

Revision of R 148 *Non-invasive non-automated sphygmomanometers*

Part 5: Verification and inspection procedures

TC18/SC1/p5

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# Non-invasive non-automated sphygmomanometers

## Part 5: Verification and inspection procedures

### Introduction

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

Included within the scope of this Recommendation are non-invasive non-automated sphygmomanometers ~~with a mechanical or integrated electro-mechanical pressure sensing element and display, utilising an inflatable cuff with a display and used in conjunction with a stethoscope or any other manual methods for estimating blood pressure. used in conjunction with a stethoscope or other manual methods for detecting Korotkoff sounds and for cuff inflation.~~

#### i) Description of the category of instrument

The basic components of a sphygmomanometer are a manometer for measuring and displaying pressure in the bladder and a pneumatic system for applying and releasing pressure in the bladder.

The pneumatic system includes a cuff that can be wrapped around a patient's limb, tubing, connectors, a valve for deflation (often in combination with rapid exhaust valve), transducers and a hand pump or electromechanical pump. For pressure control, electro-mechanical components may be used. If fitted with an electromechanical pump, ensure it is disabled prior to connecting external pressure sources. Verify that its presence does not interfere with manual test procedures.

Sphygmomanometers typically use either a mercury or an aneroid manometer or another mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff.

#### 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. The periodicity of verification shall follow national regulations. Where not specified, a recommended interval of 1~2 years may be applied based on risk analysis and usage intensity.

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 an ambient temperature range from 15 °C to 25 °C and a relative humidity range from 15 % to 85 % for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure ~~at any point of the scale range~~ shall be  $\pm 0.4$  kPa ( $\pm 3$  mmHg) at any point of the scale range for sphygmomanometers.

At verification, testing can be conducted at any set of climatic conditions within the temperature range from 15 °C to 25 °C and the relative humidity range from 15 % to 85 %. A climatic chamber is not required.

### 1.2 Air leakage

Air leakage shall not exceed a pressure drop of 0.5 kPa/min (4 mmHg/min).

## 2 Test equipment

The apparatus consists of the following:

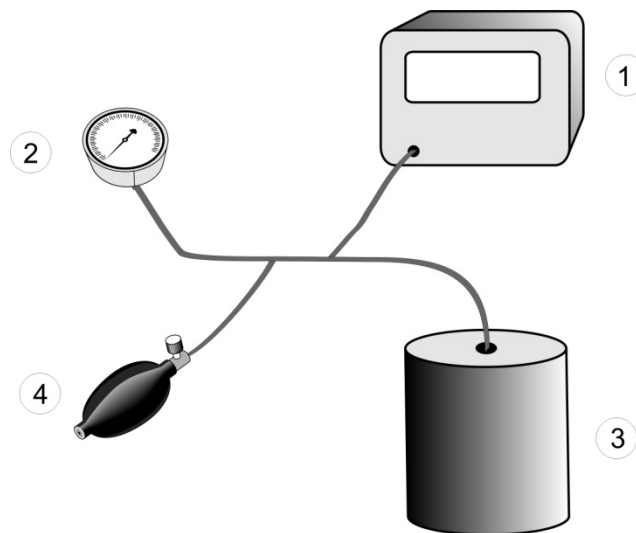
- rigid ~~metal~~ vessel with a capacity of 500 ml  $\pm$  25 ml;
- calibrated reference manometer with maximum permissible error within  $\pm 0.1$  kPa ( $\pm 0.8$  mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors;
- hoses with an overall length of no more than 600 mm.
- time measuring device with a maximum permissible error of 0.1 s.

## 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). After disabling the electromechanical pump (if fitted), connect the 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 kPa (0 mmHg) and the maximum pressure of the scale range.

Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer.



1 – Reference manometer; 2 – Manometer of the device to be tested;  
3 – ~~Metal~~ Vessel; 4 – Pressure generator

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

### 3.2 Air leakage

Wrap the cuff around the cylinder of an appropriate size, such that the internal circumference of the applied cuff exceeds the circumference cylinder by  $(7 \pm 2) \%$ .

*Note:* Electro-mechanical pumps which are part of the device may be used for the test.

Perform the test at three pressure levels that are evenly distributed across the entire measurement range (e.g. 6.7 kPa (50 mmHg), 20.0 kPa (150 mmHg), and 33.3 kPa (250 mmHg)). ~~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)).~~ Test the air leakage over a period of 5 min and determine the measured value from this.

Express the air leakage as the rate of the pressure loss per minute (e.g., kPa/min or mmHg/min).

## 4 Presentation of results

#### 4.1 Summary of test results for verification

| <a href="#">Clause from R 148-1 and R 148-2 (see R 148-3 for Test report format)</a> <del>Clause from</del> |         |         | Subject                                                                             | Test result | Passed | Failed |
|-------------------------------------------------------------------------------------------------------------|---------|---------|-------------------------------------------------------------------------------------|-------------|--------|--------|
| R 148-1                                                                                                     | R 148-2 | R 148-3 |                                                                                     |             |        |        |
| 5.1                                                                                                         | 1       | 2       | Maximum permissible errors of the cuff pressure indication under ambient conditions |             |        |        |
| 6.2.1                                                                                                       | 4       | 5       | Air leakage                                                                         |             |        |        |

*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.

#### 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) <u>All test apparatus shall have a valid calibration certificate traceable to national or international standards. The expanded uncertainty shall be documented and considered during evaluation.</u> |
| Name of the responsible person                                   |                                                                                                                                                                                                                                                                             |
| Date of signature                                                |                                                                                                                                                                                                                                                                             |
| Stamp (where applicable) and signature of the responsible person |                                                                                                                                                                                                                                                                             |
| Remarks:                                                         |                                                                                                                                                                                                                                                                             |

## Test data

Temperature: ..... °C and Relative Humidity:..... %RH relative humidity ..... Unit (.....)

| Pressure | 1st reading | 2nd reading | Mean | Error |
|----------|-------------|-------------|------|-------|
|          |             |             |      |       |
|          |             |             |      |       |
|          |             |             |      |       |
|          |             |             |      |       |



|  |  |  |  |  |
|--|--|--|--|--|
|  |  |  |  |  |
|  |  |  |  |  |

maximum error:

Air leakage (the rate of the pressure loss per minute) :

**Verification conclusion**

Passed ☐

Failed ☐

*Note:* For the full structure and layout of the test report, refer to OIML R 148-3.