

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0001 AU				ed	In general, there should be a space between numerical value and unit (see comments Austria).		Agree
0002 IR 05	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: 1- 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	We propose a clause similar to IEC 80601-2-30, 201.11.8.101 because it addresses an important safety feature.	Add: Switching off When the automated non-invasive sphygmomanometer is switched off by the operator, with the cuff inflated, the cuff shall deflate within 30 s to the values indicated in Table XXX. Table XXX: Cuff deflation pressure Mode Cuff pressure Neonatal mode ≤ 5 mmHg (0,7 kPa) Any other mode ≤ 15 mmHg (2,0 kPa) Compliance is checked by functional testing.	Disagree 6.9.1 Abort a measurement It shall be possible to abort any blood pressure measurement at any time by single key operation and this shall lead to a rapid exhaust (see 6.4.3). 6.4.3 Rapid exhaust During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 34.7 kPa to 2.0 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s. For the automated sphygmomanometer having the capability to measure in a neonatal/infant mode, the time for the pressure reduction from 20.0 kPa to 0.7 kPa (150

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
							mmHg to 5 mmHg) during the rapid exhaust of the pneumatic system with the valve fully opened shall not exceed 5 s. Stricter than the comment.
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 Modification this paragraph and addition of 6.9.4 Electrical safety. Regional or national regulations may specify electrical safety requirements.
0005 DE	1	1. Scope		ed	Delete "and" in the 1 st sentence.	This Recommendation specifies general, performance, efficiency, mechanical and electrical safety requirements,	Agree
0006 DE	1	1. Scope		te	The test methods are now in Part 2.	Delete "including test methods for type approval,"	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	The defined terms should be introduced alphabetically.	The defined terms should be introduced alphabetically.	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	The text should be improved and be aligned with the title.	It should read: A medical measuring instrument used for the intermittent non-invasive estimation of the blood pressure by utilizing an inflatable cuff, a pressure transducer a valve for deflation, and/or displays used in conjunction with automated methods for estimating blood pressure.	Agree
0011 DE	1	2.1	Note	ed	Is the note not redundant? Is there something importantly new in it?	Delete the note.	Agree
0012 JP1	1	2.1	Note	Ed	Recommend explaining briefly the close relationship between the cuff and the bladder.	In the note, replace "cuff" with "cuff <u>with bladder</u> ".	Delete the note. See comment 0011

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0013 DE	1	2.1	Title	ed	The title should be change according the title of the Recommendation, see German comment above.	The title should read: Intermittent automated non- invasive sphymomanometers	Partly agree the revised term of non- invasive automated sphymomanometers will be modified with "intermittent" in text. However, the title will not change compared with non- invasive non-automated sphymomanometers.
0014 DE	1	2.3		te	There are devices which work also during slow cuff pressure inflation. This should be covered in the text or at least as an additional note or a revised definition.	Add where appropriate: The method works in a similar way also during slow cuff pressure inflation. Alternatively, a revised definition: Method that estimates systolic, diastolic and mean arterial pressures during the slow inflation or deflation of an occluding cuff at the brachial artery.	Agree revise definition: Method that estimates systolic, diastolic and mean arterial pressures during the slow inflation or deflation of an occluding cuff at the brachial artery.
0015 DE	1	2.4		te	Add “or detected (e.g. by a microphone)”	It should read: Method whereby sounds (known as Korotkoff sounds) are heard or detected (e.g. by a microphone) over an occluded artery as the occluding pressure is slowly released, ...	Agree
0016 DE	1	2.4		ed	To remain consistent, replace “Technique” with “Method”	Replace “Technique” with “Method”	Agree
0017 DE	1	2.7		ed	Because the calculation of the MAP using only the systolic and diastolic blood pressure values is usually not suitable, a note should be added.	Note 2: The calculation of the mean arterial blood pressure using only the systolic and diastolic blood pressure values is not recommended.	Agree
0018 DE	1	3		ed	Correct the sentence.	It should read: The basic components of an automated sphymomanometer are a cuff that can be wrapped around a patient's limb, a system for applying and releasing pressure to the bladder, and a means of measuring and displaying blood pressure values.	Agree
0019 DE	1	3		ed	Why capital letters? Remove “or”	It should read: Note: Specific device types include automated sphymomanometers for self-measurement, blood pressure monitors and multi-parameter patient monitors, for home healthcare environment, or public use, etc.	Agree
0020 JP2	1	3	1 st sentence	Ed	Recommend explaining briefly the close relationship between the cuff and the bladder.	In the 1 st sentence, replace “bladder” with “bladder <u>in the cuff</u> ”.	Agree

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

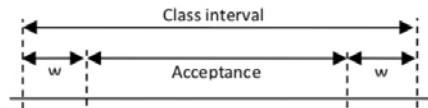
Date:2019-03-22	Document:	Project:
-----------------	-----------	----------

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0021 JP3	1	3	Note	Ed	The text may not be understood clearly.	Recommend a rephrasing as shown below. <i>Note: Specific device types included in this category are: automated sphygmomanometers for self-measurement, <u>blood pressure monitors</u> and <u>multi-parameter patient monitors used for home healthcare environment, or public use, etc.</u></i>	Agree
0022 BR	1	4		Te	The Draft of 9 th edition of the SI Brochure (which was endorsed by the CIPM at its 106 th 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 well as consideration of the actual situation of medical applications.
0023 BR	1	5		Te	According to technical work “A more effective approach to the legal metrological control of sphygmomanometers” (OIML Bulletin, Volume LVIII, n4, October 2017), in order for legal metrological control be effective, it is necessary to first understand how the indication presented by the measuring instrument is actually used. In the case of sphygmomanometers, the main objective is to identify and monitor patients who are diagnosed with hypertension. Basically this process consists of measuring the blood pressure and classifying the result in one of the classes presented in Table 1, which is according to International Society of Hypertension.	Replace all clause 5 with text below. 5. Metrological requirements 5.1 Maximum permissible error The maximum error of the blood pressure measurement shall be determined with equation below and shall be less than or equal to 0.76 kPa for systolic pressure and 0.36 kPa for diastolic pressure. <u>Once the maximum error of the blood pressure is accepted, the models can to be specified by class, as is currently the case for industrial manometers. For example, approved sphygmomanometer models with a maximum error between 0.18 kPa and 0.36 kPa would be assessed as class B and those with a maximum error less than 0.18 kPa, class A.</u>	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. In conformity assessment, when the measurement result $U = k\sqrt{u_{ref}^2 + s_r^2 + s_L^2} \leq \frac{1}{3}MPEV$, MPEV refers to the absolute value of the maximum allowable error of the measuring instrument. The

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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
---------------------------	------	-------------------	-------------------------	------------------------------	----------	-----------------	----------------------

