INTERNATIONAL
RECOMMENDATION

OIML R 16-2

Edition 2002 (E)

Non-invasive automated sphygmomanometers

Sphygmomanomètres non invasifs automatiques

OIML R 16-2 Edition 2002 (E)

ORGANISATION INTERNATIONALE
DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION
OF LEGAL METROLOGY

Contents

Foreword

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International Recommendations and International Documents are published in French (F) and English (E) and are subject to periodic revision.

This publication - reference OIML R 16-2 Edition 2002 (E) - was developed by the OIML Technical Subcommittee TC 18/SC 1 *Blood pressure instruments*. This publication was approved for final publication by the International Committee of Legal Metrology in 2001 and will be submitted to the International Conference of Legal Metrology in 2004 for formal sanction.

OIML Recommendation R 16 includes two parts: Part 1 (*Non-invasive mechanical sphygmomanometers*) and Part 2 (*Non-invasive automated sphygmomanometers*) which have been issued in 2002 as separate publications. It supersedes the former editions dated 1973 (English version) and 1970 (French version).

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Non-invasive 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 electronic or 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 upper arm, the wrist or the thigh.

Note: Luer locks shall not be used with these devices (see 6.11.3 and 7.5).

2 Terminology

2.1 Bladder

Inflatable component of the cuff.

2.2 Pressure in a blood vessel

Pressure in the arterial system of the body.

2.3 Cuff

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

2.4 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.

2.5 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.

2.6 Non-invasive blood pressure measurement

Indirect measurement of the arterial blood pressure without arterial puncture.

2.7 Pneumatic system

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

2.8 Sleeve

Essentially inelastic part of the cuff that encloses the bladder.

2.9 Sphygmomanometer

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

2.10 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.

2.11 Electro-mechanical blood pressure measuring system

System that consists of:

- at least one cuff, which is connected to the pneumatic system;
- at least one electro-mechanical transducer to measure cuff pressure;
- at least one measured value display; and
- if needed, signal inputs and outputs.

2.12 Electro-mechanical pressure transducer

Component that transforms pressure signals into electrical signals.

2.13 Oscillometric method

Method, wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced.

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, which first increase and then decrease, 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. It is possible to carry out the measurement during the inflation phase.

2.14 Zero setting

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

2.15 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 accuracy but is required in assessing stability of performance.

2.16 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 children under the age of 13, “k4” (i.e. 4th phase Korotkoff sound) may be appropriate.

2.17 Self-linearizing deflation valve

Valve for controlled linearizing exhaust of the pneumatic system during measurement.

3 Description of the category of instrument

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

4 Units of measurement

The blood pressure shall be indicated either in kilo-pascals (kPa) or in millimeters of mercury (mmHg).

5 Metrological requirements

5.1 Maximum permissible errors of the cuff pressure indication

For any set of conditions within the ambient temperature range of 15 °C to 25 °C and the relative humidity range of 20 % 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 ± 0.4 kPa (± 3 mmHg) in case of verifying the first time and ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

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

5.2 Maximum permissible errors of the overall system as measured by clinical tests*

The following maximum permissible errors shall apply for the overall system:

- 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 C.

5.3 Environmental performance

5.3.1 Storage

Blood pressure measuring systems shall maintain the requirements specified in this Recommendation after storage for 24 h at a temperature of – 5 °C and for 24 h at a temperature of 50 °C and a relative humidity of 85 % (non-condensing).

Testing shall be carried out at environmental conditions (see 5.1) in accordance with A.2 after the test sample has been placed for 24 h at a temperature of – 5 °C and immediately afterwards for 24 h at a temperature of 50 °C in a climatic chamber.

Note: Integrated multiparameter monitors may contain components which may be damaged during storage. The general temperature range as stated in A.3 has therefore been reduced compared to the requirements in R 16-1.

5.3.2 Temperature, relative humidity

For the ambient temperature range of 10 °C to 40 °C and a relative humidity of 85 % (non-condensing), the difference of the cuff pressure indication of the sphygmomanometer shall not exceed ± 0.4 kPa (± 3 mmHg).

Testing shall be carried out in accordance with A.2 and A.11.

The signal processing for the determination of the blood pressure values shall not be influenced within the range of temperature and relative humidity. For any set of conditions all the deviations between the reference pressure and the indicating cuff pressure of the instrument must be less than or equal to the maximum permissible error.

* carried out by the manufacturer

6 Technical requirements

6.1 General

Equipment, or parts thereof, using materials or having forms of construction 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 a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents (see 7.5).

Note: The optimum bladder size is one with dimensions such that its width is 40 % of the limb circumference at the midpoint of the cuff application and its length is at least 80 %, preferably 100 % of the limb circumference at the midpoint of cuff application. Use of the wrong size can affect the accuracy of the measurement.

6.3 Technical requirements for the display

The display shall be designed and arranged so that the information including measuring values can be read and easily recognized.

Testing shall be carried out by visual inspection.

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.

6.4 Effect of voltage variations of the power source

6.4.1 Internal electrical power source

6.4.1.1 Changes of the voltage within the working range determined according to A.4.1 shall not influence the cuff pressure reading and the result of the blood pressure measurement.

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

Testing shall be carried out in accordance with A.4.1 and A.5.1.

6.4.2 External electrical power source

6.4.2.1 Changes of the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure reading and the result of the blood pressure measurement.

Testing shall be carried out according to A.4.2 and A.5.2 (alternating current) or A.4.3 and A.5.3 (direct current).

6.4.2.2 Incorrect values resulting from voltage variations outside the limits given in 6.4.2.1 shall not be displayed.

Testing shall be carried out according to A.4.4 (alternating current) and A.4.5 (direct current).

Note: In the case of any malfunction of the equipment, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180 s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients.

6.5 Pneumatic system

6.5.1 Air leakage

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

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

6.5.2 Pressure reducing system for 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.

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

6.5.3 Rapid exhaust

During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s.

For blood pressure measuring systems having the capability to measure in a neonatal/infant mode, the time for the pressure reduction from 20 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.

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

6.5.4 Zero setting

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0 kPa (0 mmHg) shall exist and be displayed thereafter.

Devices performing zero setting only immediately after switching on, shall switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds 0.1 kPa (1 mmHg).

Testing shall be carried out in accordance with A.9 and A.10.

6.6 Electromagnetic compatibility

Either:

- electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement; 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 should be carried out in accordance with the relevant OIML provisions (notably those of OIML D 11).

6.7 Stability of the cuff pressure indication

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

Testing shall be carried out in accordance with A.12.

6.8 Pressure indicating device

6.8.1 Nominal range and measuring range

The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indication ranges 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.

6.8.2 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.

6.9 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.

Testing shall be carried out in accordance with A.13.

6.10 Alarms

If alarms are used they shall be of at least medium priority.

6.11 Safety

6.11.1 Cuff pressure

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 6.5.3).

Testing shall be carried out in accordance with A.14.

6.11.2 Unauthorized access

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

Testing shall be carried out by visual inspection.

6.11.3 Tubing connectors

Users of equipment intended for use in environments employing intervascular fluid systems shall take all necessary precautions to avoid connecting 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.

6.11.4 Electrical safety

Electronic or automated sphygmomanometers shall comply with the relevant national safety regulations.

6.11.5 Resistance to vibration and shock

The sphygmomanometer shall comply with the relevant provisions of OIML D 11 (e.g. subclause A.2.2 of the 1994 edition, *Mechanical conditions*).

After testing, the device shall comply with the requirements of 5.1 (of this Recommendation).

7 Metrological controls

Regional or national regulations may prescribe type approval, initial and/or periodic verification for non-invasive 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

7.2.1 Initial verification

At initial verification the requirements of 5.1 and 6.5.1 shall be fulfilled.

Testing shall be carried out according to A.2 and A.6.

7.2.2 Subsequent verification

Each instrument of an approved type of sphygmomanometer shall be verified every 2 years or after repair. At least 5.1 and 6.5.1 shall be fulfilled and tests must be carried out according to A.2 and A.6.

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 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 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 the form of labels.

7.3.3 All seals shall be accessible without using a tool.

7.4 Marking of the device

The device shall be marked with the following information:

- name and/or trademark of manufacturer;
- serial number and year of fabrication;
- measuring range and measuring unit;
- type approval number (if applicable);
- center of the bladder, indicating the correct position for the cuff over the artery; and
- marking on the cuff indicating the limb circumference for which it is appropriate (see 6.2).

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 16-2 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 to ensure that the device operates properly 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 and 6.5.1 (testing at least at 7 kPa (50 mmHg) and 27 kPa (200 mmHg));
- a reference method for clinical tests carried out according to Annex C or an equivalent method;
- a list of all components belonging to the pressure measuring system, including accessories;
- a 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, arrythmia);
- specification of the signal input/output port(s);
- specification of the rated voltage, if applicable;
- specification of the intended power source, if applicable;
- nominal range for the result of the blood pressure measurement;
- warm up time, if applicable;
- description of the meaning of the "out of range signal" (see 6.4.1.2 and 6.4.2.2, if applicable); and
- description of the alarms, if applicable.

Annex A
Test procedures
(Mandatory)

A.1 General

For digital indications an uncertainty of 0.1 kPa (1 mmHg) shall be allowed in any displayed value, because the display system cannot indicate a change of less than one unit.

A.2 Method of test for the maximum permissible errors of the cuff pressure indication

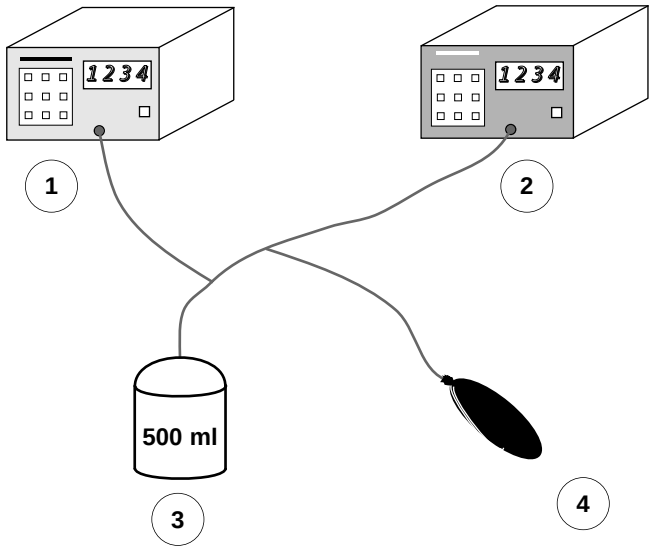
Requirements in 5.1 shall apply.

A.2.1 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 and hoses.

A.2.2 Procedure

Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector and hoses to the pneumatic circuit (see Figure 1). After disabling the electro-mechanical pump (if fitted), connect the additional 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 - Device to be tested
3 - Metal vessel
4 - Pressure generator

Figure 1 Measurement system for determining the limits of error of the cuff pressure indication

A.2.3 Expression of results

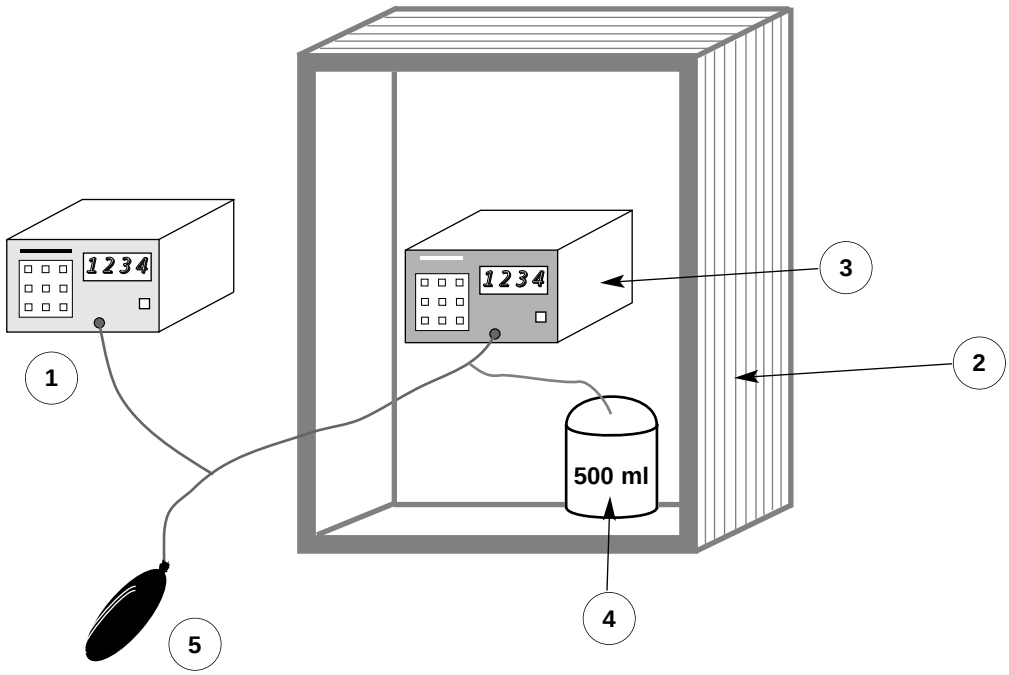
Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.2).

A.3 Method of test for the influence of temperature on cuff pressure indication

A.3.1 Apparatus

- apparatus as specified in A.2.1; plus
- climatic chamber.

* In case of doubt about the linearity, spot checks should be carried out or the width of the pressure steps should be reduced, i.e., from the normally recommended 7 kPa (50 mmHg) to 3 kPa (20 mmHg). This also applies to Table 1 in Annex B.



1 - Reference manometer
2 - Climatic chamber
3 - Device to be tested
4 - Metal vessel
5 - Pressure generator

Figure 2 Measurement system for determining the influence of temperature

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 2). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pneumatic system by means of another T-piece connector.

For each of the following combinations of temperature and humidity, condition the device for at least 3 h in the climatic chamber to allow the device to reach steady conditions:

- 10 °C ambient temperature, 85 % relative humidity (non-condensing);
- 20 °C ambient temperature, 85 % relative humidity (non-condensing);
- 40 °C ambient temperature, 85 % relative humidity (non-condensing).

Carry out the test of the cuff pressure indication as described in A.2.2 for each of the combinations of temperature and humidity mentioned above.

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 indications of the reference manometer (see B.3) at the relevant temperature value.

A.4 Test methods for the effect of voltage variations of the power source on the cuff pressure indication

A.4.1 Internal electrical power source

A.4.1.1 Apparatus

- adjustable direct current voltage supply;
- voltmeter with an uncertainty of less than 0.5 % of the measured value;
- calibrated reference manometer with an uncertainty of less than 0.1 kPa (0.8 mmHg).

A.4.1.2 Procedure

Replace the internal electrical power source of the blood pressure measuring system with a DC voltage supply having an impedance which is equivalent to the impedance of the internal electrical power source specified by the manufacturer. Measure the variation in applied DC voltage supply with a voltmeter. Test the blood pressure measuring system by altering the DC voltage supply in steps of 0.1 V and determine the lowest voltage limit at which the cuff pressure reading is still displayed.

Carry out the test with the maximum permissible impedance of the internal electrical power source.

Carry out the test according to the procedure specified in A.2 at the lowest voltage limit increased by 0.1 V and also at the nominal voltage.

A.4.1.3 Expression of results

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer at the lowest voltage limit increased by 0.1 V and at nominal voltage.

A.4.2 External electrical power source - alternating current

A.4.2.1 Apparatus

- adjustable alternating current voltage supply;
- voltmeter with an uncertainty of less than 0.5 % of the measured value;
- calibrated reference manometer with an uncertainty of less than 0.1 kPa (0.8 mmHg).

A.4.2.2 Procedure

Connect the blood pressure measuring system to the adjustable alternating current voltage supply. Measure the variation in AC voltage supply with the voltmeter.

Carry out the test according to the procedure specified in A.2 at:

- the maximum rated voltage, declared by the manufacturer, increased by 10 %;
- the mean value of the maximum and minimum rated voltage, declared by the manufacturer;
- the minimum rated voltage, declared by the manufacturer, decreased by 10 %.

A.4.2.3 Expression of results

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer.

A.4.3 External electrical power source - direct current

A.4.3.1 Apparatus

Use the apparatus listed in A.4.1.1.

A.4.3.2 Procedure

Connect the blood pressure measuring system to the DC voltage supply. Control the DC voltage supply by reference to a voltmeter.

Carry out the test according to the procedure specified in A.2 at:

- the maximum rated voltage, declared by the manufacturer, increased by 10 %;
- the mean value of the maximum and minimum rated voltage, declared by the manufacturer;
- the minimum rated voltage, declared by the manufacturer, decreased by 10 %.

A.4.3.3 Expression of results

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer.

A.4.4 Voltage variations of the external electrical power source - alternating current

A.4.4.1 Apparatus

Use the apparatus listed in A.4.2.1.

A.4.4.2 Procedure

Connect the blood pressure measuring system to the AC voltage supply. Measure the variation in the AC voltage supply with the voltmeter.

Test the blood pressure measuring system by altering the AC voltage supply in steps of 5 V and determine the lowest voltage limit at which the cuff pressure reading is displayed.

Carry out the test according to the procedure specified in A.2 at the lowest voltage limit increased by 5 V and also at the rated voltage.

A.4.4.3 Expression of results

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer at rated voltage and the lowest voltage limit increased by 5 V.

A.4.5 Voltage variations of the external electrical power source - direct current

A.4.5.1 Apparatus

Use the apparatus listed in A.4.1.1.

A.4.5.2 Procedure

Connect the blood pressure measuring system to the DC voltage supply. Measure the variation in the DC voltage supply with the voltmeter.

Test the blood pressure measuring system by altering the DC voltage supply in steps of 0.1 V and determine the lowest voltage limit at which the cuff pressure reading is displayed.

Carry out the test according to the procedure specified in A.2 at the lowest voltage limit increased by 0.1 V and also at the rated voltage.

A.4.5.3 Expression of results

Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested and that of the reference manometer at rated voltage and at the lowest voltage limit increased by 0.1 V.

A.5 Test methods for the effect of voltage variations of the power source on the result of the blood pressure measurement

A.5.1 Internal electrical power source

A.5.1.1 Apparatus

- adjustable direct current voltage supply;
- voltmeter with an uncertainty less than 0.5 % of the measured value;
- patient simulator (see 2.15) for the auscultatory and/or oscillometric method, having additional deviations originating from the simulator of not more than 0.27 kPa (2 mmHg) for the mean value of the measurements and generating signals for blood pressure values of approximately:
  - systolic: 16 kPa (120 mmHg);
  - diastolic: 11 kPa (80 mmHg);
  - pulse rate: 70 min^{-1} – 80 min^{-1}.

A.5.1.2 Procedure

Replace the internal electrical power source of the blood pressure measuring system by a DC voltage supply having an impedance which is equivalent to the impedance of the internal electrical power source specified by the manufacturer. Devices intended to be used with consumer batteries shall be tested with an impedance of less than 1 Ω.

Control the DC voltage supply by reference to the voltmeter.

Connect the blood pressure measuring system to the patient simulator. Carry out the test at the maximum permissible impedance of the internal electrical power source.

Carry out 20 simulated blood pressure measurements at the lowest voltage limit as determined in A.4.1.2 increased by 0.1 V and at nominal voltage.

A.5.1.3 Expression of results

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.

A.5.2 External electrical power source - alternating current

A.5.2.1 Apparatus

- adjustable alternating current voltage supply;
- voltmeter with an uncertainty less than 0.5 % of the measured value;
- patient simulator as described in A.5.1.1.

A.5.2.2 Procedure

Connect the blood pressure measuring system to the AC voltage supply. Control the AC voltage supply by

reference to the voltmeter. Connect the blood pressure measuring system to the simulator.

Carry out 20 simulated blood pressure measurements each at:

- the maximum rated voltage, declared by the manufacturer, increased by 10 %;
- the mean value of the maximum and minimum rated voltage, declared by the manufacturer;
- the minimum rated voltage, declared by the manufacturer, decreased by 10 %.

A.5.2.3 Expression of results

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.

A.5.3 External electrical power source - direct current

A.5.3.1 Apparatus

- adjustable direct current voltage supply;
- voltmeter with an uncertainty less than 0.5 % of the measured value;
- patient simulator as described in A.5.1.1.

A.5.3.2 Procedure

Connect the blood pressure measuring system to the DC voltage supply. Control the DC voltage supply by reference to the voltmeter. Connect the blood pressure measuring system to the simulator.

Carry out 20 simulated blood pressure measurements each at:

- the maximum rated voltage, declared by the manufacturer, increased by 10 %;
- the mean value of the maximum and minimum rated voltage, declared by the manufacturer;
- the minimum rated voltage declared by the manufacturer, decreased by 10 %.

A.5.3.3 Expression of results

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each voltage level.

A.6 Method of test for air leakage of the pneumatic system

A.6.1 Apparatus

- rigid metal cylinder of an appropriate size;
- pressure generator, e.g. ball pump (hand pump) with deflation valve;
- stopwatch.

A.6.2 Procedure

If because of technical reasons, the test as described in this subclause cannot be performed, use an alternative test procedure specified by the manufacturer.

Carry out the test at constant temperature in the range 15 °C to 25 °C.

Before beginning the test, allow the blood pressure measuring system to reach working temperature.

Wrap the cuff around the cylinder (see 6.2) such that, for devices measuring at the upper arm and the thigh, the circumference of the applied cuff does not exceed that of the cylinder by more than 7 %.

Note 1: Electro-mechanical pumps which are a part of the system may be used for the test. Valves which are permanently opened may be disconnected for the test.

Note 2: For this test no calibrated reference manometer is required because the cuff pressure display of the unit under test can be used when the error of the cuff pressure indication is taken into account. The advantage of this test is that the unit under test is in its original configuration. Additional connections can increase the leakage.

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)). Because the thermodynamic equilibrium is influenced by decreasing or increasing the pressure when changing to the next pressure step, wait at least 60 s before reading the values. Test the air leakage over a period of 5 minutes and determine the measured value from this.

A.6.3 Expression of results

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

A.7 Method of test for the pressure reduction rate

A.7.1 Apparatus

- T-piece connectors;
- calibrated reference manometer with signal output port and an uncertainty less than 0.1 kPa (0.8 mmHg);
- artificial or human limbs (see *Notes* under A.7.2);
- recording unit.

A.7.2 Procedure

Measure the pressure reduction rate either on human subjects 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: Two limb sizes should be used, being equal to the upper and lower limits of limb circumferences with which a particular size of cuff is recommended for use.

Note 3: It is intended that the characteristics of the artificial limbs reflect some elastic characteristics of human limbs.

Because the cuff deflation rate may be influenced by the way that a cuff is applied, apply and remove the cuff for each of at least ten repeated measurements on at least two different limb sizes. The deflation may be reset.

Connect the calibrated reference manometer to the cuff by means of a T-piece. Connect the output part of the calibrated reference manometer to the recording unit.

A.7.3 Expression of results

Determine the rate of pressure reduction (e.g. by graphical evaluation and drawing tangents) at the pressure values 8 kPa (60 mmHg), 16 kPa (120 mmHg) and 24 kPa (180 mmHg). Calculate the pressure reduction rate as the mean value calculated separately for the pressure values 8 kPa (60 mmHg), 16 kPa (120 mmHg) and 24 kPa (180 mmHg) and for the various limb circumferences.

If the pressure reduction rates are dependent on the pulse, record the pulse rate. In this case, express the result as pressure reduction rate per pulse.

A.8 Method of test for the rapid exhaust valve

A.8.1 Apparatus

- two rigid vessels with capacities of 100 ml ± 5 % and 500 ml ± 5 %, respectively;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connector;
- stopwatch.

A.8.2 Procedure

Carry out the test with the 500 ml vessel in place of the cuff. For blood pressure measuring systems having the capability of measuring in a neonatal/infant mode and for devices measuring at the wrist, carry out the test with the 100 ml vessel in place of the cuff.

Connect the calibrated reference manometer by means of a T-piece to the pneumatic system.

Inflate at least to the maximum pressure given in 6.5.3, wait 60 s and activate the rapid exhaust valve.

Measure the time between the pressure values specified in 6.5.3 using the stopwatch.

A.8.3 Expression of results

Express the results as the measured exhaust times.

A.9 Test method for the zero setting

A.9.1 Apparatus

- rigid vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- electro-mechanical pressure/suction pump;
- pressure generator, e.g. ball pump (hand pump) with deflation valve;
- T-piece connectors;
- hoses.

A.9.2 Procedure and evaluation

If, because of technical reasons, the test as described in this subclause cannot be performed, use an alternative test procedure specified by the manufacturer.

To test the function of the zero setting, apply a pressure of + 0.8 kPa (+ 6 mmHg) and subsequently – 0.8 kPa (– 6 mmHg) to the pneumatic system and initiate a zero setting of the device. Ensure that all displayed pressure values have a systematic error of – 0.8 kPa (– 6 mmHg) and + 0.8 kPa (+ 6 mmHg), respectively.

Before beginning the test, allow the blood pressure measuring system to reach working temperature.

Set up the blood pressure measuring system to be tested as follows:

- replace the cuff with the 500 ml vessel;
- insert the calibrated reference manometer into the pneumatic system by means of a T-piece connector;
- insert the pressure/suction pump into the pneumatic system by means of a T-piece connector;
- insert the pressure generator into the pneumatic system by means of a T-piece connector.

Note: If convenient, one adjustable pump may be used in place of the pressure/suction pump and pressure generator to generate the pressures.

Proceed in the following way:

a) Initiate a zero setting as described by the manufacturer. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards and record the displayed value.

b) Generate a constant gauge pressure of + 0.8 kPa (+ 6 mmHg) in the pneumatic system by using the pressure/suction pump at the moment of zero setting. During this period close the deflation valve of the device under test or close the hose to it, e.g. by pinching the hose tightly. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards. The zero setting is operating correctly if the displayed value decreases by 0.8 kPa (6 mmHg) compared to the value taken in a).

c) Repeat b) with a constant gauge pressure of – 0.8 kPa (– 6 mmHg) in the pneumatic system. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards. The zero setting is operating correctly if the displayed value increases by 0.8 kPa (6 mmHg) compared to the value taken in a).

A.10 Test method for the drift of the cuff pressure indication

A.10.1 General

This test applies for devices performing zero setting only immediately after switching on.

A.10.2 Apparatus

- rigid vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- stopwatch;
- T-piece connectors;
- patient simulator as described in A.5.1.1.

A.10.3 Procedure and evaluation

Replace the cuff with the 500 ml vessel. Insert the calibrated reference manometer and the patient simulator into the pneumatic circuit by means of T-piece connectors.

Before beginning the test, allow the blood pressure measuring system to reach operating temperature as described in the instructions for use.

Test the stability of the cuff pressure indication after the zero setting at a pressure value of 7 kPa (50 mmHg) according to the procedure specified in A.2.

Under the same environmental conditions determine the time (t_1) until the change of the cuff pressure indication exceeds 0.1 kPa (1 mmHg). Switch off the device and switch on afterwards. Perform one blood pressure measurement and wait until the device has switched off automatically. Determine the time (t_2) between switching on and automatically switching off. The time (t_2) shall be less than or equal to the time (t_1).

A.11 Test method for the stability of the blood pressure determination (influence of temperature and humidity)

A.11.1 Apparatus

- patient simulator as described in A.5.1.1;

- climatic chamber, capable of adjustment to an accuracy of 1 °C for the temperature and 5 % for the relative humidity.

A.11.2 Procedure

Carry out the testing of the signal processing by means of the patient simulator. For each of the following combinations of temperature and humidity, place the blood pressure measuring system for at least 3 h in the climatic chamber to allow the system to reach steady conditions:

- 10 °C ambient temperature, 85 % relative humidity (non-condensing);
- 20 °C ambient temperature, 85 % relative humidity (non-condensing);
- 40 °C ambient temperature, 85 % relative humidity (non-condensing).

