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Non-invasive sphygmomanometers —

Part 3: Clinical investigation of continuous automated measurement type

Sphygmomanomètres non invasifs —

Partie 3: Investigation clinique pour type à mesurage automatique continu

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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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 62D, *Electromedical equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

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 and www.iec.ch/national-committees.

Introduction

The number of continuously measuring non-invasive *automated sphygmomanometers* has increased significantly in the last 10 years. This document is intended to provide the necessary requirements for *clinical investigation* to ensure that the *essential performance* of these *sphygmomanometers* is at an adequate level, similar to those standards on *intermittent automated non-invasive sphygmomanometer*.

Non-invasive sphygmomanometers —

Part 3:
Clinical investigation of continuous automated measurement type

1 Scope

This document specifies the requirements and methods for the *clinical investigation* of *continuous automated non-invasive sphygmomanometers* used for the measurement of the *blood pressure* of a patient.

This document does not cover usability aspects such as the form and manner of the data display or output. This document does not specify a numerical threshold on the *minimum output period*. A *continuous automated non-invasive sphygmomanometer* providing *blood pressure* parameters (e.g., *systolic blood pressure*, *diastolic blood pressure* or *mean arterial pressure*) with an *output period* considerably larger than 30 s is not typically considered a *continuous automated non-invasive sphygmomanometer*.

This document covers both trending *continuous automated non-invasive sphygmomanometers* and absolute accuracy *continuous automated non-invasive sphygmomanometers* and focuses solely on requirements for the *clinical investigation*. Representation of output is not covered by this document.

NOTE 1 IEC 62366-1 provides requirements on the application of usability engineering to medical devices. The usability engineering *process* can be used to clarify for the intended user whether the displayed data concerns absolute accurate values or trending values.

The requirements and methods for the *clinical investigation* of *continuous automated non-invasive sphygmomanometers* provided in this document are applicable to any subject population, and any condition of use of the *continuous automated non-invasive sphygmomanometers*.

NOTE 2 Subject populations can, for example, be represented by age or weight ranges.

NOTE 3 This document does not provide a method to assess the effect of artefacts during the *clinical investigation* (e.g. motion artefacts induced by the movement of the subject or the movement of the platform supporting the subject).

This document specifies additional disclosure requirements for the *accompanying documents* of *continuous automated non-invasive sphygmomanometers* that have undergone *clinical investigation* according to this document.

This document is not applicable to:

— the *clinical investigation* of a *non-automated sphygmomanometer* as given in ISO 81060-1,

— the *clinical investigation* of an *intermittent automated non-invasive sphygmomanometer* as given in ISO 81060-2,

— an *automated non-invasive sphygmomanometer* as given in IEC 80601-2-30, or

— *invasive blood pressure monitoring equipment* as given in IEC 60601-2-34.

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 14155:2020, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

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

ISO 81060-2:2018+Amd 1:2020, *Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-2-34:2011, *Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance of invasive blood pressure monitoring equipment*

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 14155:2020, ISO 14971:2019, ISO 81060-1:2007, ISO 81060-2:2018+Amd 1:2020, IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-2-34:2011, IEC 80601-2-30:2018, and the following apply.

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

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

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

3.1
change evaluation interval
time period for which a *continuous automated non-invasive sphygmomanometer* is demonstrated to track changes in *blood pressure*

3.2
continuous automated non-invasive sphygmomanometer
ME equipment estimating *blood pressure* from each cardiac cycle without arterial puncture and providing a continual series of *blood pressure* parameters

Note 1 to entry: While the *continuous automated non-invasive sphygmomanometer* analyses each heart cycle, this does not mean the *continuous automated non-invasive sphygmomanometer* always uses data from each heart cycle to estimate the *blood pressure*. Not using data from a specific heart cycle can be useful, for example, to omit data from premature ventricular contractions.

Note 2 to entry: The only *blood pressure* parameters considered in this document are *systolic blood pressure*, *diastolic blood pressure* and *mean arterial pressure*.

Note 3 to entry: This document does not cover usability aspects such as the form and manner of the data display or output. Hence, this document does not specify a numerical threshold on the *minimum output period*. However, a *continuous automated non-invasive sphygmomanometer* providing *blood pressure* parameters (e.g. *systolic blood pressure*, *diastolic blood pressure* or *mean arterial pressure*) with an *output period* considerably larger than 30 s are not typically considered a *continuous automated non-invasive sphygmomanometer*.

Note 4 to entry: There is guidance or rationale for this definition contained in Clause A.2.

3.3
determination
determination value
result of the *process* of estimating *blood pressure* by the *continuous automated non-invasive sphygmomanometer*

[SOURCE: IEC 80601-2-30:2018, 201.3.203; modified: replaced *automated sphygmomanometer* by *continuous automated non-invasive sphygmomanometer*]

3.4
initialization
re-initialization
process of the *continuous automated non-invasive sphygmomanometer* to determine subject- or condition-specific parameters needed to estimate *blood pressure*

Note 1 to entry: In this document, the term *initialization* is used for the initial *initialization; re-initialization* is used for the repeated *initialization process* during the measurement period.

3.5
intermittent automated non-invasive sphygmomanometer
ME equipment estimating *blood pressure* from a number of cardiac cycles without arterial puncture and providing a single set of *blood pressure* parameters

Note 1 to entry: The only *blood pressure* parameters considered in this document are *systolic blood pressure*, *diastolic blood pressure* and *mean arterial pressure*.

Note 2 to entry: There is guidance or rationale for this definition contained in Clause A.2.

3.6
output period
period of time after which a specific *continuous automated non-invasive sphygmomanometer* provides updated values for *blood pressure* parameters (e.g. *systolic blood pressure, diastolic blood pressure* or *mean arterial pressure*)

Note 1 to entry: The *output period* may be constituted by a number of heart beats.

3.7
paired measurements
two measurements of a subject's *blood pressure*, one of which is recorded with the *continuous automated non-invasive sphygmomanometer* and the other with the *reference* method from the same cardiac cycles

Note 1 to entry: The two measurements of *blood pressure* can be two measurements of *systolic blood pressure*, two measurements of *diastolic blood pressure* or two measurements of *mean arterial pressure*.

3.8
paired values
pair of *blood pressure* values as a result of a *paired measurement*

Note 1 to entry: The pair of *blood pressure* values can be a pair of *systolic blood pressure*, a pair of *diastolic blood pressure* or a pair of *mean arterial pressure* values.

3.9
reference measurement
procedure with established accuracy used for the *clinical investigation* of a *continuous automated non-invasive sphygmomanometer*

3.10
reference reading
result of the *process* of measuring *blood pressure* using a *reference* method

Note 1 to entry: The result can be a *systolic blood pressure*, a *diastolic blood pressure* or a *mean arterial pressure*.

4 General requirements for the *clinical investigation*

4.1 Good clinical practice

The *clinical investigation* shall conform with the requirements of ISO 14155.

NOTE Some authorities having jurisdiction can have additional requirements.

Check conformance by application of the requirements of ISO 14155.

4.2 General

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

a) The conditions of the *clinical investigation* shall represent as closely as possible the intended conditions of use of the *continuous automated non-invasive sphygmomanometers.*

   1) If a target population is specified in the instructions for use, the subjects of the *clinical investigation* shall represent that target population as closely as possible.

      NOTE 2 Since a *clinical investigation* as described in this document requires an invasive *reference, reference invasive blood pressure monitoring equipment* will be inserted in all subjects included in the *clinical investigation*. However, some target populations for the *continuous automated non-invasive sphygmomanometers* can include patients who would not be monitored by *reference invasive blood pressure monitoring equipment* (e.g. invasive monitoring is contraindicated or not recommended for the patient's critical care due to local infection at site, prior surgery/stents in intended vasculature, etc.). Therefore, there is a limit as to how representative the subjects of the *clinical investigation* can be for the target population.

b) For the *clinical investigation*, different postures (e.g. supine or sitting) shall be evaluated to determine if they affect the performance of the *continuous automated non-invasive sphygmomanometer*.

   1) If different postures affect the performance of the *continuous automated non-invasive sphygmomanometer*, any *clinical investigation* shall be performed with all subjects in the same posture.

c) Set up the *continuous automated non-invasive sphygmomanometer* according to the instructions for use.

d) *Continuous automated non-invasive sphygmomanometers* that continuously and non-invasively provide accurate *blood pressure determinations* are classified as Type A.

e) In contrast to Type A, *continuous automated non-invasive sphygmomanometers* that continuously and non-invasively provide *blood pressure* values that can have an unknown constant subject-specific offset are classified as Type T.

   NOTE 3 Type T *continuous automated non-invasive sphygmomanometers* (trending *continuous automated non-invasive sphygmomanometers*) provide *blood pressure* values that are not intended to be absolutely accurate. However, since these *blood pressure* values have an unknown constant subject-specific offset, these *continuous automated non-invasive sphygmomanometers* enable representations of accurate *blood pressure* changes over time.

   NOTE 4 Since the *blood pressure* values provided by Type T *continuous automated non-invasive sphygmomanometers* (trending *continuous automated non-invasive sphygmomanometers*) have an unknown constant subject-specific offset, users of the *continuous automated non-invasive sphygmomanometers* could be misled to think the values displayed on the screen are intended to be absolutely accurate, when in reality they are not. This document does not cover usability study that would be used to address this matter.

f) *Continuous automated non-invasive sphygmomanometer* tests shall be performed according to Table 1.

g) If *initialization* of the *continuous automated non-invasive sphygmomanometer* is necessary, the *reference* device may not be used for this *initialization* during the *clinical investigation*.

Table 1 provides different sets of tests for Type A and Type T *continuous automated non-invasive sphygmomanometers*.

Table 1 — Applicable testing depending on functionality

		Type A	Type T
Performance assessments	5.1 Method for the accuracy of *blood pressure determination*	applicable	—
	5.2 Method for stability	applicable	applicable
	5.3 Method for *blood pressure* changes	applicable	applicable

4.3 *Reference* method

4.3.1 *Reference invasive blood pressure monitoring equipment*

NOTE 1 There is guidance or rationale for this subclause contained in Clause A.2.

a) A *continuous automated non-invasive sphygmomanometer* shall be clinically investigated by using *reference invasive blood pressure monitoring equipment*.

b) *Reference invasive blood pressure monitoring equipment* shall conform with the requirements of IEC 60601-2-34.

c) The natural frequency and damping coefficient of the *reference invasive blood pressure monitoring equipment* shall be examined and optimised to meet dynamic requirements for each subject. See Reference [1].

d) The *reference invasive blood pressure monitoring equipment* shall be referenced to the level of the right atrium.

e) Appropriate measures shall be taken to remove air bubbles and clots from the system prior to taking the *reference measurements*.

NOTE 2 The ability to accurately measure *blood pressure* could be degraded by the presence of air bubbles or blood clots in the catheter/transducer system.

f) *Reference invasive blood pressure monitoring equipment* that does not directly output the *blood pressure* waveform or beat-to-beat data may be modified to permit such data collection.

Check conformance by inspection of the *clinical investigation report*.

4.3.2 Subject requirements

4.3.2.1 Number

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) A *clinical investigation* shall consist of repeated measurements performed on test subjects.

b) The number of repeated measurements per subject shall be determined according to the *procedure* in 4.5.3.

c) The number of subjects shall be determined according to the *procedure* in 4.5.3.

Check conformance by inspection of the *clinical investigation report*.

4.3.2.2 Gender distribution

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) At least 30 % of the subjects shall be male.

b) At least 30 % of the subjects shall be female.

Check conformance by inspection of the *clinical investigation report*.

4.3.2.3 Age distribution

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

4.3.2.3.1 General

If a *continuous automated non-invasive sphygmomanometer* is intended for use in more than one of the age groups defined in 4.3.2.3.2, 4.3.2.3.3 and 4.3.2.3.4, each applicable age group shall be investigated separately.

4.3.2.3.2 *Sphygmomanometers* intended for use in subjects aged greater than 12 years

For a *continuous automated non-invasive sphygmomanometer* intended for use in subjects aged greater than 12 years, the age of every subject included in the *clinical investigation* shall be greater than 12 years, with the following age distribution:

a) 40 % shall be at least 50 years of age;

b) 25 % shall be at least 60 years of age; and

c) 10 % shall be at least 70 years of age.

Check conformance by inspection of the *accompanying document* and the *clinical investigation report*.

4.3.2.3.3 *Sphygmomanometers* intended for use in subjects aged between 1 year and 12 years

a) For a *continuous automated non-invasive sphygmomanometer* intended for use in subjects aged between 1 year and 12 years, the age of every subject included in the *clinical investigation* shall be between 1 year and 12 years.

b) Subjects aged between 1 year and 12 years are exempt from

   1) the gender distribution requirements of 4.3.2.2, and

   2) the *blood pressure* distribution requirements of 4.3.3.

Check conformance by inspection of the *accompanying document* and the *clinical investigation report*.

4.3.2.3.4 *Sphygmomanometers* intended for use in subjects of less than 1 year of age

a) A *continuous automated non-invasive sphygmomanometer* intended for use in subjects of less than 1 year of age, shall be investigated in that subject population.

b) The following age or weight ranges are required for a *clinical investigation* of *continuous automated non-invasive sphygmomanometers* intended for use in subjects of less than 1 year of age:

   1) at least 20 % of the subjects shall be less than 2 000 g in weight;

   2) at least 20 % of the subjects shall be 2 000 g to 3 000 g in weight;

   3) at least 20 % of the subjects shall be more than 3 000 g in weight; and

4) at least 20 % of the subjects shall be at least 29 days of age.

c) The remaining subjects may be from any of the above age or weight groups in order to fulfil the sample size requirement.

NOTE A subject can be in more than one category simultaneously.

d) Subjects of less than 1 year of age are exempt from

1) the gender distribution requirements of 4.3.2.2, and

2) the *blood pressure* distribution requirements of 4.3.3.

Check conformance by inspection of the *accompanying document* and the *clinical investigation report*.

4.3.2.4 Special subject populations

NOTE There is guidance or rationale for this subclause contained in Clause A.2.

a) When there is evidence that a certain subject characteristic might affect the performance of a *continuous automated non-invasive sphygmomanometer*, and if this is within its *intended use*, that population (which is well defined by such subject characteristics) shall be considered a special subject population.

b) The *continuous automated non-invasive sphygmomanometer* shall be investigated across the range of the subject characteristics that is within its *intended use*.

c) Unless otherwise justified, each special subject population identified shall be investigated separately.

d) The instructions for use of the *continuous automated non-invasive sphygmomanometer* shall disclose a summary of the definition of all special subject populations identified per clause 4.3.2.4 a).

Check conformance by inspection of the *accompanying document* and the *clinical investigation report*.

4.3.3 *Blood pressure* distribution

For the data included in the analysis of the method for the accuracy of *blood pressure determination* (see 5.1) the following requirements apply.

a) If the *continuous automated non-invasive sphygmomanometer* is intended to output *systolic blood pressure*, the following shall be fulfilled.

1) At least 5 % of the *reference readings* shall have a *systolic blood pressure* less than or equal to 90 mmHg (12,00 kPa).

2) At least 20 % of the *reference readings* shall have a *systolic blood pressure* less than or equal to 110 mmHg (14,67 kPa).

3) At least 20 % of the *reference readings* shall have a *systolic blood pressure* greater than 110 mmHg (14,67 kPa) and less than 140 mmHg (18,67 kPa).

4) At least 20 % of the *reference readings* shall have a *systolic blood pressure* greater than or equal to 140 mmHg (18,67 kPa).