Second Committee Draft (2CD) – Marked version

Project:	Revision of R 16-1:2002 *(see BIML note on p3)*
Title:	R xxx *Non-invasive non-automated sphygmomanometers* *Part 3: Test report format*
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☐ ☐ Discussion at (date and place of meeting):

☐ ☐ Comments by:

☐ ☒ Vote (P-members only) and comments by: **14 March 2019**

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every five years after its publication by the responsible TC/SC to decided whether it should be confirmed, revised, or withdrawn.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 R16-1 *"None-invasive mechanical 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 R16-1 are the following:

- OIML R16-1 should be revised into three parts according to OIML B6, and now OIML R16-3 is refer to part 3 Test Report Format;
- "Mechanical Sphygmomanometer" is replaced by "Non-automated Sphygmomanometers" to clarify the main distinction between types of Sphygmomanometers. This is also an argument consistent with the new ISO/IEC standards;
- Those terms that are no longer used on the context are deleted;
- "A manual system for applying and releasing pressure" is replaced by "a pneumatic system" to correspond with the term and also leave some room for electro-mechanical control;
- The metrological requirements on MPE no longer distinguish between "the first time" and "in use", and the value is put at "0.4kPa(3mmHg)" finally in consideration of the recent technical developments and health care concerned;
- In consideration of environmental and health protection, the requirement on internal diameter of the mercury tube is deleted to encourage an approach to reduce the total mercury volume;
- Parts of safety requirements are clarified in agreement with or according to the new ISO/IEC standards;
- Verification no longer distinguish between "initial" and "subsequent";
- ~~Additional technical parameters of some devices in annex A are given;~~

The present document constitutes the second Committee Draft (2CD). It was drawn up on the basis of the conclusions of comments from member nations on the first Committee Draft circulated since July 2011. 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 xxx, 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 16-1:2002 (E).

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Non-invasive Non-automated Sphygmomanometers

Part 3: 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~~ R16-1 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~~ R16-2 ~~of this International Recommendation~~.

It is recommended that all metrology services or laboratories evaluating types of sphygmomanometers according to OIML R 16-1 or to national or regional regulations based on OIML R 16-1 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 21)~~ 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 non-automated Sphygmomanometers

OIML R 16~~-1~~ 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 ~~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 (ordered according R16-2)

~~B.~~1.1 Summary of test results for type approval

Clause	Subject	~~Maximum deviation~~ Test result	~~Maximum permissible error~~ OIML requirement	Passed	Failed
~~B.~~2	Maximum permissible errors of the cuff pressure indication				
~~B.~~3	Effect of storage on cuff pressure indication				
~~B.~~4	Effect of temperature on cuff pressure indication				
~~B.~~5	Air leakage of the pneumatic system				
~~B.~~6	Pressure reduction rate for deflation valves				
~~B.~~7	Rapid exhaust				
~~B.~~8	Pressure indicating devices				
~~B.~~8.1	Nominal range and measuring range				
~~B.~~8.2	Analogue indication - Scale				
~~B.~~8.3	Analogue indication - First scale mark				
~~B.~~8.4	Analogue indication - Scale interval				
~~B.~~8.5	Analogue indication - Scale spacing and thickness of scale marks				
~~B.~~8.6	Digital indication				
~~B.~~9	Additional technical requirements for mercury manometers				
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~~B.~~10.5	Durability of manometer				
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~~B.~~11.2	Non-automated sphygmomanometers used during patient transport				
~~B.~~11.3	Non-automated sphygmomanometers containing a mercury manometer				
~~B.~~12	Abort a measurement				
~~B.~~13	Tamper proofing				
~~B.~~14	Electrical safety				
~~B.~~15	Tubing connectors				

~~B.~~1.2 Summary of test results for verification

Clause	Subject	Test result	OIML requirement	Passed	Failed
~~B.~~2	Maximum permissible errors of the cuff pressure indication				
~~B.~~5	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.

~~B.~~2 Maximum permissible errors of the cuff pressure indication

For the limits of temperature and humidity see R16-1 5.1: the temperature should be between 15℃ and 25℃, 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. 15℃ and 15% relative humidity, 20℃ and 60% relative humidity and 25℃ and 85% relative humidity.

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

pressure	1st reading		2nd reading		mean		deviation		hysteresis	
mmHg	up	down	up	down	up	down	up	down	1st reading	2nd reading
0	2	0	0	4	1	2	1	2	2	4
50	52	54	54	54	53	54	3	4	2	0
100	106	100	104	104	105	102	5	2	6	0
150										
200										
250										
column 1	column 2	column 3	column 4	column 5	column 6	column 7	column 8	column 9	column 10	column 11

maximum deviation: 5 mmHg maximum hysteresis: 6 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

Column 10 = 丨column 2 - column 3丨

Column 11 = 丨column 4 - column 5丨

Table 2: Temperature …□ and…% relative humidity **Unit (mmHg)**

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

Maximum deviation: ..... Maximum hysteresis: .....

