

Template for comments and convener's observations

Date:2025-06-13

Document: R 148 – 1CD

Project: TC 18/SC 1/p 5

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0001 CZ	0				No comments		
0002 KR	0	all			No comments		
0003 DE	0	Entire document		ed	Some tables are numbered, others aren't.	Please introduce numbering for all relevant tables.	Partial accepted. Add table numbers to the tables referenced in multiple places in R148-3. Other tables are used for unique items and will not be referenced, so there is no need to add numbers.
0004 JP1	1	1		ge	It is necessary to clarify the meaning of "non-automated" at the beginning of this document. In the previous versions, R16-1 (mechanical) and R16-2 (automated), they referred to the use of a mechanical sensor or an automated transducer. However, in the current R148 (non-automated) and R149 (automated), they refer to whether the method for estimating blood pressure is automated or not, as clearly specified in 2.7, which defines non-automated sphygmomanometer. Despite this shift in definition, the document still contains some confusion. For example, the second paragraph in Clause 1 (Scope) states that mechanical or integrated electro-mechanical pressure sensing elements are included in non-automated sphygmomanometers. However, following the definition in 2.7, the sensing element is no longer the determining factor for whether the device is non-automated or automated.	Add a note clarifying that "non-automated" here refers to "non-automated methods for estimating blood pressure" and not to "mechanical sensing element." Refer to Terminology 2.7, which defines "non-invasive non-automated sphygmomanometer." Add the following examples: Example: For a sphygmomanometer equipped with an electronic pressure transducer and an LCD pressure display, but where blood pressure is estimated by a human using a stethoscope, R148 is applicable. Example: For a sphygmomanometer with a mechanical hand pump, but where blood pressure is estimated by a CPU algorithm, R149 is applicable.	Agree.
0005 JP2	1	2.1		ge	The definition of the term "auscultatory method" appears unnecessary, as it is not used in Parts 1 through 5 of R 148.	Delete Clause 2.1 auscultatory method.	Disagree. Add "auscultatory method" in Clause 2.7 contrasting with "any other manual methods".
0006	1	2.1		ge	The definition in Clause 2.1 auscultatory method	If Clause 2.1 is retained, revise the definition to	Agree.

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JP3					appears to include automatic methods, as it states "e.g. by a microphone." However, this is not typical, since the term auscultatory method is typically used to describe the manual technique performed by a clinician using a stethoscope.	exclude automatic methods—e.g., by replacing "microphone" with "stethoscope." Present: 2.1 auscultatory method method whereby sounds (known as Korotkoff sounds) are heard or detected (e.g. by <u>a microphone</u>) over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with the systolic blood pressure and the disappearance of sounds with the diastolic blood pressure Revised: 2.1 auscultatory method method whereby sounds (known as Korotkoff sounds) are heard or detected (e.g. by <u>a stethoscope</u>) over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with the systolic blood pressure and the disappearance of sounds with the diastolic blood pressure	
0007 DE	1	2.7		ed	While the definition intends to introduce the term "sphygmomanometer" as a substitute for non-invasive non-automated sphygmomanometer, this can be confusing when using both R148 and R149 or for users that do not read both Recommendations very carefully.	Introduce different abbreviations in the Recommendations. E.g in R148 NI-NA sphygmomanometer or NA sphygmomanometer. This abbreviation shall be used throughout the document.	Disagree. Not necessary. Sphygmomanometer as a substitute word differs in different Recommendations.
0008 JP4	1	5.3		te	Regarding the phrase "the difference between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer," shouldn't the first "manometer" be "sphygmomanometer," as defined in Clause 2.7, where it is stated "Hereafter called sphygmomanometer"? Otherwise, is there another intended meaning?	Change the first "manometer" in the sentence to "sphygmomanometer," or alternatively clarify the intended meaning of "manometer" in this context. Present: 5.3 Maximum permissible errors of the cuff pressure indication under varying temperature conditions For an ambient temperature range from 10 °C to 40 °C and a relative humidity of 85 % (non-condensing), the difference between <u>the indicated pressure of the manometer</u> of the device to be tested and the corresponding readings of the reference manometer at the relevant temperature value shall not exceed ±0.4 kPa (±3 mmHg) or ±2 % of the reading, whichever	Agree.

