INTERNATIONAL STANDARD

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Non-invasive sphygmomanometers —

Part 2: Clinical validation of automated measurement type

Sphygmomanomètres non invasifs —

Partie 2: Validation clinique pour type à mesurage automatique

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 81060-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical Equipment in Medical Practice*, Subcommittee 62D, *Electromedical Equipment*.

ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

— *Part 1: Requirements and test methods for non-automated measurement type*

— *Part 2: Clinical validation of automated measurement type*

Introduction

Determination of **blood pressure** is an important procedure that is clinically used to assess the health of the **patient**.

Frequent determination of **blood pressure** is routine during anaesthesia. **Blood pressure** serves to aid in drug titration and fluid management and to provide warning of conditions that could affect **patient** morbidity and mortality.

In this document, the following print types are used:

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

— notes and examples: smaller roman type;

— terms defined in this document: **bold type**.

Throughout this document, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Non-invasive sphygmomanometers —

Part 2:
Clinical validation of automated measurement type

1 Scope

This part of ISO 81060 specifies the requirements and methods for the clinical validation of **me equipment** used for the intermittent non-invasive automatic estimation of the arterial **blood pressure** by utilizing a **cuff**.

This part of ISO 81060 is applicable to all **sphygmomanometers** that sense or display pulsations, flow or sounds for the estimation, display or recording of **blood pressure**. These **sphygmomanometers** need not have automatic **cuff** inflation. This part of ISO 81060 covers **sphygmomanometers** intended for use in all **patient** populations (e.g. all age and weight ranges), and all conditions of use (e.g. ambulatory **blood pressure** monitoring, stress testing **blood pressure** monitoring and **blood pressure** monitors for the **home healthcare environment** or self-measurement).

EXAMPLE **Automated sphygmomanometer** as given in IEC 80601-2-30 validated by this part of ISO 81060.

This part of ISO 81060 specifies additional disclosure requirements for the **accompanying documents** of **sphygmomanometers** validated according to this part of ISO 81060.

This part of ISO 81060 is not applicable to the validation of **non-automated sphygmomanometers** as given in ISO 81060-1 or **invasive blood pressure monitoring equipment** as given in IEC 60601-2-34.

2 Normative references

The following referenced documents are indispensable for the application 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:—[1)], *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 80601-2-30:2009, *Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers*

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

IEC 60601-1-11, *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 home care applications*

IEC 60601-2-34:2000, *Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment*

1) To be published.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14155, IEC 80601-2-30, IEC 60601-1, IEC 60601-1-11, IEC 60601-2-34 and the following apply. For convenience, an alphabetized list of the sources of all defined terms used in this document is given in Annex D.

3.1
reference
established accuracy used for clinical evaluation of other instruments

3.2
sphygmomanometer
me equipment for non-invasive estimation of systemic arterial **blood pressure**

3.3
sphygmomanometer-under-test
sphygmomanometer being clinically evaluated

4 General requirements for validation studies

4.1 Validation methods

Sphygmomanometers other than **non-automated sphygmomanometers** shall be clinically validated either by using a non-invasive (auscultatory) **reference sphygmomanometer** or by using **reference invasive blood pressure monitoring equipment** according to this part of ISO 81060 in each mode of operation.

EXAMPLE 1 Adult and neonatal mode.

EXAMPLE 2 Slow and fast **cuff** deflation rate mode.

A clinical validation study shall be considered a **type test**.

Consider compliance with the requirements of this subclause to exist when the criteria of the relevant inspections and tests in this part of ISO 81060 are met.

4.2 Ethical requirements

All clinical validation studies shall comply with the requirements of ISO 14155. Validation with **reference invasive blood pressure monitoring equipment** should not be used for **patients** or subjects solely for the purpose of validating **sphygmomanometer** performance.

NOTE Some authorities with jurisdiction have additional requirements.

Check compliance by application of the requirements of ISO 14155.