For each combination of temperature and humidity, take 20 consecutive readings of the blood pressure measuring system under test.

Place the blood pressure measuring system in the climatic chamber for at least 3 h. At each combination of temperature and humidity switch on the blood pressure measuring system before starting the test. Wait until the warm up time (described in the instructions for use) has elapsed, carry out the measurement (20 consecutive readings) and switch off the blood pressure measuring system afterwards.

A.11.3 Expression of results

Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each combination of temperature and humidity.

Note: Because the testing of the influence of temperature and humidity for the signal processing cannot be separated from the temperature/humidity effect on the pressure transducer and the deviations originating from the simulator, both contributions should be taken into account for the evaluation of the test.

A.12 Test method for the stability of cuff pressure indication following prolonged usage

A.12.1 Procedure

Carry out the test according to the procedure specified in A.2 prior to prolonged usage.

Perform 10 000 simulated measurement cycles with the complete blood pressure measurement system at which at least the following cuff pressure values shall be reached:

- adult mode: 20 kPa (150 mmHg);
- neonatal/infant mode: 10 kPa (75 mmHg).

Note 1: For devices which measure with the auscultatory and oscillometric method this test should be carried out for both modes.

Note 2: For devices which measure in both modes (adult and neonatal/infant) the test should be carried out in both modes.

A.12.2 Expression of results

Express the result as the difference between the cuff pressure indication before and after 10 000 simulated blood pressure measurement cycles at the same test pressure and under the same environmental conditions.

A.13 Test method for the effect of external voltages and abnormal connections to the signal input/output ports

A.13.1 Apparatus

- rigid vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connectors;
- pressure generator, e.g. ball pump (hand pump) with deflation valve.

A.13.2 Procedure

Replace the cuff with the 500 ml vessel, insert the calibrated reference manometer into the pneumatic system by means of a T-piece and proceed as follows.

a) Raise the pressure to 13 kPa (100 mmHg) and record the displayed value.

b) Repeat a) whilst short circuiting all contacts of the signal input/output ports belonging to the non-invasive blood pressure measuring system.

c) Repeat a) whilst applying the maximum voltage specified by the manufacturer (see 7.5) to each contact belonging to the non-invasive blood pressure measuring system.

A.13.3 Evaluation

Compare the indicated value under a) with the indicated values under b) and c).

A.14 Test method for the cuff pressure deflation following an aborted measurement

A.14.1 Apparatus

- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connectors.

A.14.2 Procedure and evaluation

Insert the calibrated reference manometer into the pneumatic system by means of a T-piece.

Start a blood pressure measurement. Abort the measurement during inflation. Start another measurement and abort it during the pressure reduction. If interval measurements are possible repeat the test in this mode.

Check by visual inspection whether the rapid exhaust (6.5.3) is activated.

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 16-2 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 16-2 or to national or regional regulations based on OIML R 16-2 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 22) 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.

Conventional true value (of a quantity) [VIM 1.20]

value attributed to a particular quantity and accepted, sometimes by convention, as having an uncertainty appropriate for given purpose.

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a) at a given location, the value assigned to the quantity realized by a reference standard may be taken as a conventional true value;

b) the CODATA (1986) recommended value for the Avogadro constant N_A: 6,022 136 7 × 10^{23} mol^{-1}.

NOTES

1 "Conventional true value" is sometimes called **assigned value**, **best estimate** of the value, **conventional value** or **reference value**. "Reference value", in this sense, should not be confused with "reference value" in the sense used in the note to VIM 5.7.

2 Frequently, a number of results of measurements of a quantity is used to establish a conventional true value.

Experimental standard deviation [VIM 3.8]

for a series of n measurements of the same measurand, the quantity s characterizing the dispersion of the results and given by the formula:

$$s = \sqrt{\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1}}$$

x_i being the result of the i^{th} measurement and $\bar{x}$ being the arithmetic mean of the n results considered.

NOTES

1 Considering the series of n values as a sample of a distribution, $\bar{x}$ is an unbiased estimate of the mean μ, and s^2 is an unbiased estimate of the variance σ^2, of that distribution.

2 The expression $s / \sqrt{n}$ is an estimate of the standard deviation of the distribution of $\bar{x}$ and is called **the experimental standard deviation of the mean**.

3 "Experimental standard deviation of the mean" is sometimes incorrectly called **standard error of the mean**.

Uncertainty of measurement [VIM 3.9]

parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

NOTES

1 The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.

2 Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.

3 It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

This definition is that of the "Guide to the expression of uncertainty in measurement" in which its rationale is detailed (see, in particular, 2.2.4 and annex D [10]).

Error (of measurement) [VIM 3.10)]

result of a measurement minus a true value of the measurand.

NOTES

1 Since a true value cannot be determined, in practice a conventional true value is used (see VIM 1.19 and VIM 1.20).

2 When it is necessary to distinguish “error“ from “relative error”, the former is sometimes called **absolute error of measurement**. This should not be confused with **absolute value of error**, which is the modulus of the error.

Deviation [VIM 3.11]

value minus its reference value.

Systematic error [VIM 3.14]

mean that would result from an infinite number of measurements of the same measurand carried out under repeatability conditions minus a true value of the measurand.

NOTES

1 Systematic error is equal to error minus random error

2 Like true value, systematic error and its causes cannot be completely known.

3 For a measuring instrument, see “bias” (VIM 5.25).

Maximum permissible errors (of a measuring instrument) [VIM 5.21]

extreme values of an error permitted by specifications, regulations, etc. for a given measuring instrument.

