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Revision of R 149 Non-invasive automated sphygmomanometers

Part 4: Type evaluation report format

TC18/SC1/p6

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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

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.

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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 149-4, edition 202x (E) - was developed by OIML Technical Subcommittee TC18/SC1 Blood pressure instruments. It was approved for final publication by the International Committee of Legal Metrology in 202x.

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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 evaluation of Non-invasive automated sphygmomanometers shall be submitted ~~with a view to its~~ for 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	☐ Yes	☐ No
Remarks:		

3 Summary of the results of the evaluation

(To be completed by the OIML Issuing Authority)

<u>Clause from R 149-1 and R 149-2 (see R 149-3 for Test report format)</u> <u>Clause from</u>			Subject	Passed	Failed	N/A	Remarks
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				

Note1: R 149-3 is only for formatting and traceability purposes.

Note2: Clinical validation must comply with ISO 81060-2 or other internationally recognized protocols as applicable.

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)	☐ Yes	☐ 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)	☐ Yes	☐ 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 :	

Note: If EMC or interference testing (Clauses 6.5.1 and 6.5.2) is performed, the laboratory must be accredited for IEC 60601-1-2 or equivalent standard.

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.):

<u>Software version / firmware identification</u>	
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		
5		
.....		

A minimum of 3–5 representative EUTs are recommended for evaluation to ensure reproducibility across device batches.

4.6 Relevant photographs taken during the examinations and tests

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Note: Photos must include front view, display unit, device markings, cuffs, connection ports, and power input label.

4.7 Documentation supplied by the applicant

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

Note: Software release notes / change log shall be included with version No. and functional description and update history

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.