

Template for comments and convener's observations

Date:2025-06-13

Document: R 149 – 1CD

Project: TC 18/SC 1/p 6

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0001 CZ	0	all			No comments		
0002 KR	0	All			No comments		
0003 SI	0	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.	Agree. 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.
0004 JP1	1	1		ge	It is necessary to clarify the meaning of "automated" at the beginning of this document. In the previous versions, R16-1 (mechanical) and R16-2 (automated), "automated" referred to the use of a mechanical sensor or an automated transducer. However, in the current R148 (non-automated) and R149 (automated), the term "automated" seems to refer to whether the method for estimating blood pressure is automated or not. Despite this shift in definition, the document still contains some confusion. For example, in section 6.4.2, the pressure reduction rate is no longer necessary for automated estimation, as no human is involved in listening to the Korotkov sound.	Add a note clarifying that "automated" here refers to "automated methods for estimating blood pressure" and not to "automated transducers" or "automated pressurizing methods." Refer to Terminology 2.8, which defines "non-invasive 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 in Clause 2.1 auscultatory method 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. (If it is necessary to refer to an automatic sphygmomanometer that uses Korotkov sounds,	Replace "are heard or detected (e.g. by a microphone)" with "are heard by a stethoscope or another manual method." Present: 2.1 auscultatory method method whereby sounds (known as Korotkoff sounds) are heard or detected (<u>e.g. by a microphone</u>) over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with	Agree.

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² Type of comment: ge = general te = technical ed = editorial

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					please call it the 'automatic Korotkov sound method' instead of the 'auscultatory method,' to avoid confusing readers.)	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 <u>by a stethoscope or another manual method</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	
0006 JP3	1	2.1		ed	While "auscultatory method" is defined in Clause 2.1, the full term does not appear elsewhere in the document. Only the partial term "auscultatory" is used. This creates a mismatch between the terminology and its actual usage.	Revise the heading of Clause 2.1 from "auscultatory method" to "auscultatory (method)."	Agree.
0007 US	1	2.6		te	Suggest more specificity of manometer definition	"instrument used to measure the pressure of liquids or gasses (including arterial blood pressure)"	Agree.
0008 DE	1	2.8		ed	While the definition intends to introduce the term "sphygmomanometer" as a substitute for non-invasive automated sphygmomanometer, this can be confusing when using both R148 and R149 or for users that do not read both Recommendations very carefully or read only fragments of the Recommendation.	Introduce different abbreviations in the Recommendations. E.g in R149 NI-A sphygmomanometer.(or alternatives). This abbreviation shall be used throughout the document.	Disagree. Not necessary. Sphygmomanometer as a substitute word differs in different Recommendations.
0009 JP4	1	2.10		ed	While "oscillometric method" is defined in Clause 2.10, the full term does not appear elsewhere in the document. Only the partial term "oscillometric" is used. This results in inconsistency between the terminology and its usage in the text.	Revise the heading of Clause 2.10 from "oscillometric method" to "oscillometric (method)."	Agree.
0010 US	1	2.13		te	Additional description of the specific meaning of "exhaust" would help better define the term	"valve for rapidly releasing air and depressurizing the pneumatic system"	Agree.
0011 US	1	2.14		ed	Unclear what is meant by "essentially"	Perhaps this means "inelastic component of the cuff encasing the bladder"	Agree.

