be measured with the cuff at the heart level. The calculation of the mean arterial blood pressure using only the systolic and diastolic blood pressure values is not recommended.

2.8 non-invasive automated sphygmomanometer

medical measuring instrument used for the intermittent non-invasive estimation of the blood pressure by utilising an inflatable cuff, a pressure transducer, a valve for deflation, and/or displays used in conjunction with automated methods for estimating blood pressure. Hereafter referred to as "sphygmomanometer" in this Recommendation

2.9 non-invasive blood pressure measurement

indirect measurement of the arterial blood pressure without arterial puncture

2.10 oscillometric method

method that estimates systolic, diastolic and mean arterial pressures during the slow inflation or deflation of an occluding cuff at the brachial artery

Note: During the inflation and deflation of the cuff, small pressure changes (oscillations) occur in the cuff as a result of the arterial blood pressure pulses. These oscillations are detected and stored together with the corresponding cuff pressure values in the measurement system. With these stored values the systolic, diastolic and mean arterial blood pressure values can be mathematically derived using an appropriate algorithm.

2.11 patient simulator

device for simulating the oscillometric cuff pulses and/or auscultatory sounds during inflation and deflation

Note: This device is not used for testing measurement accuracy but is required in assessing stability of performance.

2.12 pneumatic system

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

2.13 rapid exhaust valve

valve for rapidly exhausting the pneumatic system

2.14 sleeve

essentially inelastic part of the cuff that encloses the bladder

2.15 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.

2.16 tamper proofing

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

2.17 zero adjustment of a measuring system (VIM 3.11)

procedure that corrects a deviation of the pressure reading to 0.0 kPa (0 mmHg) at atmospheric pressure (gauge pressure: 0 kPa (0 mmHg))

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 system for applying and releasing pressure to the bladder in the cuff, and a means of measuring and displaying blood pressure values automatically.

Note 1: Specific device types included in this category are: sphygmomanometers for self-measurement, blood pressure monitors and multi-parameter patient monitors used for home healthcare, or public use.

Note 2: Components of a sphygmomanometer include: manometer, cuff, valve for deflation (often in combination with the valve for rapidly exhausting the pneumatic system), pump for inflation of the bladder, and connection tubing.

4 Units of measurement

The blood pressure shall be indicated either in kilopascals (kPa) or in millimetres 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 the ambient temperature range from 10 °C to 40 °C and the relative humidity range from 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 measurement range shall be ±0.4 kPa (±3 mmHg) or ±2 % of the reading, whichever is greater.

5.2 Maximum permissible errors of the blood pressure measurement as determined by clinical investigation[1]

The following maximum permissible errors shall apply for the sphygmomanometer:

- maximum mean error of measurement: ±0.7 kPa (±5 mmHg);
- maximum experimental standard deviation: 1.1 kPa (8 mmHg).

For further recommended test methods see Annex A.

[1] carried out by the manufacturer

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

The sphygmomanometer shall maintain the requirements specified in this Recommendation 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).

5.4 Blood pressure measurement range

The sphygmomanometer shall be capable of indicating diastolic blood pressure over at least the range from 2.7 kPa (20 mmHg) to 8.0 kPa (60 mmHg) in neonatal mode, and 5.3 kPa (40 mmHg) to 17.3 kPa (130 mmHg) otherwise.

The sphygmomanometer shall be capable of indicating systolic blood pressure over at least the range from 5.3 kPa (40 mmHg) to 14.7 kPa (110 mmHg) in neonatal mode, and 8.0 kPa (60 mmHg) to 30.7 kPa (230 mmHg) otherwise.

5.5 Repeatability of blood pressure indication

For any set of conditions within the ambient temperature range from 10 °C to 40 °C and the relative humidity in the range from 15 % to 85 %, the experimental standard deviation of the blood pressure indication of the sphygmomanometer shall not exceed 0.4 kPa (3 mmHg).

6 Technical requirements

6.1 General

Equipment, or parts thereof, using materials or designs different from those detailed in this Recommendation shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained.

