First Committee Draft (1CD) – Clean version

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Explanatory note

According to OIML B6 “Directives for OIML technical work”, each recommendation shall be reviewed every five years after its publication by the responsible TC/SC to decided whether it should be confirmed, revised, or withdrawn. The present (old) R16 which TC18/SC1 is responsible for was published in 2002, and it’s identified that there are a few technical conflicts between new ISO/IEC standard and OIML R16. To avoid different requirements worldwide on blood pressure instruments, the secretariat started the work on drafting R16-2 “*Non-invasive automated sphygmomanometers*” after the project of revision was approved at the 43rd CIML Meeting held in October 2008 in Sydney.

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

The main changes proposed to R16-2 are the following:

- OIML R16-2 should be revised into three parts according to OIML B6 with new number, and now OIML R yyy-1 is refer to part 1 Metrological and technical requirements;
- Modification of terminology as to comply with the new (2012) edition of the VIM;
- Removal of terminology not used in the document;
- Requirements for the Maximum permissible errors of the cuff pressure and environmental conditions are stated in R yyy-1 5.1, and the requirements of storage is also changed;
- Introducing blood pressure indication repeatability requirements;
- Maximum time for which the cuff is inflated is added;
- Test for stability of the cuff pressure indication is replaced by durability;
- Requirements for alarms are removed;
- Better describe of the environmental conditions for verification. No longer distinguish between “initial” verification and “subsequent” verification;
- Updating testing methods for the maximum permissible errors of the cuff pressure indication in Test procedures;
- Testing methods for resistance to vibration and shock is prescribed for sphygmomanometers;
- Technical requirements of patient simulators are modified. Considering that patient simulators have none traceability currently, they are not used for the accuracy test as the reference standard, but only used for test of the repeatability and blood pressure measuring rang;
- Modifying test report format.
- Making an agreement on electromagnetic compatibility test with the ISO/IEC standards;

The present document is the first Committee Draft (1CD), which was drawn up on the basis of the conclusions of comments from member nations on the Working Draft circulated since July 2011. It also had been discussed as preliminary 1CD in the TC 18/SC 1 meeting held on 22 to 26 October 2012 in Berlin.

Definitions and references related to the International vocabulary of metrology – Basic and general concepts and associated terms (VIM) have been modified according to the 2012 edition.

BIML note

The existing R 16 is published in two parts:

R 16-1 *Non-invasive mechanical sphygmomanometers*, and

R 16-2 *Non-invasive automated sphygmomanometers*.

These are being revised under two separate projects: TC 18/SC 1/p 1 and TC 18/SC 1/p 2 respectively.

The existing part numbering of R 16 is not consistent with current OIML practice. All Recommendations are now published with separate parts for the metrological and technical requirements (designated R xxx-1), test procedures (designated R xxx-2), and test report format (designated R xxx-3). To avoid confusion with the existing numbering of R 16, on completion of the two projects, the existing R 16-1 and R 16-2 will be replaced by two separate Recommendations with new numbers and each having three parts:

R xxx-1	*Non-invasive non-automated sphygmomanometers – Metrological and technical requirements*
R xxx-2	*Non-invasive non-automated sphygmomanometers – Test procedures*
R xxx-3	*Non-invasive non-automated sphygmomanometers – Test report format*
R yyy-1	*Non-invasive automated sphygmomanometers – Metrological and technical requirements*
R yyy-2	*Non-invasive automated sphygmomanometers – Test procedures*
R yyy-3	*Non-invasive automated sphygmomanometers – Test report format*

This CD has been re-numbered in line with this arrangement.

Contents

Foreword

The International Organization of Legal Metrology (OIML) is a worldwide, intergovernmental organization whose primary aim is to harmonize the regulations and metrological controls applied by the national metrological services, or related organizations, of its Member States. The main categories of OIML publications are:

International Recommendations (OIML R), which are model regulations that establish the metrological characteristics required of certain measuring instruments and which specify methods and equipment for checking their conformity; the OIML Member States shall implement these Recommendations to the greatest possible extent;

International Documents (OIML D), which are informative in nature and intended to improve the work of the metrological services;

International Basic Publications (OIML B), which define the operating rules of the various OIML structures and systems;

International Guides (OIML G), which are informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology.

OIML Draft Recommendations, Documents and Guides are developed by Technical Committees or Subcommittees which are formed by the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements are established between the OIML and certain institutions, such as ISO and the IEC, with the objective of avoiding contradictory requirements; consequently, manufacturers and users of measuring instruments, test laboratories, etc. may simultaneously apply OIML publications and those of other institutions.

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

Additionally, the OIML participates in the publication of **Vocabularies (OIML V)** and periodically commissions legal metrology Experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice to metrological authorities, and are written solely from the viewpoint of their author, without the involvement of a Technical Committee or Subcommittee, nor that of the CIML. Thus they do not necessarily represent the views of the OIML.

This publication - reference OIML R yyy, edition 201X (E) - was developed by the OIML Technical Subcommittee TC 18/SC 1 *Blood pressure instruments*. It was approved for final publication by the International Committee of Legal Metrology in 201X and supersedes OIML R 16-2:2002 (E).

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Non-invasive automated sphygmomanometers

Part 1: Metrological and technical requirements

1. Scope

This Recommendation specifies general, performance, efficiency and mechanical and electrical safety requirements, including test methods for type approval, 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 Non-invasive automated sphygmomanometer

A medical measuring instrument used for the non-invasive estimation of the blood pressure by utilizing an inflatable cuff, a pressure transducer a valve for deflation, and/or displays used in conjunction with automated methods for determining blood pressure.

Note: Components of an automated 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.

2.2 Non-invasive blood pressure measurement

Indirect measurement of the arterial blood pressure without arterial puncture.

2.3 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.

2.4 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.

2.5 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.

2.6 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.

2.7 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.

2.8 Pneumatic system

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

2.9 Cuff

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

2.10 Bladder

Inflatable component of the cuff.

2.11 Sleeve

Essentially inelastic part of the cuff that encloses the bladder.

2.12 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)).

2.13 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.

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, and a means of measuring and displaying the instantaneous pressure in the bladder.
Note: Specific device types include automated sphygmomanometers for self-measurement, Blood Pressure Monitors and Multi-parameter patient monitors, for home healthcare environment, or public use, etc.

4. Units of measurement

The blood pressure shall be indicated either in kilopascals (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 10 °C to 40 °C and the relative humidity range of 15% to 85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the measuring interval 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 automated 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.

5.3 Storage

The automated sphygmomanometer 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).

Strict testing shall be carried out at environmental conditions (see 5.1) in accordance with R yyy-2 after the test sample has been placed unpacked 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. For simplification，testing can also be carried out at a temperature of 20 °C ± 5 °C and at ambient humidity.

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

The abnormal status shall be recorded during the testing.

5.4 Blood pressure measuring range

The automated sphygmomanometer shall be capable of indicating diastolic blood pressure over at least the range of 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 automated sphygmomanometer shall be capable of indicating systolic blood pressure over at least the range of 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.

[1] carried out by manufacturer

5.5 Repeatability of blood pressure indication

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

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 or incorporate a bladder. The cuff shall be constructed such that when it is applied to a limb, the construction ensures that it is of the correct size or it shall be marked with an indication of the range of limb circumference for which the cuff is appropriate.

6.3 Effect of voltage variations of the power source

6.3.1 Internal electrical power source

6.3.1.1 Changes of the voltage within the working range determined according to R yyy-2 4.1 shall not influence the cuff pressure indication，which should comply with the requirement of 5.1.

6.3.1.2 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

6.3.2.1 Changes of the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure indication，which should comply with the requirement of 5.1.

6.3.2.2 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 reducing 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 automated 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 measuring system

6.4.4.1 Automated sphygmomanometers shall be capable of automatic zero adjustment. The zero adjustment shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero adjustment a gauge pressure of 0.0 kPa (0 mmHg) shall exist and be displayed thereafter.

6.4.4.2 Automated sphygmomanometers performing zero adjustment only immediately after switching on, shall switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds one scale interval (0.1 kPa or 1 mmHg).

6.4.5 Manometer test mode

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

Testing shall be carried out by visual inspection.

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

- 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 should be carried out in accordance with 202.8 of IEC 80601-2-30: 2018.

6.5.2 Electrosurgery interference recovery

If an automated 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 should be carried out in accordance with 202.8.101 of IEC 80601-2-30: 2018.

6.6 Durability

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.

6.7 Pressure indicating device

6.7.1 Nominal range and measuring range of the cuff pressure measurement

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.

6.7.2 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 recognized.

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.

6.9 Safety

6.9.1 Abort 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 Unauthorized access and tamper proofing

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

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.

6.9.3 Tubing connectors

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

6.10 Resistance to vibration and shock

The automated 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) automated sphygmomanometer is exempt from the requirements of this subclause.

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

7. Metrological controls

Regional or national regulations may prescribe type approval, initial and/or subsequent verification for non-invasive automated sphygmomanometers. These controls shall meet the following conditions.

7.1 Type approval

At least three samples of a new type of automated sphygmomanometer shall be tested.

The tests to verify conformity to metrological and technical requirements shall be carried out according to R yyy-2. A test report shall be prepared according to R yyy-3.

7.2 Verification

After type approval has been granted, verification shall be carried out before the automated sphygmomanometer is put into use and during its lifetime. At verification, testing can be conducted at any set of climatic conditions within the temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 %. A climatic chamber is not required.

Each instrument of an approved type of automated sphygmomanometer shall be verified periodically in accordance with applicable metrological laws and regulations of a member state, or after repair. At least the requirements of 5.1, 5.5 and 6.4.1 shall be fulfilled.

7.3 Sealing

7.3.1 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 automated sphygmomanometer is one part of a system: the manipulation of the metrologically relevant parts for measuring blood pressure;
- in the case of all other automated sphygmomanometers: 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 interval 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).
- For automated sphygmomanometers 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 automated sphygmomanometer.
- Automated sphygmomanometers for public use which is intended for self-use in public areas, it 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 yyy 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 is required to ensure that the device operates correctly and

safely at all times; a disclosure that applicable national or regional metrological laws and regulations have to be considered;

- 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;
- measuring interval for the systolic and diastolic blood pressure measurements;
- measuring interval of the pulse rate;
- the operating and storage temperature and humidity ranges;
- any special requirements for a battery-powered automatic automated sphygmomanometer;
- warm up time, if applicable;
- description of the meaning of the “out of range signal” (see 6.3.1.2 and 6.3.2.2, if applicable); and
- description of all symbols, abbreviations and error codes used on the instrument.

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 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., 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

C.2 AAMI/ANSI SP10, American National Standard for electronic or automated sphygmomanometers, 1992, and Amendment, 1996

C.3 ISO 81060-2-2013.