

Revision of R 149 *Non-invasive automated sphygmomanometers*

Part 5: Verification and inspection procedures

TC18/SC1/p6

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Foreword

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Non-invasive automated sphygmomanometers

Part 5: Verification and inspection procedures

Introduction

This Recommendation specifies verification and inspection procedures for Non-invasive automated sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

i) Description of the category of instrument

The basic components of a sphygmomanometer are a cuff that can be wrapped around a patient's limb, a system for applying and releasing pressure to the bladder in the cuff, and a means of measuring and displaying blood pressure values automatically.

Note 1: Specific device types included in this category are: sphygmomanometers for self-measurement, blood pressure monitors and multi-parameter patient monitors used for home healthcare, or public use.

Note 2: Components of a sphygmomanometer include: manometer, cuff, valve for deflation (often in combination with the valve for rapidly exhausting the pneumatic system), pump for inflation of the bladder, and connection tubing.

ii) Units of measurement

The units used to indicate blood pressure shall be either the kilopascal (kPa) or the millimetre of mercury (mmHg).

Verification and inspection procedures

1 Principles

After type approval has been granted, verification shall be carried out before the sphygmomanometer is put into use and during its lifetime. Each instrument of an approved type of sphygmomanometer shall be verified periodically in accordance with applicable metrological laws and regulations of a member state, or after repair. Verification should be conducted at intervals defined by national metrological regulations. In absence of such specifications, a recommended interval of 1–2 years may be applied depending on usage frequency.

Verification requirements may be selected appropriate to your national regulations. National verification requirements shall take precedence.

1.1 Maximum permissible errors of the cuff pressure indication under ambient conditions

For any set of conditions within the ambient temperature range from 10 °C to 40 °C and the relative humidity range from 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 measurement range shall be ± 0.4 kPa (± 3 mmHg) or ± 2 % of the reading, whichever is greater.

At verification, testing can be conducted at any set of climatic conditions within the temperature range from 10 °C to 40 °C and the relative humidity range from 15 % to 85 %. A climatic chamber is not required.

1.2 Repeatability of blood pressure indication

For any set of conditions within the ambient temperature range from 10 °C to 40 °C and the relative humidity in the range from 15 % to 85 %, the experimental standard deviation of the blood pressure indication of the sphygmomanometer shall not exceed 0.4 kPa (3 mmHg).

At verification, testing can be conducted at any set of climatic conditions within the temperature range from 10 °C to 40 °C and the relative humidity range from 15 % to 85 %. A climatic chamber is not required.

1.3 Pressure reduction rate of devices using the auscultatory method

The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of 0.3 kPa/pulse to 0.4 kPa/pulse (2 mmHg/pulse to 3 mmHg/pulse) shall be maintained.

2 Test equipment

The apparatus consists of the following:

- rigid metal vessel with a capacity of $500 \text{ ml} \pm 25 \text{ ml}$;
- calibrated reference manometer with maximum permissible error within $\pm 0.1 \text{ kPa}$ ($\pm 0.8 \text{ mmHg}$);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors;
- hoses with an overall length of no more than 600 mm;
- time measuring device with a maximum permissible error of 0.1 s;
- artificial or human limbs (see Notes under 3.3);
- recording unit.

3 Test methods

3.1 Maximum permissible errors of the cuff pressure indication under ambient conditions

Replace the cuff with the vessel. Connect both the calibrated reference manometer and the manometer of the device to be tested to the pneumatic system by means of a T-piece connector and hoses (see Figure 1). Set the automated sphygmomanometer to the test mode according to the information provided by the manufacturer. Connect the additional pressure generator into the pressure system by means of another T-piece connector. Carry out the test in pressure steps of not more than 6.7 kPa (50 mmHg) between 0.0 kPa (0 mmHg) and the maximum pressure of the scale range.¹

Note: If the device includes proprietary test software or diagnostic interface, its use shall be documented and validated for accuracy and repeatability.

Express the results as the differences between the cuff pressure indication of the automated sphygmomanometer to be tested and the corresponding readings of the reference manometer.

