Country Code[1]	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment[2]	Comments	Proposed change	Convener's responses
0001 US	all			gen	The US has reviewed the 2CD package of documents on OIML R16-1. We note especially the significant number of good/technical comments submitted by other countries (especially Germany). This leads us to believe that this Recommendation is not yet ready for CIML voting and publication … it needs another CD to implement suggested improvements. This document is not used in the USA, but our manufacturers have repeatedly told us that the OIML Recommendation needs to be as closely harmonized as possible with the other international standards for these instruments. We vote "abstain."		Agree This recommendation is going to be as closely harmonized as possible with the other international standards.
0002 IR 08	1			Ge	According to the experience of technical assessments, evaluation and test of Sphygmomanometers(in all type)in the laboratories,it is suggested that following items are added: 4- Principles and Statistical methods for acceptance or rejection of a shipment of Sphygmomanometer 2- Number of samples required for the test based on the build volume (statistically) 3- Number of repeating of the tests 4- The criteria for acceptance and rejection of one lot		Disagree The recommendation would like to supply the technical requirements and testing procedures for the blood meters. Acceptance quality for lot by lot inspection of the blood meters within manufactories and labs could follow the general sampling procedures for inspection, or chosen principles and statistical methods items according to specified files.
0003 DE	1			te	There is no requirement on the "durability of marking" as in ISO 81060-1, 4.3 and Annex A. A requirement like that should be included.	Adopt a similar text to ISO 81060-1, 4.3 and Annex A	Agree Add "durability of marking" items.
0004 IR 01	1	1	First Paragraph	Ge	This recommendation has not covered electrical safety requirements and basically IEC develops these issues.	It is recommended to modify the first paragraph of scope to "this recommendation specifies technical and metrological requirements including …"	Agree Although subclause 6.6.4 is Electrical safety. Regional or national regulations may specify electrical safety requirements. It's general requirement without details.

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0005 DE	1	1. Scope		ed	Delete "and" in the 1st sentence.	This Recommendation specifies general, performance, efficiency, mechanical and electrical safety requirements,	Agree
0006 DE	1	1. Scope		te	What does "The application of the cuff is not limited to a particular extremity of the human body (e.g. the upper arm)" mean? The manual auscultatory bp measurement can only be performed at the upper arm.	Delete "The application of the cuff is not limited to a particular extremity of the human body (e.g. the upper arm)"	Agree
0007 IR 03	1	2		Te	Adding definition of the "manometer" can be useful for users of this recommendation.		Agree
0008 DE	1	2.		ed		introduce the terms in an alphabetical order	Agree
0009 IR 02	1	2.1		Te		It is recommended to add the sentence "hereafter is named sphygmomanometer in this recommendation." at the end of definition.	Agree
0010 DE	1	2.1		ed	1. The wording "…for the non-invasive measurement estimation of the arterial blood pressure …" is strange. Use either "measurement" or "estimation". 2. The term sphygmomanometer is not defined; therefor it should not be used for the definition of a non-automated non-invasive sphygmomanometer.	Suggestion: Device used by a trained person for the non-invasive measurement of the arterial blood pressure by utilizing an inflatable cuff with a display and used in conjunction with a stethoscope for measuring the arterial blood pressure.	Agree Add the definition of sphygmomanometer.
0011 DE	1	2.1	Title	ed	Following our proposal to change the title and the text, add here "non-invasive".	2.1 Non-automated non-invasive sphygmomanometer	Agree
0012 DE	1	2.8		te	At present the medical societies do not recommend to use K4 for the diastolic bp but K5.	Delete: "in adults. In children under age of 13, "k4" (i.e. 4th phase Korotkoff sound) may be appropriate." It should read: Technique whereby sounds (known as Korotkoff sounds) are heard 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.	Agree
0013 DE	1	2.8		te	Why are the definitions in Rxxx and Ryyy different?	Define the same terms identically in both OIML recommendations.	Agree
0014 IR 04	1	3		Te	In the sentence of Note 1: "these devices" is not clear (indicate to which device!).it seems that some components indicated under Note1 are redundant.	It is recommended to specify "these devices" more clearly or rewrite the clause as follows: "The basic components of a sphygmomanometer are a manometer for measuring and displaying pressure in the bladder and a pneumatic system for applying and releasing pressure in the bladder. Pneumatic system includes cuff that can be wrapped	Agree

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						around a patient's limb, tubing, connectors, valve for deflation (often in combination with rapid exhaust valve), transducers and hand pump or electromechanical pump. For pressure control, electro-mechanical components may be used. Non-automated sphygmomanometers typically use either a mercury or an aneroid manometer or another mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff.	
0015 DE	1	3.	1st para	ed	Specify: "non-automated non-invasive". Other types of sphygmomanometers can have other types of components.	The sentence should read: "The basic components of a non-automated non-invasive sphygmomanometer are…."	Agree This clause will be rewritten in accordance with Comment 0014. And a description will be added in the previous section. The term sphygmomanometer appearing in this recommendation refers to non-invasive non-automatic sphygmomanometers.
0016 DE	1	3.	2nd para	te	What does "or another mechanical measuring device" mean? Does it stand for "electro-mechanic" as in 6.3.2?	It should read: Non-automated non-invasive sphygmomanometers typically use either a mercury or an aneroid manometer or electro-mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff.	Agree
0017 DE	1	3.	Note	ed	Does the note give any additional information, not given in the two paragraphs above?	Delete the note (and merge with) the text above the note.	Agree
0018 BR	1	4		Te	The Draft of 9th edition of the SI Brochure (which was endorsed by the CIPM at its 106th meeting **and will take place on 20 May 2019**), removed the milimeters of mercury of Non-Unit SI list. **So the mmHg is no longer recognized by the CIPM as a unit in use with the SI.**	Remove milimeters of mercury **in order to encourage the use of SI unit kilopascal (kPa) and eliminate confusions generated by several ancient units of pressure still in use like mmHg.**	Disagree Medical organizations such as International Society of Hypertension are still using mmHg as unit of blood pressure. However, the mmHg is no longer recognized by the CIPM as a unit in use with the SI, it also very necessary to mark kPa（mmHg）in pairs to avoid units transforming confusions. kPa should be used for prioritization. This requires a transitional time, as

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							well as consideration of the actual situation of medical applications.
0019 BR	1	5		Te	Since the measurement procedure which uses non-automated sphygmomanometer has been used as reference to measurement procedure of automated sphygmomanometer (ISO 81060-2), its accuracy must be better than that one. As good practice, the accuracy of a reference must be three times better than accuracy of an instrument. That is, the measurement error of non-automated sphygmomanometer measurement procedure must be one third of maximum permissible error of automated sphygmomanometer (MPE_{AS}), as shown in equation below. $$U_{NAS} \leq \frac{MPE_{AS}}{3}$$ Where U_{NAS} is the uncertainty that comes from the measurement procedure with non-automated sphygmomanometer. According to most recent good practice, a patient's assessment should be started based on the mean value obtained from at least two blood pressure measurements taken at intervals of 1 to 2 minutes. Thus, the value of U_{NAS} can be obtained from equation below (ISO 10576-1:2003): $$U_{NAS} = k \frac{u_{NAS}}{\sqrt{n}}$$ where u_{NAS} is the combined uncertainty, n is the number of measurements performed and k is the coverage factor. Because the measurement model of the method which uses non-automated sphygmomanometer is not determined, the combined uncertainty can be determined by equation below: $$u_{NAS}^2 = u_{sphyg}^2 + u_{person}^2$$ where u_{sphyg} is the uncertainty that comes from the non-automated sphygmomanometer and u_{person}	Replace clause 5 with text below. 5. Metrological requirements 5.1 Maximum permissible error The maximum measurement error of non-automated sphygmomanometer shall be determined with equation below and shall be less than or equal to 0.06 kPa. $$|B| + \sqrt{u_{cert}^2 + u_{\alpha,\beta}^2 + \left(\frac{Div_{min}}{2\sqrt{3}}\right)^2 + s_r^2 + s_L^2}$$ 5.2 Component B B is the measurement bias of non-automated sphygmomanometer indication. Its value shall be determined according Rxxx-2. 5.3 Components u_{cert} and $u_{\alpha,\beta}$ u_{cert} and $u_{\alpha,\beta}$ are, respectively, the uncertainties of certificate and calibration curve or reference manometer. Your values must be determined annually and the value of their combination shall be less than or equal to 0.02 kPa. 5.4 Component Div_{min} Div_{min} corresponds to the value of the smallest division of the sphygmomanometer scale. 5.5 Component s_r s_r is the repeatability of sphygmomanometer and its value shall be determined according to Rxxx-2. 5.6 Component s_L s_L is the result of the combination of several standard deviation that quantifies the influence that only one of the following sources exerts at a time on the sphygmomanometer measurement result:	Disagree The sphygmomanometer is a commonly used medical device, but it is not a high-level measuring device in measurement performance, and qualification evaluation method should be used to determines the maximum allowable error. Although non-automatic sphygmomanometers are used in clinical conformity tests, this test is not a traceable metrological test, and does not mean that non-automatic sphygmomanometers should comply with the technical requirements of the reference standard.

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					corresponds to the uncertainty due to the trained person. Thus, if we consider that u_{sphyg} and u_{pesron} are equally important we will have $u^2_{NAS} = 2u^2_{sphyg}$. Considering $k = 2$ (probability of 95%), $n = 2$ and $MPE_{AS} = 0.36$ kPa (see proposed change of item 5 of 1CD Ryyy-1), we have $u_{sphyg} \leq U/6 = 0.06$ kPa. However, in legal metrology it cannot be guaranteed that instrument owners will apply the necessary correction to compensate for the systematic component of a measurement error. Therefore, the value of u_{sphyg} must include the modulus of the measurement bias (B), as shown in equation below. $$\lvert B \rvert + u_{sphyg} \leq 0.06\ kPa$$ The both components can be determined through a typical calibration process. Then the equation can be rewritten as below. $$\lvert B \rvert + \sqrt{u^2_{cert} + u^2_{\alpha,\beta} + \left(\frac{Resol}{2\sqrt{3}}\right)^2 + s^2_r} \leq 0.06\ kPa$$ Where u_{cert} is uncertainty of certificate of reference manometer, $u_{\alpha,\beta}$ is uncertainty of calibration curve of manometer reference, Resol is sphygmomanometer resolution and s_r is the sphygmomanometer repeatability. However, legal metrological control intends to assure the reliability of measurement under the conditions of use. Thus the equation above must have an additional component which represents the combination of influence quantity, that is, the reproducibility (s_L), as shown in equation below. $$\lvert B \rvert + \sqrt{u^2_{cert} + u^2_{\alpha,\beta} + \left(\frac{Resol}{2\sqrt{3}}\right)^2 + s^2_r + s^2_L} \leq 0.06\ kPa$$	• Hysteresis; • Environmental conditions; • Storage; • Durability; • Resistance to vibration and shock (not applicable for fixed automated sphygmomanometer); • Voltage variations of the power source (only applicable if sphygmomanometer need a power source); • Electrostatic discharges (only applicable if sphygmomanometer has electronic components); • Radiated, radio-frequency, electromagnetic fields (only applicable if sphygmomanometer has electronic components); The value of each intermediate precision shall be determined according to Rxxx-2.	
0020	1	5.1		editorial	Space between numerical value and unit	… 15 °C to 25 °C…; 15 % to 85 %	Agree

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Austria							
0021 DE	1	5.1		ed	It is unnecessary to specify "for sphygmomanometers" at the end of the paragraph, but if you do, one should be precise and use the formulation "for non-automated non-invasive sphygmomanometers"	remove "for sphygmomanometers"	Agree
0022 Austria	1	5.2		editorial	Space between numerical value and unit	… -20 °C …. 70 °C …. 85 %	Agree
0023 JP1	1	5.2	1st and 2nd sentences	ed	These long sentences mention a test sequence for storage. However, it is difficult to understand clearly.	We propose the following common amendment for both sentences. *The sphygmomanometer without/with ... after a storage for 24 h at a low temperature of -5 °C and which is followed by an additional storage for 24 h at a high temperature of 70/50 °C and at a relative humidity of 85% (non-condensing).*	Agree
0024 DE	1	5.2	last sentence	ed/te	The entire test cannot be performed with the unpacked devices, only the storage itself. To check compliance with 5.1 the devices will be unpacked. (see also 3.2 in Rxxx-2, there the procedure is very clear)	Change last sentence to: "The storage shall occur with the unpacked sphygmomanometers."	Agree
0025 Austria	1	5.3		editorial	Space between numerical value and unit	… 10 °C to 40 °C …. 85 %	Agree
0026 DE	1	5.3	1st para	te	This paragraph is referencing B.4. There is not such chapter/paragraph in this document.		Agree Delete B.4, which was marked for the clause of test procedure in last vision.
0027 DE	1	5.3	1st sentence	ed	change "of" with "from"	The sentence should read: "For the ambient temperature range from 10°C to 40°C…"	Agree
0028 JP2	1	6.1	2nd paragraph	ed	Please make corrections of the comma and the multiplication sign.	Present: …0,80 x Correct: …0.80× Present: …0,40 x Correct: …0.40×	Agree
0029 IR 05	1	6.1	second Paragraph	Ed	corrections of 0,4 and 0,8 are needed.	It is recommended to modify "0,8x" to "0.8x" and "0,4x" to "0.4x". Also, it should be to describe the whole sentence more clearly.	Agree
0030 BR	1	6.3.2.3		Te	Once the suggestion on clause 5 is accepted, clause 6 needs to be modified.	Remove text below from subclause 6.3.2.3. The scale interval shall be: • 0.5 kPa for a scale graduated in kPa;	Disagree The suggestion on clause 5 is not accepted.

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						• 2 mmHg for a scale graduated in mmHg.	
0031 DE	1	6.3.2.3	1st para after bullet points	ed	change "for" to "of"	the sentence should read: "In the case of a scale graduated in kPa:…" and "In the case of a scale graduated in mmHg:…"	Agree
0032 DE	1	6.3.2.3	last para	ed	This requirement does not apply to any type of sphygmomanometer; specify "non-automated non-invasive"	The sentence should read: "For non-automated non-invasive sphygmomanometers with a manometer…"	Agree a description will be added in the previous section. The term sphygmomanometer appearing in this recommendation refers to non-invasive and non-automatic sphygmomanometers.
0033 IR 06	1	6.3.2.3	Second paragraph	Te	Description of the 6.3.2.3 does not conform to figure 1.	Based on the figure 1, it is recommended to modify the sentence to "In the case for scale graduated in kPa: Each fourth scale mark shall be indicated by greater length and each eighth scale mark shall be numbered.	Agree
0034 BR	1	6.3.3		Te	Once the suggestion on clause 5 is accepted, clause 6 needs to be modified.	Remove text "The digital scale interval shall be 0.1 kPa (1 mmHg)" from subclause 6.3.3.	Disagree The suggestion on clause 5 is not accepted.
0035 BR	1	6.4		Te	The Minamata convention on mercury promoted by United Nations entered into force on 16 August 2017 and is a global treaty to protect human health and the environment from the adverse effects of mercury.	Remove subclause 6.4 (and all subclause which mention mercury) and include a warning in Recommendation to inform that mercury manometers shall be not used.	Partly agree on 16 August 2017, the Minamata Convention on Mercury – a global treaty to protect human health and the environment from human-induced emissions and releases of mercury and mercury compounds – came into force. According to Article 6, paragraph 8 in the convention, a state or regional economic integration organization may, at the times set out in paragraphs 1 (a) and (b), register for an exemption for that product or process, which shall expire ten years after the relevant phase-out date. Each Party shall include in its national action plan with a schedule for the

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							implementation. which means, the new production of mercury-containing thermometers and mercury-containing sphygmomanometers has not been prohibited until 2026, in some states. Those may still be used in a certain area and in a short time. However, it is really necessary to add notification to inform that mercury manometers shall be not used in the future.
0036 BR	1	6.5		Te	Once the suggestion on clause 5 is accepted, this subclause needs to be modified.	Remove subclauses 6.5.4 and 6.5.5 because it is already include in subclause 5.6 and will detailed in Rxxx-2.	Disagree The suggestion on clause 5 is not accepted.
0037 Austria	1	6.5.1		editorial	Space between numerical value and unit	…0,4 kPa……	Agree
0038 DE	1	6.5.3	last sentence	te	How realistic is it to ensure compliance with 6.5.3 just by visual inspection? Most probably, a scaled magnifying glass or a similar instrument will be required.	remove "Testing shall be carried out by visual inspection."	Agree Testing shall be carried out by length instruments rather than visual inspection.
0039 DE	1	6.5.5		te	A range for the cycles has to be added. ISO 81060-1 requires <= 20 mmHg to full scale.	The last sentence should read: After 10 000 alternating pressure cycles from <= 20 mmHg (2,67 kPa) to full scale the change in the pressure indication shall be not more than 0.40 kPa (3,0 mmHg).	Partly agree Clause 11 in Rxxx-2 has given a range for the cycles. The last sentence will be modified. After 10 000 alternating pressure cycles from 3 kPa (20 mmHg) to full scale the change in the pressure indication shall be not more than 0.4 kPa (3 mmHg).
0040 DE	1	6.5.5	Title	ed	Please change the title to "Stability of the elastic sensing element"	The title should read: Stability of the elastic sensing element	Disagree The terminology in VIM of durability test is "5.22 durability test, test intended to verify whether the EUT is able to maintain its performance characteristics over a period of

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							use". Additionally, the stability test is relevantly more general to check its performance as time passes, while durability test is one kind of specific stability tests that to check not only as time passes but also in consideration of the periodic use.
0041 BR	1	6.6		Te	Once the suggestion on clause 5 is accepted, this subclause needs to be modified.	Remove subclause 6.6.1 and 6.6.4 because they are already include in subclause 5.6 and will detailed in Rxxx-2.	Disagree The suggestion on clause 5 is not accepted.
0042 DE	1	6.6.1.1		te	Why are fixed sphygmomanometers exempt from this rule? They can still be hit (unintentionally), roughly handled or fall down. And what about the mobile sphygmomanometers (fixed on a portable/mobile frame/stand)?	Discuss in the working group	Mechanical safety requirements are based on the following three conditions. The first category is for non-fixed requirements. It is generally believed that the probability of accidental hitting or rough handling of a fixed sphygmomanometer is much lower than that of a non-fixed sphygmomanometer. This requirement does not include mercury sphygmomanometers, which contain glass components, and falling down could lead to breakage of glass. The second type is that the sphygmomanometer needs to undergo continuous random shock and vibration during patient transportation. The third type is the package drop test for mercury sphygmomanometer to prevent leakage of mercury.
0043 DE	1	6.6.1.1	title	ed	add "non-automate non-invasive"		Agree
0044	1	6.6.1.3		Te	Same as item 6.4	Remove subclause 6.6.1.3	Disagree

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BR							The suggestion on clause 6.4 is not accepted.
0045 DE	1	6.6.1.3	1st para	te	The change from "in a condition of normal use" (identical to ISO 81060-1, 6.4.3) to "under condition of packed" loosens the requirement. This is not acceptable for environmental reasons to limit the spilling of mercury.	Keep the former text: … in a condition of normal use.	Disagree Mercury sphygmomanometers contain glass components, and falling down "in a condition of normal use" could lead to breakage of glass. This change was made in consideration of the actual situation.
0046 BR	1	6.6.3		Te	Same as item 6.4	Remove the text "for mercury non-automated sphygmomanometers, the separation of reservoir and scale".	Disagree The suggestion on clause 6.4 is not accepted.
0047 DE	1	7.	1st para	ed	Add "non-automated" in the 1st sentence. Add "metrological" in the 2nd sentence.	"…, initial and/or subsequent verification for non-automated non-invasive sphygmomanometers. These metrological controls shall meet the following conditions."	Agree
0048 BR	1	7.1		Ed	The code "R16-2" and "R16-3" will be replaced by "Rxxx-2" and "Rxxx-3".	Replace "OIML R16-2" by "Rxxx-2" and "OIML R16-3" by "Rxxx-3".	Agree
0049 BR	1	7.2		Te	Once the suggestion on clause 5 is accepted, this subclause needs to be modified.	Change the text of subclause 7.2, as indicated below, in bold. After type approval has been granted, verification shall be carried out before the non-automated sphygmomanometer is put into use and during its lifetime. At verification, testing can be conducted at any set of climatic conditions within the temperature range of **10** °C to **40** °C and the relative humidity range of 15 % to 85 %. A climatic chamber is not required. Each instrument of an approved type of non-automated sphygmomanometer shall be verified **before put into use,** periodically in accordance with applicable metrological laws and regulations of a member state **and** after repair. **Each verification shall evaluate the air leakage, according 6.2.1, and measurement error according according 5.1. The values of B, u_{cert}, $u_{\alpha,\beta}$ and s_r shall be determine according 5.2 to 5.5 and the value of Div_{min} and s_L shall be the same of type approval report.**	Disagree The suggestion on clause 5 is not accepted.
0050 BR	1	7.3.1		Te	Same as item 6.4	Remove the text "in the case of mercury manometers: the separation of reservoir and scale".	Disagree The suggestion on clause 6.4

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							is not accepted.
0051 DE	1	7.4		ed/te ?	What does "measuring unit" stand for? Units of measurement (kPa/mmHg)? Please clarify.	Use better/clearer wording or delete.	Agree Replace the text with "Units of measurement (kPa/mmHg)".
0052 BR	1	7.4		Te	Same as item 6.4	Remove the text "information for containing mercury are required for mercury manometers".	Disagree The suggestion on clause 6.4 is not accepted.
0053 BR	1	7.4		Te	The information requested in this subclause must be reordered because some refer to indicating device and other refer to the cuff.	Replace the text of subclause 7.4 with the text below. 7.4 Marking of the device The sphygmomanometer shall be marked with the following information: 7.4.1 On the indicating device a) name or trademark of manufacturer; b) type of sphygmomanometer; c) measuring unit, positioned close to the displayed values; d) type approval number (if applicable); e) serial number; f) year of fabrication; g) country of origin. 7.4.2 On the cuff: a) name or trademark of manufacturer; b) type approval number (if applicable); c) limb circumference for which it is appropriate; d) marking of the limb circumference indication range; e) center of the bladder, indicating the correct position for the cuff over the artery; f) country of origin.	Partly agree Modification of comments. It is not required that same information shall be marked both on the indicating device and on the cuff.
0054 BR	1	7.5		Te	Same as item 6.4	Remove the text "detailed instructions for the safe handling of mercury (see Annex A)".	Disagree The suggestion on clause 6.4 is not accepted.
0055 BR	1	7.5		Te	Instruction manual needs to be more complete.	Replace subclause 7.5 with text below. 7.5 Manufacturer's information Information supplied by the manufacturer shall comply with the specifications and requirements given in this Recommendation.	Agree

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						The manufacturer's instruction manual shall contain the following information: • reference to OIML Ryyy including the complete title; • explanation of the operating procedures which are important for correct application (such as the selection of the appropriate cuff size, positioning of the cuff at the heart level and adjustment of the pressure reduction rate); • methods for cleaning reusable cuffs; • if the bladder is removable, the method for ensuring the correct repositioning of the bladder in the cuff; • nature and frequency of the maintenance is required to ensure that the device operates correctly and safely at all times; a disclosure that applicable national or regional metrological laws and regulations have to be considered; • a list of all components belonging to the pressure measuring system, including accessories; • remarks on the environmental or operational factors which may affect the performance (e.g. electromagnetic fields, arrythmia); • specification of the rated voltage, if applicable; • specification of the intended power source, if applicable; • measuring interval; • the operating and storage temperature and humidity ranges; • warm up time, if applicable; • description of all symbols, abbreviations and error codes used on the instrument; and • Name and address of manufacturer.	
0056 DE	1	7.5	5th bullet,	ed	substitute "have to be" with "shall be"	the sentence should read: "…regulations shall be considered"	Agree
0057 BR	1	Annex A		Te	Same as item 6.4	Remove Annex A.	Disagree The suggestion on clause 6.4 is not accepted.
0058 DE	1	Title and text		ge	The title is unusual compared to the ISO document: OIML:Non-invasive non-automated sphygmomanometers	Non- automated non- invasive sphygmomanometers	Agree

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					ISO 81060-1: Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type The term "non-invasive sphygmomanometer" should be kept together. The change should be made throughout the whole document (including Terminology).		
0059 DE	1	Whole document		ed	ISO and IEC are using the comma to separate decimals, not the decimal point, e.g. 0,4 kPa not 0.4 kPa.	Change to decimal comma	Agree
0060 DE	1	Whole document		te	Giving integer numbers like "3 mmHg" opens the door for interpretation. Some would argue a limit of 3 mmHg is fulfilled also for 3,4 mmHg (probably mathematically correct), others would understand the limit as 3,0000 mmHg. To avoid discussions at least for the values given in "mmHg" ",0" should always be added.	Add to all mmHg-values ",0", e.g. change 3 mmHg to 3,0 mmHg.	Disagree Scale interval is 2 mmHg for a scale graduated in mmHg usually. The reading can only be estimated at 1 mmHg without a scaled magnifying glass; therefore, results of error can only be rounded to integers.
0061 BR	2	1		Te	Once the suggestion on clause 2 of Rxxx-2 is accepted, this clause needs to be removed.	Remove this clause.	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.
0062 DE	2	1.1		te	What is the justification for "hoses with an overall length of no more than 600 mm"?	Delete "hoses with an overall length of no more than 600 mm".	Disagree. The deflation rate of 0.3 kPa/s to 0.4 kPa/s is empirically obtained from the real operations of mercury sphygmomanometer through past decades. The hose length of 600 mm is basically according to the hose length of the mercury sphygmomanometer that used in clinic. The greater of the hose length means the greater of the air volume in the whole connection system, which would induce extremely low of deflation rate of pressure during testing even the valve is already totally full-opened.
0063	2	1.1	Figure 1	Te	Item 2 in the figure needs correction.	It is recommended to modify the phrase "the device to	Agree

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IR 07						be tested" to "Manometer of the device to be tested"	
0064 BR	2	2		Te	Once the suggestion on clause 5 of Rxxx-1 is accepted, this clause needs to be modified. The proposed change consists in perform a three-factor fully-nested experiment, as described in ISO 5725-3:1994, to determine the repeatability of sphygmomanometer because it is already considering the influence of environmental conditions and hysteresis. This is necessary because the temperature and humidity during verification process cannot be controlled. The number of 5 measurements was determined according to subclause 9.8 of ISO 5725-3:1994, which determines 2^{n-1} measurements for an n factor fully-nested experiment.	Replace clause 2 with text below. 2 Determination of measurement bias (B) and repeatability of sphygmomanometer (including influence of hysteresis and environmental conditions) 2.1 Apparatus • T-piece connectors and hoses; • Rigid vessel with a capacity of 500 ml ±25 ml; • Calibrated reference manometer which complies subclause 5.3 of Rxxx-1; • Pressure generator, e.g. ball pump (hand pump) with a deflation valve. • Climatic chamber with temperature range from -20 °C to +70 °C (rate of change 1 °C/min and instability within ±1 °C) and relative humidity range from 50% to 85% (instability within ±5%). 2.2 Procedure Connect, as shown in the figure 2, the non-automated sphygmomanometer with the rigid vessel and the reference manometer. For each of the following combinations of temperature and humidity, place the non-automated sphygmomanometer for at least 3 h in the climatic chamber to allow the system to reach steady conditions: • 10 °C ambient temperature, 85% relative humidity (non-condensing); • 20 °C ambient temperature, 85% relative humidity (non-condensing); • 40 °C ambient temperature, 85% relative humidity (non-condensing). At each combination of temperature and humidity perform the following steps: • switch on the non-automated sphygmomanometer (if applicable); • wait until the warm up time (described in the instructions for use) has elapsed; • set pressure in steps of not more than 7 kPa	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.

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						between 0 kPa and 37 kPa or the maximum pressure of the scale range (whichever is less);
						• wait 5 min at maximum pressure;
						• reduce pressure in the same steps;
						• repeat the increasing and decreasing pressure cycles;
						• switch off the automated sphygmomanometer afterwards.
						
						Note: for verification, there is no need to perform this steps in each combination of temperature.
						
						2.3 Results
						
						The measurement bias and repeatability shall be determined for each pressure step separately.
						
						2.3.1 Type approval
						The repeatability of sphygmomanometer (including influence of hysteresis and environmental conditions) is calculated as follows:
						
						$$s_r^2 = A + B$$
						
						$$A = \left(\frac{1}{t-1} - \frac{pr-1}{ptr-p-t+1}\right)\sum_j(\bar{y}_j - \bar{y})^2$$
						
						$$B = \left(1 - \frac{1}{pr}\right)\frac{\sum_i\sum_j\sum_k(y_{ijk}-\bar{y})^2 - tr\sum_i(\bar{y}_i-\bar{y})^2}{ptr-p-t+1}$$
						
						Where,
						p = number of samples of the type of sphygmomanometer;
						t = number of temperatures;
						r = number of replicates;
						$\bar{y}$ = mean of all measurements;
						$\bar{y}_i$ = mean of measurements of one sample;
						$\bar{y}_j$ = mean of measurements in one temperature;
						i = subscript which represents a sample;
						j = subscript which represents a temperature;	

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						k = subscript which represents a replicate. The measurement bias is calculated as follows: $$B = \bar{y} - y_{ref}$$ Where y_{ref} is the reference manometer indication. 2.3.2 Verification The repeatability of sphygmomanometer is calculated as follows: $$s_r^2 = \frac{1}{r-1}\sum_k (y_k - \bar{y})^2$$ Where r is the number of measurements in each step (r = 4)	
0065 DE	2	2.1	2nd bullet	ed	no need for capital letters in the enumeration	"Non" -> "non" "Instability" -> "instability"	Agree
0066 BR	2	3		Te	Once the suggestion on clause 5 of Rxxx-1 is accepted, this clause needs to be modified. The equation proposed to determine the standard deviation is different from item 2.3.1 because it not include repeatability.	Replace the clause 3 with text below. 3 Determination of the standard deviation due to the storage 3.1 Apparatus Same apparatus listed in 2.1 3.2 Procedure Connect, as shown in the figure 2, the non-automated sphygmomanometer with the rigid vessel and the reference manometer. Perform steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity. Switch off the non-automated sphygmomanometer and perform storage for 24 h at temperature of -20 °C and for 24 h at a temperature of 70 °C and a relative humidity of 85% (non-condensing). Afterwards, perform again the steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity.	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.

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						3.3 Results
						
						The standard deviation due to the storage (s_{L1}) is calculated as follows:
						
						$$s_{L1}^2 = C - D$$
						
						$$C = \left(\frac{1}{f-1} - \frac{1}{pfr - p - f + 1}\right)\sum_j (\bar{y}_J - \bar{y})^2$$
						
						$$D = \frac{\sum_i \sum_j \sum_k (y_{ijk} - \bar{y})^2 - fr\sum_i (\bar{y}_i - \bar{y})^2}{pr(pfr - p - f + 1)}$$
						
						Where,
						p = number of samples of the type of sphygmomanometer;
						f = number of conditions;
						r = number of replicates;
						$\bar{y}$ = mean of all measurements;
						$\bar{y}_i$ = mean of measurements of one sample;
						$\bar{y}_J$ = mean of measurements in one condition;
						i = subscript which represents a sample;
						j = subscript which represents a condition (before and after storage);
						k = subscript which represents a replicate.
						
						The standard deviation shall be determined for each pressure step separately.	

0067 DE	2	3.2		ed	there is no figure 3 in this document	Replace "figure 3" with "figure 2"	Agree
0068 DE	2	4		ed		Add the following text: "To comply with the requirement of Rxxx-1, 6.2.1, the following test shall be performed."	Agree
0069 DE	2	4.1	1st bullet	ed/te	The referenced R16-1 6.1, describes the requirements for the cuff and bladder with respect to a limb. There might be an assumption that a limb can be substituted with a cylinder, but this is nowhere specified (not in the referenced 6.1 and not in the current paragraph) and this type of documents should not be confusing.	To avoid confusion, remove the reference R16-1 6.1 and add a text concerning "the appropriate size" in the procedure.	Agree

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0070 DE	2	5		ed		Add the following text: "To comply with the requirement of Rxxx-1, 6.2.2, the following test shall be performed."	Agree
0071 DE	2	7		ed		Add the following text: "To comply with the requirement of Rxxx-1, 6.3.2.4, the following test shall be performed."	Agree
0072 DE	2	5.1	4th bullet	te/ed	"recording unit" is nowhere defined, described or represented.	Add a definition in Rxxx-1.	Agree Recording unit can record the output of the calibrated reference manometer，giving deflation rate in kPa/s or mmHg/s.
0073 DE	2	5.2	Note 1&2	ed		replace "intention" with "recommendation" replace "intended" with "recommended"	Agree
0074 DE	2	6		ed		Add the following text: "To comply with the requirement of Rxxx-1, 6.2.3, the following test shall be performed."	Agree
0075 DE	2	10		ed		Add the following text: "To comply with the requirement of Rxxx-1, 6.5.4, the following test shall be performed."	Agree
0076 DE	2	11		ed		Add the following text: "To comply with the requirement of Rxxx-1, 6.5.5, the following test shall be performed."	Agree
0077 BR	2	10		Te	Once the suggestion on clause 2 of Rxxx-2 is accepted, this clause needs to be removed.	Remove this clause.	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.
0078 DE	2	11		ed	Please see the 1st comment on 6.5.5 of P1 (title).		Disagree, but the 2nd comment on 6.5.5 of P1 is about title. The terminology in VIM of durability test is "5.22 durability test, test intended to verify whether the EUT is able to maintain its performance characteristics over a period of use". The elastic sensing elements shall be aged. The 2nd comment on 6.5.5 of P1 is not accepted.
0079 BR	2	11		Te	Once the suggestion on clause 5 of Rxxx-1 is accepted, this clause needs to be modified.	Replace the clause 11 with text below. 11 Determination of the standard deviation due to the	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.

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Country Code[1]	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment[2]	Comments	Proposed change	Convener's responses
						durability 11.1 Apparatus • T-piece connectors and hoses; • Rigid vessel with a capacity of 500 ml ±25 ml; • Calibrated reference manometer which complies subclause 5.3 of Rxxx-1; • Pressure generator, e.g. ball pump (hand pump) with a deflation valve; • Alternating pressure generator, which generates a sinusoidal pressure variation between 3 kPa and 30 kPa at a maximum rate of 60 cycles per minute. 11.2 Procedure Connect, as shown in the figure 2, the non-automated sphygmomanometer with the rigid vessel and the reference manometer. Perform steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity. Connect non-automated sphygmomanometer (without cuff) to alternating pressure generator and perform 10000 pressure cycles. Afterwards, perform again the steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity. 11.3 Results The standard deviation due to the durability (s_{L2}) is calculated according to subclause 3.3 with subscript j representing the conditions of before and after 10000 pressure cycles.	
0080 DE	2	11.2		te	Please see the 2nd comment on 6.5.5 of P1 (range).		Agree, but the 1st comment on 6.5.5 of P1 is range. A full-scale cycle is a pressure change from 20mmHg to full scale, and then back to 20mmHg.
0081 DE	2	11.2		ed	A comma is missing.	"One hour after the stress test, carry out the procedure…"	Agree
0082 BR	2	12 (New)		Te	Once the suggestion on clause 5 of Rxxx-1 is accepted, this clause needs to be added.	12 Determination of the standard deviation due to the to the resistance to vibration and shock	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.

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Country Code[1]	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment[2]	Comments	Proposed change	Convener's responses

						12.1 Apparatus
						• T-piece connectors and hoses;
						• Rigid vessel with a capacity of 500 ml ±25 ml;
						• Calibrated reference manometer which complies subclause 5.3 of Rxxx-1;
						• Pressure generator, e.g. ball pump (hand pump) with a deflation valve;
						• Shaker.
						
						12.2 Procedure
						Connect, as shown in the figure 2, the non-automated sphygmomanometer with the rigid vessel and the reference manometer. Perform steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity.
						Perform one free fall on each side of sphygmomanometer from a height of 25 cm onto a 50 mm ± 5 mm thick hardwood (hardwood density > 600 kg/m3) board lying flat on a concrete or a similar rigid base. If sphygmomanometer is marked as 'Shock Resistant' the height is 1 m.
						If sphygmomanometer is intended for use during transport outside a healthcare facility, perform shock and vibration tests with the following conditions:
						  a) Shock
						    – peak acceleration: 1000 m/s² (10² g);
						    – duration: 6 ms;
						    – pulse shape: half sine;
						    – number of shocks: 3 shocks per direction per axis (18 total).
						  b) Broad-band random vibration
						    Frequency range: 10 Hz to 2000 Hz
						    Resolution: 10 Hz
						    Acceleration amplitude:
						    – 10 Hz to 100 Hz: 5.0 (m/s²)²/Hz;
						    – 100 Hz to 200 Hz: −7 dB/octave;
						    – 200 Hz to 2 000 Hz: 1.0 (m/s²)²/Hz;
						    Duration: 30 min per each perpendicular axis (3 total).
						Afterwards, perform again the steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity.	

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Country Code[1]	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment[2]	Comments	Proposed change	Convener's responses
						12.3 Results The standard deviation due to the resistance to vibration and shock (s_{L3}) is calculated according to subclause 3.3 with subscript j representing the conditions of before and after shock and vibration tests.	
0083 BR	2	13 (New)		Te	Once the suggestion on clause 5 of Rxxx-1 is accepted, this clause needs to be added.	13 Determination of the standard deviation due to the voltage variations of the power source 13.1 Apparatus • T-piece connectors and hoses; • Rigid vessel with a capacity of 500 ml ±25 ml; • Calibrated reference manometer which complies subclause 5.3 of Rxxx-1; • Pressure generator, e.g. ball pump (hand pump) with a deflation valve; • Adjustable direct current voltage supply; • Voltmeter with maximum permissible error within 0.5 % of the measured value. 13.2 Procedure Connect, as shown in the figure 2, the non-automated sphygmomanometer with the rigid vessel and the reference manometer. Replace the internal electrical power source of the non-automated sphygmomanometer with a DC voltage supply having an impedance which is equivalent to the impedance of the internal electrical power source specified by the manufacturer. Measure the variation in applied DC voltage supply with a voltmeter. Test the non-automated sphygmomanometer by altering the DC voltage supply in steps of 0.1 V and determine the lowest voltage limit at which the cuff pressure indication is still displayed. Carry out this test with the maximum permissible impedance of the internal electrical power source. Perform steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity, and at the lowest voltage limit described above increased by 0.1 V and also at the nominal voltage.	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.

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Country Code[1]	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment[2]	Comments	Proposed change	Convener's responses
						13.3 Results The standard deviation due to the internal electrical power source (s_{L4}) is calculated according to subclause 3.3 with subscript j representing the conditions of minimum and nominal voltage.	
0084 BR	2	14 (New)		Te	Once the suggestion on clause 5 of Rxxx-1 is accepted, this clause needs to be added.	14 Determination of standard deviation due to the electrostatic discharges 14.1 Apparatus • T-piece connectors and hoses; • Rigid vessel with a capacity of 500 ml ±25 ml; • Calibrated reference manometer which complies subclause 5.3 of Rxxx-1; • Pressure generator, e.g. ball pump (hand pump) with a deflation valve; • Equipment to apply electrostatic discharges according to the latest version of IEC 61000-4-2. 14.2 Procedure Connect, as shown in the figure 2, the non-automated sphygmomanometer with the rigid vessel and the reference manometer. Set pressure to value between 0 kPa and 37 kPa or the maximum pressure of the scale range (whichever is less) at 20 °C ±5 °C and ambient humidity at: • no electrostatic discharge; • direct contact discharges of 6 kV and positive polarity. Repeat with negative polarity; • indirect contact discharges of 6 kV and positive polarity. Repeat with negative polarity; • air discharges of 8 kV and positive polarity. Repeat with negative polarity. The latest version of IEC 61000-4-2 shall be used as reference. Direct contact discharges shall be applied to the conductive surfaces of the sample. Indirect contact discharges shall be applied to the horizontal coupling plane and the vertical coupling planes placed in the vicinity of the sample according to the reference standard. Air discharges shall be applied to the insulation surfaces of the sample. All discharges shall	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.

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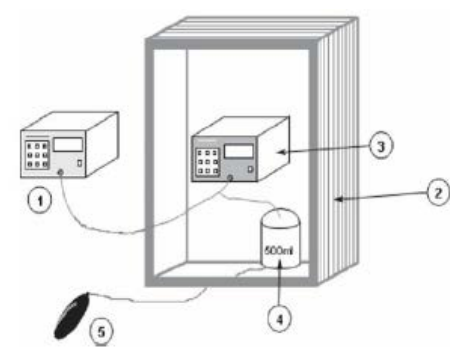**2**   Type of comment: ge **= general**   te **= technical**   ed **= editorial**

Country Code[1]	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment[2]	Comments	Proposed change	Convener's responses
						only be applied to the parts of the sample which are accessible to the operator during normal use of the instrument. The time interval between successive discharges must be at least 10 s. 14.3 Results The standard deviation due to the electrostatic discharges (s_{L5}) is calculated according to subclause 3.3 with subscript j representing each combination of electrostatic discharge.	
0085 BR	2	15 (New)		Te	Once the suggestion on clause 5 of Rxxx-1 is accepted, this clause needs to be added.	15 Determination of standard deviation due to the radiated, radio-frequency, electromagnetic fields 15.1 Apparatus • T-piece connectors and hoses; • Rigid vessel with a capacity of 500 ml ±25 ml; • Calibrated reference manometer which complies subclause 5.3 of Rxxx-1; • Pressure generator, e.g. ball pump (hand pump) with a deflation valve; • Equipment to generate radio-frequency, electromagnetic fields according to the latest version of IEC 61000-4-3. 15.2 Procedure Connect, as shown in the figure 3, the non-automated sphygmomanometer with the rigid vessel and the reference manometer. Perform steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity. Set pressure to value between 0 kPa and 37 kPa or the maximum pressure of the scale range (whichever is less).	Disagree The suggestion on clause 5 of Rxxx-1 is not accepted.

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						(see below)	

1 – Reference manometer;
2 – Anechoic Chamber (or equivalent);
3 – Device to be tested;
4 – Rigid vessel;
5 – Pressure generator.
Figure 3

Apply the following electromagnetic fields:
- 3 V/m at frequency range from 80 MHz to 800 MHz and from 960 MHz to 1.4 GHz;
- 10 V/m at frequency range from 800 MHz to 960 MHz and from 1.4 GHz to 2.0 GHz.

The latest version of IEC 61000-4-3 shall be used as reference. Each combination of electromagnetic field shall be applied with 80% AM Modulation on 1 kHz sinusoidal signal, 3 s of dwell time and horizontal and vertical polarization.

During application, determine the frequency at which the sphygmomanometer indication has the maximum deviation. In this frequency, perform again the steps described in 2.2 (without wait 5 min) at 20 °C ±5 °C and ambient humidity.

16.3 Results
The standard deviation due to the radiated, radio-frequency, electromagnetic fields (s_{L6}) is calculated

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						according to subclause 3.3 with subscript j representing the conditions of before and during application.	
0086 DE	2	Whole document		ge	The three comments regarding the title, the decimal commas and the decimal ponts for P1 apply here as well.		Partly agree The comment of decimal commas is accepted.
0087 DE	3		Table 2, column 1	DE	No need for capital letter for "up"	replace "Up" with "up"	Agree
0088 DE	3		Table 3, 4, 5, 6	te	Why are the pressure values (0, 50, 100, …) deleted?	Keep the pressure values (0, 50, 100, …).	Disagree Values differ with unit in kPa and in mmHg, delete table unit "mmHg".
0089 DE	3	1.1	10.5	ed	"Stability"	change "durability" to "stability"	Disagree The 2nd comment on 6.5.5 of P1 is not accepted.
0090 JP3	3	2	Table 1	ed	The Celsius sign is not shown correctly. Please make a correction by replacing "□" with "°C ".	Present: …Table 1 Example: Temperature 20◇ and...% relative humidity Correct: …Table 1 Example: Temperature 20°C and...% relative humidity	Agree
0091 JP4	3	2	Table 2	ed	The Celsius sign is not shown correctly. Please make a correction by replacing "□" with "°C ".	Present: … Table 2: Temperature ...◇ and...% relative humidity Correct: …Table 2: Temperature ... °C and...% relative humidity	Agree
0092 DE	3	2	Table 2	te/ed ?	Probably the pressure values (0, 50, 100, …) are deleted because these cannot be matched exactly for the hysteresis test. Therefor we recommend to add "(approximately)" between "pressure" and "mmHg" on top of the column and keep the pressure values for orientation.	Do not delete the pressure values (0, 50, 100, …), but change the head of the first column to "Pressure, approximately" or "Approximate pressure"	Disagree Values differ with unit in kPa and in mmHg, delete table unit "mmHg".
0093 DE	3	9.4	Note	ed/te	This note is a requirement in Rxxx-1 6.4.4. If the intention is to consider this as a requirement for the passing and failing of the devices, the text should be moved up, after the first question and not as a note. As a note, it does not make any impact on the result of this test.	If the requirement in the note are not relevant, remove the note. If the note includes important requirement for this test, move the text up, as a normal text, not a note.	Agree remove the note.
0094 DE	3	10.5	Title	ed	Change the title according the 1st comment on 6.5.5 for P1.	The title should read: Stability of the elastic sensing element	Disagree The 2nd comment on 6.5.5 of P1 is not accepted.
0095 DE	3	13	1st sentence	ed	add "special"	"..shall be achieved by requiring the use of a special tool"	Agree
0096	3	14	note	ed/te	This entire paragraph cannot be a note. Notes are not	remove "Note:"	Agree

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DE					requirements and cannot decide the passing or failing of a device. They also do not use "shall". Additionally, this text is a requirement in Rxxx-1 6.6.5, not a note.		remove the note.
0097 DE	3	Table 1	title	ed		replace □ with °C	Agree
0098 SI	3	Table 1. example		ed	In the title of the table there is missing °C, there is some other character.		Agree
0099 DE	3	Table 2	title	ed		replace □ with °C	Agree
0100 SI	3	Table 2. example		ed	In the title of the table there is missing °C, there is some other character.		Agree
0101 DE	3	TEST REPORT, page 7		te	Add for the reference manometer also "model" and "expanded".	Reference manometer (model, serial number, expanded uncertainty, calibration certificate)	Agree
0102 DE	3	TEST REPORT, page 7		te	Include a line for the time measuring device.	Time measuring device (model, serial number, expanded uncertainty, calibration certificate)	Agree
0103 DE	3	Whole document		ge	The three comments regarding the title, the decimal commas and points from P1 apply here as well.		Partly agree The comment of decimal commas is accepted.

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Z:\TCSC\tc18_sc1\tc18_sc1_p1_Revision_R16-1\2CD\335-AUSTRIA-TC18_SC1_P1_Rxxx_2CD_Comments_Austria_R16-1_CD_2_2019.docx: Collation successful
Z:\TCSC\tc18_sc1\tc18_sc1_p1_Revision_R16-1\2CD\335-UNITED STATES-TC18_SC1_P1_Rxxx_2CD_Comments -US comments- 14 Mar 2019.docx: Collation successful
Z:\TCSC\tc18_sc1\tc18_sc1_p1_Revision_R16-1\2CD\335-JAPAN-TC18_SC1_P1_Rxxx-R16-1-_2CD_Comments-Japan-190314.docx: Collation successful
Z:\TCSC\tc18_sc1\tc18_sc1_p1_Revision_R16-1\2CD\335-GERMANY-TC18_SC1_P1_Rxxx_2CD_Comments_PTB.docx: Collation successful
Z:\TCSC\tc18_sc1\tc18_sc1_p1_Revision_R16-1\2CD\335-BRAZIL-TC18_SC1_P1_Rxxx_2CD_Comments_template_BR_non-auto_Final.docx: Collation successful
Collation of files was successful. Number of collated files: 7
SELECTED   (number of files): 7
PASSED TEST   (number of files): 7
FAILED TEST   (number of files): 0
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