IEC 80601-2-30

Edition 2.0 2018-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-30: Exigences particulières pour la sécurité de base et les performances essentielles des sphygmomanomètres non invasifs automatiques

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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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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 second edition cancels and replaces the first edition published in 2009 and Amendment 1:2013. This edition constitutes a technical revision.

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

a) alignment with IEC 60601-1:2005/AMD1:2012 and IEC 60601-1-8:2006/AMD1:2012 [1][1], and with IEC 60601-1-2:2014 and IEC 60601-1-11:2015;

b) referencing IEC 60601-1-10:2007 and IEC 60601-1-12;

c) changing an OPERATOR-accessible CUFF-sphygmomanometer connector from not compatible with the ISO 594 series to compatible with the ISO 80369 series;

d) added additional requirements for public self-use sphygmomanometers;

e) added a list of PRIMARY OPERATING FUNCTIONS.

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;

1 Figures in square brackets refer to the Bibliography.

– "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 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.

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.

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 as a result of developments in technology. However, the Annex AA does not form part of the requirements of this document.

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[2] 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 a 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 60601-1:2005.

NOTE 2 See also 4.2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

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.

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2 The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

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.

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 corresponds 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.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 54.

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 60601-1-6:2010, *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

Addition:

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

IEC 60068-2-64:2008, *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 60601-1-11:2015, *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 60601-1-12:2014, *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 60601-2-2:2017, *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 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*

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

ISO 80369-1:—[3], *Small-bore connectors for liquids and gases in healthcare applications –Part 1: General requirements*

ISO 81060-2:2013, *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 and IEC 62366-1:2015 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 56.

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 level of the heart.

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3 Under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2017.

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 level of the heart.

201.3.207
NEONATAL MODE
mode of AUTOMATED SPHYGMOMANOMETER for use with neonates or infants

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

Note 2 to entry: The approximate age range for an infant is 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 81060-2:2013, 6.1.3).

Note 3 to entry: The NEONATAL MODE is used to limit the maximum pressure to 150 mmHg and frequently has a different algorithm from other modes intended for older PATIENTS.

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

Note 1 to entry: Components of these instruments include 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 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 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

201.3.212
PROTECTION DEVICE
part of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

201.3.213
SELF-MEASUREMENT AUTOMATIC MODE
mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated and overseen by the OPERATOR and in which a limited number of repeated DETERMINATIONS are made over a finite period

201.3.214
*** SHORT-TERM AUTOMATIC MODE**
mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated by the OPERATOR and in which rapid repetitive automatic DETERMINATIONS are made within a specified time period

201.3.215
SYSTOLIC BLOOD PRESSURE
SYSTOLIC BLOOD PRESSURE VALUE
maximum value of the BLOOD PRESSURE as a result of the contraction of the systemic ventricle

Note 1 to entry: Because of hydrostatic effects, this value should be determined with the CUFF at the level of the heart.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Additional ESSENTIAL PERFORMANCE requirements for an AUTOMATED SPHYGMOMANOMETER are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Electrosurgery interference recovery	202.8.101
Limits of the error of the manometer [a],	201.12.1.102
or generation of a TECHNICAL ALARM CONDITION	201.11.8.102 201.12.1.101
Reproducibility of the BLOOD PRESSURE DETERMINATION and	201.12.1.107
low and high BLOOD PRESSURE PHYSIOLOGICAL ALARM CONDITIONS (if provided),	201.12.3.101
or generation of a TECHNICAL ALARM CONDITION	201.11.8.102 201.12.1.101
[a] 202.8.1.101 d) indicates methods of evaluating limits of the error of the manometer as acceptance criteria following specific tests required by this document.	

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.4 * ACCESSORIES

Addition:

A CUFF shall be marked with an indication of the correct positioning for the CUFF on the designated limb over the artery.

Additional subclauses:

201.7.2.101 Display of AUTOMATED SPHYGMOMANOMETERS

If abbreviations are used on the display, they shall be as follows:

– "S" or "SYS" for the value of SYSTOLIC BLOOD PRESSURE;

– "D" or "DIA" for the value of DIASTOLIC BLOOD PRESSURE;

– "M" or "MAP" for the value of MEAN ARTERIAL PRESSURE.

Single letter abbreviations shall be positioned in such a way as to avoid confusion with SI units.

The numerical step of BLOOD PRESSURE readings shall be 1 mmHg or 0,1 kPa.

201.7.2.102 * AUTOMATED SPHYGMOMANOMETER with NEONATAL MODE

If an AUTOMATED SPHYGMOMANOMETER is intended for use with neonatal PATIENTS and other PATIENTS, it should have means for detecting that a CUFF intended for use with a neonatal PATIENT is connected to the AUTOMATED SPHYGMOMANOMETER and means for automatically placing the AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE when such a CUFF is present. If these means are not present, the instructions for use shall describe the method for placing the AUTOMATED SPHYGMOMANOMETER into NEONATAL MODE and include a warning statement describing the RISKS associated with using other than the NEONATAL MODE on a neonatal PATIENT.

All ACCESSORIES intended for use only in the NEONATAL MODE and where the use in other modes results in an unacceptable RISK shall be marked for neonatal use only.

201.7.2.103 * AUTOMATED SPHYGMOMANOMETER intended for self-use in public areas

If the AUTOMATED SPHYGMOMANOMETER is intended for self-use in public areas, it shall be marked on the USER INTERFACE with the following:

a) precautions for use, including a statement concerning the need to consult a physician for interpretation of BLOOD PRESSURE values;

b) adequate operating instructions; and

c) this sphygmomanometer complies with IEC 80601-2-30:2017.

EXAMPLES Self-measurement station in a pharmacy, fitness centre, workplace intended for use by the general population without professional assistance.

If intended for use with a single CUFF size, the AUTOMATED SPHYGMOMANOMETER shall be marked on the USER INTERFACE with the following:

d) the range of arm circumference for which the CUFF is intended – specifically minimum and maximum upper arm (midpoint) circumference thresholds in centimetres and in inches; and

e) a statement to the effect that results might not be accurate if your arm is outside specified circumference range.

201.7.2.104 * Component replacement

If a component can be replaced by the OPERATOR or SERVICE PERSONNEL, and if replacement could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the AUTOMATED SPHYGMOMANOMETER, the AUTOMATED SPHYGMOMANOMETER or the component shall be marked with either a caution to the effect that substitution of a component different from that supplied might result in measurement error, or with a safety sign ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, safety sign 10).