Note 1: The hysteresis error is the absolute value of difference between the indications of the instrument when the same pressure is reached by increasing or decreasing the pressure.

Note 2: 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)?

Yes □	→	Passed □
No □	→	Failed □

~~B.~~3 Effect of storage on cuff pressure indication

~~Refer to 5.1.2.~~ Determine the error after the storage for 24 h at a temperature of -20℃ and for 24 h at a temperature of 70℃ and a relative humidity of 85%.~~(refer to Note 1 below).~~

Note: The measurements are to be performed before and after applying the test conditions, respectively:

- First measurement at 20℃ and 60% relative humidity before the test (refer to Table 2);
- Storage of the instrument under test for 24 hours at -20℃ and 85% relative humidity, immediately followed by storage of the instrument under test for 24 hours at 70℃ and 85% relative humidity;
- Second measurement at 20℃ and 60% relative humidity after the test.

~~The percentages for the relative humidity are arbitrary. The first measurement gives the reference values.~~

Each measurement requires two readings. Calculate the deviation of the mean of the two readings after storage in Table 3 from the mean calculated in Table 2. The result should be within the error limits

mentioned below.

~~*Note 2:* These conditions apply for **non-automated** blood pressure measuring instruments only.~~

Table 3 Measurement at 20℃ and 60% relative humidity after storage at -20℃ and 70℃

Unit (mmHg)

pressure mmHg	1st reading after storage		2nd reading after storage		~~mean~~ Mean after storage		deviation between the mean after storage and 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 the cuff pressure indication (mean value), after storage at -20℃ and 70℃, less than or equal to ±0.4 kPa (±3 mmHg) compared to the mean values at 20℃ and 60% relative humidity before storage?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~4 Effect of temperature on cuff pressure indication

~~Refer to 5.1.3.~~

~~*Note 1:* For a type approval test report testing has to be carried out also at 10℃ and 40℃ (see A.2.2).~~

~~*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 4) 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 to allow the device to reach steady conditions.

Table 4 Temperature 10℃ and 85% relative humidity **Unit (mmHg)**

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 5 Temperature 40℃ and 85% relative humidity **Unit (mmHg)**

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 difference between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer at the relevant temperature value less than or equal to ±0.4kPa (±3 mmHg), or ±2% of the reading, whichever is greater?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

~~B.~~5 Air leakage ~~rate~~ of the pneumatic system

Carry out the test over the whole measuring range at ~~five~~ three 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 R16-2 4.2), and determine the measured value from this. Wait at least 60 s before reading each value.

Table 6 **Unit (mmHg)**

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

Does the pressure drop over a period of 5 minutes correspond to an air leakage rate less than or equal to 0.5 kPa/min (4 mmHg/min)?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~6 Pressure reduction rate for deflation valves

Are the pneumatic system deflation valves capable of adjustment to a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s)?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

Are the pneumatic system deflation valves easily adjusted to these values.

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~7 Rapid exhaust ~~valve~~

Time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg):

t_{Re} = s,

Is t_{Re} less than or equal to 10 s?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~**B.8 Mechanical safety**~~

~~**B.8.1 Resistance to vibration and shock**~~

~~Refer to **6.6.1.1** the mechanical conditions can be found in OIML D 11 (for example clause A.2.2 of the 1994 edition).~~

~~**B.8.2 Non-automated sphygmomanometers for transport**~~

~~**The mechanical conditions can be found in 6.6.1.2.**~~

~~**B.8.3 Non-automated sphygmomanometers containing a mercury manometer**~~

~~**The mechanical conditions can be found in 6.6.1.3.**~~

~~Does the instrument comply with 5.1.1 of this Recommendation after the vibration and shock test?~~

~~yes ☐ → passed ☐~~

~~no ☐ → failed ☐~~

~~B.~~8 Pressure indicating devices

~~B.~~8.1 Nominal range and measuring range

Does the nominal range extend from 0 kPa to at least 35 kPa (0 mmHg to at least 260 mmHg)?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~8.2 Analogue indication - Scale

Is the scale designed and arranged so that the measuring values can be read clearly and easily recognized?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~8.3 Analogue indication - First scale mark

Does graduation begin with the first scale mark at 0 kPa (0mmHg)?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~8.4 Analogue indication - Scale interval

Is the scale interval 0.5 kPa or 2 mmHg for a scale graduated in kPa or mmHg, respectively?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

