

Third edition
2018-11

Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type

Sphygmomanomètres non invasifs —

*Partie 2: Investigation clinique pour type ponctuel à mesurage
automatique*



Reference number
ISO 81060-2:2018(E)

© ISO 2018

This is a preview of "ISO 81060-2:2018". [Click here to purchase the full version from the ANSI store.](#)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

This is a preview of "ISO 81060-2:2018". Click here to purchase the full version from the ANSI store.

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements for CLINICAL INVESTIGATIONS	2
4.1 CLINICAL INVESTIGATION methods.....	2
4.2 Good clinical practice.....	3
4.3 Status of previous CLINICAL INVESTIGATIONS.....	3
4.4 Disclosure of summary of CLINICAL INVESTIGATION.....	3
5 CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER	3
5.1 Subject requirements.....	3
5.1.1 * Number.....	3
5.1.2 * Gender distribution.....	3
5.1.3 * Age distribution.....	4
5.1.4 * Limb size distribution.....	4
5.1.5 Blood pressure distribution.....	4
5.1.6 * Special PATIENT populations.....	5
5.2 CLINICAL INVESTIGATION method with a REFERENCE SPHYGMOMANOMETER.....	5
5.2.1 * Subject preparation.....	5
5.2.2 * Observer preparation.....	6
5.2.3 * REFERENCE readings.....	6
5.2.4 CLINICAL INVESTIGATION methods.....	7
5.2.5 * Additional requirements for a SPHYGMOMANOMETER intended for use in exercise stress testing environments.....	15
5.2.6 * Additional requirements for a SPHYGMOMANOMETER intended for use in ambulatory monitoring.....	16
6 CLINICAL INVESTIGATION with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT	17
6.1 PATIENT requirements.....	17
6.1.1 Number.....	17
6.1.2 * Gender distribution.....	17
6.1.3 * Age distribution.....	17
6.1.4 Limb size distribution.....	18
6.1.5 BLOOD PRESSURE distribution.....	18
6.1.6 Special PATIENT populations.....	19
6.2 CLINICAL INVESTIGATION methods with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT.....	19
6.2.1 * REFERENCE measurement.....	19
6.2.2 * Arterial REFERENCE site.....	20
6.2.3 PROCEDURE.....	20
6.2.4 * Determining the REFERENCE BLOOD PRESSURE.....	21
6.2.5 Determining the error of the BLOOD PRESSURE measurement.....	22
6.2.6 Data analysis.....	22
6.2.7 MEAN ARTERIAL PRESSURE (MAP).....	23
7 * Pregnant PATIENT populations	23
Annex A (informative) Rationale and guidance	25
Annex B (informative) Reference to the ESSENTIAL PRINCIPLES	33
Annex C (informative) Terminology — alphabetized index of defined terms	34
Bibliography	35

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.

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) or the IEC list of patent declarations received (see <http://patents.iec.ch>).

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*.

This third edition cancels and replaces the second edition (ISO 81060-2:2013), which has been technically revised.

The main changes compared to the previous edition are as follows:

- same arm simultaneous method has been deleted;
- numerous clarifications have been added and kPa equivalent values for the mmHg values have been included.

A list of all parts in the ISO/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.

This is a preview of "ISO 81060-2:2018". [Click here to purchase the full version from the ANSI store.](#)

Introduction

Determining BLOOD PRESSURE is an important PROCEDURE that is clinically used to assess the status of a PATIENT.

BLOOD PRESSURE serves as aid to control the drug titration and fluid management and to provide warning about the changes in PATIENT'S state of health.

Frequently determining BLOOD PRESSURE is routine during anaesthesia. BLOOD PRESSURE serves to aid to control drug titration and fluid management and to provide warning about the changes in the PATIENT'S state of health.

In this document, the following print types are used:

- requirements, compliance with which can be verified, and definitions: roman type;
- informative material appearing outside of tables, such as notes, examples and references: in smaller roman type. Normative text of tables is also in a smaller roman type;
- *test methods: italic type*; and
- TERMS DEFINED IN [CLAUSE 3](#) OF THE GENERAL STANDARD, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS 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.

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

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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](#).

[Annex B](#) maps the clauses and subclauses of this document with the ESSENTIAL PRINCIPLES of ISO 16142-1:2016.

This is a preview of "ISO 81060-2:2018". [Click here to purchase the full version from the ANSI store.](#)

This is a preview of "ISO 81060-2:2018". [Click here to purchase the full version from the ANSI store.](#)

Non-invasive sphygmomanometers —

Part 2: Clinical investigation of intermittent automated measurement type

1 Scope

This document 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 document 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 document 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 for self-measurement as well as use in a professional healthcare facility).

EXAMPLE AUTOMATED SPHYGMOMANOMETER as given in IEC 80601-2-30 undergoing CLINICAL INVESTIGATION according to this document.

This document specifies additional disclosure requirements for the ACCOMPANYING DOCUMENTS of SPHYGMOMANOMETERS that have passed a CLINICAL INVESTIGATION according to this document.

This document 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.

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 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the Bibliography.

ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

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*

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

This is a preview of "ISO 81060-2:2018". [Click here to purchase the full version from the ANSI store.](#)

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 home care applications*

IEC 60601-2-34:2011, *Medical electrical equipment — Part 2-34: Particular requirements for the basic safety and 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*