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Non-invasive sphygmomanometers —

Part 5:
Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*.

A list of all parts in the ISO 81060 series and the IEC 81060 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The repeatability and reproducibility of *NIBP simulators* intended to test *automated sphygmomanometers* should be ensured, as they are often used to check the stability of an *automated sphygmomanometer* over time of use, after repair or to compare *automated sphygmomanometers* of the same type.

This document should be used to determine the quality of the *NIBP simulator* once it is produced, sold or received by the *responsible organization* and thereafter periodically tested for the purpose of quality control. It specifies acceptance limits for repeatability and reproducibility regarding the amplitude and shape of the generated oscillations. Indirectly, it also tests the repeatability and reproducibility of the shape of the envelope of generated oscillations over (*cuff*) pressure, since the document specifies measurements at different static pressures at the same setting of the *NIBP simulator*, thus measuring the envelope at 2 or 3 pressure values. If there are reasons to doubt that this number is too low, the test might be extended to 5 or more static pressures. It is not practically hard to do, to compare the whole envelope of the generated oscillations by a dynamic *process*, i.e. by recording the data during the deflation or inflation of the *cuff*. This kind of dynamic measurement would require an identical deflation or inflation curve. Technically, this can be done by a closed-loop *process*, which is not a simple task. Since the oscillations at constant pressures are not different from those during small pressure changes, the proposed approach is adequate.

The tests described in this document should be repeated periodically to ensure the long-term stability of the *NIBP simulator*.

In this document, it is intended to balance the tests necessary to ensure the stability of the *NIBP simulator* required to work properly and the effort to do it. Many of the recordings required can be evaluated under different aspects.

In this document, the following print types are used:

— requirements, conformance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— *defined terms and test methods: italic type;*

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

— "shall" means that conformance with a requirement or a test is mandatory for conformance with this document;

— "should" means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe a possibility or capability; and

— "must" is used to express an external constraint.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

Non-invasive sphygmomanometers —

Part 5: Requirements for the repeatability and reproducibility of NIBP simulators for testing of automated non-invasive sphygmomanometers

1 Scope

This document specifies requirements for the repeatability and reproducibility of *non-invasive blood pressure* (*NIBP*) simulators intended to test *automated sphygmomanometers* utilizing the oscillometric non-continuous method only.

In addition, the pulse rate set on the *NIBP simulator* is tested.

This document is not intended to relate the signals, generated by the *NIBP simulator*, to the oscillometric signal recorded in a *cuff* attached to a human. It does not intend to test the interaction between the *NIBP simulator* and the tested *automated sphygmomanometer* (e.g. the agreement of the set values of the *NIBP simulator* and the displayed values of the tested *automated sphygmomanometer* or the properties of the *cuff* and tubing, such as design or elastic properties).

NOTE 1 These parameters can be tested separately in a *clinical investigation* or by using different special test setups.

This document does not check whether or not the *NIBP simulator* is able to test the accuracy of the absolute *blood pressure* value of oscillometric *automated sphygmomanometers*.

NOTE 2 Usually this is tested by a *clinical investigation* according ISO 81060-2 or other protocols.

This document is applicable to *NIBP simulators* testing *automated sphygmomanometers* for adults, children and neonates at the upper arm, thigh etc. and *automated sphygmomanometers* measuring at the wrist.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 81060-1:2007, *Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type*

IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 80601-2-30:2018, *Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14155:2011, ISO 81060-1:2007, IEC 60601-1:2005+AMD1:2012, IEC 60601-2-30:2018 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

NOTE An index of defined terms can be found in Annex B.

3.1
*** non-invasive blood pressure stimulator**
NIBP simulator
device generating artificial *blood pressure* oscillations in the *pneumatic system* of *automated sphygmomanometers*, which is used to test *automated sphygmomanometers*

Note 1 to entry: *NIBP simulators* are not able to confirm the accuracy of an *automated sphygmomanometer*. They are used to assess the repeatability and reproducibility of the *automated sphygmomanometer*.