				<div>Table 1: Blood pressure classification (Values in mmHg)</div> <table><tr><th>Class</th><th>Systolic</th><th>Diastolic</th></tr><tr><td>Normal</td><td>< 120</td><td>< 80</td></tr><tr><td>Prehypertension</td><td>120 – 139</td><td>80 – 89</td></tr><tr><td>Hypertension Stage 1</td><td>140 – 159</td><td>90 – 99</td></tr><tr><td>Hypertension Stage 2</td><td>≥ 160</td><td>≥ 100</td></tr></table> <p>That is, the use of the sphygmomanometer is equivalent to a process of conformity assessment with the following steps:</p> <ol style="list-style-type: none">Measurement of a quantity (blood pressure);Comparison of the measurement result with requirements (Table 1);Decision on the action to be taken (medical decision). <p>Since this process of conformity assessment uses the results of measurements made by an instrument, it is important to consider the influence of the measurement uncertainty in order to render the decision making more effective. The most common way to do this is through the binary decision rule, which consists of establishing a safety margin within each class of Table 1, as shown in Figure 1.</p> <div></div> <p>Figure 1: Acceptance interval</p> <p>Based on industrial practice, the value of the expanded uncertainty, U, associated with the measurement made by the sphygmomanometer, has been adopted as the safety margin, w. 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.</p>	Class	Systolic	Diastolic	Normal	< 120	< 80	Prehypertension	120 – 139	80 – 89	Hypertension Stage 1	140 – 159	90 – 99	Hypertension Stage 2	≥ 160	≥ 100	<div>$B_{IC} _{max} + k \sqrt{\frac{u_{IC}^2 + u_{ref}^2 + s_r^2 + s_L^2}{n}}$</div> <p>Each component of the equation is described below.</p> <p>5.2 Components B_{IC} and u_{IC}</p> <p>B_{IC} and u_{IC} are, respectively, the mean error of measurement and the experimental standard deviation determined from the clinical investigation, which shall be performed in accordance with latest version of the ISO 81060-2 or ISO 81060-3 (carried out by manufacturer).</p> <p>5.3 Component u_{ref}</p> <p>u_{ref} is the repeatability of patient simulator and its value shall be determined annually according to IEC TS 81060-5 (note: this document has been introduced in the programme of work in IEC and will be circulated as committee draft in 2019-06-28).</p> <p>5.4 Component s_r</p> <p>s_r is the repeatability of sphygmomanometer and its value shall be determined according to Ryyy-2.</p> <p>5.5 Component s_L</p> <p>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:</p> <ul style="list-style-type: none">• Environmental conditions;• Storage;• Voltage variations of the power source;• Durability;• Resistance to vibration and shock (not applicable for fixed automated sphygmomanometer);• Electrostatic discharges;	<p>influence of measurement uncertainty in conformity assessment can be neglected or neglected, that is, the probability of misjudgement of conformity determination is very small. It should be noted that here is the measurement result of the cuff pressure indication. The maximum allowable error of reference manometer is not more than (± 0.8 mmHg), so the u_{ref} is not more than $\frac{0.8}{\sqrt{3}} = 0.46$ mmHg. s_r and s_L can be calculated separately as uncertainty components of static pressure measurement results, but they are usually small and negligible. Testing the blood meters can directly determine whether it is qualified, without considering the uncertainty of measurement results. So the requirement of static blood pressure of sphygmomanometer is much higher than the interval width of the recommended value of hypertension in medicine. The interval width of the recommended value of hypertension should not be used as a technical requirement of sphygmomanometer. The concepts of measurement range and maximum allowable error are different. According to the requirements of legal metrology, the</p>
Class	Systolic	Diastolic																			
Normal	< 120	< 80																			
Prehypertension	120 – 139	80 – 89																			
Hypertension Stage 1	140 – 159	90 – 99																			
Hypertension Stage 2	≥ 160	≥ 100																			

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
					<p>Therefore, it is proposed to consider that the safety margin is the sum of U with the highest modulus of the measurement bias (B_{max}), as shown in equation below.</p> $ B_{max} + U \leq w$ <p>In conformity assessment, it is considered reasonable that the safety margin has a value less than or equal to 30 % of the span of the tolerance interval. In Table 1, the maximum permissible value for w would be 30 % of the class having the smallest interval. That is, the maximum permissible error for the legal metrological control of sphygmomanometers would be equal to 5.7 mmHg (0.76 kPa) and 2.7 mmHg (0.36 kPa), since it corresponds, respectively, to 30% of the difference between the maximum and minimum values of systolic and diastolic pressure of the prehypertension class of Table 1.</p> $ B_{max} + U_{SIS} \leq 0.76 \text{ kPa}$ $ B_{max} + U_{DIA} \leq 0.36 \text{ kPa}$ <p>This proposal establishes a direct and clear linking of legal metrological control with the needs of society. Once the international medical community changes the values in Table 1, the maximum permissible measurement error should also be changed. As a consequence, the medical community, which is the main user of the measurement results of a sphygmomanometer, becomes an important player in the elaboration or revision of the Recommendation. With this in mind, the rest of the Recommendation should present the steps to determine the values of U and B_{max}.</p> <p>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</p>	<ul style="list-style-type: none"> Radiated, radio-frequency, electromagnetic fields; Conducted disturbances induced by radio-frequency fields (only applicable if sphygmomanometer carries out blood pressure measurements when connecting power or signal and control cables to the instrument); Electrical fast transients (only applicable if sphygmomanometer carries out blood pressure measurements when connecting power or signal and control cables to the instrument); Voltage dips and short interruptions (only applicable if the instrument is powered by alternating current). <p>The value of each intermediate precision shall be determined according to Ryyy-2.</p> <p>5.6 Component <i>k</i> <i>k</i> is the coverage factor. Typically, <i>k</i> = 2 for probability of 95%.</p> <p>5.7 Component <i>n</i> <i>n</i> is the number of blood pressure measurements that should be performed for appropriate patient evaluation. Most recent good practice recommend <i>n</i> = 2.</p>	<p>measurement performance of each sphygmomanometer shall meet the requirements, and the tests shall be carried out on each meter. The clinical conformity test is not conducted for each sphygmomanometer, which is not operable. Even if the clinical investigation conformity results of one type could be used for the measurement, the manufacturer has to provide corresponding data, and the amount of test data in ISO 81060 is limited. Clinical conformity results could be influenced by many factors, such as human performance. It does not have traceability, nor corresponding mathematical model, let alone evaluation uncertainty.</p>

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
					<p>measurements taken at intervals of 1 to 2 minutes. Thus, the value of U can be obtained from equation below:</p> $U = k \frac{u}{\sqrt{n}}$ <p>where u is the combined uncertainty, n is the number of measurements performed and k is the coverage factor. Because the algorithm used by sphygmomanometers to estimate blood pressure is generally not provided to users by the manufacturer, the measurement model becomes unavailable. In this case, the uncertainty u can be determined by equation below:</p> $u^2 = u_{ref}^2 + s_r^2 + s_L^2$ <p>where u_{ref} is the uncertainty obtained from the calibration certificate of the reference, s_r is the repeatability and s_L is the result of the combination of several intermediate precisions. Each intermediate precision is represented by an experimental standard deviation that quantifies the influence that only one source exerts on the measurement result of the sphygmomanometer.</p> <p>The B_{max} value can be determined from the mean error of measurement determined in the clinical investigation, since there is still no standard that provides a reference blood pressure. In this case, the equation which calculates u shall include the uncertainty determined from the standard deviation of the error calculated in the clinical investigation.</p>		
0024 JP4	1	5.1, 5.5 and 7.2		Ed	Use an expression “range <u>from</u> X to Y” to specify a range of number.	<p>Replace “range <u>of</u> X to Y” with “range <u>from</u> X to Y” for all applicable expressions.</p> <p>For all applicable expressions, replace "the range from X to y" with "the range from X to y".</p>	Agree

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22	Document:	Project:
-----------------	-----------	----------

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0025 JP5	1	5.3	1 st sentence	Ed	This long sentence mentions a test sequence for storage. However, it is difficult to understand clearly.	We propose the following amendment. <i>The automated sphygmomanometer shall maintain the requirements specified in this Recommendation after a storage for 24 h at a <u>low</u> temperature of -5 °C and which is followed by an additional storage for 24 h at a <u>high</u> temperature of 50 °C and <u>at</u> a relative humidity of 85% (non-condensing).</i>	Agree
0026 DE	1	5.3	2 nd para, 1 st sentence	ed	What does "strict" mean?		Compared with the simplified test, delete it. See comment 0027~0029.
0027 DE	1	5.3	2 nd para, 2 nd sentence	ed	This is a recommendation/guideline, it should become a note.	It should read: Note 1:For simplification, testing can also be carried out at a temperature of 20 °C ± 5 °C and at ambient humidity.	Agree The text of simplified test shall move to be a note, and the simplified testing method may be only applied to the integrated multi-parameter monitors.
0028 JP6	1	5.3	2 nd paragraph	Te/Ed	If a simplified test method (20 ± 5 °C) is permitted in the 2 nd sentence, there is no need to specify the strict test in the 1 st sentence (-5 °C and 50 °C). For what purposes are these different methods applied? Is the simplified method used for the monitors mentioned in the note (see JP7)?	Use either the strict test or the simplified test. Otherwise, please explain the different targets of each test method.	Agree The text of simplified test shall move to be a note, and the simplified testing method may be only applied to the integrated multi-parameter monitors.
0029 JP7	1	5.3	Note	Te/ed	The 2 nd and 3 rd sentences are difficult to understand. We recommend applying the simplified method to such monitors if this method is maintained in 5.3 (see JP6).	We propose replacing the 2 nd and 3 rd sentences with the sentence below. <i>The simplified testing method may be applied to the integrated multi-parameter monitors.</i>	Agree The text of simplified test shall move to be a note, and the simplified testing method may be only applied to the integrated multi-parameter monitors.
0030 DE	1	5.3	Note 2	te	The sentence "The abnormal status shall be recorded during the testing." cannot be part of a note, it is using the verb "shall".	Move to normal text, becoming a 3 rd paragraph: If any abnormal status occurs during the test, this shall be recorded.	Agree
0031 DE	1	5.5		ed	Add "in the"	For any set of conditions within the ambient temperature range of 10°C to 40°C and the relative humidity in the range of ...	Agree
0032 DE	1	5.5		ed/te	IEC 80601-2-30, 201.12.1.107 Reproducibility of the BLOOD PRESSURE DETERMINATION has practically identical requirements. Because	Discuss this point in the project group.	in terms of reproducibility, test/re-test reliability demonstrates that constructs

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
					repeatability is much easier to fulfil this topic should be discussed by the project group.		are not expected to alter over time and not be influenced by environmental aspects. Actually, this testing procedure is based on the repeatability testing procedure addition with a series of performance tests. however, in the document, the test of 5.1 Maximum permissible errors will be carried out after every performance test. if the devices pass these tests, repeatability is much easier to fulfil.
0033 BR	1	6		Te	Once the suggestion on clause 5 is accepted, clause 6 needs to be modified.	Remove subclauses 6.3, 6.5.1, 6.6 and 6.10 because they are already mentioned in the subclause 5.4 and will be detailed in Ryyy-2.	Disagree The suggestion on clause 5 is not accepted.
0034 DE	1	6.1		ed	Replace “having forms or construction” with ”designs”	Equipment, or parts thereof, using materials or designs different from those detailed in this Recommendation...	Agree
0035 DE	1	6.2		ed	The 2 nd sentence should be reformulated.	The cuff shall be designed and marked (i.e. using permitted circumference indicators) to ensure and restrict the use of the appropriate cuff size corresponding to a given limb circumference.	Agree
0036 JP8	1	6.2	2 nd sentence	Ed	It is difficult to understand the latter part of 2 nd sentence.	We propose a simple expression as shown below. <i>The cuff ... that it is of the correct size or it shall be marked with an indication of the range of limb circumference for which so that the cuff is <u>attached appropriately</u>.</i>	Agree See comment 0035
0037 JP9	1	6.3.1 and 6.3.2	All	Te	The working range of an internal power source is not given in 4.1 of R yyy-2, which mentions a test method. The information of working range is usually provided by the manufacturer and it is already mentioned in 6.3.2 with a reference to 7.5 (the manufacturer's information).	Clause 6.3.1 is not necessary, and it can be merged into 6.3.2. If it is merged, the title of 6.3.2 should be corrected to “Electrical power source”.	Disagree instead “determined according to Ryyy-2 4.1” of specified by the manufacturer (see 7.5)
0038 DE	1	6.3.1.1		ed	Since no change is allowed, it will always comply with 5.1.	Delete “which should comply with the requirement of 5.1”.	Agree
0039	1	6.3.2.1		ed	Since no change is allowed, it will always comply	Delete “which should comply with the requirement of	Agree

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
DE 0040 PL	1	6.4			with 5.1. External powe supply is also removed.	5.1”.	Disagree Now clause No. is 6.3.2.
0041 PL	1	6.4.1.2			Outside this working range no cuff pressure reading and no result of the blood pressure measurement shall be displayed. Why it is removed?		Disagree Now clause No. is 6.3.2.
0042 DE	1	6.4.4		ed	Add “a” See 2.12	Zero adjustment of a measuring system	Agree
0043 BR	1	6.4.4		Te	According to technical work “A more effective approach to the legal metrological control of sphygmomanometers” (OIML Bulletin, Volume LVIII, n4, October 2017), it was observed that some models presented error over the entire measurement range, which suggests that the transducer is nonlinear in the region close to zero. It does not make sense to perform the zero adjustment if the transducer presents non-linearity at the beginning of the range, as it will result in the introduction of a systematic error. A manufacturer using a non-linear transducer will perform adjustment of the calibration curve only for points within the linear range resulting in the introduction of a systematic error when the instrument performs the automatic zero adjustment.	Include item 6.4.4.3: The pressure curve of the transducer must be linear over the entire measuring range, which must always start at zero pressure.	Disagree The pressure curve of the transducer must be linear over the entire measuring range, which must always start at zero pressure. This is an ideal model, which is too strict to meet in practice. See comment 0044
0044 DE	1	6.4.4 and 6.4.4.1		ed/te	In IEC 80601-2-30 there is no such requirement (any more) because JWG felt it is too design restrictive. We feel that the requirement makes sense, but maybe an additional sentence should be included to allow a little bit more flexibility.	Add a sentence: If the same objective is achieved by different means or procedures, the manufacturer shall demonstrate the equivalence.	Disagree There is no validation method to verify equivalence and the description is meaningless.
0045 JP10	1	6.4.4.2		Te	The entire clause is difficult to understand. We propose a rephrasing.	We propose the following amendment if we understand correctly. <i>Automated sphygmomanometers shall be capable of automatic zero adjustment. The zero adjustment shall be carried out at appropriate intervals, at least <u>when starting after switching on the device is powered on. At the moment of After a the zero adjustment, the device shall keep the indication of a gauge pressure of 0.0 kPa (0 mmHg) shall exist and be displayed thereafter.</u> Automated sphygmomanometers shall repeat aperforming zero adjustment only immediately after switching on, shall or shall be</i>	Agree

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<i>switched off automatically when the drift output of the pressure transducer and the analog signal processing exceeds drifts one scale interval (0.1 kPa or 1 mmHg) or more.</i>	
0046 JP11	1	6.4.5	The last sentence	Te/ed	What is meant by the expression “testing shall be carried out by visual inspection”? It may not be necessary.	This sentence may be deleted.	Agree
0047 PL	1	6.5.1			" electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication, i.e. the maximum permissible error for the measurement of the cuff pressure shall be ± 0.4 kPa (± 3 mmHg) or $\pm 2\%$ of the reading, whichever is greater; or" or what????		"Or" refers to the relationship between two sub-clauses.
0048 DE	1	6.5.1 and 6.5.2		ed	“Testing should be carried out in accordance with...”	Since these are requirements, replace should with shall.	Agree
0049 DE	1	6.6		ed	The new title can be misunderstood.	Keep the old title or shorten to “Stability”	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 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.
0050 DE	1	6.8		ed	Add a note for clarification.	Note: An error message or a blank display would be sufficient.	Agree
0051 PL	1	6.9			Alarms (it is removed)		/ See explanatory note of the document.
0052 JP12	1	6.9	Title	Ed	The title is in an imperative form and it should be changed to a noun.	It should be corrected to “Abort of a measurement”	Agree

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0053 DE	1	6.9.2		ed	Add "special". Not every tool can be used to remove tamper-resistant components.	...by requiring the use of a special tool....	Agree
0054 DE	1	6.10		te	Why are fixed automated 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 project group.	Mechanical safety requirements are based on the following two 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. The second type is that the sphygmomanometer needs to undergo continuous random shock and vibration during patient transportation.
0055 BR	1	7.2		Te	Once the suggestion on clause 5 is accepted, the verification process 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 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 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 6.4.1, and blood pressure measurement error according 5.1. The values of u_{ref} and s_r shall be determined according 5.3 and 5.4 and the values of B_{IC}, u_{CI}, $s_{L,k}$ and n must be taken from type approval report.	Disagree The suggestion on clause 5 is not accepted.
0056 DE	1	7.2	2 nd para	te	To list 5.5 in the requirements to be fulfilled means, that the test office requires to use a simulator.	Discuss in the project group.	Simulator does not have metrological traceability, and

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
					The benefit of such a requirement would be much higher, if a correspondence list exists, which lists blood pressure values that have to be displayed depending of the simulator, its setting etc. It would be a great step forward, if such correspondence table can be established. At present it does not exist. It should be established by international cooperation.		is not used for the accuracy test as the reference standard, it is only used for the repeatability test. The suggestion and discussion of simulator could continue more broadly. Adding appendices related to simulator performance testing can be discussed.
0057 DE	1	7.3.1 and 7.3.2		ed	Keep the used term consistent: 7.3.1 Control marks 7.3.2 Metrological control marks	Use “metrological control marks” throughout the document only.	Agree
0058 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 in kPa positioned close to the displayed values; d) measuring interval of systolic and diastolic pressures; e) type approval number (if applicable); f) serial number; g) year of fabrication; h) country of origin; i) name of responsible for type approval. 7.4.2 On the cuff: a) name or trademark of manufacturer; b) type approval number (if applicable); c) limb circumference in cm 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. 7.4.3 For automated sphygmomanometer applied to the	Agree but with modification

