
**Non-invasive sphygmomanometers —
Part 5:
Requirements for the repeatability
and reproducibility of NIBP simulators
for testing of automated non-invasive
sphygmomanometers**

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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.

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).

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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](#).

