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ISO 81060-1
Non-invasive sphygmomanometers
Part 1: Requirements and test methods for non-automated measurement type

Report reference No. ..... :	**CSTSM20080003**
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Testing laboratory..... :	**CCIC Huatongwei International Inspection (Suzhou) Co.,Ltd.**
Address..... :	Room 101, Building G, Ruoshui Road 388, Industrial Park, Suzhou, Jiangsu, China.
Applicant ..... :	**Wuxi Exanovo Medical Instrument Co.,Ltd.**
Address..... :	No.42 Xixin Road, Zhangjing Xibei Town, Wuxi City 214194 Jiangsu China
Standard ..... :	ISO 81060-1: 2007
Test procedure ..... :	Test Report Only
Procedure deviation..... :	N/A
Non-standard test method ..... :	N/A
Type of test object ..... :	**ANEROID SPHYGMOMANOMETER**
Trademark..... :	N/A
Model/type reference..... :	MC-20A, MC-20B, MC-30, MC-50
Manufacturer..... :	Wuxi Exanovo Medical Instrument Co.,Ltd.
Address..... :	No.42 Xixin Road, Zhangjing Xibei Town, Wuxi City 214194 Jiangsu China
Rating ..... :	No power supply

GENERAL INFORMATION

Test item particulars (see also clause 5):

Classification of installation and use……..:	~~transportable /~~ portable ~~/ stationary / mobile / fixed / permanently installed / hand-held~~
Supply connection……:	No power supply~~/ internally powered /permanently installed / appliance coupler / non-detachable cord~~
Accessories and detachable parts included in the evaluation..:	N/A
Options included……...:	N/A

Possible test case verdicts:

- test case does not apply to the test object…….:	N/A
- test object does meet the requirement……:	P(ass)
- test object does not meet the requirement……..:	F(ail)

Abbreviations used in the report:

- normal condition……...:N.C.	- Single fault condition ....:S.FC.
- operational insulation……:OP	- basic insulation ..... …….:BI
- basic insulation between parts of opposite polarity……:BOP	- supplementary insulation..... …….:SI
- double insulation……..…….:DI	- reinforced insulation ..... …….:RI

General remarks:

1. The sphygmomanometer is intended to use with medical environment;
2. This series include MC-20A, MC-20B, MC-50 and MC-30, only cuff material is different and cuff material do not affect test result, differences refer to difference table;
3. All the tests are conducted on model MC-20A to represent other models.

"Difference table"

REF	Cuff material	Cuff size(L x W)	Arm circumference
MC-20A	Cotton cloth for outside layer	540mm*145mm	From 25.4cm to 40.6cm
MC-20B	Nylon cloth for outside layer	540mm*145mm	From 25.4cm to 40.6cm
MC-50	Nylon cloth for outside layer	540mm*145mm	From 25.4cm to 40.6cm
MC-30	Nylon cloth for outside layer	540mm*145mm	From 25.4cm to 40.6cm

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Copy of marking plate

(The artwork below may be only a draft)

