INTERNATIONAL RECOMMENDATION

OIML R 148-3

Edition 2020 (E)

Non-invasive non-automated sphygmomanometers

Part 3: Test report format

Sphygmomanomètres non invasifs non automatiques

Partie 3: Format du rapport d'essai

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

Contents

Foreword **4**

1 Test review **8**
1.1 Summary of test results for type approval 8
1.2 Summary of test results for verification 9

2 Maximum permissible errors of the cuff pressure indication **10**

3 Maximum permissible error of the cuff pressure indication under storage conditions **12**

4 Maximum permissible errors of the cuff pressure indication under varying temperature conditions **13**

5 Air leakage of the pneumatic system **14**

6 Pressure reduction rate for deflation valves **15**

7 Rapid exhaust **15**

8 Pressure indicating devices **15**
8.1 Nominal range and measurement range 15
8.2 Analogue indication 16
8.3 Digital indication 17

9 Additional technical requirements for mercury manometers **18**
9.1 Portable devices 18
9.2 Device to prevent mercury from being spilled during use and transport 18
9.3 Quality of the mercury 18
9.4 Graduation of the mercury tube 19

10 Additional requirements for aneroid manometers **19**
10.1 Scale mark at zero 19
10.2 Zero 20
10.3 Pointer 20
10.4 Hysteresis error 20
10.5 Durability of the manometer 21

11 Mechanical safety **21**
11.1 Resistance to shock for handheld sphygmomanometers 21
11.2 Non-automated sphygmomanometers used during patient transport 21
11.3 Non-automated sphygmomanometers containing a mercury manometer 21

12 Aborting a measurement **22**

13 Unauthorised access and tamper proofing **22**

14 Tubing connectors **22**

15 Electrical safety **23**

16 Durability of markings **23**

Foreword

The International Organisation of Legal Metrology (OIML) is a worldwide, intergovernmental organisation whose primary aim is to harmonise the regulations and metrological controls applied by the national metrological services, or related organisations, 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. OIML Member States shall implement these Recommendations to the greatest possible extent;
- **International Documents (OIML D)**, which are informative in nature and which are intended to harmonise and improve work in the field of legal metrology;
- **International Guides (OIML G)**, which are also informative in nature and which are intended to give guidelines for the application of certain requirements to legal metrology; and
- **International Basic Publications (OIML B)**, which define the operating rules of the various OIML structures and systems.

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Non-invasive non-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 R 148-1 in national regulations, presents a standardised 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 R 148-2.

It is recommended that all metrology services or laboratories evaluating types of sphygmomanometers according to OIML R 148 or to national or regional regulations based on OIML R 148 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 Certification System (OIML-CS), 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 OIML V 2-200:2012 *International Vocabulary of Basic and General Terms in Metrology* (VIM) are used.

Non-invasive non-automated sphygmomanometers

Test report

Type approval test report ☐

Verification test report ☐

Note: 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, measurement range, range of display):

Additional devices (printer, interface, etc.):

Reference manometer (model, serial number, expanded uncertainty, calibration certificate):

Time measuring device (model, serial number, expanded uncertainty, calibration certificate):

Stamp/signature: ---

1 Test review

1.1 Summary of test results for type approval

Clause from			Subject	Test result	OIML requirement	Pass	Fail
R 148-1	R 148-2	R 148-3					
5.1	1	2	Maximum permissible errors of the cuff pressure indication				
5.2	3	0	Maximum permissible errors of the cuff pressure indication under storage conditions				
5.3	2	4	Maximum permissible errors of the cuff pressure indication under varying temperature conditions				
6.2.1	4	5	Air leakage of the pneumatic system				
6.2.2	5	6	Pressure reduction rate for deflation valves				
6.2.3	6	7	Rapid exhaust				
6.3		8	Pressure indicating devices				
6.3.1		8.1	Nominal range and measurement range				
6.3.2		8.2	Analogue indication				
6.3.2.1		8.2.1	Scale				
6.3.2.2		8.2.2	First scale mark				
6.3.2.3		8.2.3	Scale interval				
6.3.2.4	7	8.2.4	Scale spacing and thickness of scale marks				
6.3.3		8.3	Digital indication				
6.4		9	Additional technical requirements for mercury manometers				
6.4.1		9.1	Portable devices				
6.4.2	8, 9	9.2	Device to prevent mercury from being spilled during use and transport				
6.4.3		9.3	Quality of the mercury				
6.4.4		9.4	Graduation of the mercury tube				
6.5		10	Additional requirements for aneroid manometers				
6.5.1		10.1	Scale mark at zero				
6.5.2		10.2	Zero				
6.5.3		10.3	Pointer				
6.5.4	10	10.4	Hysteresis error				

6.5.5	11	10.5	Durability of manometer				
6.6.1	12	11	Mechanical safety				
6.6.1.1	12.1	11.1	Resistance to shock for handheld sphygmomanometers				
6.6.1.2	12.2	11.2	Non-automated sphygmomanometers used during patient transport				
6.6.1.3	12.3	11.3	Non-automated sphygmomanometers containing a mercury manometer				
6.6.2		0	Aborting a measurement				
6.6.3		13	Unauthorised access and tamper proofing				
6.6.5		14	Tubing connectors				
6.6.4		15	Electrical safety				
6.7	13	16	Durability of markings				

1.2 Summary of test results for verification

Clause from			Subject	Test result	OIML requirement	Pass	Fail
R 148-1	R 148-2	R 148-3					
5.1	1	2	Maximum permissible errors of the cuff pressure indication				
6.2.1	4	5	Air leakage				

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 R 148-1, 5.1: the temperature shall be between 15 ºC and 25 ºC, the relative humidity shall be between 15 % and 85 %.

To determine the error of the cuff pressure indication, conduct up and down runs at three different temperatures: e.g. 15 ºC and 15 % relative humidity, 20 °C and 60 % relative humidity, and 25 °C and 85 % relative humidity.

Table 1

Example: Temperature 20 °C and 60 % relative humidity Unit (mmHg)

Pressure	**1st reading**		**2nd reading**		**Mean**		**Deviation**		**Hysteresis**	
	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 = ⎪ column 2 – column 3 ⎪

Column 11 = ⎪ column 4 – column 5 ⎪

Table 2

Temperature …… °C and …… % relative humidity Unit (……)

Pressure	1st reading		2nd reading		Mean		Deviation		Hysteresis	
	Up	Down	Up	Down	Up	Down	Up	Down	1st reading	2nd reading

maximum deviation: _____ maximum hysteresis: _____

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

Note 2: The time between the up and down runs should not be less than five 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 ☐

3 Maximum permissible error of the cuff pressure indication under storage conditions

Determine the error after storage for 24 h at a temperature of −20 °C and for 24 h at a temperature of 70 °C and a relative humidity of 85 % (non-condensing).

Table 3

Measurement at …… °C and …… % relative humidity after storage at −20 °C and 70 °C Unit (……)

Pressure	1st reading after storage		2nd reading after storage		Mean after storage		Deviation after storage	
	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)?

Yes ☐ Passed ☐

No ☐ Failed ☐

4 Maximum permissible errors of the cuff pressure indication under varying temperature conditions

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 …… °C and …… % relative humidity Unit (……)

Pressure	1st reading		2nd reading		Mean		Deviation	
	Up	Down	Up	Down	Up	Down	Up	Down

Maximum deviation: ----------

Table 5

Temperature …… °C and …… % relative humidity Unit (……)

Pressure	1st reading		2nd reading		Mean		Deviation	
	Up	Down	Up	Down	Up	Down	Up	Down

Maximum deviation: ----------

Note: Repeat the same procedure for the set of conditions: 20 °C ambient temperature, 85 % relative humidity (non-condensing) and 40 °C ambient temperature, 85 % relative humidity (non-condensing).