Note 2 to entry: Not all *NIBP simulators* and *automated sphygmomanometer* are compatible.

4 Requirement for technical parameters

4.1 Accuracy of the static pressure

4.1.1 Apparatus

4.1.1.1 Calibrated reference pressure manometer, with an accuracy of ≤±0,3 mmHg (≤±0,04 kPa).

4.1.1.2 (Hand) pump.

4.1.1.3 Tubing.

4.1.1.4 T-pieces.

4.1.1.5 Air reservoirs, with a capacity of (500 ± 25) ml and (100 ± 10) ml.

NOTE The setup is shown in Figure 1.

4.1.2 Requirements

4.1.2.1 The minimum resolution of the *NIBP simulator* shall be 0,1 mmHg (0,013 kPa) or less.

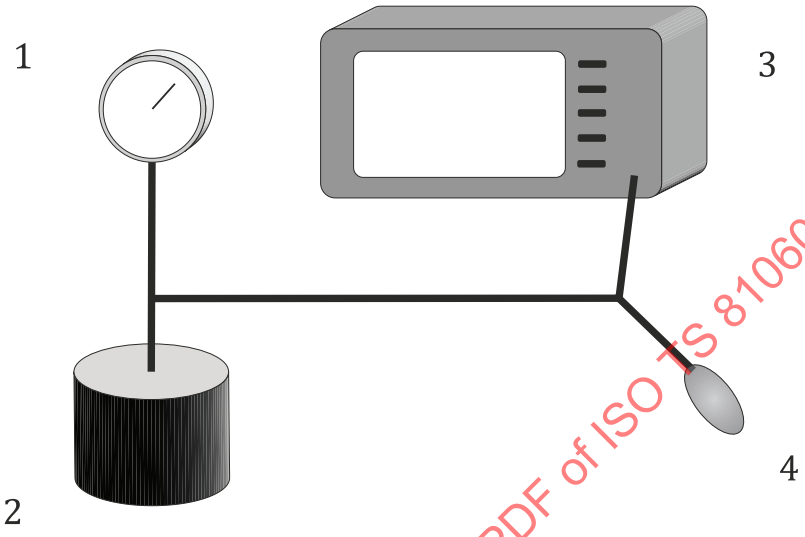
4.1.2.2 Over a temperature range from 15 °C to 25 °C and a relative humidity range from 15 % to 85 % (non-condensing) the maximum error for the measurement of the pressure at any point of the *nominal* measurement range shall be less than or equal to ±1,0 mmHg (±0,13 kPa), if not specified differently in the accompanying documents.

During the test, ensure that the temperature stays within 1 °C and that the relative humidity stays within 5 % of these values. Changes of the atmospheric pressure during the test can influence the results, thus e.g. the opening and closing of doors and windows should be avoided.

Check conformance with the following test:

Perform measurements in steps not greater than 50 mmHg (6,67 kPa) from 0 mmHg (0,00 kPa) to maximum *rated* pressure for increasing and decreasing pressures specified by the manufacturer. See Table 1.

NOTE There is no check on hysteresis because this is not a *type test*.



Key

1 reference manometer
2 air reservoir
3 *NIBP simulator*
4 pump

Figure 1 — Schematic drawing of a setup to test the static pressure measurement

Table 1 — Example of a table to record the accuracy of the static pressure

No.	Pressure, ref. mmHg [a]	Pressure, *NIBP simulator*, increasing mmHg [a]	Error (sim. –ref.), increasing mmHg [a]	Pressure, *NIBP simulator*, decreasing mmHg [a]	Error (sim. –ref.), decreasing mmHg [a]
1	0				
2	50				
3	100				
4	150				
5	200				
6	250				
7	300				

[a] 1 mmHg = 0,133 kPa.