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>wrist, the marks required in 7.4.1 and 7.4.2 can be positioned on indicating device or cuff.</p> <p>7.4.4 For automated sphygmomanometer for home healthcare environment, the sales packaging shall display the following information:</p> <p>a) the operating and storage temperature and humidity ranges;</p> <p>b) any special requirements for a battery-powered automated sphygmomanometer.</p> <p>7.4.5 Automated sphygmomanometers for public use which is intended for self-use in public areas shall be marked with the following:</p> <p>a) precautions for use, including a statement concerning the need to consult a physician for interpretation of blood pressure measurements;</p> <p>b) adequate operating instructions.</p>	
0059 DE	1	7.4	3rs bullet point	ed/te	<p>a)why change to “interval”? Keep “range”.</p> <p>b) Is the marking on the device regarding the “measuring range” still necessary, when the device has to indicate out of range values by itself automatically.</p>	<p>a) keep “range”</p> <p>b) discuss to delete “measuring range/interval”.</p>	<p>Agree</p> <p>Keep “measuring range”.</p>
0060 DE	1	7.5	5 th bullet point	ed	Add “which” or remove “is”	<p>It should read:</p> <p>nature and frequency of the maintenance which is required to ensure that ...</p> <p>or:</p> <p>nature and frequency of the maintenance required to ensure that the device operates correctly</p>	<p>Agree</p> <p>Add “which” in 7.5.</p>
0061 DE	1	7.5	7 th bullet point	ed	An example should be given for “any special requirements for a battery-powered automated sphygmomanometer”	<p>Change to:</p> <p>any special requirements for a battery-powered automated non-invasive sphygmomanometer, e.g. ...</p>	<p>Agree</p> <p>e.g. safety warnings.</p>
0062 BR	1	7.5		Te	Instruction manual shall be contain name and address of manufacturer.	<p>Include the following ballot:</p> <ul style="list-style-type: none"> Name and address of manufacturer. 	<p>Agree</p>
0063 PL	1	7.5			<p>a warning to users of equipment intended for use in environments employing intervacular 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;</p> <p>Why it is removed?</p>		<p>Clause No. 6.9.3 include the requirement.</p>

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0064 DE	1	7.5	5 th bullet, 2 nd sentence	ed	substitute “have to be” with “shall be”	the sentence should read: “...regulations shall be considered”	Agree
0065 BR	1	Annex A		Te	Once the suggestion on clause 5 is accepted, the text of Annex A needs to be removed because it is already incorporated in subclause 5.2.	Remove Annex A.	Disagree The suggestion on clause 5 is not accepted.
0066 DE	1	Annex A	C.2	ed	AAMI/ANSI SP 10 is withdrawn.	Delete C.2	Agree
0067 DE	1	Annex A	C.3	ed	The last version of ISO 81060-2 was published 2018.	Refer to 2018 or refer undated to ISO 81060-2.	Agree
0068 DE	1	Title and text		ge	The title is unusual compared to the ISO or IEC documents: OIML:Non-invasive automated sphygmomanometers IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ISO 81060-2: Non-invasive sphygmomanometers -- Part 2: Clinical investigation of intermittent automated measurement type The term “non-invasive sphygmomanometer” should be kept together. We propose also to add “intermittent” to differ from “continuous automated non- invasive sphygmomanometers” which are starting to enter the markets. The change should be made throughout the whole document (including Terminology).	Intermittent automated non- invasive sphygmomanometers	Partly agree the revised term of non-invasive automated sphygmomanometers will be modified with "intermittent" in text. However, the title will not change compared with non- invasive non-automated sphygmomanometers.
0069 DE	1	Whole document		ed	ISO and IEC documents are using the decimal comma as a decimal separator, e.g. 0,4kPa instead of 0.4 kPa	Change to comma Substitute decimal points with decimal commas	Agree
0070 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 For all types of sphygmomanometers, metrological requirements should be the same. And there is no data to prove that measuring 0.1 mmHg is significance for blood pressure medically. Even at night, during sleep, there are fluctuations of blood pressure value from 5mmHg to 10 mmHg.

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
0071 DE	1	Whole document		ge	“interval” and “range” seem to address the same topic (e.g. 7.4, 7.5, 12th and 13th bullet points).	Use “range” only	Agree
0072 DE	1, 2, 3	Whole document		ge	Quite often “~” is used instead of “-” for describing ranges. “~” indicates an approximation .	Please modify	Agree
0073 CZ	1,2,3				Czech Republic has no comments		/
0074 KR	2			ge	Should add the environmental condition for test in the view of ambient temperature, relative humidity and atmospheric pressure. Such three factors of environmental condition for test could be a reference point and contribute to the accurate test data for compliance of the requirement.		The measurement of sphygmomanometer is not affected by atmospheric pressure.
0075 BR	2	1		Te	Once the suggestion on clause 5 of Ryyy-1 is accepted, the text of 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. 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 the clause 1 with the text below. 1 Determination of the repeatability of sphygmomanometer (including influence of environmental conditions) 1.1 Apparatus <ul style="list-style-type: none"> • Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹; • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff; • Climatic chamber with temperature range from -5 °C to +50 °C (rate of change 1 °C/min and instability within ±1 °C) and relative humidity range from 50% to 85% (instability within ±5%). 1.2 Procedure Connect, as shown in the figure 1, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values. For each of the following combinations of temperature	Disagree The suggestion on clause 5 is not accepted.

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

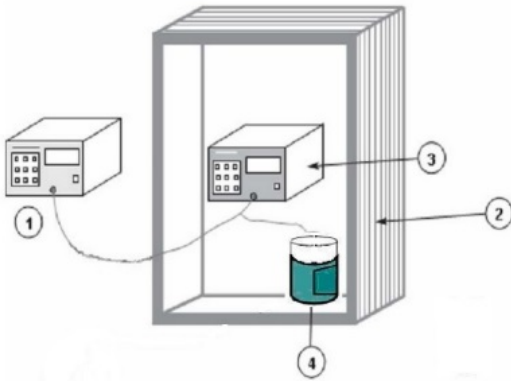
2 Type of comment: ge = general te = technical ed = editorial

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>and humidity, place the automated sphygmomanometer for at least 3 h in the climatic chamber to allow the system to reach steady conditions:</p> <ul style="list-style-type: none"> • 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). <p>At each combination of temperature and humidity switch on the automated sphygmomanometer before starting the test. Wait until the warm up time (described in the instructions for use) has elapsed, perform 5 consecutive measurements and switch off the automated sphygmomanometer afterwards.</p> <p>Note: for verification, there is no need to perform 5 measurements in each combination of temperature. Perform only 10 measurements with temperature within range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 %.</p>  <p>1 – Patient simulator; 2 – Climatic chamber; 3 – Device to be tested; 4 – Rigid cylinder</p> <p>Figure 1</p>	

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>1.3 Results</p> <p>The repeatability shall be determined for systolic and diastolic pressure separately.</p> <p>1.3.1 Type approval</p> <p>The repeatability of sphygmomanometer is calculated as follows:</p> $s_r^2 = A + B$ $A = \left(\frac{1}{t-1} - \frac{pr-1}{ptr-p-t+1} \right) \sum_j (\bar{y}_j - \bar{y})^2$ $B = \left(1 - \frac{1}{pr} \right) \frac{\sum_i \sum_j \sum_k (y_{ijk} - \bar{y})^2 - tr \sum_i (\bar{y}_i - \bar{y})^2}{ptr-p-t+1}$ <p>Where,</p> <p>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; k = subscript which represents a replicate.</p> <p>1.3.2 Verification</p> <p>The repeatability of sphygmomanometer is calculated as follows:</p> $s_r^2 = \frac{1}{r-1} \sum_k (y_k - \bar{y})^2$	

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						Where r is the number of replicates ($r = 5$)	
0076 DE	2	1.1	5 th bullet point	ed	no need for capital letters in the enumeration	“Non” -> “non” “Instability” -> “instability”	Agree
0077 DE	2	1.2	last paragraph	ed	comma is missing	At each combination of temperature and humidity, switch on...	Agree
0078 BR	2	2		Te	<p>Once the suggestion on clause 5 of Ryyy-1 is accepted, there is no need to keep a test for blood pressure measuring range. Instead, this clause should describe the storage test.</p> <p>The equation proposed to determine the standard deviation is different from item 1.3.1 because it not include repeatability.</p>	<p>Replace the clause 2 with text below.</p> <p>2 Determination of the standard deviation due to the storage</p> <p>2.1 Apparatus</p> <p>Same apparatus listed in 1.1</p> <p>2.2 Procedure</p> <p>Connect, as shown in the figure 1, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values.</p> <p>Switch on the automated sphygmomanometer before starting the test, wait until the warm up time (described in the instructions for use) has elapsed and perform 5 consecutive measurements at $20\text{ °C} \pm 5\text{ °C}$ and ambient humidity.</p> <p>Switch off the automated sphygmomanometer and perform storage for 24 h at temperature of -5 °C and for 24 h at a temperature of 50 °C and a relative humidity of 85% (non-condensing). Afterwards, perform another 5 consecutive measurements at $20\text{ °C} \pm 5\text{ °C}$ and ambient humidity.</p> <p>2.3 Results</p> <p>The standard deviation due to the storage (s_{L1}) is calculated as follows:</p> $s_{L1}^2 = C - D$	<p>Disagree</p> <p>The suggestion on clause 5 is not accepted.</p>

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						$C = \left(\frac{1}{f-1} - \frac{1}{pfr - p - f + 1} \right) \sum_j (\bar{y}_j - \bar{y})^2$ $D = \frac{\sum_i \sum_j \sum_k (y_{ijk} - \bar{y})^2 - fr \sum_i (\bar{y}_i - \bar{y})^2}{pr(pfr - p - f + 1)}$ <p>Where,</p> <p>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 temperature; i = subscript which represents a sample; j = subscript which represents a condition (before and after storage); k = subscript which represents a replicate.</p> <p>The standard deviation shall be determined for systolic and diastolic pressure separately.</p>	
0079 DE	2	2.1 and 3.1	1 st sentence	ed	<p>The experimental standard deviation will probably refer to the repeatability or reproducibility (which one?). How is that tested or proven?</p> <p>The draft of “ISO/TS 81060-5 Non-invasive sphygmomanometers — Part 5: Requirement for the repeatability and reproducibility of simulators for testing of automated non-invasive sphygmomanometers” does not cover that aspect. Although ISO/TS 81060-5 does not describe how to determine the standard deviation, it might be sufficient to require that the requirements state there shall be fulfilled.</p>	<p>It should/could read: Patient simulator for the auscultatory and/or oscillometric method, having an experimental standard deviation for the repeatability/reproducibility of not more than 0.13 kPa (1,0 mmHg).</p> <p>Add a reference how to test this requirement or include some procedure in an annex. Alternative approach: Patient simulator for the auscultatory and/or oscillometric method shall follow ISO/TS 81060-5.</p>	<p>Partly agree</p> <p>Patient simulator for the auscultatory and/or oscillometric method, having an experimental standard deviation for the repeatability of not more than 0.13 kPa (1 mmHg).</p> <p>Adding appendices related to simulator performance testing can be discussed</p>
0080 JP13	2	2.1 and 3.1: apparatus	1 st paragraph	Te/ed	<p>What “experimental standard deviation” means? We consider it means a standard uncertainty (k=1) of the pressure.</p>	<p>Recommend replacing “an experimental standard deviation” with “a standard uncertainty of the generated pressure obtained experimentally”.</p>	<p>See comment 0079</p>
0081 BR	2	3		Te	<p>Once the suggestion on clause 1 of Ryyy-2 is accepted, there is no need to keep this clause.</p>	<p>Remove clause 3.</p>	<p>Disagree</p> <p>The suggestion on clause 1 of Ryyy-2 is not accepted.</p>
0082	2	3.1		te	<p>"Patient simulator for the auscultatory and/or</p>		<p>See comment 0079</p>

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
KR					oscillometric method, having an experimental standard deviation for the simulator of not more than 0.13 kPa (1mmHg)“ It does not show how to measure this part, which is ‘experimental standard deviation of 1 mmHg’. If you connect it to the blood pressure monitor and repeat it, it will fall into the contradiction (Zanzibar effect) that the blood pressure meter evaluates the accuracy of the instrument for measuring the blood pressure.		
0083 DE	2	3.2	1 st sentence	ed	specify which figure	“..., as shown in figure 2, ...”	Agree
0084 DE	2	3.2	2 nd sentence	ed	The sentence should be reformulated. “at” requires a specific temperature, not an interval, “~” should be substituted with “-”. The working group should discuss this test, because in the case of “repeatability” a specific temperature is required, in the case of “reproducibility” it is a rage to make is feasible.	The sentence should read in the case of “repeatability”: “Perform 20 consecutive measurements at any temperature in the range 10°C - 40°C and for any relative humidity in the range 15% - 85%.” in the case of reproducibility: “Perform 20 consecutive measurements in the temperature range 10°C - 40°C and in the relative humidity range 15% - 85%.”	Agree in the case of “repeatability”
0085 DE	2	3.3		ed	Clause 5.5 in Part 1 has a different title and requires a test on an experimental standard deviation.	It should read: 3.3 Repeatability of blood pressure indication The experimental standard deviation of the repeatability of ...	Agree
0086 DE	2	3.3	Legend of formula	ed	Change for clarity.	Change to: AAA being the display value repeatability of systolic (or diastolic) blood pressure of the device under test; BBB being the displayed systolic (or diastolic) blood pressure at the ith measurement of the device under test; CCC being the displayed mean of systolic (or diastolic) blood pressure of the device under test.	
0087 BR	2	4		Te	Once the suggestion on clause 5 of Ryyy-1 is accepted, the text of this clause needs to be modified The subclause 4.4 and 4.5 can be incorporated in subclause 4.2 and 4.3, respectively.	Replace the clause 4 with text below. 4 Determination of the intermediate precision due to the voltage variations of the power source 4.1 Internal electrical power source 4.1.1 Apparatus • Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic:	Disagree The suggestion on clause 5 of Ryyy-1 is not accepted.

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

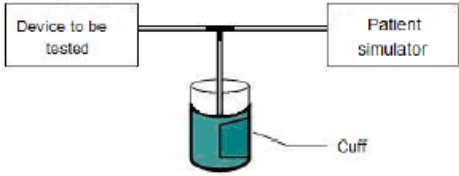
2 Type of comment: ge = general te = technical ed = editorial

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹;</p> <ul style="list-style-type: none"> • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff; • Adjustable direct current voltage supply; • Voltmeter with maximum permissible error within 0.5 % of the measured value. <p>4.1.2 Procedure</p> <p>Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values. Replace the internal electrical power source of the 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 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.</p> <p>Perform 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity, and at the lowest voltage limit described above increased by 0.1 V and also at the nominal voltage.</p>  <p>Figure 2</p> <p>4.1.3 Results</p> <p>The standard deviation due to the internal electrical</p>	

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>power source (s_{L2}) is calculated according to subclause 2.3 with subscript j representing the conditions of minimum and nominal voltage.</p> <p>4.2 External electrical power source - alternating current</p> <p>4.2.1 Apparatus</p> <ul style="list-style-type: none"> • Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹; • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff; • Adjustable alternating current voltage supply; • Voltmeter with maximum permissible error within 0.5 % of the measured value. <p>4.2.2 Procedure</p> <p>Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values. Connect the automated sphygmomanometer to the adjustable alternating current voltage supply. Measure the variation in AC voltage supply with the voltmeter.</p> <p>Perform 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity at:</p> <ul style="list-style-type: none"> • the maximum rated voltage, declared by the manufacturer, increased by 5 V; • the maximum rated voltage; • the mean value of the maximum and minimum rated voltage, declared by the manufacturer; • the minimum rated voltage; • the minimum rated voltage, declared by the manufacturer, decreased by 5 V. <p>Note: The maximum rated voltage is declared by the manufacturer as well as the minimum rated voltage. When the rated voltage is not described with a range but only one nominal value, it means that the minimum</p>	

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>rated voltage equals to the maximum rated voltage.</p> <p>4.2.3 Results The standard deviation due to the internal electrical power source (s_{L3}) is calculated according to subclause 2.3 with subscript j representing the conditions of minimum, mean and maximum rated voltage.</p> <p>At the maximum rated voltage increased by 5 V and minimum rated voltage decreased by 5 V no blood pressure measurement shall be displayed by sphygmomanometer.</p> <p>4.3 External electrical power source - direct current</p> <p>4.3.1 Apparatus Same apparatus listed in 4.1.1</p> <p>4.3.2 Procedure Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values. Connect the automated sphygmomanometer to the adjustable alternating current voltage supply. Measure the variation in DC voltage supply with the voltmeter. Perform 5 measurements at a temperature of $20\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at ambient humidity at:</p> <ul style="list-style-type: none"> the maximum rated voltage, declared by the manufacturer, increased by 0.1 V; the maximum rated voltage; the mean value of the maximum and minimum rated voltage, declared by the manufacturer; the minimum rated voltage; the minimum rated voltage, declared by the manufacturer, decreased by 0.1 V. <p>Note: The maximum rated voltage is declared by the manufacturer as well as the minimum rated voltage. When the rated voltage is not described with a range but only one nominal value, it means that the minimum rated voltage equals to the maximum rated voltage.</p>	

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>4.3.3 Results</p> <p>The standard deviation due to the internal electrical power source (<i>s_{L4}</i>) is calculated according to subclause 2.3 with subscript j representing the conditions of minimum, mean and maximum rated voltage.</p> <p>At the maximum rated voltage increased by 0.1 V and minimum rated voltage decreased by 0.1 V no blood pressure measurement shall be displayed by sphygmomanometer.</p>	
0088 DE	2	4.2.2	note	ed/te	Does the 2 nd sentence in the note make any sense? The range is 0 kPa (?).	Delete 2 nd sentence or improve wording.	Delete the sentence.
0089 DE	2	4.2.2, 4.3.2, 4.4.2, 4.5.2		ed	reformulation	Testing may be carried out at only one cuff pressure point within the range 6.7kPa -33.3kPa (50mmHg - 250mmHg).	Agree
0090 DE	2	4.4.2	note	te	This is not a note ("shall").	Change the note to normal text.	Agree
0091 DE	2	4.5.2	note	te	This is not a note ("shall").	Change the note to normal text.	Agree
0092 IR 04	2	5		Te	It should be better to specify time interval for every pressure recording over a period of 5 minutes. This can be useful for choosing monomer which is to log pressure over a specified time.		Time interval is in Ryyy-3 clause 8.
0093 DE	2	5		te	Either add the requirement from OIML R XXX, 6.4.1 ("Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min).") or reference it.	<p>Version 1: Add the following text:</p> <p>Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min). Check compliance by means of the following test.</p> <p>Version 2: Add the following sentence:</p> <p>Compliance with OIML R XXX, 6.4.1 shall be checked by means of the following test.</p>	Agree Version 1
0094 DE	2	5.2	1 st sentence	ed	add a comma after if	If, because of technical reasons,...	Agree
0095 DE	2	5.2	Note 2	ed	Note 2 ends after the 3 rd sentence. ("Additional connections can increase the leakage."), the rest is part of the procedure.	"Carry out the test over the whole measuring range at at least three equally spaced pressure steps (e.g. 6.7 kPa (50 mmHg), 20.0 kPa (150 mmHg), and 33.3 kPa (250 mmHg)). Because the thermodynamic equilibrium is influenced by decreasing or increasing the pressure when changing to the next pressure step, wait at least 60 s before reading the values. Test the air leakage over	Agree

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						a period of 5 minutes and determine the measured value from this.” should be written as part of the procedure.	
0096 DE	2	6.2	Note 1 Note 3	ed		replace “intention” with “recommendation” and “intended” with “recommended”	Agree
0097 DE	2	6.2	Note 2	ed		replace “size of cuff” with “cuff size”	Agree
0098 BR	2	8		Te	Although unintentionally, embedded software of automatic sphygmomanometers may include the zero adjustment only in manometer mode and do not perform zero adjustment in blood pressure measurement. Thus, this test should be performed with the sphygmomanometer performing a measurement of blood pressure.	Replace the clause 8 with text below: 8.1 Apparatus <ul style="list-style-type: none"> rigid vessel with a capacity of 500 ml \pm25 ml; calibrated reference manometer with an uncertainty less than maximum permissible error within \pm0.1 kPa (\pm0.8 mmHg); patient simulator; foil; pressure selector switch; T-piece connectors; hoses. 8.2 Procedure and evaluation <p>If, because of technical reasons, the test as described in this subclause cannot be performed, use an alternative test procedure specified by the manufacturer.</p> <p>To test the function of the zero adjustment, apply a pressure of +0.8 kPa and subsequently -0.8 kPa to the pneumatic system and initiate a zero setting of the device.</p> <p>Ensure that all displayed pressure values have a systematic error of -8 kPa and +0.8 kPa, respectively.</p> <p>Before beginning the test, allow the blood pressure measuring system automated sphygmomanometer to reach working temperature.</p> <p>Set up the blood pressure measuring system automated sphygmomanometer to be tested as follows:</p> <ul style="list-style-type: none"> replace the cuff with the 500 ml vessel; insert the calibrated reference manometer into the pneumatic system by means of a T-piece connector; insert the foil by means of a T-piece connector; insert the patient simulator by means of a T-piece connector; 	Disagree Do not perform zero adjustment in blood pressure measurement. NIBP simulator can only be used for repeatability test, and its accuracy cannot be ensured. It does not have traceability. Therefore, the method of Figure 3 in this article is meaningless. The comments on dynamic pressure measurement by simulators had not been accepted in previous CD files.

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

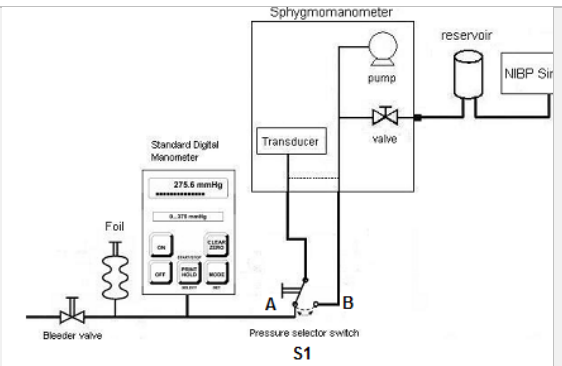
Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<ul style="list-style-type: none"> in the automated sphygmomanometer, separate the silicone tube which connects the electronic circuit to the transducer in two ways and connect them to the pressure selector switch, as show in figure 3. <p>Note: If convenient, one adjustable pump may be used in place of the foil to generate the pressures.</p> <p>Proceed in the following way:</p> <p>a) Connect, as shown in the figure 3, the automated sphygmomanometer with the reference manometer, foil, pressure selector switch (S1) and the patient simulator, which is set to target systolic and diastolic blood pressure values; meter;</p> <p>b) with switch S1 in position "B", perform five measurements of the blood pressure and calculate the mean of the measurements;</p> <p>c) With switch S1 in position "A", adjust the pressure until the reference manometer indicates +0.8 kPa and switch on the equipment. When the pump starts inflation change the position of switch S1 to "B" to measure blood pressure and record the result;</p> <p>d) Perform five measurements of the blood pressure and calculate the mean of the measurements. The result of systolic and diastolic pressures should be equal to that found in item "b" plus $(0,8 \pm 0,13)$ kPa;</p> <p>e) With switch S1 in position "A", adjust the pressure until the reference manometer indicates -0.8 kPa and switch on the equipment. When the pump starts inflation change the position of switch S1 to "B" to measure blood pressure and record the result;</p> <p>f) Perform five measurements of the blood pressure and calculate the mean of the measurements. The result of systolic and diastolic pressures should be equal to that found in item "b" minus $(0,8 \pm 0,13)$ kPa;</p>	

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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
						 <p>Figure 3</p> <p>8.3 Expression of results Express the results as shown in the d) and f).</p>	
0099 JP14	2	9.3	3 rd sentence	Ed	It is difficult to understand the meaning of “and determine this time(t)”.	Rephrase the sentence to read “Perform one blood pressure measurement, then <u>determine the time(t)</u> until the automated sphygmomanometer has switched off automatically”.	Agree
0100 DE	2	10.2		ed	add the word “simultaneously”	The sentence should read: “ Simultaneously start a blood pressure measurement and...”	Agree
0101 BR	2	11		Te	Once the suggestion on clause 5 of Ryyy-1 is accepted, the text of this clause needs to be modified	<p>Replace the clause 11 with text below.</p> <p>11 Determination of the standard deviation due to the durability</p> <p>11.1 Apparatus</p> <ul style="list-style-type: none"> • Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹; • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff. <p>11.2 Procedure</p> <p>Connect, as shown in the figure 2, the automated</p>	<p>Disagree</p> <p>The suggestion on clause 5 of Ryyy-1 is not accepted.</p>

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values and perform 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity. Perform 10000 simulated measurement cycles with the complete automated sphygmomanometer at which at least the following cuff pressure values shall be reached:</p> <ul style="list-style-type: none"> adult mode: 20.0 kPa; neonatal/infant mode: 10.0 kPa. <p>Note 1: For devices which measure with the auscultatory and oscillometric method this test should be carried out for both modes.</p> <p>Note 2: For devices which measure in both modes (adult and neonatal/infant) the test should be carried out in both modes.</p> <p>Note 3: It is not mandatory but is desirable to use the patient simulator to perform the 10000 measurement cycles.</p> <p>After that, perform another 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity.</p> <p>11.3 Results</p> <p>The standard deviation due to the durability (<i>SLS</i>) is calculated according to subclause 2.3 with subscript <i>j</i> representing the conditions of before and after 10000 simulated measurement cycles.</p>	
0102 DE	2	11	title	ed	The old title should be kept. (See also the comment for P1, 6.6)	Change to “Test for stability ”	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 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

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
							time passes but also in consideration of the periodic use.
0103 DE	2	12		ed	Add a sentence to reference P1, 6.8	Add: "To comply with the requirement of Ryyy-1, 6.8, the following test shall be performed."	Agree
0104 DE	2	13		ed	Add a sentence to reference P1, 6.9.1	Add: "To comply with the requirement of Ryyy-1, 6.9.1, the following test shall be performed."	Agree
0105 BR	2	14		Te	Once the suggestion on clause 5 of Ryyy-1 is accepted, the text of this clause needs to be modified	<p>Replace the clause 14 with text below.</p> <p>14 Determination of the standard deviation due to the resistance to vibration and shock</p> <p>14.1 Apparatus</p> <ul style="list-style-type: none"> • Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹; • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff; • Shaker. <p>14.2 Procedure</p> <p>Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values and perform 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity. Perform shock test in accordance with IEC 60068-2-27:2008 using the conditions of test type 1 or 2:</p> <p>Note 1: This represents IEC TR 60721-4-7, Class 7M2.</p> <p>1) test type: Type 1:</p> <ul style="list-style-type: none"> – peak acceleration: 150 m/s² (15 g); – duration: 11 ms; – pulse shape: half sine; – number of shocks: 3 shocks per direction per axis (18 total). <p>2) test type: Type 2:</p> <ul style="list-style-type: none"> – peak acceleration: 300 m/s² (30 g); - duration: 6 ms; - pulse shape: half sine; 	Disagree The suggestion on clause 5 of Ryyy-1 is not accepted.

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>- number of shocks: 3 shocks per direction per axis (18 total).</p> <p>After that, perform broad-band random vibration according to IEC 60068-2-64:2008 using the following conditions:</p> <p>Note 2: This represents IEC TR 60721-4-7, Classes 7M1 and 7M2</p> <p>1) acceleration amplitude:</p> <ul style="list-style-type: none"> - 10 Hz to 100 Hz: 1.0 (m/s²)/Hz; - 100 Hz to 200 Hz: -3 dB/octave; - 200 Hz to 2 000 Hz: 0.5 (m/s²)/Hz; <p>2) duration: 30 min per each perpendicular axis (3 total).</p> <p>After that, perform another 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity.</p> <p>14.3 Results</p> <p>The standard deviation due to the resistance to vibration and shock (s_{L6}) is calculated according to subclause 2.3 with subscript j representing the conditions of before and after shock test and broad-band random vibration.</p>	
0106 BR	2	15 (New)		Te	Once the suggestion on clause 5 of Ryyy-1 is accepted, this clause needs to be added.	<p>15 Determination of standard deviation due to the electrostatic discharges</p> <p>15.1 Apparatus</p> <ul style="list-style-type: none"> • Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹; • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff; • Equipment to apply electrostatic discharges according to the latest version of IEC 61000-4-2. <p>15.2 Procedure</p> <p>Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values and perform 5 measurements at a</p>	Disagree The suggestion on clause 5 of Ryyy-1 is not accepted.

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>temperature of 20 °C ± 5 °C and at ambient humidity at:</p> <ul style="list-style-type: none"> no electrostatic discharge; direct contact discharges of 6 kV and positive polarity (2 discharges to each measurement); direct contact discharges of 6 kV and negative polarity (2 discharges to each measurement); indirect contact discharges of 6 kV and positive polarity (2 discharges to each measurement); indirect contact discharges of 6 kV and negative polarity (2 discharges to each measurement); air discharges of 8 kV and positive polarity (2 discharges to each measurement); air discharges of 8 kV and negative polarity (2 discharges to each measurement). <p>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 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.</p> <p>15.3 Results</p> <p>The standard deviation due to the electrostatic discharges (s_{L7}) is calculated according to subclause 2.3 with subscript j representing each combination of electrostatic discharge.</p>	
0107 BR	2	16 (New)		Te	<p>Once the suggestion on clause 5 of Ryyy-1 is accepted, this clause needs to be added.</p> <p>As an example, we performed the procedure suggested in one automated sphygmomanometer. It was subjected to electromagnetic fields and presented the largest measurement error (+9 mmHg) in the range of</p>	<p>16 Determination of standard deviation due to the radiated, radio-frequency, electromagnetic fields</p> <p>16.1 Apparatus</p> <ul style="list-style-type: none"> Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 	<p>Disagree</p> <p>The suggestion on clause 5 of Ryyy-1 is not accepted.</p>

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

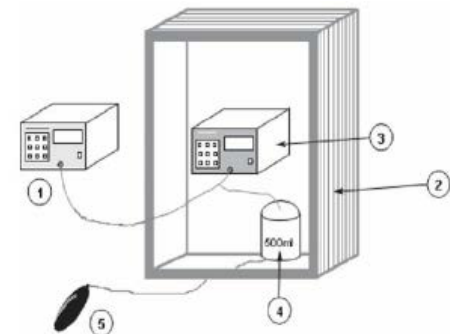
Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
					<p>800 to 960 MHz, with 10 V/m, Horizontal polarization, Front face. Then the sphygmomanometer performed 3 blood pressure measurements with a simulator set to 120/80 mmHg and 80 bpm and presented the results that are in the table below.</p> <p style="text-align: center;">*Measurements without EMC field **Measurement with EMC field</p> <p>Observing the results, it is verified that the difference between the means in the systolic pressure is zero and in the diastolic is 11 mmHg. This demonstrates that the indication error in the manometer mode does not always reflect the behavior of the sphygmomanometer. With the calculation of the intermediate precision (sL) it is possible to determine the impact that the magnitude of influence (in this case, the EM fields) exerts directly on the blood pressure measurement of the instrument, since it becomes a source of uncertainty that can be inserted in a balance of uncertainties.</p>	<p>10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹;</p> <ul style="list-style-type: none"> • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff; • Rigid vessel with a capacity of (500 ± 25) mL; • Calibrated reference manometer with maximum permissible error within ±0.1 kPa; • 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. <p>16.2 Procedure Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values and perform 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity. Set the automated sphygmomanometer to the manometer test mode, connect it as shown in the figure 3 and set pressure to value between 6.7 kPa and 33.3 kPa.</p>	

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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
						 <p>1 – Reference manometer; 2 – Anechoic Chamber (or equivalent); 3 – Device to be tested; 4 – Rigid vessel; 5 – Pressure generator.</p> <p>Figure 3</p> <p>Apply the following electromagnetic fields:</p> <ul style="list-style-type: none"> • 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. <p>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. If the sphygmomanometer carries out blood pressure measurements, when connecting signal and control cables to the instrument, this test shall be carried out with the signal and control cables connected to the instrument (in this case the length of the cable exposed to the electromagnetic field shall be of at least 1 m).</p> <p>During application, determine the frequency at which the sphygmomanometer indication has the maximum deviation. In this frequency, remove pressure</p>	

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>generator, replace reference manometer with patient simulator and rigid vessel with rigid cylinder wrapped by the cuff and perform another 5 measurements.</p> <p>16.3 Results The standard deviation due to the radiated, radio-frequency, electromagnetic fields (s_{LS}) is calculated according to subclause 2.3 with subscript j representing the conditions of before and during application.</p>	
0108 BR	2	17 (New)		Te	Once the suggestion on clause 5 of Ryyy-1 is accepted, this clause needs to be added.	<p>17 Determination of standard deviation due to the conducted disturbances induced by radio-frequency fields</p> <p>17.1 Apparatus</p> <ul style="list-style-type: none"> • Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹; • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff; • Rigid vessel with a capacity of (500 ± 25) mL; • Calibrated reference manometer with maximum permissible error within ±0.1 kPa; • Pressure generator, e.g. ball pump (hand pump) with a deflation valve • Equipment to generate conducted disturbances induced by radio-frequency fields according to the latest version of IEC 61000-4-6. <p>17.2 Procedure Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values and perform 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity. Set the automated sphygmomanometer to the manometer test mode, connect it as shown in the figure 3 (without anechoic chamber) and set pressure to value between 6.7 kPa and 33.3 kPa.</p>	Disagree The suggestion on clause 5 of Ryyy-1 is not accepted.