Is each second scale mark indicated by greater length and is each fourth scale mark numbered in the case for a scale graduated in kPa?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

Is each fifth scale mark indicated by greater length and is each tenth scale mark numbered in the case for a scale graduated in mmHg?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~8.5 Analogue indication - Scale spacing and thickness of scale marks

Is the distance between adjacent scale marks not less than 1.0 mm and does the thickness of the scale marks not exceed 20 % of the smallest scale spacing?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

Are the scale marks of equal thickness?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

~~B.~~8.6 Digital indication

Is the digital scale interval 0.1 kPa (1 mmHg)?
If the measured value of a parameter is indicated on more than one display, do all the displays indicate the same numerical value?
Are numbers and characters clearly legible?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

~~B.9 Electrical safety (This test is optional within the OIML Certificate System)~~

~~If the instrument is equipped with electrical devices, do these devices comply with regional and national safety regulations?~~

~~yes ☐~~	~~→~~	~~passed ☐~~
~~no ☐~~	~~→~~	~~failed ☐~~

~~B.~~9 Additional technical requirements for mercury manometers

~~B.~~9.1 Portable devices

Does the portable device have an adjusting or locking mechanism to secure it in a specified position of use?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

~~B.~~9.2 Device to prevent mercury from being spilled during use and transport

Does the tube have a device to prevent the mercury from being spilled during transport and use and is this device efficient?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

Is the exhaust time taken for the mercury column to fall from 27 kPa to 5 kPa (from 200 mmHg to 40 mmHg) less than or equal to 1.5 s when the pressure in the system drops rapidly from 27 kPa to 0 kPa (from 200 mmHg to 0 mmHg)?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

~~B.~~9.3 Quality of the mercury

For type approval only:

Does the supplier confirm that the purity of the mercury is not less than 99.99 %?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

For type approval and for verification:

Does a visual inspection show a clean meniscus and no bubbles of air?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

~~B.~~9.4 Graduation of the mercury tube

Are the graduations permanently marked on the tube containing mercury?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

Note: Numbered at each fifth scale mark, the numbering shall be alternately on the right-hand and left-hand side of, and adjacent to, the tube.

~~B.~~10 Additional requirements for aneroid manometers

~~B.~~10.1 Scale mark at zero

If a tolerance zone is shown at zero, is it less than or equal to ±0.4kPa (±3 mmHg)? Is it clearly marked?

Is a scale mark at zero indicated?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

Note: Graduations within the tolerance zone are optional.

~~B.~~10.2 Zero

Is the movement of the elastic sensing element including the pointer unobstructed within 0.8 kPa (6 mmHg) below zero?

Yes ☐	→	Passed ☐
No ☐	→	Failed ☐

Note: Neither the dial nor the pointer shall be adjustable by the user.

~~B.~~10.3 Pointer

Does the pointer cover between 1/3 and 2/3 of the length of the shortest scale mark of the scale?

Yes ☐	→	Passed ☐

No ☐ → Failed ☐

Is the pointer thinner than the scale mark at the place of indication and is the distance between the pointer and the dial less than or equal to 2 mm?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~10.4 Hysteresis error

Is the maximum hysteresis error throughout the pressure range less than or equal to 0.5 kPa (4 mmHg) according to Table 2?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

Note: The purpose of this test is to determine if the elastic sensing element has been exposed to a tension within the elastic range (i.e. the “Hooke’s” range) or not throughout the whole pressure range.

~~B.~~10.5 Durability of manometer

Is the change in the pressure indication after 10 000 alternating pressure cycles less than or equal to 0.4kPa (3 mmHg) throughout the pressure range?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~11 Mechanical safety

~~B.~~11.1 Resistance to shock for handheld sphygmomanometer

Does it have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping, and rough handling?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~11.2 Non-automated sphygmomanometers used during patient transport

Does it have adequate mechanical strength when subjected to mechanical stress caused by normal use, pushing, impact, dropping, and rough handling?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~11.3 Non-automated sphygmomanometers containing a mercury manometer

Does it comply with the requirements of 5.1 after testing.

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~12 Abort a measurement

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

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~13 Tamper proofing

Tamper proofing of the manometer shall be achieved by requiring the use of a tool.

Are means provided to prevent tampering and unauthorized access?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

Is it clear to an operator if tampering or authorized access has happened?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~14 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. 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.

Are Luer locks used?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

Is the warning (see Note above and R16-1 7.5) mentioned in the instruction manual?

Yes ☐ → Passed ☐

No ☐ → Failed ☐

~~B.~~15 Electrical safety (This test is optional within the OIML Certificate System)

If the instrument is equipped with electrical devices, do these devices comply with regional and national safety regulations?

Yes ☐ → Passed ☐

No ☐ → Failed ☐