5 Validation with auscultatory reference sphygmomanometer

5.1 Subject requirements

5.1.1 * Number

An auscultatory **reference sphygmomanometer** validation study shall consist of a minimum of 85 subjects. If not otherwise specified, at least three valid **blood pressure** determinations shall be taken for each subject. There shall be a minimum of 255 valid paired **blood pressure** determinations.

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

5.1.2 * Gender distribution

At least 30 % of the subjects shall be male and at least 30 % of the subjects shall be female.

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

5.1.3 * Age distribution

For a **sphygmomanometer** intended for use on adults and/or adolescent **patients**, the ages of the subjects included in the validation study shall be > 12 y.

NOTE 1 Minimum total of 85 subjects.

For a **sphygmomanometer** additionally intended for use in children, 35 child subjects aged between 3 y and 12 y shall be included in the validation study.

NOTE 2 Minimum total of 85 subjects.

If the **sphygmomanometer** has a special mode for children, in that mode, children shall be considered a special **patient** population (see 5.1.6). In that mode, children are exempt from the **blood pressure** distribution requirements of 5.1.5.

Children < 3 y shall not be included in an auscultatory **reference sphygmomanometer** validation study.

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

5.1.4 * Limb size distribution

For a **sphygmomanometer** intended for use with a single **cuff** size, at least 40 % of the subjects shall have a limb circumference which lies within the upper half of the specified range of use of the **cuff** and at least 40 % shall have a limb circumference within the lower half. At least 20 % of the subjects should have a limb circumference which lies within the upper quarter of the specified range of use of the **cuff** and at least 20 % should have a limb circumference within the lower quarter.

For a **sphygmomanometer** intended for use with multiple **cuff** sizes, each **cuff** size shall be tested on at least $1/(2 \times n)$ of the subjects, where n is the number of **cuff** sizes.

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

5.1.5 * Blood pressure distribution

At least 5 % of the readings shall have a **systolic blood pressure** ⩽ 100 mmHg.

At least 5 % of the readings shall have a **systolic blood pressure** ⩾ 160 mmHg.

At least 20 % of the readings shall have a **systolic blood pressure** ⩾ 140 mmHg.

At least 5 % of the readings shall have a **diastolic blood pressure** ⩽ 60 mmHg.

At least 5 % of the readings shall have a **diastolic blood pressure** ⩾ 100 mmHg.

At least 20 % of the readings shall have a **diastolic blood pressure** ⩾ 85 mmHg.

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

5.1.6 * Special patient populations

A **sphygmomanometer** that is intended for use in special **patient** populations where there is **objective evidence** that the accuracy of the **sphygmomanometer** might be problematic in those **patient** populations, shall be clinically evaluated in those **patient** populations. See also Clause 7.

EXAMPLES Use with **patients** who have atrial fibrillation (AF), premature ventricular beats and peripheral arterial disease (PAD).

If the **sphygmomanometer** has been evaluated according to the requirements of 5.1.1, it shall then be validated in at least an additional 35 special population subjects. Otherwise, the evaluation in accordance with the requirements of 5.1.1 shall only consist of subjects from the special population.

The special population shall be defined in clear terms and address the following attributes: gender (see 5.1.2), age (see 5.1.3), limb size (see 5.1.4) and **blood pressure** (see 5.1.5). A summary of this information shall be disclosed in the instructions for use.

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

5.2 Validation method with reference sphygmomanometer

5.2.1 * Subject preparation

See Reference [32].

Unless otherwise indicated by the instructions for use of the **sphygmomanometer-under-test**, position the subject such that the subject:

— is comfortable;

EXAMPLE Comfortably seated with legs uncrossed and feet flat on the floor.

— has the back, elbow and forearm supported;

— has the middle of **cuff** at the level of the right atrium of the heart.

Recommend that the subject be as relaxed as possible and that they avoid talking during the entire procedure. Before the first reading is taken, 5 min should elapse.

5.2.2 * Observer preparation

Observers should be trained in using a proper methodology for performing a resting **blood pressure** determination by utilizing an accepted clinical protocol for **blood pressure** measurement. See References [8], [28], [29], [32] and [45]. They should have sufficient practice in performing **blood pressure** determinations.

