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Non-invasive sphygmomanometers —

Part 2:
Clinical investigation of automated measurement type

Sphygmomanomètres non invasifs —

Partie 2: Validation clinique pour type à mesurage automatique

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[Revision of first edition (ISO 81060-2:2009)]

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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.

This second edition cancels and replaces the first edition (ISO 81060-2:2009), subclauses 5.2.4.3.1 and 6.2.4 of which have been technically revised. Numerous clarifications have been added and kPa equivalent values for the mmHg values have been included in the standard including the Criterion 2 requirements of 5.2.4.1.2.

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 investigation of automated measurement type*

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;

— test methods: *italic type*;

— terms defined in this document: SMALL CAPITALS TYPE.

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

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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.

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1 Scope

This part of ISO 81060 specifies the requirements and methods for the clinical investigation of ME EQUIPMENT used for the intermittent non-invasive automated 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 clinically investigated by this part of ISO 81060.

This part of ISO 81060 specifies additional disclosure requirements for the ACCOMPANYING DOCUMENTS of SPHYGMOMANOMETERS clinically investigated according to this part of ISO 81060.

This part of ISO 81060 is not applicable to clinical investigations of NON-AUTOMATED SPHYGMOMANOMETERS as given in ISO 81060-1 or INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as given in IEC 60601-2-34.

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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 14155:2011, *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 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 60601-1-11:2010, *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*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14155:2011, IEC 80601-2-30:2009 IEC 60601-1:2005, IEC 60601-1-11:2010, IEC 60601-2-34:2000 and the following apply. For convenience, an alphabetized index of defined terms is found beginning on page 43.

3.1
REFERENCE, adj
established accuracy used for clinical investigation 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 investigated

4 General requirements for clinical investigations

4.1 Clinical investigation methods

SPHYGMOMANOMETERS other than NON-AUTOMATED SPHYGMOMANOMETERS shall be clinically investigated 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 investigation 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 Good clinical practice

All clinical investigations shall comply with the requirements of ISO 14155:2011. Clinical investigation with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT should not be used for PATIENTS or subjects solely for the purpose of investigating SPHYGMOMANOMETER performance.

NOTE Some authorities with jurisdiction have additional requirements.

The following requirements that are more specific to a SPHYGMOMANOMETER prevail on the corresponding requirements of ISO 14155:2011.

Check compliance by application of the requirements of ISO 14155:2011.

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5 Clinical investigation with auscultatory REFERENCE SPHYGMOMANOMETER

5.1 Subject requirements

5.1.1 * Number

An auscultatory REFERENCE SPHYGMOMANOMETER clinical investigation 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 age of every subject included in the clinical investigation shall be greater than 12 years.

NOTE 1 Minimum total of 85 subjects.

For a SPHYGMOMANOMETER additionally intended for use in children, 35 child subjects aged between 3 years and 12 years shall be included in the clinical investigation.

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 such a study, children are exempt from the BLOOD PRESSURE distribution requirements of 5.1.5.

Children aged less than 3 years shall not be included in a clinical investigation utilizing auscultatory DETERMINATIONS by observers with a REFERENCE SPHYGMOMANOMETER.

Check compliance by inspection of the ACCOMPANYING DOCUMENT and the CLINICAL INVESTIGATION REPORT.

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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; and

— at least 20 % of the subjects shall have a limb circumference which lies within the upper quarter of the specified range of use of the CUFF and at least 20 % shall 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.

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Check compliance by inspection of the ACCOMPANYING DOCUMENT *and the* CLINICAL INVESTIGATION REPORT.

5.1.5 * BLOOD PRESSURE distribution

At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≤ 100 mmHg (13,33 kPa).

At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≥ 160 mmHg (21,33 kPa).

At least 20 % of the REFERENCE BLOOD PRESSURE readings shall have a SYSTOLIC BLOOD PRESSURE ≥ 140 mmHg (18,66 kPa).

At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≤ 60 mmHg (8,0 kPa).

At least 5 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≥ 100 mmHg (13,33 kPa).

At least 20 % of the REFERENCE BLOOD PRESSURE readings shall have a DIASTOLIC BLOOD PRESSURE ≥ 85 mmHg (11,33 kPa).

Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.

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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 investigated in those PATIENT populations.

NOTE Clause 7 has a specific example of a special PATIENT population with specific requirements.

If the SPHYGMOMANOMETER has been clinically investigated according to the requirements of 5.1.1 and 5.2, it shall then be clinically investigated in at least an additional 35 special population subjects. If the SPHYGMOMANOMETER has not been previously clinically investigated according to the requirements of 5.1.1 and 5.2, the clinical investigation in accordance with the requirements of 5.1.1 and 5.2 shall only consist of subjects from the special PATIENT population.

The special PATIENT 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 Clinical investigation method with REFERENCE SPHYGMOMANOMETER

5.2.1 * Subject preparation

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.

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

NOTE Additional details can be found in Reference [32].

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. References [8], [28], [29], [32] and [45] contain additional information. Observers 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 when Korotkoff sounds are still audible with the CUFF deflated or in children between 3 years and 12 years of age, where the fourth phase (K4) is used. If K4 is not audible in a child, either K5 is used or the subject is excluded.

NOTE Other than for children, K4 should be reserved for subjects in whom there is a large discrepancy between muffling and disappearance (with the latter at times approaching zero mmHg).

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 investigation shall be disclosed in the instructions for use of a SPHYGMOMANOMETER.

EXAMPLE 3 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 clinical investigation 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 (0,53 kPa) shall be excluded. The observers' individual values of each DETERMINATION shall be averaged according to Equation (1) to create the REFERENCE BLOOD PRESSURE DETERMINATION.

$$p_{ref_i} = \frac{p_{ref_{i,1}} + p_{ref_{i,2}}}{2} \quad (1)$$

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