Non-invasive automated sphygmomanometers

OIML R 16-2 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 temperature on cuff pressure indication				
B.4	Effect of voltage variations of the power source				
B.4.1	Internal electrical power source				
B.4.2	External electrical power source				
B.5	Environmental performance				
B.5.1	Effect of storage on cuff pressure indication				
B.5.2	Electromagnetic interferences				
	Normal operation again, when?				
B.6	Air leakage rate				
B.7	Pressure reducing system				
B.8	Rapid exhaust				
B.9	Zero setting				
B.10	Stability of the cuff pressure indication				
B.11	Pressure indicating device				
B.11.1	Nominal range and measuring range				
B.11.2	Digital indication				
B.12	Signal input and output ports				
B.13	Maximum permissible error of the overall system				
B.13.1	Maximum mean error				
B.13.2	Maximum experimental standard deviation				
B.14	Alarms				
B.15	Safety				
B.15.1	Electrical safety				
B.15.2	Resistance to vibration and shock				
B.15.3	Cuff pressure				
B.15.4	Unauthorized access				
B.15.5	Tubing connectors				
B.16	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.6	Air leakage rate				
B.15	Safety				
B.15.3	Cuff pressure				
B.15.4	Unauthorized access				
B.15.5	Tubing connectors				
B.15.5.1	Regular use				
B.15.5.2	Warning in the manual				
B.16	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: the temperature should be between 15 °C and 25 °C, 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 °C and 20 % relative humidity, 20 °C and 60 % relative humidity and 25 °C and 85 % relative humidity.

Table 1 Example: Temperature 20 °C and .... % relative humidity

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

Maximum deviation: 5 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

Table 2 Temperature ..... °C and ..... % relative humidity

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

Maximum deviation: .....

Note: The time between up and down run should not be less than 5 minutes at the maximum pressure. 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) for type approval test and first verification and less than or equal to ± 0.5 kPa (± 4 mmHg) for subsequent verification, respectively (see 5.1)?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

B.3 Effect of temperature on cuff pressure indication

Refer to A.3.

Note 1: For a type approval test report testing has to be carried out also at 10 °C and 40 °C (see A.3.2.1, A.3.2.2, A.3.2.3).

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 3) 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 (see A.3.1) to allow the device to reach steady conditions.

Table 3 Temperature 10 °C 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 4 Temperature 40 °C 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 deviation of all of the readings of the instrument under test and the reference manometer less than or equal to ± 0.4 kPa (± 3 mmHg) (see 5.3.2)?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

B.4 Effect of voltage variations of the power source

B.4.1 Internal electrical power source

For reference see A.5.1.

Do the changes of voltage within the working range of the internal power source influence the result of the blood pressure measurement in such a way that the results of the blood pressure measurement deviate more than the maximum permissible error (MPE, see 5.2) from the values of a measurement by the reference manometer?

yes ☐ ➡ failed ☐

no ☐ ➡ passed ☐

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

Does a change of voltage outside of the working range of the internal power source lead to a result of a blood pressure measurement?

yes ☐ ➡ failed ☐

no ☐ ➡ passed ☐

Testing should be carried out in accordance with A.4.1 and A.5.1.

B.4.2 External electrical power source

For reference see A.5.2 and A.5.3.

Do the changes of voltage within the working range of the external power source influence the result of the blood pressure measurement in such a way that the results of the blood pressure measurement deviate more than the maximum permissible error (MPE, see 5.2) from the values of a measurement by the reference manometer?

yes ☐ ➡ failed ☐

no ☐ ➡ passed ☐

Testing should be carried out in accordance with A.4.2 and A.5.2 (alternating current) or A.4.3 and A.5.3 (direct current).

Note: Incorrect values resulting from voltage variations outside the limits given above shall not be displayed.

Does a change of voltage outside of the working range of the external power source lead to a result of a blood pressure measurement?

yes ☐ ➡ failed ☐

no ☐ ➡ passed ☐

Testing shall be carried out according to Annex A.4.4 (alternating current) and A.4.5 (direct current).

B.5 Environmental performance

B.5.1 Storage

Determine the error after the storage for 24 h at a temperature of – 5 °C and for 24 h at a temperature of 50 °C and a relative humidity of 85 %.

Table 5 Measurement at 20 °C and 60 % relative humidity after storage at – 5 °C and 50 °C

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: .....

Refer to 5.3.1. and A.2.

Is the maximum deviation of the cuff pressure indication (mean value), after storage at – 5 °C and 50 °C, less than or equal to ± 0.4 kPa (± 3 mmHg) compared to the mean values at 20 °C and 60 % relative humidity before storage?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

Note: Integrated multiparameter monitors may contain components which may be damaged during storage. The general temperature range has therefore been reduced.

B.5.2 Electromagnetic compatibility

Do electrical and/or electromagnetic interferences lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement?

yes ☐ ➡ failed ☐

no ☐ ➡ passed ☐

If electrical and/or electromagnetic interferences lead to an abnormality, is the abnormality clearly indicated and is it possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

Testing should be carried out in accordance with OIML D11.

B.6 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.6.2) and determine the measured value from this. Wait at least 60 s before reading each value.

Table 6

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

Does the air leakage rate over a period of 5 minutes correspond to a pressure drop less than or equal to 0.8 kPa/min (6 mmHg/min)?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

B.7 Pressure reducing system for devices using the auscultatory method

Is the 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 maintained?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

For devices which control the pressure reduction as a function of the pulse rate:

Is a deflation rate of 0.3 kPa/pulse and 0.4 kPa/pulse (2 mmHg/pulse and 3 mmHg/pulse) maintained?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

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

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

B.8 Rapid exhaust

Does the time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) during the rapid exhaust of the pneumatic system with the valve fully opened exceed 10 s?

yes ☐ ➡ failed ☐

no ☐ ➡ passed ☐

For blood pressure measuring systems, having the capability to measure in a neonatal/infant mode:

Does the time for the pressure reduction from 20 kPa to 0.7 kPa (150 mmHg to 5 mmHg) during the rapid exhaust of the pneumatic system with the valve fully opened exceed 5 s?

yes ☐ ➡ failed ☐

no ☐ ➡ passed ☐

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

B.9 Zero setting

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0 kPa (0 mmHg) shall exist and be displayed thereafter.

