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Revision of R 148 *Non-invasive non-automated sphygmomanometers*

Part 4: Type evaluation report format

TC18/SC1/p5

P.R. China – 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

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:

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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 148-4, 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 non-automated sphygmomanometers

Part 4: Type evaluation report format

Introduction

The subject of OIML R 148-4 aims at presenting a standardised format for type evaluation report. The results of the evaluation to a type of non-invasive non-automated sphygmomanometers shall be submitted with a view to its approval.

The summary 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 148-1 and -2. The words or condensed sentences intend to remind the examiner of the requirements of R 148-1 and -2 without reproducing them.

Applicability of this report format

All metrology services evaluating types of Non-invasive non-automated sphygmomanometers according to OIML R 148-1 and -2 or to national or regional regulations based on OIML R 148-1 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.

Note: See OIML-CS-PD-05 for full procedural requirements regarding concurrent applications and authority notifications.

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 sphygmomanometer fulfils all the applicable requirements according to OIML R148-1 and R148-2	☐ Yes	☐ No
Remarks:		

3. Summary of the results of the evaluation

(To be completed by the OIML Issuing Authority)

Clause from R 148-1 and R 148-2 (see R 148-3 for Test report format)			Subject	Passed	Failed	N/A
R 148-1	R 148-2	R 148-3				

5.1	1	2	Maximum permissible errors of the cuff pressure indication under ambient conditions			
5.2	2	3	Maximum permissible errors of the cuff pressure indication under storage conditions			
5.3	3	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		12	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			

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-	☐ Yes	☐ No

PD-05, 4.1.2 b)		
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 sphygmomanometers tested

For type approval of sphygmomanometers, three samples shall be supplied for the tests specified in R148-1 and R148-2. The same meter shall be subjected to all testing, except in circumstances where not doing so can be justified by the organization performing the type evaluation.

Justification of the selection of the sphygmomanometers:

Remarks:

The following sphygmomanometers have taken part in the examination:

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

4.6 Relevant photographs taken during the examinations and tests

At minimum, photographs must include: front view, scale or digital display, labeling/markings, accessories (e.g., cuffs), and overall configuration.

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.