No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
1.	JP	General（Suggested. Revision. 5(5.3.2)、6(5.4)、24(A.15.2)）	Employ “Pa” as a formal unit and use “mmHg” in parentheses as shown in the right column since Pa is an SI unit of pressure.	Suggested. Revision. 5(5.3.2) 3mmHg (0.4kPa) → 0.4kPa (3mmHg) Suggested. Revision. 6(5.4) 20mmHg (2.7kPa) to 60mmHg (8.0kPa) → 2.7kPa (20 mmHg) to 8.0kPa (60mmHg) 40 mmHg (5.3kPa) to 130 mmHg (17.3kPa) → 5.3kPa (40mmHg) to 17.3kPa (130mmHg) 40mmHg (5.3kPa) to 110mmHg (14.7kPa) → 5.3kPa (40mmHg) to 14.7kPa (110mmHg) 60mmHg (8.0kPa) to 230mmHg (30.7kPa) → 8.0kPa (60mmHg) to 30.7kPa (230mmHg) Suggested. Revision. 24(A.15.2) 20mmHg (2.7kPa) → 2.7kPa (20mmHg) 110mmHg (14.7kPa) → 14.7kPa (110mmHg) 60mmHg (8.0kPa) → 8.0kPa (60mmHg)x2 230mmHg (30.7kPa) → 30.7kPa (230mmHg)	Accepted “kPa” is the unit of SI, “mmHg” is the unit often used in clinical application. The unit of SI should be in the first place.
2.	JP	general	Environmental requirements in this draft such as, electromagnetic compatibility, mechanical environment and temperature/humidity environment should be compatible with the requirements in the OIML D11 “General requirements for electronic measuring instruments”.	This is a general recommendation. We therefore do not request any changes in this regard.	Not accepted D11 is a general recommendation and gives general requirements.
3.	DE	general	The comma instead of the point should be used in real numbers as it is done in ISO, IEC or EN standards, e.g. 0,4 kPa.	Taking the place of the point (“.”) in real number by comma (“,”).	Not accepted “.” Is usually used in OIML documents.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
4.	DE	general	To avoid discussions on rounding numbers regarding acceptance criteria "…,0" should be added to integer numbers, especially to numbers given in mmHg, e.g. ±3,0 mmHg instead of ±3 mmHg .	Add 1 decimal digit to integer numbers. e.g. ±3,0 mmHg instead of ±3 mmHg	Accepted
5.	DE	general	in some clauses mmHg values comes first and kPa values are in brackets, in other clauses it is just the opposite, this should be done in a uniform way	Suggested. Revision. 5(5.3.2) 3mmHg (0.4kPa) → 0.4kPa (3mmHg) Suggested. Revision. 6(5.4) 20mmHg (2.7kPa) to 60mmHg (8.0kPa) → 2.7kPa (20 mmHg) to 8.0kPa (60mmHg) 40 mmHg (5.3kPa) to 130 mmHg (17.3kPa) → 5.3kPa (40mmHg) to 17.3kPa (130mmHg) 40mmHg (5.3kPa) to 110mmHg (14.7kPa) → 5.3kPa (40mmHg) to 14.7kPa (110mmHg) 60mmHg (8.0kPa) to 230mmHg (30.7kPa) → 8.0kPa (60mmHg) to 30.7kPa (230mmHg) Suggested. Revision. 24(A.15.2) 20mmHg (2.7kPa) → 2.7kPa (20mmHg) 110mmHg (14.7kPa) → 14.7kPa (110mmHg) 60mmHg (8.0kPa) → 8.0kPa (60mmHg)x2 230mmHg (30.7kPa) → 30.7kPa (230mmHg)	Accepted Reason: as no.1

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
6.	AU	General	(a) Throughout the document, differing terms are used to refer to non-invasive automated sphygmomanometers: blood pressure measuring system, sphygmomanometers, automated sphygmomanometers and etc. Suggest using term "sphygmomanometer" when referring to the complete instrument. (b) References named in the Recommendation should have consistent naming. Example IEC 80601-2-30 (2009) is referred to by different names including ISO 80601-2-30. This causes confusion. (c) Create a references section at the end of the document to state which documents have been referred to including the version numbers.	(a) Simplify the document and maintain internal consistency (b) Editorial and maintain internal consistency of the document (c) create the reference section	(a) accepted reason: “blood pressure measuring system, sphygmomanometers, automated sphygmomanometers” showed no difference in meaning. We suggested simplified as “sphygmomanometer” and keep consistent in the article. (b) Accepted reason: We shall maintain the internal consistency of the document. (c) accepted reason: there is a references section in IEC & ISO documents.
7.	AU	Title	Delete word "automatic" and replace with "automated"	Maintain consistency with OIML R 16-1.	Accepted Reason: The “automatic” is the procedure without human intervention. There would be human element in “automated” .

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
8.	BR	Title	The original term “automated” is better than the new “automatic”. An automatic sphygmomanometer shall perform all necessary measurement procedures (inflate/deflate the bladder and measure the blood pressure) without human intervention and not all models fulfil this condition (some have manual inflation/deflation, the so-called “semi-automatic” sphygmomanometers). The term “automated” is also consistent with the term used at R 16-1 (non-automated sphygmomanometers).	Keep the previous title “Non-invasive automated sphygmomanometers” and replace “automatic” with “automated” throughout the text.	Accepted Reason: same as no.7
9.	AU	1 Scope	(a)The terms 'electronic' and 'automatic/automated' do not have the same meaning. Non-automated sphygmomanometers can have electronic manometers to display the pressure values and in such instances, OIML R 16-1 should be applicable. (b) Maintain consistency with OIML R 16-1	(a) Delete phrase "electronic or" from second line. (b) Insert reference to Luer locks - "Note: Luer locks shall not be used with these devices (see 6.11.3 and 7.5)"	(a) accepted reason: “electronic” is not as same as “automated”. (b) accepted

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
10.	BR	1 Scope	a) "Electronic" and "automated" sphygmomanometers are not the same kind of device. There are non-automated sphygmomanometers using electronic manometers to display the pressure values (see example at www.adctoday.com/ecatalog/catpage.php?itemnum=7002-11ABK). In this situation, I think R16-1 should apply, not R 16-2. b) Throughout the text different expressions are used to refer to "non-invasive automated sphygmomanometers": "non-invasive sphygmomanometer", "automated sphygmomanometer", "blood pressure measuring system", "sphygmomanometer", etc. It's recommended to simplify and use only the term "sphygmomanometer" when referring to the complete instrument. c) Is it necessary to define where the sphygmomanometer may be applied on the patient? Recently we tested a weighing scale combined with a sphygmomanometer and the blood pressure measurement was performed at the forearm. d) Reference to clauses concerning Luer locks should be added to the note needs to keep alignment with R 16-1.	a) Remove the words "...electronic or...". b) "...including test methods for type approval, for non-invasive automated sphygmomanometers (from now on called "sphygmomanometers") and their accessories which...". It's also necessary to search the text for all other expressions and replace them with "sphygmomanometer(s)". c) Change the 2nd § to "This Recommendation only applies to devices measuring at the arm or the thigh" d) "Note: Luer locks shall not be used with these devices (see 6.11.3 and 7.5)"	（a）accepted Same as no.9 （b）accepted Same as no.9 （c）accepted Now we perform the blood pressure measurement at the different part on human body. （d）accepted Same as no.9
11.	JP	1 Scope	The scope says "electronic or automated", but it should cover both electronic and automated.	Change "for non-invasive electronic or automated sphygmomanometers" into "for non-invasive electronic sphygmomanometers and non-invasive automated sphygmomanometers".	Partly accepted.(delete the "electronic".) Same as no.9

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
12.	DE	1 Note	The note describes a requirement, therefore a note is not appropriate.	move to a new clause under 6.	accepted the note is a technical requirement.
13.	BR	2.2	The term “pressure in a blood vessel” is not used in the text, so it’s not necessary to define it. We should define the term “blood pressure” which is constantly presented on the text.	Replace the term “pressure in a blood vessel” with the term “blood pressure”.	accepted there is no “pressure in a blood vessel” be consistent with “IEC 80601-2-30:2009”201.3.203
14.	DE	2.2 – 2.10	The titles end with a colon (:), this makes no sense.	Delete (:)	accepted
15.	Sw	5.4	I think that it is important to maintain a distinction between “first time” and “in use” measurement, with a smaller permissible error for the “first time”. However due to the fact that the permissible error is reduced compared to the previous edition, I could accept it as it is proposed.		
16.	AU	2.12	Maintaining consistency with VIM terminology	Delete phrase, "zero setting" and replace with "zero adjustment of a measuring system". Include definition provided in the VIM (OIML V 2-200:2010)	accepted
17.	BR	2.12	The term “zero setting” needs alignment with the International Vocabulary of Metrology 2008 (VIM 3.12)	“Zero adjustment of a measuring system”	accepted
18.	JP	2.11, 2.12 2.16	It is not simply possible to replace 2.11 and 2.12 by 2.16 from IEC80601-2-30, because the scopes of R16-2 and IEC80601-2-30 are slightly different as shown below. (1) R16-2: Electronic or automated. (Electronic and manual instruments are in the scope.) (2) IEC80601-2-30: Automated. (Electrically powered and manual instruments are out of the scope) If the replacement is done, there would be no definition of electro-mechanical and non-automated instruments.	Request maintaining the original statements in R16-2 (2002).	Not accepted The appropriate scope of R16-2 has been changed accord to IEC.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
19.	AU	2.13	Current wording is ambiguous.	Insert term "measurement" between words 'testing' and 'accuracy'. Note should read, "This device is not used for testing measurement accuracy but is required in assessing stability of performance".	Accepted According to OIML V 2-200:2010. (measurement accuracy)
20.	BR	2.13	The term “accuracy” needs alignment with the International Vocabulary of Metrology 2008 (VIM 2.13)	Replace “accuracy” with “measurement accuracy”	Accepted Same as no.19
21.	BR	2.15	The term “Self-linearizing deflation valve” is not used in the text, so it’s not necessary to define it.	Remove clause 2.15	Accepted it is the interpret of principle
22.	BR	Sug. rev. 2	Accepted with changes. It’s necessary to “align” the definitions 2.9 (sphygmomanometer) and 2.16 (non-invasive automated sphygmomanometer): “instrument” vs. “medical measuring instrument”; “non-invasive measurement” vs. “non-invasive estimation”; no components description vs. long (and repeated) components description. The definition of “sphygmomanometer” already refers to non-invasive measurement, so “non-invasive (...) sphygmomanometer” is a redundancy.	Revised definition: “Automated sphygmomanometer: instrument that automatically detects the oscillometric pulses and/or auscultatory sounds and calculates and indicates systolic, diastolic and/or mean arterial blood pressure values of a patient”	Not accepted Different concept
23.	BR	3	The cuff comprises a bladder, so if we list them separately it seems they are two different parts to be applied in the patient.	Remover “...and bladder...”	Accepted
24.	JP	3	Suggested Revision 3 proposes to replace “a system” by “a pneumatic system”, but we consider that the definition of a pneumatic system includes cuffs which are already listed.	Request maintaining the original statements in R16-2 (2002).	Accepted

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
25.	JP	3	The explanation of specific device types should be a 'note' because it is intended only for helping readers' understanding.	Move the explanation of specific device types into a note.	Accepted Made a good article constructure
26.	DE	3	accepted with small modification: the list of devices are examples and therefore it should be written in this way; I think that the term "Digital electronic sphygmomanometer" is laboratory slang (as we say in German), it should read "automated sphygmomanometer for self-measurement".	The basic components of a sphygmomanometer are a cuff and bladder that can be wrapped around a patient's limb, a pneumatic system for applying and releasing pressure to the bladder, and a means of measuring and displaying the instantaneous pressure in the bladder. Examples: automated sphygmomanometer for self-measurement, blood pressure monitors and multi-parameter patient monitors, for home healthcare environment, or public use, etc.	accepted but changed as "Examples: automated sphygmomanometer for self-measurement, blood pressure monitors , blood pressure unit of multi-parameter patient monitors, automated sphygmomanometer for home healthcare environment, or public use, etc."
27.	BR	4	There's no dash on "kilo-pascals".	Replace with "kilopascals".	accepted
28.	AU	4	Remove dash (-) from term "kilo-pascals". Wording should be "kilopascals".	Replace with "kilopascals".	accepted
29.	JP	5.1 Sug. rev. 2	This Suggested Revision is not correct. The 15 - 25 degrees of 5.1 means general test condition and the 10 - 40 degrees of 5.3.2 mean operating temperature range. This Suggested Revision uses IEC's upper limit of operating temperature range for the general test condition, but they are fundamentally different.	Request maintaining the original statements in R16-2 (2002).	Not accepted (10-40) °C is the operating temperature range.
30.	JP	5.1	This Suggested Revision is not correct. It proposes to cite A.1 instead of A.2 for testing, but A.1 only describes a digital permissible error.	Request maintaining the original statements in R16-2 (2002).	Accepted The description of the test for the maximum permissible error is in A.2

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
31.	JP	5.1	Test conditions (15-40°C and 20-85% humidity) shall be specified in another clause of environmental performance. Like other international recommendations, only MPE shall be specified in the clause of metrological requirements.	Remove the test conditions of 15-25°C and 20-85%.	Not accepted The clinical environment of the sphygmomanometer is multiple, Removed the condition of （15°C -25°C） equals raise the standards of the sphygmomanometer.
32.	DE	5.1	accepted with modification: The ambient temperature range should run from 10 °C, because it is the value required by IEC 80601-2-30 and it is the same value as required in clause 5.3.2.	For any set of conditions within the ambient temperature range of 10℃ to 40℃ and the relative humidity range of 15% to 85%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ±0.4 kPa (±3,0 mmHg) or ±2%.	accepted
33.	BR	5.1	Accepted with changes. a) The temperature range at ISO starts at 10 ºC. We should align both limits (minimum and maximum) or keep the previous R 16-2 limits. b) It's necessary to establish when we'll use ± 3.0 mmHg or 2%. It's also necessary to add the 2 % error to the R 16-1. c) There's no test procedure at A.1	a) The temperature range should start at 10 ºC. b) Add the expression "whichever is greater" after the error. c) Keep the previous test reference (A.2).	a) accepted. b) accepted c) accepted same as no.30

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
34.	BR	5.1	a) The term MPE （Maximum permissible errors ） needs alignment with the International Vocabulary of Metrology 2008 (VIM 4.26) b) When the term “cuff pressure indication” appears in the text it is related with static pressure measurement, which is perform with the device on the test mode. This meaning should be clearer. c) The term “scale range” needs alignment with the International Vocabulary of Metrology 2008 (VIM 4.7)	a) & b) Change the title to “Maximum permissible measurement errors of the pressure indication in the manometer test mode”. Replace “cuff pressure indication” with “pressure indication in the test mode” throughout the text. c) Replace “scale range” with “measuring interval”.	A&b)not accepted The “Maximum permissible errors”is as same as “Maximum permissible measurement errors”according to International Vocabulary of Metrology 2010 (VIM 4.26) Note 1. The cuff pressure indication is the test value of testing mode in the context. c) accepted
35.	AU	5.1	(a) The suggested revision 4 states that the ambient temperature range is 15°C to 40°C. Delete '15°C' and replace with "10°C". (b) The suggested revision 4 states that the 'maximum permissible error for the measurement of the cuff pressure shall be ±0.4 kPa (±3 mmHg) or ±2%'. This should be clarified - when will these values be applicable? How does one determine which one to use? Insert phrase "whichever is greater" at end of current wording.	(a) Maintain consistency with the reference to IEC 80601-2-30 clause 202.12.1.102 (b) Current wording is not clear.	a) accepted same as no.32 b) accepted

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
36.	BR	5.2	a) The term MPE needs alignment with the International Vocabulary of Metrology 2008 (VIM 4.26). b) It should be clearer that the error and standard deviation stated at this clause are also valid when we use the patient simulator. c) Maybe we should later discuss if a reduction of the maximum mean error is applicable when using the patient simulator. At the clinical trial the automated sphygmomanometer is compared to a measurement performed by a trained person, so a larger variance is acceptable. But situation is more "stable" when the device is connected to a patient simulator, so the variance should be smaller.	a) & b) Use the following text: "5.2 Maximum permissible measurement errors of the blood pressure measurement: The following maximum permissible measurement errors apply for the overall system: • maximum mean error of measurement: ±0.7 kPa (±5 mmHg); Note: once the patient simulator is not suitable for testing accuracy, this error value is applicable only when comparing the sphygmomanometer's indications at different conditions. • maximum experimental standard deviation: 1.1 kPa (8 mmHg). Note: when using the patient simulator, the 20 consecutive measurements can only be considered valid if the standard deviation is below 1.1 kPa (8 mmHg). For further recommended clinical test protocols see Annex C."	a)not accepted same as 34.a)、b). b)not accepted Clinical accuracy test is confirmed. The simulator is not used for the accuracy test as the reference standard, it is only used for the repeatability test. The suggestion of confirming the accuracy of a simulator is not scientific. c)not accepted same as b)
37.	BR	5.3.1	a) There should be an indication if the test must be performed with the instrument packed or unpacked. Revised R 16-1 demands the test with the unpacked device. b) It would be interesting also perform a dynamic test (patient simulator) after the storage.	a) "...after the test sample has been placed unpacked for 24 h at..." b) Add a test procedure for dynamic measurement.	a) accepted b) not accepted the clause is for clearing how the environment to effect the measurement capability of a sphygmomanometer(indication error).

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
38.	AU	5.3.1	Delete phrase "...after the test sample has been placed for 24 h at..." and replace with following phrase, "...after the test sample has been placed unpacked for 24 hours at…"	Provides clarity that testing is performed on the instrument following unpacking and maintains consistency with OIML R 16-1.	accepted
39.	JP	5.3.2	Suggested Revision 5 specifies not only the error of cuff pressure but also the error of blood pressure. However, an evaluation of blood pressure in a clinical test is not realistic. With regard to temperature and relative humidity, a performance test of a manometer used for cuff pressure measurement is enough.	Request maintaining the original statements in R16-2 (2002).	Not accepted 5.3.2 is withdrawn. And new requirement is added in clause 5.1.
40.	DE	5.3.2	accepted with modification: the text can be shortened if the modification above is accepted	For the ambient temperature range of 10℃ to 40 ℃ and a relative humidity of 85% (non-condensing), the difference of the cuff pressure indication of ~~the sphygmomanometer shall not exceed ±0.4 kPa (±3 mmHg), and~~ the blood pressure determination of the sphygmomanometer shall be less than 3,0 mmHg (0.4 kPa).	Not accepted 5.3.2 is withdrawn. And new requirement is added in clause 5.1.
41.	DE	5.3.2	with the modification above the reference to A.2 is no more necessary	Testing shall be carried out in accordance with ~~A.2 and~~ A.11.	Not accepted 5.3.2 is withdrawn. And new requirement is added in clause 5.1.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
42.	DE	5.3.2	with the modification above it would make more sense to move the last paragraph on the top of the clause and modify it a little bit and add a NOTE for explanation.	The clause should read: *5.3.2 Temperature, relative humidity* The signal processing for the determination of the blood pressure values shall not be influenced within the range of temperature and relative humidity. ~~For any set of conditions all the deviations between the reference pressure and the indicating cuff pressure of the instrument must be less than or equal to the maximum permissible error.~~ For the ambient temperature range of 10℃ to 40 ℃ and a relative humidity of 85% (non-condensing), the difference of the cuff pressure indication of ~~the sphygmomanometer shall not exceed ±0.4 kPa (±3 mmHg), and~~ the blood pressure determination of the sphygmomanometer shall be less than 3,0 mmHg (0.4 kPa). NOTE Although there is the requirement to have no influence on the blood pressure determination, a small deviation must be accepted due to the permissible deviation in the pressure measurement, see 5.1.	Not accepted 5.3.2 is withdrawn. And new requirement is added in clause 5.1.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
43.	BR	5.3.2	Not accepted	"For the ambient temperature interval of 10 ºC to 40 ºC and a relative humidity of 85% (non-condensing), the sphygmomanometer's indications shall be in accordance with 5.1 and 5.2." *Considering the new text, the 2nd § ("The signal processing...") may be removed.*	a) Not accepted b) Not accepted 5.3.2 is withdrawn. And new requirement is added in clause 5.1.
44.	BR	5.3.2	Test procedure A.2 is not for temperature variation.	Testing shall be carried out in accordance with A.3 and A.11.	Not accepted 5.3.2 is withdrawn. And new requirement is added in clause 5.1.
45.	AU	5.3.2	Delete references to A.2 and A.11 and insert "A.3"	Incorrect referencing. Editorial	Not accepted 5.3.2 is withdrawn. And new requirement is added in clause 5.1.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
46.	JP	5.4 A.15	(1)Suggested Revision 6 proposes to harmonize the requirement of measuring range with that of IEC80601-2-30, but R16-2 already has another requirement at the clause 6.8.1. They are inconsistent. (2)IEC80601-2-30 includes a mistake that actual test for adult starts from 60 mmHg although the lower limit is specified as 40 mmHg. IEC is therefore going to issue a corrigendum. Suggested Revision 6 includes the original mistake. (3)Suggested Revision 24 modified IEC80601-2-30 and added a systolic test at 60 mmHg for adult (see the final 2 lines of A.15.2). Is this an intentional modification, or only a mistake when copying the sentence from IEC?	Request maintaining the original statements in R16-2 (2002).	Partly accepted (1) Combined the 6.8.1 with 5.4 （2）、（3）Change 60 mmHg to 40 mmHg.
47.	BR	5.4	Accepted Most patient simulators on the market don't allow independent configuration of systolic and diastolic blood pressures. It can be a problem to check this requirement because to reach systolic value of 230 mmHg, diastolic will be much more than requirement (e.g. Dynatech' CuffLink will simulate diastolic value of 180 mmHg). This situation can cause instrument error which causes a wrong evaluation. The same problem may occur with systolic limit of 60 mmHg.	We should analyze if the proposed values are feasible or if the difference between systolic and diastolic values is too large.	Not accepted We can find a simulator for comparasion while the simulator doesn't allow independent configuration of systolic and diastolic blood pressures in most of cases.
48.	CZ	5.4	Page 5, row -8: Change „30,7“ into „30.7“.		accepted 30.7

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49.	JP	5.5 A.16	Suggested Revision 7 and 25 propose an evaluation of short-time stability throughout the 20 times measurement. In addition, the criterion in 5.5 does not conform to the test method in A.16. The requirement in 5.5 specifies the criteria as the maximum difference, but A.16 explains a procedure to evaluate the standard deviation. This Suggested Revision does not harmonize with IEC80601-2-30. The stability requirement in the IEC standard is different.	Request maintaining the original statements in R16-2 (2002).	Partly accepted Clause of 5.5 is the blood pressure indication repeatability with requirement of standard deviation evaluation.

50.	DE	5.5	It is not totally clear what is the concern. If the repeatability is getting worse with the time of usage, either the software or the hardware or both is/are getting worse. It is very unlikely that the software is getting worse (if is a bad one, the clinical investigation should show it). Therefore components of the hardware will fail with the time of usage. The transducer will age, that is checked by re-verification and by clause 6.7 of this Recommendation. Valves or leakage might be the main reason for the observed increase in data scattering. A leaking valve, hose or pneumatic connection will increase the deflation rate of the measurement. If the algorithm to determine systolic and diastolic blood pressure is not able to compensate higher than the original deflation rates, the blood pressure determination will become worse. Simple (cheap) automated sphygmomanometer have linearizing valves, which are permanently open, made from rubber. This rubber will age with time or environment. I am quite sure that this is the reason for the observed data scattering. It is probably difficult to simulate this aging process in the laboratory. I see only the possibility to add an adjustable leakage to the pneumatic system by connecting an extra valve to the pneumatic system of the sphygmomanometer under test, which allows the test house to check how such leakage will affect the determination of the blood pressure values. By doing so, using the test procedure A.16, one might investigate how stable the determination is.	The manufacturer shall disclose up to which deflation (or inflation) rates, minimum and maximum, he guaranties the accuracy of the blood pressure determination and how this is controlled automatically by the sphygmomanometer. The increase of the value of the empirical standard deviation shall not be more than 2,0 mmHg (0,27 kPa) for the least favourable condition compared to the optimal condition. Testing shall be carried out according A.16. (to be modified from the draft version)	Partly accepted Use the repeatability instead of stability for avoiding the misunderstanding. 1) the test is a repeatability test. 2) Linear exhaust is one of the affections. Every company has its own deflation rate and algorithms .it's not necessary to test valves and leakage when the MPE is fulfilled.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
			我认为只有使被测的血压计改造为放气率可调的形式，使测试人员可以检测泄漏对确定血压值的影响。只有这样做，才能用 A.16 的测试程序检查血压值确定的稳定性。 What is the possible consequence for the manufacturer? I think practically every automated sphygmomanometer will have a limit for the maximum deflation rate it can handle without the loss of accuracy of the determination. When this limit is found (known), the sphygmomanometer software shall check if this maximum deflation rate is exceeded and if it is, the device shall display an error message, but no blood pressure values. 我认为每个自动血压计都有一个放气率上限，在上限以内血压计可保证其血压测量准确度。如上限值已知，血压计便可设计成：一但检测出泄漏率超出上限，血压计给出错误信息，而并非是血压值。 I suggest that the manufacturer has to state up to which deflation (or inflation) rates, minimum and maximum, he guaranties the accuracy of the blood pressure determination and how this is controlled automatically by the sphygmomanometer. The test house then shall validate these values by using a simulator. 我建议制造商应给出放气（充气）率的最大和最小值，并保证血压测量准确度和如何控制自动测量。这样测试人员才能用模拟器确定血压计的量值。		

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
51.	AU	5.5	Accepted with changes: a) Alignment with ISO temperature range (10 ºC to 40 ºC) b) The condition “both for increasing and for decreasing pressure” is valid only for static pressure measurement c) Bland and Altman (1986) stated the repeatability as an indication based on the standard deviation. So this requirement shall comply the maximum experimental standard deviation at 5.2 (8 mmHg). d) This requirement or A.16 test procedure doesn’t allow to check for problems caused by few years of use.	“For any set of conditions within the ambient temperature range of 10 ºC to 40 ºC and the relative humidity range of 20% to 85%, the sphygmomanometer shall comply the following requirements: • Measurement of diastolic blood pressure: maximum experimental standard deviation shall not exceed 1.1 kPa (8 mmHg) at least the interval of 2.7 kPa (20 mmHg) to 8.0 kPa (60 mmHg) in neonatal mode and 5.3 kPa (40 mmHg) to 17.3 kPa (130 mmHg) otherwise; • Measurement of systolic blood pressure: maximum experimental standard deviation shall not exceed 1.1 kPa (8 mmHg) at least the interval 5.3 kPa (40 mmHg) to 14.7 kPa (110 mmHg) in neonatal mode and 8.0 kPa (60 mmHg) to 30.7 kPa (230 mmHg) otherwise. Testing shall be carried out in accordance with A.16.”	a)accepted b) accepted the simulator is used in the test, the test is not a static test. Removing the ““both for increasing and for decreasing pressure” c)not accepted “8 mmHg”is according to the requirement of clinical test. d)accepted changed to repeatability

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
52.	BR	5.6	According to Fraga and Farias (2011) and Amoore *et al.* (1998), the pulse rate can affect the blood pressure measurement made by automated non-invasive sphygmomanometer. We suggest addition of a requirement and a test procedure related with the pulse rate.	"Pulse rate The difference of the blood pressure indications shall not exceed ±0.4 kPa (±3 mmHg) when the sphygmomanometer is subject to changes of the pulse rate within the interval determined according to A.17.1. Outside this interval, no result of the blood pressure measurement shall be displayed Testing shall be carried out in accordance with A.17."	Not accepted The affection of pulse rate in the blood pressure testing need to be certificated more. We don not discuss it in R16-2. By the way, we found the pulse rate affect nothing with the blood pressure testing in the inform test in our department.
53.	JP	6.2	Suggested Revision 8 proposes replacing the original requirements to cuff and bladder with the description in the IEC standard. This is however an additional and unnecessary requirement because it specifies the cuff structure and does not mention a metrological requirement to sphygmomanometers.	Request maintaining the original statements in R16-2 (2002).	Not accepted The size of cuff and bladder is the one of the most important element affects the uncertainty of the test.
54.	BR	6.2	a) This Note contains requirements. It's no longer a Note on R 16-1. b) The bladder's width doesn't need to be *exactly* 40%, as it may be understood from the sentence. c) Once these values are under consideration, it would be interesting if we leave room for different dimensions as long as they are validated by the clinical test.	a) Change the Note into a requirement 6.2.2 b) Change the text to "The optimum bladder size is one with dimensions such that its width is approximately 40%...". c) Add a new Note with the following text: "Dimensions different from those stated at 6.2.2 may be accepted if they are validated by the clinical tests results"	a)accepted b) accepted c) accepted

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
55.	BR	6.2.3 （增加）	In some models the user can easily remove the bladder from the cuff without using any kind of tool. In the accompanying documents should be some instruction regarding the correct repositioning of the bladder into the cuff. The previous part of the requirement regarding cleaning methods may be relocated at this new clause.	Add the new clause 6.2.3: “6.2.3 If the bladder can be removed from the cuff without using a tool, the accompanying documents shall contain instruction regarding the correct repositioning of the bladder into the cuff. For reusable cuffs, the accompanying documents shall also indicate the method for cleaning.”	Princinple accepted The requirement of removing the bladder is belongs to the operation instruments. It is not appropriate to be listed as a measurement requirement. To anther clause
56.	JP	6.3	Please make a correction as written in the right column.	“M” or “MAF” → “M” or “MAP”	Accepted
57.	DE	6.3	wrong abbreviation for mean arterial blood pressure		accepted
58.	BR	6.3	a) The requirements in this clause are strictly related with the requirements at 6.8 (pressure indicating device). Why do we need different clauses? b) The term “measuring values” needs alignment with the International Vocabulary of Metrology 2008 (VIM 2.10). c) The abbreviation for the mean arterial blood pressure is wrong. d)The indication of the test procedure (visual inspection) should be placed at the end of the clause.	Move the content to clause 6.8 into the new clause 6.8.3	a) accepted the contents of 6.3 describe the matter of indication of test result as same as 6.8. Move the content to clause 6.7.3(sequence Numbers were modified) b) accepted the express in VIM-2010 is“measured quantity value”。 c)accepted same as 56。 d) accepted Adding “Testing shall be carried out by visual inspection.”

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
59.	JP	6.4.1.1	Suggested Revision 9 tries to clarify ambiguous criteria. However, the criteria 5.1 and 5.2 refer unrealistic contents such as clinical test. Therefore, we propose to revise 6.4.1.1 using explicit numerical criteria as shown on the right column.	Instead of the reference to 5.1 and 5.2, the criteria should be expressed as ±0.4 kPa (±3 mmHg).	Not accepted Requirement is modified.
60.	BR	6.4.1.1 Sug. rev. 9	Not accepted The deletion of the highlighted part reduces the original application of the requirement. The term "cuff pressure reading" is used when we are comparing the sphygmomanometer (in the test mode) with the reference manometer; the term "blood pressure measurement" is used when we are performing measurements with the patient simulator. That's why this requirement refers to test procedures A.4.1 (using the reference manometer) and A.5.1 (using the patient simulator). The specific criteria are the uncertainty allowed when using the reference manometer (1 mmHg) and the patient simulator (2 mmHg)	Keep the original text and add the following criteria: "The maximum difference between the indications at nominal voltage and at the lowest voltage increased by 0.1 V shall be: • 0.1 kPa or 1 mmHg when the manometer is in the test mode; and • 0.2 kPa or 2 mmHg when the sphygmomanometer is performing measurements connected to a patient simulator. Note: The parameters stated above are already including the uncertainty mentioned at A.1"	Not accepted This clause is not for the calculation of blood pressure but for keeping the accuracy of the indication of pressure test.
61.	BR	6.4.1.2	This requirement is not necessary because the lowest voltage limit is that where the device no longer displays cuff pressure values.	Remove the clause.	Not accepted The affection to test result of power resource is limited by this clause and 6.4.1.1.
62.	JP	6.4.2.1	Suggested Revision 10 tries to clarify ambiguous criteria. However, the criteria 5.1 and 5.2 refer unrealistic contents such as clinical test. Therefore, we propose to revise 6.4.2.1 using explicit numerical criteria as shown on the right column.	Instead of the reference to 5.1 and 5.2, the criteria should be expressed as ±0.4 kPa (±3 mmHg).	Not accepted Same as no.59

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
63.	BR	6.4.2.1 Sug. rev. 10	Not accepted The deletion of the highlighted part reduces the original application of the requirement. The term "cuff pressure reading" is used when we are comparing the sphygmomanometer (in the test mode) with the reference manometer; the term "blood pressure measurement" is used when we are performing measurements with the patient simulator. That's why this requirement refers to test procedures A.4.2/3 (using the reference manometer) and A.5.2/3 (using the patient The specific criteria are the uncertainty allowed when using the reference manometer (1 mmHg) and the patient simulator (2 mmHg).	Keep the original texts and add the following criteria: "The maximum difference on the indications within the working range specified by the manufacturer shall be: • 0.1 kPa or 1 mmHg when the manometer is in the test mode; and • 0.2 kPa or 2 mmHg when the sphygmomanometer is performing measurements connected to a patient simulator. Note: The parameters stated above are already including the uncertainty mentioned at A.1"	Not accepted Same as no.60
64.	BR	6.4.2.1	The indication of the test procedure ("testing shall be carried out...") should be placed after clause 6.4.2.2 because it's applicable for both requirements (6.4.2.1 and 6.4.2.2).	Move the indication of the test procedure and change the text to: "Testing to check for compliance with 6.4.2.1 and 6.4.2.2 shall be carried out according to A.4.2, A.4.4 and A.5.2 (alternating current) and A.4.3, A.4.5 and A.5.3 (direct current)."	Not accepted It is easy to understand.
65.	JP	6.4.2.2	Suggested Revision 11 proposes to shorten the adult's maximum deflation time from 180 s to 30 s in accordance with IEC80601-2-30. But it results in a shorter time of adults comparing to that of neonatal patients.	Change deflation time both of adults and neonatal patients into 30s in accordance with the requirement of IEC.	Accepted New clause 6.4.6 is added for maximum time for which the cuff is inflated. "180s" is right.
66.	DE	6.4.1, 6.4.2	not accepted, because I do not understand the argument		accepted

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
67.	DE	6.4.2.2, NOTE	not accepted, something is misunderstood, the values of the original text are identical to clause 201.104 in IEC 80601-2-30 *(Revised)* *Note:* In the case of any malfunction of the equipment, deflation to below 2 kPa (15 mmHg) must be guaranteed within 30 s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients.		Not accepted same as no.65
68.	BR	6.4.2.2	"Incorrect values" is not a clear expression and may lead to misunderstanding.	Change the text: "6.4.2.2 Results obtained from measurements performed outside the working range specified by the manufacturer shall comply with the requirements at 5.1 (sphygmomanometer in the test mode) and 5.2 (sphygmomanometer connected to a patient simulator)."	Partly accepted Change to "Incorrect measured quantity value" The express in VIM-2010 is "measured quantity value. And add examples Change to "outside the working range specified by the manufacturer".

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
69.	BR	6.4.2.2 Sug. rev. 11	Accepted with changes a) Notes shouldn't contain requirements. This must be turned into a clause because it's a requirement b) The deflation time in neonatal mode wasn't updated (ISO 201.101 requires 30 s for both modes). c) ISO allows some kind of devices to be exempt from this requirement. We should follow this intention d) There's no reference to test procedure.	a) Number the requirement as clause 6.4.2.3 b) change the text to "In the case of any malfunction of the equipment, it is required a maximum deflation time of 30 s to perform the deflation to below 2 kPa (15 mmHg) in the case of adult patients and to below 0.7 kPa (5 mmHg) in the case of neonatal/infant patients" c) Add the following text: "Sphygmomanometers intended for self measurement or where the operator is intended to be in continual attendance and where the pressure can be released from the cuff by the operator are exempt from this requirement" d) Develop a test procedure for this requirement.	accepted same as no.65
70.	AU	6.4.2.2	Delete term 'incorrect values' and replace with "Where the sphygmomanometer is operated outside the voltage range specified by the manufacturer, the results displayed on the indicator shall comply with the requirements specified in 5.1 and 5.2".	Current wording is ambiguous.	Partly accepted Same as no.68.
71.	AU	6.4.2.2 Suggested revision 11	*Replace suggested wording with following, "In the case of any malfunction of the equipment, a maximum deflation time of 30 s is required to below 2 kPa (15 mmHg) for adult patients and to below 0.7 kPa (5 mmHg) for neonatal/infant patients."	Maintain consistency with ISO 201.101	accepted same as no.65.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
72.	BR	6.5.1	It seems the requirement is only concerned about air leakage in the test mode. If so, we should move it to the new clause 6.5.5 (manometer test mode) and add at 6.5.1 conditions related to the performance of the device in the dynamic measurement. These conditions shall protect the user from wrong measurement results if the air leakage on the device increases over time due to aging or any other problem and the software is not able to compensate this air leakage.	Replace the current text with: "The difference of the blood pressure measurement indications shall comply with 5.2 within the air leakage range determined according to A.6.2. Outside this range, no result of blood pressure measurement shall be displayed. Testing shall be carried out in accordance with A.6"	Not accepted Leakage is a very important requirement whenever static test or not. A.6.2 test procedure is unclear .clause 5.2 is missing detail test procedure.
73.	CZ	6.5.2	Pulse is not SI-unit. Recommendation to introduce T as a pulse length in seconds, hence having e.g. 0.3/T kPa/s. What range of pulse rate is taken into account? The same as in A.5.1.1?		Not accepted Not necessary.
74.	BR	6.5.4	a) The term "zero setting" needs alignment with the International Vocabulary of Metrology 2008 (VIM 3.12). b) There are two requirements on this clause. We should separate them. c) It's not necessary to specify where the drift may occur ("pressure transducer and the analog signal processing).	a) New title: "Zero adjustment of a measuring system" b) "6.5.4.1 Sphygmomanometers shall be capable of automatic adjustment to zero. The adjustment shall be carried out at appropriate intervals, at least starting after switching on the sphygmomanometer. At the moment of the adjustment a gauge pressure of 0 kPa (0 mmHg) shall exist and be displayed thereafter." c) "6.5.4.2 The instrumental drift of sphygmomanometers performing adjustment to zero only immediately after switching on shall not exceed 0.1 kPa or 1 mmHg until the sphygmomanometer switches off."	a)accepted Changing to "zero adjustment of a measuring system" according to VIM2010. b) Accepted 6.4.4.1\6.4.4.2 is modified.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
75.	AU	6.5.4 Zero setting	Replace current heading with "Zero adjustment of a measuring system".	Maintain internal consistency of the document (see comment for clause 2.12)	Accepted Same as no.74
76.	BR	6.5.5 Sug. rev. 12	Accepted with changes. a) Alignment with 5.4 b) Add condition related to the duration of the test mode. Some devices have a limited time in the test mode and don't allow the completion of the test procedures. c) Usually setting the manometer to the test mode is not enough to close all air outlets and is necessary to use some special test connector to perform static pressure measurement. For some models, the test connector is the original connector placed in the reversed position. For most models, the test connector is a completely different connector which is not easily available for metrological authorities (we need to ask it to the manufacturer and wait). Usually is not very difficult to have these connectors for type approval tests but the situation is completely different when it comes to periodic verification. Another problem at periodic verification is caused by knowing which test connector fits each model and also to carry all of them around because the verification officers don't know in advance which models will be verified (the test connector also get lost over time). The first solution (original connector used in the reversed position) is much more simple, easy and cheap, so I think it should be mandatory.	a) & b) "The sphygmomanometer shall have a manometer test mode that allows static pressure measurement over at least the blood pressure measuring range while the sphygmomanometer is pressurized. This mode shall..." c) Add the following 2nd paragraph: "The manufacturer shall design the internal components of the sphygmomanometer in a way that one of the following conditions is fulfilled when the manometer is set to the test mode: • all internal air outlets are electronically blocked by the test mode procedures; OR • all internal air outlets are physically blocked when the cuff connector is inserted in the reversed position into the manometer."	a) not accepted it is not a requirement of measurement. b) Not accepted c) Not accepted It is not the requirement of measurement but the details of testing.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
77.	JP	6.6.1 Sugg. Rev. 13	With regard to electromagnetic compatibility, Suggested Revision 13 proposes clearer definition using a numerical value (± 3 mmHg). We would agree this proposal if an original test method defined by a member state is accepted.	In addition to Suggested Revision 13, add the following statement: *Practical method to test (i.e. fixing the cuff pressure at 0 mmHg or another value and detecting the effect of disturbance) is permitted.*	Partly accepted with modification
78.	DE	6.6.1 Sugg. Rev. 13	not accepted, but accepted with modification: The text in IEC 80601-2-30, 202.6.6.1.10 is: Under the test conditions specified in IEC 60601-1-2:2007, 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE. Under these conditions, the maximum change in the reading for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to 2 mmHg (0,3 kPa). Thus the text has to be modified as proposed. Please not that "±" is not written. *(Revised)* *6.6.1 Compliance criteria* 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	6.6.1 Compliance criteria • electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication, i.e. the maximum change for the measurement of the cuff pressure shall be 0.3 kPa (2,0 mmHg); or • if electrical and/or electromagnetic …	Partly accepted with modification

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79.	BR	6.6.1 Sugg. Rev. 13	Accepted with changes a) There should be a little “introduction” to the requirement. b) The text should refer to the requirement at 5.1, not write it again every time.	a) Add the following text after the title: “When submitted to electrical and/or electromagnetic interferences, the sphygmomanometer shall fulfil one of the following conditions:” a) Add the following text after the title: “When submitted to electrical and/or electromagnetic interferences, the sphygmomanometer shall fulfil one of the following conditions:” b) “ - the cuff pressure indication shall be in accordance with 5.1; or - if any abnormality occurs, it shall be clearly indicated and it shall be possible to restore the normal operation within 30 s after cessation of the interference.”	a)partly accepted add “either” c) not accepted it is easy to understand
80.	JP	6.6.2 Sugg. Rev. 14	Suggested Revision 14 proposed a requirement against the interference from electrosurgical instruments. However, we do not agree this proposal because this is a safety requirement and not a general metrological requirement to sphygmomanometers.	Request maintaining the original statements in R16-2 (2002).	Not accepted According to the requirements in IEC 80601-2-30 “The test date would not be lost after disturbing”

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
81.	DE	6.6.2 Sugg. Rev. 14	accepted, but only for devices intended for that purpose as in IEC 80601-2-30: 202.6.2.101 * Electrosurgery interference recovery If an AUTOMATED SPHYGMOMANOMETER is intended to be used together with HF SURGICAL EQUIPMENT, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT, without loss of any stored data. "A testing item of "Restoration of Electrosurgical Interferences" should be added for the type approval test and the testing may be carried out in accordance with 202.6.2.101 in IEC/DIS 80601-2-30. "	If an automated sphygmomanometer is intended to be used together with HF surgical equipment, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF surgical equipment, without loss of any stored data.	accepted
82.	BR	6.6.2 Sugg. Rev. 14	Accepted with changes Will the test procedure for "Restoration of Electrosurgical Interferences" be added to R 16-2 or will we have only the reference to ISO?	Add the ISO test procedure to R 16-2.	Not accepted Refer to IEC/DIS 80601-2-30.202.6.2.101

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
83.	BR	6.7	The requirement should also focus on the effect of usage on the blood pressure measurement. The test procedure at A.12 shall be updated to this suggested condition.	"Effects of usage on the measurement After 10,000 simulated measurement cycles, the sphygmomanometer shall comply with the following conditions: • the change in the pressure indication shall not exceed ±0.4 kPa (±3 mmHg) when the sphygmomanometer is in the test mode; AND • the difference on the mean error of the blood pressure measurement shall not exceed ±0.4 kPa (±3 mmHg) with maximum experimental standard deviation of 1.1 kPa (8 mmHg)."	Partly accepted Adding the contents of checking the function of the blood pressure measurement by simulator. The second proposal is not accepted.
84.	BR	6.8.1	Once we set requirements for the blood pressure measuring range (new 5.4) it's no longer necessary to set requirements for the static pressure ranges.	Delete the clause	Not accepted The range of blood pressure test is relative to the range of static pressure test. But there is differences between them. The scope of the range of blood pressure test is always larger than the range of static pressure test.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
85.	BR	6.8.2	This clause should comprise all requirements related to indication. Requirements at 6.3 should be moved to this clause. Some terms need alignment with VIM 2008.	"6.8.2 Display 6.8.2.1 The displaying device resolution shall be at least 0.1 kPa or 1 mmHg. 6.8.2.2 The display shall be designed and arranged so that the information including measured quantity （原为：measuring values ）values can be read and easily recognized. If abbreviations are used on the display they shall be as follows: • "S" or "SYS": systolic blood pressure (value); • "D" or "DIA": diastolic blood pressure (value); • "M" or "MAP": mean arterial blood pressure (value) Single letter abbreviations shall be positioned in such a way to avoid confusion with SI units. 6.8.2.3 If the measured value of a parameter is indicated on more than one display, all displays shall indicate the same numerical value. *Note:* a personal computer's monitor is also considered a display. 6.8.2.4 Measured numerical values on the display(s) and the symbols defining the units of measurement shall be arranged in such a way to avoid misinterpretation. Testing shall be carried out by visual inspection. *(relocated)*"	Accepted Combined 6.8.2 with 6.3 make the "resolution of a displaying device "instead of "digital scale interval" according to VIM2010
86.	BR	6.10	A definition of *medium priority alarms* is required.	Define "medium priority alarms".	Not accepted This clause is withdrawn.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
87.	BR	6.11.4	Considering the suggestion for clause 1, electronic sphygmomanometers are not included in the scope of R 16-2.	Remove the words “Electronic or”.	Accepted Same as no.9.
88.	JP	6.11.5 Sugg. Rev. 15	Please refer our general comment on D11.	Request maintaining the original statements in R16-2 (2002).	According to IEC80601-2-30
89.	AU	6.11.5	Insert following wording: "The sphygmomanometer or their parts, intended for use during patient transport outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by normal use, impact, pushing, dropping and rough handling. (a) Shock according to IEC 60068-2-27: 2008 and (b) broad band random vibration according to IEC 60068-2-64: 2008. After the tests check that the sphygmomanometer functions normally by performing tests outlined in 5.1	Insert section on requirements for sphygmomanometers for transport, to include instances where the instrument is intended for use during patient transport outside a healthcare facility. Should include situations where the instruments are subject to mechanical stress caused by pushing, dropping and rough handling for instance. Current wording does not cover such situations.	Not accepted Sphygmomanometers used in special field could fulfil the requirement according to the specification of the access systerm other than OIML recommendation.
90.	BR	7	The term “periodic verification” does not include verification after repair. There’s a missing dash on “noninvasive”	Change the text to “…initial and/or subsequent verification for non-invasive…”	accepted
91.	JP	All of clause 7	The present International Recommendation is written about the general technical requirements regarding sphygmomanometers. However, section 7.1-7.3 in this recommendation mentions the metrological control, which is supposed to be an annex (informative). If this proposal is accepted, the title of the Clause 7 should be “Marking,” then 7.4 and 7.5 should be numbered and titled”correctly.	Move 7.1, 7.2 and 7.3 to Annex D (informative). Change the title “7. Metrological controls” to “7. Marking”.	Not accepted It is metrological control requirement not imformation.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
92.	AU	7.1 Type approval	Delete sentence 'At least three samples of a new type of sphygmomanometer shall be tested and replace with, "Type evaluation shall be carried out on at least one unit, which represents the definitive type."	Present wording places a lot of restrictions on the type approval process. The exact process of type approval that is to be carried out should be left to the discretion of each relevant national authority.	Not accepted At least 3 samples
93.	BR	7.2.1	a) 5.1 and 6.5.1 are the minimum requirements, not the only ones to be fulfilled. Align the wording with clause 7.2.2 b) The text should open the possibility to use a sampling plan. In Brazil we are performing initial verification based on a sampling plan and the results are very good (the rate of rejection is below 0.5 %). A suggestion is to use a double sampling plan like the one used at OIML R 115 (clinical electrical thermometers).	a) Replace the first sentence with “At least 5.1 and 6.5.1 shall be fulfilled at initial verification”. b) “Testing shall be carried out according to A.2 and A.6 on all units or using the statistical sampling plan at Annex D”	a)not accepted b)not accepted it is depend on the government body
94.	JP	7.2.2 Sugg. Rev. 17	Suggested Revision 17proposes a requirement to the marking of devices, and this requirement complies with the IEC80601-2-30. However, we wonder if such requirement is necessary to an OIML international recommendation.	We accept the proposal by the secretariat although some concerns still remain.	Not accepted
95.	BR	7.2.2 Sugg. Rev. 17	Accepted with changes The requirements for sales packaging would fit better at clause 7.5 because they are manufacturer’s information, not a marking on the device	Move these requirements to an specific bullet point at clause 7.5	Not accepted
96.	JP	7.3	Sealing method is not limited to a method using lead and so forth. New sealing method may be developed in the future.	Change “lead seals” into “seals”.	accepted

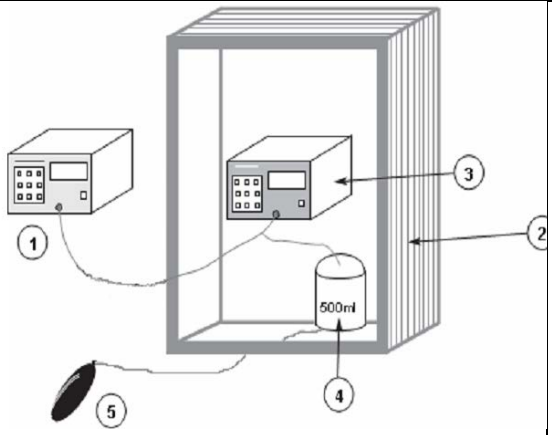
No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
97.	BR	7.4	The term “measuring range” (3rd bullet) needs alignment with the International Vocabulary of Metrology 2008 (VIM 4.7)	• “measuring interval and measuring unit;”	Accepted
98.	JP	7.5	It is better to indicate the necessary information also in the instruction manual because the package is very likely to be discarded. All information, which is required to the package in 7.4, should be also indicated in the manual.	Please add the following information in the list: *“The range of temperature and humidity when operating and storing.”* *“The minimum information of special requirements for automated sphygmomanometers using batteries.”*	accepted

99.	BR	7.5	Some requirements were added/changed to agree with previous suggestions or changes.	• reference to either OIML R 16-2, regional or national regulation, including the complete title; • *(no change)* • *(no change)* • methods for cleaning reusable cuffs and instructions regarding the correct repositioning of the bladder into the cuff, if applicable; • nature and frequency of the maintenance to ensure that the device operates properly and safely at all times, including a warning that the sphygmomanometer shall be verified periodically according to regional or national regulation; • *(no change)* • *(no change)* • *(no change)* • *(no change)* • *(no change)* • *(no change)* • nominal indication interval for the result of the blood pressure measurement (systolic and diastolic separately); • *(new bullet)* measuring interval of the pulse rate; • *(no change)* • *(new bullet)* description of all sound/visual alarms, symbols, abbreviations and error codes. • （5）*增加声/可视报警信号、标志、缩略语及出错码的说明* • *(delete)* • （7）*删除："超范围信号"的含义说明* • *(delete)* • （7）*删除：报警含义的说明，如适用*	1) accepted 2) Not accepted The instructions of installing the bladder should be in the instructions of operation manu. 3) accepted 4) not accepted The note does not describe the range of systolic and diastolic pressure but the range of pressure test. 5) accepted

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
100.	BR	A	There's no test procedure to check the compliance with the storage requirement (5.3.1)	Add a test procedure similar to the test procedure A.3 at R 16-1.	Not accepted There are enough information in the paragraph in 5.3.1
101.	PO	A	Change "0.1kPa(0.08mmHg)" to "0.1kPa(0.8mmHg)"		accepted
102.	JP	A.1 Sugg. Rev. 18	This Suggested Revision is not correct. The minimum step of digital indication is specified as 0.1 kPa (1 mmHg) in the clause 6.8.2. Therefore, permissible digital error also should be 0.1 kPa (1 mmHg).	Request maintaining the original statements in R16-2 (2002).	accepted
103.	DE	A.1 Sugg. Rev. 18	not accepted, but text modification of the original text proposed; The values given here are not pressure values, but values for the numerical resolution of the display, therefore a conversion of units makes no sense.	For digital indications an uncertainty of the last digit of 0.1kPa (1 mmHg) shall be allowed in any displayed value, because the display system cannot indicate a change of less than one unit.	accepted
104.	BR	A.1 Sugg. Rev. 18	Not accepted In this situation we shouldn't convert kPa to mmHg: we should only state what the unitary indications are. If the pressure is displayed in mmHg is not possible to see 0.8 mmHg (the convert value of 0.1 kPa), only 1 mmHg.	"For digital indications an uncertainty of 0.1 kPa or 1 mmHg shall be allowed in any displayed value..."	accepted
105.	CZ	A.1 Sugg. Rev. 18	A.1 vs. 6.5.4 vs. 6.8.2: If there should be 0.08 mmHg in A.1, then also in 6.5.4 and 6.8.2. Not to mention that it should be 0.8 mmHg (as is correctly in A.2.1 and further)!		accepted
106.	BR	A.x.1 (apparatus lists)	We need to harmonize the way to write them. In some cases we refer to the apparatus listed at previous clauses (e.g., A.3.1, A.4.3.1, A.4.4.1, etc) and in other situations we write again the same apparatus listed before (A.4.2.1 = A.4.1.1; A.5.3.1 = A.5.2.1)	Align the writing. The suggestion is always write again the list of apparatus.	Accepted Keep the internal consistency

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
107.	BR	New reference temperature range	The previous R 16-2 establishes a reference temperature range from 15 ºC to 25 ºC, which is smaller than the temperature range in the temperature variation test. Now the temperature ranges will be the same and the test procedure A.2 will be pointless because A.3 will "include" it.		Accepted A.3 is withdrawn. A.2 is modified.
108.	BR	A.2.1	The reference manometer characteristics need improvement.	• calibrated reference manometer with nominal indication interval between -1.3 kPa (-10 mmHg) and 40 kPa (300 mmHg), measuring interval between 0 kPa (0 mmHg) and 40 kPa (300 mmHg), resolution of the displaying device equal or less than 0.01 kPa (0.1 mmHg), an uncertainty less than 0.1 kPa (0.8 mmHg) and bias equal or less than 0.04 kPa (0.3 mmHg);	Not accepted.
109.	CZ	A2.1	A.2.1, A.7.2, A.9.1, A.10.2 and A.13.1 summing millilitres and percents!		accepted
110.	BR	A.2.2 A.3.2	There should be a reference to the use of test mode. With this addition is not necessary to refer to electro-mechanical pumps.	Replace the sentence "After disabling the electro-mechanical pump (if fitted)" with "Set the manometer to the test mode according to the instructions provided by the manufacturer".	accepted There are the contents about the test mode in a sphygmomanometer in this version. But there are not the contents of when to use it.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
111.	CZ	A 3.1	Does it mean 5 % of relative humidity or indication? E.g. (50 +- 5) % RH or (50.0 +- 2.5) % RH?		Accepted Should be:climatic chamber, instruments of temperature and humidity. capable of adjustment to an accuracy of 1℃ for the temperature and 5% for the relative humidity.”
112.	JP	A.3.2	Please change the test condition of temperature and humidity by adding some ranges as shown in the right column. A testing condition usually has a range allowing a variation. A testing at a fixed temperature without a range is not realistic.	10 °C± 2 °C ambient temperature, 85% ± 5% relative humidity (no condensing) 20 °C ± 2 °C ambient temperature, 85% ± 5% relative humidity (no condensing) 40 °C ± 2 °C ambient temperature, 85% ± 5% relative humidity (no condensing)	Not accepted 10 °C± 2 °C, 40 °C± 2 °C.means range of (8-42) °C. it is more strict. And temperature can be controlled or adjusted by the testing engineers. It’s not a fixed temperature.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
113.	BR	A.3 Figure 2	The air from the pump should connect first to the metal vessel and then to both manometers.	 Use the new Figure 3 at R 16-1 revision (below)	accepted
114.	DE	A.3 .2Fig. 2	The tube from the pressure generator (5) should go to the lower part of the metal vessel (4).	I can send revised drawing later.	accepted
115.	JP	A.3 Sugg. Rev. 19	Since A.3 specifies the performance requirements to the climatic chamber, the expression using the term “accuracy” is not clear. Propose to describe the requirements as shown in the right column.	The climatic chamber shall fulfil the following performance requirements: Non- uniformity of temperature: less than ± 1°C Instability of temperature: less than ± 1°C Non- uniformity of relative humidity: less than ± 5% Instability of relative humidity: less than ± 5%	Accepted

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
116.	BR	Sug. rev. 19	Accepted with changes 修改后接受 Accuracy is a qualitative characteristic, according to International Vocabulary of Metrology JCGM 200:2008. The ramp adjustment is important to avoid thermal shock	• "climatic chamber, capable of temperature ramp adjustment of 1 ºC/min with an uncertainty of 1 ºC for the temperature and 5% for the relative humidity."	Not accepted Because No.115 is accepted.
117.	DE	A.4.1.1	A calibrated reference manometer is not necessary.	delete 3rd bullet point	Not accepted
118.	BR	A.4.1.2	If we consider the real use of the sphygmomanometer, it would be more logical to establish the minimum voltage performing a blood pressure measurement, not a static pressure measurement. The user will never be able to perform a blood pressure measurement with the minimal voltage of the static pressure.	Change the text to "… by altering the DC voltage supply in steps of 0.1 V and determine the lowest voltage limit at which the result of blood pressure measurement is still displayed.	Not accepted The wave of voltage will affect the work of sensor when on the minimum voltage.
119.	DE	A.4.1.3	A calibrated reference manometer is not necessary.	Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested ~~and that of the reference manometer~~ at the lowest voltage limit increased by 0.1 V and at nominal voltage.	Not accepted It is a misunderstanding. The "that" in "and *that* of the reference manometer" means the indication of the reference manometer.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
120.	BR	A.4.1.3	The purpose of the test is to check how the voltage variations influence the device's indications and that's why we compare the indications at nominal and lowest + 0.1 V voltage. We don't need to check for the MPE at both situations because the requirement says that voltage variations "shall not influence" the indications. This means that only a 1 mmHg difference (digital indication's uncertainty) is allowed. The same suggestion applies to A.4.4.3, A.4.5.3 and A.5.1.3 with the necessary adaptations.	"Express the results as the difference between the cuff pressure indications of the manometer of the device to be tested at the lowest voltage limit increased by 0.1 V and at nominal voltage".	Not accepted The affection is not only on the indicator but also on the whole instrument includes the pressure senor, ect. It is a common matter that the affection is judged by the MPE or the quantity of changed.
121.	DE	A.4.2.1	A calibrated reference manometer is not necessary.	delete 3rd bullet point	Not accepted Same as 117
122.		A.4.2.2	Is the proposed revision (interchange of increase and decrease) of A.4.2.2 valid also in A.4.3.2 and A.5.2.2?	*(Original)* Change "the maximum rated voltage, declared by the manufacturer, increased by 10%; the mean value of the maximum and minimum rated voltage, declared by the manufacturer; the minimum rated voltage, declared by the manufacturer, decreased by 10%." to "the maximum rated voltage that declared by the manufacturer, or rated voltage increased by 10%; the mean value of the maximum and minimum rated voltage, declared by the manufacturer; the minimum rated voltage that declared by the manufacturer, rated voltage decreased by 10%."	Accepted princinple Increased or decrease by 5% to 10%.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
123.	DE	A.4.2.3	A calibrated reference manometer is not necessary.	Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested ~~and that of the reference manometer~~ at the different voltages.	Not accepted Same as no.119
124.	BR	Sug. rev. 20	Not accepted The procedure is correct but it needs improvement. The requirement at 6.4.2.1 says “changes of the voltage within the working range...” and we are not testing the device at these limits. These points should be added. The requirement at 6.4.2.2 says “Incorrect values resulting from voltage variations outside the limits given in 6.4.2.1...” and this is why we need to test 10% above the maximum and 10% below the minimum voltage. The same suggestion applies to A.4.3.2, A.5.2.2 and A.5.3.2 with the necessary adaptations.	Suggested voltage steps considering we need to check at the limits and outside them: a) the maximum rated voltage declared by the manufacturer, increased by 10%; b) the maximum rated voltage declared by the manufacturer; c) the mean value of the maximum and minimum rated voltage declared by the manufacturer; d) the minimum rated voltage declared by the manufacturer; e) the minimum rated voltage declared by the manufacturer decreased by 10%.	Not accepted Same as no.122,124-126
125.	JP	A.4.2 Sugg. Rev. 20	This Suggested Revision is not correct. The 10% is a margin to cover all products by the result of type evaluation using a limited number of prototypes. It does not intend using the prototypes within the rated voltage.	Request maintaining the original statements in R16-2 (2002).	Not accepted Same as no.122

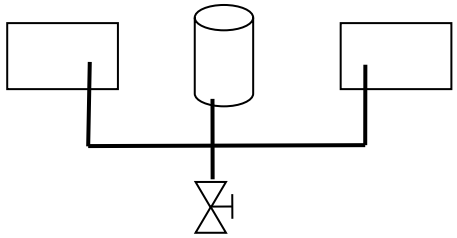
No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
126.	SW	A.4.2 Sugg. Rev. 20	To my opinion, there is no error in the original version of R16-2. The original version only asks 10% more tolerance to voltage change than what is specified by the manufacturer. This insures that even in case of small variations in the production or ageing the system remains within specifications. One could eventually argue that 10% seems to be a lot and that it should be reduced to 5% or 2.5%. The proposition "maximum decreased by 10% & minimum increased by 10%" will not test all the voltage span that is specified in most of the cases. It could however test outside of the specified range in some cases , when the manufacturer specifies for example "220 V to 230 V".		Not accepted Same as no.122
127.	BR	A.4.2.3	The original text doesn't allow checking compliance with 6.4.2.1 or 6.4.2.2. "*Shall not influence* the cuff pressure reading" (6.4.2.1) means a maximum difference of 1 mmHg. "*Incorrect values*" (6.4.2.2) means values that exceed the maximum permissible errors of ±3 mmHg or 2 %. The same suggestion applies to A.4.3.3, A.5.2.3 and A.5.3.3 with the necessary adaptations.	Considering all previous suggestions for this subject, the adequate text is: "To check for compliance with 6.4.2.1, calculate the differences between the indications of the manometer to be tested at conditions c) and b) and at conditions c) and d). To check for compliance with 6.4.2.2, calculate the difference between the indications of the manometer to be tested and that of the reference manometer at condition a) and at condition e)".	Not accepted Because requirement has been changed.
128.	DE	A.4.3.3	A calibrated reference manometer is not necessary.	Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested ~~and that of the reference manometer~~ at the different voltages.	Not accepted Same as no.119

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
129.	DE	A.4.3.3	A calibrated reference manometer is not necessary.	Express the results as the difference between the cuff pressure indication of the blood pressure measuring system to be tested ~~and that of the reference manometer~~ at rated voltage and the lowest voltage limit increased by 5V.	Not accepted Same as no.119
130.	CZ	A.4.4.3	Change „5V“ into „5 V“. Inconsistent use of space between a number and percent symbol.		accepted
131.	JP	A.5.1.1	Please make a correction.	Please correct as shown below. 2.15 → 2.13	Not accepted A.5 is withdrawn.
132.	JP	A.5.1 Sugg. Rev. 21	Suggested Revision 21 proposes to change the word “*patient simulator*” to “*technical requirement*” of the simulator. But the original description is already interpreted as a technical requirement because whole this clause describes requirements to the apparatus.	Request maintaining the original statements in R16-2 (2002).	Not accepted
133.	DE	A.5.1.1 Sugg. Rev. 21	accepted, when slightly modified	patient simulator, its technical requirements for the stability of patient simulator (see 2.15) are for the auscultatory and/or oscillometric method, that additional deviations originating from the simulator do not contribute not more than 0.27 kPa (2,0 mmHg) for the mean value of the measurements and that it is generating signals for blood pressure values of approximately: - systolic blood pressure: 16 kPa (120 mmHg); - diastolic blood pressure: 11 kPa (80 mmHg); - pulse rate: 70 min-1- 80 min^{-1}.	Not accepted A.5 is withdrawn.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
134.	BR	Sug. rev. 21	Accepted with changes The correct reference for the definition is 2.13. The patient simulator's specifications need some improvement. These specifications are based on the requirements and procedure tests as indicated in this list.	"Patient simulator (see2.13) with following specifications: • Generating signals for diastolic blood pressures at least the interval of 2.7 kPa (20 mmHg) to 8.0 kPa (60 mmHg) in neonatal mode and 5.3 kPa (40 mmHg) to 17.3 kPa (130mmHg) otherwise; • Generating signals for systolic blood pressures at least the interval 5.3 kPa (40 mmHg) to 14.7 kPa (110 mmHg) in neonatal mode and 8.0 kPa (60 mmHg) to 30.7 kPa (230 mmHg) otherwise; • Generating pulse rate at least the interval of 40 min^{-1} to 200 min^{-1} with, at least, systolic of 16 kPa (120 mmHg) and diastolic of 11 kPa (80 mmHg)."	Not accepted A.5 is withdrawn.
135.	BR	A.5.1.2	There's no reference for the patient simulator configuration.	"Connect the sphygmomanometer to the patient simulator configured to 120 mmHg / 80 mmHg / 80 min^{-1} (systolic/diastolic/pulse rate). Carry out..."	Not accepted A.5 is withdrawn.
136.	DE	Sugg. Rev. 22 Fig. 3	accepted, when slightly modified; The legend has to be modified for "3-Cuff"	3-Cuff wrapped around a rigid cylinder	Not accepted A.5 is withdrawn.
137.	BR	Sug. rev. 22	Accepted with changes It's better to use the metal vessel instead of the cuff.	Replace the item #3 ("cuff") with a metal vessel and add this apparatus to A.5.1.	Not accepted A.5 is withdrawn.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
138.	BR	A.6.1	This suggestion is based on suggested revision for 6.5.1. The list of components shall be modified to comply the procedure.	• Two rigid vessels with a capacities of 100 ml ± 5% and 500 ml ±5%; • Device to control the air leakage; • Patient simulator (see A.5.1.1).	Not accepted Because not accepted in 6.5.1

139.	BR	A.6.2	This suggestion is based on suggested revision for 6.5.1.	Change the text to: Replace the cuff with 500 ml vessel. For sphygmomanometers having the capability of measuring in a neonatal/infant mode and for devices measuring at the wrist, carry out the test with the 100 ml vessel. Connect the vessel, the air leakage device, the sphygmomanometer and the patient simulator as indicated in Figure 5. Configure patient simulator to simulate a blood pressure with: systolic = 16 kPa (120 mmHg) and diastolic = 11 kPa (80 mmHg). Note 1: The device to be tested for adult blood pressure measurement: pulse rate set at 80 min^{-1}. Note 2: The device to be tested for neonatal/infant blood pressure measurement: pulse rate set at 120 min^{-1}. Test the sphygmomanometer, increasing the air leakage by opening the air leakage device and determine the highest air leakage at which the blood pressure measurement result is still displayed. Note 3: The air leakage device shall be adjusted before the blood pressure measurement is started Carry out 20 simulated blood pressure measurements each at: • Air leakage device fully closed (0 mmHg/min, approximately);	Not accepted Because not accepted in 6.5.1 Not accepted No.72

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
				• Air leakage device adjusted to the highest air leakage as possible.	
140.	BR	Figure 5	This figure is mentioned in A.6.2	 1 – Patient simulator; 2 – Sphygmomanometer 3 – Vessel; 4 – Air leakage device	Not accepted Because not accepted in 6.2
141.	BR	A.6.3	This suggestion is based on suggested revision for A.6.2.	Change the text to: Express the result as the difference between of mean value determined with the air leakage device fully closed and at the highest air leakage as possible (systolic and diastolic values separately).	Not accepted Because not accepted in 6.2
142.	DE	A.8.1	add another bullet point for the pressure generator	• pressure generator	accepted
143.	BR	A.9	Change the title to agree with International Vocabulary of Metrology JCGM 200:2008	“Test method for the zero adjustment of a measuring system”	Accepted Same as no.17

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
144.	BR	A.9.2	The procedures at a), b) and c) are a little confusing. Some clarification is necessary.	a) Perform a regular adjustment to zero on the device; b) Apply 100 mmHg and register the indication (e. g., 99 mmHg); c) Apply +6 mmHg pressure while performing another adjustment to zero; d) Raise the pressure to 100 mmHg and register the indication. It shall be 6 mmHg below the one obtained at “b” (e. g., 93 mmHg); e) Apply -6 mmHg pressure while performing another adjustment to zero; f) Raise the pressure to 100 mmHg and register the indication. It shall be 6 mmHg above the one obtained at “b” (e. g., 105 mmHg).	accepted with changed 1） Create the value in kPa 2） Shall beyond/below 6mmHg
145.	CZ	A9.2	A.9.2 Change „-0.8 kPa (+6 mmHg)“ into „-0.8 kPa (-6 mmHg)“!		accepted
146.	BR	A.10	Agreement with International Vocabulary of Metrology JCGM 200:2008	Test method for the instrumental drift of the cuff pressure indication	accepted
147.	DE	A.10.3	add two commas for clarification	Test the stability of the cuff pressure indication, after the zero setting, at a pressure value of 7 kPa (50 mmHg) according to the procedure specified in A.2.	Not accepted Because no.148 is accepted.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
148.	BR	A.10.3	The procedure on the last paragraph considers that the device will effectively drift its indication more than 1 mmHg. It's not guaranteed this situation will happen and if it does we don't know how long will it take. The suggestion is to start the procedure determining the time between switching on and switching off after one blood pressure measurement (currently time t2) and then check if during this time the device will drift more than 1 mmHg	Change the 3rd and 4th paragraphs to: "Perform one blood pressure measurement and wait until the device has switched off automatically. Determine the time (t) between switching on and automatically switching off. Switch off the device and switch on afterwards. Set the device to the test mode, apply a pressure of 7 kPa (50 mmHg) according to the procedure specified in A.2 and start the stopwatch. During the time (t) the change of the cuff pressure indication shall not exceed 0.1 kPa or 1 mmHg."	accepted
149.	CZ	A.10.3	Missing subscript in t1!		Not accepted Because no.148 is accepted.
150.	BR	A.11.1	a) Refer climatic chamber specification. b) rigid vessels are necessary：	• climatic chamber (see A.3.1). • Two rigid vessels with a capacities of 100 ml ± 5% and 500 ml ±5%;	Not accepted Test equipments are consistent with A.3.1 No requirement anymore.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
151.	BR	A.11.2	The procedure is confused.	Change text to: Replace the cuff with 500 ml vessel. For sphygmomanometers having the capability of measuring in a neonatal/infant mode and for devices measuring at the wrist, carry out the test with the 100 ml vessel in place of the cuff. Connect the device, patient simulator and cuff in climatic chamber as showed in figure 4. For each of the following combinations of temperature and humidity, condition the device for at least 3 h in the climatic chamber to allow the device to reach steady conditions: • 10 ºC ambient temperature, 85% relative humidity (non-condensing); • 20 ºC ambient temperature, 85% relative humidity (non-condensing); • 40 ºC ambient temperature, 85% relative humidity (non-condensing); At each combination of temperature and humidity, switch on the blood pressure measuring system before starting the test, wait until the warm up time (described in the instructions for use) has elapsed, carry out the measurement (20 consecutive readings) and switch off the blood pressure measuring system afterwards.	Not accepted As same as 150
152.	DE	Sugg. Rev. 23 Fig. 4	accepted, when slightly modified; The legend has to be modified for “3-Cuff”	3-Cuff wrapped around a rigid cylinder	Not accepted Because accepted no.153

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
153.	BR	Sug. rev. 23	Accepted with changes It's better to use the metal vessel instead of the cuff	Replace the item #4 ("cuff") with a metal vessel and add this apparatus to A.11.1	Not accepted A.11 is withdrawn
154.	BR	A.11.3	The results shall be compared with the requirement in suggested revision 5.	Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each combination of temperature and humidity. Express the result as the maximum difference between of mean value determined at three situations (systolic and diastolic values separately).	Not accepted A.11 is withdrawn
155.	BR	A.12	There's no apparatus list	Add the apparatus list at A.12.1	Accepted Keep the internal consistency

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
156.	BR	A.12.1	This suggestion is based on suggested revision for 6.7.	a) Carry out the test according to the procedure specified in A.2 and 20 blood pressure measurements with patient simulator (see A.5.1.1) at least at ambient temperature of 20 ºC. b) Perform 10,000 simulated measurement cycles with the complete blood pressure measurement system at which at least the following cuff pressure values shall be reached: • adult mode: 20 kPa (150 mmHg); • neonatal/infant mode: 10 kPa (75 mmHg). Note 1: For devices which measure with the auscultatory and oscillometric method this test should be carried out for both modes. Note 2: For devices which measure in both modes (adult and neonatal/infant) the test should be carried out in both modes. c) One hour after finishing the cycles, repeat the measurements stated at a)	Not accepted Not accepted all the contents in 6.7 Only create the sphygmomanometer function checking.
157.	BR	A.12.2	This suggestion is based on suggested revision for A.12.1.	Add the following text: "... and the differences between the mean values (systolic and diastolic values separately) of the 20 consecutive measurements before and after the cycles."	Not accepted The simulator is not used in the test.

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
158.	AU	A.12	Insert section above procedure outlining the apparatus required. This section should be "A.12.1 Apparatus" and number current headings accordingly (i.e. A.12.2 Procedure, A.12.3 Expression of results)		Accepted Keep the internal consistency
159.	DE	A.14.1	delete the two bullet points and substitute them by a new bullet point as proposed	A.14.1 Apparatus • simulator or human subject	Accepted
160.	DE	A.14.1	delete the first sentence and substitute by proposed sentence	Apply the automated sphygmomanometer at a human or connect it with a simulator.	Accepted
161.	BR	A.14.1	The listed apparatus is not necessary to perform the test	The only necessary apparatus is an artificial limb or a human volunteer.	Accepted Same a no.159
162.	JP	A.15 Sugg. Rev. 24	See the comment for Suggested Revision 6.	Request maintaining the original statements in R16-2 (2002).	Not accepted Same as no.45
163.	JP	A.16 Sugg. Rev. 25	See the comment for Suggested Revision 7.	Request maintaining the original statements in R16-2 (2002).	Not Accepted Same as no.49.
164.	DE	A.16 Sugg. Rev. 25	see comment on Sugg. Rev. 7, too early to comment now		Not Accepted Test methods are for repeatability not for stability. Same as no.50
165.	CZ	A.16.3	N versus n!		Accepted

166.	BR	Addition A.17	This suggestion is based on the suggested addition of requirement 5.6	A.17 Test method for pulse rate A.17.1 Apparatus • Patient simulator (see A.5.1.1); • Two rigid vessels with a capacities of 100 ml ± 5% and 500 ml ±5%; A.17.2 Procedure Replace the cuff with 500 ml vessel. For sphygmomanometers having the capability of measuring in a neonatal/infant mode and for devices measuring at the wrist, carry out the test with the 100 ml vessel in place of the cuff. Connect vessel with sphygmomanometer and patient simulator by means of T-piece connectors. Configure patient simulator to simulate a blood pressure with: systolic = 16 kPa (120 mmHg), diastolic = 11 kPa (80 mmHg) and pulse rate = 80 min^{-1}. Test the sphygmomanometer by decreasing the pulse rate and determine the lowest pulse rate limit at which the blood pressure measurement result is still displayed. At the same way, determine the highest pulse rate limit. Carry out 20 simulated blood pressure measurements each at: • Pulse rate = the lowest limit increased by at least 10 min-1; • Pulse rate = 80 min-1;	Not accepted Same as no.52

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
				• Pulse rate = the highest limit decreased by at least 10 min-1. A.17.3 Expression of results Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each situation. Express the result as the maximum difference between of mean value determined at three situations (systolic and diastolic values separately). 因不采纳,故无需翻译此段。	
167.	JP	Annex B Sugg. Rev. 27	We cannot agree the revision. Citing of related parts of VIM is beneficial for the users, which helps reducing unnecessary misunderstandings.	Request maintaining the original statements in R16-2 (2002).	Not accepted Not necessary

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
168.	BR		A general revision is required because: a) some tables doesn't reflect the test procedures stated at Annex A (e.g., B.2 demands to perform the test at three different temperatures and with two readings); b) there are no tables for some requirements (e.g., B.4.3, B.4.4, B.4.5); c) alignment with new/different acceptance parameters is necessary (e.g., B2 is still considering the old MPE) Is the maximum deviation of all of the readings of the instrument under test and of the reference manometer less than or equal to ±0.4 kPa (±3 mmHg) for type approval test and first verification and less than or equal to ±0.5 kPa (±4 mmHg) for subsequent verification, respectively (see 5.1)?		Not accepted Tables in B.2 can be used also in B.4.3 to B.4.5
169.	JP	B.4.1 Sugg. Rev. 28	Agree to the suggestion. Tests for both A 4.1(cuff pressure) and A 5.1 (simulator) are required for the effects of internal power source/supply. But the test format in B.4.1 does not conform to these requirements. This revision requires including formats correspond to the both tests.		Accepted principle Tables addition
170.	DE	B.4.1 Sugg. Rev. 28	not accepted, see comment on A.4.1 below		Same as 117
171.	JP	B.4.2 Sugg. Rev. 29	Agree to the suggestion. Tests for both A 4.1(cuff pressure) and A 5.1 (simulator) are required for the effects of internal power source/supply. But the test format in B.4.2 does not conform to these requirements. This revision requires including formats correspond to the both tests.		Accepted principle Tables addition

No.	MB	Paragraph/ Figure/Table/Note (e.g. Table 1)	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
172.	DE	B.4.2 Sugg. Rev. 29	not accepted, see comment on A.4.2 below		Same as 121
173.	DE	B	B.4.3, B.4.4 and B.4.5 are missing		Not accepted Tables in B.2 can be used also in B.4.3 to B.4.5
174.	JP	Annex C Sugg. Rev. 30	Correct the number and year as shown in the right column.	ISO 81060 → ISO 81060-2:2009	Accepted
175.	DE	Annex C Sugg. Rev. 30	not accepted, wrong reference	C.4 IEC 80601-2-30	Accepted
176.	DE	C.2,C.3	Regarding the clinical test C.2 and C.3 in Annex C, both are withdrawn and substituted by ISO 81060-2. Also I would like to discuss to make it mandatory to use either the BHS protocol or the ISO 81060-2. I personally would prefer to require only ISO 81060-2 because it is newer, published in 2009 and in the process of a small revision at present (estimated publication: 2012), and it was widely discussed with international experts representing physicians, manufacturers and test houses.		Accepted
177.	BR	Annex C	E DIN 58130 is withdrawn and AAMI/ANSI SP10 will be replaced by ISO 81060-2	Keep only the BHS and ISO protocols	Accepted