4.2 Accuracy of the pulse rate

4.2.1 Apparatus

The apparatus specified in 4.1.1 and the following shall be used:

4.2.1.1 Recording unit with the following specification:

a) pressure measurement, with an accuracy of ≤±0,3 mmHg (≤±0,04 kPa);

b) pressure range, ≤500 mmHg, [typically up to 330 mmHg (44,0 kPa)];

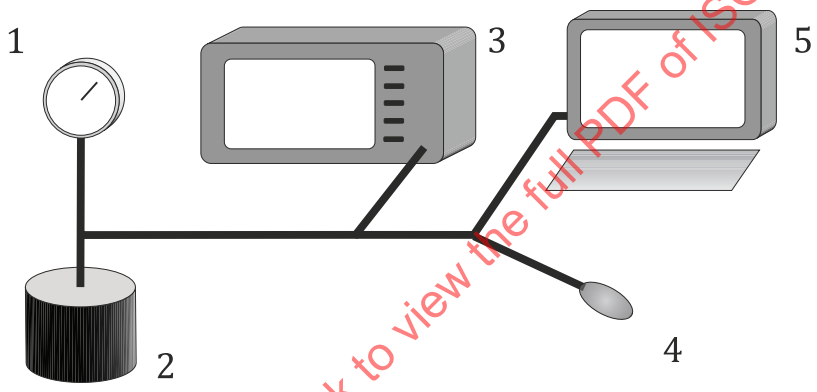
c) time base, with an accuracy of ≤±0,2 s;

d) recording time, ≥60 s;

e) analogue to digital converter, ≥12 bit;

f) sampling rate ≥100 Hz.

NOTE A schematic drawing of a setup to test the pulse rate is shown in Figure 2.



Key

1 reference manometer
2 air reservoir
3 *NIBP simulator*
4 pump
5 recording unit

Figure 2 — Schematic drawing of a setup to test the pulse rate and the repeatability and reproducibility of the oscillation amplitudes

4.2.2 Requirement

Over a temperature range from 15 °C to 25 °C and a relative humidity range from 15 % to 85 % (non-condensing) the maximum error for the measurement of the pulse rate at any selectable pulse rate shall be less than or equal to ±1,0 min^{-1}, if not specified differently in the accompanying documents.

During the test, ensure that the temperature stays within 1 °C and that the relative humidity stays within 5 % of these values.

Check conformance with the following test:

Record the signals generated by the *NIBP simulator* at applied constant pressures for at least 60 s for different *NIBP simulator* settings and different attached air reservoirs. The reservoir of 500 ml is used to simulate upper arm *cuffs* and the 100 ml reservoir is used to simulate wrist and neonatal *cuffs*.

Count the number of oscillations, n, in the time interval of 60 s, to determine the pulse rate from this recording. The number *n* represents the pulse rate in pulses per minute. Record at least three different pulse rates arbitrarily chosen for the adult mode and two different pulse rates arbitrarily chosen for the *neonatal mode*, if available.

To reduce the numbers of measurements the required data may be taken from the measurements performed in 4.3.

4.3 Repeatability of oscillation amplitudes

4.3.1 Apparatus

The apparatus specified in 4.2.1 and shown in Figure 2 shall be used.

4.3.2 Requirements

Over a temperature range from 15 °C to 25 °C and a relative humidity range from 15 % to 85 % (non-condensing) the experimental standard deviation of the oscillation amplitude (peak-to-peak value) of 10 repeated oscillations shall be less than or equal to 0,05 mmHg (0,007 kPa), if not otherwise specified in the accompanying documents.

During the test, ensure that the temperature stays within 1 °C and that the relative humidity stays within 5 %. Changes of the atmospheric pressure during the test can influence the results; thus e.g. the opening and closing of doors and windows should be avoided.

Calculate the mean value of the oscillation amplitude. This mean value becomes the reference value for the test on reproducibility (see 4.4.2).