Label

cuff

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Clause	Requirement + Test	Result - Remark	Verdict
4	Identification and marking		P
4.1	Units of measurement		P
	The cuff pressure shall be indicated in either millimetres of mercury (mmHg) or kilopascals (kPa).	millimetres of mercury	P
4.2	Legibility of markings		P
	for warning statements, instructive statements, safety signs and drawings on the outside of the non-automated sphygmomanometer, from the intended position of the person performing the related function;		P
	for markings on the inside of the non-automated sphygmomanometer or non-automated sphygmomanometer parts, from the intended position of the person performing the related function.		P
4.3	Durability of markings		P
	The markings required by 4.4 and 4.6 shall be removable only with a tool or by appreciable force and shall be sufficiently durable to remain clearly legible during the expected service life of the non-automated sphygmomanometer. In considering the durability of the markings, the effect of normal use shall be taken into account.		P
4.4	Marking of non-automated sphygmomanometer		P
	The non-automated sphygmomanometer, the cuff and/or their components shall be marked clearly and legibly with the following:		P
	the name or trademark and address of the manufacturer;	Marked on the label	P
	model or type reference		P
	where appropriate, an identification reference to the serial or batch number, or Symbol 5.16 or 5.14 from ISO 15223-1:2007		P
	the non-automated sphygmomanometer and its parts shall be marked with regard to proper disposal, as appropriate		P
	The numbering on the scale or digital display shall not exceed the measurement range as determined in 7.1.2.		P
	safety sign for mandatory action “Refer to instruction manual/booklet” in accordance with M002 of ISO 7010:2003 and safety sign for warning “General warning” in accordance with W-001 of ISO 7010:2003	No mercury manometer used	N/A
	an indication that the tube contains mercury		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
4.5	Usability of reading		P
	Means shall be provided to address legibility and parallax error of reading the scale of a non-automated sphygmomanometer in normal use by ensuring that there is an indication to the operator when the parallax error results in a reading error that exceeds ± 2 mmHg (0,3 kPa).		P
4.6	Marking of the cuff		P
	indication of the correct positioning for the cuff over the artery	Marked on the cuff	P
	indication the limb circumference for which it is appropriate (see 7.2.4)	See above	P
4.7	Marking of the non-automated sphygmomanometer packaging		P
	Details to enable the responsible organization to identify the contents of the packaging		P
	for a sterile non-automated sphygmomanometer, cuff or component, the appropriate Symbol 5.20. 5.21， 5.22，5.23 or 5.24 from ISO 15223-1:2007	Not sterile non-automated sphygmomanometer	N/A
	for a non-automated sphygmomanometer, cuff or component with an expiry date, Symbol 5.12 from ISO 15223-1:2007		P
	for a single use non-automated sphygmomanometer, cuff or component, the words “single use only*’ or “do not re-use” or Symbol 5.2 from ISO 15223-1:2007	No single used	N/A
	any special storage and/or handling instructions	Refer to “specifications” in user manual	P
	the intended use of the cuff	Refer to “Intended Use” in user manual	P
5	General requirements for testing non-automated sphygmomanometers		P
5.1	Type tests		P
	The tests described in this standard are type tests	Type test	P
5.2	Representative sample		P
	Type tests are performed on a representative sample of the item being tested		P
5.3	Environmental conditions		P
	Unless otherwise specified in this part of ISO 81060， the non-automated sphygmomanometer complies with this part of ISO 81060 under the least favourable working conditions within the environmental temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing).		P

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Clause	Requirement + Test	Result - Remark	Verdict
	The non-automated sphygmomanometer is shielded from other influences (for example, draught), which might affect the validity of the tests.		P
5.4	Repairs and modifications	No such events	N/A
	In the event of the necessity for repairs or modifications after a failure or a probability of future failure during the sequence of tests, the testing laboratory and the supplier of the non-automated sphygmomanometer for the test can agree, either upon the presentation of a new sample on which all tests inliuencing the result are performed again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests are repeated.		N/A
5.5	Humidity preconditioning treatment		P
	Perform the humidity preconditioning treatment in a humidity cabinet containing air with a relative humidity of 85 % ± 5 %. Maintain the temperature of the air in the cabinet, at all places where a non-automated sphygmomanometer can be located, within 2 °C of any convenient temperature, *T*，in the range of + 20 °C to + 32 °C. Before being placed in the humidity cabinet, bring the non-automated sphygmomanometer to a temperature between *T* and r + 4 °C, and maintain this temperature for at least 4 h before the humidity treatment.	85%, 25°C, 48h	P
6	General requirements		P
6.1	Equipment or parts thereof using materials or having forms of construction different from those detailed in this part of ISO 81060, shall be accepted as equivalent if it can be demonstrated that an equivalent degree of safety and performance is obtained.	No such equipment or parts	N/A
6.2	Electrical safety		N/A
	Non-automated sphygmomanometers that utilize electrical power shall meet the applicable requirements in IEC 60601-1，in addition to the requirements in this part of ISO 81060	No power used	N/A
6.3	Mechanical safety		P
	Rough surfaces, sharp corners and edges that can cause injury or damage shall be avoided or covered. Particular attention shall be paid to flange or frame edges and the removal of burrs	No rough surfaces, sharp corners or edges	P
6.4	Mechanical strength		P
6.4.1	Non-automated sphygmomanometers		P
	Non-automated sphygmomanometers or their parts shall have adequate mechanical strength when	See appended table 6.4.1	P

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Clause	Requirement + Test	Result - Remark	Verdict
	subjected to mechanical stress caused by normal use, pushing, impact, dropping and rough handling. Stationary non- automated sphygmomanometers are exempt from the requirements of this subclause. The non-automated sphygmomanometer shall function normally following a free fall from a distance, *d,* of 25 cm. A non-automated sphygmomanometer that is marked “Shock Resistant” shall function normally following a free fall from a distance, *d,* of 1 m.		
6.4.2	Non-automated sphygmomanometers for transport		P
	Non-automated sphygmomanometers 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, pushing, impact, dropping and rough handling	See appended table 6.4.2	P
	Shock (according to IEC 60068-2-27)		P
	Broad-band random vibration (according to IEC 60068-2-64)		P
	After the test, check that the non-automated sphygmomanometer functions normally by performing the tests described in 7.1.1		P
6.4.3	Non-automated sphygmomanometers containing a mercury manometer	No mercury manometer used	N/A
	A non-automated sphygmomanometer containing a mercury manometer shall not leak mercury following a free fall from a distance, of 1 m under conditions of normal use		N/A
7	Requirements		P
7.1	Pressure indicating means		P
7.1.1	Limits of the error of the cuff pressure indication	See appended table 7.1.1	P
	Over the temperature range of 15 °C to 25 °C and the relative humidity range of 15 % to 85 % (non-condensing), for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to ± 3 mmHg (± 0,4 kPa)		P
	Over the temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing), for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to ± 3 mmHg (± 0,4 kPa) or 2 % whichever is greater		P
7.1.2	Nominal range and measuring range		P

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Clause	Requirement + Test	Result - Remark	Verdict
	The nominal range for the cuff pressure measurement shall be disclosed in the accompanying document [see 12.2.1 l)]. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of cuff pressure measurement outside the nominal range of cuff pressure shall be clearly indicated as out of range.	Refer to “SPECIFICATIONS” in user manual	P
	For a non-automated sphygmomanometer, the nominal range for the cuff gauge pressure shall extend from 0 mmHg (0 kPa) to at least 260 mmHg (35 kPa)	Extend from 0 mmHg to 300 mmHg	P
7.2	Pneumatic system		P
7.2.1	Air leakage		P
	Air leakage shall not cause a pressure drop that exceeds 4 mmHg/min (0,5 kPa/min).	See appended table 7.2.1	P
7.2.2	Pressure reduction rate		P
	Manually-operated and self-linearizing deflation valves shall be capable of adjustment to a deflation rate of 2 mmHg/s (0,3 kPa/s) to 3 mmHg/s (0,4 kPa/s).	Capable	P
	Deflation valves that control the deflation rate per pulse shall be capable of adjustment to a deflation rate of 2 mmHg/pulse (0,3 kPa/pulse) to 3 mmHg/pulse (0,4 kPa/pulse)	No such case	N/A
7.2.3	Rapid exhaust		P
	During the rapid exhaust of the pneumatic system with the deflation valve fully open, the time for the pressure reduction from 260 mmHg (35 kPa) to 15 mmHg (2 kPa) shall not exceed 10 s	See appended table 7.2.3	P
7.2.4	Cuff		P
	The bladder length should be approximately 0,80 x the circumference of the limb at the midpoint of the intended range of the cuff. The width of the bladder should be at least 0,40 x the circumference of the limb at the midpoint of the intended range of the cuff.	complied	P
7.2.5	Cuff and bladder		P
	The cuff and bladder and integral tubing shall maintain their integrity and be capable of withstanding an internal pressure equal to the maximum pressure intended for the cuff in normal use. For cuffs with removable bladder, the bladder shall be completely retained in the cuff during pressurization to the maximum pressure intended for the cuff in normal use.	cuffs without removable bladder	P
7.2.6	Tubing connectors		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Tubing connectors, if provided, shall incorporate a means of preventing accidental disconnection. Tubing connectors shall not be equipped with a connector that connects with a connector complying with ISO 594-1 or ISO 594-2.	No tubing connectors	N/A
7.3	Tamper proofing or unauthorized access		P
	Means shall be provided to prevent tampering or unauthorized access:		P
	—for all non-automated sphygmomanometers, any adjustment or function that affects accuracy		P
	—for mercury non-automated sphygmomanometers, the separation of reservoir and scale	Not mercury non-automated sphygmomanometers	N/A
7.4	Dynamic response in normal use		P
	The delay in the settling of the cuff pressure indication shall not exceed 1,5 s for the change in indication from 200 mmHg to 50 mmHg or from 25 kPa to 5 kPa when the pressure in the system drops from 200 mmHg to 0 mmHg or from 25 kPa to 0 kPa	Delay about 1s	P
8	Additional requirements for non-automated sphygmomanometer with mercury manometer	No mercury manometer used	N/A
8.1	Internal diameter of the tube containing mercury		N/A
	The nominal internal diameter of the tube containing mercury shall be at least 3,9 mm. The tolerance on the diameter shall not exceed ± 0，2 mm. See also 12.2.1 q)		N/A
8.2	Portable non-automated sphygmomanometer		N/A
	A portable non-automated sphygmomanometer shall be provided with an adjusting or locking mechanism to secure it in the position for use as indicated in the accompanying document.		N/A
8.3	Prevention of mercury spillage during transport		N/A
	To prevent the spillage of mercury during transport, a means shall be provided of keeping the mercury in its reservoir		N/A
8.4	Prevention of mercury spillage in normal use		N/A
	A mercury gravity non-automated sphygmomanometer shall incorporate a means (stopping device) at the top of the tube that both permits the inward and outward flow of air and prevents the passage of liquid mercury. The reservoir itself shall be fitted with a means (stopping device) to prevent mercury from flowing out of the reservoir neck and into the attached tubing and permits the inward and outward flow of air.		N/A
8.5	Quality of the mercury		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	The mercury shall have a purity of not less than 99,99 %.		N/A
9	Non-automated sphygmomanometers with aneroid manometer		P
9.1	Scale mark at zero		P
	If a tolerance zone is shown at zero，it shall not exceed ± 3 mmHg (± 0,4 kPa) and shall be clearly indicated. Graduations within the tolerance zone may be used.		P
9.2	Zero		P
	The movement of the elastic sensing element, including the pointer, shall not be obstructed within 6 mmHg (0.8 kPa) below zero.		P
	Neither the dial nor the pointer shall be adjustable by the operator.		P
9.3	Hysteresis error		P
	The hysteresis error throughout the pressure range shall not exceed 4 mmHg (0.5 kPa).	See appended table 9.3	P
9.4	Construction and materials		P
	The construction of the non-automated sphygmomanometer and the material for the elastic sensing elements shall ensure adequate stability of the measurement. The elastic sensing elements shall be aged with respect to pressure and temperature.		P
	The difference in the pressure indication of the non-automated sphygmomanometer before and after 10 000 full-scale cycles (where a full-scale cycle is a pressure change from 20 mmHg or less to full scale, and then back to 20 mmHg or less) shall be not more than 3 mmHg (0,4 kPa) throughout the pressure range.		P
10	Cleaning, sterilization and disinfection		P
10.1	Reusable non-automated sphygmomanometer and parts	Refer to “MAINTENANCE” in user manual	P
	All components specified for re-use in the accompanying documents, and which come into contact with the patient shall be capable of being either cleaned and disinfected or cleaned and sterilized	See above	P
10.2	Non-automated sphygmomanometer and parts requiring processing before use		N/A
	All components specified in the accompanying documents to be cleaned and disinfected or cleaned and sterilized before use and which come into contact with the patient shall be capable of being	No such parts	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	cleaned and disinfected or cleaned and sterilized.		
10.3	Non-automated sphygmomanometer and parts delivered sterile	No such parts	N/A
	Non-automated sphygmomanometers or accessories labelled sterile shall have been sterilized using an appropriate, validated method as described in ISO 14937.		N/A
11	Biocompatibility		N/A
	Non-automated sphygmomanometers and parts thereof intended to come into contact with biological tissues, cells, body fluids, or breathing gases shall be assessed and documented according to the guidance and principles given in ISO 10993-1.	Evaluated by manufacture	N/A
12	Information supplied by the manufacturer		P
12.1	Accompanying document		P
	The non-automated sphygmomanometer and accessories shall have accompanying document(s) containing at least the instructions for use and a technical description. The accompanying document shall be regarded as a part of the non-automated sphygmomanometer.	Refer to user manual	P
12.2	Instructions for use		P
12.2.1	General		P
	The instructions for use shall include:		P
	the intended use of the non-automated sphygmomanometer, in particular:	Refer to “INTENDED USE” in user manual	P
	—intended medical indication		P
	—any known restrictions on use or contra-indication(s) to the use of the non-automated sphygmomanometer		P
	—intended patient population		P
	a brief description of the non-automated sphygmomanometer, including its significant physical and performance characteristics		P
	all information necessary to operate the non-automated sphygmomanometer in accordance with its specification		P
	how the non-automated sphygmomanometer functions		P
	an explanation of the selection of a suitable cuff size and application to the patient	Refer to “PATIENT” in user manual	P
	an explanation of operating steps of the non-automated sphygmomanometer including		P
	- adjustment of the pressure reduction rate		P

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Clause	Requirement + Test	Result - Remark	Verdict
	- patient position in normal use (see Bibliography [18]，including		P
	- comfortably seated		P
	- legs uncrossed		P
	- back and arm supported		P
	-middle of cuff on the upper arm at the level of the right atrium		P
	- a recommendation that the patient relax as much as possible and not talk or move during the measurement procedure		P
	- a recommendation that 5 min should elapse before the first reading is taken		P
	- operator position in normal use		P
	- a recommendation for the use of K5 in auscultation of adults		P
	- a recommendation for the use of K4 in auscultation of children aged 3 to 12		N/A
	- a recommendation for the use of K5 in auscultation of pregnant female patients, unless sounds are audible with the cuff deflated, in which case K4 should be used (see Bibliography [181)		N/A
	the information required in 4.4		P
	a description of all markings on the non-automated sphygmomanometer		P
	for cuffs, the information required in 4.6		P
	the nature and frequency of the maintenance needed to ensure that the non-automated sphygmomanometer operates accurately and safely at all times	Refer to “MAINTENANCE” in user manual	P
	if installation of the non-automated sphygmomanometer or its parts is required, a reference to where the installation instructions are to be found (e.g. the technical description)		P
	the nominal range of cuff pressure measurement (see 7.1.2)		P
	a statement, if applicable, that the performance of the non-automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude	Refer to “SPECIFICATIONS” in user manual	P
	for non-automated sphygmomanometers intended for use in environmental conditions beyond those specified in this part of ISO 81060，the limits of the error of the cuff pressure indication over those environmental conditions;		P

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Clause	Requirement + Test	Result - Remark	Verdict
	if the non-automated sphygmomanometer is intended to be dismantled by the operator, the correct method of reassembly		P
	recommended storage conditions		P
	internal nominal diameter and tolerance of the tube containing mercury	No such parts	N/A
	detailed instructions for the safe handling of mercury		N/A
	for portable non-automated sphygmomanometers, a caution regarding the necessity to maintain the verticality of the mercury column to perform a valid measurement		N/A
	information concerning the disposal of the non-automated sphygmomanometer or components thereof		P
12.2.2	Cleaning, disinfection and sterilization	Refer to “MAINTENANCE” in user manual	P
	For non-automated sphygmomanometer parts or accessories that can become contaminated through contact with the patient or with body fluids or expired gases during normal use, the instructions for use shall contain		P
	the details about cleaning and disinfection or cleaning and sterilization methods that may be used		P
	a list of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such non-automated sphygmomanometer parts or accessories can tolerate.		P
12.2.3	Maintenance	Refer to “MAINTENANCE” in user manual	P
	The instructions for use shall inform the operator or responsible organization that the reference manometer used for calibration should be traceable against international or national measurement standards		P
	The instructions for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the non-automated sphygmomanometer.		P
	Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by service personnel, including the recommended frequency to be applied, but not necessarily including details about the actual performance of such maintenance.		P
	For non-automated sphygmomanometers containing rechargeable batteries that are intended		P

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Clause	Requirement + Test	Result - Remark	Verdict
	to be maintained by anyone other than service personnel, the instructions for use shall contain instructions to ensure adequate maintenance.		
12.2.4	Accessories，supplementary equipment, used material	Refer to “WARRANTY” in user manual	P
	The instructions for use shall include a list of accessories, detachable parts and materials that the manufacturer has indicated are intended for use with the non-automated sphygmomanometer		P
12.2.5	Environmental protection		P
	identify any risks associated with the disposal of waste products, residues, etc., and of the non-automated sphygmomanometer and accessories at the end of their expected service life;	Refer to “WARRANTY” in user manual	P
	provide advice on minimizing these risks;		P
	provide a caution to comply with regional law when non-automated sphygmomanometer or accessory is discarded;		P
	provide a warning to comply with regional law when a mercury sphygmomanometer is discarded.	No mercury used	N/A
12.2.6	Reference to the technical description		P
	The instructions for use shall contain the information specified in 12.3 or a reference to where the material specified in 12.3 is to be found (e.g. in a service manual)		P
12.3	Technical description		P
	The technical description shall provide all data that is essential for safe operation, transport and storage, and measures or conditions necessary for installing the non-automated sphygmomanometer, and preparing it for use.		P
	the permissible environmental conditions of use including conditions for transport and storage	Refer to “SPECIFICATIONS” in user manual	P
	all characteristics of the non-automated sphygmomanometer, including range(s) and accuracy of the displayed values or an indication where they can be found	Refer to “CALIBRATION CHECK” in user manual	P
	any correction factors to be applied for changes in ambient conditions		P
	a warning statement that addresses the hazards that can result from unauthorized modification of the non-automated sphygmomanometer, e.g. a statement to the effect: —“WARNING: No modification of this equipment is allowed.” —“WARNING: Do not modify this equipment without		P

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Clause	Requirement + Test	Result - Remark	Verdict
	authorization of the manufacturer." —"WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure its continued safe use."		
	the information required in 4.4		P
	for cuffs, the information required in 4.6		P
	a brief description of the non-automated sphygmomanometer, how the non-automated sphygmomanometer functions and its significant physical and performance characteristics		P
	instructions for correct replacement of interchangeable or detachable parts that the manufacturer specifies as replaceable by service personnel		P
	for a non-automated sphygmomanometer containing a mercury manometer	No mercury used	N/A
	- the nominal internal diameter and tolerance of the tube containing mercury (see 8.1),	No mercury used	N/A
	- the material of the tube containing mercury	No mercury used	N/A
	where replacement of a component could result in an unacceptable risk, appropriate warnings that identify the nature of the hazard and, if the manufacturer specifies the component as replaceable by service personnel, all information necessary to safely replace the component	No unacceptable risk	N/A
	a statement that the manufacturer will make available on request, circuit diagrams, component part lists, descriptions, calibration instructions or other information that will assist service personnel to repair those parts of the non-automated sphygmomanometer that are designated by the manufacturer as repairable by service personnel		P
	Instructions for the operator or responsible organization in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.	Refer to "MAINTENANCE" in user manual	P
	The manufacturer may designate the minimum qualifications for service personnel. If present, these requirements shall be documented in the technical description		N/A

6.4.1/6.4.3 Non-automated sphygmomanometers	**P**

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Part under test	Drop distance d	Function	Result
Sphygmomanometers	25cm	Function normally by performing the tests described in 7.1.1.	Can work normally
Supplementary information:			

6.4.2 Non-automated sphygmomanometers for transport		**P**
Test Item	Function	Result
Shock	Function normally by performing the tests described in 7.1.1.	No damage
Broad-band random vibration	Function normally by performing the tests described in 7.1.1.	No damage
Supplementary information: The IEC 60068-2-27:2008 shock test is subcontracted. The IEC 60068-2-64:2008 vibration test is subcontracted. refer to Attachment File1		

7.1.1 Limits of the error of the cuff pressure indication			**P**
Reference manometer (mmHg)	Sphygmomanometer Display (mmHg)	Display Difference (mmHg)	Remarks (≦± 3mmHg)
50	53	3	Pass
100	98	2	Pass
150	150	0	Pass
200	203	3	Pass
250	248	2	Pass
300	301	1	Pass
Supplementary information:			

7.2.1 Air leakage (Increasing)			**P**
Measure point(mmHg)	Start reading (mmHg)	5min reading (mmHg)	Leakage rate (mmHg/min)
50	50	48	0.4
100	100	96	0.8
150	150	145	1.0
200	200	196	0.8
250	250	241	1.8
Supplementary information:			

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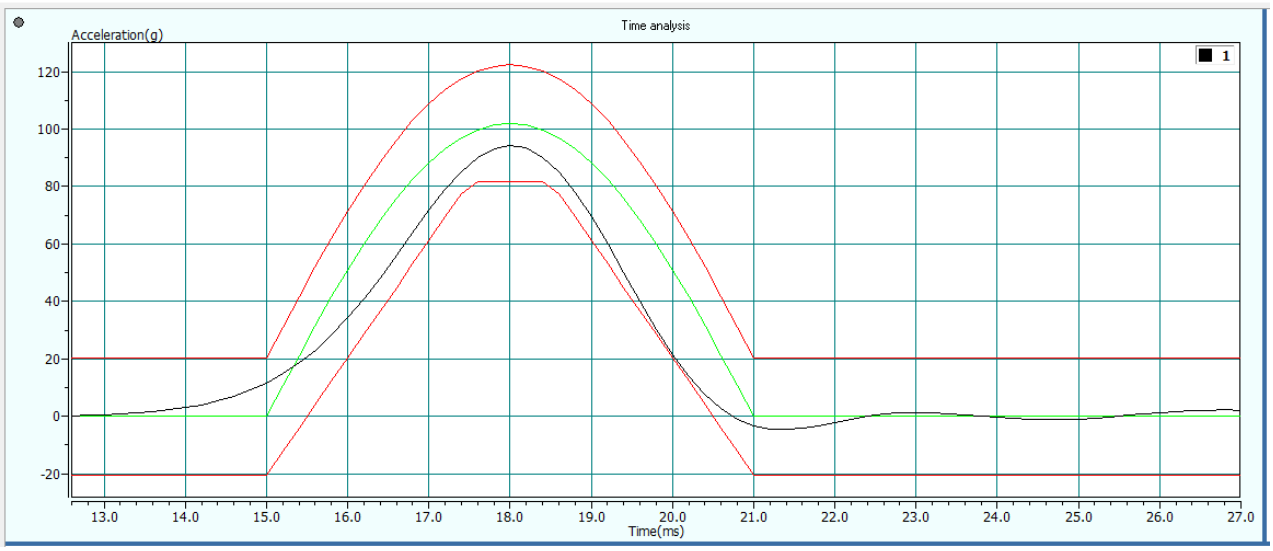
7.2.1 Air leakage (Decreasing)			**P**
Measure point(mmHg)	Start reading (mmHg)	5min reading (mmHg)	Leakage rate (mmHg/min)
250	250	241	1.8
200	200	191	1.8
150	150	145	1.0
100	100	97	0.6
50	50	49	0.2
Supplementary information:			

7.2.3 Rapid exhaust			**P**
Manometer pressure at start (mmHg)	Manometer stop pressure (mmHg)	Time to 15 mmHg	Requirement time
260	15	4.8s	10s
Supplementary information:			

