TECHNICAL SPECIFICATION

ISO/TS 81060-5

First edition
2020-02

Non-invasive sphygmomanometers —

Part 5:

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

Reference number
ISO/TS 81060-5:2020(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

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).

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. 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 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*