EXAMPLES CUFF, microphone, connection tube, external power supply

201.7.2.105 Disposal

The AUTOMATED SPHYGMOMANOMETER and its parts shall be marked with regard to disposal, as appropriate, in accordance with national or regional regulations.

NOTE See also IEC 60601-1-9 [4].

201.7.9.2 Instructions for use

201.7.9.2.1 General

Replacement of the first three dashed items:

– the use of the AUTOMATED SPHYGMOMANOMETER as intended by the MANUFACTURER, and in particular:

  1) intended medical indication;

     EXAMPLE 1 Condition(s) or disease(s) to be screened for, monitored, treated, diagnosed, or prevented.

  2) any known restrictions on use or contraindication(s) to the use of the AUTOMATED SPHYGMOMANOMETER;

     EXAMPLE 2 AUTOMATED SPHYGMOMANOMETER for use in an ambulance or helicopter, for use in the HOME HEALTHCARE ENVIRONMENT, for use with neonatal or pre-eclamptic PATIENTS.

  3) intended PATIENT population, including whether or not the AUTOMATED SPHYGMOMANOMETER is intended:

     i) for use with neonatal PATIENTS,

     ii) for use with pregnant, including pre-eclamptic, PATIENTS;

     EXAMPLE 3 Age, weight, region of body, health, condition or diagnosis.

  4) intended placement of the CUFF; and

  5) intended conditions of use;

     EXAMPLE 4 Environment, including hygienic, requirements, frequency of use, location, mobility.

– the frequently used functions;

– the permissible environmental conditions of use, including at least a temperature range of 10 °C to 40 °C with a relative humidity range of 15 % to 85 % (non-condensing).

201.7.9.2.2 Warning and safety notices

Addition, following the note:

The instructions for use shall include a warning:

aa) regarding the effect of blood flow interference and resulting harmful injury to the PATIENT caused by continuous CUFF pressure due to connection tubing kinking;

bb) indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference;

cc) regarding the application of the CUFF over a wound, as this can cause further injury;

dd) regarding the application of the CUFF and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because of temporary interference with blood flow and could result in injury to the PATIENT;

ee) regarding the application of the CUFF and its pressurization on the arm on the side of a mastectomy or lymph node clearance;

ff) regarding the information that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb;

gg) regarding the need to check (for example, by observation of the limb concerned) that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the PATIENT.

201.7.9.2.5 ME EQUIPMENT description

Addition, after the third dashed item in the first paragraph:

– a description of the operating principles of the AUTOMATED SPHYGMOMANOMETER; and

– RATED ranges of the DETERMINATION.

201.7.9.2.9 Operating instructions

Addition:

The instructions for use shall contain the following information:

aa) an explanation of the selection of a suitably sized CUFF and the application of the CUFF to the PATIENT;

bb) an explanation of the operating steps needed to obtain accurate routine resting BLOOD PRESSURE values for the condition hypertension [7] [8] [9] [10] [11], including:

1) adjustment of the pressure reduction rate, if applicable:

2) PATIENT position in NORMAL USE, including:

i) comfortably seated,

ii) legs uncrossed,

iii) feet flat on the floor,

iv) back and arm supported, and

v) middle of the CUFF at the level of the right atrium of the heart;

3) a recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE;

4) a recommendation that 5 min should elapse before the first reading is taken;

5) OPERATOR position in NORMAL USE;

cc) an explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT (standing, sitting, lying down) [12], exercise, or the PATIENT'S physiologic condition;

dd) details of what the OPERATOR should do if unexpected readings are obtained;

ee) details of the environmental or operational factors which can affect the performance of the AUTOMATED SPHYGMOMANOMETER and/or its BLOOD PRESSURE reading (e.g. common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, PATIENT motion, trembling, shivering) [13] [14] [15];

ff) a statement, if applicable, that the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude;

gg) if applicable, an explanation of the need to avoid compression or restriction of the connection tubing; and

hh) the RATED range of CUFF pressure.

201.7.9.2.13 * Maintenance

Addition, after the second paragraph:

If the AUTOMATED SPHYGMOMANOMETER is intended to be dismantled by the OPERATOR, the instructions for use shall indicate the correct method of reassembly.

If the BLADDER can be incorrectly inserted into the inelastic part of the CUFF (e.g. after cleaning), the CUFF or the instructions for use shall include a detailed description of the correct manner of insertion of the BLADDER into the inelastic part of the CUFF.

Additional subclauses:

201.7.9.2.101 Compatibility with HF SURGICAL EQUIPMENT

If the AUTOMATED SPHYGMOMANOMETER complies with the requirements of 202.8.101, the instructions for use shall include a statement to the effect that this ME EQUIPMENT is suitable for use in the presence of electrosurgery.

If parts of the PRESSURE TRANSDUCER or AUTOMATED SPHYGMOMANOMETER are provided with protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT, such means shall be drawn to the attention of the OPERATOR in the instructions for use. If such means are absent, such parts shall be identified in the instructions for use.

201.7.9.2.102 AUTOMATED SPHYGMOMANOMETERS for use in NEONATAL MODE

If the AUTOMATED SPHYGMOMANOMETER is equipped with a NEONATAL MODE, the instructions for use shall include:

a) the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in NEONATAL MODE;

b) the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER can accommodate when in the NEONATAL MODE; and

c) the ACCESSORIES that the MANUFACTURER recommends for use in NEONATAL MODE to avoid errors and excessive pressure.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

Additional subclause:

201.8.5.5.101 * PATIENT CONNECTIONS of AUTOMATED SPHYGMOMANOMETERS

If the APPLIED PART of an AUTOMATED SPHYGMOMANOMETER has PATIENT CONNECTIONS, it shall be classified as a DEFIBRILLATION-PROOF APPLIED PART.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.11.8 Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

Addition:

201.11.8.101 * Switching off

When the AUTOMATED SPHYGMOMANOMETER is switched off by the OPERATOR, with the CUFF inflated, the CUFF shall deflate within 30 s to the values indicated in Table 201.102.

Table 201.102 – CUFF deflation pressure

Mode	CUFF pressure
NEONATAL MODE	≤ 5 mmHg (0,7 kPa)
Any other mode	≤ 15 mmHg (2,0 kPa)

Compliance is checked by functional testing.

201.11.8.102 Interruption of the SUPPLY MAINS

When the SUPPLY MAINS to the AUTOMATED SPHYGMOMANOMETER is interrupted, the CUFF shall deflate within 30 s to the values indicated in Table 201.102, and any indication of BLOOD PRESSURE shall be cancelled.

When the SUPPLY MAINS is restored, the AUTOMATED SPHYGMOMANOMETER:

a) shall continue in the same mode of operation and with all OPERATOR settings unchanged, or

b) shall

   1) remain inoperative, and

   2) if provided with SHORT-TERM AUTOMATIC MODE or LONG-TERM AUTOMATIC MODE, be equipped with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION that indicates the AUTOMATED SPHYGMOMANOMETER is inoperative.

An AUTOMATED SPHYGMOMANOMETER that automatically switches over to operation from an INTERNAL ELECTRICAL POWER SOURCE and continues to operate normally shall be exempt from these requirements.

Compliance is checked with the following test.

c) *Make a DETERMINATION utilizing a PATIENT SIMULATOR and observe the AUTOMATED SPHYGMOMANOMETER operating mode. Interrupt the SUPPLY MAINS for a period exceeding 30 s.*

d) *Confirm that the CUFF is sufficiently deflated and that the indicated BLOOD PRESSURE disappears within 30 s.*

e) *Restore the SUPPLY MAINS and confirm that the AUTOMATED SPHYGMOMANOMETER:*

- *continues in the same mode of operation and with all OPERATOR settings unchanged; or*
- *remains inoperative and, if equipped with SHORT-TERM AUTOMATIC MODE or LONG-TERM AUTOMATIC MODE, that a TECHNICAL ALARM CONDITION is generated.*

201.11.8.103 * INTERNAL ELECTRICAL POWER SOURCE

An AUTOMATED SPHYGMOMANOMETER powered from an INTERNAL ELECTRICAL POWER SOURCE shall incorporate means:

a) in case of INTERNAL ELECTRICAL POWER SOURCE failure or depletion, which does not allow the AUTOMATED SPHYGMOMANOMETER to meet the BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of this document,
   1) for protective shutdown, and
   2) for cancelling the indicated BLOOD PRESSURE;

b) of determining the state of the power supply.

Compliance is checked by functional testing.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 Measuring and display ranges

The measuring and display ranges of the CUFF pressure shall be equal to the RATED range for CUFF pressure.

Values of BLOOD PRESSURE outside the RATED range for BLOOD PRESSURE shall not be displayed, and the AUTOMATED SPHYGMOMANOMETER shall be equipped with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION that indicates when the determined BLOOD PRESSURE is outside the RATED range.

Compliance is checked by functional testing.

201.12.1.102 Limits of the error of the manometer from environmental conditions

Over the temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing), the maximum error for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to ±3 mmHg (±0,4 kPa) or 2 % of the reading, whichever is greater.

Compliance is checked by functional testing.

201.12.1.103 * NOMINAL BLOOD PRESSURE indication range

The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating DIASTOLIC BLOOD PRESSURE over at least the range of 20 mmHg (2,7 kPa) to 60 mmHg (8,0 kPa) in NEONATAL MODE and 40 mmHg (5,3 kPa) to 130 mmHg (17,3 kPa) otherwise.

The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating SYSTOLIC BLOOD PRESSURE over at least the range of 40 mmHg (5,3 kPa) to 110 mmHg (14,7 kPa) in NEONATAL MODE and 60 mmHg (8,0 kPa) to 230 mmHg (30,7 kPa) otherwise.

Compliance is checked with the following test:

a) Connect the AUTOMATED SPHYGMOMANOMETER to a PATIENT SIMULATOR.

b) Adjust the PATIENT SIMULATOR to generate signals in such a way that the AUTOMATED SPHYGMOMANOMETER displays DIASTOLIC BLOOD PRESSURE values of 20 mmHg (2,7 kPa) or less and SYSTOLIC BLOOD PRESSURE values of 110 mmHg (14,7 kPa) or more in NEONATAL MODE and DIASTOLIC BLOOD PRESSURE values of 40 mmHg (5,3 kPa) or less and SYSTOLIC BLOOD PRESSURE values of 230 mmHg (30,7 kPa) or more otherwise.

201.12.1.104 Maximum pressure in NORMAL CONDITION

The maximum pressure obtainable in NORMAL CONDITION shall not exceed 150 mmHg (20 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE and not exceed 300 mmHg (40 kPa) otherwise. An AUTOMATED SPHYGMOMANOMETER may have one, or more than one, mode.

Compliance is checked by functional testing in NORMAL CONDITION.

201.12.1.105 * Maximum pressure in SINGLE FAULT CONDITION

In any automatic cycling mode of operation, a PROTECTION DEVICE shall be provided, functioning independently of the normal PNEUMATIC SYSTEM control, which in any SINGLE FAULT CONDITION, shall:

a) prevent the pressure in the PNEUMATIC SYSTEM from exceeding the maximum RATED value specified in 201.12.1.104 by more than 10 % for more than 3 s (see Figure 201.101); and

b) activate if the pressure in the PNEUMATIC SYSTEM exceeds the maximum RATED value specified in 201.12.1.104 for 15 s (see Figure 201.102).

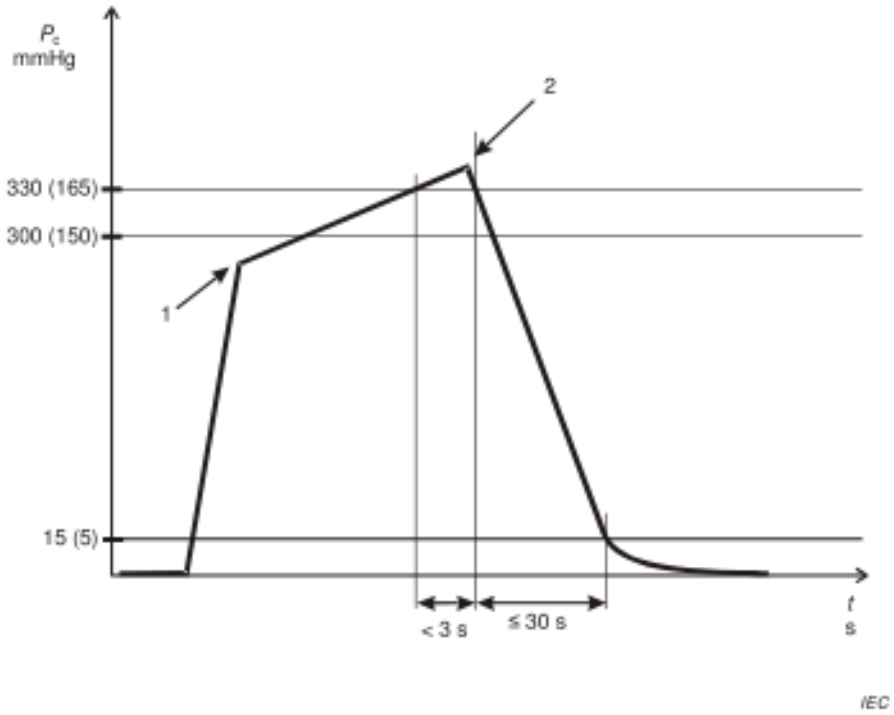
When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s to ≤ 15 mmHg (2,0 kPa) and to ≤ 5 mmHg (0,7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE.

An AUTOMATED SPHYGMOMANOMETER that only operates in the SELF-MEASUREMENT AUTOMATIC MODE, where the PATIENT is the OPERATOR or the OPERATOR is intended to be in continual attendance, and where the pressure can be released from the CUFF by the OPERATOR is exempt from this requirement.

EXAMPLE 1 Pressure released by disconnecting the CUFF from the AUTOMATED SPHYGMOMANOMETER.

EXAMPLE 2 Pressure released by removing the CUFF from the limb.

Compliance is checked by functional testing in SINGLE FAULT CONDITION.



Key

1 SINGLE FAULT CONDITION occurs

2 PROTECTION DEVICE activates due to overpressure

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.101 – CUFF pressure PROTECTION DEVICE, triggered by overpressure in SINGLE FAULT CONDITION

201.12.1.106 * Manometer test mode

The AUTOMATED SPHYGMOMANOMETER shall have a manometer test mode that permits static pressure measurement over at least the NOMINAL BLOOD PRESSURE indication range (see 201.12.1.103). This mode shall not be available in NORMAL USE, but restricted to SERVICE PERSONNEL.

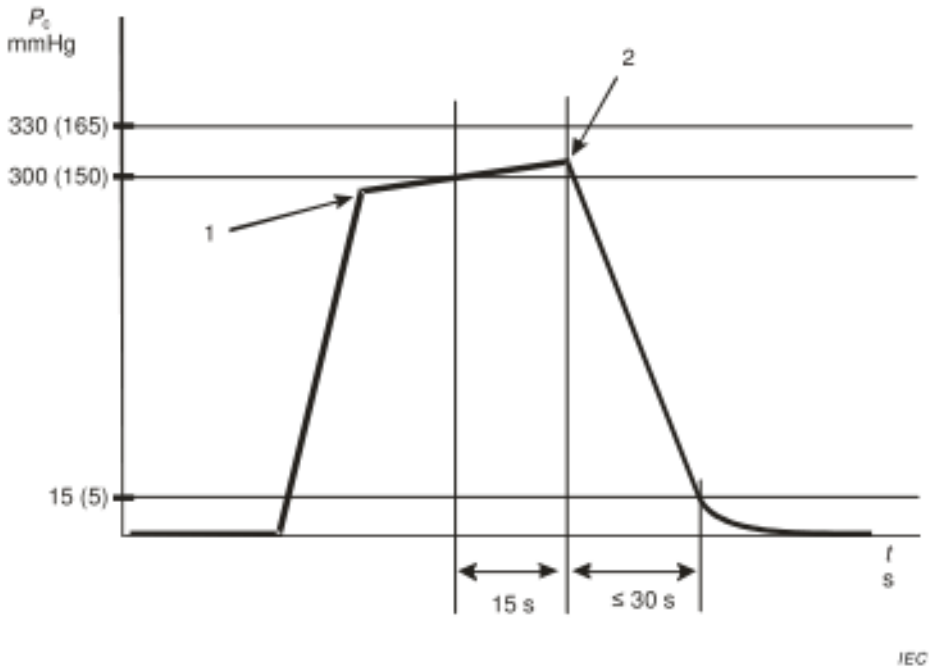
EXAMPLE 1 A port for connection to a pressure source so that the pressure can be measured by the AUTOMATED SPHYGMOMANOMETER in a test mode.

EXAMPLE 2 A port for connection to a reference manometer that can be pressurized by the AUTOMATED SPHYGMOMANOMETER in a test mode.

NOTE This mode can be used to verify manometer pressure accuracy.

The technical description shall include a test method that can be used to verify the calibration of the AUTOMATED SPHYGMOMANOMETER.

Compliance is checked by inspection and functional testing.



Key

1 SINGLE FAULT CONDITION occurs

2 PROTECTION DEVICE activates due to prolonged overpressure

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.102 – CUFF pressure PROTECTION DEVICE, triggered by prolonged overpressure in SINGLE FAULT CONDITION

201.12.1.107 * Reproducibility of the BLOOD PRESSURE DETERMINATION

The laboratory reproducibility of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER shall be less than or equal to 3,0 mmHg (0,4 kPa).

Compliance is checked with the following test:

Two samples of the AUTOMATED SPHYGMOMANOMETER of the same MODEL OR TYPE REFERENCE are needed to perform this test PROCEDURE.

NOTE At the beginning of this compliance test, neither sample has been subjected to the mechanical stress tests of the general standard and the collateral standards. Step h) subjects AUTOMATED SPHYGMOMANOMETER A to the stress tests, and the laboratory limits of the change in error of the BLOOD PRESSURE DETERMINATION are compared before and after these mechanical stresses.

a) Label one sample of the AUTOMATED SPHYGMOMANOMETER as A and the other sample as B.

b) Prior to performing the other tests of this document, adjust the PATIENT SIMULATOR to generate signals in such a way that the AUTOMATED SPHYGMOMANOMETER displays approximately a DIASTOLIC BLOOD PRESSURE value of 40 mmHg (5,3 kPa) and a SYSTOLIC BLOOD PRESSURE value of 70 mmHg (9,33 kPa) at a pulse rate of 140 beats/min in NEONATAL MODE and a DIASTOLIC BLOOD PRESSURE value of 80 mmHg (10,67 kPa) and a SYSTOLIC BLOOD PRESSURE value of 120 mmHg (16,0 kPa) at a pulse rate of 80 beats/min otherwise. Either sample of the AUTOMATED SPHYGMOMANOMETER may be used for this step.

c) Perform 20 consecutive DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER B. Calculate the means and standard deviations for both the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.

d) Record these results as the AUTOMATED SPHYGMOMANOMETER B starting values.

e) Confirm that the standard deviation of the DIASTOLIC BLOOD PRESSURE and of the SYSTOLIC BLOOD PRESSURE are ≤ 2,0 mmHg (≤ 0,27 kPa) for the AUTOMATED SPHYGMOMANOMETER B starting values. If either one of these criteria is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.

f) Using the same PATIENT SIMULATOR and settings as in b), perform 20 consecutive DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER A. Calculate the means and standard deviations for both the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.

g) Record these results as the AUTOMATED SPHYGMOMANOMETER A starting values.

h) Using AUTOMATED SPHYGMOMANOMETER A, perform at least the following tests, without the simulation of SINGLE FAULT CONDITIONS, of this particular standard: 201.12.1.102, 201.15.3.5.101, and IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 15.3.2, 15.3.3 and 15.3.4 as well as, if applicable, IEC 60601-1-11:2015, 8.3.1, 10.1, and IEC 60601-1-12:2014, 8.1.1 and 10.1.1.

i) Using the same PATIENT SIMULATOR and settings as in b), perform 20 DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER A. Calculate the means of the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.

j) Record these results as the AUTOMATED SPHYGMOMANOMETER A ending values.

k) Using the same PATIENT SIMULATOR and settings as in b), perform 20 DETERMINATIONS with AUTOMATED SPHYGMOMANOMETER B. Calculate the means of the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.

l) Record these results as the AUTOMATED SPHYGMOMANOMETER B ending values.

m) For AUTOMATED SPHYGMOMANOMETER B ending values, confirm that the standard deviation of the DIASTOLIC BLOOD PRESSURE and of the SYSTOLIC BLOOD PRESSURE are ≤ 2,0 mmHg (≤ 0,27 kPa). If either one of these criteria is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.

n) For AUTOMATED SPHYGMOMANOMETER B, confirm that the absolute value of the difference between the mean starting values calculated in c) and ending values calculated in m) are ≤ 2,0 mmHg (≤ 0,27 kPa). If either one of these criteria is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient stability to perform this test PROCEDURE.

o) For AUTOMATED SPHYGMOMANOMETER A, confirm that the absolute value of the difference between the mean starting values calculated in f) and ending values calculated in i) are ≤ 5,0 mmHg (≤ 0,67 kPa).

201.12.3 ALARM SYSTEMS

Addition:

201.12.3.101 Additional ALARM SYSTEM requirements

If an AUTOMATED SPHYGMOMANOMETER has an ALARM SYSTEM that includes PHYSIOLOGICAL ALARM CONDITIONS, it shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate both a PHYSIOLOGICAL ALARM CONDITION for low BLOOD PRESSURE and a PHYSIOLOGICAL ALARM CONDITION for high BLOOD PRESSURE. These ALARM CONDITIONS shall be at least MEDIUM PRIORITY, unless an INTELLIGENT ALARM SYSTEM is utilized that uses additional physiological information to determine that these ALARM CONDITIONS are not true. These ALARM CONDITIONS may be for SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE, or MEAN ARTERIAL PRESSURE.

Compliance is checked by functional testing.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3.5 Rough handling test

Additional subclauses:

201.15.3.5.101 * Shock and vibration (robustness)

An AUTOMATED SPHYGMOMANOMETER or its parts shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping, and rough handling. A FIXED AUTOMATED SPHYGMOMANOMETER is exempt from the requirements of this subclause.

After the following tests, the AUTOMATED SPHYGMOMANOMETER shall not cause an unacceptable RISK and shall function normally.

NOTE 1 Additional requirements are found in IEC 60601-1-11 and IEC 60601-1-12.

Compliance is checked by the following tests:

a) Shock test in accordance with IEC 60068-2-27:2008 using the conditions of test type 1 or 2:

NOTE 2 This represents IEC TR 60721-4-7 [16], Class 7M2.

1) test type: Type 1:

- *peak acceleration: 150 m/s^2 (15 g);*
- *duration: 11 ms;*
- *pulse shape: half sine;*
- *number of shocks: 3 shocks per direction per axis (18 total).*

2) test type: Type 2:

- *peak acceleration: 300 m/s^2 (30 g);*
- *duration: 6 ms;*
- *pulse shape: half sine;*
- *number of shocks: 3 shocks per direction per axis (18 total).*

For a HAND-HELD AUTOMATED SPHYGMOMANOMETER, the requirements in 15.3.4.1 of the general standard may be substituted for this requirement.

b) Broad-band random vibration according to IEC 60068-2-64:2008 using the following conditions:

NOTE 3 This represents IEC TR 60721-4-7, [16] Classes 7M1 and 7M2.

1) acceleration amplitude:

- *10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz;*

- *100 Hz to 200 Hz: −3 db/octave;*
- *200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2$/Hz;*

2) *duration: 30 min per each perpendicular axis (3 total).*

The requirements in IEC 60601-1-11:2015, 10.1 or IEC 60601-1-12:2014, 10.1.1, in total or in part, may be substituted for the corresponding requirements of this subclause.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

Additional clauses:

201.101 Requirements for CUFFS

201.101.1 * Construction

The CUFF shall contain or incorporate a BLADDER.

The CUFF shall be constructed such that when the CUFF is applied to a limb, the construction ensures that the CUFF is the correct size or the CUFF shall be marked with an indication of the range of limb circumference for which the CUFF is appropriate.

NOTE Additional marking requirements for AUTOMATED SPHYGMOMANOMETERS intended for self-use in public areas are found in 201.7.2.104.

Compliance is checked by inspection.

201.101.2 * Pressurization

The CUFF and BLADDER and connection tubing shall be capable of withstanding an internal pressure equal to 180 mmHg (24 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE and equal to 360 mmHg (48 kPa) otherwise. The BLADDER shall be completely retained in the CUFF during this pressurization.

Compliance is checked by functional testing. Utilize a mandrel for these tests.

201.101.3 * AUTOMATED SPHYGMOMANOMETER intended for self-use in public areas with a single CUFF size

For an AUTOMATED SPHYGMOMANOMETER intended for adult self-use in public areas with a single CUFF size:

a) the limb size distribution (see ISO 81060-2:2013, 5.1.4) of the CUFF shall have a RATED range of mid-upper-arm circumference that includes at least 22 cm to 42 cm [17]; or

b) the AUTOMATED SPHYGMOMANOMETER shall not display a BLOOD PRESSURE reading when the mid-upper-arm circumference is outside the RATED range of the CUFF.

Compliance is checked by inspection.

201.102 * Connection tubing and CUFF connectors

OPERATOR-accessible, without the use of a TOOL, SMALL-BORE connections between the AUTOMATED SPHYGMOMANOMETER, CUFF, and connection tubing shall be equipped with a connector that complies with ISO 80369-1[4] or IEC 80369-5.

Compliance is checked by inspection.

201.103 Unauthorized access

To prevent tampering or unauthorized access, means shall be provided to restrict access to the RESPONSIBLE ORGANIZATION, for all controls, including those for PEMS, which can affect the accuracy of the AUTOMATED SPHYGMOMANOMETER.

EXAMPLE Requiring a TOOL for opening.

Compliance is checked by inspection.

201.104 * Maximum inflating time

In NORMAL CONDITION in any automatic cycling mode of operation, a pressure relief PROTECTION DEVICE shall ensure that the CUFF shall not inflate above the values in Table 201.103 for more than 180 s, or in NEONATAL MODE 90 s. See Figure 201.103.

In SINGLE FAULT CONDITION, in any automatic cycling mode of operation, a pressure relief PROTECTION DEVICE, functioning independently of the NORMAL CONDITION PROTECTION DEVICE, shall ensure that the CUFF does not inflate above the values in Table 201.103 for more than 180 s, or in NEONATAL MODE 90 s. See Figure 201.103.

Table 201.103 – CUFF inflation pressure

Mode	CUFF pressure
NEONATAL MODE	> 5 mmHg (0,7 kPa)
Any other mode	> 15 mmHg (2,0 kPa)

An AUTOMATED SPHYGMOMANOMETER that only operates in the SELF-MEASUREMENT AUTOMATIC MODE, where the PATIENT is the OPERATOR or the OPERATOR is intended to be in continual attendance, and where the pressure can be released from the CUFF or the limb by the OPERATOR is exempt from the SINGLE FAULT CONDITION requirement.

EXAMPLE 1 Pressure released by the OPERATOR by disconnecting the CUFF from the AUTOMATED SPHYGMOMANOMETER.

EXAMPLE 2 Pressure released by the OPERATOR by removing the CUFF from the limb.

Compliance is checked by introducing any SINGLE FAULT CONDITION and measuring the time that the CUFF remains inflated, beginning the timing measurement as soon as the CUFF pressure exceeds either 15 mmHg (2,0 kPa) or 5 mmHg (0,7 kPa), as appropriate.

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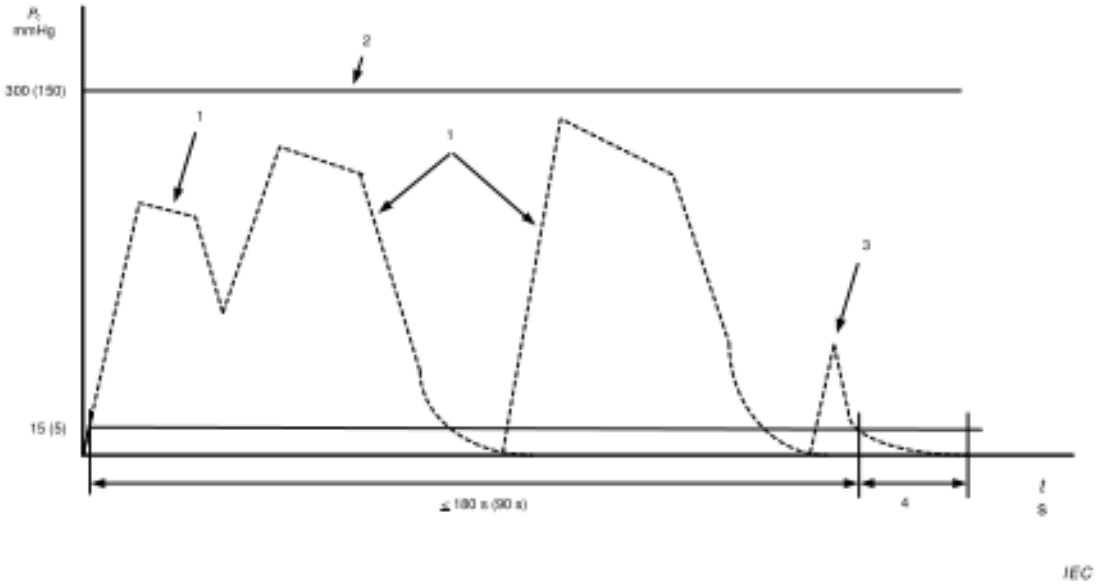
4 Under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2017.



Key

1 Unsuccessful DETERMINATION

2 Pressure limit

3 Aborted DETERMINATION

4 ≥ 30 s for LONG-TERM AUTOMATIC MODE and ≥ 5 s for SELF-MEASUREMENT AUTOMATIC MODE

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.103 – CUFF pressure and maximum inflation time, NORMAL CONDITION and SINGLE FAULT CONDITION

201.105 * Automatic cycling modes

201.105.1 LONG-TERM AUTOMATIC MODE

If an AUTOMATED SPHYGMOMANOMETER is equipped with a LONG-TERM AUTOMATIC MODE, a PROTECTION DEVICE shall be provided to ensure that:

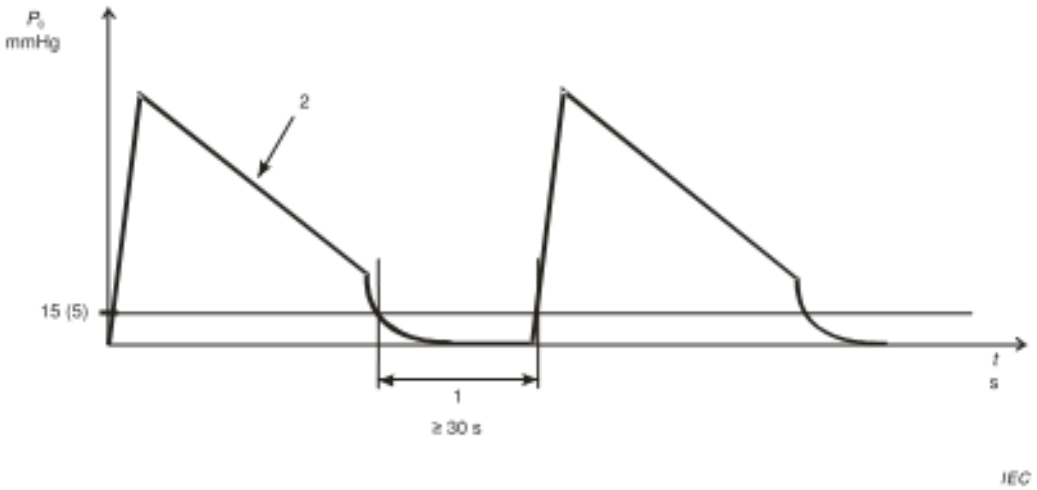
a) in NORMAL CONDITION:

- the total duration of the alternating inflation/deflation periods in an unsuccessful DETERMINATION (see Figure 201.103) shall not exceed the maximum inflation time specified in 201.104; and
- after each successful DETERMINATION, the CUFF pressure shall be released and shall remain below the values in Table 201.102 for at least 30 s (see Figure 201.104); and

b) in SINGLE FAULT CONDITION:

- if the duration of deflation below the values in Table 201.102 is less than 30 s (see Figure 201.105), then a pressure relief PROTECTION DEVICE functioning independently of the NORMAL CONDITION PROTECTION DEVICE, shall release the CUFF pressure to the values in Table 201.102.

Compliance is checked by functional testing.



Key

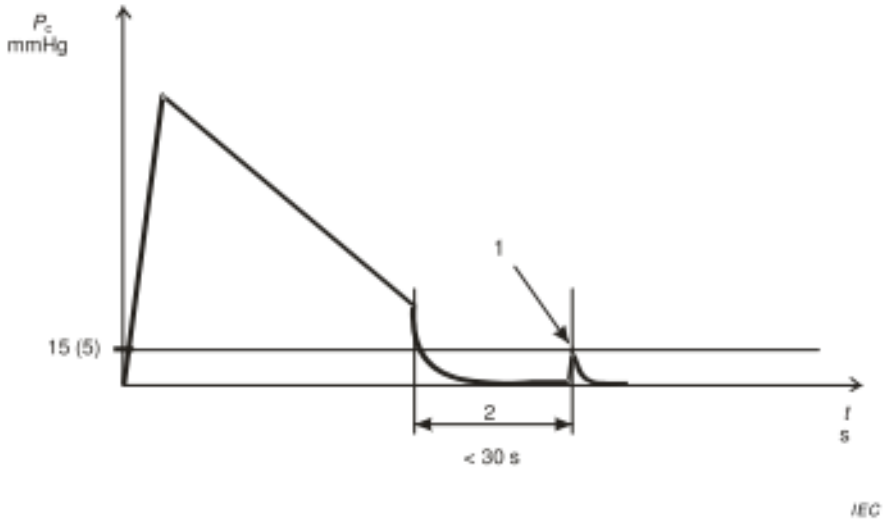
1 Deflated time

2 Linear CUFF deflation shown

NOTE Stepwise, exponential or other waveforms can be used for CUFF deflation.

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.104 – LONG-TERM AUTOMATIC MODE CUFF pressure in NORMAL CONDITION



Key

1 Pressure relief PROTECTION DEVICE activates

2 Deflated time

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.105 – LONG-TERM AUTOMATIC MODE CUFF pressure in SINGLE FAULT CONDITION

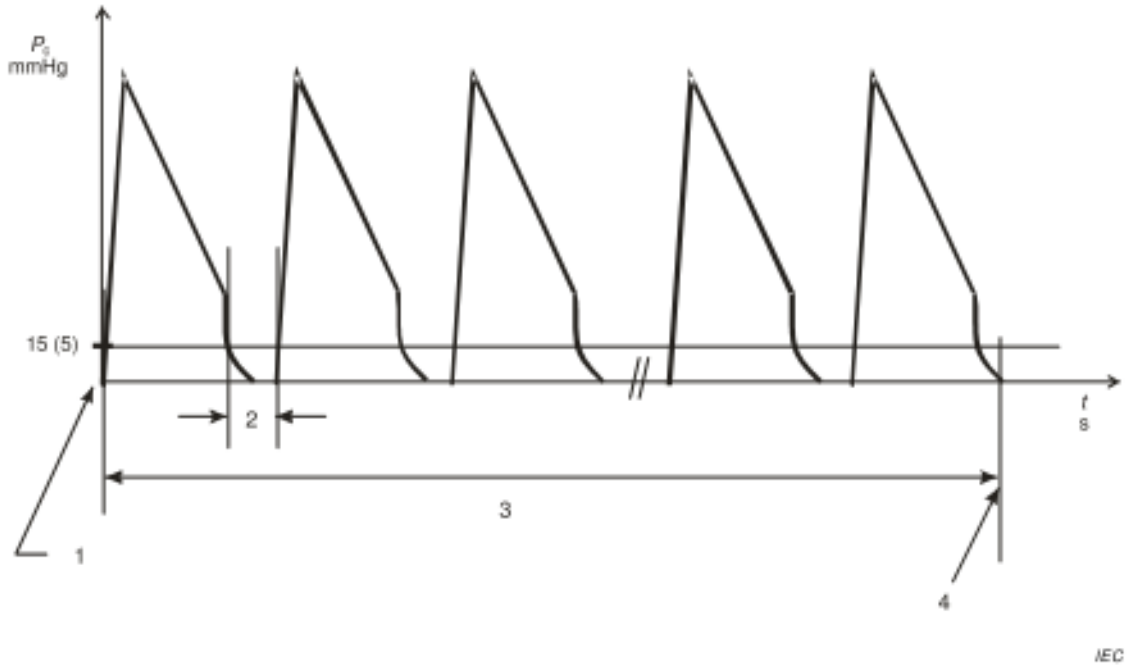
201.105.2 * SHORT-TERM AUTOMATIC MODE

If a SHORT-TERM AUTOMATIC MODE is available, a PROTECTION DEVICE shall be provided to:

a) ensure that following each individual DETERMINATION, the pressure in the CUFF shall be reduced to the values indicated in Table 201.102 for at least 2 s, to allow venous return (see Figure 201.106), and

b) restrict the duration of the SHORT-TERM AUTOMATIC MODE to a maximum of 15 min (see Figure 201.106). At the end of this time, the AUTOMATED SPHYGMOMANOMETER shall revert to the LONG-TERM AUTOMATIC MODE or a manual mode. A further period of the SHORT-TERM AUTOMATIC MODE may be selected by a deliberate action of the OPERATOR.

Compliance is checked by functional testing.



Key

1 OPERATOR starts SHORT-TERM AUTOMATIC MODE

2 Deflated time ≥ 2 s after each DETERMINATION

3 SHORT-TERM AUTOMATIC MODE limited to 15 min

4 SHORT-TERM AUTOMATIC MODE ends

CUFF pressure, P_c, as a function of time. NEONATAL MODE values in parentheses.

Figure 201.106 – SHORT-TERM AUTOMATIC MODE CUFF pressure

201.105.3 * SELF-MEASUREMENT AUTOMATIC MODE

201.105.3.1 General

If a SELF-MEASUREMENT AUTOMATIC MODE is available, the AUTOMATED SPHYGMOMANOMETER shall perform only a manually initiated series of less than 7 DETERMINATIONS (see Figure 201.107). The maximum duration of the SELF-MEASUREMENT AUTOMATIC MODE shall not exceed 30 min. After the completion of this series of DETERMINATIONS, the AUTOMATED

SPHYGMOMANOMETER shall revert to a manual mode. A subsequent SELF-MEASUREMENT AUTOMATIC MODE may be selected by a deliberate action of the OPERATOR.

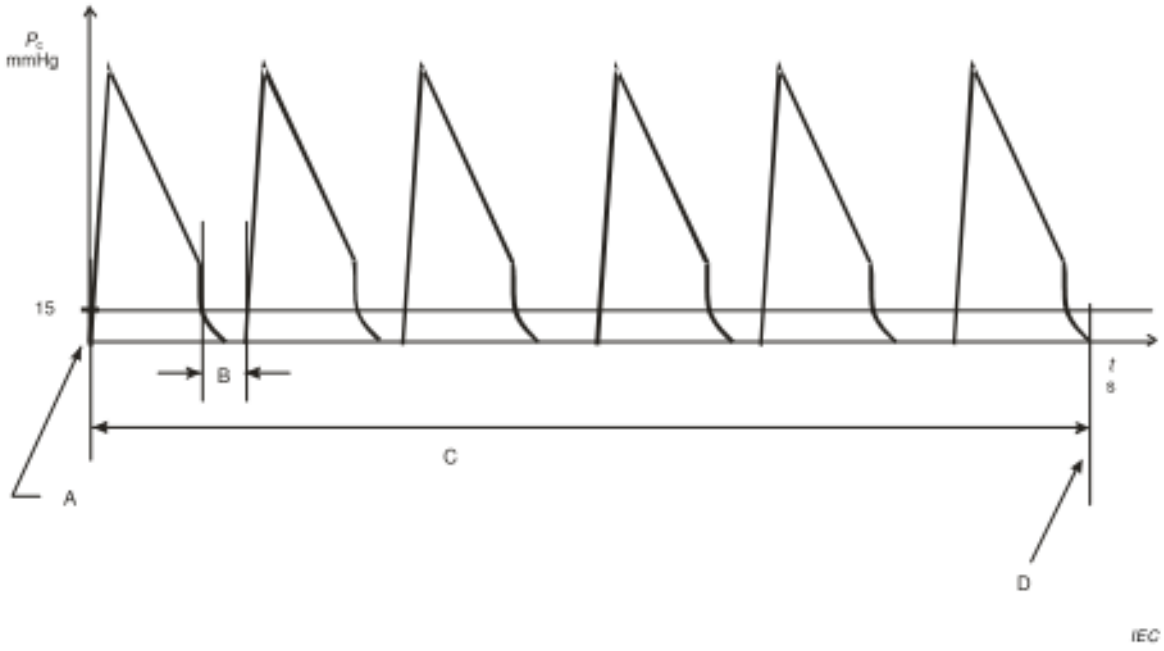
An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall not be intended for use with neonatal or infant PATIENTS. An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall be intended for use where:

a) the PATIENT is the OPERATOR; or

b) the OPERATOR is in continual attendance during the series of DETERMINATIONS.

An AUTOMATED SPHYGMOMANOMETER operating in the SELF-MEASUREMENT AUTOMATIC MODE may indicate only a single set of values derived from the series of DETERMINATIONS.

Compliance is checked by inspection and functional testing.



Key

A Start of SELF-MEASUREMENT MODE by the OPERATOR

B Deflated time ≥ 5 s after each DETERMINATION

C SELF-MEASUREMENT AUTOMATIC MODE

NOTE SELF-MEASUREMENT AUTOMATIC MODE is limited to 6 DETERMINATIONS

D SELF-MEASUREMENT AUTOMATIC MODE ends

CUFF pressure, P_c, as a function of time

Figure 201.107 – SELF-MEASUREMENT AUTOMATIC MODE CUFF pressure

201.105.3.2 NORMAL CONDITION

A PROTECTION DEVICE shall be provided to ensure that in NORMAL CONDITION:

a) the total duration of the alternating inflation/deflation periods in an unsuccessful DETERMINATION (see Figure 201.103) shall not exceed the maximum inflation time specified in 201.104; and

b) after each successful DETERMINATION, the CUFF pressure shall be released and shall remain below the pressure values in Table 201.102 for at least 5 s (see Figure 201.107).

Compliance is checked by functional testing.

201.105.3.3 * SINGLE FAULT CONDITION

A PROTECTION DEVICE shall be provided to ensure that in SINGLE FAULT CONDITION either:

a) if the duration of deflation below the pressure values in Table 201.102 is less than 5 s (see Figure 201.107), then a pressure relief PROTECTION DEVICE functioning independently of the NORMAL CONDITION PROTECTION DEVICE shall release the CUFF pressure to the values in Table 201.102;

b) the pressure can be released from the CUFF by the OPERATOR; or

c) the CUFF can be removed from the limb by the intended OPERATOR when the CUFF is inflated to 360 mmHg (48 kPa).

Compliance is checked by functional testing and inspection of the USABILITY ENGINEERING FILE.

201.106 * Clinical accuracy

Except for the SHORT-TERM AUTOMATIC MODE, each clinical operating mode of an AUTOMATED SPHYGMOMANOMETER shall comply with ISO 81060-2:2013, which contains the requirements for clinical accuracy and the protocols for investigating the clinical accuracy.

The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.

NOTE Additional requirements for the ACCOMPANYING DOCUMENTS are found in ISO 81060-2.

Compliance is checked by application of the tests of ISO 81060-2:2013.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 applies except as follows:

202.4.3.1 Configurations

Addition, after the last dashed item in the second paragraph:

– if applicable, attachment of ACCESSORIES as necessary to achieve the BASIC SAFETY and ESSENTIAL PERFORMANCE of the AUTOMATED SPHYGMOMANOMETER.

202.5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

Addition to item b) in the second paragraph:

NOTE The requirements of this particular standard are not considered deviations or allowances.

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

Clause 8 of the coll