¹ In case of doubt about the linearity, spot checks should be carried out or the width of the pressure steps should be reduced, i.e. from the normally recommended 6.7 kPa (50 mmHg) to 2.7 kPa (20 mmHg). This also applies to Table 1 in R 149-3.

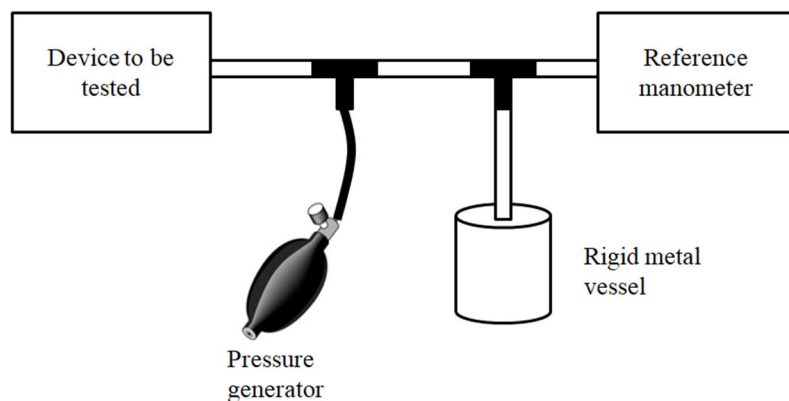


Figure 1 – Measurement system for determining the limits of error of the cuff pressure indication

3.2 Repeatability of blood pressure indication

Connect the automated sphygmomanometer with the cuff and the patient simulator, which is set to the target systolic and diastolic blood pressure values (see Figure 2).

Perform 20 consecutive measurements at any temperature in the range 10 °C to 40 °C and for any relative humidity in the range 15 % to 85 %.

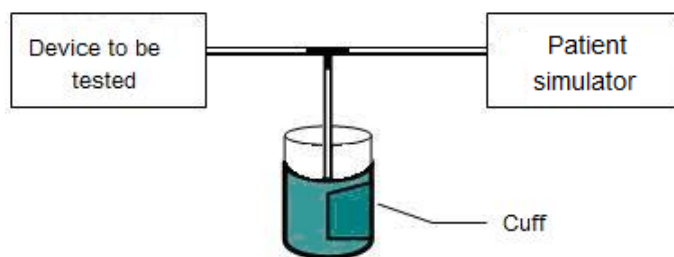


Figure 2 – Setup for testing the repeatability of blood pressure indication using a patient simulator

Note 1: If the device is being tested for adult blood pressure measurement, the generated signal values of the patient simulator shall be set: systolic: 16.0 kPa (120 mmHg); diastolic: 10.7 kPa (80 mmHg); pulse rate: 80 min⁻¹.

Note 2: If the device is being tested for neonatal/infant blood pressure measurement, the generated signal values of the patient simulator shall be set: systolic: 9.3 kPa (70 mmHg); diastolic: 5.3 kPa (40 mmHg); pulse rate: 140 min⁻¹.

3.3 Air leakage of the pneumatic system

Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min). Check compliance by means of the following test. If, because of technical reasons, the test as described in this subclause cannot be performed, use an alternative test procedure specified by the manufacturer.

Testing shall be carried out at environmental conditions.

Before beginning the test, allow the automated sphygmomanometer to reach working temperature.

Wrap the cuff around the cylinder such that, for devices measuring at the upper arm and the thigh, the circumference of the applied cuff does not exceed that of the cylinder by more than 7 %.

Carry out the test over the whole measurement range at at least three equally spaced pressure steps (e.g. 6.7 kPa (50 mmHg), 20.0 kPa (150 mmHg), and 33.3 kPa (250 mmHg)). Because the thermodynamic equilibrium is influenced by decreasing or increasing the pressure when changing to the next pressure step, wait at least 60 s before reading the values. Test the air leakage over a period of 5 minutes and determine the measured value from this.

Note 1: Electro-mechanical pumps which are a part of the system may be used for the test. Valves which are permanently opened may be disconnected for the test.

