

Title: Revision of R 149:2020 *Non-invasive automated sphygmomanometers*

Part 4: Type evaluation report format

Project Group: OIML TC 18/SC 1/p 6

Convenership: P.R. China

Convener: Ms Can Wang

Contents

Foreword.....	3
Introduction.....	5
Applicability of this report format	5
Guidance for the application of this report format.....	5
The type evaluation report	6

Foreword

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This publication - reference OIML R 149-4, 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.

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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 automated sphygmomanometers

Part 4: Type evaluation report format

Introduction

The subject of OIML R 149-4 aims at presenting a standardised format for type evaluation report. The results of the evaluation to a type of Non-invasive automated sphygmomanometers shall be submitted with a view to its approval.

The summary of the results of the evaluation includes the conclusions of the results of the tests performed, experimental or visual checks based on the required performance criteria and associated tests in OIML R 149-1 and -2. The words or condensed sentences intend to remind the examiner of the requirements of R 149-1 and -2 without reproducing them.

Applicability of this report format

All metrology services evaluating types of Non-invasive automated sphygmomanometers according to OIML R 149-1 and -2 or to national or regional regulations based on OIML R 149-1 and -2 are strongly advised to use this type evaluation report format, directly or after translation into a language other than English or French. In the framework of the OIML Certification System (OIML-CS), usage of the type evaluation report format is mandatory.

Guidance for the application of this report format

Key to the symbols and expressions used on the following pages:

	passed	Failed
When the instruments has passed the test:	×	
When the instruments has failed the test:		×
When the test is not applicable:	/	/

The “Summary of the results” shall be completed according to the following example:

Clause	Requirement or test	Observations	Passed	Failed	N/A*	Remarks

* N/A: Requirement or test is not applicable to this instrument

The type evaluation report

The format for the report is presented on the following pages, starting with space for the cover page.

Cover page
by the
Issuing Authority

1. References of the authority responsible for this report

Name	
Address	
Number of report	
Application No.	
Period of execution of the tests	
Date of issuing the report	
Name and signature of the person responsible for the report and stamp(s) (if applicable)	

2. Synopsis of the results of the evaluation

The evaluated EUT fulfils all the applicable requirements according to OIML R149-1 and R149-2	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Remarks:		

3. Summary of the results of the evaluation

(To be completed by the OIML Issuing Authority)

Clause from			Subject	Passed	Failed	N/A
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 blood pressure measurement as determined by clinical investigation			

5.3		4	Maximum permissible errors of the cuff pressure indication under storage conditions			
5.4	2	5	Blood pressure measurement range			
5.5	3	6	Repeatability of blood pressure indication			
6.3	4	7	Effect of voltage variations of the power source			
6.4.1	5	8	Air leakage			
6.4.2	6	9	Pressure reduction rate for deflation valves			
6.4.3	7	10	Rapid exhaust			
6.4.4	8、9	11	Zero adjustment of a measuring system			
6.4.5		12	Manometer test mode			
6.4.6	10	13	Maximum time for which the cuff is inflated			
6.5.1		14.1	Immunity			
6.5.2		14.2	Electrosurgery interference recovery			
6.6	11	15	Durability			
6.7.1		16.1	Nominal range and measurement range of the cuff pressure measurement			
6.7.2		16.2	Digital indication			
6.7.3		16.3	Technical requirements for the display			
6.8	12	17	Signal input and output ports			
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	19	Resistance to vibration and shock			
6.11	15	20	Durability of markings			

4. General information

4.1 Manufacturer

Company	
Address	

4.2 Applicant

Company			
Representative			
Address			
Reference			
Date of application			
Application number			
Applicant authorised by the manufacturer (documented)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Statement that no concurrent application for OIML type evaluation has been made to any other OIML Issuing Authority (see OIML-CS-PD-05, 4.1.2 b)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Remarks:			

4.3 Testing laboratories involved in the tests

Name	
Address	
Application number	
Tests by this laboratory	
Date/period of tests	
Name(s) of test engineer(s)	

Details of relevant peer assessment or assessment by other means where applicable		
	Accreditation number:	Expires (date):
Entry area for detailed information if tests have not been performed on the premises of this laboratory but at a different location		
Name of the responsible person		
Date of signature		
Stamp (where applicable) and signature of the responsible person		
Remarks:		

4.4 General information concerning the type

Name	
Type	
Model	
Characteristic values	(principle of measurement, measuring unit, nominal range and measurement range, range of display, maximum permissible errors, temperature and humidity conditions, Height × width × length dimension, etc):

Additional devices	(cuff and bladder, printer, interface, other accessories, etc.):
Remarks	

4.5 Selection of EUTs tested

Justification of the selection of the EUTs:
Remarks:

The following EUTs have taken part in the examination:

EUT No.	Model	Serial No.
1		
2		
3		
.....		

4.6 Relevant photographs taken during the examinations and tests

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4.7 Documentation supplied by the applicant

Name of the document	Version No. / date of issue	Content

5. OIML test report(s)

Note: Here is the content of the OIML test report(s) in the format of OIML R148-3, which should be used as the basis for the type evaluation report.