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						is greater. Revised: 5.3 Maximum permissible errors of the cuff pressure indication under varying temperature conditions For an ambient temperature range from 10 °C to 40 °C and a relative humidity of 85 % (non-condensing), the difference between <u>sphygmomanometers</u> of the device to be tested and the corresponding readings of the reference manometer at the relevant temperature value shall not exceed ±0.4 kPa (±3 mmHg) or ±2 % of the reading, whichever is greater.	
0009 BR	1	5.3		Te	Current sphygmomanometer technology is capable of meeting ±3 mmHg of error across the entire measurement range.	Remove the ±2% criterion	Disagree. This criterion is mainly set for aneroid manometer with elastic element.
0010 BR	1	6.3.3	1st	Te	Digital pressure gauges can have a scale with resolution of less than 1 mmHg	Rewrite the text to require the digital scale interval to be less than or equal to 1 mmHg	Agree.
0011 BR	1	6.4		Te	In compliance with the Minamata Agreement, the Recommendation should not establish criteria for sphygmomanometers using mercury as a manometric liquid.	Replace “mercury” with “manometric liquid” throughout the text of the Recommendation and establish a requirement prohibiting the use of this metal.	Disagree. There is still a certain amount of mercury sphygmomanometers in use that need to be tested.
0012 US	1	6.4.3		ed	Because 6.4.3 identifies three properties (purity, bubbles, meniscus) related to mercury, those that are “tested” by visual inspection could be clearly specified. Also, “clean” meniscus is vague; smooth curvature?	“6.4.3.2 The mercury shall exhibit a clean meniscus and shall not contain air bubbles. Meniscus shape and absence of air bubbles shall be assessed by visual inspection.”	Agree.
0013 US	1	6.4.4		ed	“If numbered at each fifth scale mark, the numbering shall be alternately on the right- and left-hand side of, and adjacent to, the tube.”	“If numbered at each fifth scale mark, the numbering shall be adjacent to the tube and alternately marked on the right- and left-hand side of the tube.”	Agree.
0014 DE	1	6.6.1		te	The sentence “Wall mounted sphygmomanometers and mercury manometers are exempt from the requirements of this subclause.” Should be removed. Wall mounted sphygmomanometers can be subjected to mechanical stress caused by normal use, pushing,	Remove the sentence “Wall mounted sphygmomanometers and mercury manometers are exempt from the requirements of this subclause”	Disagree. Wall-mounted sphygmomanometers and mercury manometers shall be exempt from mechanical stress testing. They shall be

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					impact, dropping and rough handling as well, so they should be tested as well.		protected from mechanical external forces under normal use conditions. Therefore, mechanical stress testing will cause damage to the test samples.
0015 US	1	7.3.2		ed	If the construction of the instrument guarantees security against any interference, the metrological control marks or the security marks may be attached in form of labels.	If the construction of the instrument guarantees security against any interference, the metrological control marks or the security marks may be attached in <u>the</u> form of labels.	Agree.
0016 BR	1	7.4.2		Te	It is important that the cuffs have a unique identification, linked to the clinical investigation in which they were used.	In addition to the inscriptions required in the Recommendation, require: - unique identification (model); - type approval number; - trademark, and; - country of origin.	Disagree. The blood pressure cuff is a component of the device, not a measuring instrument subject to separate type evaluation. The above information has already been marked on the main body of the sphygmomanometer.
0017 BR	1	7.5		Te		It should be noted that the instruction manual must be written in accordance with the International Vocabulary of Metrology and the International Vocabulary of Legal Metrology.	Yes. This is a general principle, which inspectors shall take into account during examination.
0018 DE	2			ge	It seems to be an issue with the page format.	Please check and correct.	Agree. Delete unnecessary page breaks.
0019 DE	2	1.1		te	Why only hoses with an overall length of no more than 600 mm?	Please remove this requirement	Disagree. Overly long hoses shall increase air flow resistance, leading to additional pressure loss along the way, which affects the accuracy of pressure measurements.
0020 DE	2	2.1 3.1		ed	There is no need for “; plus”	Remove “; plus” or at least “; ”	Agree. Delete “plus”.