Each observer's recording of observations of the **reference sphygmomanometer** shall not be visible to the other observer. The readings of the **sphygmomanometer-under-test** shall not be visible to either of these observers.

EXAMPLE 1 Utilizing a third observer for recording the readings of the **sphygmomanometer-under-test**.

EXAMPLE 2 Utilizing an electronic means for recording the readings of the **sphygmomanometer-under-test**.

Instruct the observers to determine **diastolic blood pressure** as the last audible Korotkoff sound (fifth phase or K5), except in children between 3 y and 12 y, pregnant subjects, and subjects during exercise, where the fourth phase (K4) is used.

Instruct the observers to use K4 for the determination of **diastolic blood pressure** when sounds are audible with the **cuff** deflated.

Instruct the observers to record which Korotkoff sound has been used for the determination of **diastolic blood pressure**.

The Korotkoff sound used for determination of **diastolic blood pressure** in the clinical validation study shall be disclosed in the instructions for use of a **sphygmomanometer**.

EXAMPLE K5 was used on 65 subjects and K4 was used on 20 subjects.

5.2.3 * Reference determination

Two observers shall make simultaneous **blood pressure** determinations on each subject using a double stethoscope.

Unless the **sphygmomanometer-under-test** is intended for use during significantly irregular heart rhythm and if either observer detects significantly irregular heart rhythm, that determination shall be excluded.

EXAMPLES Bigeminy, trigeminy, isolated VPB, atrial fibrillation.

NOTE 1 Although evaluation of **blood pressure** in **patients** with atrial fibrillation is clinically important, there are currently no generally-accepted guidelines for determining the **blood pressure** in such individuals.

Any pair of observers' determinations with a difference greater than 4 mmHg shall be excluded. The observers' individual values of each determination shall be averaged to create the **reference blood pressure** determination.

The observer-to-observer differences shall be reviewed after completing a set of pairs of test-**reference** determinations. If any determinations are excluded, additional pair(s) of determinations shall be taken to ensure that the needed number of valid test-**reference** pairs are available. A maximum of eight pairs of determinations should be taken.

Use a **reference sphygmomanometer** that complies with the requirements of ISO 81060-1, except that the maximum permissible error shall be ± 1 mmHg. Reading of the values on the **reference sphygmomanometer** should be as accurate as possible. When reading the value on the **reference sphygmomanometer**, the observers should avoid parallax errors. Rounding has a negative effect on the results of the clinical validation.

NOTE 2 The **cuff** is considered part of the **reference sphygmomanometer**. A **cuff** that does not comply with ISO 81060-1 cannot be used.

5.2.4 Validation methods

5.2.4.1 Same arm simultaneous method

5.2.4.1.1 * Procedure

This method shall only be used with a **sphygmomanometer-under-test**:

— that is designed for use on the upper arm;

— where:

  — the continuous linear deflation rate is 2 mmHg/s to 3 mmHg/s or

  — for a **sphygmomanometer-under-test** that controls the deflation as a function of the pulse rate, the deflation rate is between 2 mmHg/pulse and 3 mmHg/pulse.

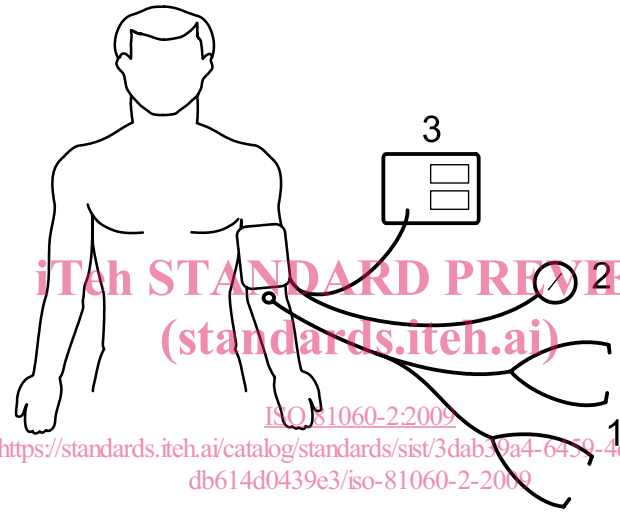
This method shall only be used when the **sphygmomanometer-under-test cuff** meets the requirements of ISO 81060-1.

The **sphygmomanometer-under-test** shall not deflate prior to the detection of the **reference diastolic blood pressure**. The **sphygmomanometer-under-test** may be modified to meet this criterion.

NOTE Valid same arm simultaneous determinations require the **sphygmomanometer-under-test** to inflate the **cuff** to at least 20 mmHg higher than the actual **systolic blood pressure**, as determined by the **reference sphygmomanometer**, and to at least 20 mmHg below the actual **diastolic blood pressure**, as determined by the **reference sphygmomanometer**.

Perform the following:

a) Have the observers using the **reference sphygmomanometer** and the **sphygmomanometer-under-test** simultaneously determine the subject's **blood pressure** utilizing the same **cuff** and inflation/deflation cycle (see Figure 1).



Key

1 double stethoscope

2 **reference sphygmomanometer** display

3 **sphygmomanometer-under-test**

Figure 1 — Illustration of same arm simultaneous method

b) Clear the **sphygmomanometer-under-test** memory of the previous determination and then wait at least 60 s.

EXAMPLE Switching the power off and on, removing the **blood pressure** module or issuing a reset command as methods to clear any memory of the previous determination.

c) These data points are not used in the determination of accuracy.

d) Have the observers using the **reference sphygmomanometer** and the **sphygmomanometer-under-test** simultaneously determine the subject's **blood pressure** utilizing the same **cuff** and inflation/deflation cycle.

e) Wait at least 60 s between determinations.

f) Repeat d) and e) until the needed number of determinations have been performed.

If an individual subject is unstable during the period of the test, two valid determination pairs may be used. In this case, additional subjects may be used to complete the method. No more than 10 % of the subjects shall have fewer than three valid determination pairs.

All data from a subject shall be excluded if any two **reference systolic blood pressure** determinations differ by more than 12 mmHg or if any two **reference diastolic blood pressure** determinations differ by more than 8 mmHg.

5.2.4.1.2 * Data analysis

The **sphygmomanometer-under-test** shall meet the following two criteria.

a) Criterion 1

For **systolic** and **diastolic blood pressures**, the mean error of determination, $\bar{x}_n$, of the n individual paired determinations of the **sphygmomanometer-under-test** and the **reference sphygmomanometer** for all subjects shall not be greater than 5,0 mmHg, with a standard deviation, s_n, no greater than 8,0 mmHg when calculated according to Equation (1) and Equation (2):

$$\bar{x}_n = \frac{1}{n} \times \sum_{i=1}^{n} \left(p_{\mathrm{sut}_i} - p_{\mathrm{ref}_i} \right) \tag{1}$$

$$s_n = \sqrt{\frac{1}{n-1} \times \sum_{i=1}^{n} \left(x_i - \bar{x}_n \right)^2} \tag{2}$$

where

$\bar{x}_n$ is the mean error;

x_i = $p_{\mathrm{sut}_i} - p_{\mathrm{ref}_i}$ of a paired **blood pressure** determination (**sphygmomanometer-under-test** – **reference sphygmomanometer**);

i is the index for the individual element;

n is the number of determinations.

$\bar{x}_n$ and s_n shall be calculated and expressed to 0,1 mmHg.

EXAMPLE 1 n = 255 for a **sphygmomanometer** intended for use in adults and/or adolescent **patients** (an 85 subject study).

EXAMPLE 2 n = 255 for a **sphygmomanometer** intended for use in adults and/or adolescents and children aged between 3 y and12 y (an 85 subject study).

EXAMPLE 3 n = 105 for a **sphygmomanometer** intended for a special intended use (a 35 subject study). The **sphygmomanometer** that has a separate 85 subject study.