Check conformance with the following test:

Record the signals generated by the *NIBP simulator* at applied constant pressures for at least 60 s for different *NIBP simulator* settings and different attached air reservoirs. The reservoir of 500 ml is used to simulate upper arm *cuffs* and the 100 ml reservoir is used to simulate wrist and neonatal *cuffs*. The recording shall last at least 60 s to allow the calculation of the experimental standard deviation of 10 peak-to-peak amplitudes of the generated oscillations for each parameter combination. Calculate the mean value for these 10 amplitudes, if the requirement for the standard deviation is met for each parameter combination.

Test the repeatability of the oscillation amplitude at static pressure levels, as indicated in Table 2 and Table 3. If the *NIBP simulator* cannot be set to the values given in Table 2 and Table 3, choose the nearest possible one.

4.4 Reproducibility of oscillation amplitudes

The reproducibility of the oscillation amplitude and the pulse rate shall be tested after repair and at regular intervals recommended by the manufacturer of the *NIBP simulator*, but not exceeding 2 years, at static pressure levels, as indicated in Table 2 and Table 3. The results shall be compared with the results from the initial or the last measurements previously performed.

4.4.1 Apparatus

The apparatus specified in 4.2.1 and shown in Figure 2 shall be used.

Table 2 — Example of *NIBP simulator* settings for adult mode for pressures in mmHg

***Cuff* site**	**Reservoir** ml	**Static pressure** mmHg [b]	***NIBP simulator***	
			systolic blood pressure / diastolic blood pressure mmHg [b]	**Pulse rate** [a] min^{-1}
upper arm or thigh	500	120	120 / 80	60
		80		60
		130	120 / 80	80
		100		80
		70		80
		120	120 / 80	120
		80		120
		100	120 / 80	40
				120
				160
		80	100 / 65	40
				60
		130	150 / 100	120
				160
wrist	100	120	120 / 80	60
		80		60
		130	120 / 80	80
		100		80
		70		80
		120	120 / 80	120
		80		120
		100	120 / 80	40
				120
				160
		80	100 / 65	40
				60
		130	150 / 100	120
				160

[a] Total = 28 recorded files.

[b] 1 mmHg = 0,133 kPa.

4.4.2 Requirements

Over a temperature range from 15 °C to 25 °C and a relative humidity range from 15 % to 85 % (non-condensing) the experimental standard deviation of the oscillation amplitude (peak-to-peak value) of 10 repeated oscillations shall be less than or equal to 0,05 mmHg (0,007 kPa), if not otherwise specified in the instruction for use.

During the test, ensure that the temperature stays within 1 °C and that the relative humidity stays within 5 % of these values. Changes of the atmospheric pressure during the test can influence the results, thus, e.g. the opening and closing of doors and windows should be avoided.

Calculate the mean value of the oscillation amplitude. Compare this mean value with the reference value determined in 4.3.2. The difference between the two values for each static pressure shall be less than or equal to ±0,1 mmHg (±0,013 kPa).

The 500 ml reservoir shall be used for *automated sphygmomanometers* measuring at the upper arm or thigh, and the 100 ml reservoir for *automated sphygmomanometers* measuring at the wrist and neonatal *cuffs*.

Check conformance with the following test:

Record the signals generated by the *NIBP simulator* at applied constant pressures for at least 60 s for different *NIBP simulator* settings and different attached air reservoirs. For each parameter combination the recording shall last at least 60 s to allow the calculation of the experimental standard deviation of 10 peak-to-peak amplitudes of the generated oscillations. Calculate the mean value for these 10 amplitudes, if the requirement for the standard deviation is met.

Test the repeatability of the oscillation amplitude at static pressure levels, as indicated in Table 2 and Table 3.

Table 3 — Example of *NIBP simulator* settings for *neonatal mode* for pressures in mmHg

Reservoir	**Static pressure** [a]	***NIBP simulator***	
		systolic blood pressure / diastolic blood pressure mmHg [b]	**Pulse rate** [a] min^{-1}
100	80	80 / 50	120
	60		
	40		
	80	80 / 50	≥140
	60		
	40		
[a] Total = 6 recorded files.			
[b] 1 mmHg = 0,133 kPa.			

4.5 Repeatability and reproducibility of the envelope of the oscillations

As the requirements of 4.3 and 4.4 include sufficient characteristic parameters to ensure the repeatability and reproducibility of the envelope of the oscillations, no additional requirements are necessary.

4.6 Repeatability of the shape of oscillations

4.6.1 *Procedure*

Take the data from the measurements performed in 4.3 for the repeatability of the shape of oscillations recordings. Analyse the correlation of the repeatability of the shape of oscillations and the averaged shapes of different times of recording.

4.6.2 Requirement

The squared correlation coefficient, R^2, shall be equal to or greater than 0,998.

Check conformance with the following test:

Choose the 3 data files of the *NIBP simulator* setting *systolic blood pressure* = 120 mmHg (16,0 kPa) / *diastolic blood pressure* = 80 mmHg (10,7 kPa), pulse rate 80 min^{-1} at static pressures of 130 mmHg (17,3 kPa), 100 mmHg (13,3 kPa), and 70 mmHg (9,3 kPa) for the *cuff* sites upper arm or thigh and wrist respectively. If the *NIBP simulator* has a *neonatal mode* add 2 data files for the *NIBP simulator* setting *systolic blood pressure* = 80 mmHg (10,7 kPa) / *diastolic blood pressure* = 50 mmHg (6,7 kPa), pulse rate 120 min^{-1} at static pressures of 80 mmHg (10,7 kPa), 60 mmHg (8,0 kPa), and 40 mmHg (5,3 kPa).

Use the averaged shape of 10 repeated oscillations in the first 15 s of the recording and the averaged shape of 10 repeated oscillations in the last 15 s of the recording to determine the squared correlation coefficient, R^2.

4.7 Reproducibility of the shape of oscillation

4.7.1 *Procedure*

Take the data from the measurements performed in 4.3 for the test of the reproducibility of the shape of oscillations recordings recorded in the *process* of periodic tests and re-tests of the *NIBP simulator* months or years ago. Take the other half of the data from the present measurements. If this test is the initial test of the *NIBP simulator*, additional data shall be recorded one or more days later.

The reproducibility of the shape of oscillations is determined by analysing the correlation of averaged shapes of different times of recording.

4.7.2 Requirement

The squared correlation coefficient, R^2, shall be equal to or greater than 0,998. The amplitude shall not vary by more than 5 %.

Check conformance with the following test:

Select two data sets, the current and an older one. The older one shall either be the last collected data set or the initial data set of the *NIBP simulator*.

Choose the 3 data files of the *NIBP simulator* setting *systolic blood pressure* = 120 mmHg (16,0 kPa) / *diastolic blood pressure* = 80 mmHg (10,7 kPa), pulse rate 80 min^{-1} at static pressures of 130 mmHg (17,3 kPa), 100 mmHg (13,3 kPa) and 70 mmHg (9,3 kPa) for the *cuff* sites upper arm or thigh and wrist respectively. If the *NIBP simulator* has a *neonatal mode* add two data files for the *NIBP simulator* setting *systolic blood pressure* = 80 mmHg (10,7 kPa) / *diastolic blood pressure* = 50 mmHg (6,7 kPa), pulse rate 120 min^{-1} at static pressures of 80 mmHg (10,7 kPa), 60 mmHg (8,0 kPa) and 40 mmHg (5,3 kPa).

Use the averaged shape of 10 repeated oscillations in the first 15 s of the current recording and the averaged shape of 10 repeated oscillations in the first 15 s of the older recording to determine the squared correlation coefficient, R^2.