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>Apply 3 V radio-frequency fields at frequency range from 150 kHz to 80 MHz, 80% AM Modulation on 1 kHz sinusoidal signal and 3 s of dwell time. The latest version of IEC 61000-4-6 shall be used as reference.</p> <p>During application, determine the frequency at which the sphygmomanometer indication has the maximum deviation. In this frequency, remove pressure generator, replace reference manometer with patient simulator and rigid vessel with rigid cylinder wrapped by the cuff and perform another 5 measurements.</p> <p>17.3 Results The standard deviation due to the conducted disturbances induced by radio-frequency fields (s_{L9}) is calculated according to subclause 2.3 with subscript j representing the conditions of before and during application.</p>	
0109 BR	2	18 (New)		Te	Once the suggestion on clause 5 of Ryyy-1 is accepted, this clause needs to be added.	<p>18 Determination of standard deviation due to the electrical fast transients</p> <p>18.1 Apparatus</p> <ul style="list-style-type: none"> • Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹; • T-piece connectors and hoses; • Rigid cylinder with circumference suitable to be wrapped by the cuff; • Equipment to apply electrical fast transients according to the latest version of IEC 61000-4-4. <p>18.2 Procedure Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values and perform 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity at:</p> <ul style="list-style-type: none"> • no electrical fast transients; • electrical fast transients of +1 kV and 5 kHz on 	Disagree The suggestion on clause 5 of Ryyy-1 is not accepted.

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<p>power supply;</p> <ul style="list-style-type: none"> electrical fast transients of -1 kV and 5 kHz on power supply; electrical fast transients of +0.5 kV and 5 kHz on signal and control lines; electrical fast transients of -0.5 kV and 5 kHz on signal and control lines. <p>The latest version of IEC 61000-4-4 shall be used as reference.</p> <p>18.3 Results The standard deviation due to the electrical fast transients (S_{L10}) is calculated according to subclause 2.3 with subscript j representing each combination of electrical fast transients.</p>	
0110 BR	2	19 (New)		Te	Once the suggestion on clause 5 of Ryyy-1 is accepted, this clause needs to be added.	<p>19 Determination of standard deviation due to the voltage dips and short interruptions</p> <p>19.1 Apparatus</p> <ul style="list-style-type: none"> Patient simulator for the auscultatory and/or oscillometric method. The generated signal values shall be approximately: systolic: 16.0 kPa; diastolic: 10.7 kPa; pulse rate: 70 min⁻¹- 80 min⁻¹; T-piece connectors and hoses; Rigid cylinder with circumference suitable to be wrapped by the cuff; Equipment to apply voltage dips and short interruptions according to the latest version of IEC 61000-4-11. <p>19.2 Procedure Connect, as shown in the figure 2, the automated sphygmomanometer with the cuff and the patient simulator, which is set to target systolic and diastolic blood pressure values and perform 5 measurements at a temperature of 20 °C ± 5 °C and at ambient humidity at:</p> <ul style="list-style-type: none"> no voltage dips and short interruptions; 0% of reference voltage supply amplitude during 8 ms (2 discharges to each measurement); 	Disagree The suggestion on clause 5 of Ryyy-1 is not accepted.

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
						<ul style="list-style-type: none"> 0% of reference voltage supply amplitude during 16 ms (2 discharges to each measurement); 70% of reference voltage supply amplitude during 480 ms (2 discharges to each measurement); 0% of reference voltage supply amplitude during 4.8 s (2 discharges to each measurement); air discharges of 8 kV and positive polarity (2 discharges to each measurement); air discharges of 8 kV and negative polarity (2 discharges to each measurement). <p>The latest version of IEC 61000-4-11 shall be used as reference. The time interval between successive interruptions must be at least 10 s. If the difference between maximum and minimum voltage supply declared by manufacturer is less than 20% of minimum voltage, then reference voltage supply is the minimum value. Otherwise, each combination of interruption shall be performed with maximum and minimum voltage supply.</p> <p>19.3 Results</p> <p>The standard deviation due to the voltage dips and short interruptions (s_{L11}) is calculated according to subclause 2.3 with subscript j representing each combination of interruption.</p>	
0111 DE	2	Whole document		ge	The three comments regarding the title, the decimal commas and decimal points from P1 apply here as well.		Partly agree The comment of decimal commas is accepted.
0112 KR	3			ge	<p>The environmental condition should be indicated for data record.</p> <p>For the reproducibility on the tested and recorded data due to some reason, the environmental condition needs to be recorded in the conducted test item or in any confirmed part of test record (Namely, in the view of ambient temperature, relative humidity and atmospheric pressure).</p>		The measurement of sphygmomanometer is not affected by atmospheric pressure
0113 DE	3		Table 2, column 5	ed	No need for capital letters for “up” and “down”		Agree

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
			Table 3, 2 nd and last columns				
0114 DE	3		Table 3 and 5	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".
0115 DE	3	1.1	Clause 15	ed	See comments for P1, 6.6 and P2, 11	change "Durability" to "Stability"	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 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.
0116 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".
0117 DE	3	7.1		ed		Change "Rxxx-1 5.1" to "Ryyy-1 6.3.1"	Agree
0118 DE	3	7.2		ed		Change "Rxxx-1 5.1" to "Ryyy-1 6.3.2"	Agree
0119 DE	3	8		ed		Change "Rxxx-2 5.2" to "Ryyy-2 5.2"	Agree
0120 DE	3	8	table 5	ed		Delete "Unit (mmHg)" in the right upper corner, above the table.	Agree delete table unit "mmHg".
0121 DE	3	15		ed	See comments for P1, 6.6 and P2, 11	change "Durability" to "Stability"	Disagree The terminology in VIM of durability test is "5.22

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22

Document:

Project:

Country Code ¹	Part	Clause/ Subclause	Paragraph/ Figure/Table	Type of comment ²	Comments	Proposed change	Convener's responses
							durability test, test intended to verify whether the EUT is able to maintain its performance characteristics over a period of 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.
0122 DE	3	18.2	page 17	ed	add the word "special"	"...by requiring the use of a special tool or breaking a seal."	Agree
0123 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
0124 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
0125 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.

Z:\TCSC\tc18_sc1\tc18_sc1_p2_Revision_R16-2\1CD\337-KOREA -R.- -TC18_SC1_P2_Ryyy_1CD_Comments_KR.docx: Collation successful

Z:\TCSC\tc18_sc1\tc18_sc1_p2_Revision_R16-2\1CD\337-IRAN -TC18_SC1_P2_Ryyy_1CD_Comments_template.docx: Collation successful

Z:\TCSC\tc18_sc1\tc18_sc1_p2_Revision_R16-2\1CD\337-GERMANY -TC18_SC1_P2_Ryyy_1CD_Comments_PTB.docx: Collation successful

Z:\TCSC\tc18_sc1\tc18_sc1_p2_Revision_R16-2\1CD\337-JAPAN -TC18_SC1_P2_Ryyy-R16-2-_1CD_Comments-Japan-190314.docx: Collation successful

Z:\TCSC\tc18_sc1\tc18_sc1_p2_Revision_R16-2\1CD\337-BRAZIL -TC18_SC1_P2_Ryyy_1CD_Comments_template_BR_auto_Final.docx: Collation successful

Z:\TCSC\tc18_sc1\tc18_sc1_p2_Revision_R16-2\1CD\337-POLAND -R.- -TC18_SC1_P2_Ryyy_1CD_Comments_KR.docx: Collation successful

Z:\TCSC\tc18_sc1\tc18_sc1_p2_Revision_R16-2\1CD\337-AUSTRIA -Comment_Austria_R16-2.docx: Collation successful

Z:\TCSC\tc18_sc1\tc18_sc1_p2_Revision_R16-2\1CD\337-CZECH REPUBLIC -TC18_SC1_P2_Ryyy_1CD_Comments_CMI.docx: Collation successful

Collation of files was successful. Number of collated files: 8

SELECTED (number of files): 8

PASSED TEST (number of files): 8

FAILED TEST (number of files): 0

CCT - Version 4.0/2015

¹ Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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

Template for comments and convener's observations

Date:2019-03-22	Document:	Project:
-----------------	-----------	----------

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

1 Country code (enter the ISO 3166 two-letter country code, e.g. CN for China)

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