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Medical electrical equipment —

Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

Appareils électromédicaux —

Partie 2-30: Exigences particulières de sécurité de base et de performances essentielles des sphygmomanomètres non invasifs automatiques

ICS: ISO ics

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

FOREWORD

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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

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International standard IEC 80601-2-30 has been prepared by a Joint Working Group of subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and of subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This third edition cancels and replaces the second edition published in 2018. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

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a) a clarified definition of neonate and infant and associated modes;

b) relabeling of some primary operating functions;

c) additional requirements for monitoring equipment to avoid the misuse of misleading or “stale” data;

d) updated normative references to the current versions where applicable.

This publication is published as a double logo standard.

The text of this document is based on the following documents of IEC:

FDIS	Report on voting
62D/1548/FDIS	62D/1560/RVD

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 14 P members out of 15 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this document, the following print types are used:

– requirements and definitions: roman type;

– *test specifications: italic type;*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

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 Clause 7 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.

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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 D

(informative)

Application Programming Interface Framework

D.1 General guidance

This annex provides a minimal informative framework for Electronic Automated Blood Pressure device digital connectivity. It is common for health monitoring devices that are being used at all levels of patient acuity to be ”connected” for the purpose of direct transmission of device data to a distant dashboard, electronic medical record and even from the patient’s home to their health provider. In this annex, the term Application Programming Interface (API) is used in its most generic sense, representing the flow of data and commands to and from a device that provides connectivity and has NIBP determination capability. A conceptual API is presented without specifics of data structures or communication protocols. The annex is intended to serve as a starting point for discussion about the design of an API for an NIBP device. It is by no means a comprehensive or required framework but a starting point, listing basic functionality that an NIBP API should consider. There is no intention to provide a comprehensive model for an API that meets all the needs of all server/client interactions. Nor is there any intention to imply that the implementation of this API framework will provide any level of market acceptance or interoperability of NIBP devices.

The committee presents the following minimum set of API functionality for your consideration in the development of connected NIBP devices:

API shall include

- Start BP reading
- Stop BP reading
- Abort an NIBP cycle
- Get NIBP results - sys, dia, HR ,MAP, Error code
- Set BP mode to Neonate
- Set BP mode to Pediatric (if applicable)
- Set BP mode to Adult
- Set BP mode to special.
- Reset the API
- Set API Parameters (protocol, Baud …)
- Control Pump
- Control valve
- Calibrate or cal-check pressure transducers
- Capability to support testing of single-fault failsafe components and controls

Annex AA.

A list of all parts of the 80601 International standard, published under the general title *Medical electrical equipment,* can be found on the IEC website.

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The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of an AUTOMATED SPHYGMOMANOMETER.

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington DC in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or because of developments in technology. However, the Annex AA does not form part of the requirements of this document.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

201.1.1 Scope

Replacement:

This part of the 80601 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of AUTOMATED SPHYGMOMANOMETERS, hereafter referred to as ME EQUIPMENT, which by means of an inflatable CUFF, are used for non-continuous indirect estimation of the BLOOD PRESSURE without arterial puncture.

NOTE 1 Equipment that performs indirect DETERMINATION of the BLOOD PRESSURE without arterial puncture does not directly measure the BLOOD PRESSURE. It only estimates the BLOOD PRESSURE.

This document specifies requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE for this ME EQUIPMENT and its ACCESSORIES, including the requirements for the accuracy of BLOOD PRESSURE DETERMINATION.

This document covers automatic electrically-powered ME EQUIPMENT used for the intermittent, indirect estimation of the BLOOD PRESSURE without arterial puncture, including BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT.

Requirements for indirect estimation of the BLOOD PRESSURE without arterial puncture ME EQUIPMENT with an electrically-powered PRESSURE TRANSDUCER and/or displays used in conjunction with a stethoscope or other manual methods for determining BLOOD PRESSURE (NON-AUTOMATED SPHYGMOMANOMETERS) are specified in document ISO 81060-1 [2].

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 201.11 and 201.105.3.3, as well as 7.2.13 and 8.4.1 of IEC 60601-1:2022.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for an AUTOMATED SPHYGMOMANOMETER as defined in 201.3.201.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 apply as modified in Clauses 202, 206, 210, 211 and 212 respectively. IEC 60601-1-3 [3] does not apply. All other published collateral standards in the IEC 60601-1 series apply as published [1] [4].

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard correspond to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x", where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

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201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 56.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD 1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD 1:2013
IEC 60601-1-6:2010/AMD 2:2020

Addition:

IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock*

IEC 60068-2-64:2008+AMD1:2019, *Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broad-band random and guidance*

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD 1:2012

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*
IEC 60601-1-10:2007/AMD1:2013
IEC 60601-1-10:2007/AMD2:2020

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 the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*
IEC 60601-2-2:2017/AMD1:2023

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
IEC 62366-1:2015/AMD1:2020

IEC 80369-5:2016, *Small-bore connectors for liquids and gases in healthcare applications – Part 5: Connectors for limb cuff inflation applications*

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ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications – Part 1: General requirements*

ISO 81060-2:— [1], *Non-invasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 60601-1-8, IEC 60601-2-2:2017, IEC 60601-2-2:2017/AMD1:2023, IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 59.

Addition:

201.3.201
AUTOMATED SPHYGMOMANOMETER
ME EQUIPMENT used for the non-invasive estimation of the BLOOD PRESSURE by utilizing an inflatable CUFF, a PRESSURE TRANSDUCER, a valve for deflation, and/or displays used in conjunction with automatic methods for determining BLOOD PRESSURE

Note 1 to entry: Components of an AUTOMATED SPHYGMOMANOMETER include manometer, CUFF, valve for deflation (often in combination with the valve for rapidly exhausting the PNEUMATIC SYSTEM), pump for inflation of the BLADDER, and connection tubing.

201.3.202
CUFF
part of the AUTOMATED SPHYGMOMANOMETER that is wrapped around the limb of the PATIENT

Note 1 to entry: A CUFF usually comprises a BLADDER and an inelastic part that encloses the BLADDER, or has an integral BLADDER (i.e., the CUFF, including the BLADDER, is one piece).

[SOURCE: ISO 81060-1:2007 [2], 3.5, modified – In the definition, "non-automated" has been replaced by "automated", and in the Note 1 to entry "might comprise" has been replaced by "usually comprises".]

201.3.203
DETERMINATION
DETERMINATION VALUE
result of the PROCESS of estimating BLOOD PRESSURE by the AUTOMATED SPHYGMOMANOMETER

201.3.204
DIASTOLIC BLOOD PRESSURE
DIASTOLIC BLOOD PRESSURE VALUE
minimum value of the BLOOD PRESSURE as a result of relaxation of the systemic ventricle

Note 1 to entry: Because of hydrostatic effects, this value should be determined with the CUFF at the same elevation as the heart (phlebostatic axis).

[1] New revision under preparation. Stage at the time of publication: ISO/xx 80601-2:20xx.

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201.3.205
LONG-TERM AUTOMATIC MODE
mode in which a timer, set by the OPERATOR, initiates multiple DETERMINATIONS

201.3.206
MEAN ARTERIAL PRESSURE
MEAN ARTERIAL PRESSURE VALUE
value of the integral of one heartbeat cycle of the BLOOD PRESSURE curve divided by the time of that cycle

Note 1 to entry: Because of hydrostatic effects, this value should be determined with the transducer at the same elevation as the heart (phlebostatic axis).

201.3.207
NEONATAL MODE
mode of an AUTOMATED SPHYGMOMANOMETER intended for use on neonate patients

Note 1 to entry: Some devices are designed to utilise a mode called “Neonatal Mode” that includes infants as well as neonates.

Note 2 to entry: The approximate age range for a newborn (neonate) is from birth to 1 month [5] [6].

Note 3 to entry: The approximate age range for an infant is commonly from 1 month to 2 years [5] [6]. For the purposes of this document, up to 3 years of age are considered infants (see ISO 81060-2:20xx, 6.1.3).

Note 4 to entry: The NEONATAL MODE is used to limit the maximum pressure to 150 mmHg and often has a neonate-specific algorithm that is different than algorithms intended for older PATIENTS.

201.3.208
NON-AUTOMATED SPHYGMOMANOMETER
ME EQUIPMENT used for the non-invasive estimation of BLOOD PRESSURE by utilizing an inflatable CUFF with a pressure-sensing element, a valve for deflation, and a display used in conjunction with a stethoscope or other manual methods for estimating BLOOD PRESSURE

Note 1 to entry: Components of these instruments include a manometer, CUFF, valve for deflation (often in combination with the valve for rapidly exhausting the PNEUMATIC SYSTEM), hand pump or electro-mechanical pump for inflation of the BLADDER, and connection tubing. A NON-AUTOMATED SPHYGMOMANOMETER can also contain electro-mechanical components for cuff pressure control.

[SOURCE: ISO 81060-1:2007 [2], 3.11, modified – The definition and the note to entry have been rephrased.]

201.3.209
PATIENT SIMULATOR
equipment for simulating the oscillometric CUFF pulses and/or auscultatory signals during inflation and deflation

Note 1 to entry: This equipment is not used for testing clinical accuracy but is used in assessing stability of performance.

201.3.210
PNEUMATIC SYSTEM
part of the AUTOMATED SPHYGMOMANOMETER that includes all pressurized and pressure-controlling components

EXAMPLES CUFF, tubing, connectors, valves, PRESSURE TRANSDUCER and pump.

[SOURCE: ISO 81060-1:2007 [2], 3.16, modified – In the definition, replacement of "non automated" by "automated", and in the examples, addition of "pressure".]

201.3.211
PRESSURE TRANSDUCER
component that transforms sensed pressure into an electrical signal

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