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0021 DE	2	2.2		ed	Add the word "metal"	Replace the cuff with the vessel. Should read "Replace the cuff with the metal vessel."	Disagree. Actually, the cylinder vessel used in the test does not have to be made of metal, but must have sufficient rigidity and sealing to prevent deformation or air leakage during the experiment. Delete "metal".
0022 US	2	4.2		ed	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))	Perform the test at three pressure levels that are evenly distributed across the entire measurement range (e.g. 6.7 kPa (50 mmHg), 20.0 kPa (150 mmHg), and 33.3kPa (250 mmHg))	Agree.
0023 US	2	4.3		te	Acceptable units for expressing results would be helpful	Give an example of preferred units to express result (e.g., kPa/min)	Agree. (e.g., kPa/min or mmHg/min).
0024 BR	2	5		Te	The test involves the use of volunteers or phantoms and establishes the determination of the deflation rate graphically. Although it is interesting, it is not unfeasible.	Simplify the procedure using a pressure gauge and a stopwatch	Disagree. There is the same procedure in R149. Using recording unit, which can record the output of the calibrated reference manometer, and giving deflation rate in kPa/s or mmHg/s.
0025 DE	2	5.1 5.2		ed	Recording unit is not defined	A definition of "recording unit" should be included in Part 1	Disagree. The recording unit is used to record the output of the calibrated reference manometer, and It is not a technical requirement of sphygmomanometer.
0026 BR	2	11		Te	To vary pressure in specific waveforms it is necessary to use a pressure control. Varying compressed pressure by opening and closing valves is simpler, but the waveform is closer to a sawtooth waveform.	Exclude "sinusoidal" and keep only "pressure variation"	Disagree. Sinusoidal pressure variation simulates the dynamic fluctuation variable of blood pressure during the cardiac

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							cycle, i.e., the periodic changes in vascular pressure caused by cardiac contraction and relaxation.
0027 DE	2	11.2		ed		replace “10 000 alternating pressure cycles” with “10 000 alternating pressure measurement cycles”	Agree.
0028 BR	2	2 and 3		Te	The use of the cuff is viable and better reflects reality	Remove the reservoir and keep the cuff surrounding a cylinder with dimensions similar to the limb	Partial accepted. It is recommended to use a cylinder vessel, which can simultaneously meet the requirements of an appropriate size.
0029 SI	3	All	-	ge	A reference linking Part 3 to Part 2 should be incorporated to maintain structural coherence and traceability of related content.	In all clauses within Part 3, the corresponding clause numbers from Part 2 shall be appended to the titles. This alignment should follow the referencing approach used in OIML R 46-3.	Partial accepted. In Part 3, Clause 1.1, 'Summary of Test Results for Type Approval,' structural coherence and traceability of related content are established to link Part 3 to Part 2.
0030 SI	3	3.4	(4.2)	ge	References to verification in Part 3 are no longer required, as all verification-related content has been relocated to the newly established Part 5.	On page 5, remove the section titled “Verification Test Report” along with the associated note. Merge Table 1.2 from Section 3 into Table 1.1, ensuring consistent formatting and numbering. All other references to verification throughout the document should be either removed or revised accordingly to reflect this change.	Disagree. According to B006-2-e23/4.13.3 The test report format may also apply to verification. Part 3 shall be used to record the Original testing data. Part 5 shall give instructions concerning the verification and inspection procedures for checking compliance of a measuring instrument with the respective OIML certificate.
0031	3	Page 6		ed	The stamp should not stand alone on a single page.	Please correct the format of the page in such a way	Agree. Delete unnecessary

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DE						that the stamp is not standing alone on a page.	page breaks.
0032 DE	3	Pages 5, 8, 9, 11, 12, 13		ed	It seems to be an issue with the format throughout the document, especially concerning tables, but not only.	Please check and correct.	Agree. Delete unnecessary page breaks.
0033 IR	4		OIML-CS Procedural References (p. 5)	TE	Page 5 notes mandatory usage under OIML-CS but does not guide users on where to find relevant procedures or what those entail. So, include a footnote or annex reference to key procedural documents, especially OIML-CS PD-05 .	Add a footnote to the sentence in the “Applicability of this report format” (p. 5): <i>“See OIML-CS-PD-05 (4.1.2 b) for full procedural requirements regarding concurrent applications and authority notifications.”</i>	Agree. Add a note.
0034 IR	4	. “Introduction ,”	(p. 5)	ED	Sentence reads: “The summary of the results of the evaluation includes the conclusions of the results of the tests performed...”. Simplify to avoid redundancy.	Replace sentence (p. 5): <i>“The summary of the evaluation includes the conclusions of the tests performed...”</i>	Agree.
0035 IR	4	.“Guidance for the application of this report format,”	(p. 5)	ED	Section “Guidance for Application” (p. 5) uses × for both passed and failed, creating ambiguity. Use ✓ for passed, X for failed, and / for N/A.	Replace symbol legend (p. 5) with: - Passed: ✓ - Failed: X - Not Applicable: /	Disagree. "x" means occupied, not a judgment of right or wrong.
0036 IR	4	.Introduction	(p. 50)	GE	The document lacks clarity on whether devices with semi-automated components are included in scope. Hence, clearly state inclusion/exclusion criteria for semi-automated sphygmomanometers.	Add the following sentence to the end of the “Introduction” (p. 5): <i>“This format applies strictly to fully non-automated devices and does not extend to hybrid or semi-automated sphygmomanometers.”</i>	Disagree. In R148 (non-automated) and R149 (automated), they refer to whether the method for estimating blood pressure is automated or not, as clearly specified in 2.7, which defines non-automated sphygmomanometer.
0037 IR	4	4.5		TE	Section 4.5 mentions justification for EUT selection but gives no indication of standard testing strategies (e.g., number of samples, selection rationale, acceptance thresholds). So, reference a recognized testing strategy (ISO 2859 or OIML guidelines on statistical sampling) or include a note directing users to supporting documents.	Add a paragraph below the table in Section 4.5: <i>“Note: Sample size and selection shall be based on statistically sound sampling plans as defined in ISO 2859-1 or the applicable OIML D document. The rationale for sample selection must be documented.”</i>	Partial accepted. Add indication of standard testing strategies. For type approval of sphygmomanometers, three samples shall be supplied for the tests specified in R148-1 and R148-2. The same meter

