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Non-invasive sphygmomanometers —

Part 3:
Clinical investigation of continuous automated measurement type

Sphygmomanomètres non invasifs —

Partie 3: Validation clinique pour type à mesurage automatique continu

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1.

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 document 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO and IEC shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

ISO/IEC 81060-3 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee 62D, *Electromedical equipment*, in accordance with ISO/IEC mode of cooperation 5.

Introduction

The number of continuously measuring non-invasive *automated sphygmomanometers* has increased significantly in the last 10 years. This standard 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*.

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 standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— “shall” means that conformance with a requirement or a test is mandatory for conformance with this standard;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this standard;

— “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 3:
Clinical investigation of continuous automated measurement type

1 Scope

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

Since this document covers both trending devices and absolute accuracy devices 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 which can be used to clarify for the intended user whether the shown data concerns absolute accurate values or trending values.

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

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

NOTE 3 Conditions of use can, for example, refer to ambulatory *blood pressure* monitoring, stress testing *blood pressure* monitoring and *blood pressure* monitors for the *home healthcare environment* or self-measurement as well as use in professional healthcare facility or the emergency medical service environment (EMS).

This document specifies additional disclosure requirements for the *accompanying documents* of *continuous non-invasive automated 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 sphygmomanometer* as given in ISO 81060-2, an *intermittent 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.

NOTE Informative references are listed in the Bibliography.

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

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

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

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

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

IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

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

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

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

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

Note 1 to entry For convenience, the sources of all defined terms used in this document are given in Annex C.

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

3.2
continuous non-invasive automated sphygmomanometer
device able to estimate *blood pressure* from the pulse wave of each heart cycle without arterial punctureNote 1 to entry: While the *continuous non-invasive automated sphygmomanometer* is able to estimate the *blood pressure* from the pulse wave of each heart cycle, this does not mean the device needs to use data from the pulse wave at each heart cycle. Not using data from a pulse wave at a specific heart cycle can be useful, for example to omit data from premature ventricular contractions.Note 2 to entry: The *manufacturer* may choose the form and manner of the data display or output.

3.3
initialization
re-initialization
process of the *continuous non-invasive automated sphygmomanometer* to determine subject- or condition-specific parameters needed to estimate the *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 *process* during the measurement period.

3.4
intermittent automated non-invasive sphygmomanometer
automated sphygmomanometer estimating at intervals *systolic blood pressure, diastolic blood pressure* or *mean arterial pressure* values over a series of cardiac cycles

3.5
paired measurement
two measurements of the same *blood pressure* event within a subject's cardiac cycles, one of which is recorded with the *continuous non-invasive automated sphygmomanometer* and the other with the *reference* method

Note 1 to entry: An example for a *blood pressure* event is the occurrence of a *systolic* or a *diastolic blood pressure*.

3.6
paired values
pair of *blood pressure* values as a result of a *paired measurement*

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

3.7
reference measurement
procedure defined in this standard with established accuracy used for the *clinical investigation* of a *continuous non-invasive automated sphygmomanometer*

3.8
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 Requirements specific to the *reference* methods

4.1 * Invasive *reference* method

4.1.1 *Reference invasive blood pressure monitoring equipment*

a) *Reference invasive blood pressure monitoring equipment*:

   1) shall conform with the requirements of IEC 60601-2-34; except that

   2) the maximum allowable error shall be ± 2 mmHg (± 0,27 kPa).

b) The resonance frequency and damping coefficient of the *reference invasive blood pressure monitoring equipment* shall be shall be examined and optimised to meet dynamic requirements. See Reference[2].

c) The transducer shall be kept at the level of the heart.

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

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

e) *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.

4.1.2 Subject requirements

4.1.2.1 Number

A *clinical investigation* shall consist of

a) a minimum of 15 subjects,

b) with the exception of *sphygmomanometers* intended for use in neonates, infants and children of less than 3 years of age for which it shall consist of a minimum of 18 subjects.

Check conformance by inspection of the clinical investigation report.

4.1.2.2 Gender distribution

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.

4.1.2.3 * Age distribution

4.1.2.3.1 *Sphygmomanometers* intended for use in adults and adolescents

For a *continuous non-invasive automated sphygmomanometer* intended for use in adult or adolescent subjects, the age of every subject included in the *clinical investigation* shall be greater than 12 years.

NOTE Minimum total of 15 subjects.

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

4.1.2.3.2 *Sphygmomanometers* intended for use in children aged between 3 years and 12 years

a) For a *continuous non-invasive automated sphygmomanometer* intended for use in children aged between 3 years and 12 years, the age of every subject included in the *clinical investigation* shall be between 3 years and 12 years.

NOTE Minimum total of 15 subjects.

b) Children are exempt from:

1) the gender distribution requirements of 4.1.2.2; and

2) the *blood pressure* distribution requirements of 4.1.3.

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

4.1.2.3.3 *Sphygmomanometer* intended for use in neonates, infants and children of less than 3 years of age

a) A *continuous non-invasive automated sphygmomanometer* intended for use in neonates, infants and children of less than 3 years of age, shall be investigated in those subject populations.

b) The following age or weight ranges are required for a *neonatal mode clinical investigation*:

1) At least 3 subjects shall be less than 1 000 g in weight.

2) At least 3 subjects shall be 1 000 g to 2 000 g in weight.

3) At least 3 subjects shall be more than 2 000 g in weight.

4) At least 3 subjects shall be at least 29 days but not yet 1 year of age.

5) At least 3 subjects shall be at least 1 year but not yet 3 years of age.

c) The remaining subjects may be from any of the above age or weight groups in order to complete the sample size of 18.

NOTE 1 Minimum total of 18 subjects.

NOTE 2 A subject can be in more than one category simultaneously.

d) Neonates, infants and children of less than 3 years of age are exempt from:

1) the gender distribution requirements of 4.1.2.2; and

2) the *blood pressure* distribution requirements of 4.1.3.

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

4.1.2.4 * Special subject populations

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

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

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

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

4.1.3 *Blood pressure* distribution

a) At least 5 % of the *reference readings* shall have a *systolic blood pressure* less than or equal to 100 mmHg (13,33 kPa).

b) At least 5 % of the *reference readings* shall have a *systolic blood pressure* greater than or equal to 160 mmHg (21,33 kPa).

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

d) At least 5 % of the *reference readings* shall have a *diastolic blood pressure* less than or equal to 60 mmHg (8,00 kPa).

e) At least 5 % of the *reference readings* shall have a *diastolic blood pressure* greater than or equal to 100 mmHg (13,33 kPa).

f) At least 20 % of the *reference readings* shall have a *diastolic blood pressure* greater than or equal to 85 mmHg (11,33 kPa).

Check conformance by inspection of the clinical investigation report.

4.1.4 * Arterial *reference* site

a) Any *reference* site may be used for simultaneous comparison of intra-arterial *blood pressure* readings and *continuous non-invasive automated sphygmomanometer blood pressure determinations*, but

b) the instructions for use of the *continuous non-invasive automated sphygmomanometer* shall disclose the arterial site used as the *reference* site.

NOTE Different sites can produce different results due to the pressure difference between the central aorta and other arteries.

c) If the opposite limb is used as the *reference* site, the lateral difference in *blood pressure* may be determined and used according to 4.3.

d) A *continuous non-invasive automated sphygmomanometer* claiming to output central or aortic *blood pressure* values shall utilize a central or aortic arterial *reference* site for the *clinical investigation*.

Check conformance by inspection of the accompanying document.

4.2 Auscultatory *reference* method

4.2.1 *Reference sphygmomanometer*

a) The auscultatory *reference measurement* shall be performed on the upper arm.

b) Use a *reference sphygmomanometer* that conforms with the requirements of ISO 81060-1, except that the maximum permissible error shall be ± 1 mmHg (0,13 kPa).

4.2.2 Subject requirements

4.2.2.1 * Number

a) An auscultatory *reference sphygmomanometer* validation study shall consist of a minimum of 85 subjects.

b) For each parameter (e. g. *systolic* or *diastolic blood pressure*) to be validated at least 3 valid *paired measurements* shall be carried out for each subject.

NOTE This results in a minimum of 255 valid *paired values* for each parameter (e. g. *systolic* or *diastolic blood pressure*) to be validated.

Check conformance by inspection of the clinical investigation report.

4.2.2.2 * Gender distribution

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.

4.2.2.3 * Age distribution

4.2.2.3.1 *Sphygmomanometers* intended for use in adults and adolescents

For a *continuous non-invasive automated sphygmomanometer* intended only for use in adults or adolescent subjects, the age of every subject included in the *clinical investigation* shall be greater than 12 years.

NOTE Minimum total of 85 subjects.

4.2.2.3.2 *Sphygmomanometers* intended for use in children aged between 3 years and 12 years

a) For a *continuous non-invasive automated sphygmomanometer* intended for use in children aged between 3 years and 12 years, the age of every subject included in the *clinical investigation* shall be between 3 years and 12 years.

NOTE Minimum total of 85 subjects.

b) Children are exempt from:

1) the gender distribution requirements of 4.2.2.2; and

2) the *blood pressure* distribution requirements of 4.2.3.

NOTE The auscultatory *reference* method is not usable for neonates, infants and children of less than 3 years of age since it is not reliable in these subjects. In these cases, the invasive *reference* method can be used (see 4.1.2.3.3).

Check conformance by inspection of the clinical investigation report.

4.2.2.4 * Special subject populations

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

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

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

NOTE For certain special subject populations (e. g. subjects with atrial fibrillation) the auscultatory *reference* method is not usable since it is not reliable in these subjects. In these cases, the invasive *reference* method is an alternative (see 4.1).

Check conformance by inspection of the instructions for use and the clinical investigation report.

4.2.3 *Blood pressure* distribution

a) At least 5 % of the *reference readings* shall have a *systolic blood pressure* less than or equal to 100 mmHg (13,33 kPa).

b) At least 5 % of the *reference readings* shall have a *systolic blood pressure* greater than or equal to 160 mmHg (21,33 kPa).

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

d) At least 5 % of the *reference readings* shall have a *diastolic blood pressure* less than or equal to 60 mmHg (8,00 kPa).

e) At least 5 % of the *reference readings* shall have a *diastolic blood pressure* greater than or equal to 100 mmHg (13,33 kPa).

f) At least 20 % of the *reference readings* shall have a *diastolic blood pressure* greater than or equal to 85 mmHg (11,33 kPa).

4.2.4 * Observer preparation

a) Observers shall be trained.

b) Observers shall have sufficient practice in using a proper methodology for performing a *blood pressure reference measurement* by utilizing an accepted clinical protocol for *blood pressure reference measurement*. References [5],[6],[7],[8] and[9] contain additional information.

c) Each observer's recording of observations of the *reference sphygmomanometer* shall not be visible to the other observer.

d) The *determinations* of the *continuous non-invasive automated sphygmomanometer* shall not be visible to either of these observers.

EXAMPLE 1 Utilizing a third observer for recording the *determinations* of the *continuous non-invasive automated sphygmomanometer*.