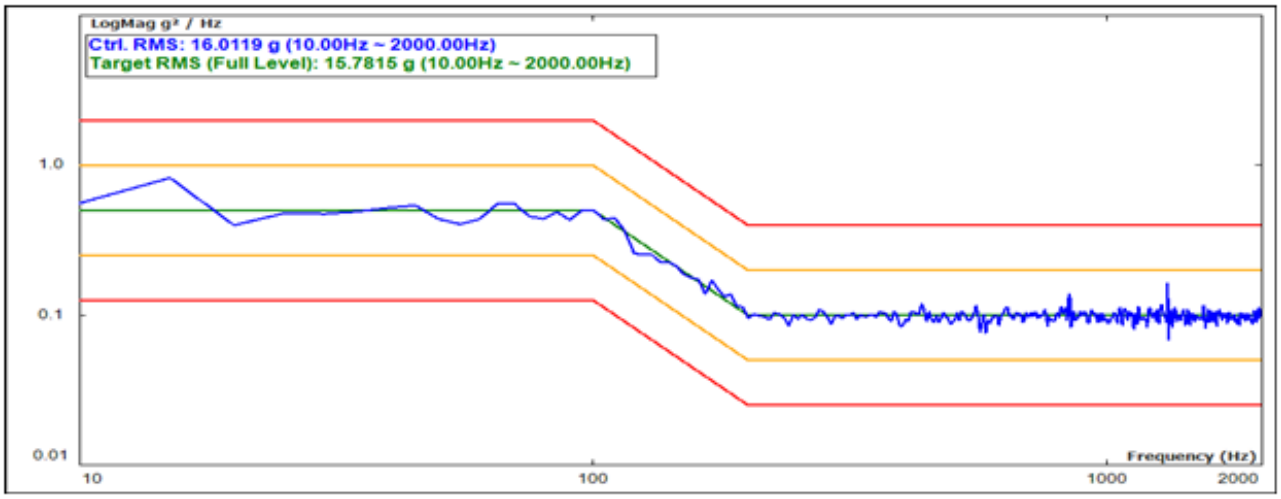
7.4	**Dynamic response**	**P**
Manometer pressure at start (mmHg)	Time to 50 mmHg	Requirement time
200	1s	1.5s
Supplementary information:		

9.3 Hysteresis error			**P**
Reference manometer(mmHg)	Tested Sphygmomanometer(mmHg)	Display Difference(mmHg)	Remarks (≦ ±4mmHg)
50	52	2	Pass
100	101	1	Pass
150	153	3	Pass
200	201	1	Pass
250	249	1	Pass
300	298	2	Pass
Supplementary information:			

Attachment File1 Shock test & vibration test curve

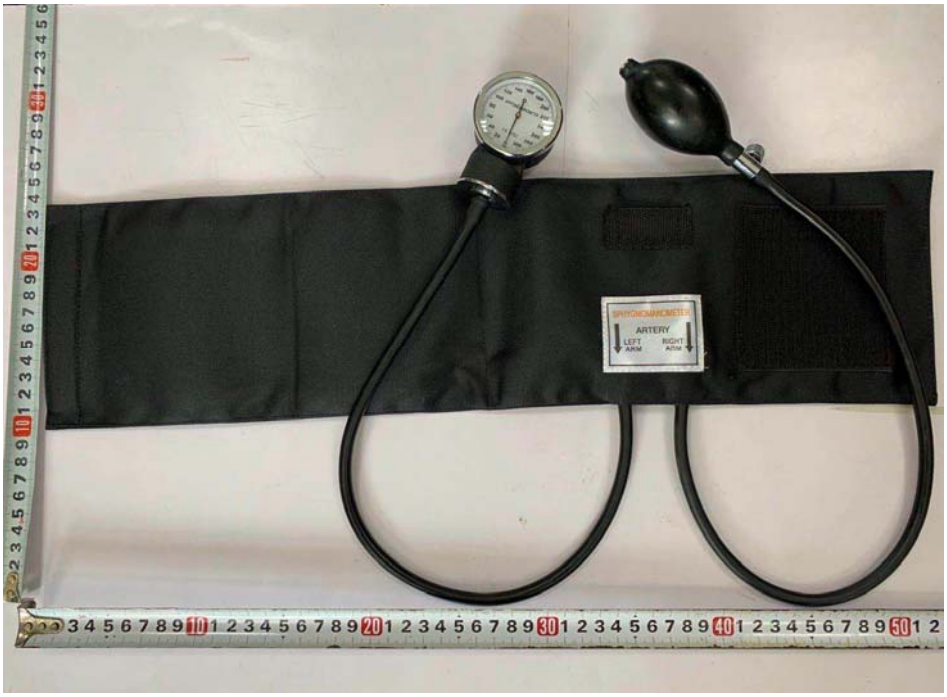


1. Shock test curve



2. Vibration test curve

Attachment photos of the DUT

Photo 1 [√] complete	

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