Do devices performing zero setting only immediately after switching on, switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds 0.1 kPa (1 mmHg)?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

At the moment of the zero setting does a gauge pressure of 0 kPa (0 mmHg) exist and is it displayed?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

Testing shall be carried out in accordance with A.9 and A.10.

B.10 Stability of the cuff pressure indication

Is the change of the cuff pressure indication less than 0.4 kPa (3 mmHg) throughout the pressure range after 10 000 simulated measurement cycles?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

Testing shall be carried out in accordance with 6.7 and A.12.

B.11 Pressure indicating device

B.11.1 Nominal range and measuring range

The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range.

Are values of blood pressure measurement results outside the nominal range of cuff pressure clearly indicated as out of range?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

Testing shall be carried out by visual inspection.

B.11.2 Digital indication

Is the digital scale interval 0.1 kPa (1 mmHg)?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

Note 1: 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.

Note 2: 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.

Note 3: Numbers and characters should be clearly legible.

Testing shall be carried out by visual inspection. For reference see 6.8.

B.12 Signal input and output ports

Note: 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.

Testing shall be carried out in accordance with A.13.

For reference see 6.9.

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

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

An erroneous indication is an indication with an error bigger than the MPE.

B.13 Maximum permissible error of the overall system as measured by clinical tests

The error of each measurement is to be calculated according to definition 3.10 of the VIM (see paragraph iii of the explanatory notes at the beginning of Annex B). The reference values are derived from the conventional measurement carried out by a medical doctor using a mechanical sphygmomanometer and the Korotkoff method. Usually a set of at least 3 measurements per patient has to be carried out. Having one instrument under test, a sample of at least 85 persons and at least 2 medical doctors should be involved in the tests.

The mean of the errors measured within each set of measurements has to be calculated and the maximum of these mean errors relating to the sets of measurement of the different patients has to be determined. Refer also to C.3 (AAMI/ANSI SP10, 1992 and Amendment 1996).

B.13.1 Maximum mean error

Is the maximum mean error obtained by the clinical tests less than or equal to ± 0.7 kPa (± 5 mmHg)?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

For reference see 5.2.1.

B.13.2 Maximum experimental standard deviation

Is the maximum experimental standard deviation less than or equal to 1.1 kPa (8 mmHg)?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

For reference see 5.2.2. For definitions see paragraph iii of the explanatory notes at the beginning of Annex B.

B.14 Alarms

Note: If alarms are used they shall be of at least medium priority.

The alarms are of acoustic nature and can be delivered with different volume, frequencies and even different melodical patterns. Different alarms are correlated to different events. These alarms/events have different priorities. A low level priority could indicate e.g. beginning of problems with the battery, highest priority would be reserved for an alarm indicating a situation which is dangerous for the life of the patient.

For reference see 6.10.

B.15 Safety

B.15.1 Electrical safety (This test is optional within the *OIML Certificate System*)

Refer to 6.11.4.

Are the requirements of the regional and national regulations fulfilled?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

B.15.2 Resistance to vibration and shock

Refer to 6.11.5.

The mechanical conditions can be found in OIML D 11 (e.g. subclause A.2.2 of the 1994 edition).

Are the requirements according to OIML D 11 fulfilled?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

B.15.3 Cuff pressure

Note: 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 B.8).

Testing shall be carried out in accordance with A.14.

Is it possible to abort any blood pressure measurement at any time by single key operation and does this lead to a rapid exhaust (see B.8)?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

B.15.4 Unauthorized access

Are all controls which affect accuracy sealed against unauthorized access?

yes ☐ ➡ passed ☐

no ☐ ➡ failed ☐

Note: Controls are any part of the instrument which can be used for adjusting the measurement values, the subsequent computation and the display, including adjusting screws, potentiometers, adjusting modules, pressure sensing devices, etc.

Testing shall be carried out by visual inspection.

For reference see 6.11.2.

B.15.5 Tubing connectors

Note: Users of equipment intended for use in environments employing intervascular fluid systems shall take all necessary precautions to avoid connecting 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[1].

For reference see 6.11.3 and 7.5.

B.15.5.1

Are Luer locks used?

yes ☐ ➡ failed ☐

no ☐ ➡ passed ☐

[1] Luer lock connectors shall not be used with the tubing which connects the cuff to the manometer or measuring equipment, in order to avoid the possibility of inadvertent misconnection with other clinical systems.

B.15.5.2

Is the warning (see *Note* above and 7.5) mentioned in the instruction manual?

yes	☐	➡	passed	☐
no	☐	➡	failed	☐

B.16 Tamper proofing

Is the manometer tamper proof?

yes	☐	➡	passed	☐
no	☐	➡	failed	☐

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

Testing shall be carried out by visual inspection.

Annex C

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 would be necessary only for changes affecting the overall system accuracy.

Recommended protocols for the clinical investigations are given in:

C.1 O'Brien E., Petrie J., Littler W., de Swiet M., Padfield P.L., Altman D.G., Bland M., Coats A. and Atkins N. The British Hypertension Society protocol for the evaluation of blood measuring devices. Journal of Hypertension 1993, 11 (Suppl 2): S 43 - 62

C.2 E DIN 58130: 1995, Non-invasive sphygmomanometers - Clinical investigation

C.3 AAMI/ANSI SP10, American National Standard for electronic or automated sphygmomanometers, 1992, and Amendment, 1996

Printed in France GRANDE IMPRIMERIE DE TROYES