Note 2: For this test no calibrated reference manometer is required because the cuff pressure display of the unit under test can be used when the error of the cuff pressure indication is considered. The advantage of this test is that the unit under test is in its original configuration. Additional connections can increase the leakage.

3.4 Pressure reduction rate of devices using the auscultatory method

Measure the pressure reduction rate either on human subjects or artificial limbs.

Note 1: The recommendation is to use artificial limbs, but measurements performed with human volunteers are acceptable.

Note 2: Two limb sizes should be used, being equal to the upper and lower limits of the limb circumferences with which a particular cuff size is recommended for use.

Note 3: It is recommended that the characteristics of the artificial limbs reflect some elastic characteristics of human limbs.

Because the cuff deflation rate may be influenced by the way in which a cuff is applied, apply and remove the cuff for each of at least ten repeated measurements on at least two different limb sizes. The deflation may be reset.

Connect the calibrated reference manometer to the cuff by means of a T-piece. Connect the output part of the calibrated reference manometer to the recording unit.

Determine the rate of pressure reduction (e.g. by graphical evaluation and drawing tangents) at the pressure values 8.0 kPa (60 mmHg), 16.0 kPa (120 mmHg) and 24.0 kPa (180 mmHg). Calculate the pressure reduction rate as the mean value calculated separately for the pressure values 8.0 kPa (60 mmHg), 16.0 kPa (120 mmHg) and 24.0 kPa (180 mmHg) and for the various limb circumferences.

If the pressure reduction rate is dependent on the pulse, record the pulse rate. In this case, express the result as cuff deflation rate per pulse.

For pulse-dependent deflation, the pulse rate should be measured in real-time or simulated, and device behaviour should be recorded and compared against expected deflation timing with $\pm 10\%$ tolerance.

Note: Manually operated deflation valves should be easily adjustable to these values.

4 Presentation of results

4.1 Summary of test results for verification

Clause from R 149-1 and R 149-2 (see R 149-3 for Test report format)			Subject	Test result	Passed	Failed
R 149-1	R 149-2	R 149-3				
5.1	1	2	Maximum permissible errors of the cuff pressure indication under ambient conditions			
5.5	3	6	Repeatability of blood pressure indication			
6.4.1	5	8	Air leakage of the pneumatic system			
6.4.2	6	9	Pressure reduction rate for deflation valves			

Note 1: The sequence of the different tests is arbitrary; it follows the sequence of the different clauses in the text. The sequence of testing is at the discretion of the person conducting the tests.

Note 2: To be considered as approved or verified, an instrument must have successfully passed all the applicable tests.

Note 3: R 149-3 is only for formatting and traceability purposes.

4.2 Verification report

General information

Number of report	
Applicant's name	
Applicant's address	
Object	
Type	
Serial number	
Manufacturer's name	
Manufacturer's address	

Date of receipt	
Date/period of tests	
Name(s) of test engineer(s)	
Test laboratory's name	
Test laboratory's address	
Test apparatus used for the test	(model, serial number, expanded uncertainty, calibration certificate)
Name of the responsible person	
Date of signature	
Stamp (where applicable) and signature of the responsible person	
Remarks :	

Test data

Maximum permissible errors of the cuff pressure indication under ambient conditions
 Temperature °C and % relative humidity Unit ()

Pressure	1st reading	2nd reading	Mean	Error

maximum error:

Repeatability of blood pressure indication

Temperature ____ °C and ____ % relative humidity Unit (____)

Measurement no.	1	2	3	4	5	6	7	8	9	10
Systolic blood pressure										
Diastolic blood pressure										

Measurement no.	11	12	13	14	15	16	17	18	19	20
Systolic blood pressure										
Diastolic blood pressure										

Experimental standard deviation of systolic blood pressure: _____ mmHg

Experimental standard deviation of diastolic blood pressure: _____ mmHg

Pressure reduction rate for deflation valves:

Verification conclusion

Passed ☐

Failed ☐

Remarks: