INTERNATIONAL RECOMMENDATION

OIML R 149-3

Edition 2020 (E)

Non-invasive automated sphygmomanometers

Part 3: Test report format

Sphygmomanomètres non invasifs automatiques

Partie 3: Format du rapport d'essai

ORGANISATION INTERNATIONALE DE MÉTROLOGIE LÉGALE

INTERNATIONAL ORGANIZATION OF LEGAL METROLOGY

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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.

OIML Draft Recommendations, Documents and Guides are developed by Project Groups linked to Technical Committees or Subcommittees which comprise representatives from the Member States. Certain international and regional institutions also participate on a consultation basis. Cooperative agreements have been 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, Guides and Basic Publications are published in English (E) and translated into French (F) and are subject to periodic revision.

Additionally, the OIML participates in Joint Committees with other Institutions for the development of **Vocabularies (OIML V)** and **Joint Guides (G)** and periodically commissions legal metrology experts to write **Expert Reports (OIML E)**. Expert Reports are intended to provide information and advice, 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.

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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 149-1 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 149-2.

It is recommended that all metrology services or laboratories evaluating types of sphygmomanometers according to OIML R 149 or to national or regional regulations based on OIML R 149 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 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 149-1	R 149-2	R 149-3					
5.1	1	2	Maximum permissible errors of the cuff pressure indication under ambient conditions				
5.2		3	Maximum permissible errors of the overall system as measured by clinical investigation				
		0	Maximum mean error				
		3.2	Maximum experimental standard deviation				
5.3	1	4	Maximum permissible errors of the cuff pressure indication under storage conditions				
5.4	2	5	Blood pressure measurement range				
5.5	3	0	Repeatability of the blood pressure indication				
6.3	4	0	Effect of voltage variations of the power source				
6.3.1	4.1	7.1	Internal electrical power source				
6.3.2	4.2, 4.3, 4.4, 4.5	7.2	External electrical power source				
6.4.1	5	8	Air leakage of the pneumatic system				
6.4.2	6	9	Pressure reduction rate for devices using the auscultatory method				
6.4.3	7	110	Rapid exhaust				
6.4.4	8, 9	0	Zero adjustment of a measuring system				
6.4.5		12	Manometer test mode				
6.4.6	10	0	Maximum time for which the cuff is inflated				
6.5		14	Electromagnetic compatibility				
6.5.1		14.1	Immunity				
6.5.2		0	Electrosurgery interference recovery				
6.6	11	15	Durability				
6.7		16	Pressure indicating device				
6.7.1		16.1	Nominal range and measurement range				
6.7.2		16.2	Digital indication				

6.7.3		16.3	Technical requirements for the display				
6.8	12	0	Signal input and output ports				
6.9		18	Safety requirements				
6.9.1	13	18.1	Aborting a measurement				
6.9.2		18.2	Unauthorised access and tamper proofing				
6.9.3		18.3	Tubing connectors				
6.9.4		18.4	Electrical safety				
6.10	14	0	Resistance to vibration and shock				
6.11	15	20	Durability of markings				

1.2 Summary of test results for verification

Clause from			Subject	Test result	OIML requirement	Pass	Fail
R 149-1	R 149-2	R 149-3					
5.1	1	2	Maximum permissible errors of the cuff pressure indication under ambient conditions				
5.5	3	0	Repeatability of the blood pressure indication				
6.4.1	5	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 under ambient conditions

For the limits of temperature and humidity see R 149-1, 5.1: the temperature shall be between 10 ºC and 40 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. 10 ºC and 15 % relative humidity, 20 °C and 60 % relative humidity, and 40 °C and 85 % relative humidity.

Table 1

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

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

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

maximum deviation: _____ mmHg

Note: The time between the up and down runs shall 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) 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 shall 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 three measurements per patient has to be carried out. One instrument under test, a sample of at least 85 persons, and at least two medical doctors should be involved in the tests.

The mean of the errors measured within each set of measurements shall be calculated and the maximum of these mean errors relating to the sets of measurement of the different patients shall 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 Maximum permissible error of the cuff pressure indication under storage conditions

Determine the error 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).

Table 3

Measurement at …… °C and …… % relative humidity after storage at −5 °C and 50 °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) or ±2 % of the reading, whichever is greater?

Yes	☐	Passed	☐
No	☐	Failed	☐

5 Blood pressure measurement range

Is the automated sphygmomanometer capable of indicating diastolic blood pressure over at least the range from 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 from 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 the blood pressure indication

Table 4
Repeatability of blood pressure indication Unit (……)

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: ---------- mmHg

Experimental standard deviation of diastolic blood pressure: ---------- mmHg

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 changes of voltage within the working range of the internal power source influence the cuff pressure indication, which should comply with the requirement of R 149-1, 6.3.1?

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 in the voltage to a value outside 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 changes in the voltage to a value within the working range of the external power source influence the cuff pressure indication, which should comply with the requirement of R 149-1, 6.3.2?

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 in the voltage to a value outside 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 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 149-2, 5.2), and determine the measured value from this. Wait at least 60 s before reading each value.

Table 5

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 0.8 kPa/min (6 mmHg/min)?

Yes ☐ Passed ☐

No ☐ Failed ☐

9 Pressure reduction 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 kPa 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 automated sphygmomanometers 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

At the moment of zero adjustment (at appropriate intervals, and at least after switching on the device), 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 analogue 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 and which is not be available in normal use, but is restricted to service / test personnel?

Yes	☐	Passed	☐
No	☐	Failed	☐

When the automated sphygmomanometer is put into the test mode, are all air outlets 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?

Yes	☐	Passed	☐
No	☐	Failed	☐

Is the total time for which the pressure exceeds 0.7 kPa (5 mmHg) 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	☐	Passed	☐
No	☐	Failed	☐

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

If an automated sphygmomanometer is intended to be used together with HF surgical equipment, does it return to the previous operating mode within 10 s after exposure to the field produced by HF surgical equipment, without loss of any stored data?

Yes	☐	Passed	☐
No	☐	Failed	☐

15 Durability

Is the change in 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 measurement range

Are the values of the blood pressure measurement results which are outside the nominal range of cuff pressure clearly indicated as being 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	☐

If the measured value of a parameter is indicated on more than one display, do all the displays indicate the same numerical value?

Yes	☐	Passed	☐
No	☐	Failed	☐

Are the measured numerical values on the display(s), and the symbols defining the units of measurement arranged in such a way so as to avoid misinterpretation?

Yes	☐	Passed	☐
No	☐	Failed	☐

Are the numbers and characters clearly legible?

Yes	☐	Passed	☐
No	☐	Failed	☐

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 recognised?

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 do not result in erroneous indication of cuff pressure or erroneous indication of blood pressure?

Yes	☐	Passed	☐
No	☐	Failed	☐

18 Safety requirements

18.1 Aborting a measurement

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

Yes	☐	Passed	☐
No	☐	Failed	☐

18.2 Unauthorised access and tamper proofing

Are all controls which affect accuracy sealed against unauthorised 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	☐

Is tamper proofing of the instrument achieved by requiring the use of a special tool or breaking a seal?

Yes	☐	Passed	☐
No	☐	Failed	☐

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	☐

Testing shall be carried out by visual inspection.

18.4 Electrical safety

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

Are the requirements of the regional and national regulations fulfilled?

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.

19 Resistance to vibration and shock

Does the automated sphygmomanometer comply with the requirements of R 149-1, 5.1 but only at a temperature of 20 °C ± 5 °C and at ambient humidity?

Yes	☐	Passed	☐
No	☐	Failed	☐

20 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	☐