

Title: Revision of R 148:2020 *Non-invasive non-automated sphygmomanometers*

Part 5: Verification and inspection procedures

Project Group: OIML TC 18/SC 1/p 5

Convenership: P.R. China

Conveners: Ms. Can Wang

Contents

Foreword.....	3
Introduction.....	5
Verification and inspection procedures	5
1 Principles.....	6
2 Test equipment	6
3 Test methods	7
4 Presentation of results	8

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.

This publication - reference OIML R 148-5, edition 202x (E) - was developed by OIML Technical Subcommittee TC 18/SC 1 *Blood pressure instruments*. It was approved for final publication by the International Committee of Legal Metrology in 202x.

OIML Publications may be downloaded from the OIML website in the form of PDF files. Additional information on OIML Publications may be obtained from the Organisation'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

Internet: www.oiml.org

Non-invasive non-automated sphygmomanometers

Part 5: Verification and inspection procedures

Introduction

This Recommendation specifies verification and inspection procedures for non-invasive non-automated sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

Included within the scope of this Recommendation are non-invasive non-automated sphygmomanometers with a mechanical or integrated electro-mechanical pressure sensing element and display, used in conjunction with a stethoscope or other manual methods for detecting Korotkoff sounds and for cuff inflation.

i) Description of the category of instrument

The basic components of a sphygmomanometer are a manometer for measuring and displaying pressure in the bladder and a pneumatic system for applying and releasing pressure in the bladder.

The pneumatic system includes a cuff that can be wrapped around a patient's limb, tubing, connectors, a valve for deflation (often in combination with rapid exhaust valve), transducers and a hand pump or electromechanical pump. For pressure control, electro-mechanical components may be used.

Sphygmomanometers typically use either a mercury or an aneroid manometer or another mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff.

ii) Units of measurement

The units used to indicate blood pressure shall be either the kilopascal (kPa) or the millimetre of mercury (mmHg).

Verification and inspection procedures

1 Principles

After type approval has been granted, verification shall be carried out before the sphygmomanometer is put into use and during its lifetime. Each instrument of an approved type of sphygmomanometer shall be verified periodically in accordance with applicable metrological laws and regulations of a member state, or after repair.

1.1 Maximum permissible errors of the cuff pressure indication under ambient conditions

For any set of conditions within an ambient temperature range from 15 °C to 25 °C and a relative humidity range from 15 % to 85 % for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 0.4 kPa (± 3 mmHg) for sphygmomanometers.

At verification, testing can be conducted at any set of climatic conditions within the temperature range from 15 °C to 25 °C and the relative humidity range from 15 % to 85 %. A climatic chamber is not required.

1.2 Air leakage

Air leakage shall not exceed a pressure drop of 0.5 kPa/min (4 mmHg/min).

2 Test equipment

The apparatus consists of the following:

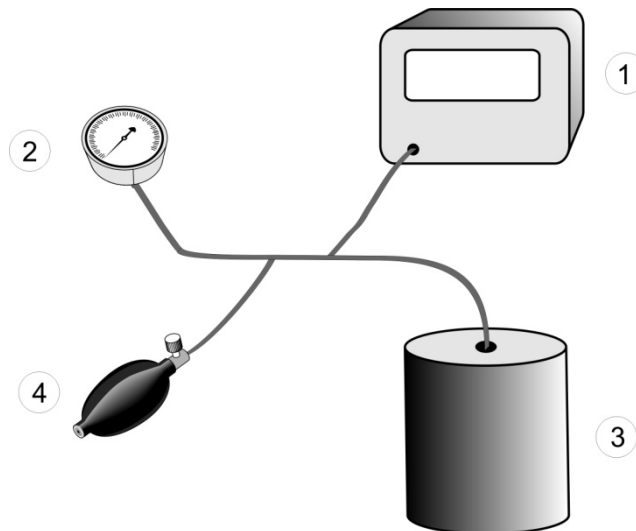
- rigid metal vessel with a capacity of 500 ml \pm 25 ml;
- calibrated reference manometer with maximum permissible error within ± 0.1 kPa (± 0.8 mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors;
- hoses with an overall length of no more than 600 mm.
- time measuring device with a maximum permissible error of 0.1 s.

3 Test methods

3.1 Maximum permissible errors of the cuff pressure indication under ambient conditions

Replace the cuff with the vessel. Connect both the calibrated reference manometer and the manometer of the device to be tested to the pneumatic system by means of a T-piece connector and hoses (see Figure 1). After disabling the electromechanical pump (if fitted), connect the pressure generator into the pressure system by means of another T-piece connector. Carry out the test in pressure steps of not more than 6.7 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range.

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer.



1 – Reference manometer; 2 – Manometer of the device to be tested;
3 – Metal vessel; 4 – Pressure generator

Figure 1 - Measurement system for determining the limits of error of the cuff pressure indication

3.2 Air leakage

Wrap the cuff around the cylinder of an appropriate size, such that the internal circumference of the applied cuff exceeds the circumference cylinder by $(7 \pm 2) \%$.

Note: Electro-mechanical pumps which are part of the device may be used for the test.

Carry out the test over the whole measurement range at at least three equally spaced pressure steps (e.g. 6.7 kPa (50 mmHg), 20.0 kPa (150 mmHg), and 33.3kPa (250 mmHg)). Test the air leakage over a period of 5 min and determine the measured value from this.

Express the air leakage as the rate of the pressure loss per minute.

4 Presentation of results

4.1 Summary of test results for verification

Clause from			Subject	Test result	Passed	Failed
R 148-1	R 148-2	R 148-3				
5.1	1	2	Maximum permissible errors of the cuff pressure indication under ambient conditions			
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.

4.2 Verification report

General information

Number of report	
Applicant's name	
Applicant's address	
Object	
Type	
Serial number	
Manufacturer's name	

Manufacturer's address	
Date of receipt	
Date/period of tests	
Name(s) of test engineer(s)	
Test laboratory's name	
Test laboratory's address	
Test apparatus used for the test	(model, serial number, expanded uncertainty, calibration certificate)
Name of the responsible person	
Date of signature	
Stamp (where applicable) and signature of the responsible person	
Remarks:	

Test data

Temperature °C and % relative humidity				Unit (.....)
Pressure	1st reading	2nd reading	Mean	Error

maximum error:

Air leakage (the rate of the pressure loss per minute) :

Verification conclusion

Passed ☐

Failed ☐

Remarks: