Template for comments and secretariat observations

OIML TC 18/SC 1/p 1

Secretariat: P.R. China

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Date: 2018-12-10

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
1.	**Brazil**	**2.1 Bladder** **2.2 Cuff** **2.3 Non-invasive blood pressure measurement** **2.4 Pneumatic system** **2.5 Sleeve** **2.6 Sphygmomanometer** **2.7 Non-automated sphygmomanometer** **2.8 Auscultatory method** **2.9 Deflation valve** **2.10 Rapid exhaust valve** **2.11 Tamper proofing**	The terms are not listed in alphabetical order or in a logical order, which is a little confusing.	Reorganize the terms following a “logical” order. Suggested order is (considering the withdrawal proposed below): 2.6, 2.7, 2.3, 2.2, 2.1, 2.5, 2.4, 2.9, 2.10 and 2.11.	Not accepted The order of the terms are consistent with the previous version. It was not examined strictly whether the layout would mislead the readers or not.
2.	**Brazil**	**2.6 Sphygmomanometer** Instrument used for the non-invasive measurement of the arterial blood pressure.	The definition should list all sphygmomanometer usual components, just like clause 2.2 describes the cuff components.	“Instrument used for the non-invasive measurement of the arterial blood pressure, composed of a cuff, a pneumatic system and a manometer”.	Deleted New definition addtion clause 2.7
3.	**Brazil**	**2.7 Non-automated sphygmomanometer** Sphygmomanometer which allows a trained person to use an inflatable cuff for the non-invasive measurement estimation of the arterial blood pressure by means of the pressure display of a cuff manometer. (See also Note under 3.)	1 I agree with “non-invasive measurement of the arterial blood pressure” and also with “non-invasive estimation...”, but I’m not sure if “non-invasive measurement estimation...” is correct. 2 It seems the term “cuff manometer” was removed but it still appears in some clauses like this one.	Remove the word “estimation”. The expression “non-invasive measurement” is already used in several parts of the document.	1 Not accepted The word “Estimation” is from Germany, refer to judged by the skilled people. 2 Accepted

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4.	**Brazil**	**2.8 Auscultatory method** 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 in adults. In children under age of 13, "k4" (i.e. 4th phase Korotkoff sound) may be appropriate.	The term "auscultatory method" is not used in the text, so it's not necessary to define it.	Withdraw clause 2.8	Accepted
5.	**Brazil**	3. 2nd para **Mechanical** 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.	The term "Mechanical sphygmomanometers" was left here.	Replace with "Non-automated sphygmomanometers".	Accepted
6.	**Germany**	3. 2nd para **Mechanical** 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.	The term "mechanical sphygmomanometer" has been substitude by "non-automated sphygmomanometer", this forgotten here.	Non-automated sphygmomanometer typically use either …	
7.	**Brazil**	4 **Units of measurement** The blood pressure shall be indicated either in kilo-Pascal (kPa) or in millimeters of mercury (mmHg).	There's no dash on "kilo-pascals".	Replace with "kilopascals".	Accepted kilopascal or in millimter

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
8.	Germany	*5.1.1 Under ambient conditions* For any set of conditions within the ambient temperature range of 15℃to 25℃and the relative humidity range of **15**% to 85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be **±0.4kPa (±3 mmHg)**for sphygmomanometers.	If we do not want to values like 0,44 kPa to be rounded to 0,4 kPa, we have to write 0,40 kPa (3,0 mmHg) in this and in ALL similar pressure requirements.	… ± 0,40 kPa (± 3,0 mmHg) …	Not accepted The resolution of sphygmomanometers is 1 decimal number.
9.	**Brazil**	*5.1.1 Under ambient conditions* For any set of conditions within the ambient temperature range of 15℃to 25℃and the relative humidity range of **15**% to 85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be **±0.4kPa (±3 mmHg)**for sphygmomanometers. Testing shall be carried out in accordance with **A.1**.	1 When used to measure the blood pressure the sphygmomanometer's indications are recorded only during **deflation**. Is it really necessary to test it increasing and decreasing the pressure? ISO 81060-1 refers only to decreasing pressure. 2 I also suggest adding one decimal number to all pressure values along the whole text.	1(2) "For any set of conditions within the ambient temperature range of 15 ℃ to 25 ℃ and the relative humidity range of 15% to 85%, the maximum permissible error for the measurement of the **decreasing** cuff pressure at any point of the scale range shall be ± **0.40** kPa (± **3.0** mmHg) for sphygmomanometers."	Partially accepted Both mercury and electronic sphygmomanometer work in decreasing pressure. The sphygmomanometer with elastic component s shall be tested when increasing and decreasing pressure for the hysteresis error. Not accepted Same as 8

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
10.	**Brazil**	*5.1.2 Under storage conditions* The sphygmomanometer shall maintain the maximum permissible error requirements for the measurement of the cuff air pressure specified in this Recommendation (5.1.1) after storage for 24 h at a temperature of -20℃ and for 24 h at a temperature of 70℃ and a relative humidity of 85% (non-condensing). **The test shall be performed with the unpacked sphygmomanometer.** Testing shall be carried out in accordance with A.3.	The term “cuff **air** pressure” was left here.	Replace with “cuff pressure”.	Accepted
11.	**Brazil**	*5.1.3 Under varying temperature conditions* For the ambient temperature range of 10℃ to 40℃ and the relative humidity of 85% (non-condensing), the difference **between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.4) at the relative temperature value** shall not exceed **±0.4kPa (±3 mmHg)**. Testing shall be carried out in accordance with A.2.	The new text is not correct. The test purpose is to detect the **indication’s changes** (comparison between device’s own indications) under varying temperature, not the **indication’s error** (comparison between device and reference manometer) under varying temperature.	“… (non-condensing), the difference**s** **between the cuff pressure indications of the sphygmomanometer at and at other temperatures** shall not exceed…”	Not accepted But requirement is modified.

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
12.	**Brazil**	*5.1.3 Under varying temperature conditions* For the ambient temperature range of 10℃ to 40℃ and the relative humidity of 85% (non-condensing), the difference **between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.4) at the relevant temperature value** shall not exceed **±0.4kPa (±3 mmHg)**. Testing shall be carried out in accordance with A.2.	It should be clearer that the sphygmomanometer's indication at the second testing temperature (20 ºC) must lie within the MPE of ± 3.0 mmHg.	Add the following Note: "The sphygmomanometer's indication values under the conditions specified on 5.1.1 must comply with the maximum permissible error of ± 0.40 kPa (± 3.0 mmHg)."	Same as no.11

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
13.	**Brazil**	**6.1 Technical requirements for the cuff and bladder** The cuff shall contain a bladder. For reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents (see 7.5). **The bladder length should be approximately 0,80 x 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 x the circumference of the limb at the midpoint of the intended range of the cuff.** ***Note:* These recommended dimensions are subject to ongoing consideration.**	The words “at least” and “approximately” are in the wrong positions: **at least** must refer to the length and **approximately** must refer to the width. The notation “80%” is better than “0.8 x”. The Note says “dimensions are subject to ongoing consideration”. For how long? The current revision is eight years old and already had these values. When a country takes this Recommendation to turn it into its national regulation for legal metrology is very complicated to leave room for this kind of Note.	“The bladder length should be **at least 80%** of the circumference of the limb at the midpoint of the intended range of the cuff. The **bladder width** should be **approximately 40%** of the circumference of the limb at the midpoint of the intended range of the cuff.” *(remove the Note)*	Not accepted But remove the note
14.	**Brazil**	*6.2.1 Air leakage* Air leakage shall not exceed a pressure drop of 0.5 kPa/min (4 mmHg/min). Testing shall be carried out in accordance with A.4.	Once this requirement has no influence on the sphygmomanometer’s real use, I think it is too severe. I’ve discussed this before with Dr. Mieke and he told me it was added just to make sure we could perform tests without leaks. If this is the real purpose we should withdraw it because, on the other hand, if a device does not allow us to perform any specific test it can’t be approved on this test and the manufacturer must solve the situation.	Withdraw.	Not accepted This is the test for the whole equipment. These requirements is the main technical requirements .

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15.	Germany	*6.2.2 Pressure reduction rate* **The pneumatic system** deflation valves shall be capable of adjustment to a deflation rate from 0.3kPa/s to 0.4kPa/s (2mmHg/s to 3mmHg/s). **The pneumatic system** deflation valves shall be easily adjusted to these values. Deflation valves shall be tested in accordance with A.5.	Please revise the wording.	The deflation valves in the pneumatic system shall be capable of adjustment to a deflation rate from 0.3kPa/s to 0.4kPa/s (2mmHg/s to 3mmHg/s). The deflation valves in the pneumatic system shall be easily adjusted to these values.	Accepted
16.	**Brazil**	*6.2.3 Rapid exhaust* During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10s. Testing shall be carried out in accordance with A.6.	It's missing a space between "10" and "s".	"… shall not exceed **10 s**".	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
17.	**Brazil**	*6.3.1 Nominal range and measuring range* The nominal range shall be equal to the measuring range. The nominal range for the cuff gauge pressure shall extend from 0 kPa to at least 35 kPa (0 mmHg to at least 260 mmHg).	Change the wording on the second paragraph to combine with the wording used previously on the text.	"The nominal range for the cuff **pressure indication** shall extend…"	Accepted

18.	Germany	6.3.2.3 Scale interval The scale interval shall be: ·**0.5** kPa for a scale graduated in kPa; ·2 mmHg for a scale graduated in mmHg. Each **second** scale mark shall be indicated by greater length and each **fourth** scale mark shall be numbered. An example of a scale in mmHg is given in Figure 1. **Where the sphygmomanometer uses a manometer with elastic or electro-mechanical sensing elements, no scale mark is needed within the range of 0-2kPa (0-20 mmHg).** Testing shall be carried out by visual inspection.	The wording has to differ between 2 cases and some clarification is needed.	The scale interval shall be: • ·0.5 kPa for a scale graduated in kPa; • 2 mmHg for a scale graduated in mmHg. In the case for a scale graduated in kPA: Each second scale mark shall be indicated by greater length and each fourth scale mark shall be numbered.. In the case for a scale graduated in mmHg: Each fifth scale mark shall be indicated by greater length and each tenth scale mark shall be numbered. An example of a scale in mmHg is given in Figure 1 For sphygmomanometer with a manometer with elastic or electro-mechanical sensing elements, no graduation is needed within the range of > 0 kPa to < 2 kPa (> 0 mmHg to < 20 mmHg).	Accepted

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19.		**6.3.2.3**	The requirements for scale marks length and numbering refers only to manometers with kPa unit. The info for mmHg unit is missing.		Accepted
20.		6.3.2.4 Scale spacing and thickness of the scale marks The distance between adjacent scale marks shall be not less than 1.0 mm. The thickness of the scale marks shall not exceed 20% of the smallest scale spacing. All scale marks shall be of equal thickness. Testing shall be carried out in accordance with A.7	In Brazil we established the minimum distance of 0.7 mm for aneroid type. We have several models approved with less than 1.0 mm distance and the measuring values can be read clearly and are easily recognized, fulfilling the requirement at 6.3.2.1. About the thickness, we follow the 20% rule but I think it's too severe. One third is enough to avoid the pointer over two scale marks simultaneously.	Establish two different minimum distances: 0.7 mm for aneroid type and 1.0 mm for other types. Change the maximum thickness to 1/3 of the smallest scale spacing. (*Question: is it allowed unequal scale spacing? The word "smallest" gives this impression)*	Not accepted Keep consistent with last version.
21.	Germany	*6.4.1 Internal diameter of the tube containing mercury* The tolerance on diameter shall not exceed ±0.2 mm (see also 7.4). Testing shall be carried out in accordance with A.8.	The internal diameter affects the accuracy of the pressure measurement, therefore it cannot be deleted. Keep the requirement, do not delete it.	The nominal internal diameter of the tube containing mercury shall be at least 3,9 mm. The tolerance on the diameter shall not exceed ± 0,2 mm.	Not accepted
22.			I agree with the restriction for the total amount of mercury **if it is used** but I don't understand why delete the requirement for internal diameter.	Keep the requirement for internal diameter and **add** a restriction about mercury total amount	Not accepted 6.4.1 is withdrawn.

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23.		*6.4.5 Graduation of the mercury tube* Graduations shall be permanently marked on the tube containing mercury. If numbered at each fifth scale mark, the numbering shall be alternately on the right- and left-hand side of, and adjacent to, the tube. Testing shall be carried out by visual inspection.	Add information related with the size and positioning of numbers used on scale graduation.	"The number shall have adequate size and positioning to avoid confusion about indication readings".	Not accepted Not necessary

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
24.		*6.5.3 Pointer* The pointer shall cover between 1/3 and 2/3 of the length of the shortest scale mark of the scale. At the place of indication it shall be not thicker than the scale mark. The distance between the pointer and the dial shall not exceed 2 mm. Testing shall be carried out by visual inspection.	1 If we change the maximum thickness to 1/3 of the smallest scale spacing I suggest to relate the pointer thickness with the distance between scale marks. We'll have enough indication readability. 2 2 mm for maximum distance between the pointer and the dial is too restrictive, specifically for large (wall mounted) manometers. If the reason for this requirement is to avoid parallax error we should clearly refer to it and perform a visual inspection.	"… mark of the scale. At the place of indication it shall not be thicker than the **distance between two adjacent scale marks**. **When the manometer is placed on its correct *(or recommended)* use position,** the distance between the pointer and the dial shall not **allow parallax error**".	1 Not accepted See 6.3.2.4 Same as no.20
25.		*6.5.5 Construction and materials.* The construction of **the cuff manometer** and the material for the elastic sensing elements shall ensure an adequate stability of the measurement. **When elastic sensing elements are used, they** shall be aged with respect to pressure and temperature. After 10 000 alternating pressure cycles the change in the pressure indication of **the cuff manometer** shall be not more than **0.4 kPa (3 mmHg)** throughout the pressure range. Testing shall be carried out in accordance with A.12.	The term "cuff manometer" was left here.	Remove "cuff manometer" from 1st and 4th lines.	Accepted
26.	Germany	6.5.5	The term "cuff manometer" is not used in the document.	The construction of the ~~cuff~~ manometer and the	Accepted

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27.	**Brazil**	**6.6.1.1 Resistance to vibration and shock** The sphygmomanometer shall comply with the relevant paragraphs of International Document OIML D 11 (e.g. sub-clause A.2.2 of the 1994 edition for mechanical shock). After testing, the device shall comply with the requirements of 5.1.1 (of this Recommendation)	1 I suggest to put back the text presented on the WD2 but applying only to hand-held devices and making the following changes:The clause doesn't establish vibration resistance requirements, only shock requirements. It's not clear what a "stationary sphygmomanometer" is. How to classify large models that can be fixed on the wall **or** placed on the table? Are they exempt from the clause? 2 There's no test procedure on clause 5.1.1.	1 Remove second paragraph and change title to "Resistance to shock for handheld sphygmomanometers". 2 Last paragraph, replace "5.1.1" by "A.1".The info between "check compliance..." and "in 5.1.1" is a test procedure, so it must be moved to Annex A.	1 Accepted But modification 2 Not accdepted A.1 is the test procedure of requirement 5.1.1

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28.	**Brazil**	**6.6.1.2 Non-automated sphygmomanometers for transport**	The title is not clear. There's no test procedure on clause 5.1.1.	Change the title to "Non-automated sphygmomanometers used during patient transport". Last paragraph, replace "5.1.1" by "A.1".	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
29.		**6.6.1.3 Non-automated sphygmomanometers containing a mercury manometer** A non-automated sphygmomanometer containing a mercury manometer shall not leak mercury following a free fall from a distance d=1 m in a condition of normal use. Check compliance by the following test. Allow the non-automated sphygmomanometer to fall freely 6 times (once on each side) from a height of distance d onto a 50 mm ± 5 mm thick hardwood (hardwood density > 600 kg/m3) board lying flat on a concrete or a similar rigid base. Care should be taken while testing to ensure that there is no escape of mercury into the environment should the non-automated sphygmomanometer under test fail this test. After the test, visually inspect to check that there is no leakage of mercury from the manometer of the non-automated sphygmomanometer.	Mercury sphygmomanometers usually have glass tubes that will break after the first fall. And why 1 m height if they're not labelled as "shock resistant"?	Remove the clause	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
30.		**7. Metrological controls** Regional or national regulations may prescribe type approval, initial and/or periodic verification for noninvasive sphygmomanometers. These controls shall meet the following conditions.	1-The term “periodic verification” does not include verification after repair. 2-There’s a missing dash on “noninvasive”	Change the text to “…initial and/or **subsequent** verification for **non-invasive**…”	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
31.		**7.2 Verification** Each instrument of an approved type of sphygmomanometer **shall be verified periodically in accordance with applicable metrological laws and regulations of a member state** or after repair. At least 5.1.1 shall be fulfilled and tests must be carried out according to A.1.	The term "verified periodically" may lead to an understanding that no initial verification is required.	Change the text to "…shall be **submitted to verification** in accordance with…"	Accepted in principle

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
32.		**7.4 Marking of the device** • **<u>on the cuff an indication</u>** of the correct positioning for the cuff over the artery; • **<u>on the cuff an indication</u>** of the limb circumference for which it is appropriate (see 6.1). The following additional markings are required for mercury manometers: · symbol for “see instructions for use”; · indication of the internal nominal diameter and the tolerance of the tube containing mercury (see 6.4.1).	I don’t agree with the original items’ removal. Trademark, serial number/year of manufacturing, measuring unit and approval marks are very important markings. Only the measuring range is unnecessary because the scale provides this information.	Put back the original items and at the 3rd item remove “measuring range and”.	Accepted

33.		**7.5 Manufacturer's information** Information supplied by the manufacturer shall comply with the specifications and requirements given in this Recommendation. The manufacturer's instruction manual shall contain the following information: · reference to OIML R 16-1, 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 and adjustment of the pressure reduction rate); · a warning to users of equipment intended for use in environments employing intervascular fluid systems not to connect the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used; · methods for cleaning reusable cuffs; · nature and frequency of the maintenance required to ensure that the device operates correctly and safely at all times; it is recommended that the performance should be checked at least every 2 years and after maintenance and repair, by re-verifying at least the requirements in 5.1.1, 6.2.1 (testing at least at 7 kPa (50 mmHg) and 27 kPa (200 mmHg)) and 6.4.4; · internal nominal diameter and tolerance of the tube containing mercury; and	The second part of 5th item shall not be determined by the manufacturer because they may be in conflict with national regulations. Probably the manufacturer will provide the information stated on national regulation but the wording says he can decide what to do. It's quite obvious but the last item is applicable only to mercury sphygmomanometers.	Delete the second part of 5th item and add a new item with the text "reference to subsequent verifications in accordance with the requirements stated on metrological laws and regulations of the member state". Add a "…, if applicable" at the end of last item.	Accepted

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		· detailed instructions for the safe handling of mercury (see Annex C).			

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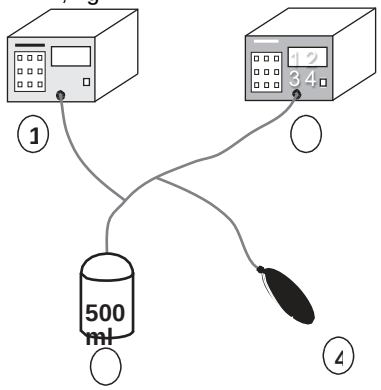
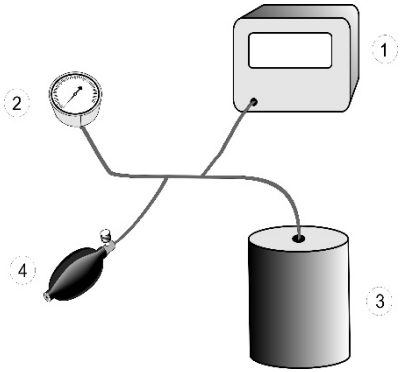
34.	Germany	A.1.2, fig 2 	The figure is not fitting to non-automated sphygmomanometer.		Accepted
35.	**Brazil**	**Annex A**	All figures of the “manometer of the device to be tested” doesn’t look like a non-automated sphygmomanometer. They look like an automated sphygmomanometer.	Replace them with the figure of an aneroid manometer.	Accepted

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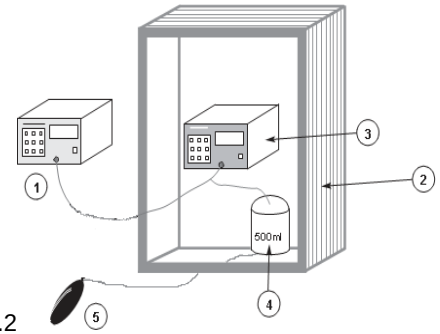
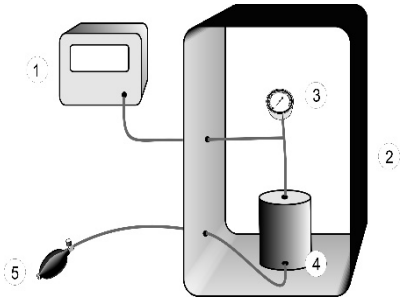
36.	Germany	**A.2.1 Apparatus** · apparatus as specified in A.1.1; plus · a climatic chamber. **(Accuracy of temperature less then ±1ºC and humity less than ±5%)**	Clarification.	a climatic chamber. (Stability of temperature less or equal ±1ºC and humity less or equal ±5%)	Accepted Same as the requirement in R16-2
37.	Germany	A.2.2 	The figure is not fitting to non-automated sphygmomanometer		Accepted

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38.		**A.2.3 Expression of results** Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.4) at the relevant temperature value. *5.1.3 Under varying temperature conditions* For the ambient temperature range of 10°C to 40°C and the relative humidity of 85% (non-condensing), the difference **between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.4) at the relevant temperature value** shall not exceed **±0.4kPa (±3 mmHg)**. Testing shall be carried out in accordance with A.2.	The formula for calculation is different from table at B.4.	Change the text to "Express the results as the differences between the device to be tested **indications at 20 ºC and its own indications at 10 ºC and 40 ºC** (see B.4)".	Not accepted Requirement is changed

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39.		**A.3.1 Apparatus** Apparatus as specified in A.1.1.	Wrong reference to A.1.1. We need a climatic chamber to perform this test and this apparatus is not listed at A.1.1.	Change the text to “Apparatus as specified in **A.2.1**” or “Apparatus as specified in A.1.1 **plus a climatic chamber”**	Accepted

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40.		**A.3.2 Procedure** Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system (see Figure 3). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pneumatic system by means of another T-piece connector. Store the instrument under test for 24 h at a temperature of -20°C and subsequently for 24 h at a temperature of 70°C and a relative humidity of 85 % (no condensing). *Note:* This is one test and not two separate tests. Carry out the test in pressure steps of not more than 7 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range.	1-It's not necessary to set the measurement system before storage. 2-It's also valid to establish some "rest time" after storage and before perform the accuracy check.	Reorganize the text as follows: "**Unpack the sphygmomanometer and store it** for 24 h (…) of 85% (non-condensing). **At least after one hour under ambient conditions,** replace the cuff with a vessel **and** connect (…) and the maximum pressure of the scale range" *(remove the Note)*	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
41.		**A.4.2 Procedure** Wrap the cuff around the cylinder. *Note:* Electro-mechanical pumps which are part of the device may be used for the test. Carry out the test over the whole measuring range at at least five equally spaced pressure steps (e.g. 7 kPa (50 mmHg), 13 kPa (100 mmHg), 20 kPa (150 mmHg), 27 kPa (200 mmHg) and 34 kPa (250 mmHg)). Test the air leakage over a period of 5 min and determine the measured value from this.	As suggested above (#12), I think this procedure should be removed. But if it's not acceptable, I think it's unnecessary to measure air leakage on 5 different pressure values.	Remove the test procedure or, if not possible, reduce the number of pressure steps to one or two only.	Accepted
42.	Germany	A.4.1, A.6.1, A.9.2, A.10.1, A.11.1 **A.4.1 Apparatus** · rigid metal cylinder of an appropriate size (see 6.1); · pressure generator, e.g. ball pump (hand pump) with a deflation valve; · time measuring device with **minimum resolution of 0.1s**	The accuracy of the time measuring device is required, not only the resolution.	Add: …, maximum permissible error: 0,1 s.	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
43.		**A.5.2 Procedure** Measure the pressure reduction rate either on human limbs or artificial limbs. *Note 1*: The intention is to use artificial limbs, but as these are still under consideration, measurements performed with human volunteers are acceptable. *Note 2*: It is intended that the properties of the artificial limbs reflect some elastic properties of human limbs.	Artificial limbs are under consideration since 2002. Will we keep this information?	Change the text on Note 1 to "The intention is to use artificial limbs **but** measurements performed with human volunteers are acceptable".	Accepted
44.		**A.6.1 Apparatus** · rigid metal cylinder of an appropriate size (see 6.1); · pressure generator, e.g. ball pump (hand pump) with a deflation valve; · T-piece connector; · time measuring device with **minimum resolution of 0.1**	The test should be performed on a situation as close as possible to the real use conditions. That means using the sphygmomanometer's pneumatic system without adding a reference manometer.	Remove items 1, 2 and 3. Add the item "artificial limb or human volunteer with appropriated circumference for the cuff".	Not accepted But modification
45.		**A.6.2 Procedure** Carry out the test with the vessel in place of the cuff. Connect the calibrated reference manometer by means of a T-piece to the pneumatic system. Inflate to the maximum pressure and open the rapid exhaust valve.	Adapting to suggestion #34 and changing the maximum pressure value. It's harder to correctly start the stopwatch if we pressurize more than 260 mmHg.	"Wrap the cuff around the artificial limb or human volunteer. Inflate the sphygmomanometer to 35 kPa (260 mmHg). Immediately open the rapid exhaust valve and start the time measuring device. Stop the time measuring device when the sphygmomanometer indication reaches 2 kPa (15 mmHg)".	Not accepted But modification

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
46.		**A.6.3 Expression of results** Measure the time between the pressure values specified in 6.2.3.	Better wording.	"Express the result as the time for pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg)".	Accepted
47.		**A.7.2 Procedure** Determine the thickness of the scale marks and the scale spacing using the scaled magnifying lens.	It's not clear how many scale marks and spaces should be measured.	"Determine the thickness of the scale marks and the scale spacing **of five equally spaced pressure values (e.g. 7 kPa (50 mmHg), 13 kPa (100 mmHg), 20 kPa (150 mmHg), 27 kPa (200 mmHg) and 34 kPa (250 mmHg))**"	Not accepted But modification, three points
48.		**A.7.3**	If suggestion #37 is accepted, it's necessary to add this clause.	"Express the results as the mean thickness and the mean distance between adjacent scale marks of all pressure values (means shall be calculated with one decimal figure). The reason between these numbers shall be no more than **1/3**" *(considering sug. #16)*	Not accepted same as no.47
49.		**A.8 Method of test for the internal diameter of the mercury tube** **A.8.1 Apparatus** · limit plug gauges or similar devices, with a tolerance less than 0.05 mm. **A.8.2 Procedure** Test the nominal internal diameter of the tube at each end by using the limit plug gauge	How to express the results?	"Express the results as the mean internal diameter of each sphygmomanometer tested".	Not accepted Remove the clause in A8 No requirement anymore

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
50.		A.9 Method of test for security against mercury losses A.10 Method of test for the influence of the mercury stopping device	These two tests should be applicable even if the device uses other manometric liquid than mercury.	Replace the word “mercury” on the titles and other parts with “manometric liquid”	Not accepted It is impossible to find a liquid such as mercury.
51.	**brazil**	**A.9.2 Procedure** · collecting vessel of an adequate size;	The term “calibrated reference manometer” was left here.	Replace “calibrated reference manometer” with “alternative manometer”.	Not accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
52.	Germany	· **alternative** manometer, with an uncertainty **less than 1mmHg**; · T-piece connector; · pressure generator, e.g. ball pump (hand pump) with a deflation valve. **· time measuring device with minimum resolution of 0.1s** Place the sphygmomanometer to be tested in the collecting vessel. Connect the pressure generator and a T-piece connector attached to a calibrated reference manometer directly to the hose leading to the mercury reservoir. Use the pressure generator to raise the pressure in the manometer to 13.3 kPa (100 mmHg) greater than the maximum indicated scale reading on the test manometer. Maintain this pressure for 5 s and then release the pressure in the system. Check that no mercury has spilled.	Revise wording regarding the reference manometer and add range.	• calibrated reference manometer with a nominal range up to 41,3 kPa (400 mmHg) and an uncertainty less or equal 0,133 kPa (1 mmHg)	Accepted
53.		**A.11.2 Procedure** Replace the cuff with the vessel.	The reference manometer must be disconnected during the 5 min wait only if it is subjected to hysteresis effect. A digital manometer may remain connected.	Add the following text to the end of procedure "…, if it has elastic sensing elements."	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
54.	Germany	Connect the calibrated reference manometer by means of a T-piece connector to the pneumatic system. After disabling the electromechanical pump (if fitted) connect the additional pressure generator into the pneumatic system by means of another T-piece connector. Test the device with increasing pressure steps of not more than 7 kPa (50 mmHg) to the scale maximum, at which point hold the pressure for 5 min and then decrease it by the same steps. Disconnect the calibrated reference manometer during the 5 min at maximum pressure.	For this measurement tapping shall not be allowed.	… and then decrease it by the same steps. Do not tap on the manometer housing to reduce the friction to move the pointer.	Accepted
55.	**Brazil**	**A.11.3 Expression of results** Express the results as the difference between the indicated values on the manometer at the same test pressure steps when increasing the pressure and when decreasing the pressure.	It's not clear that hysteresis values are absolute values.	Change the text to "Express the results as the **absolute values of the** difference between…"	Not accepted
56.	**Brazil**	A.11 Method of test for the hysteresis error of the aneroid manometer A.12 Method of test for the construction	Both A.11 and A.12 are applicable only to aneroid manometers. To be consistent with A.11, the test procedure title needs the word "aneroid".	"Method of test for the construction **of the aneroid manometer**".	Accepted
57.	Germany	**A.12.3 Expression of results** Express the results as the **changes** between the indicated values on the manometer at the same test pressure steps before and after the stress test.	For clarification, modify the text a little and add formula.	Express the results as the changes Δp_{Hyst} between the indicated values on the manometer at the same test pressure steps after p_{down} and before p_{up} the stress test ($\Delta p_{Hyst} = p_{down} - p_{up}$).	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
58.		Express the results as the differences between the indicated values on the manometer at the same test pressure steps before and after the stress test.	Repeated text.	Remove 2nd paragraph.	Accepted
59.		iii) Definitions and formula For the purposes of this test report format, the following definitions and formula, taken from the International Vocabulary of Basic and General Terms in Metrology **(VIM, 1993 edition)** are used.	Dated VIM reference for the 1993 edition.	Updated the reference to "**2007 edition**".	Accepted principle
60.	Germany	**1 Clause/** **2 Subject/** **3 Maximum deviation/** **4 Maximum permissible error/** **5 Passed/** **6 Failed**	Columns 3 and 4 (Maximum deviation and mpe) need different title.	Column 3: "test result" or "tested device" Column 4: OIML requirement	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
61.		**B.2 Maximum permissible errors of the cuff pressure indication** For the limits of temperature and humidity see 5.1.1: the temperature should be between 15°C and 25°C, the relative humidity should be between 20% and 85%. To find out the error of the cuff pressure indication proceed as follows (up and down runs) at three different temperatures: e.g. 15°C and 20% relative humidity, 20°C and 60% relative humidity and 25°C and 85% relative humidity. **Table 1 Example: Temperature 20°C and…% relative humidity** **Table 2: Temperature 20°C and…% relative humidity**	To perform the procedure at three different temperatures and humidity values is necessary to use a climatic chamber. This is too severe. performing the hysteresis test (A.11), not the maximum permissible errors test (A.1). Maximum permissible error now is only ± 3 mmHg.	Remove the 2nd paragraph. Remove columns 10 and 11 from tables 1 and 2, wording “maximum hysteresis” and both Notes. This information should be placed on a new clause, specific for hysteresis test. Remove the error. ± 4 mmHg	Partly accepted Remove the error. ± 4 mmHg Initial verification only test under 20°Cand 60%RH
62.	Germany	1 Pressure mmHg 2/3 1st reading 4/5 2nd reading 6/7 Mean 8/9 Deviation 10/11 Hysteresis	The 2nd reading is optional, therefore – even in an example – this should be clear. For the hysteresis the sign is important, it has to be added. The unit (mmHg) is missing in most places. The device in this example would fail for 2 reasons: accuracy and hysteresis	Column 4/5: 2nd reading (optional) Column 10: -2, 2, -6 Maximum hysteresis: -6 mmHg Columns 2 – 11: add “mmHg”	Partly accepted Add mmHg Hysteresis is absolute value of the difference.

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
63.	Germany	B.2, table explanation	Columns 10 and 11 are calculated incorrectly.	Column 10 = column 3 - column 2 Column 11 = column 5 - column 4	Not accepted Hysteresis is absolute value of the difference.
64.	Germany	1 Pressure mmHg 2/3 1st reading 4/5 2nd reading 6/7 Mean 8/9 Deviation 10/11 Hysteresis *Note 1:* The hysteresis error is the difference between the indications of the instrument when the same pressure is reached by increasing or decreasing the pressure. *Note 2:* The time between up and down run should not be less than 5 minutes at the maximum pressure (see A.11.2). A time difference from the first run to the second run of one hour is recommended.	The 2nd reading is optional, see comment on table 1. The unit (mmHg) is missing in most places. Columns for “mean” and “hysteresis” are not correct.	Column 4/5: 2nd reading (optional) Column “mean”: up, down Column “hysteresis”: 1st reading, 2nd reading Columns 2 – 11: add “mmHg”	Partly accepted 2nd reading is necessary.
65.	Germany		Delete “±0.5 kPa (±4 mmHg)” it is not in the requirement anymore.	… less than or equal to ±0.4 kPa (±3 mmHg) ~~or ±0.5 kPa (±4 mmHg)~~	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
66.	Germany	Is the maximum deviation of all of the readings of the instrument under test and of the reference manometer less than or equal to **±0.4 kPa (±3 mmHg) or ±0.5 kPa (±4 mmHg)** (see 5.1.1)? Is the maximum deviation of the cuff pressure indication (mean value), after storage at -20℃ and 70℃, less thanor equal to **±0.4 kPa (±3 mmHg) or ±0.5 kPa (±4 mmHg)** compared to the mean values at 20℃ and 60% relative humidity before storage?	The unit (mmHg) is missing in most places.	Columns 2 – 9: add “mmHg”	Accepted

67.		**B.3 Effect of storage on cuff pressure indication** Refer to 5.1.2. Determine the error after the storage for 24 h at a temperature of -20℃ and for 24 h at a temperature of 70℃ and a relative humidity of 85% (refer to Note 1 below). *Note 1:* The measurements are to be performed before and after applying the test conditions, respectively: · First measurement at 20℃ and 60% relative humidity before the test (refer to Table 2); · Storage of the instrument under test for 24 hours at -20℃ and 85% relative humidity, immediately followed by storage of the instrument under test for 24 hours at 70℃ and 85% relative humidity; ·Second measurement at 20℃ and 60% relative humidity after the test. The percentages for the relative humidity are arbitrary. The first measurement gives the reference values. Each measurement requires two readings. Calculate the deviation of the mean of the two readings after storage in Table 3 from the mean calculated in Table 2. The result should be within the error limits mentioned below. *Note 2:* These conditions apply for **non-auotomated** blood pressure measuring instruments only.	Note 1, table 3 and the final question are not consistent with the storage requirements at 5.1.2 and test procedure at A.3, specifically expression of results.	Harmonize (5.1.2 and A.3) with B.3.	Accepted Modification was done.

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
68.		**B.4 Effect of temperature on cuff pressure indication** Refer to 5.1.3. *Note 1:* For a type approval test report testing has to be carried out also at 10℃ and 40℃ (see A.2.2). *Note 2:* Take the first mean of the readings of the measuring instrument before storage as reference value (Table 2) and calculate the deviation of the mean of the values measured after storage (mean values here in Table 4) from the mean values of Table 2. The result should be within the error limits mentioned below. For each of the following combinations of temperature and humidity, condition the device for at least 3 h in the climatic chamber to allow the device to reach steady conditions.	Note 1 is unnecessary and Note 2 describes the **storage test** procedure instead of the influence of temperature test. Note 2 is also unnecessary because the test procedure (for influence of temperature test) is at A.2. The final question is inconsistent with the test purpose, which **is not** to check compliance with MPE at all temperatures.	Remove both Notes. Change the final question text to "Is the maximum **difference between the indications of the tested device at 20 ºC and its own indications at 10 ºC and 40 ºC** less than or equal to **± 0.4 kPa (± 3 mmHg**)?"	Partly accepted Remove both Notes. Difference is between the indication and reference manometer.
69.	Germany	1 pressure mmHg 2/3 1st reading 4/5 2nd reading 6/7 mean 8/9 deviation from Table 2	The 2nd reading is optional, see comment on table 1.	Column 4/5: 2nd reading (optional)	Not accepted 2nd reading is necessary.
70.		B.6 Pressure reduction rate for deflation valves **The pneumatic system** deflation valves shall be capable of adjustment to a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s)? **The pneumatic system** deflation valves shall be easily adjusted to these values.	The sentence is written in the affirmative form but it has an interrogation mark at the end.	Replace with "**Are** the pneumatic system deflation valves **capable of**...".	Accepted
71.	Germany		Due to the proposed change in 6.2.2, change wording here as well.	The deflation valves in the pneumatic system shall be … (2 times)	Accepted

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
72.		**B.10 Pressure indicating devices** All the tests can be carried out by visual inspection. For reference see: Scale readable: 6.3.2.1 First scale mark: 6.3.2.2 Scale interval: 6.3.2.3 Scale spacing and thickness of scale marks: 6.3.2.4	Scale spacing and thickness of scale marks can't be checked by visual inspection.	Harmonize the text.	Accepted principle Deleted all the sentences.
73.		**B.10.4 Analogue indication - Scale interval** Is the scale interval 0.2 kPa or 2 mmHg for a scale graduated in kPa or mmHg, respectively?	The scale interval for kPa is not updated.	Replace "0.2 kPa" with "0.5 kPa".	Accepted
74.	Germany	**B.11.1 Internal diameter of the tube containing mercury** Is the nominal internal diameter of the mercury tube at least 3.5 mm±0.2 mm?	The number should be change as proposed for 6.4.1	Is the nominal internal diameter of the mercury tube at least 3,9 mm±0.2 mm?	Not accepted There is no "nominal internal diameter" requirement anymore

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
75.		**B.12.4 Hysteresis error** Is the maximum hysteresis error throughout the pressure range less than or equal to 0.4 kPa (3 mmHg) according to Table 2? *Note:* The purpose of this test is to determine if the elastic sensing element has been exposed to a tension within the elastic range (i.e. the "Hooke's" range) or not throughout the whole pressure range. For reference see 6.5.4. The test should be carried out according to A.11.	The report format doesn't allow registering the device's indications. The pressure values are wrong. The Note is unnecessary.	Turn it into a report similar with B.3. Replace "0,4 kPa (3 mmHg)" with "0.5 kPa (4 mmHg)". Remove the Note.	Accepted
76.		**B.12.5 Construction and materials** Is the difference in the pressure indication of the aneroid manometer after 10 000 alternating pressure cycles more than **±0.4kPa (±3 mmHg)**at any point within the pressure range? For reference see 6.5.5. The test should be carried out according to A.12. The pressure test has to be performed according to B.2. *Note:* The construction of the aneroid manometer and the material for the elastic sensing elements shall ensure an adequate stability of the measurement. The elastic sensing elements shall be aged with respect to pressure and temperature.	The report format doesn't allow registering the device's indications. The question is inconsistent with the requirement. The Note is unnecessary.	Turn it into a report similar with B.3. Change the text to "…after 10,000 alternating pressure cycles **less than or equal to** ± 0.4 kPa…". Remove the Note.	Accepted Delete he note.

No.	MB	Paragraph/Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
77.		**Initial verif.**	Add a sampling plan for initial verification.	Use double sampling plan (e.g. OIML R 115)	Not accepted It is not nessary