6.2 Technical requirements for the cuff and bladder

The cuff shall contain or incorporate a bladder. The cuff shall be designed and marked (i.e. using permitted circumference indicators) to ensure and restrict the use of the appropriate cuff size corresponding to a given limb circumference.

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.

For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents.

6.3 Effect of voltage variations of the power source

6.3.1 Internal electrical power source

Changes in the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure indication.

Outside this working range no cuff pressure indication and no result of the blood pressure measurement shall be displayed.

6.3.2 External electrical power source

Changes in the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure indication.

Outside the working range specified by the manufacturer, no cuff pressure indication and no result of the blood pressure measurement shall be displayed.

6.4 Pneumatic system

6.4.1 Air leakage

Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min).

6.4.2 Pressure reduction rate of devices using the auscultatory method

The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of 0.3 kPa/pulse to 0.4 kPa/pulse (2 mmHg/pulse to 3 mmHg/pulse) shall be maintained.

Note: Manually operated deflation valves should be easily adjustable to these values.

6.4.3 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.

For the sphygmomanometer having the capability to measure in a neonatal/infant mode, the time for the pressure reduction from 20.0 kPa to 0.7 kPa (150 mmHg to 5 mmHg) during the rapid exhaust of the pneumatic system with the valve fully opened shall not exceed 5 s.

6.4.4 Zero adjustment of a measuring system

The sphygmomanometer shall be capable of automatic zero adjustment. The zero adjustment shall be carried out at appropriate intervals, at least when the device is powered on. After a zero adjustment, the device shall keep the indication of a gauge pressure of 0.0 kPa (0 mmHg).

The sphygmomanometer shall repeat a zero adjustment or shall be switched off automatically when the output of the pressure transducer drifts one scale interval (0.1 kPa or 1 mmHg) or more.

6.4.5 Manometer test mode

The sphygmomanometer shall have a manometer test mode that permits static pressure measurement over at least the nominal blood pressure indication range. This mode shall not be available in normal use, but restricted to service / test personnel.

When the sphygmomanometer is put into the test mode, all air outlets shall be closed.

The manufacturer shall confirm that the test results obtained in 5.1 and 6.4.4 are identical to the results in the normal use mode.

6.4.6 Maximum time for which the cuff is inflated

The total time for which the pressure exceeds 2.0 kPa (15 mmHg) shall be no longer than 180 s in the case of adult patients. The total time for which the pressure exceeds 0.7 kPa (5 mmHg) shall be no longer than 90 s in the case of neonatal/infant patients.

6.5 Electromagnetic compatibility

6.5.1 Immunity

The following requirements apply:

- electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication, i.e. the maximum permissible error for the measurement of the cuff pressure shall be ±0.4 kPa (±3 mmHg) or ±2 % of the reading, whichever is greater; or
- if electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance.

Testing shall be carried out in accordance with 202 of IEC 80601-2-30:2018 *Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*.

6.5.2 Electrosurgery interference recovery

If a sphygmomanometer is intended to be used together with HF surgical equipment, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF surgical equipment, without loss of any stored data.

Testing shall be carried out in accordance with 202.8.101 of IEC 80601-2-30:2018 *Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*.

6.6 Durability

The change in the cuff pressure indication shall not be greater than 0.4 kPa (3 mmHg) throughout the pressure range after 10 000 simulated measurement cycles.

6.7 Technical requirements for the pressure indicating device

6.7.1 Nominal range and measurement range of the cuff pressure measurement

The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measurement range of the cuff pressure shall be equal to the nominal range. Values of blood pressure measurement results outside the nominal range of cuff pressure shall be clearly indicated as out of range.

Testing shall be carried out by visual inspection.

6.7.2 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.

6.7.3 Technical requirements for the display

The display shall be designed and arranged so that all information can be read and easily recognised.

If abbreviations are used on the display they shall be as follows:

- “S” or “SYS”: systolic blood pressure (value);
- “D” or “DIA”: diastolic blood pressure (value);
- “M” or “MAP”: mean arterial blood pressure (value)

Single letter abbreviations shall be positioned in such a way to avoid confusion with SI units.

Testing shall be carried out by visual inspection.

6.8 Signal input and output ports

The construction of the signal input and output ports (excluding internal interfaces, e.g. microphone signal input) relevant to the non-invasive blood pressure measurement shall ensure that incorrectly fitted or defective accessories shall not result in erroneous indication of cuff pressure or erroneous indication of blood pressure.

Note: An error message or a blank display is sufficient.

6.9 Safety requirements

6.9.1 Aborting a measurement

It shall be possible to abort any blood pressure measurement at any time by single key operation and this shall lead to a rapid exhaust (see 6.4.3).

6.9.2 Unauthorised access and tamper proofing

All controls which affect accuracy shall be sealed against unauthorised access.

Tamper proofing of the instrument shall be achieved by requiring the use of a special tool or breaking a seal.

Testing shall be carried out by visual inspection.

It shall be clear to an operator if tampering or unauthorised access has occurred.

6.9.3 Tubing connectors

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

6.9.4 Electrical safety

Regional or national regulations may specify electrical safety requirements.

6.10 Resistance to vibration and shock

The sphygmomanometer or its parts not 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 fixed (e.g. wall mounted) sphygmomanometer is exempt from the requirements of this subclause.

After the test for the resistance to vibration and shock, the sphygmomanometer shall comply with the requirements of 5.1 but only at a temperature of 20 °C ± 5 °C and at ambient humidity.

6.11 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 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 R 149-2. A test report shall be prepared according to R 149-3.

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 10 °C to 40 °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, 5.5 and 6.4.1 shall be fulfilled.

7.3 Sealing

Metrological control marks shall be put on seals. These seals shall prevent, without destruction of the control marks:

- in the case of patient-monitors in which the sphygmomanometer is one part of a system: the manipulation of the metrologically relevant parts for measuring blood pressure;
- in the case of all other sphygmomanometers: the opening of the casing.

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

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/mmHg), positioned close to the displayed values;
- measurement range;
- type approval number (if applicable);
- serial number;
- year of fabrication;
- country of origin.

Testing shall be carried out by visual inspection

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.

For sphygmomanometers applied to the wrist, the marks required in 7.4.1 and 7.4.2 can be positioned on the indicating device or on the cuff.

For sphygmomanometers used for home healthcare environment, the sales packaging shall display information needed by the end user including, as a minimum:

- the operating and storage temperature and humidity ranges;
- any special requirements for a battery-powered sphygmomanometer.

Sphygmomanometers for public use which are intended for self-use in public areas, shall be marked with the following:

- precautions for use, including a statement concerning the need to consult a physician for interpretation of blood pressure measurements;
- adequate operating instructions

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 149 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 which is required to ensure that the device operates correctly and safely at all times;
- disclosure that applicable national or regional metrological laws and regulations have to be considered;
- list of all components belonging to the pressure measuring system, including accessories;
- description of the operating principles of the blood pressure measuring device;
- remarks on the environmental or operational factors which may affect the performance (e.g. electromagnetic fields, arrhythmia);
- specification of the signal input/output port(s);
- specification of the rated voltage, if applicable;
- specification of the intended power source, if applicable;
- measurement range for the systolic and diastolic blood pressure measurements;
- measurement range of the pulse rate;
- operating and storage temperature and humidity ranges;
- any special requirements for a battery-powered automatic sphygmomanometer, e.g. safety warnings;
- warm-up time, if applicable;
- description of the meaning of the "out of range signal" (see 0 and 0, 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

Rationale for the maximum permissible errors of the overall system

(Informative)

Note: This Annex provides a rationale for the values of maximum permissible errors presented in 5.2.

Overall system accuracy

A clinical investigation is strongly recommended to demonstrate compliance with the requirements specified in 5.2.

A new clinical investigation is necessary only for changes affecting the overall system accuracy.

Recommended protocols for the clinical investigations are given in:

- O'Brien E., Petrie J., Littler W., de Swiet M, Padfield P.L., Altman D.G., Coats A. and Aikins N. The British Hypertension Society protocol for the evaluation of blood measuring devices. Journal of Hypertension 1993, 11 (Suppl 2): S 43 – 62
- ISO 81060-2.