First Committee Draft (1CD) – Clean version

Project:	Revision of R 16-2:2002 *(see BIML note on p3)*
Title:	R yyy *Non-invasive automated sphygmomanometers* *Part 3: Test report format*
Date:	14 December 2018
Document number:	TC18_SC1_P2_N014
Supersedes document:	TC18_SC1_P2_N008
Project Group:	OIML TC 18/SC 1/p 2
Convenership:	P.R. China
Conveners:	Ms. Can Wang

Circulated to P- and O-members and liaison international bodies and external organizations for:

☐ ☐ Discussion at (date and place of meeting):

☐ ☒ Comments by: **14 March 2019**

☐ ☐ Vote (P-members only) and comments by:

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every five years after its publication by the responsible TC/SC to decided whether it should be confirmed, revised, or withdrawn.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 Rxxx-3 is refer to part 3 Test report format;
- 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 Rxxx-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 Rxxx, 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).

OIML Publications may be downloaded from the OIML web site in the form of PDF files. Additional information on OIML Publications may be obtained from the Organization’s headquarters:

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

Non-invasive automated sphygmomanometers

Part 3: Test Report Format

Explanatory notes on the test report format

i General

This Test report format, which is informative with regard to the implementation of Rxxx in national regulations, presents a standardized format for the results of the various tests and examinations to which a type of automated sphygmomanometer shall be submitted with a view to its approval as well as for the results of verification tests. The tests are listed in Rxxx-2.

It is recommended that all metrology services or laboratories evaluating types of automated sphygmomanometers according to OIML Rxxx or to national or regional regulations based on OIML Rxxx 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 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, 2012 edition) are used.

Non-invasive automated sphygmomanometers
OIML Rxxx Edition 201X (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 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:

1 Test review

1.1 Summary of test results for type approval

Clause	Subject	Test result	OIML requirement	Passed	Failed
2	Maximum permissible errors of the cuff pressure indication				
3	Maximum permissible errors of the overall system as measured by clinical investigation				
3.1	Maximum mean error				
3.2	Maximum experimental standard deviation				
4	Storage				
5	Blood pressure measuring range				
6	Repeatability of blood pressure indication				
7	Effect of voltage variations of the power source				
7.1	Internal electrical power source				
7.2	External electrical power source				
8	Air leakage of the pneumatic system				
9	Pressure reducing rate for devices using the auscultatory method				
10	Rapid exhaust				
11	Zero adjustment of a measuring system				
12	Manometer test mode				
13	Maximum time for which the cuff is inflated				
14	Electromagnetic compatibility				
14.1	Immunity				
14.2	Electrosurgery interference recovery				
15	Durability				
16	Pressure indicating device				
16.1	Nominal range and measuring range				
16.2	Digital indication				
16.3	Technical requirements for the display				
17	Signal input and output ports				
18	Safety				
18.1	Abort a measurement				
18.2	Unauthorized access and tamper proofing				

18.3	Tubing connectors				
18.4	Electrical safety				
19	Resistance to vibration and shock				

1.2 Summary of test results for verification

Clause	Subject	Test result	OIML requirement	Passed	Failed
2	Maximum permissible errors of the cuff pressure indication				
6	Repeatability of blood pressure indication				
8	Air leakage of the pneumatic system				

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.

2 Maximum permissible errors of the cuff pressure indication

For the limits of temperature and humidity see Rxxx-1 5.1: the temperature should be between 10℃ and 40℃, the relative humidity should be between 15% 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. 10℃ and 15% relative humidity, 20℃ and 60% relative humidity and 40℃ and 85% relative humidity.

Table 1 Example: Temperature 20℃ and …% relative humidity Unit (mmHg)

pressure mmHg	1st reading		2nd reading		mean		deviation	
	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 ...℃ and ... % relative humidity Unit (mmHg)

Pressure mmHg	1st reading		2nd reading		mean		Deviation	
	up	down	up	Down	up	down	up	down

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 the readings of the instrument under test and the reference manometer less than or equal to ±0.4 kPa (±3 mmHg) or ±2% of the reading, whichever is greater?

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

3 Maximum permissible errors of the overall system as measured by clinical investigation

The error of each measurement is to be calculated according to definition 2.16 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.

3.1 Maximum mean error

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

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

3.2 Maximum experimental standard deviation

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

Yes	□	→	Passed □
No	□	→	Failed □

4 Storage

Determine the error after the storage for 24 h at a temperature of -5℃ and for 24 h at a temperature of 50℃ and a relative humidity of 85% (non-condensing).

Table 3 Measurement at 20℃ and 60% relative humidity after storage at -5℃ and 50℃ Unit (mmHg)

pressure mmHg	1st reading		2nd reading		Mean		deviation from Table 2	
	Up	down	up	down	up	down	up	Down

Maximum deviation: .....

Is the maximum deviation of all the readings of the instrument under test and the reference manometer less than or equal to ±0.4 kPa (±3 mmHg) or ±2% of the reading, whichever is greater?

Yes	□	→	Passed □
No	□	→	Failed □

5 Blood pressure measuring range

Is the automated sphygmomanometer 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) ?

Yes	□	→	Passed □
No	□	→	Failed □

Is the automated sphygmomanometer 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)?

Yes	□	→	Passed □
No	□	→	Failed □

6 Repeatability of blood pressure indication

Table 4 Unit (mmHg)

Measurement No.	1	2	3	4	5	6	7	8	9	10
Systolic blood pressure										
Diastolic blood pressure										
Measurement No.	11	12	13	14	15	16	17	18	19	20
Systolic blood pressure										
Diastolic blood pressure										

Experimental standard deviation of Systolic blood pressure:

Experimental standard deviation of Diastolic blood pressure:

Is the experimental standard deviation of the blood pressure measurement of the automated sphygmomanometer less than or equal to 0.4 kPa (3 mmHg)?

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

7 Effect of voltage variations of the power source

7.1 Internal electrical power source

Do the changes of voltage within the working range of the internal power source influence the cuff pressure indication, which should comply with the requirement of Rxxx-1 5.1?

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

Note: Outside this working range no cuff pressure indication 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 ☐

7.2 External electrical power source

Do the changes of voltage within the working range of the external power source influence the cuff pressure indication, which should comply with the requirement of Rxxx-1 5.1?

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

Note: Outside the working range specified by the manufacturer, no cuff pressure indication and no result of the blood pressure measurement shall 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	☐

8 Air leakage of the pneumatic system

Carry out the test over the whole measuring range at five equally spaced pressure steps at least (e.g. 6.7 kPa (50 mmHg), 20.0 kPa (150 mmHg) and 33.3 kPa (250 mmHg)). Test the air leakage rate over a period of 5 minitues (see Rxxx-2 5.2) and determine the measured value from this. Wait at least 60 s before reading each value.

Table 5 Unit (mmHg)

Pressure mmHg	first reading	reading after 5 min	difference between the readings

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	☐

9 Pressure reducing rate 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.

10 Rapid exhaust

Does the time for the pressure reduction from 34.7 to 2.0 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 the automated sphygmomanometer, 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 ☐

11 Zero adjustment of a measuring system

The automated sphygmomanometer 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 kPa (0 mmHg) shall exist and be displayed thereafter.

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

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

Do devices performing zero adjustment 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 ☐

12 Manometer test mode

Does the automated sphygmomanometer 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.

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

13 Maximum time for which the cuff is inflated

Is the total time for which the pressure exceeds 2.0 kPa (15 mmHg) less than or equal to 180 s in the case of adult patients?
Is 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.

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

14 Electromagnetic compatibility

14.1 Immunity

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

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 ☐

14.2 Electrosurgery interference recovery

Does it 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, if an automated sphygmomanometer is intended to be used together with HF surgical equipment?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

15 Durability

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

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

16 Pressure indicating device

16.1 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.

16.2 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.

16.3 Technical requirements for the display

Is the display designed and arranged so that all information can be read and easily recognized?

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

Testing shall be carried out by visual inspection.

17 Signal input and output ports

Does 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 ensure that incorrectly fitted or defective accessories, or 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.

18 Safety

18.1 Abort a measurement

Is it possible to abort any blood pressure measurement at any time by single key operation and does this lead to a rapid exhaust?

Yes	☐	→	Passed ☐
No	☐	→	Failed ☐

18.2 Unauthorized access and tamper proofing

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.

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.

18.3 Tubing connectors

Note: Users of equipment intended for use in environments employing intravascular 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]

Are Luer locks used?

Yes ☐	→	Failed ☐
No ☐	→	Passed ☐

Is the warning (see Note above and Rxxx-1 7.5) mentioned in the instruction manual?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

Testing shall be carried out by visual inspection.

18.4 Electrical safety (This test is optional within the OIML Certificate System)

Are the requirements of the regional and national regulations fulfilled?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

19 Resistance to vibration and shock

Does the automated sphygmomanometer comply with the requirements of Rxxx-1 5.1 but only at a temperature of 20 °C ± 5 °C and at ambient humidity?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

[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.