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 ±0.4 kPa (±3 mmHg), or ±2 % of the reading, whichever is greater?

Yes ☐ Passed ☐

No ☐ Failed ☐

5 Air leakage of the pneumatic system

Carry out the test over the whole measurement range and at at least three equally spaced pressure steps (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 five minutes (see R 148-2, 4.2), and determine the measured value from this. Wait at least 60 s before reading each value.

Table 6

Air leakage of the pneumatic system Unit (……)

Pressure	First reading	Reading after 5 min	Difference between the readings

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

Yes ☐ Passed ☐

No ☐ Failed ☐

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	☐

7 Rapid exhaust

Time for the pressure reduction from 34.7 kPa to 2.0 kPa (260 mmHg to 15 mmHg):

t_{Re} = …… s

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

Yes	☐	Passed	☐
No	☐	Failed	☐

8 Pressure indicating devices

8.1 Nominal range and measurement range

Does the nominal range extend from 0 kPa to at least 34.7 kPa (0 mmHg to at least 260 mmHg)?

Yes	☐	Passed	☐
No	☐	Failed	☐

8.2 Analogue indication

8.2.1 Scale

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

Yes	☐	Passed	☐
No	☐	Failed	☐

8.2.2 First scale mark

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

Yes	☐	Passed	☐
No	☐	Failed	☐

8.2.3 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 fourth scale mark indicated by a greater length and is each eighth scale mark numbered in the case of a scale graduated in kPa?

Yes	☐	Passed	☐
No	☐	Failed	☐

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

Yes	☐	Passed	☐
No	☐	Failed	☐

8.2.4 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	☐

8.3 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 the numbers and characters clearly legible?

Yes	☐	Passed	☐
No	☐	Failed	☐

9 Additional technical requirements for mercury manometers

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	☐

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 26.6 kPa to 5.3 kPa (from 200 mmHg to 40 mmHg) less than or equal to 1.5 s when the pressure in the system drops rapidly from 26.6 kPa to 0 kPa (from 200 mmHg to 0 mmHg)?

Yes	☐	Passed	☐
No	☐	Failed	☐

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	☐

9.4 Graduation of the mercury tube

Are the graduations permanently marked on the tube containing mercury?

Yes	☐	Passed	☐
No	☐	Failed	☐

10 Additional requirements for aneroid manometers

10.1 Scale mark at zero

If a tolerance zone is shown at zero, is it less than or equal to ±0.4 kPa (±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.

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.

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	☐

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.

10.5 Durability of the manometer

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

Yes ☐ Passed ☐

No ☐ Failed ☐

11 Mechanical safety

11.1 Resistance to shock for handheld sphygmomanometers

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

Yes ☐ Passed ☐

No ☐ Failed ☐

11.2 Non-automated sphygmomanometers used during patient transport

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

Yes ☐ Passed ☐

No ☐ Failed ☐

11.3 Non-automated sphygmomanometers containing a mercury manometer

Does the instrument comply with the requirements of R 148-1, 5.1 after testing?

Yes ☐ Passed ☐

No ☐ Failed ☐

12 Aborting 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	☐

13 Unauthorised access and tamper proofing

Are means provided to prevent tampering and unauthorised access?

Yes	☐	Passed	☐
No	☐	Failed	☐

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

Yes	☐	Passed	☐
No	☐	Failed	☐

14 Tubing connectors

Are Luer locks used?

Yes	☐	Failed	☐
No	☐	Passed	☐

15 Electrical safety

Note: This test is optional within the OIML Certification System (OIML-CS)

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

Yes	☐	Passed	☐
No	☐	Failed	☐

16 Durability of markings

Do the required markings fulfil the requirements that they shall be removable only with a tool or by appreciable force and shall be sufficiently durable to remain clearly legible during the expected service life of the sphygmomanometer?

Yes	☐	Passed	☐
No	☐	Failed	☐