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							shall be subjected to all testing, except in circumstances where not doing so can be justified by the organization performing the type evaluation.
0038 IR	4	4.6	(p. 11)	TE	clause 4.6 requires photos but does not specify what views or details are mandatory. It is recommended to provide a checklist or example views required (e.g., device label, manometer scale, physical configuration).	Add a bulleted note below Section 4.6 (p. 11): <i>"At minimum, photographs must include: front view, scale or digital display, labeling/markings, accessories (e.g., cuffs), and overall configuration."</i>	Agree.
0039 IR	4	2	(p. 7)	GE	"EUT" (Equipment Under Test) appears in multiple sections (especially 2 and 4.5) without definition. A glossary entry or define "EUT" on first use to be added.	Revise first instance in Section 2 (p. 7) as: <i>"The evaluated Equipment Under Test (EUT) fulfils..."</i>	Delete "EUT". "sphygmomanometer" is used to replace "EUT".
0040 IR	4	3	(p. 7–9)	TE	The report format references requirements from OIML R 148-1 and R 148-2 but does not clearly cite or include the specific normative clauses, which may hinder traceability and auditing. Explicitly cite or footnote the source clause from R 148-1 or R 148-2 for each test item. Cross-references should use a standard format (e.g., "[R 148-1: Clause 5.1]").	In the "Summary of Results" table (Section 3, pp. 7–9) it is recommended to reformat 3 first column to 1 column with heading "Reference Clause in R 148-1/2" to ensure each test criterion is traceable. Alternatively, include a footnote mapping test items to their sources.	Yes. Each test criterion is traceable now.
0041 IR	4	4	(pp. 9–12).	ED	Sections 3 and 4 use uneven formats and inconsistent sub-section labeling. So, standardize heading formats and use consistent section numbers (e.g., 4.3.1, 4.3.2).	Reformat all sub-headings in Section 4 to use decimal notation: 4.3.1 Name 4.3.2 Address 4.3.3 Application number (etc.)	Sub-section labelling is not necessary; however, information should be collected and presented in tables within the type evaluation report.
0042 JP5	5			ge	The verification recommendations in Part 5 conflict with Japan's current national verification framework. It is essential for an international standard to allow flexibility to ensure broader applicability.	Since Part 5 is understood not to be mandatory, we propose addition one of the following: a) Adding a statement to Clause 1, 'Principles,' to clarify that national verification requirements take precedence.	Agree. Add a sentence to Clause 1, 'Principles', to clarify that national verification requirements take precedence.

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						b) Part 5 is provided for informational purposes, in a similar manner to the approach used in the annex. Non-invasive non-automated sphygmomanometers Part 5: Verification and inspection procedures <u>(Informative)</u>	
0043 BR	5			Te	The test methods do not include checking the marking of the device and hysteresis testing, which we consider important in the metrological control of instruments in use. In addition, it is important to establish tests for cuffs that are sold separately, as they are an important part of the instrument's measurement chain.	Include checking the marking of the device and hysteresis testing. Include tests for cuffs that are sold separately.	Part 5 is not to be mandatory, and only the two basic items have been included. National verification requirements shall take precedence.
0044 IR	5	1.1	(p. 6)	ED	Sentence reads "...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." The phrase "for sphygmomanometers" is redundant. Remove unnecessary text for clarity.	Revise sentence (p. 6) to: "...the maximum permissible error shall be ± 0.4 kPa (± 3 mmHg) at any point of the scale range."	Agree. Remove "for sphygmomanometers", also in R148-1/2.
0045 IR	5	3.1	(p. 7)	TE	In Section 3.1, test results are expressed as differences between measured and reference values, but no formula or error calculation guidance is included. Include a formula for determining error at each pressure point.	Insert at the end of Section 3.1 (p. 7): <i>"The error shall be calculated as:</i> <i>Error=Pdevice–Preference</i> <i>Pdevice is the pressure indicated by the device under test</i> <i>PreferenceP is the reading of the calibrated reference manometer."</i>	formula or error calculation guidance is included in R148-1/3.
0046 IR	5	3.1	(p. 7)	GE	The introduction acknowledges that some devices include electromechanical parts (p. 5), but test procedures don't clarify how these should be handled (e.g., pumps). Include instructions for disabling or isolating electromechanical systems when required.	Add to Section 3.1, just before the test steps: "If fitted with an electromechanical pump, ensure it is disabled prior to connecting external pressure sources. Verify that its presence does not influence manual test procedures."	Partial accepted. Add to introduction.
0047 IR	5	3.2	(p. 8)	ED	Section 3.2 contains the phrase "...at at least three equally spaced pressure steps...". Fix typographical error.	Replace with: "...at least three equally spaced pressure steps..."	Agree. Same as 0022.

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0048 IR	5	3.2	(p. 8)	TE	Section 3.2 describes testing at various pressures but does not specify what constitutes a pass/fail outcome in terms of rate-of-leakage tolerance. So, explicitly restate the acceptance criterion from Section 1.2 or reference it during the procedural step to ensure clarity.	Add a sentence at the end of Section 3.2 (p. 8): <i>"The instrument shall be considered compliant if the pressure drop does not exceed 0.5 kPa/min (4 mmHg/min), as per Clause 1.2."</i>	Not necessary. The acceptance criterion is in Clause 1.2 with same title "Air leakage".
0049 IR	5	4.1	(p. 8)	ED	The Clause mapping table (p. 8) shows ambiguous references (e.g., "R 148-3"), but Part 3 pertains to test reports, not verification methods. Clarify or remove R 148-3 if irrelevant to test procedure validation.	Update column header in table (Section 4.1) to: "Clause from R 148-1 and R 148-2 (see R 148-3 for report format)"	Agree. Update column header in table, also in R148-3/4/5.
0050 IR	5	4.2	(p. 9)	GE	While data are presented in Section 4.2, the relationship to the structured test report format in R 148-3 is not referenced, leading to potential inconsistencies. Provide a reference to R 148-3 for test report format alignment.	At the end of Section 4.2 (Verification Report), add: "For the full structure and layout of the test report, refer to OIML R 148-3."	Agree.
0051 IR	5	4.2	(p. 9)	ED	Test data fields in Section 4.2 show "Temperature °C and % relative humidity" without placeholders or standardized format. So, standardize placeholders for consistent data entry.	Update field to: "Temperature: ____ °C; Relative Humidity: ____ % RH"	Agree.
0052 IR	5	1	(Principles), p. 6.	TE	Section 1 (Principles) describes that verification is done "periodically" but offers no clear reference to time intervals or national practices. So, clarify that periodic verification intervals are defined by the Member State, and optionally include recommended practices or typical intervals (e.g., annually, biennially).	Add a sentence to the end of Section 1 (p. 6): "The periodicity of verification shall follow national regulations. Where not specified, a recommended interval of 1–2 years may be applied based on risk analysis and usage intensity."	Agree.
0053 IR	5	2	(p. 6)	TE	Section 2 lists required equipment but omits information on calibration status, traceability, or certificates. State that all measuring equipment must be calibrated and traceable to national or international standards.	Add a paragraph after the equipment list in Section 2 (p. 6): "All test equipment shall have a valid calibration certificate traceable to national or international standards. The expanded uncertainty shall be documented and considered during evaluation."	Agree. Add to table of clause 4.2. follow requirements within "Test apparatus used for the test".

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C:\Users\MussioL\Documents\comments\R148\580-UNITED STATES_74-R 148 tc18sc01p05_1cd_comments_US.docx: Collation successful
C:\Users\MussioL\Documents\comments\R148\tc18sc01p05_1cd_comments_template-brazil.docx: Collation successful
Collation of files was successful. Number of collated files: 8
SELECTED (number of files): 8
PASSED TEST (number of files): 8
FAILED TEST (number of files): 0
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