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0012 JP5	1	3		ge	Descriptions of the components that make up a sphygmomanometer appear multiple times — in Clause 2.8 and Clause 3 — and they are not fully consistent. This redundancy and inconsistency may cause confusion for readers. To improve clarity and avoid duplication, consolidate all content related to the sphygmomanometer's components — including the notes — into a single location: Clause 2.8. During consolidation, the following issue should be addressed: The phrase “a pressure transducer” in Clause 2.8 is no longer a defining feature of automated sphygmomanometers, as some non-automated devices may also include pressure transducers.	Revise Clause 2.8 as follows: - Delete the phrase “a pressure transducer”. - Move Note 1 from Clause 3 to Clause 2.8. Delete Clause 3 in its entirety. Proposed Replacement Text for Clause 2.8: 2.8 non-invasive automated sphygmomanometer medical measuring instrument used for the intermittent non-invasive estimation of the blood pressure by utilising an inflatable cuff, a valve for deflation, and/or displays used in conjunction with automated methods for estimating blood pressure. Hereafter referred to as “sphygmomanometer” in this Recommendation Note 1 to entry: Specific device types included in this category are: sphygmomanometers for self-measurement, blood pressure monitors and multi-parameter patient monitors used for home healthcare, or public use.	Partially agree. Clause 3 “Description of the category of instrument” is an essential element which cannot be deleted. The descriptions of component parts in 2.8 and 3 are now unified. Revise Note 2.
0013 BR	1	5.1		Te	Current sphygmomanometer technology easily meets the ± 3 mmHg limit across the entire measurement range.	Remove the $\pm 2\%$ criterion, keeping only the ± 3 mmHg limit for the entire measurement range	Disagree.Consistent with IEC 80601-2-30.
0014 DE	1	5.4		ed	Replace “from” with “of”	The sphygmomanometer shall be capable of indicating diastolic blood pressure over at least the range of 2.7 kPa (20 mmHg) to 8.0 kPa (60 mmHg) in neonatal mode, and 5.3 kPa (40 mmHg) to 17.3 kPa (130 mmHg) otherwise. The sphygmomanometer shall be capable of indicating systolic blood pressure over at least the range of 5.3 kPa (40 mmHg) to 14.7 kPa (110 mmHg) in neonatal mode, and 8.0 kPa (60 mmHg) to 30.7 kPa (230 mmHg) otherwise.	Agree.

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0015 US	1	5.4		ed	"The sphygmomanometer shall be capable of indicating diastolic blood pressure over at least the range from 2.7 kPa (20 mmHg) to 8.0 kPa (60 mmHg) in neonatal mode, and 5.3 kPa (40 mmHg) to 17.3 kPa (130 mmHg) otherwise. "	The sphygmomanometer shall be capable of indicating diastolic blood pressure over a minimum range of 2.7 kPa (20 mmHg) to 8.0 kPa (60 mmHg) while in neonatal mode. Otherwise, the sphygmomanometer shall be capable of indicating over a range of 5.3 kPa (40 mmHg) to 17.3 kPa (130 mmHg). "	Agree.
0016 JP6	1	5.5			The 3 mmHg standard deviation requirement is too strict, as it includes variation from the patient simulator. Since the simulator is not designed to match the device's algorithm, its own deviation can be significant and distort the results.	Add the phrase "excluding the standard deviation of the patient simulator" at the end of the paragraph to ensure only the device's performance is assessed. Revised: 5.5 Repeatability of blood pressure indication For any set of conditions within the ambient temperature range from 10 °C to 40 °C and the relative humidity in the range from 15 % to 85 %, the experimental standard deviation of the blood pressure indication of the sphygmomanometer shall not exceed 0.4 kPa (3 mmHg), <u>excluding the standard deviation of the patient simulator.</u>	Disagree. The patient simulator used in test has reached its own requirement of repeatability. There is no reason to exclude the standard deviation of the patient simulator.
0017 DE	1	5.5 and throughout the document		ed	Please either use: in the range of x to y, or from x to y. The formulation "in the range from" is not correct. I might have missed pointing out some examples, please check the entire document.	For any set of conditions within the ambient temperature range of 10 °C to 40 °C and the relative humidity in the range of 15 % to 85 %, the experimental standard deviation of the blood pressure indication of the sphygmomanometer shall not exceed 0.4 kPa (3 mmHg).	Agree.
0018 US	1	6.2		ed	"For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents."	"For reusable cuffs, the manufacturer shall describe the proper method of cleaning the cuffs in the accompanying documents."	Disagree. Detailed cleaning method is not essential.
0019 JP7	1	6.2	1 st paragraph	te	Clause 6.2 "Technical requirements for the cuff and bladder" currently states that "The cuff shall be designed and marked...". This represents a significant change from both the previous version of this document (R16-2), which did not specify either requirement, and the referenced document (IEC 80601-2-30), which allows for either "designed" or	Revise the sentence to: "The cuff shall be designed or marked..." Present: The cuff shall be designed <u>and</u> marked... Revised: The cuff shall be designed <u>or</u> marked...	Agree.

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					"marked." Requiring both design and marking imposes an unnecessary constraint.		
0020 BR	1	6.2	2nd	Te	It is not necessary to specify the cuff dimensions as these are assessed in the clinical investigation.	Remove this paragraph and require that the dimensions of the cuff used be described in the clinical investigation report.	Agree.
0021 JP8	1	6.2	2 nd paragraph	te	Clause 6.2 "Technical requirements for the cuff and bladder" currently recommends that the bladder length be 80% of the limb circumference and the width be 40% of the limb circumference. This represents a significant change from both the previous version of this document (R16-2), which included this information only as a note, and the referenced document (IEC 80601-2-30), which no longer includes this recommendation. While such dimensional guidance may be appropriate for a reference cuff used in clinical validation, it is now generally considered unnecessary for devices undergoing validation.	The recommendation regarding bladder dimensions in Clause 6.2, second paragraph — "The bladder length should be approximately 0.80 × the circumference of the limb at the midpoint of the intended range of the cuff. The width of the bladder should be at least 0.40 × the circumference of the limb at the midpoint of the intended range of the cuff." — should be deleted.	Partially agree. The paragraph which specifies the dimensions of the cuff has been deleted.
0022 BR	1	6.3	2nd	Te	Subclauses 6.3.1 and 6.3.2 are identical. Furthermore, the expression "shall not influence the cuff pressure indication" is subjective.	Simplify item 6.3 and establish a criterion and acceptance to replace the mentioned phrase	Disagree. The test procedure of internal electrical power source and external electrical power source is different. It will be better to declare them separately to keep structural coherence with following parts.
0023 JP9	1	6.3.16.3.2	2 nd paragraph	te	Clause 6.3.1 and 6.3.2 specifies: "Outside the working range no cuff pressure indication and no result of the blood pressure shall be displayed." However, this requirement is practically incompatible with correct operation near the boundaries inside the working range, where some margin is typically necessary. Requiring indication suppression immediately outside the range may interfere with reliable operation near the specified limits within the working range.	Delete the requirement that no indication be shown immediately outside the working range. Present (6.3.1): 6.3.1 Internal electrical power source Changes in the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure indication. Outside this working range no cuff pressure indication and no result of the blood pressure measurement shall	Agree.

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						be displayed. Present (6.3.2): 6.3.2 External electrical power source Changes in the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure indication. Outside the working range specified by the manufacturer, no cuff pressure indication and no result of the blood pressure measurement shall be displayed.	
0024 JP10	1	6.4.1	1paragraph	te	Clause 6.4.1, Air leakage is no longer necessary for automated sphygmomanometers, which generally refer to devices using the oscillometric method in current practice. These devices estimate blood pressure by analyzing analog fluctuations in cuff pressure and are less sensitive to deflation speed compared to non-automated devices, which rely on detecting discrete sounds.	Delete Clause 6.4.1, Air leakage.	Disagree. Automatic sphygmomanometers that use Korotkov sounds still exist.
0025 JP11	1	6.4.2		te	Clause 6.4.2, "Pressure reduction rate of devices using the auscultatory method," is not necessary for R149, where clinicians do not estimate blood pressure using a stethoscope. Automated sphygmomanometers estimate blood pressure using a CPU algorithm and may not rely on the direct use of Korotkov sounds.	Delete Clause 6.4.2, "Pressure reduction rate of devices using the auscultatory method."	Disagree. Automatic sphygmomanometers that use Korotkov sounds still exist.
0026 BR	1	6.4.4	1st	Te	The expression "zero adjustment" does not correctly indicate the requirement, which is to check whether the sphygmomanometer is capable of identifying oscillations in the measurement due to its components.	Replace the term "zero adjustment" with "offset adjustment"	Disagree. "Zero adjustment" is more intuitive for reader to comprehend the goal of adjustment.
0027 BR	1	6.4.4	2nd	Te	It is not necessary for the sphygmomanometer to indicate 0 mmHg, if it has some indication that it is ready for measurement.	Eliminate the requirement for the sphygmomanometer to start the measurement scale at zero	Disagree. The indication of 0 mmHg is helpful for users to ensure the initial condition of measurement.

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0028 BR	1	6.4.5	1st	Te	Although restricted, access to manometer test mode should not require additional equipment, in order to facilitate periodic verification activities.	Include a sentence stating that access to manometer test mode must be done using the keys available to the operator and without the use of additional tools.	Agree.
0029 BR	1	6.4.5	3rd	Te	We propose a test to replace compliance with this requirement with a manufacturer's declaration because, in a sample of 10 sphygmomanometer models, we found that one of them only made zero adjustment in manometer mode.	Test proposal: 1) Take 10 measurements with a simulator, under normal conditions, and calculate the average; 2) Introduce a residual pressure of up to ± 3 mmHg into the pneumatic circuit of the sphygmomanometer and maintain it until its internal pump is activated. Take 20 measurements and calculate the average; 3) Calculate the average error and check if it meets the limit of ± 3 mmHg;	Disagree. Specific test proposal is not essential in this clause.
0030 BR	1	6.5.1		Te		See the comment of 5.1	Disagree. Same as no.0013
0031 US	1	6.6		ed	The technical requirement within this clause on durability could be clarified	Possibly: "The change in the cuff pressure indication shall not exceed 0.4 kPa (3 mmHg) at any level across the entire pressure range after 10 000 simulated measurement cycles."	Agree.
0032 BR	1	6.6		Te	Considering that there is already a standard for evaluating simulators (ISO 81060-5) and that they are usually quite repetitive, their use in tests is more appropriate than the manometer as it is closer to the reality of using sphygmomanometers.	Replace the expression "cuff pressure indication" with "blood pressure indication"	Disagree. The meaning of "cuff pressure" and "blood pressure" are not the same.
0033 BR	1	6.7.2	1st	Te	There are already sphygmomanometers on the market with a resolution of less than 1 mmHg	Rewrite the paragraph to clarify that the digital scale interval must be less than or equal to 1 mmHg	Agree.
0034 BR	1	6.7.2	2nd	Te	Currently, there are sphygmomanometers whose indicating unit is not a display physically connected to the rest of the circuit, but rather a separate device or a mobile application. This requires the Recommendation to address the issue of modularity	Establish, for example, that in the case of an indicator unit being a generic device for personal use, such as cell phones, the manufacturer must specify the compatible hardware and software version and demonstrate this through climate and EMC test reports.	Agree.
0035	1	6.10		te	The sentence "A fixed (e.g. wall mounted)	Remove the sentence "A fixed (e.g. wall mounted)	Disagree. A fixed

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DE					sphygmomanometer is exempt from the requirements of this subclause.” should be removed. Wall mounted sphygmomanometers can be subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling as well, so they should be tested as well.	sphygmomanometer is exempt from the requirements of this subclause.”	sphygmomanometers normally be exempt from pushing, impact, dropping, and rough handling. They shall be protected from mechanical external forces.
0036 US	1	7.2		ed	After type approval has been granted, verification shall be carried out before the sphygmomanometer is put into use and during its lifetime.	“After type approval has been granted, a sphygmomanometer shall be verified before it is put into use and throughout its lifetime of operation.”	Agree.
0037 US	1	7.3		ed	Awkward presentation of conditional requirements	“Metrological control marks shall be put on seals. These seals shall prevent, without destruction of the control marks: - manipulation of the metrological components for measuring blood pressure in patient-monitors for which the sphygmomanometer is only one part of a system; and - opening of the casing of all other types of sphygmomanometers.”	Agree.
0038 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.	Partially agree. The above information has already been marked on the main body of the sphygmomanometers. The blood pressure cuff is a component of the device, not separated during type evaluation. Add “Note: It is necessary to select and use the appropriate cuff model specified in the manufacturer's instruction manual.”
0039 BR	1	Annex A		Te	The content of this Annex is very important and should be included directly as a requirement.	Migrate the content of Annex A to item 5.2, excluding the term “recommended” to make it mandatory	Disagree. The content of this Annex is highly recommended, but keeping

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					The ISO 81060-2 standard is already recognized as a “universal protocol” and was also prepared considering the guidelines of the 1993 BHS protocol. It is also important that the investigation be carried out impartially and that its results be adequately published.	Remove the BHS document from the list of recommended protocols Include requirements regarding impartiality and publication of results in journals.	this Annex Informative will be better. The BHS document is not fully covered by ISO 81060-2. Specific requirements of clinical investigation need further discussion.
0040 BR	2	3		Te	The influence of environmental conditions on blood pressure measurement is important, as we have identified models that work well in manometer mode, but do not work well with blood pressure	Unify this test with item 1, carrying out the measurement with a simulator at the three temperatures and calculating the average error between them	Disagree. The influence of environment temperature is quite important. But a broader agreement among most countries is needed to consider temperature effect on blood pressure measurement. The practicability of changing environment temperature in test still needs further discussion.
0041 DE	2	3.1		te	What is the reason for removing the sentence: “The generated signal values shall be approximately: systolic: 16.0 kPa (120 mmHg); diastolic: 10.7 kPa (80 mmHg); pulse rate: 70 min-1 to 80 min-1 .”? It is important that the device works properly at values relevant for a human being.	Either leave the sentence in or propose another pertinent requirement.	The generated signal values are expressed in following Note 1 and Note 2 with details.
0042 US	2	3.2	Note 1	Ed	“the generated signal values of the patient simulator shall be set: systolic: 16.0 kPa (120 mmHg); diastolic: 10.7 kPa (80 mmHg); pulse rate: 80 min-1.”	“the generated signal values of the patient simulator shall be set to: 16.0 kPa (120 mmHg) systolic pressure; 10.7 kPa (80 mmHg) diastolic pressure; 80 min-1 pulse rate.” And similar edits for the Note 2	Agree.
0043 BR	2	4		Te	Manufacturers have difficulty in correctly specifying the working voltage range of the types. Since the important is to ensure the accuracy of the type for any input voltage at which a blood pressure measurement can be made, the minimum voltage limits can be those obtained in procedures and	Simplify and unify test procedures taking measurements only at the minimum voltage limit obtained in the test procedures 4.1.2, 4.4.2 and 4.5.2 and the maximum limit specified by the manufacturer, independent of the type of power supply (internal or external electric power source, direct or alternating	Disagree. Manufacturers should give a correct working voltage range.

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					request only information about the maximum voltage limit, which cannot be obtained in test procedures.	current), and requiring measurements with a simulator	
0044 JP12	2	4.1.14.2.17.1 8.19.211.112 .1	2nd bullet point	te	The required accuracy for the apparatus manometer is too strict. According to widely accepted metrology guidelines, test equipment should have an accuracy at least three times better than that of the device under test (a 3:1 Test Accuracy Ratio).	Change the accuracy requirement from ± 0.1 kPa (± 0.8 mmHg) to ± 0.13 kPa (± 1 mmHg). Present: calibrated reference manometer with a maximum permissible error within <u>± 0.1 kPa (± 0.8 mmHg)</u> . Revised: calibrated reference manometer with a maximum permissible error within <u>± 0.13 kPa (± 1 mmHg)</u> .	Disagree. At Present, calibrated reference manometer with a maximum permissible error within ± 0.1 kPa (± 0.8 mmHg) is a commonly achievable specification and is not a stringent requirement. The same requirement also applies in R 148.
0045 JP13	2	5.		te	Clause 5, Test for air leakage of the pneumatic system is no longer necessary for automated sphygmomanometers, which generally refer to devices using the oscillometric method in current practice. These devices estimate blood pressure by analyzing analog fluctuations in cuff pressure and are less sensitive to deflation speed compared to non-automated devices, which rely on detecting discrete sounds.	Delete Clause 5, Test for air leakage of the pneumatic system.	Disagree. Automatic sphygmomanometers that use Korotkov sounds still exist, which air leakage test is required.
0046 BR	2	5.2	4th	Te	The 7% criterion does not seem to be very operational	Replace “7%” with a value between half and the maximum limit of the range	Disagree. Changing the 7% criterion may make the cuff too tight or too loose.
0047 JP14	2	6.1	2 nd paragraph		The required accuracy for the apparatus manometer is too strict. According to widely accepted metrology guidelines, test equipment should have an accuracy at least three times better than that of the device under test (a 3:1 Test Accuracy Ratio).	Present: calibrated reference manometer with a signal output port and a maximum permissible error within <u>± 0.1 kPa (± 0.8 mmHg)</u> . Revised: calibrated reference manometer with a signal output port and a maximum permissible error within <u>± 0.13 kPa (± 1 mmHg)</u> .	Disagree. Same as no.0044
0048 BR	2	9.1		Te	The criterion for applying the drift test only to those that adjust to zero when switching on, as well as the procedure for obtaining the time waiting for the model to switch off, seems to have been designed for models that have a button to switch on and another to start measurement, but most portable models only	Include a note stating that this test is not applicable to sphygmomanometers that make adjustments before starting a blood pressure measurement. Another note would state that portable devices that have only one button and make adjustments when	Agree.

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					have one button for both functions. To perform a new measurement on most portable models, if not all, it is necessary to swith it off and on again, and thus, saying that it does it when swiching on is equivalent to saying that it does it before each measurement. Thus, the greatest applicability would be for models with 2 buttons, one to swith on and another to start and stop BP measurement. Equipment with these 2 buttons would be blood pressure and multifunction monitors, as well as ABPM.	switched on, which is equivalent to saying that they make adjustments at each measurement. Another note stating that for monitors and ABPM that remain turned on and do not make adjustments at each measurement, the time for the drift test will be 24 hours.	
0049 US	2	11.2		ed	Carry out the test for the maximum permissible errors of the cuff pressure indication but only at a temperature of 20 °C ± 5 °C and at ambient humidity prior to prolonged usage.	“Prior to substantial usage of the sphygmomanometer under test, carry out the test for the maximum permissible errors of the cuff pressure indication at a temperature of 20 °C ± 5 °C and at ambient humidity. . .”	Agree.
0050 BR	2	12.3		Te	There is no established criteria	Accept a maximum deviation of ±1 mmHg	Agree.
0051 BR	2	13.2		Te		Rewrite the text to make it clear that the term “Abort the measurement during inflation” refers to the procedure described in the operating manual.	Agree.
0052 US	2	15		ed	markings are rubbed by hand, without undue pressure, first for 15 s with a cloth soaked with distilled water, then for 15 s with a cloth soaked with methylated spirits and then for 15 s with a cloth soaked with isopropyl alcohol;	“markings are rubbed by hand with moderate pressure . . .” “markings are gently rubbed by hand . . .”	Agree.
0053 BR	2	4	and 8,11	Te	The use of the patient simulator is more appropriate than the manometer mode	Rewrite the test procedure to use the patient simulator instead of manometer mode	Disagree. Manometer mode is essential in test procedure.
0054 DE	3		Page 7,8	ed	It seems to be an issue with the format throughout the document, especially concerning tables, but not only.		Partially agree. Formats of several tables are edited.
0055 SI	3	4.2	(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	Disagree. According to B006-2-e23/4.13.3 The test report

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						formatting and numbering. All other references to verification throughout the document should be either removed or revised accordingly to reflect this change.	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.
0056 IR	4	0 Guidance for the application of this report format.	(p. 5)	ED	The symbol guide (p. 5) indicates “x” for both “Passed” and “Failed,” which is contradictory and unclear. Replace symbols with		

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IR					instruction or check on test lab compliance with ISO/IEC 60601-1-2 test environments. Require that EMC testing be conducted in a lab with ISO 17025 accreditation or equivalence.	"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."	
0062 IR	4	4.4	(p. 10)AND 4.7 (p. 12)	TE	As automated sphygmomanometers rely on embedded software, the evaluation format lacks any field for versioning, validation status, or firmware update traceability. Add a subsection under Section 4.4 for software version and include it in the documentation list (Section 4.7).	Under Section 4.4, add: "Software version / firmware identification: _____" And in Section 4.7, include a new row: "Software release notes / change log – Version X – Functional description and update history"	Agree.
0063 IR	4	4.5	(p. 11	TE	The form does not specify how many units (EUTs) are required to constitute a representative sample for evaluation. Introduce a guideline for sample size, or reference OIML D documents or relevant ISO standards.	Add at the end of Section 4.5: "A minimum of 3–5 representative EUTs are recommended for evaluation to ensure reproducibility across device batches."	Agree.
0064 IR	4	4.6	(p. 11)	TE	Section 4.6 lists "photographs," but does not define views or quality standards required. Specify minimum photo documentation (e.g., full device, serial number label, ports, and screen).	Add to Section 4.6: "Photos must include front view, display unit, device markings, cuffs, connection ports, and power input label."	Agree.
0065 IR	4	3	(p. 8)	TE	Section 3 (Evaluation Summary) includes 5.2 "clinical investigation" but lacks detail on what constitutes acceptable methods or standards (e.g., ISO 81060-2, AAMI/ESH/ISO). Add a note specifying the acceptable clinical validation procedures and reference applicable standards.	Add a footnote to Clause 5.2 entry (p. 8): "Note: Clinical validation must comply with ISO 81060-2 or other internationally recognized protocols as applicable."	Agree.
0066 JP15	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. b) Part 5 is provided for informational purposes, in a similar manner to the approach used in the annex. Non-invasive non-automated sphygmomanometers	Partially agree. International recommendations require a consensus among most countries regarding sphygmomanometer. Any country can implement the recommendations based on national reality. Add a sentence to Clause 1,

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						Part 5: Verification and inspection procedures <u>Informative</u>	'Principles', to clarify that national verification requirements take precedence.								
0067 BR	5			Te	The test methods do not include checking the marking of the device, test for air leakage and test for rapid exhaust, 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, test for air leakage and test for rapid exhaust. Include tests for cuffs that are sold separately.	Partially agree. Add a clause of test for air leakage .Cuffs that are sold separately are not included in this test.								
0068 IR	5		Figure 2 caption, p. 8	ED	Figure 2 caption says “Setup to test the repeatability of the blood pressure indication” — slightly awkward phrasing. Improve clarity.	Revise to: “Setup for testing the repeatability of blood pressure indication using a patient simulator”	Agree.								
0069 IR	5	1	(p. 6)	TE	Test criteria (e.g., ±3 mmHg) appear within the text, but no summary table consolidates all permissible limits for quick reference. Include a table summarizing test limits for error, repeatability, and pressure reduction rate.	Add a table at the end of Section 1: <table><thead><tr><th>Test Item</th><th>Permissible Limit</th></tr></thead><tbody><tr><td>Cuff pressure error (5.1)</td><td>±0.4 kPa (±3 mmHg) or ±2%, which</td></tr><tr><td>Repeatability (5.5)</td><td>≤0.4 kPa (3 mmHg) SD</td></tr><tr><td>Pressure reduction (6.4.2)</td><td>0.3–0.4 kPa/s (2–3 mmHg/s) or per</td></tr></tbody></table>	Test Item	Permissible Limit	Cuff pressure error (5.1)	±0.4 kPa (±3 mmHg) or ±2%, which	Repeatability (5.5)	≤0.4 kPa (3 mmHg) SD	Pressure reduction (6.4.2)	0.3–0.4 kPa/s (2–3 mmHg/s) or per	Partially agree. summary table is in clause 4.1
Test Item	Permissible Limit														
Cuff pressure error (5.1)	±0.4 kPa (±3 mmHg) or ±2%, which														
Repeatability (5.5)	≤0.4 kPa (3 mmHg) SD														
Pressure reduction (6.4.2)	0.3–0.4 kPa/s (2–3 mmHg/s) or per														
0070 BR	5	1.1	1st	Te	The text establishes the same maximum permissible error for initial and periodic checks	Return the ±4 mmHg criterion for periodic and maintain ±3 mmHg for initial and repair	Disagree.The text establishes the same maximum permissible error for initial and periodic checks. It 's commonly achievable specification.								
0071 IR	5	1.Principles	p. 6	TE	Section 1 (Principles) states periodic verification is required but does not define recommended time intervals or provide examples. Provide a baseline recommendation or reference national regulations more clearly.	Add at the end of Section 1 (p. 6): “Verification should be conducted at intervals defined by national metrological regulations. In absence of such specifications, a recommended interval of 1–2 years may be applied depending on usage frequency.”	Agree.								
0072 IR	5	2	(p. 7)	TE	Patient simulators are used in Section 3.2 but there's no mention of required calibration or uncertainty. Specify that simulators must be calibrated with	Add to Section 2: “Patient simulators used shall have valid calibration certificates traceable to national standards, and the	Disagree. The requirement of patient simulator has been described in Clause 3.1 of								

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					traceable standards and provide expanded uncertainty values.	uncertainty of their generated pressures shall not exceed ± 0.2 kPa (± 1.5 mmHg)."	Part2.
0073 IR	5	2	(p. 7)	ED	Section 2 mentions "recording unit" without explanation or example (e.g., oscilloscope, data logger). Clarify expected functionality or give examples.	Revise bullet under Section 2: "Recording unit (e.g., digital data logger or oscilloscope capable of capturing deflation curves)"	Disagree. The recording unit is used to record the output of the calibrated reference manometer, and It is not a technical requirement of sphygmomanometer.
0074 IR	5	3.1	(p. 7)	TE	Devices with test modes often require custom software for data capture. This is not addressed. Include a clause recognizing the use of manufacturer-provided software and criteria for acceptance.	Add to Section 3.1: "If the device includes proprietary test software or diagnostic interface, its use shall be documented and validated for accuracy and repeatability."	Agreed.
0075 IR	5	3.3	(p. 9)	TE	For pressure reduction rate per pulse (Section 3.3), the method lacks guidance on capturing valid pulse intervals and rates. Define how to verify and record pulse rates and recommend allowable tolerance for pulse-timed deflation.	Add at the end of Section 3.3: "For pulse-dependent deflation, the pulse rate should be measured in real-time or simulated, and device behavior should be recorded and compared against expected deflation timing with $\pm 10\%$ tolerance."	Agree.
0076 IR	5	3.3	(p. 9)	TE	In Note 3 Artificial limb use is permitted, but their specifications (e.g., elasticity, compliance) are vague. Reference any known standard (if available) or minimum properties for artificial limb simulation.	In Section 3.3 Note 3, revise to: "It is recommended that artificial limbs exhibit elastic properties comparable to human limbs, such as a compliance range of 0.5–1.0 mL/mmHg."	Disagree. It is difficult to reach a consensus about Elastic properties of human limbs among different countries and peoples.
0077 IR	5	4.1	(p. 10)	TE	Section 4.1 refers to "R 149-3" but does not clarify its function (formatting/reporting vs technical requirement). Clarify distinction.	In Section 4.1 Table heading, revise to: "Clause from R 149-1 / R 149-2 (see R 149-3 for reporting format only)"	Agree.
0078 IR	5	4.2 and 4.3	(p. 11–12)	ED	Sections 4.2 and 4.3 provide placeholders for data entry but use inconsistent alignment and lack clear units. Standardize input format for clarity and consistency.	Revise all data fields to follow format: "Temperature: ____ °C; Relative Humidity: ____ % RH; Unit: ____" And use aligned column format for repeated measurements (Section 4.2).	Agree.

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