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Edition 2.0 2018-03
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

IEC 80601-2-30:2018-03 RLV(en)

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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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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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.

1 Figures in square brackets refer to the Bibliography.

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.

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.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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 ~~intermittent~~ non-continuous indirect ~~measurement~~ estimation of the BLOOD PRESSURE without arterial puncture.

NOTE 1 Equipment that performs indirect ~~measurement~~ 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 ~~measurement~~ estimation of the BLOOD PRESSURE without arterial puncture~~,~~ ~~ME EQUIPMENT with automatic methods for estimating BLOOD PRESSURE~~, including BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT.

Requirements for indirect ~~measurement~~ 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 is amended by 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 ~~3.139~~ 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 58.

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

Replacement:

IEC 60601-1-2:~~2007~~ 2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic ~~compatibility~~ 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 60068-2-31:2008, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment type specimens*~~

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:~~2009~~ 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*

~~ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*~~

~~ISO 594-2:1991, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*~~

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 ~~validation~~ 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~~:2005, IEC 60601-1-2:2007~~, IEC 60601-1-8~~:2006~~, IEC 60601-2-2:~~2009~~ 2017 and IEC 62366-1:2015 and the following apply~~, except as follows~~.

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 61.

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**~~
~~**BLADDER**~~
~~part of the CUFF that is inflatable~~

~~[ISO 81060-1:2007, definition 3.2]~~

~~**201.3.203**~~
~~**BLOOD PRESSURE**~~
~~pressure in the systemic arterial system of the body~~

~~[ISO 81060-1:2007, definition 3.3]~~

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

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

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.

~~**201.3.207**~~
~~**HOME HEALTHCARE ENVIRONMENT**~~
~~dwelling place in which a patient lives or other environments that patients can occupy, excluding professional healthcare facility environments where operators with medical training are continually available when patients are present~~

~~NOTE 1 Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, multiple treatment facilities and ambulance services.~~

~~NOTE 2 In some countries, nursing homes are considered professional healthcare facilities.~~

~~NOTE 3 The home healthcare environment includes use in the outdoor environment and in personal automobiles.~~

~~[IEC 60601-1-11___[4], definition 3.2]~~

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 ~~CUFF~~ 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.

~~4 IEC 60601-1-11___, *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* (in preparation).~~

201.3.208
NON-AUTOMATED SPHYGMOMANOMETER
ME EQUIPMENT used for the non-invasive ~~measurement~~ 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	~~202.6.2.101~~ 202.8.101
Limits of the error of the manometer [a], or generation of a TECHNICAL ALARM CONDITION	201.12.1.102 201.11.8.102 201.12.1.101
~~Limits of the change in the error~~ Reproducibility of the BLOOD PRESSURE DETERMINATION and low and high BLOOD PRESSURE PHYSIOLOGICAL ALARM CONDITIONS (if provided), or generation of a TECHNICAL ALARM CONDITION	201.12.1.107 201.12.3.101 201.11.8.102 201.12.1.101
[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 sphygmomanometers for home healthcare environment**~~

~~If the AUTOMATED SPHYGMOMANOMETER is intended for use in the HOME HEALTHCARE ENVIRONMENT, the sales packaging shall display information needed by the end user including, as a minimum:~~

~~– identification of the appropriate arm circumference;~~

~~– the operating and storage temperature and humidity ranges;~~

~~– any special requirements for a battery-powered AUTOMATED SPHYGMOMANOMETER.~~

201.7.2.~~103~~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.~~104~~103 * AUTOMATED SPHYGMOMANOMETER intended for ~~public~~ 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 ~~measurements~~ 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.~~105~~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.~~106~~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 ~~to~~ 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 ~~measurements~~ 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.

~~NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa).~~

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 ~~202.6.2.101~~ 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~~, except as follows~~.

~~**201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**~~

~~*Replacement:*~~

~~ENCLOSURES of an AUTOMATED SPHYGMOMANOMETER, intended for use during PATIENT transport outside a healthcare facility, shall be designed to give an IPX2 degree of protection against harmful ingress of water or particulate matter and shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE following the tests in IEC 60529:1989 for IPX2.~~

~~*Compliance is checked by application of the tests of IEC 60529:1989 with the AUTOMATED SPHYGMOMANOMETER in the least favourable position of NORMAL USE and by inspection and functional testing.*~~

~~*After these PROCEDURES, ensure that the ME EQUIPMENT shows no signs of bridging of insulation (or electrical components) that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests. Ensure that ESSENTIAL PERFORMANCE is maintained.*~~

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 ~~equipped~~ 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) ~~Determine whether~~ Confirm that the CUFF is sufficiently deflated and that the indicated BLOOD PRESSURE disappears within 30 s.

e) Restore the SUPPLY MAINS and ~~determine either~~ 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:

~~Replacement:~~

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 ~~60~~ 40 mmHg (~~8,0~~ 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).

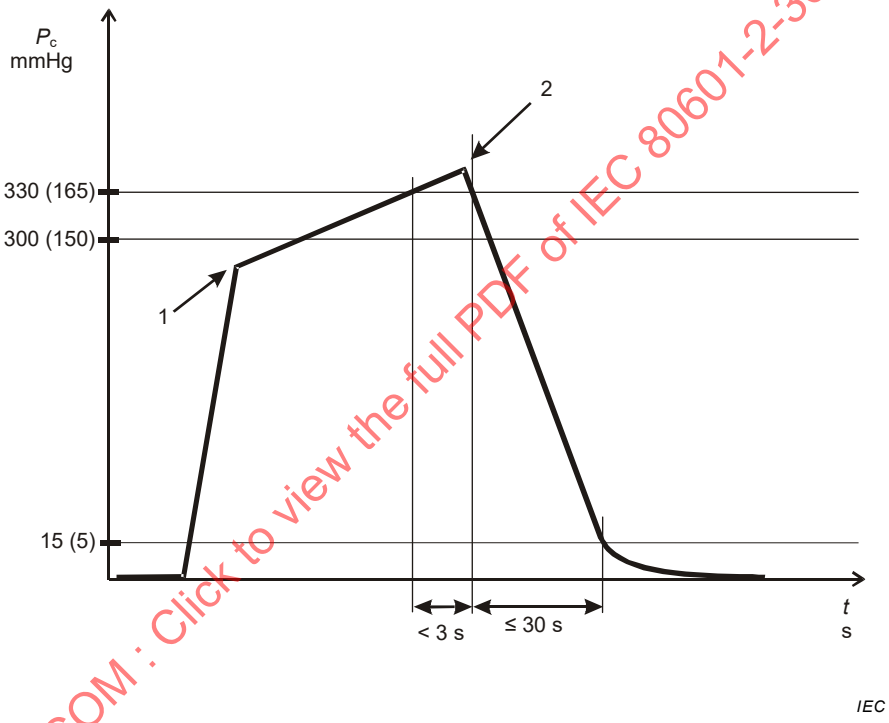
When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s to ≤ 15 mmHg (2,0 kPa) and to ≤ 5 mmHg (0,7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE.

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.

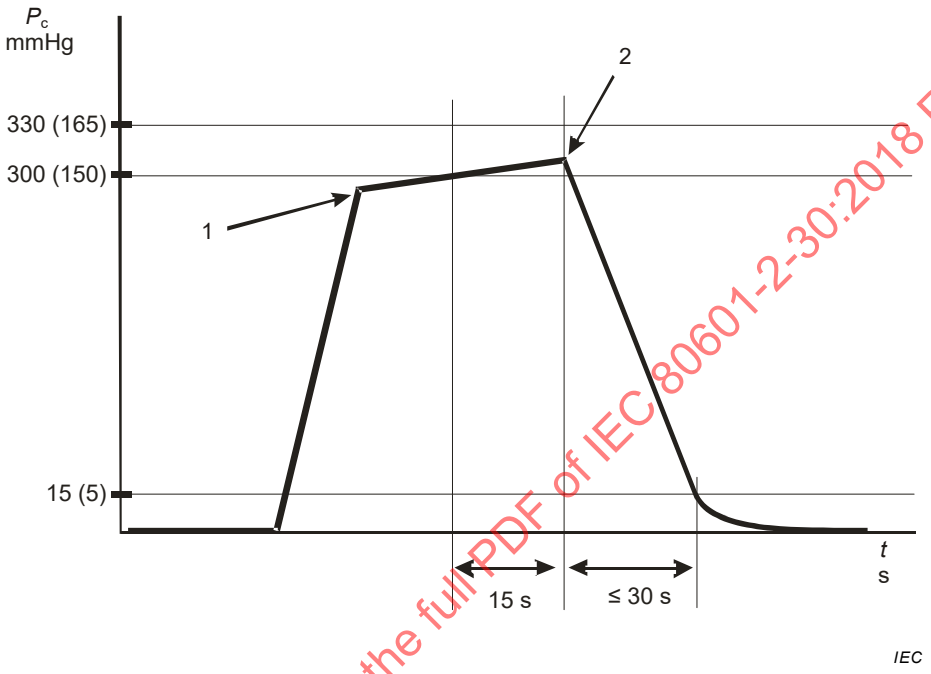
EXAMPLE 1 A port for connection to a pressure source so that the pressure can be measured by the AUTOMATED SPHYGMOMANOMETER in a test mode.

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 ~~Limits of the change in error~~ * Reproducibility of the BLOOD PRESSURE DETERMINATION

The laboratory ~~limits of the change in error~~ 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 (~~2,7~~ 5,3 kPa) and a SYSTOLIC BLOOD PRESSURE value of 70 mmHg (~~18,0~~ 9,33 kPa) at a pulse rate of 140 beats/min in NEONATAL MODE and a DIASTOLIC BLOOD PRESSURE value of 80 mmHg (~~5,3~~ 10,67 kPa) and a SYSTOLIC BLOOD PRESSURE value of 120 mmHg (~~30,7~~ 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.

~~c) Perform all the tests of this standard, except 201.106.~~

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

~~e) Calculate the difference of the means calculated in b) and d)~~

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) Ensure that the difference is below the limit.~~

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 ~~have~~ 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 ~~of at least MEDIUM PRIORITY~~. 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 ~~inspection and~~ 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 ~~for other than transport~~ (robustness)

An AUTOMATED SPHYGMOMANOMETER or its parts ~~not intended for use during PATIENT transport outside a healthcare facility~~ 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 ~~1~~ 2 This represents IEC TR 60721-4-7 ~~:1995~~ [16], Class 7M2.

1) test type: Type 1:

- *peak acceleration: ~~100~~ 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 ~~2~~ 3 This represents IEC TR 60721-4-7:~~1995~~ [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 ~~201.15.3.5.102~~ 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.

~~**201.15.3.5.102 * Shock and vibration for transport**~~

~~An AUTOMATED SPHYGMOMANOMETER or its parts, intended for use during PATIENT transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping, and rough handling.~~

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

~~*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 1 This represents IEC 60721-4-7:1995, Class 7M3.~~

~~*1) test type: Type 1:*~~

~~– *peak acceleration: 300 m/s^2 (30 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: 1 000 m/s^2 (100 g);*~~

~~– *duration: 6 ms;*~~

~~– *pulse shape: half sine;*~~

~~– *number of shocks: 3 shocks per direction per axis (18 total).*~~

~~*b) Broadband random vibration according to IEC 60068-2-64:2008 using the following conditions:*~~

~~NOTE 2 This represents IEC 60721-4-7:1995, Class 7M3.~~

~~*1) acceleration amplitude:*~~

~~– *10 Hz to 100 Hz: 5,0 $(m/s^2)^2$/Hz;*~~

~~– *100 Hz to 200 Hz: −7 db/octave;*~~

~~– 200 Hz to 1 000 Hz: 1,0 $(m/s^2)^2/Hz$;~~

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

~~c) Free fall according to IEC 60068-2-31:2008, using Procedure 1:~~

~~NOTE 3 This represents IEC 60721-4-7:1995, Class 7M2.~~

~~1) fall height:~~

~~– for mass < 1 kg, 0,25 m;~~

~~– for mass between 1 kg and < 10 kg, 0,1 m;~~

~~– for mass between 10 kg and < 50 kg, 0,05 m;~~

~~– for mass ≥ 50 kg, 0,01 m;~~

~~2) number of falls: 2 in each specified attitude.~~

~~For a PORTABLE AUTOMATED SPHYGMOMANOMETER that is intended to be used with a carrying case, that case may be applied to the AUTOMATED SPHYGMOMANOMETER during this test.~~

~~d) Verify that BASIC SAFETY is maintained and that the AUTOMATED SPHYGMOMANOMETER functions normally.~~

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~~, except as follows~~.

~~*Addition:*~~

~~NOTE An AUTOMATED SPHYGMOMANOMETER is not considered LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM as defined in IEC 60601-1-2.~~

~~*New*~~ *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 ~~not~~ be equipped with a connector that ~~couples with a connector complying with ISO 594-1 or ISO 594-2~~ complies with ISO 80369-1[5] 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 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and~~ for more than 180 s ~~otherwise~~, 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 ~~shall~~ does not inflate above the values in Table 201.103 ~~for more than 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and otherwise~~ 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)

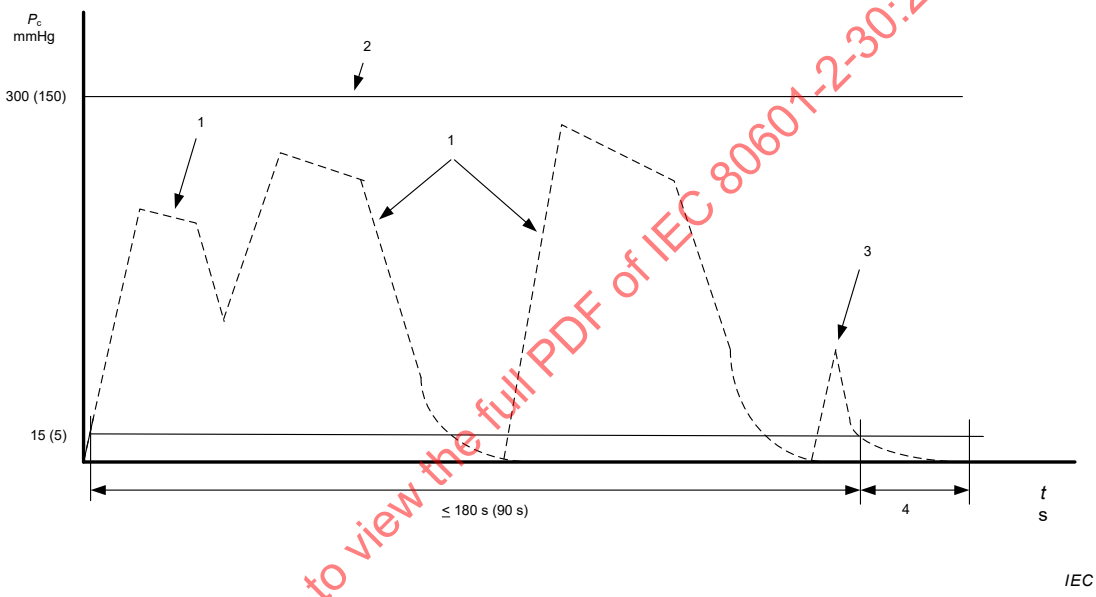
5 Under preparation. Stage at the time of publication: ISO/FDIS 80369-1:2017.

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.



Key

1 Unsuccessful DETERMINATION

2 Pressure limit; ~~NEONATAL MODE values in parentheses~~

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:

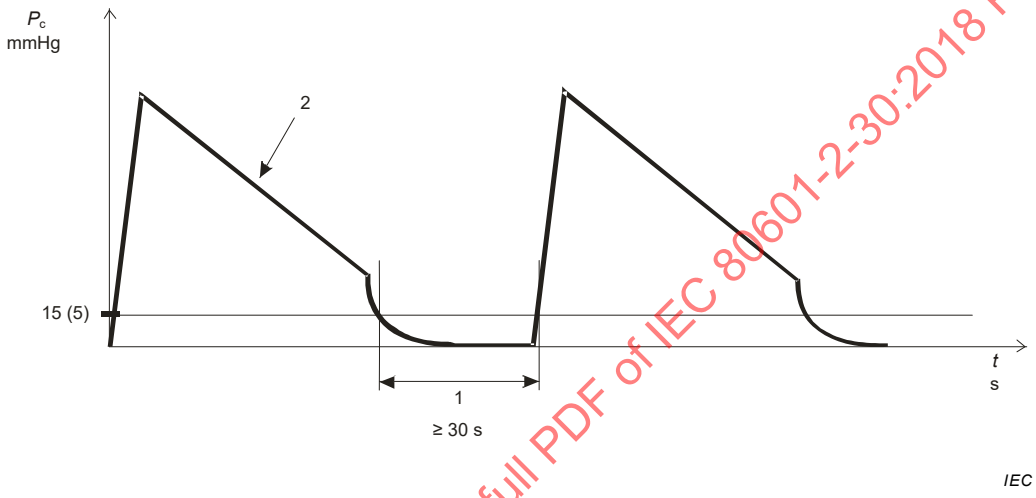
- the total duration of the alternating inflation/deflation periods in an unsuccessful DETERMINATION (see Figure 201.103) shall not exceed the maximum inflation time specified in 201.104; and

- 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

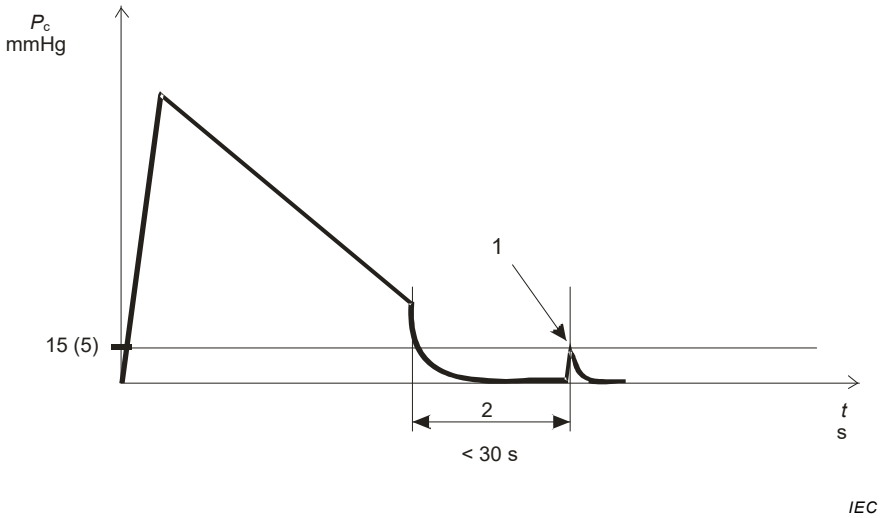
1 Deflated time

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

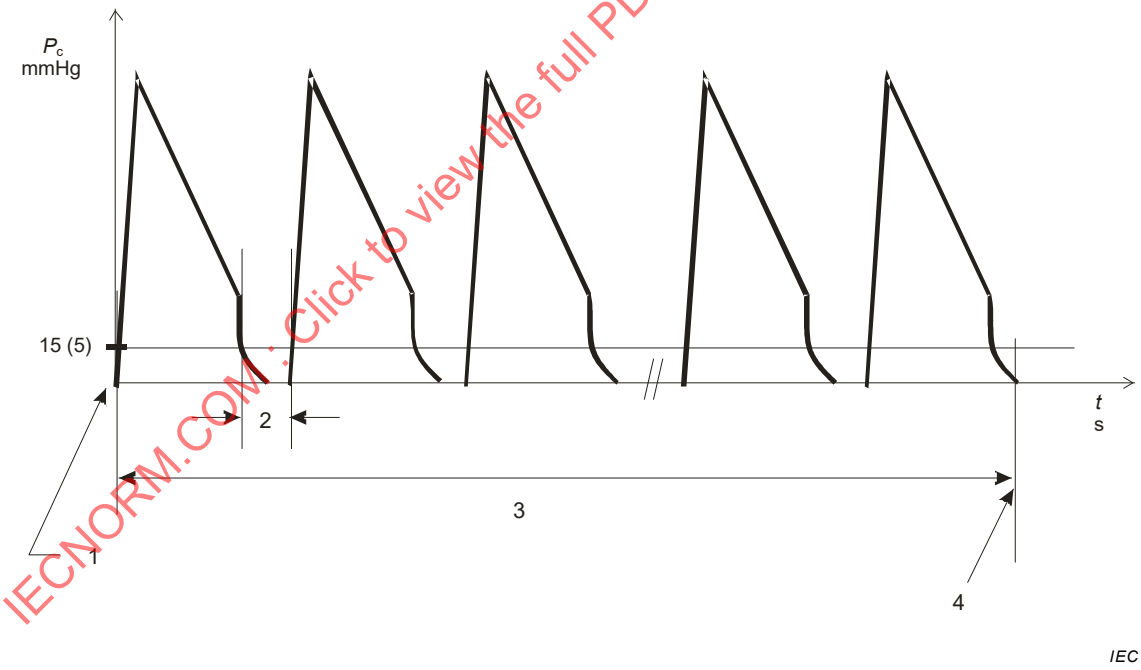
201.105.2 * SHORT-TERM AUTOMATIC MODE

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.

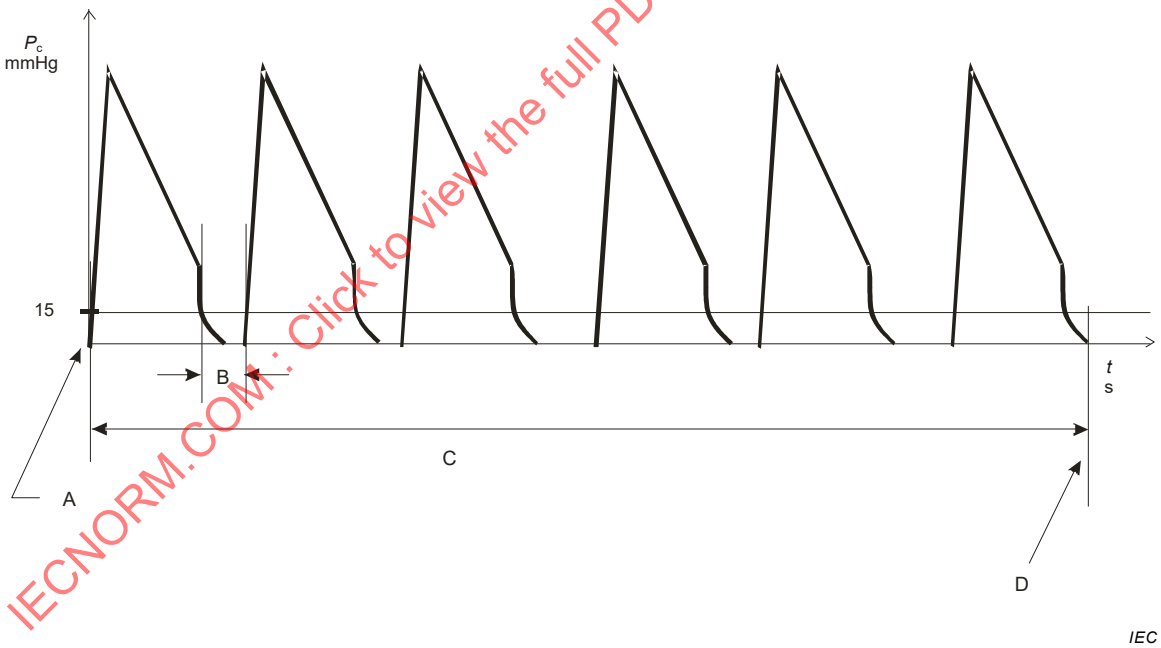
An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall not be intended for use with neonatal or infant PATIENTS. An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall be intended for use where:

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.~~104~~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 ~~30~~ 5 s (see Figure 201.~~105~~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 ~~validating~~ 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 ~~compatibility~~ disturbances – Requirements and tests

IEC 60601-1-2:~~2007~~ 2014 applies except as follows:

~~**202.4 General requirements**~~

~~*Additional subclause:*~~

~~**202.4.101 Classification**~~

~~An AUTOMATED SPHYGMOMANOMETER shall not be considered LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM.~~

~~**202.6.2 Immunity**~~

~~**202.6.2.1.10 Compliance criteria**~~

~~*Replacement:*~~

~~Under the test conditions specified in IEC 60601-1-2:2007, 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE. Under these conditions, the maximum change in the reading for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to 2 mmHg (0,3 kPa).~~

~~**202.6.2.3.1 Requirements**~~

~~a) General~~

~~*Replacement:*~~

~~An AUTOMATED SPHYGMOMANOMETER, except as specified in c) below or in the EXCLUSION BAND as specified in d) below, shall comply with the requirements of IEC 60601-1-2:2007, 6.2.1.10, at an IMMUNITY TEST LEVEL of 3 V/m over the frequency range 80 MHz to 2,5 GHz.~~

~~In addition, an AUTOMATED SPHYGMOMANOMETER intended for use during PATIENT transport outside the healthcare facility, except as specified in c) below or in the EXCLUSION BAND as specified in d) below, shall comply with the requirements of 6.2.1.10 at the IMMUNITY TEST LEVEL of 20 V/m (80 % amplitude modulated at 1 000 Hz) over the range of 80 MHz to 2 500 MHz.~~

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 collateral standard applies, except as follows:

202.8.1 General

Addition:

202.8.1.101 Additional general requirements

The following degradations, if associated with BASIC SAFETY or ESSENTIAL PERFORMANCE, shall not be allowed:

a) component failures;

b) changes in programmable parameters or settings;

c) reset to default settings; and

d) change in the reading for the measurement of the CUFF pressure at any point of the NOMINAL measurement range greater than 2 mmHg (0,3 kPa):

1) during and after exposure to non-transient phenomena; and

2) after exposure to transient phenomena.

Additional subclause:

~~202.6.2.101~~ 202.8.101 * Electrosurgery interference recovery

If an AUTOMATED SPHYGMOMANOMETER is intended to be used together with HF SURGICAL EQUIPMENT, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT, without loss of any stored data.

Compliance is checked by functional testing using the test setup indicated in Figure 202.101 and Figure 202.102.

a) Use HF SURGICAL EQUIPMENT that complies with IEC 60601-2-2 and that:

- *has a cut mode with at least 300 W of power,*
- *has a coagulation mode with a least 100 W of power, and*
- *has a working frequency of 450 kHz ± ~~100~~ 150 kHz.*

b) Test in cut mode:

Set up the ME EQUIPMENT to operate from a PATIENT SIMULATOR set to simulate a BLOOD PRESSURE of 100/70 mmHg ± 10 mmHg (13,3/9,3 kPa ± 1,3 kPa). On the HF SURGICAL EQUIPMENT, ~~select~~ set the cut mode at 300 W.

Touch the metal plate in the test setup (see Figure 202.101) with the active electrode and remove the electrode slowly to produce a spark (generate high-frequency interference).

Terminate the interference. Wait 10 s. ~~Determine whether~~ Confirm that displayed parameters on the ME EQUIPMENT have returned to their pre-test readings.

Repeat this PROCEDURE as described, five times.

c) Test in coagulation mode:

Set up the ME EQUIPMENT to operate from a PATIENT SIMULATOR set to simulate a BLOOD PRESSURE of about 100/70 mmHg ± 10 mmHg (13,3/9,3 kPa ± 1,3 kPa). On the HF SURGICAL EQUIPMENT, ~~select~~ set the coagulation mode at 100 W.

Touch the metal plate in the test setup (see Figure 202.101) with the active electrode and remove the electrode slowly to produce a spark (generate high-frequency interference).

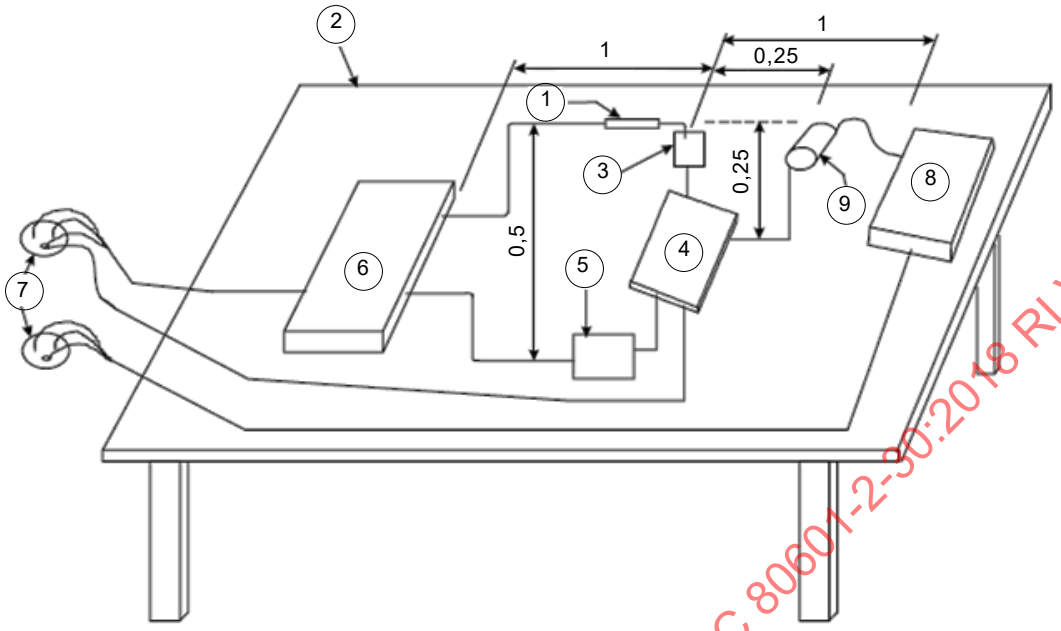
Terminate the interference. Wait 10 s. ~~Determine whether~~ Confirm that displayed parameters on the ME EQUIPMENT have returned to their pre-test readings.

Repeat this PROCEDURE as described, five times.

~~NOTE 1~~ *Test of ~~the~~ other modes (e.g. spray coagulation) is not required.*

NOTE ~~2~~ If the HF SURGICAL EQUIPMENT interferes with the PATIENT SIMULATOR, shield the PATIENT SIMULATOR.

Dimensions in m



Key

1 Active electrode

2 Table made of insulating material

3 Metal plate

4 Simulated PATIENT for HF SURGICAL EQUIPMENT

5 Neutral electrode

6 HF SURGICAL EQUIPMENT

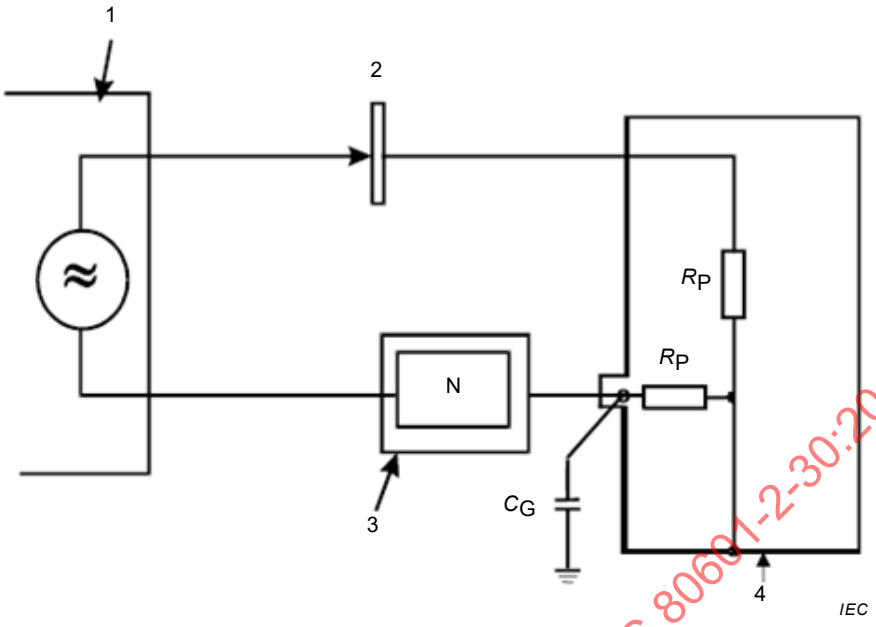
7 SUPPLY MAINS

8 AUTOMATED SPHYGMOMANOMETER under test

9 CUFF wrapped in metal foil that is wrapped around the mandrel of a PATIENT SIMULATOR

The PATIENT SIMULATOR is connected via a 'T' to the PNEUMATIC SYSTEM. The simulated PATIENT is connected to the foil wrap of CUFF.

Figure 202.101 – HF SURGICAL EQUIPMENT test layout



Key

1 HF SURGICAL EQUIPMENT

2 Metal plate

3 Metal plate

4 Metal box for shielding

R_P = 220 Ω, 200 W (low inductance, simulates PATIENT impedance)

C_G = 47 nF (minimizes the influence of different types of high frequency surgery equipment designs)

Figure 202.102 – Simulated PATIENT test set-up for HF SURGICAL EQUIPMENT

206 Usability

IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 apply, except as follows:

Addition:

For an AUTOMATED SPHYGMOMANOMETER, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) observing the displayed BLOOD PRESSURE; and
b) properly applying the CUFF to the PATIENT.

For an AUTOMATED SPHYGMOMANOMETER, if available, the following shall be considered PRIMARY OPERATING FUNCTIONS:

c) selecting the proper CUFF for the PATIENT;
d) setting the OPERATOR-adjustable controls;
e) setting ALARM LIMITS;
f) inactivating ALARM SIGNALS; and
g) switching between different modes.

The following actions associated with making a DETERMINATION shall be considered PRIMARY OPERATING FUNCTION:

h) properly positioning the PATIENT.

210 Requirements for the development of physiologic closed-loop controllers

IEC 60601-1-10:2007 applies, except as follows:

210.4 General requirements

Replacement of the first dashed item in the first paragraph:

– * latency times, including the aperiodic nature of AUTOMATED SPHYGMOMANOMETER DETERMINATIONS;

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015 applies, except as follows:

211.4.2.2 Environmental conditions of transport and storage between uses

*Addition, in the first sentence after the phrase "*The instructions for use*", of the words "*and the sales packaging*".*

211.4.2.3.1 Continous operating conditions

*Addition, in the first sentence after the phrase "*The instructions for use*", of the words "*and the sales packaging*".*

211.7.4.5 Additional requirements for operating instructions

Addition:

The instructions for use and the sales packaging shall indicate the RATED range of arm circumferences of the CUFF.

211.8.3.1 Ingress of water or particulate matter into ME EQUIPMENT

Replacement, in the second sentence, of the word "IP21" *by* "IP20".

212 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

IEC 60601-1-12:2014 applies except as follows:

212.10.1.1 General requirements for mechanical strength

Addition, before the first paragraph, of the following new paragraph:

The tests of Clause 10 of IEC 60601-1-12:2014 and 15.3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 shall be performed on the same sample of the AUTOMATED SPHYGMOMANOMETER after the cleaning and disinfection PROCEDURES of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 11.6.6, have been performed unless there are no cleaning and disinfection PROCEDURES specified in the instructions for use. If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE shall be so tested. A separate sample of the AUTOMATED SPHYGMOMANOMETER may be used for each specified PROCEDURE.

Annexes

The annexes of the general standard apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of the general standard applies, except as follows.

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of the AUTOMATED SPHYGMOMANOMETER or its parts are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of AUTOMATED SPHYGMOMANOMETERS or their parts

Description of marking	Subclause
As appropriate, proper disposal methods	201.7.2.~~106~~105
Correct positioning for the CUFF on the designated limb over the artery	201.7.2.4
~~For the HOME HEALTHCARE ENVIRONMENT, packaging marked with any special requirements for battery-powered equipment~~	~~201.7.2.102~~
~~For the HOME HEALTHCARE ENVIRONMENT, packaging marked with appropriate arm circumference~~	~~201.7.2.102~~
~~For the HOME HEALTHCARE ENVIRONMENT, packaging marked with operating and storage temperature and humidity ranges~~	~~201.7.2.102~~
For self-use in public ~~use~~ areas, adequate operating instructions	201.7.2.~~104~~103
For self-use in public ~~use~~ areas, ~~the measurement accuracy of the AUTOMATED~~ this SPHYGMOMANOMETER complies with IEC 80601-2-30:2018	201.7.2.~~104~~103
For self-use in public ~~use~~ areas, the need to consult a physician for interpretation of BLOOD PRESSURE measurements	201.7.2.~~104~~103
For self-use in public ~~use~~ areas, precautions for use	201.7.2.~~104~~103
For self-use in public areas with a single CUFF size, range of arm circumference for which the CUFF is intended	201.7.2.103
For self-use in public areas with a single CUFF size, statement to the effect that results might not be accurate if your arm is outside the specified circumference range	201.7.2.103
If applicable, ACCESSORIES intended for use only in the NEONATAL MODE	201.7.2.~~103~~102
If applicable, caution to the effect that substitution of a component different from that supplied might result in measurement error, or with ~~symbol~~ safety sign ISO 7010-M002	201.7.2.~~105~~104
If applicable, a detailed description of correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2.13
~~An indication of whether the CUFF is the correct size~~	~~201.101.1~~
The range of limb circumference for which the CUFF is appropriate	201.101.1

201.C.3 Marking of controls and instruments

Addition:

Additional requirements for marking of controls and instruments of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.102.

Table 201.C.102 – Marking of controls and instruments of AUTOMATED SPHYGMOMANOMETERS or their parts

Description of marking	Subclause
If applicable, display abbreviations for SYSTOLIC, DIASTOLIC and MEAN ARTERIAL PRESSURE	201.7.2.101

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

Additional requirements for general information to be included in the accompanying documents of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.103.

Table 201.C.103 – ACCOMPANYING DOCUMENTS, general information for AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
Additional requirements can be found in ISO 81060-2.	201.106
Disclosure that the AUTOMATED SPHYGMOMANOMETER was clinically investigated according to ISO 81060-2:2013.	201.106

201.C.5 ACCOMPANYING DOCUMENTS, Instructions for use

Addition:

Additional requirements for ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.104.

Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
An explanation of the need to avoid compression or restriction of the connection tubing	201.7.9.2.9 gg)
An explanation of the operating steps of the AUTOMATED SPHYGMOMANOMETER needed to obtain routine resting BLOOD PRESSURE measurements for the diagnosis of hypertension	201.7.9.2.9 bb)
An explanation of the selection of a suitable size and application of the CUFF to the PATIENT	201.7.9.2.9 aa)
An explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition	201.7.9.2.9 cc)
Description of the operating principles	201.7.9.2.5
Details of the environmental or operation factors which can affect the performance of the AUTOMATED SPHYGMOMANOMETER and/or its BLOOD PRESSURE reading	201.7.9.2.9 ee)
Details of what the OPERATOR should do if unexpected readings are obtained	201.7.9.2.9 dd)
For the sales packaging, conditions of transport and storage between uses	211.4.2.2
For the sales packaging, continous operating conditions	211.4.2.3.1
For the sales packaging, RATED range of arm circumferences of the CUFF	211.7.4.5
Frequently used functions	201.7.9.2.1
If applicable, the correct method of reassembly	201.7.9.2.13
If applicable, a detailed description of the correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2.13
If applicable, that the ME EQUIPMENT is suitable for use in the presence of electrosurgery	201.7.9.2.101

Description of disclosure	Subclause
If applicable, the protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2.101
If applicable, the absence of protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2.101
If applicable, the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in the NEONATAL MODE	201.7.9.2.102 a)
If applicable, the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER can accommodate when in the NEONATAL MODE	201.7.9.2.102 b)
If applicable, recommended ACCESSORIES to avoid errors and excessive pressure	201.7.9.2.102 c)
If applicable, method for placing into the NEONATAL MODE	201.7.2.~~103~~102
If applicable, a statement that the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude	201.7.9.2.9 ff)
Intended conditions of use	201.7.9.2.1 5)
Intended medical indication	201.7.9.2.1 1)
Intended PATIENT population, including whether or not intended for use with neonatal and infant PATIENTS and with pregnant, including pre-eclamptic, PATIENTS	201.7.9.2.1 3)
Intended placement of the CUFF	201.7.9.2.1 4)
Permissible environmental conditions of use	201.7.9.2.1
RATED range of arm circumferences of the CUFF	211.7.4.5
RATED range of CUFF pressure	201.7.9.2.9 hh)
RATED ranges of the DETERMINATION	201.7.9.2.5
Restrictions or contraindications to use	201.7.9.2.1 2)
Use as intended by the MANUFACTURER	201.7.9.2.1
Warning indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference	201.7.9.2.2 bb)
Warning regarding application of the CUFF and its pressurization on a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because of temporary interference with blood flow and resulting injury to the PATIENT	201.7.9.2.2 dd)
Warning regarding application of the CUFF and its pressurization on the arm on the side of a mastectomy	201.7.9.2.2 ee)
Warning regarding applying the CUFF over a wound, as this can cause further injury	201.7.9.2.2 cc)
Warning regarding the need to check that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the PATIENT	201.7.9.2.2 gg)
Warning regarding the effect of continuous CUFF pressure due to connection tubing kinking on blood flow and possible injury to PATIENT	201.7.9.2.2 aa)
Warning that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb	201.7.9.2.2 ff)
Warning regarding the RISKS of not using the NEONATAL MODE on a neonatal PATIENT	201.7.2.~~103~~102

201.C.6 ACCOMPANYING DOCUMENTS, technical description

Addition:

Additional requirements for ACCOMPANYING DOCUMENTS, technical description of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.105.

Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description of AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
Test method that can be used to verify the calibration	201.12.1.106

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of IEC 80601-2-30, and is intended for those who are familiar with the subject of IEC 80601-2-30 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of IEC 80601-2-30 necessitated by those developments.

AUTOMATED SPHYGMOMANOMETERS are used in almost all clinical environments in healthcare. As such, BLOOD PRESSURE monitoring is used on almost all PATIENTS when they encounter the healthcare system. They are increasingly being used by PATIENTS in the HOME HEALTHCARE ENVIRONMENT.

Faults in the inflation and deflation cycles of AUTOMATED SPHYGMOMANOMETERS are the main non-electrical BASIC SAFETY issues. In the inflation cycle, the problems could be as follows:

– too high a target pressure for neonatal or young paediatric use, causing bruising and possibly bone deformation;

– too long an inflated period resulting in extended venous (and possibly arterial) occlusion; or

– a rapid repetition rate for an extended period, resulting in excessive venous occlusion, and hence venous blood pooling.

In the deflation cycle, there is only one non-electrical BASIC SAFETY issue that occurs, and that is the failure to deflate. In the short term, this can cause discomfort to a conscious PATIENT, but to an unconscious PATIENT the failure to deflate over an extended period of time can result in irreversible neuromuscular injury [18] [19].

Various clauses in this document have, as their express purpose, the avoidance of these non-electrical BASIC SAFETY issues.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationale corresponds to the numbering of the clauses in IEC 80601-2-30. The numbering is, therefore, not consecutive.

Subclause 201.3.~~217~~214 – SHORT-TERM AUTOMATIC MODE

The SHORT-TERM AUTOMATIC MODE of an AUTOMATED SPHYGMOMANOMETER is particularly relevant during the administration of anaesthesia, but also finds application in accident and emergency departments, when a PATIENT is hemodynamically unstable. The ability to follow the trend of the BLOOD PRESSURE is more important to the OPERATOR than the absolute accuracy of individual DETERMINATIONS. As a result, the time between measurements is permitted to be very short even though that can negatively affect the clinical accuracy of DETERMINATIONS. Therefore, an AUTOMATED SPHYGMOMANOMETER is not required to meet the clinical accuracy requirements when operating in this mode.

Subclause 201.7.2.4 – ACCESSORIES

The accuracy of a DETERMINATION requires the use of the correct size CUFF. If the CUFF used is too large or too small relative to the limb circumference of the PATIENT, or incorrectly positioned on the limb of the PATIENT, clinically significant errors in BLOOD PRESSURE estimation could result [20] [21] [22].

Subclause 201.7.2.~~103~~102 – AUTOMATED SPHYGMOMANOMETER~~S~~ with NEONATAL MODE

This document specifies the use of lower maximum CUFF pressures and shorter measurement times with neonatal PATIENTS to reduce the RISK of injury. AUTOMATED SPHYGMOMANOMETERS need clear instructions for the OPERATOR to ensure that the proper mode is used with neonatal PATIENTS.

Subclause 201.7.2.~~104~~103 – AUTOMATED SPHYGMOMANOMETER~~S~~ intended for self-use in public ~~use~~ areas

AUTOMATED SPHYGMOMANOMETERS intended for use in public areas are typically used by OPERATORS measuring their own BLOOD PRESSURE. These OPERATORS do not have access to the instructions for use. The most important instructions need to be marked on the ME EQUIPMENT.

Subclause 201.7.2.~~105~~104 – Component replacement

Replacement of components or parts that can impact BASIC SAFETY or ESSENTIAL PERFORMANCE should occur only with the appropriate awareness of the potential consequences of the replacement. Both clinical OPERATORS and SERVICE PERSONNEL need this awareness. Appropriate PROCEDURES, for example re-calibration, should occur following such replacements. The marking requirement is intended to give this awareness.

Subclause 201.7.9.2.13 – Maintenance

The performance should be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.106) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa).

Subclause 201.8.5.5.101 – PATIENT CONNECTIONS of AUTOMATED SPHYGMOMANOMETERS

AUTOMATED SPHYGMOMANOMETERS are frequently used in environments in which other pieces of ME EQUIPMENT are also connected to the same PATIENT. If the AUTOMATED SPHYGMOMANOMETER has PATIENT CONNECTIONS, it is important for the safety of the PATIENT and the OPERATOR that it be a DEFIBRILLATION-PROOF APPLIED PART.

Subclause 201.11.8.101 – Switching off

The intent of this requirement is to ensure reduced RISK of injury to a PATIENT due to excessive pressure applied to the limb when the AUTOMATED SPHYGMOMANOMETER is turned off or loses power unintentionally. The requirement is intended to ensure that the AUTOMATED SPHYGMOMANOMETER is in a safe state when power is removed. Examples include AUTOMATED SPHYGMOMANOMETERS for use on neonatal or infant PATIENTS and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple DETERMINATIONS without OPERATOR intervention over extended periods of time. See also the rationale for 201.12.1.105 for a discussion of pressure levels and deflation acceptance criterion.

Subclause 201.11.8.103 – INTERNAL ELECTRICAL POWER SOURCE

Failure to deflate the CUFF within 30 s to the values indicated in Table 201.102 is considered a failure to maintain BASIC SAFETY.

Subclause 201.12.1.103 – NOMINAL BLOOD PRESSURE indication range

This test is a compromise as it is not practicable to perform this test in human subjects since these BLOOD PRESSURE values are extremely rare in clinical care. It is important for AUTOMATED SPHYGMOMANOMETERS to be able to indicate BLOOD PRESSURES above the range over which they are clinically ~~validated~~ investigated. An AUTOMATED SPHYGMOMANOMETER that either blanks or artificially limits the value of the display above that range would "hide" the condition of the PATIENT from the OPERATOR.

Subclause 201.12.1.105 – Maximum pressure in SINGLE FAULT CONDITION

The intent of this requirement is to ensure reduced RISK of injury to a PATIENT due to excessive pressure applied to the limb when the primary pressure sensing and protection mechanism of the AUTOMATED SPHYGMOMANOMETER is not functioning due to a SINGLE FAULT CONDITION. The requirement is intended to reduce RISK in situations where the PATIENT is unable to remove the CUFF in the case of overpressure and there is no OPERATOR likely to be present. In these cases, it is necessary to provide a PROTECTION DEVICE to release pressure from the CUFF without the intervention of the OPERATOR or the PATIENT. Examples include AUTOMATED SPHYGMOMANOMETERS for use on neonatal PATIENTS and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple DETERMINATIONS with no OPERATOR intervention over long periods of time.

Failure of the CUFF to deflate over an extended period of time can result in injury to the PATIENT. Reduction of the CUFF pressure to less than 15 mmHg is considered sufficient to reduce or eliminate the RISK of injury to adults. Since neonates are particularly sensitive to the effects of prolonged pressure on a limb, reduction of the CUFF pressure to 5 mmHg is required for these PATIENTS.

An alternative RISK CONTROL method is provided for AUTOMATED SPHYGMOMANOMETERS that operate in SELF-MEASUREMENT AUTOMATIC MODE. Since the total number of DETERMINATIONS is limited and the PATIENT is conscious and expected to be able to remove the CUFF or otherwise release the pressure, a PROTECTION DEVICE is not necessary. This alternative RISK CONTROL method is intended to provide a balance between the benefits of the availability of low-cost AUTOMATED SPHYGMOMANOMETERS intended for SELF-MEASUREMENT AUTOMATIC MODE and the added cost of the SINGLE FAULT CONDITION PROTECTION DEVICE.

The evaluation of the acceptance criterion for the performance of the PROTECTION DEVICE includes the time required to deflate the CUFF, which is affected by both the pressure in and the volume of the CUFF. The initial pressure chosen for the test should represent the highest pressure expected in NORMAL USE, which occurs at the end of the inflation cycle. In the NEONATAL MODE, the maximum pressure of 150 mmHg should be used; otherwise, the allowable maximum pressure is 300 mmHg, but rarely exceeds 250 mmHg.

Since it can be difficult to establish consistent volumes with CUFFS, one method to standardize this test is to utilize ~~fixed~~ standardized volumes to represent the CUFF (e.g. 100 ml ± 5 ml in NEONATAL MODE or for wrist AUTOMATED SPHYGMOMANOMETERS and 500 ml ± 25 ml otherwise). An alternative method is to utilize the largest CUFF specified in the instructions for use for each mode of operation. The CUFF should be wrapped around a rigid mandrel that represents the midpoint of the marked range for the CUFF.

The time of 3 s allows for momentary artefacts, common with this technology, which could cause the CUFF pressure to rise temporarily above the maximum permitted pressure without creating an ALARM CONDITION.

Subclause 201.12.1.106 – Manometer test mode

A manometer test mode of an AUTOMATED SPHYGMOMANOMETER is used to verify or calibrate the accuracy of the PRESSURE TRANSDUCER. Depending on its design and material, the accuracy of the PRESSURE TRANSDUCER can be affected by temperature, drift, aging PROCESSES, etc. Therefore it is necessary for SERVICE PERSONNEL to have a means to check the accuracy of the PRESSURE TRANSDUCER for maintenance and calibration of an AUTOMATED SPHYGMOMANOMETER. Such checks are recommended by some MANUFACTURERS and are required by some authorities with jurisdiction. Since a manometer test mode is not used clinically, access is restricted to SERVICE PERSONNEL, which can include use of a TOOL to open the ENCLOSURE.

Subclause 201.12.1.107 – Reproducibility of the BLOOD PRESSURE DETERMINATION

This requirement is designed to demonstrate that an AUTOMATED SPHYGMOMANOMETER continues to have acceptable reproducibility following the environmental stresses of this particular standard. During the development of this particular standard, concern was raised that the simulator used might not have sufficient reproducibility to successfully perform this test. This test PROCEDURE was developed to address this concern. The PROCEDURE allows one to confirm that the combination of the AUTOMATED SPHYGMOMANOMETER and simulator works in a repeatable way, and that the simulator is generating the signals in a reproducible way, i.e. consistently for at least the time required to perform the whole test sequence.

To accomplish these objectives, two samples of the AUTOMATED SPHYGMOMANOMETER are required. The first sample (A) is one that undergoes the TYPE TEST to the requirements of the subclause while the second sample (B) is used to demonstrate that the AUTOMATED SPHYGMOMANOMETER and the simulator work in a repeatable way for the period required for completing the test sequence. Sample B is only used to demonstrate that the combination of AUTOMATED SPHYGMOMANOMETER and simulator works in a repeatable way and that the simulator is generating the signals in a reproducible way. As such, its use is not necessary to perform the TYPE TESTS on sample A, but its use allows the tester to confirm when the test setup is inadequate.

Steps b) to e) are used to confirm that the combination of the AUTOMATED SPHYGMOMANOMETER (sample B) and simulator works in a repeatable way. If either BLOOD PRESSURE standard deviation fails the acceptance criterion, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient reproducibility to perform this test PROCEDURE. Either the simulator needs adjustment or different simulator is required.

EXAMPLE For the wrist-type AUTOMATED SPHYGMOMANOMETER, the amplification of the generated signals often has to be reduced.

These steps are repeated at the end of the test PROCEDURE on sample B [steps k) to n)] and the resulting values compared to the earlier ones. If either one of these criteria is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient long-term stability to perform this test PROCEDURE.

The actual TYPE TEST occurs with sample A. Sample A is evaluated with the simulator, subjected to the environmental stresses as indicated and then is evaluated a second time with the simulator. Failing the acceptance criterion indicates that the AUTOMATED SPHYGMOMANOMETER subjected to the TYPE TEST has been unacceptably affected by the environmental stresses.

The limit in step o) is ≤ 5,0 mmHg (0,67 kPa) because up to 2,0 mmHg (0,27 kPa) is permitted due to the contribution of the stability of the AUTOMATED SPHYGMOMANOMETER and simulator combination in step n) in addition to the ≤ 3,0 mmHg (0,4 kPa) criterion permitted for the AUTOMATED SPHYGMOMANOMETER undergoing the TYPE TEST.

Subclause 201.15.3.5.101 – Shock and vibration ~~for other than transport~~ (robustness)

AUTOMATED SPHYGMOMANOMETERS in NORMAL USE will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, an AUTOMATED SPHYGMOMANOMETER needs to be robust enough to withstand the vibration, shock, bumps and drops that it will encounter in NORMAL USE.

These tests were chosen by first reviewing the results of the work published in other PATIENT monitoring standards where those committees qualitatively assessed the relative severity of the scenarios within various environments (i.e., HOME HEALTHCARE ENVIRONMENT, healthcare institution and professional transport (wings and wheels)), by various sizes and types of ME EQUIPMENT (i.e., HAND-HELD, PORTABLE and MOBILE ME EQUIPMENT) [23] [24].

After that qualitative assessment, those committees assessed the relevant particular standards for environmental testing in the IEC 60068 series and their respective rationales, as well as the IEC 60721 series of guidance documents. In selecting the requirements, those committees reviewed other sources for material related to these tests (e.g., FDA Reviewers Guidance for premarket notification submissions, Mil Std 810, etc.) but found the best fit was with IEC 60721-3-7~~:1995~~ [25]. There is also a guidance document, IEC TR 60721-4-7~~:2001~~ [16], which helps to correlate environmental condition classes of IEC 60721-3-7 to environmental tests according the IEC 60068 series. The aforementioned standards specify 3 classes of mechanical conditions: 7M1, 7M2 and 7M3. Those committees found that classes 7M1 and 7M3 best represent the conditions seen during PATIENT transport within healthcare facilities and PATIENT transport outside healthcare facilities, respectively. Those committees agreed that different tests and test levels should be applied to ME EQUIPMENT intended for use in a healthcare facility versus ME EQUIPMENT intended for use during PATIENT transport outside the healthcare facility.

Verifying that the instrument is functioning within the MANUFACTURER'S specifications while the vibration (random and sinusoidal) tests are being conducted was not believed necessary. This line of thought was considered and it was decided that a test done in this manner would be overly burdensome and would add only a minimum additional level of safety to the ME EQUIPMENT that would not outweigh the costs. Verifying proper functioning after completion of the tests is believed adequate.

~~**Subclause 201.15.3.5.102 – Shock and vibration for transport**~~

~~The tests of this subclause are intended to demonstrate that an AUTOMATED SPHYGMOMANOMETER can survive the mechanical stresses associated with PATIENT transport outside a healthcare facility. These tests are not intended to evaluate the clinical efficacy of AUTOMATED SPHYGMOMANOMETER during PATIENT transport outside a healthcare facility.~~

~~AUTOMATED SPHYGMOMANOMETERS used for PATIENT transport outside a healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock, bump, and drop) and could randomly be subjected to additional stresses. Therefore, instruments intended to be used for PATIENT transport outside a healthcare facility need to be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7 level 7M3. IEC 60721-3-7 indicates that in addition to the conditions covered by class 7M2, the class 7M3 applies to use at, and direct transfer between, locations with significant vibrations, or with high level shocks. Rough handling and transfer of ME EQUIPMENT is expected in these environments.~~

~~An additional shock test for this class of ME EQUIPMENT is added even though there are no established generalized test programs that exactly reproduce the range of vibration and shock conditions that ME EQUIPMENT might meet when installed in a range of land vehicles and aircraft. Therefore the dynamic tests specified in this subclause have been chosen on the basis that ME EQUIPMENT tested to these levels are likely to withstand the normal dynamic disturbances that they will be subjected to when used in the vehicles and aircraft (including helicopters) likely to be used for transporting PATIENTS.~~

~~The use of ME EQUIPMENT in road ambulance, fixed-wing and rotary-wing aircraft, naval vessels, etc. can require additional tests and verification of safety when used in these different environments.~~

Subclause 201.101.1 – Construction

This document does not specify the details of the construction of CUFFS and BLADDERS. Studies [20] [21] [22] have suggested that the appropriate BLADDER size for the placement at the upper arm for auscultatory estimates of BLOOD PRESSURE is one with dimensions such that its width is 40 % of the limb circumference at the maximum range for each CUFF size and its length is 80 % to 100 % of the limb circumference at the centre of the range for each CUFF size. In auscultation, use of the wrong size CUFF can affect the accuracy of the estimates of BLOOD PRESSURE. These recommended dimensions are subject to ongoing consideration. AUTOMATED SPHYGMOMANOMETERS can be designed with different CUFF dimensions.

Use of an incorrect CUFF size (too small or too large) is a source of inaccurate DETERMINATION, for example CUFFS that are too small can result in erroneously high DETERMINATIONS. This RISK should be avoided by a design that does not allow a DETERMINATION to be initiated or displayed if the limb circumference is outside the permissible range. Alternatively, the RISK can be reduced by marking on the CUFF the permissible range of limb circumference.

The appropriate BLADDER size for placement at the wrist is dependent on the design of the AUTOMATED SPHYGMOMANOMETER. Commonly used wrist CUFFS have a width of approximately 6 cm and a length of 10 cm to 14 cm for a wrist circumference range of 13,5 cm to 19,5 cm.

Subclause 201.101.2 – Pressurization

While the maximum pressure allowed in the PNEUMATIC SYSTEM is 330 mmHg, prudent engineering design requires that the CUFF be tested at a higher pressure (+ 10 %). This is similar to the derating methods used to ensure that electronic components meet the requirements of a design.

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

The committees have determined that any AUTOMATED SPHYGMOMANOMETER available to the public, and intended for self-use by the public and regardless of intended use labelling, should be appropriate for the clear majority of the general adult population. This is in the interest of public health and safety. The mid-upper-arm circumference range of 22 cm to 42 cm was chosen as the minimum range based on available data. While worldwide statistics are lacking, this arm circumference range has been shown (through high quality National Institutes of Health data) to include 95 % of adults in the US. Further, worldwide professional systems of BLOOD PRESSURE CUFFS generally offer "adult" and "large adult" CUFFS covering this same range, which supports that this is a reasonable range for an AUTOMATED SPHYGMOMANOMETER intended for self-use in public settings.

Subclause 201.102 – Connection tubing and CUFF connectors

In the 1990s, concern grew regarding the proliferation of medical devices fitted with Luer connectors [26] [27] and the reports of PATIENT death or injury arising from misconnections that resulted in the inappropriate delivery of enteral solutions, intrathecal medication or compressed gases, including connections between an AUTOMATED SPHYGMOMANOMETER and CUFF.

Concerns regarding the use of Luer connectors with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN/BT and the European Commission. In November 1997, the CHeF steering group set up a Forum Task Group to consider the problem. It produced CEN Report CR 13825 [28], in which they concluded that there is a

problem arising from the use of a single connector design to a number of incompatible applications. In a coronary care unit, there are as many as 40 Luer connectors on the medical devices used with a single PATIENT. Therefore, it is not surprising that misconnections are made.

Based on these concerns, the ISO 80369 series was developed to create new non-Luer connectors for medical device applications other than for intravascular or hypodermic applications. The connectors of this series are designed such that connectors for the different applications do not connect. IEC 80369-5 was specifically developed for use with tubing for limb CUFF inflation, including sphygmomanometers and CUFFS.

Subclause 201.104 – Maximum inflating time

The pressures indicated in Table 201.102 were chosen, following clinical advice, as being CUFF pressures at which reasonable venous return can take place. They are also pressures that can be measured with reasonable reliability.

Two or more attempts at determining the BLOOD PRESSURE of restless or hypertensive PATIENTS can occur in 180 s. A large safety margin is still allowed before any neuromuscular injury is likely to take place.

The shortened maximum time in NEONATAL MODE is not only obviously desirable to reduce discomfort and trauma in these fragile PATIENTS, but also justified since the maximum pressure is 150 mmHg (20,0 kPa), which results in a shorter deflation time, and the typical heart rate of these PATIENTS is higher. An additional issue is that the longer the CUFF remains inflated, the more distressed an infant becomes, thus producing more artefacts that could cause more readings to be taken.

Since this requirement applies in SINGLE FAULT CONDITION, it is necessary to guard against the failure of a deflation valve by having two independent means of reducing the pressure.

An alternative RISK CONTROL method is provided for AUTOMATED SPHYGMOMANOMETERS that operate in SELF-MEASUREMENT AUTOMATIC MODE. See 201.12.1.105.

Subclause 201.105 – Automatic cycling modes

Table AA.1 provides a summary of the requirements and differences between the automatic cycling modes described in this document.

The figures shown in this subclause are drawn to illustrate the DETERMINATION of BLOOD PRESSURE during the deflation cycle. Some AUTOMATED SPHYGMOMANOMETERS determine BLOOD PRESSURE during inflation. This results in a longer inflation cycle and a shorter deflation cycle when compared to the figures. This does not change the intent of the figures or any of the other requirements of this document.

Table AA.1 – Summary of requirements by mode

	LONG-TERM AUTOMATIC MODE **201.105.1**	SHORT-TERM AUTOMATIC MODE **201.105.2**	SELF-MEASUREMENT AUTOMATIC MODE **201.105.3**
Number of DETERMINATIONS	Unlimited	Limited [a]	< 7
Duration of mode	Unlimited	≤15 min	~~Not Applicable~~ ≤ 30 min [b]
Maximum inflating time (per DETERMINATION) (201.104)	180 s or 90 s in NEONATAL MODE	180 s or 90 s in NEONATAL MODE	180 s [c]
Deflated period	≥ 30 s	≥ 2 s	≥ 5 s
Maximum pressure (201.12.1.104)	300 mmHg or 150 mmHg in NEONATAL MODE	300 mmHg or 150 mmHg in NEONATAL MODE	300 mmHg [c]
Pressure protection in SINGLE FAULT CONDITION	PROTECTION DEVICE	PROTECTION DEVICE	Manual means [d] or PROTECTION DEVICE
PATIENT population	All	All	Limited [e]
Clinical ~~validation~~ investigation (201.106)	ISO 81060-2	Not required	ISO 81060-2

[a] The number of DETERMINATIONS is not specified, but is limited by the duration.

[b] The number of DETERMINATIONS is limited to 6, but ~~there is no absolute~~ with a 30 min time limit.

[c] NEONATAL MODE is not permitted in SELF-MEASUREMENT AUTOMATIC MODE.

[d] If an independent PROTECTION DEVICE is not provided, means are provided for the release of pressure by the OPERATOR or PATIENT.

[e] The PATIENT population is intended only for conscious adults and is required to be disclosed in the instructions for use.

Subclause 201.105.2 – SHORT-TERM AUTOMATIC MODE

SHORT-TERM AUTOMATIC MODE is valuable for continuous surveillance of PATIENTS undergoing anaesthetic PROCEDURES as well as emergency care where there can be a clinical need for frequent readings. However, a minimum period of deflation between inflations is necessary to allow some venous return. In addition, the total duration of the SHORT-TERM AUTOMATIC MODE should be limited to prevent venous pooling and reduce bruising.

Subclause 201.105.3 – SELF-MEASUREMENT AUTOMATIC MODE

SELF-MEASUREMENT AUTOMATIC MODE is useful for measurement of BLOOD PRESSURE both in physicians' offices and in the home. Current recommendations for measurement of BLOOD PRESSURE for use in the diagnosis of hypertension [7] recommend that at least 2 DETERMINATIONS should be taken at intervals of at least 1 min, and the average of those DETERMINATIONS should be taken as the PATIENT'S BLOOD PRESSURE.

The use of this mode in a physician's office provides the ability to obtain multiple measurements from a PATIENT without a clinician being present. This could reduce or eliminate the white coat hypertension effect [29].

The ability to access the individual DETERMINATIONS is useful to ~~determine~~ ascertain if there is significant variability in a PATIENT'S BLOOD PRESSURE.

While the use of the average of multiple DETERMINATIONS is widely used, other measures can be used to represent a PATIENT'S BLOOD PRESSURE (e.g. median or mode).

Subclause 201.105.3.3 – SINGLE FAULT CONDITION

The intent of this requirement is to provide a means of RISK CONTROL for potential injury to a PATIENT due to the HAZARDOUS SITUATION of excessive pressure applied to the limb when the primary pressure sensing or PROTECTION DEVICE of the AUTOMATED SPHYGMOMANOMETER is not functioning due to a SINGLE FAULT CONDITION. The requirement for a PROTECTION DEVICE is intended to reduce RISK to acceptable levels in situations where the PATIENT is commonly unable to remove the CUFF in the case of over pressure and there is no other OPERATOR likely to be present to physically remove the pressurized CUFF from the limb. In this case, it is necessary to provide an independent PROTECTION DEVICE to release pressure from the CUFF without the intervention of the OPERATOR or the PATIENT. Example cases include AUTOMATED SPHYGMOMANOMETERS for use on neonatal PATIENTS or PATIENTS in critical care units and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple DETERMINATIONS without OPERATOR intervention over an extended period.

An alternative means of RISK CONTROL is provided for AUTOMATED SPHYGMOMANOMETERS that only operate in the SELF-MEASUREMENT AUTOMATIC MODE. In this mode, it is assumed that the period of operation will be relatively short while a single DETERMINATION is performed and that the OPERATOR is present during the entire operation and is available to release the pressure from the CUFF or remove the CUFF in the case of a SINGLE FAULT CONDITION. This also applies to the SELF-MEASUREMENT AUTOMATIC MODE when the PATIENT is the OPERATOR.

The alternative RISK CONTROL method is intended to provide an acceptable RESIDUAL RISK by trading off the cost of a PROTECTION DEVICE with OPERATOR action when OPERATOR/PATIENT action can be relied upon for RISK CONTROL. It is clearly an unacceptable RISK to PATIENTS if accurate, low cost AUTOMATED SPHYGMOMANOMETERS are not available for PATIENT self-measurement for use in the management of hypertension.

Subclause 201.106 – Clinical accuracy

The SHORT-TERM AUTOMATIC MODE is valuable for continuous surveillance of PATIENTS undergoing anaesthetic PROCEDURES as well as emergency care where there can be a clinical need for very frequent readings to monitor critical, unstable PATIENTS. However, because of the minimal period of deflation permitted between inflations that enables the OPERATOR to obtain BLOOD PRESSURE readings in the shortest possible time, it is expected that accuracy is degraded to some extent.

In addition, the total duration of the SHORT-TERM AUTOMATIC MODE should be limited to prevent venous pooling and reduce bruising.

Subclause 202.8.1.101 – Additional general requirements

Transient electromagnetic phenomena (e.g. ESD, lightening, switching of large inductive loads) are random, infrequent events of short duration. They have amplitudes of several thousand volts referred to earth. Thus, it is hardly possible to design a SPHYGMOMANOMETER having a protective or functional earth connection or operating from mains power that is completely immune against these transient phenomena. On the other hand, a short disturbance and recovery period do not impact the treatment of PATIENTS. Therefore, this document allows disturbances and interruptions with a recovery period of maximum 10 s after transient electromagnetic phenomena.

Subclause ~~202.6.2.101~~ 202.8.101 – Electrosurgery interference recovery

If an AUTOMATED SPHYGMOMANOMETER is intended to be used together or in the presence with HF SURGICAL EQUIPMENT, OPERATORS should expect that the AUTOMATED SPHYGMOMANOMETER can determine BLOOD PRESSURE following a recovery time. Since an AUTOMATED SPHYGMOMANOMETER determines BLOOD PRESSURE aperiodically and not continually, the committee judged that it was not a requirement for an AUTOMATED SPHYGMOMANOMETER to be able to make a DETERMINATION during the operation of HF SURGICAL EQUIPMENT, but that it

would be an unacceptable RISK to a PATIENT if an AUTOMATED SPHYGMOMANOMETER were unable to make the expected DETERMINATION following operation of the HF SURGICAL EQUIPMENT.

Annex BB
(informative)

Environmental aspects

The environmental impact generated by an AUTOMATED SPHYGMOMANOMETER performing DETERMINATIONS is mainly isolated to the following occurrences:

– impact at local environment during operation, including routine inspection and adjustments by the OPERATOR, according to the instructions for use or routine PROCEDURES;

– use, cleaning and disposal of consumables during operation, including routine inspection and adjustments by the OPERATOR, according to the instructions for use or routine PROCEDURES;

– scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this document addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of an AUTOMATED SPHYGMOMANOMETER.

See Table BB.1 for a mapping of the life cycle of an AUTOMATED SPHYGMOMANOMETER to aspects of the environment.

Table BB.1 – Environmental aspects addressed by clauses of this document

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in	Addressed in	Addressed in	Addressed in
1	Resource use	IEC 60601-1-9 [a]	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
2	Energy consumption	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
3	Emission to air	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.106
4	Emission to water	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.~~106~~105
5	Waste	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.~~106~~105
6	Noise	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
7	Migration of hazardous substances	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.~~106~~105
8	Impacts on soil	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.~~106~~105
9	RISKS to the environment from accidents or misuse	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
[a] See IEC 60601-1-9:2007.					

Annex CC
(informative)

Reference to the ESSENTIAL PRINCIPLES

This particular standard has been prepared to support the ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE of AUTOMATED SPHYGMOMANOMETERS as medical devices according to ISO/~~TR~~ 16142-1:2016 [30]. This particular standard is intended to be acceptable for conformity assessment purposes.

Compliance with this particular standard provides one means of demonstrating conformance with the specific ESSENTIAL PRINCIPLES of ISO/~~TR~~ 16142-1:2016 [30]. Other means are possible.

See Table CC.1 for a mapping of the clauses and subclauses of this document to ESSENTIAL PRINCIPLES of ISO/~~TR~~ 16142-1:~~2006~~ 2016.

Table CC.1 – Correspondence between this particular standard and the ESSENTIAL PRINCIPLES

~~Corresponding essential principle of ISO/TR 16142:2006~~	~~Clause(s)/sub-clause(s) of this International Standard~~	~~Qualifying remarks/Notes~~
~~A.1, A.2, A.3~~	~~All~~	
~~A.4~~	~~201.4, 201.7, 201.15~~	
~~A.5~~	~~201.4, 201.7, 201.15, 201.16~~	
~~A.6~~	~~201.4.3, 201.7.9.2.2~~	
~~A.7.1~~	~~201.9, 201.11, 201.15~~	
~~A.7.2~~	~~201.11, 201.15, 201.16~~	
~~A.7.3~~	~~201.4, 201.11~~	
~~A.7.4~~	~~-~~	
~~A.7.5~~	~~201.11, 201.13~~	
~~A.7.6~~	~~201.11, 201.13~~	
~~A.8.1~~	~~201.11, 201.16~~	
~~A.8.1.1~~	~~-~~	
~~A.8.1.2~~	~~-~~	
~~A.8.2~~	~~201.11~~	
~~A.8.3~~	~~201.11~~	
~~A.8.4~~	~~201.11~~	
~~A.8.5~~	~~201.11~~	
~~A.8.6~~	~~201.7~~	
~~A.9.1~~	~~201.4, 201.8, 201.9, 201.11, 201.14, 201.16, 201.101, 201.102~~	
~~A.9.2~~	~~201.4.3, 201.5, 201.8, 201.9, 201.12, 201.15, 201.103, 201.104, 201.105, 202~~	
~~A.9.3~~	~~201.4, 201.8, 201.11, 201.13, 201.15~~	
~~A.10.1~~	~~201.4, 201.12~~	
~~A.10.2~~	~~201.4, 201.12~~	
~~A.10.3~~	~~201.7~~	
~~A.11.1~~	~~201.4, 201.10, 201.12, 201.17, 202~~	
~~A.11.2.1~~	~~201.4, 201.10, 201.12~~	

~~Corresponding essential principle of ISO/TR 16142:2006~~	~~Clause(s)/sub-clause(s) of this International Standard~~	~~Qualifying remarks/Notes~~
~~A.11.2.2~~	~~201.4, 201.12~~	
~~A.11.3~~	~~201.4, 201.10, 201.12~~	
~~A.11.4~~	~~201.4, 201.7~~	
~~A.11.5.1~~	~~201.4, 201.10, 201.12~~	
~~A.11.5.2~~	~~201.4, 201.10, 201.12~~	
~~A.11.5.3~~	~~201.4, 201.10, 201.12~~	
~~A.12.1~~	~~201.4, 201.14~~	
~~A.12.2~~	~~201.11.8~~	
~~A.12.3~~	~~201.4, 201.7, 201.12, 201.11.8~~	
~~A.12.4~~	~~201.4, 201.7, 201.12~~	
~~A.12.5~~	~~201.4, 201.17, 202~~	
~~A.12.6~~	~~201.4, 201.8~~	
~~A.12.7.1~~	~~201.4, 201.9, 201.15~~	
~~A.12.7.2~~	~~201.4, 201.9~~	
~~A.12.7.3~~	~~201.4, 201.9~~	
~~A.12.7.4~~	~~201.4, 201.8~~	
~~A.12.7.5~~	~~201.4, 201.8, 201.11, 201.15, 201.16~~	
~~A.12.8.1~~	~~201.4, 201.12, 201.105~~	
~~A.12.8.2~~	~~201.4, 201.7, 201.12~~	
~~A.12.8.3~~	~~201.4, 201.7, 201.12~~	
~~A.13.1~~	~~201.7, 201.16~~	
~~A.14.1~~	~~201.4, 201.11, 19~~	

ESSENTIAL PRINCIPLE of ISO 16142-1:2016, Tables B.1 and B.2 [30]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
1	All	The part relating to manufacturing is not addressed.
a)	206	
b)	206	
2	201.4	The part relating to manufacturing is not addressed.
a)	All	
b)	201.4	The part relating to manufacturing is not addressed.
c)	201.7, 201.11, 201.12, 201.13, 208	
d)	201.7	
3	All	The part relating to manufacturing is not addressed.
4	All	
5	201.4, 201.15	
6	201.4	
8.1	201.11	
a)	201.11	
b)	201.4, 201.11	

ESSENTIAL PRINCIPLE of ISO 16142-1:2016, Tables B.1 and B.2 [30]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
c)	201.9, 201.15	
8.2	201.11	
8.5	201.11, 211.8.3.1, 212	
9.1	201.11, 211	
12.1	201.7, 201.14, 201.16, 201.101, 201.102	
12.2	—	
a)	201.9, 201.11, 201.101, 206, 208	
b)	201.7.2.4, 201.101, 206	
c)	202	
d)	201.11	
e)	201.14, 201.16	
f)	201.11	
g)	202	
12.4	201.11	
12.5	201.7, 201.8, 201.12.1.106	
12.6	201.1.3, 201.7.2.105	
13.1	201.7.2.101, 201.12.1, 201.101, 201.105, 201.106	
13.2	201.7, 201.12.1.101, 201.12.1.103	
13.3	201.7, 201.102, 206, 208	
13.4	201.7	
14.1	201.10	
14.3	201.10	
15.1	201.14	
15.2	201.14	
16.1	201.4, 201.13, 201.104, 201.105.1 b), 201.105.3.3	
16.3	201.11.8, 211	
16.4	201.11.8, 201.12.3, 208	
16.5	202	
16.6	202	
16.7	201.8	
17.1	201.9	
17.2	201.9	
17.3	201.9	
17.4	201.15	
17.5	201.7.2.4, 201.9, 201.102	
17.6	201.11	
18.1	201.12.1	
18.2	201.12.1.101, 201.12.1.104, 201.12.1.105, 201.104, 201.105	
19.1	201.7, 201.7.2.101, 201.12.1.101, 201.12.1.103, 201.101.1, 206	

ESSENTIAL PRINCIPLE of ISO 16142-1:2016, Tables B.1 and B.2 [30]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
19.2	201.7, 201.12.1.101, 201.101.1, 201.101.3 b), 206	
20.1	211	
20.2	211	
20.3	211	
21.1	201.7	
21.2	201.7	
21.3	201.7	
21.4	201.7	
21.5	—	
a)	201.7	The part relating to authorized representative is not addressed
e)	201.7	
l)	201.7	
21.6	201.7	
21.7	—	
i)	201.7.9.2.2	
k)	201.7.9.2.9, 201.16	
n)	201.16	
q)	201.7	
21.8	201.7	
21.9	—	
b)	211	
d)	211	
f)	201.7	

Bibliography

[1] IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012

[2] ISO 81060-1:2007, *Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type*

[3] IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

[4] IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

[5] DEVBHANDARI, MP., SHARIFF Z., and DUNCAN AJ. Skin necrosis in a critically ill patient due to a blood pressure cuff. *J Postgrad Med*, 2006, 52:2, pp. 136-138

[6] FDA, *Guidance for Industry and FDA Staff – Premarket Assessment of Pediatric Medical Devices*. March 24, 2014 [6]

[7] PICKERING T., HALL J., APPEL L., FALKNER B., GRAVES J., HILL M., JONES D., KURTZ T., SHEPS S., ROCCELLA E. Recommendations for Blood Pressure Measurement in Humans and experimental Animals. *Circulation*, 2005, 111, pp. 697-716

[8] *Blood pressure Measurement*. CD ROM, The British Hypertension Society. BMJ Books. BMA House, Travistock Square, London WC1H9JR, 1998

[9] COLEMAN A., STEEL S., ASHWORTH M., VOWLER S., SHENNAN A. Accuracy of the pressure scale of sphygmomanometers in clinical use within primary care. *Blood Press Mon*, 2005, 10:4, pp. 181-188

[10] O'BRIEN E., PETRIE J., LITTLER WA., DE SWIET M., PADFIELD PD., DILLON MJ., COATS A., MEE, F., *Blood pressure Measurement: Recommendations of the British Hypertension Society*. BMJ Publishing Group. Third Edition 1997

[11] Recommendations of the World Health Organisation: "WHO Technical Report, Arterial hypertension; Series 628". 1978

[12] KEMPEN, P., Complication of a non-invasive blood pressure cuff during prone positioning. *Can J Anesth*, 2005, 53:1, pp. 106–111

[13] CLELAND M., PHAM B., MILLER D. Influence of arrhythmias on accuracy of non-invasive blood pressure monitors. *Can J Anaesth*, 1998, 45, pp. 699-705

[14] OKAMOTO H., SUGIMACHI M., HOKA S. Accuracy of a new algorithm for oscillometric non-invasive blood pressure measurement in patients with atrial fibrillation. *Anesthesiology,* 2001, 95:A, p. 580

6 Available from FDA at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf

[15] WEINGER MB., SCANLON TS., MILLER L. A widely unappreciated cause of failure of an automatic non-invasive blood pressure monitor. *J Clin Monit*, 2005, 8:4, pp. 291-294

[16] IEC TR 60721-4-7, *Classification of environmental conditions – Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 – Portable and non-stationary use*

[17] OSTCHEGA, Y., PHD, RN. Nurse consultant to the NHAMES project Hyattsville MD report to the AAMI/ISO Sphyg committee, May 9, 2013

[18] CELORIA, G., DAWSON, JA., and TERES, D. Compartment syndrome in a patient monitored with an automated pressure cuff. 1987, *J Clin Monit,* , 3, pp. 139-141

[19] LIN, C., et al. Blood Pressure Cuff Compression Injury of the Radial Nerve. *J of Clin Anesth*, 2001, 13, pp. 306–308

[20] GEDDES, ME., Whistler, SJ. The error in indirect blood pressure measurement with the incorrect size of cuff. *Am Heart J*, 1978, 96:1, pp. 1-8

[21] MARKS, LA., GROCH, A. Optimizing cuff width for non-invasive measurement of blood pressure. *Bld Press Mon*, 2000, 5:153, pp. 153-158

[22] PRINEAS, RJ., et al. US demographic trends in mid-arm circumference and recommended blood pressure cuffs for children and adolescents: data from the National Health and Nutrition Examination Survey 1988-2004. *Cl meth & pathphy*, 2007, 12:2, pp. 75-80

[23] ISO 9919:2005, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use*

[24] ISO 21647:2004, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors*

[25] IEC 60721-3-7, *Classification of environmental conditions – Part 3: Classification of groups of environmental parameters and their severities – Section 7: Portable and non-stationary use*

[26] ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*

[27] ISO 594-2:1991, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

[28] CEN CR 13825:2000, *Luer connectors – A report to CEN CHeF from the CEN forum task group "Luer fittings"*

[29] *La prise de la pression artérielle au cabinet médical.* Société Française d'Hypertension Artérielle. 1998 (available in French only)

[30] 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/TR 16142:2006, *Medical devices – Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*~~

GARDNER, RM., Direct blood pressure measurement – Dynamic response requirements. *Anaesthesiology*, 1981, 54, pp. 227-236

Index of defined terms

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

IEC 80601-2-30:2018-03(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

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.

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.

[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).

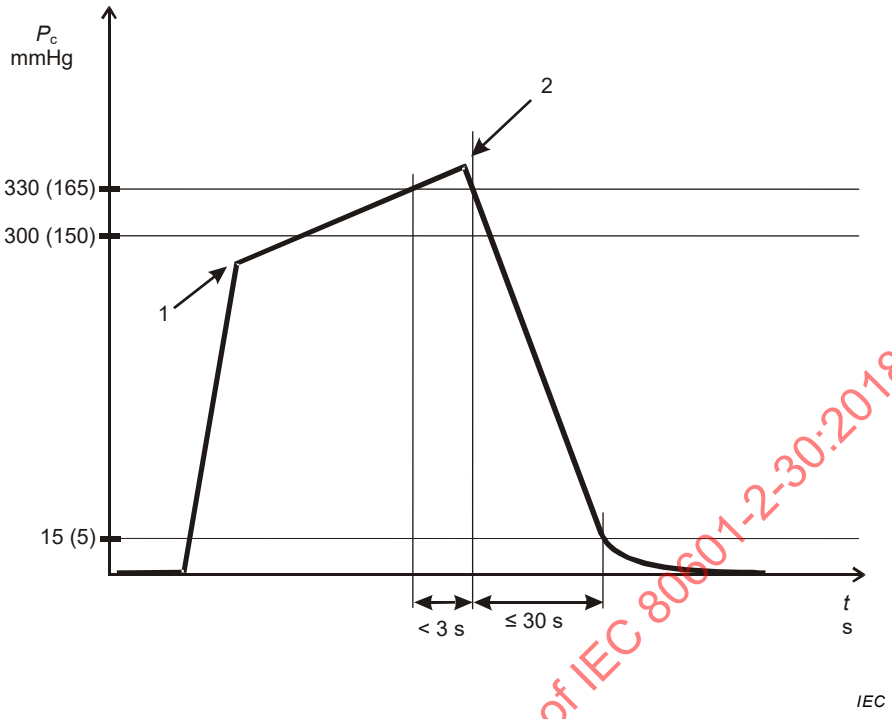
When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s to ≤ 15 mmHg (2,0 kPa) and to ≤ 5 mmHg (0,7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE.

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.

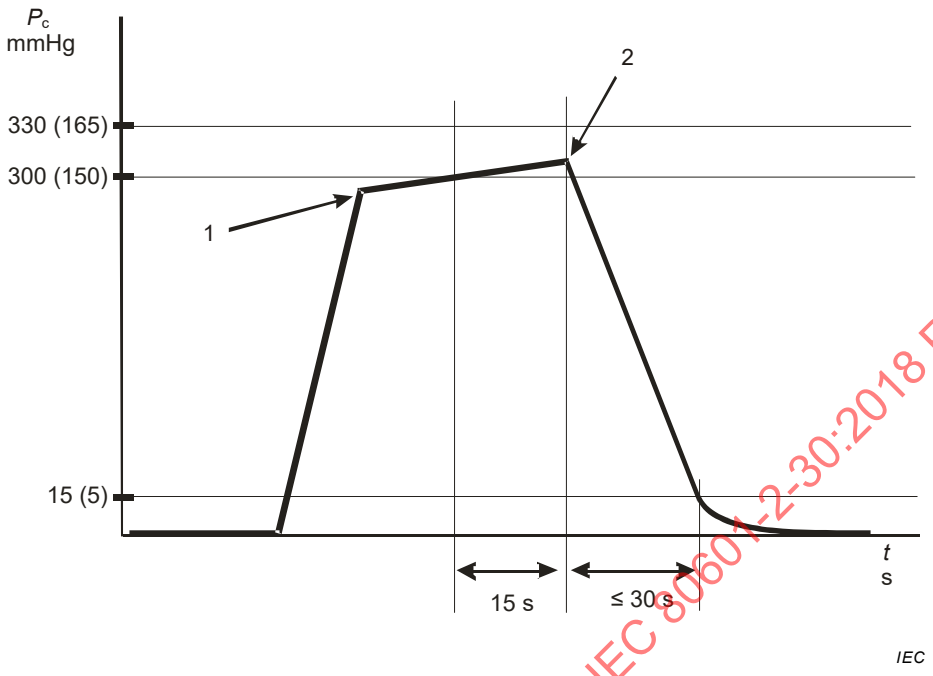
EXAMPLE 1 A port for connection to a pressure source so that the pressure can be measured by the AUTOMATED SPHYGMOMANOMETER in a test mode.

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)

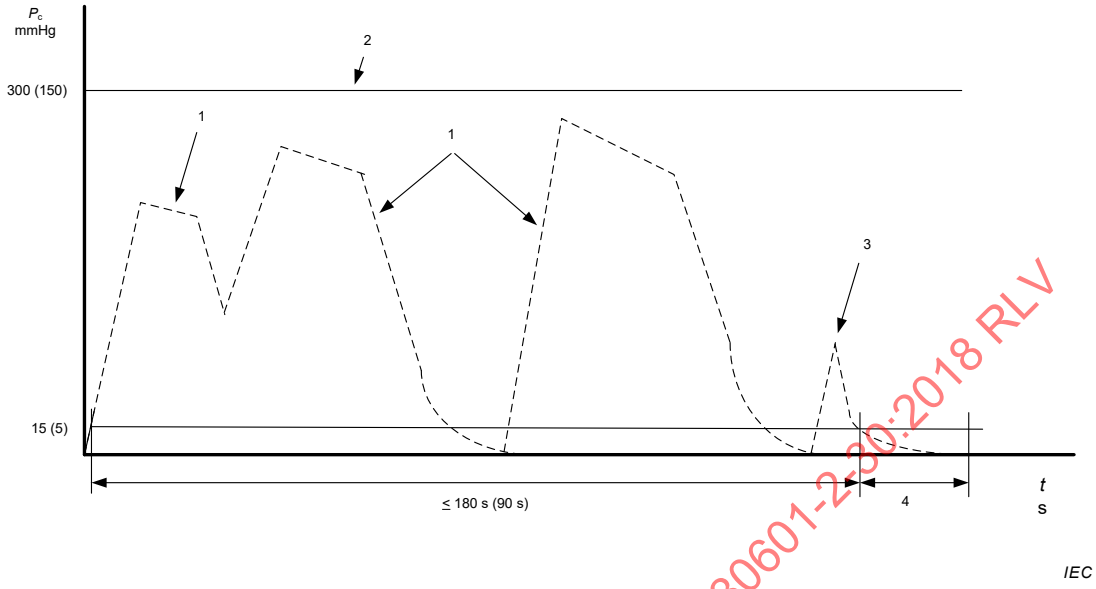
An AUTOMATED SPHYGMOMANOMETER that only operates in the SELF-MEASUREMENT AUTOMATIC MODE, where the PATIENT is the OPERATOR or the OPERATOR is intended to be in continual attendance, and where the pressure can be released from the CUFF or the limb by the OPERATOR is exempt from the SINGLE FAULT CONDITION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

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:

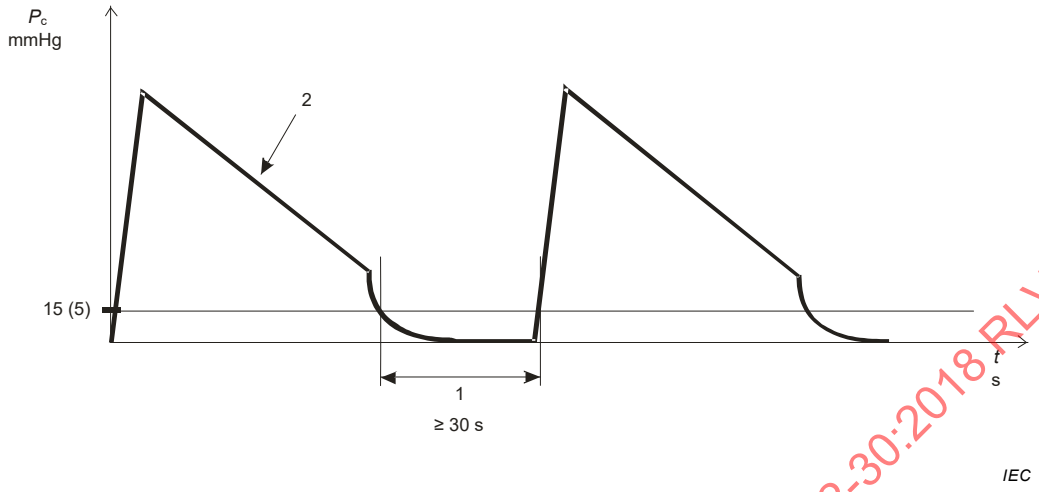
a) in NORMAL CONDITION:

- 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

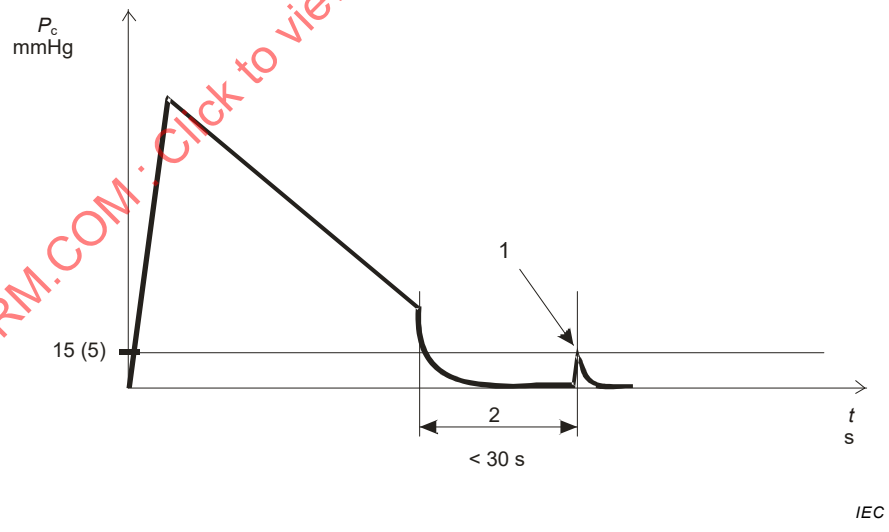
1 Deflated time

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

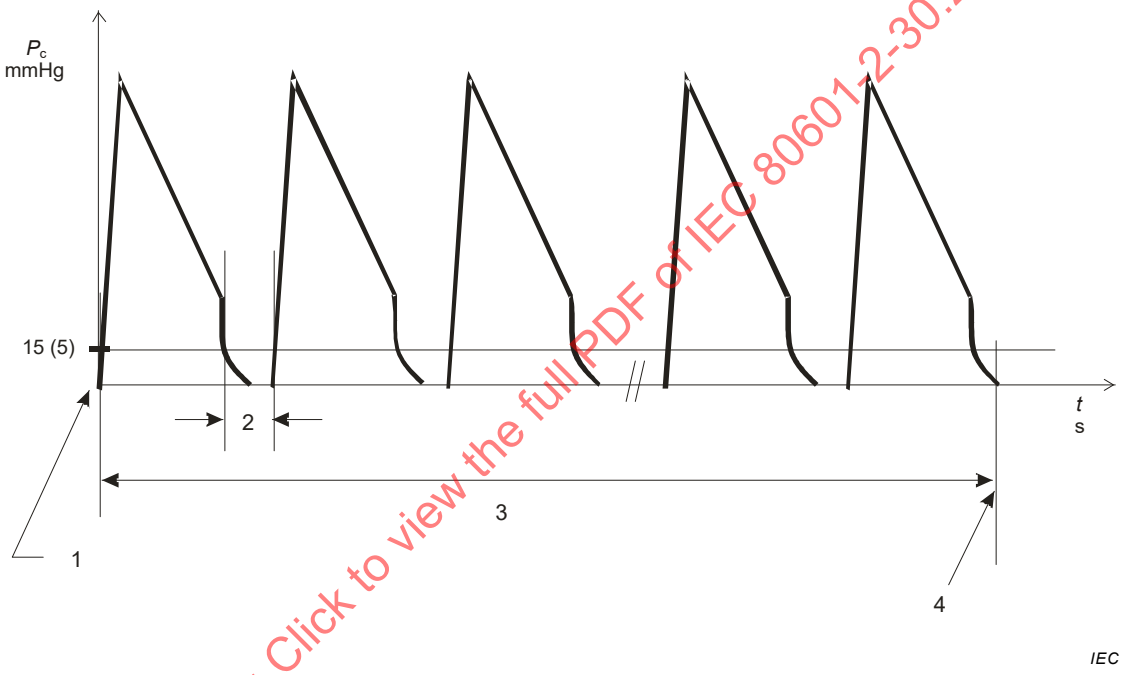
201.105.2 * SHORT-TERM AUTOMATIC MODE

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.

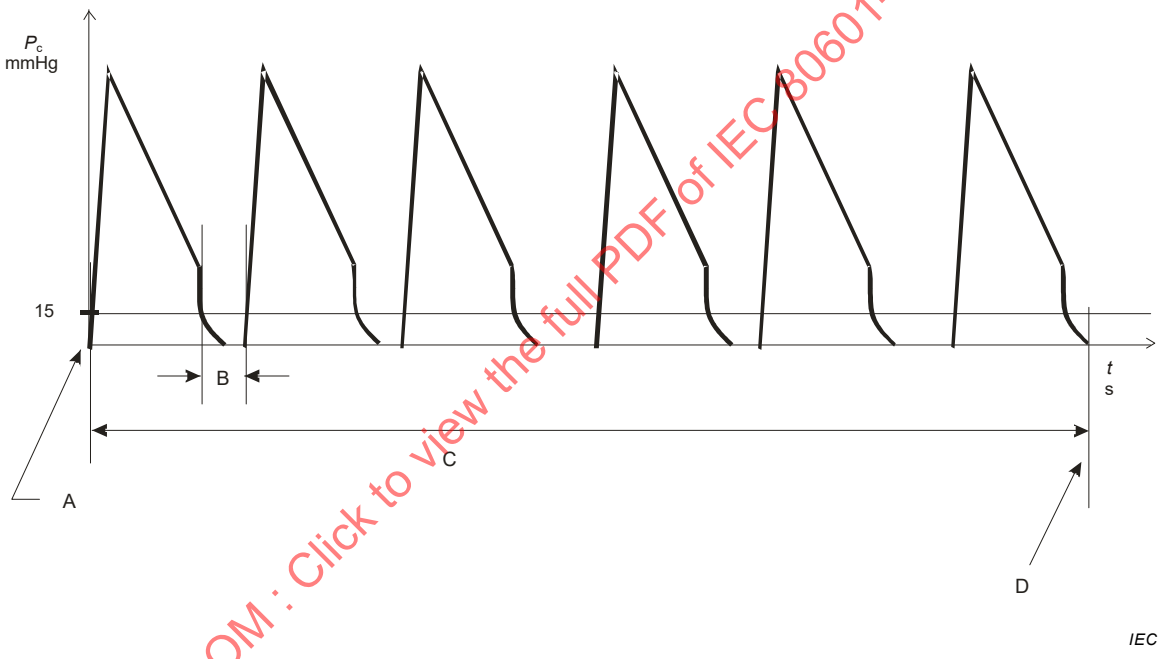
An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall not be intended for use with neonatal or infant PATIENTS. An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall be intended for use where:

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 collateral standard applies, except as follows:

202.8.1 General

Addition:

202.8.1.101 Additional general requirements

The following degradations, if associated with BASIC SAFETY or ESSENTIAL PERFORMANCE, shall not be allowed:

a) component failures;

b) changes in programmable parameters or settings;

c) reset to default settings; and

d) change in the reading for the measurement of the CUFF pressure at any point of the NOMINAL measurement range greater than 2 mmHg (0,3 kPa):

   1) during and after exposure to non-transient phenomena; and

   2) after exposure to transient phenomena.

Additional subclause:

202.8.101 * Electrosurgery interference recovery

If an AUTOMATED SPHYGMOMANOMETER is intended to be used together with HF SURGICAL EQUIPMENT, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT, without loss of any stored data.

Compliance is checked by functional testing using the test setup indicated in Figure 202.101 and Figure 202.102.

a) Use HF SURGICAL EQUIPMENT that complies with IEC 60601-2-2 and that:

- *has a cut mode with at least 300 W of power,*
- *has a coagulation mode with a least 100 W of power, and*
- *has a working frequency of 450 kHz ± 150 kHz.*

b) Test in cut mode:

Set up the ME EQUIPMENT to operate from a PATIENT SIMULATOR set to simulate a BLOOD PRESSURE of 100/70 mmHg ± 10 mmHg (13,3/9,3 kPa ± 1,3 kPa). On the HF SURGICAL EQUIPMENT, set the cut mode at 300 W.

Touch the metal plate in the test setup (see Figure 202.101) with the active electrode and remove the electrode slowly to produce a spark (generate high-frequency interference).

Terminate the interference. Wait 10 s. Confirm that displayed parameters on the ME EQUIPMENT have returned to their pre-test readings.

Repeat this PROCEDURE as described, five times.

c) Test in coagulation mode:

Set up the ME EQUIPMENT to operate from a PATIENT SIMULATOR set to simulate a BLOOD PRESSURE of about 100/70 mmHg ± 10 mmHg (13,3/9,3 kPa ± 1,3 kPa). On the HF SURGICAL EQUIPMENT, set the coagulation mode at 100 W.

Touch the metal plate in the test setup (see Figure 202.101) with the active electrode and remove the electrode slowly to produce a spark (generate high-frequency interference).

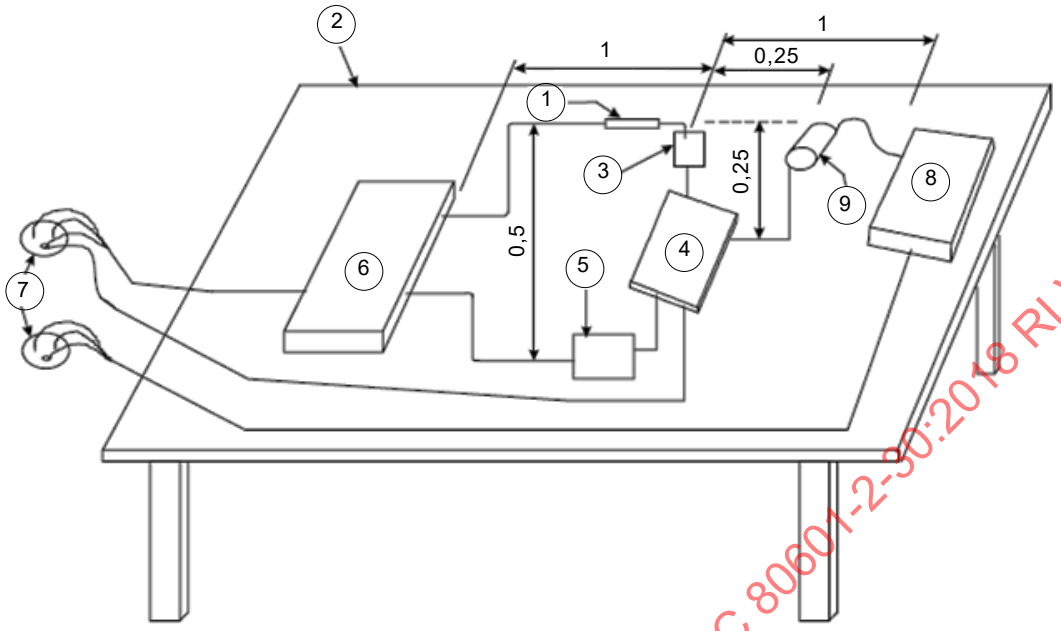
Terminate the interference. Wait 10 s. Confirm that displayed parameters on the ME EQUIPMENT have returned to their pre-test readings.

Repeat this PROCEDURE as described, five times.

Test of other modes (e.g. spray coagulation) is not required.

NOTE If the HF SURGICAL EQUIPMENT interferes with the PATIENT SIMULATOR, shield the PATIENT SIMULATOR.

Dimensions in m



Key

1 Active electrode

2 Table made of insulating material

3 Metal plate

4 Simulated PATIENT for HF SURGICAL EQUIPMENT

5 Neutral electrode

6 HF SURGICAL EQUIPMENT

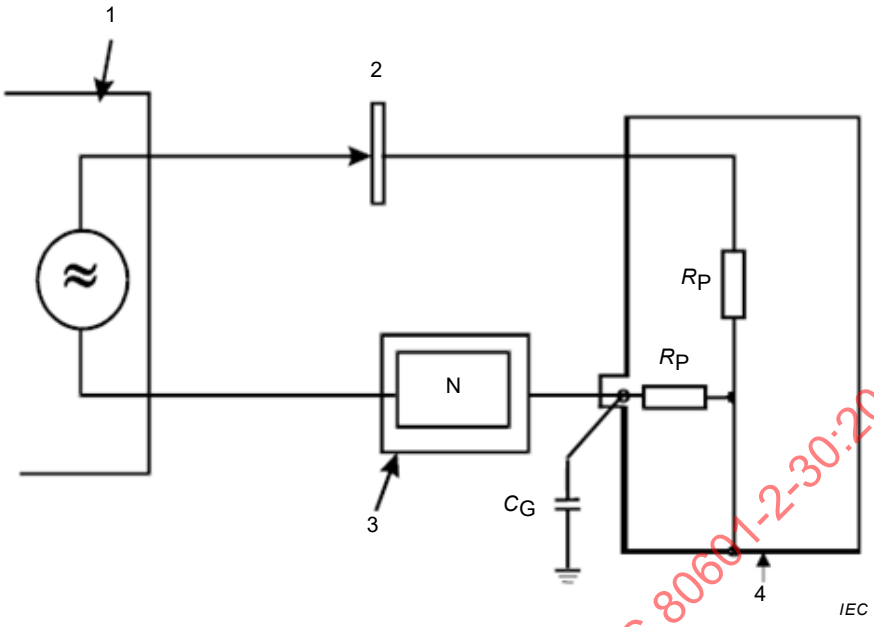
7 SUPPLY MAINS

8 AUTOMATED SPHYGMOMANOMETER under test

9 CUFF wrapped in metal foil that is wrapped around the mandrel of a PATIENT SIMULATOR

The PATIENT SIMULATOR is connected via a 'T' to the PNEUMATIC SYSTEM. The simulated PATIENT is connected to the foil wrap of CUFF.

Figure 202.101 – HF SURGICAL EQUIPMENT test layout



Key

1 HF SURGICAL EQUIPMENT

2 Metal plate

3 Metal plate

4 Metal box for shielding

R_P = 220 Ω, 200 W (low inductance, simulates PATIENT impedance)

C_G = 47 nF (minimizes the influence of different types of high frequency surgery equipment designs)

Figure 202.102 – Simulated PATIENT test set-up for HF SURGICAL EQUIPMENT

206 Usability

IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 apply, except as follows:

Addition:

For an AUTOMATED SPHYGMOMANOMETER, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) observing the displayed BLOOD PRESSURE; and
b) properly applying the CUFF to the PATIENT.

For an AUTOMATED SPHYGMOMANOMETER, if available, the following shall be considered PRIMARY OPERATING FUNCTIONS:

c) selecting the proper CUFF for the PATIENT;
d) setting the OPERATOR-adjustable controls;
e) setting ALARM LIMITS;
f) inactivating ALARM SIGNALS; and
g) switching between different modes.

The following actions associated with making a DETERMINATION shall be considered PRIMARY OPERATING FUNCTION:

h) properly positioning the PATIENT.

210 Requirements for the development of physiologic closed-loop controllers

IEC 60601-1-10:2007 applies, except as follows:

210.4 General requirements

Replacement of the first dashed item in the first paragraph:

– * latency times, including the aperiodic nature of AUTOMATED SPHYGMOMANOMETER DETERMINATIONS;

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015 applies, except as follows:

211.4.2.2 Environmental conditions of transport and storage between uses

*Addition, in the first sentence after the phrase "*The instructions for use*", of the words "*and the sales packaging*".*

211.4.2.3.1 Continous operating conditions

*Addition, in the first sentence after the phrase "*The instructions for use*", of the words "*and the sales packaging*".*

211.7.4.5 Additional requirements for operating instructions

Addition:

The instructions for use and the sales packaging shall indicate the RATED range of arm circumferences of the CUFF.

211.8.3.1 Ingress of water or particulate matter into ME EQUIPMENT

Replacement, in the second sentence, of the word "IP21" *by* "IP20".

212 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

IEC 60601-1-12:2014 applies except as follows:

212.10.1.1 General requirements for mechanical strength

Addition, before the first paragraph, of the following new paragraph:

The tests of Clause 10 of IEC 60601-1-12:2014 and 15.3 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 shall be performed on the same sample of the AUTOMATED SPHYGMOMANOMETER after the cleaning and disinfection PROCEDURES of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 11.6.6, have been performed unless there are no cleaning and disinfection PROCEDURES specified in the instructions for use. If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE shall be so tested. A separate sample of the AUTOMATED SPHYGMOMANOMETER may be used for each specified PROCEDURE.

Annexes

The annexes of the general standard apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

Annex C of the general standard applies, except as follows.

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of the AUTOMATED SPHYGMOMANOMETER or its parts are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of AUTOMATED SPHYGMOMANOMETERS or their parts

Description of marking	Subclause
As appropriate, proper disposal methods	201.7.2.105
Correct positioning for the CUFF on the designated limb over the artery	201.7.2.4
For self-use in public areas, adequate operating instructions	201.7.2.103
For self-use in public areas, this sphygmomanometer complies with IEC 80601-2-30:2018	201.7.2.103
For self-use in public areas, the need to consult a physician for interpretation of BLOOD PRESSURE measurements	201.7.2.103
For self-use in public areas, precautions for use	201.7.2.103
For self-use in public areas with a single CUFF size, range of arm circumference for which the CUFF is intended	201.7.2.103
For self-use in public areas with a single CUFF size, statement to the effect that results might not be accurate if your arm is outside the specified circumference range	201.7.2.103
If applicable, ACCESSORIES intended for use only in the NEONATAL MODE	201.7.2.102
If applicable, caution to the effect that substitution of a component different from that supplied might result in measurement error, or with safety sign ISO 7010-M002	201.7.2.104
If applicable, a detailed description of correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2.13
The range of limb circumference for which the CUFF is appropriate	201.101.1

201.C.3 Marking of controls and instruments

Addition:

Additional requirements for marking of controls and instruments of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.102.

Table 201.C.102 – Marking of controls and instruments of AUTOMATED SPHYGMOMANOMETERS or their parts

Description of marking	Subclause
If applicable, display abbreviations for SYSTOLIC, DIASTOLIC and MEAN ARTERIAL PRESSURE	201.7.2.101

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

Additional requirements for general information to be included in the accompanying documents of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.103.

Table 201.C.103 – ACCOMPANYING DOCUMENTS, general information for AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
Additional requirements can be found in ISO 81060-2.	201.106
Disclosure that the AUTOMATED SPHYGMOMANOMETER was clinically investigated according to ISO 81060-2:2013.	201.106

201.C.5 ACCOMPANYING DOCUMENTS, Instructions for use

Addition:

Additional requirements for ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.104.

Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
An explanation of the need to avoid compression or restriction of the connection tubing	201.7.9.2.9 gg)
An explanation of the operating steps of the AUTOMATED SPHYGMOMANOMETER needed to obtain routine resting BLOOD PRESSURE measurements for the diagnosis of hypertension	201.7.9.2.9 bb)
An explanation of the selection of a suitable size and application of the CUFF to the PATIENT	201.7.9.2.9 aa)
An explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition	201.7.9.2.9 cc)
Description of the operating principles	201.7.9.2.5
Details of the environmental or operation factors which can affect the performance of the AUTOMATED SPHYGMOMANOMETER and/or its BLOOD PRESSURE reading	201.7.9.2.9 ee)
Details of what the OPERATOR should do if unexpected readings are obtained	201.7.9.2.9 dd)
For the sales packaging, conditions of transport and storage between uses	211.4.2.2
For the sales packaging, continous operating conditions	211.4.2.3.1
For the sales packaging, RATED range of arm circumferences of the CUFF	211.7.4.5
Frequently used functions	201.7.9.2.1
If applicable, the correct method of reassembly	201.7.9.2.13
If applicable, a detailed description of the correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2.13
If applicable, that the ME EQUIPMENT is suitable for use in the presence of electrosurgery	201.7.9.2.101
If applicable, the protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2.101
If applicable, the absence of protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2.101
If applicable, the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in the NEONATAL MODE	201.7.9.2.102 a)
If applicable, the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER can accommodate when in the NEONATAL MODE	201.7.9.2.102 b)

Description of disclosure	Subclause
If applicable, recommended ACCESSORIES to avoid errors and excessive pressure	201.7.9.2.102 c)
If applicable, method for placing into the NEONATAL MODE	201.7.2.102
If applicable, a statement that the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude	201.7.9.2.9 ff)
Intended conditions of use	201.7.9.2.1 5)
Intended medical indication	201.7.9.2.1 1)
Intended PATIENT population, including whether or not intended for use with neonatal and infant PATIENTS and with pregnant, including pre-eclamptic, PATIENTS	201.7.9.2.1 3)
Intended placement of the CUFF	201.7.9.2.1 4)
Permissible environmental conditions of use	201.7.9.2.1
RATED range of arm circumferences of the CUFF	211.7.4.5
RATED range of CUFF pressure	201.7.9.2.9 hh)
RATED ranges of the DETERMINATION	201.7.9.2.5
Restrictions or contraindications to use	201.7.9.2.1 2)
Use as intended by the MANUFACTURER	201.7.9.2.1
Warning indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference	201.7.9.2.2 bb)
Warning regarding application of the CUFF and its pressurization on a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present because of temporary interference with blood flow and resulting injury to the PATIENT	201.7.9.2.2 dd)
Warning regarding application of the CUFF and its pressurization on the arm on the side of a mastectomy	201.7.9.2.2 ee)
Warning regarding applying the CUFF over a wound, as this can cause further injury	201.7.9.2.2 cc)
Warning regarding the need to check that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the PATIENT	201.7.9.2.2 gg)
Warning regarding the effect of continuous CUFF pressure due to connection tubing kinking on blood flow and possible injury to PATIENT	201.7.9.2.2 aa)
Warning that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb	201.7.9.2.2 ff)
Warning regarding the RISKS of not using the NEONATAL MODE on a neonatal PATIENT	201.7.2.102

201.C.6 ACCOMPANYING DOCUMENTS, technical description

Addition:

Additional requirements for ACCOMPANYING DOCUMENTS, technical description of AUTOMATED SPHYGMOMANOMETERS are found in Table 201.C.105.

Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description of AUTOMATED SPHYGMOMANOMETERS

Description of disclosure	Subclause
Test method that can be used to verify the calibration	201.12.1.106

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of IEC 80601-2-30, and is intended for those who are familiar with the subject of IEC 80601-2-30 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of IEC 80601-2-30 necessitated by those developments.

AUTOMATED SPHYGMOMANOMETERS are used in almost all clinical environments in healthcare. As such, BLOOD PRESSURE monitoring is used on almost all PATIENTS when they encounter the healthcare system. They are increasingly being used by PATIENTS in the HOME HEALTHCARE ENVIRONMENT.

Faults in the inflation and deflation cycles of AUTOMATED SPHYGMOMANOMETERS are the main non-electrical BASIC SAFETY issues. In the inflation cycle, the problems could be as follows:

– too high a target pressure for neonatal or young paediatric use, causing bruising and possibly bone deformation;
– too long an inflated period resulting in extended venous (and possibly arterial) occlusion; or
– a rapid repetition rate for an extended period, resulting in excessive venous occlusion, and hence venous blood pooling.

In the deflation cycle, there is only one non-electrical BASIC SAFETY issue that occurs, and that is the failure to deflate. In the short term, this can cause discomfort to a conscious PATIENT, but to an unconscious PATIENT the failure to deflate over an extended period of time can result in irreversible neuromuscular injury [18] [19].

Various clauses in this document have, as their express purpose, the avoidance of these non-electrical BASIC SAFETY issues.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationale corresponds to the numbering of the clauses in IEC 80601-2-30. The numbering is, therefore, not consecutive.

Subclause 201.3.214 – SHORT-TERM AUTOMATIC MODE

The SHORT-TERM AUTOMATIC MODE of an AUTOMATED SPHYGMOMANOMETER is particularly relevant during the administration of anaesthesia, but also finds application in accident and emergency departments, when a PATIENT is hemodynamically unstable. The ability to follow the trend of the BLOOD PRESSURE is more important to the OPERATOR than the absolute accuracy of individual DETERMINATIONS. As a result, the time between measurements is permitted to be very short even though that can negatively affect the clinical accuracy of DETERMINATIONS. Therefore, an AUTOMATED SPHYGMOMANOMETER is not required to meet the clinical accuracy requirements when operating in this mode.

Subclause 201.7.2.4 – ACCESSORIES

The accuracy of a DETERMINATION requires the use of the correct size CUFF. If the CUFF used is too large or too small relative to the limb circumference of the PATIENT, or incorrectly positioned on the limb of the PATIENT, clinically significant errors in BLOOD PRESSURE estimation could result [20] [21] [22].

Subclause 201.7.2.102 – AUTOMATED SPHYGMOMANOMETER with NEONATAL MODE

This document specifies the use of lower maximum CUFF pressures and shorter measurement times with neonatal PATIENTS to reduce the RISK of injury. AUTOMATED SPHYGMOMANOMETERS need clear instructions for the OPERATOR to ensure that the proper mode is used with neonatal PATIENTS.

Subclause 201.7.2.103 – AUTOMATED SPHYGMOMANOMETER intended for self-use in public areas

AUTOMATED SPHYGMOMANOMETERS intended for use in public areas are typically used by OPERATORS measuring their own BLOOD PRESSURE. These OPERATORS do not have access to the instructions for use. The most important instructions need to be marked on the ME EQUIPMENT.

Subclause 201.7.2.104 – Component replacement

Replacement of components or parts that can impact BASIC SAFETY or ESSENTIAL PERFORMANCE should occur only with the appropriate awareness of the potential consequences of the replacement. Both clinical OPERATORS and SERVICE PERSONNEL need this awareness. Appropriate PROCEDURES, for example re-calibration, should occur following such replacements. The marking requirement is intended to give this awareness.

Subclause 201.7.9.2.13 – Maintenance

The performance should be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.106) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa).

Subclause 201.8.5.5.101 – PATIENT CONNECTIONS of AUTOMATED SPHYGMOMANOMETERS

AUTOMATED SPHYGMOMANOMETERS are frequently used in environments in which other pieces of ME EQUIPMENT are also connected to the same PATIENT. If the AUTOMATED SPHYGMOMANOMETER has PATIENT CONNECTIONS, it is important for the safety of the PATIENT and the OPERATOR that it be a DEFIBRILLATION-PROOF APPLIED PART.

Subclause 201.11.8.101 – Switching off

The intent of this requirement is to ensure reduced RISK of injury to a PATIENT due to excessive pressure applied to the limb when the AUTOMATED SPHYGMOMANOMETER is turned off or loses power unintentionally. The requirement is intended to ensure that the AUTOMATED SPHYGMOMANOMETER is in a safe state when power is removed. Examples include AUTOMATED SPHYGMOMANOMETERS for use on neonatal or infant PATIENTS and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple DETERMINATIONS without OPERATOR intervention over extended periods of time. See also the rationale for 201.12.1.105 for a discussion of pressure levels and deflation acceptance criterion.

Subclause 201.11.8.103 – INTERNAL ELECTRICAL POWER SOURCE

Failure to deflate the CUFF within 30 s to the values indicated in Table 201.102 is considered a failure to maintain BASIC SAFETY.

Subclause 201.12.1.103 – NOMINAL BLOOD PRESSURE indication range

This test is a compromise as it is not practicable to perform this test in human subjects since these BLOOD PRESSURE values are extremely rare in clinical care. It is important for AUTOMATED SPHYGMOMANOMETERS to be able to indicate BLOOD PRESSURES above the range over which they are clinically investigated. An AUTOMATED SPHYGMOMANOMETER that either blanks or artificially limits the value of the display above that range would "hide" the condition of the PATIENT from the OPERATOR.

Subclause 201.12.1.105 – Maximum pressure in SINGLE FAULT CONDITION

The intent of this requirement is to ensure reduced RISK of injury to a PATIENT due to excessive pressure applied to the limb when the primary pressure sensing and protection mechanism of the AUTOMATED SPHYGMOMANOMETER is not functioning due to a SINGLE FAULT CONDITION. The requirement is intended to reduce RISK in situations where the PATIENT is unable to remove the CUFF in the case of overpressure and there is no OPERATOR likely to be present. In these cases, it is necessary to provide a PROTECTION DEVICE to release pressure from the CUFF without the intervention of the OPERATOR or the PATIENT. Examples include AUTOMATED SPHYGMOMANOMETERS for use on neonatal PATIENTS and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple DETERMINATIONS with no OPERATOR intervention over long periods of time.

Failure of the CUFF to deflate over an extended period of time can result in injury to the PATIENT. Reduction of the CUFF pressure to less than 15 mmHg is considered sufficient to reduce or eliminate the RISK of injury to adults. Since neonates are particularly sensitive to the effects of prolonged pressure on a limb, reduction of the CUFF pressure to 5 mmHg is required for these PATIENTS.

An alternative RISK CONTROL method is provided for AUTOMATED SPHYGMOMANOMETERS that operate in SELF-MEASUREMENT AUTOMATIC MODE. Since the total number of DETERMINATIONS is limited and the PATIENT is conscious and expected to be able to remove the CUFF or otherwise release the pressure, a PROTECTION DEVICE is not necessary. This alternative RISK CONTROL method is intended to provide a balance between the benefits of the availability of low-cost AUTOMATED SPHYGMOMANOMETERS intended for SELF-MEASUREMENT AUTOMATIC MODE and the added cost of the SINGLE FAULT CONDITION PROTECTION DEVICE.

The evaluation of the acceptance criterion for the performance of the PROTECTION DEVICE includes the time required to deflate the CUFF, which is affected by both the pressure in and the volume of the CUFF. The initial pressure chosen for the test should represent the highest pressure expected in NORMAL USE, which occurs at the end of the inflation cycle. In the NEONATAL MODE, the maximum pressure of 150 mmHg should be used; otherwise, the allowable maximum pressure is 300 mmHg, but rarely exceeds 250 mmHg.

Since it can be difficult to establish consistent volumes with CUFFS, one method to standardize this test is to utilize standardized volumes to represent the CUFF (e.g. 100 ml ± 5 ml in NEONATAL MODE or for wrist AUTOMATED SPHYGMOMANOMETERS and 500 ml ± 25 ml otherwise). An alternative method is to utilize the largest CUFF specified in the instructions for use for each mode of operation. The CUFF should be wrapped around a rigid mandrel that represents the midpoint of the marked range for the CUFF.

The time of 3 s allows for momentary artefacts, common with this technology, which could cause the CUFF pressure to rise temporarily above the maximum permitted pressure without creating an ALARM CONDITION.

Subclause 201.12.1.106 – Manometer test mode

A manometer test mode of an AUTOMATED SPHYGMOMANOMETER is used to verify or calibrate the accuracy of the PRESSURE TRANSDUCER. Depending on its design and material, the accuracy of the PRESSURE TRANSDUCER can be affected by temperature, drift, aging PROCESSES, etc. Therefore it is necessary for SERVICE PERSONNEL to have a means to check the accuracy of the PRESSURE TRANSDUCER for maintenance and calibration of an AUTOMATED SPHYGMOMANOMETER. Such checks are recommended by some MANUFACTURERS and are required by some authorities with jurisdiction. Since a manometer test mode is not used clinically, access is restricted to SERVICE PERSONNEL, which can include use of a TOOL to open the ENCLOSURE.

Subclause 201.12.1.107 – Reproducibility of the BLOOD PRESSURE DETERMINATION

This requirement is designed to demonstrate that an AUTOMATED SPHYGMOMANOMETER continues to have acceptable reproducibility following the environmental stresses of this particular standard. During the development of this particular standard, concern was raised that the simulator used might not have sufficient reproducibility to successfully perform this test. This test PROCEDURE was developed to address this concern. The PROCEDURE allows one to confirm that the combination of the AUTOMATED SPHYGMOMANOMETER and simulator works in a repeatable way, and that the simulator is generating the signals in a reproducible way, i.e. consistently for at least the time required to perform the whole test sequence.

To accomplish these objectives, two samples of the AUTOMATED SPHYGMOMANOMETER are required. The first sample (A) is one that undergoes the TYPE TEST to the requirements of the subclause while the second sample (B) is used to demonstrate that the AUTOMATED SPHYGMOMANOMETER and the simulator work in a repeatable way for the period required for completing the test sequence. Sample B is only used to demonstrate that the combination of AUTOMATED SPHYGMOMANOMETER and simulator works in a repeatable way and that the simulator is generating the signals in a reproducible way. As such, its use is not necessary to perform the TYPE TESTS on sample A, but its use allows the tester to confirm when the test setup is inadequate.

Steps b) to e) are used to confirm that the combination of the AUTOMATED SPHYGMOMANOMETER (sample B) and simulator works in a repeatable way. If either BLOOD PRESSURE standard deviation fails the acceptance criterion, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient reproducibility to perform this test PROCEDURE. Either the simulator needs adjustment or different simulator is required.

EXAMPLE For the wrist-type AUTOMATED SPHYGMOMANOMETER, the amplification of the generated signals often has to be reduced.

These steps are repeated at the end of the test PROCEDURE on sample B [steps k) to n)] and the resulting values compared to the earlier ones. If either one of these criteria is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient long-term stability to perform this test PROCEDURE.

The actual TYPE TEST occurs with sample A. Sample A is evaluated with the simulator, subjected to the environmental stresses as indicated and then is evaluated a second time with the simulator. Failing the acceptance criterion indicates that the AUTOMATED SPHYGMOMANOMETER subjected to the TYPE TEST has been unacceptably affected by the environmental stresses.

The limit in step o) is ≤ 5,0 mmHg (0,67 kPa) because up to 2,0 mmHg (0,27 kPa) is permitted due to the contribution of the stability of the AUTOMATED SPHYGMOMANOMETER and simulator combination in step n) in addition to the ≤ 3,0 mmHg (0,4 kPa) criterion permitted for the AUTOMATED SPHYGMOMANOMETER undergoing the TYPE TEST.

Subclause 201.15.3.5.101 – Shock and vibration (robustness)

AUTOMATED SPHYGMOMANOMETERS in NORMAL USE will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, an AUTOMATED SPHYGMOMANOMETER needs to be robust enough to withstand the vibration, shock, bumps and drops that it will encounter in NORMAL USE.

These tests were chosen by first reviewing the results of the work published in other PATIENT monitoring standards where those committees qualitatively assessed the relative severity of the scenarios within various environments (i.e., HOME HEALTHCARE ENVIRONMENT, healthcare institution and professional transport (wings and wheels)), by various sizes and types of ME EQUIPMENT (i.e., HAND-HELD, PORTABLE and MOBILE ME EQUIPMENT) [23] [24].

After that qualitative assessment, those committees assessed the relevant particular standards for environmental testing in the IEC 60068 series and their respective rationales, as well as the IEC 60721 series of guidance documents. In selecting the requirements, those committees reviewed other sources for material related to these tests (e.g. FDA Reviewers Guidance for premarket notification submissions, Mil Std 810, etc.) but found the best fit was with IEC 60721-3-7 [25]. There is also a guidance document, IEC TR 60721-4-7 [16], which helps to correlate environmental condition classes of IEC 60721-3-7 to environmental tests according the IEC 60068 series. The aforementioned standards specify 3 classes of mechanical conditions: 7M1, 7M2 and 7M3. Those committees found that classes 7M1 and 7M3 best represent the conditions seen during PATIENT transport within healthcare facilities and PATIENT transport outside healthcare facilities, respectively. Those committees agreed that different tests and test levels should be applied to ME EQUIPMENT intended for use in a healthcare facility versus ME EQUIPMENT intended for use during PATIENT transport outside the healthcare facility.

Verifying that the instrument is functioning within the MANUFACTURER'S specifications while the vibration (random and sinusoidal) tests are being conducted was not believed necessary. This line of thought was considered and it was decided that a test done in this manner would be overly burdensome and would add only a minimum additional level of safety to the ME EQUIPMENT that would not outweigh the costs. Verifying proper functioning after completion of the tests is believed adequate.

Subclause 201.101.1 – Construction

This document does not specify the details of the construction of CUFFS and BLADDERS. Studies [20] [21] [22] have suggested that the appropriate BLADDER size for the placement at the upper arm for auscultatory estimates of BLOOD PRESSURE is one with dimensions such that its width is 40 % of the limb circumference at the maximum range for each CUFF size and its length is 80 % to 100 % of the limb circumference at the centre of the range for each CUFF size. In auscultation, use of the wrong size CUFF can affect the accuracy of the estimates of BLOOD PRESSURE. These recommended dimensions are subject to ongoing consideration. AUTOMATED SPHYGMOMANOMETERS can be designed with different CUFF dimensions.

Use of an incorrect CUFF size (too small or too large) is a source of inaccurate DETERMINATION, for example CUFFS that are too small can result in erroneously high DETERMINATIONS. This RISK should be avoided by a design that does not allow a DETERMINATION to be initiated or displayed if the limb circumference is outside the permissible range. Alternatively, the RISK can be reduced by marking on the CUFF the permissible range of limb circumference.

The appropriate BLADDER size for placement at the wrist is dependent on the design of the AUTOMATED SPHYGMOMANOMETER. Commonly used wrist CUFFS have a width of approximately 6 cm and a length of 10 cm to 14 cm for a wrist circumference range of 13,5 cm to 19,5 cm.

Subclause 201.101.2 – Pressurization

While the maximum pressure allowed in the PNEUMATIC SYSTEM is 330 mmHg, prudent engineering design requires that the CUFF be tested at a higher pressure (+ 10 %). This is similar to the derating methods used to ensure that electronic components meet the requirements of a design.

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

The committees have determined that any AUTOMATED SPHYGMOMANOMETER available to the public, and intended for self-use by the public and regardless of intended use labelling, should be appropriate for the clear majority of the general adult population. This is in the interest of public health and safety. The mid-upper-arm circumference range of 22 cm to 42 cm was chosen as the minimum range based on available data. While worldwide statistics are lacking, this arm circumference range has been shown (through high quality National Institutes of Health data) to include 95 % of adults in the US. Further, worldwide professional systems of BLOOD PRESSURE CUFFS generally offer "adult" and "large adult" CUFFS covering this same range, which supports that this is a reasonable range for an AUTOMATED SPHYGMOMANOMETER intended for self-use in public settings.

Subclause 201.102 – Connection tubing and CUFF connectors

In the 1990s, concern grew regarding the proliferation of medical devices fitted with Luer connectors [26] [27] and the reports of PATIENT death or injury arising from misconnections that resulted in the inappropriate delivery of enteral solutions, intrathecal medication or compressed gases, including connections between an AUTOMATED SPHYGMOMANOMETER and CUFF.

Concerns regarding the use of Luer connectors with enteral feeding tubes and gas sampling and gas delivery systems were raised with CEN/BT and the European Commission. In November 1997, the CHeF steering group set up a Forum Task Group to consider the problem. It produced CEN Report CR 13825 [28], in which they concluded that there is a problem arising from the use of a single connector design to a number of incompatible applications. In a coronary care unit, there are as many as 40 Luer connectors on the medical devices used with a single PATIENT. Therefore, it is not surprising that misconnections are made.

Based on these concerns, the ISO 80369 series was developed to create new non-Luer connectors for medical device applications other than for intravascular or hypodermic applications. The connectors of this series are designed such that connectors for the different applications do not connect. IEC 80369-5 was specifically developed for use with tubing for limb CUFF inflation, including sphygmomanometers and CUFFS.

Subclause 201.104 – Maximum inflating time

The pressures indicated in Table 201.102 were chosen, following clinical advice, as being CUFF pressures at which reasonable venous return can take place. They are also pressures that can be measured with reasonable reliability.

Two or more attempts at determining the BLOOD PRESSURE of restless or hypertensive PATIENTS can occur in 180 s. A large safety margin is still allowed before any neuromuscular injury is likely to take place.

The shortened maximum time in NEONATAL MODE is not only obviously desirable to reduce discomfort and trauma in these fragile PATIENTS, but also justified since the maximum pressure is 150 mmHg (20,0 kPa), which results in a shorter deflation time, and the typical heart rate of these PATIENTS is higher. An additional issue is that the longer the CUFF remains

inflated, the more distressed an infant becomes, thus producing more artefacts that could cause more readings to be taken.

Since this requirement applies in SINGLE FAULT CONDITION, it is necessary to guard against the failure of a deflation valve by having two independent means of reducing the pressure.

An alternative RISK CONTROL method is provided for AUTOMATED SPHYGMOMANOMETERS that operate in SELF-MEASUREMENT AUTOMATIC MODE. See 201.12.1.105.

Subclause 201.105 – Automatic cycling modes

Table AA.1 provides a summary of the requirements and differences between the automatic cycling modes described in this document.

The figures shown in this subclause are drawn to illustrate the DETERMINATION of BLOOD PRESSURE during the deflation cycle. Some AUTOMATED SPHYGMOMANOMETERS determine BLOOD PRESSURE during inflation. This results in a longer inflation cycle and a shorter deflation cycle when compared to the figures. This does not change the intent of the figures or any of the other requirements of this document.

Table AA.1 – Summary of requirements by mode

	LONG-TERM AUTOMATIC MODE 201.105.1	SHORT-TERM AUTOMATIC MODE 201.105.2	SELF-MEASUREMENT AUTOMATIC MODE 201.105.3
Number of DETERMINATIONS	Unlimited	Limited [a]	< 7
Duration of mode	Unlimited	≤15 min	≤ 30 min [b]
Maximum inflating time (per DETERMINATION) (201.104)	180 s or 90 s in NEONATAL MODE	180 s or 90 s in NEONATAL MODE	180 s [c]
Deflated period	≥ 30 s	≥ 2 s	≥ 5 s
Maximum pressure (201.12.1.104)	300 mmHg or 150 mmHg in NEONATAL MODE	300 mmHg or 150 mmHg in NEONATAL MODE	300 mmHg [c]
Pressure protection in SINGLE FAULT CONDITION	PROTECTION DEVICE	PROTECTION DEVICE	Manual means [d] or PROTECTION DEVICE
PATIENT population	All	All	Limited [e]
Clinical investigation (201.106)	ISO 81060-2	Not required	ISO 81060-2

[a] The number of DETERMINATIONS is not specified, but is limited by the duration.

[b] The number of DETERMINATIONS is limited to 6, but with a 30 min time limit.

[c] NEONATAL MODE is not permitted in SELF-MEASUREMENT AUTOMATIC MODE.

[d] If an independent PROTECTION DEVICE is not provided, means are provided for the release of pressure by the OPERATOR or PATIENT.

[e] The PATIENT population is intended only for conscious adults and is required to be disclosed in the instructions for use.

Subclause 201.105.2 – SHORT-TERM AUTOMATIC MODE

SHORT-TERM AUTOMATIC MODE is valuable for continuous surveillance of PATIENTS undergoing anaesthetic PROCEDURES as well as emergency care where there can be a clinical need for frequent readings. However, a minimum period of deflation between inflations is necessary to allow some venous return. In addition, the total duration of the SHORT-TERM AUTOMATIC MODE should be limited to prevent venous pooling and reduce bruising.

Subclause 201.105.3 – SELF-MEASUREMENT AUTOMATIC MODE

SELF-MEASUREMENT AUTOMATIC MODE is useful for measurement of BLOOD PRESSURE both in physicians' offices and in the home. Current recommendations for measurement of BLOOD PRESSURE for use in the diagnosis of hypertension [7] recommend that at least 2 DETERMINATIONS should be taken at intervals of at least 1 min, and the average of those DETERMINATIONS should be taken as the PATIENT'S BLOOD PRESSURE.

The use of this mode in a physician's office provides the ability to obtain multiple measurements from a PATIENT without a clinician being present. This could reduce or eliminate the white coat hypertension effect [29].

The ability to access the individual DETERMINATIONS is useful to ascertain if there is significant variability in a PATIENT'S BLOOD PRESSURE.

While the use of the average of multiple DETERMINATIONS is widely used, other measures can be used to represent a PATIENT'S BLOOD PRESSURE (e.g. median or mode).

Subclause 201.105.3.3 – SINGLE FAULT CONDITION

The intent of this requirement is to provide a means of RISK CONTROL for potential injury to a PATIENT due to the HAZARDOUS SITUATION of excessive pressure applied to the limb when the primary pressure sensing or PROTECTION DEVICE of the AUTOMATED SPHYGMOMANOMETER is not functioning due to a SINGLE FAULT CONDITION. The requirement for a PROTECTION DEVICE is intended to reduce RISK to acceptable levels in situations where the PATIENT is commonly unable to remove the CUFF in the case of over pressure and there is no other OPERATOR likely to be present to physically remove the pressurized CUFF from the limb. In this case, it is necessary to provide an independent PROTECTION DEVICE to release pressure from the CUFF without the intervention of the OPERATOR or the PATIENT. Example cases include AUTOMATED SPHYGMOMANOMETERS for use on neonatal PATIENTS or PATIENTS in critical care units and AUTOMATED SPHYGMOMANOMETERS that can initiate multiple DETERMINATIONS without OPERATOR intervention over an extended period.

An alternative means of RISK CONTROL is provided for AUTOMATED SPHYGMOMANOMETERS that only operate in the SELF-MEASUREMENT AUTOMATIC MODE. In this mode, it is assumed that the period of operation will be relatively short while a single DETERMINATION is performed and that the OPERATOR is present during the entire operation and is available to release the pressure from the CUFF or remove the CUFF in the case of a SINGLE FAULT CONDITION. This also applies to the SELF-MEASUREMENT AUTOMATIC MODE when the PATIENT is the OPERATOR.

The alternative RISK CONTROL method is intended to provide an acceptable RESIDUAL RISK by trading off the cost of a PROTECTION DEVICE with OPERATOR action when OPERATOR/PATIENT action can be relied upon for RISK CONTROL. It is clearly an unacceptable RISK to PATIENTS if accurate, low cost AUTOMATED SPHYGMOMANOMETERS are not available for PATIENT self-measurement for use in the management of hypertension.

Subclause 201.106 – Clinical accuracy

The SHORT-TERM AUTOMATIC MODE is valuable for continuous surveillance of PATIENTS undergoing anaesthetic PROCEDURES as well as emergency care where there can be a clinical need for very frequent readings to monitor critical, unstable PATIENTS. However, because of the minimal period of deflation permitted between inflations that enables the OPERATOR to obtain BLOOD PRESSURE readings in the shortest possible time, it is expected that accuracy is degraded to some extent.

In addition, the total duration of the SHORT-TERM AUTOMATIC MODE should be limited to prevent venous pooling and reduce bruising.

Subclause 202.8.1.101 – Additional general requirements

Transient electromagnetic phenomena (e.g. ESD, lightening, switching of large inductive loads) are random, infrequent events of short duration. They have amplitudes of several thousand volts referred to earth. Thus, it is hardly possible to design a SPHYGMOMANOMETER having a protective or functional earth connection or operating from mains power that is completely immune against these transient phenomena. On the other hand, a short disturbance and recovery period do not impact the treatment of PATIENTS. Therefore, this document allows disturbances and interruptions with a recovery period of maximum 10 s after transient electromagnetic phenomena.

Subclause 202.8.101 – Electrosurgery interference recovery

If an AUTOMATED SPHYGMOMANOMETER is intended to be used together or in the presence with HF SURGICAL EQUIPMENT, OPERATORS should expect that the AUTOMATED SPHYGMOMANOMETER can determine BLOOD PRESSURE following a recovery time. Since an AUTOMATED SPHYGMOMANOMETER determines BLOOD PRESSURE aperiodically and not continually, the committee judged that it was not a requirement for an AUTOMATED SPHYGMOMANOMETER to be able to make a DETERMINATION during the operation of HF SURGICAL EQUIPMENT, but that it would be an unacceptable RISK to a PATIENT if an AUTOMATED SPHYGMOMANOMETER were unable to make the expected DETERMINATION following operation of the HF SURGICAL EQUIPMENT.

Annex BB
(informative)

Environmental aspects

The environmental impact generated by an AUTOMATED SPHYGMOMANOMETER performing DETERMINATIONS is mainly isolated to the following occurrences:

– impact at local environment during operation, including routine inspection and adjustments by the OPERATOR, according to the instructions for use or routine PROCEDURES;

– use, cleaning and disposal of consumables during operation, including routine inspection and adjustments by the OPERATOR, according to the instructions for use or routine PROCEDURES;

– scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this document addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of an AUTOMATED SPHYGMOMANOMETER.

See Table BB.1 for a mapping of the life cycle of an AUTOMATED SPHYGMOMANOMETER to aspects of the environment.

Table BB.1 – Environmental aspects addressed by clauses of this document

Environmental aspects (inputs and outputs)		Product life cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in	Addressed in	Addressed in	Addressed in
1	Resource use	IEC 60601-1-9 [a]	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
2	Energy consumption	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
3	Emission to air	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.106
4	Emission to water	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.105
5	Waste	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.105
6	Noise	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9
7	Migration of hazardous substances	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.105
8	Impacts on soil	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9 and 201.7.2.105
9	RISKS to the environment from accidents or misuse	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9	IEC 60601-1-9

[a] See IEC 60601-1-9:2007.

Annex CC
(informative)

Reference to the ESSENTIAL PRINCIPLES

This particular standard has been prepared to support the ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE of AUTOMATED SPHYGMOMANOMETERS as medical devices according to ISO 16142-1:2016 [30]. This particular standard is intended to be acceptable for conformity assessment purposes.

Compliance with this particular standard provides one means of demonstrating conformance with the specific ESSENTIAL PRINCIPLES of ISO 16142-1:2016 [30]. Other means are possible.

See Table CC.1 for a mapping of the clauses and subclauses of this document to ESSENTIAL PRINCIPLES of ISO 16142-1:2016.

Table CC.1 – Correspondence between this particular standard and the ESSENTIAL PRINCIPLES

ESSENTIAL PRINCIPLE of ISO 16142-1:2016, Tables B.1 and B.2 [30]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
1	All	The part relating to manufacturing is not addressed.
a)	206	
b)	206	
2	201.4	The part relating to manufacturing is not addressed.
a)	All	
b)	201.4	The part relating to manufacturing is not addressed.
c)	201.7, 201.11, 201.12, 201.13, 208	
d)	201.7	
3	All	The part relating to manufacturing is not addressed.
4	All	
5	201.4, 201.15	
6	201.4	
8.1	201.11	
a)	201.11	
b)	201.4, 201.11	
c)	201.9, 201.15	
8.2	201.11	
8.5	201.11, 211.8.3.1, 212	
9.1	201.11, 211	
12.1	201.7, 201.14, 201.16, 201.101, 201.102	
12.2	—	
a)	201.9, 201.11, 201.101, 206, 208	
b)	201.7.2.4, 201.101, 206	
c)	202	
d)	201.11	

ESSENTIAL PRINCIPLE of ISO 16142-1:2016, Tables B.1 and B.2 [30]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
e)	201.14, 201.16	
f)	201.11	
g)	202	
12.4	201.11	
12.5	201.7, 201.8, 201.12.1.106	
12.6	201.1.3, 201.7.2.105	
13.1	201.7.2.101, 201.12.1, 201.101, 201.105, 201.106	
13.2	201.7, 201.12.1.101, 201.12.1.103	
13.3	201.7, 201.102, 206, 208	
13.4	201.7	
14.1	201.10	
14.3	201.10	
15.1	201.14	
15.2	201.14	
16.1	201.4, 201.13, 201.104, 201.105.1 b), 201.105.3.3	
16.3	201.11.8, 211	
16.4	201.11.8, 201.12.3, 208	
16.5	202	
16.6	202	
16.7	201.8	
17.1	201.9	
17.2	201.9	
17.3	201.9	
17.4	201.15	
17.5	201.7.2.4, 201.9, 201.102	
17.6	201.11	
18.1	201.12.1	
18.2	201.12.1.101, 201.12.1.104, 201.12.1.105, 201.104, 201.105	
19.1	201.7, 201.7.2.101, 201.12.1.101, 201.12.1.103, 201.101.1, 206	
19.2	201.7, 201.12.1.101, 201.101.1, 201.101.3 b), 206	
20.1	211	
20.2	211	
20.3	211	
21.1	201.7	
21.2	201.7	
21.3	201.7	
21.4	201.7	
21.5	—	
a)	201.7	The part relating to authorized representative is not addressed

ESSENTIAL PRINCIPLE of ISO 16142-1:2016, Tables B.1 and B.2 [30]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
e)	201.7	
l)	201.7	
21.6	201.7	
21.7	—	
i)	201.7.9.2.2	
k)	201.7.9.2.9, 201.16	
n)	201.16	
q)	201.7	
21.8	201.7	
21.9	—	
b)	211	
d)	211	
f)	201.7	

Bibliography

[1] IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012

[2] ISO 81060-1:2007, *Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type*

[3] IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*

[4] IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

[5] DEVBHANDARI, MP., SHARIFF Z., and DUNCAN AJ. Skin necrosis in a critically ill patient due to a blood pressure cuff. *J Postgrad Med*, 2006, 52:2, pp. 136-138

[6] FDA, *Guidance for Industry and FDA Staff – Premarket Assessment of Pediatric Medical Devices*. March 24, 2014 [5]

[7] PICKERING T., HALL J., APPEL L., FALKNER B., GRAVES J., HILL M., JONES D., KURTZ T., SHEPS S., ROCCELLA E. Recommendations for Blood Pressure Measurement in Humans and experimental Animals. *Circulation*, 2005, 111, pp. 697-716

[8] *Blood pressure Measurement*. CD ROM, The British Hypertension Society. BMJ Books. BMA House, Travistock Square, London WC1H9JR, 1998

[9] COLEMAN A., STEEL S., ASHWORTH M., VOWLER S., SHENNAN A. Accuracy of the pressure scale of sphygmomanometers in clinical use within primary care. *Blood Press Mon*, 2005, 10:4, pp. 181-188

[10] O'BRIEN E., PETRIE J., LITTLER WA., DE SWIET M., PADFIELD PD., DILLON MJ., COATS A., MEE, F., *Blood pressure Measurement: Recommendations of the British Hypertension Society*. BMJ Publishing Group. Third Edition 1997

[11] Recommendations of the World Health Organisation: "WHO Technical Report, Arterial hypertension; Series 628". 1978

[12] KEMPEN, P., Complication of a non-invasive blood pressure cuff during prone positioning. *Can J Anesth*, 2005, 53:1, pp. 106–111

[13] CLELAND M., PHAM B., MILLER D. Influence of arrhythmias on accuracy of non-invasive blood pressure monitors. *Can J Anaesth*, 1998, 45, pp. 699-705

[14] OKAMOTO H., SUGIMACHI M., HOKA S. Accuracy of a new algorithm for oscillometric non-invasive blood pressure measurement in patients with atrial fibrillation. *Anesthesiology,* 2001, 95:A, p. 580

5 Available from FDA at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf

[15] WEINGER MB., SCANLON TS., MILLER L. A widely unappreciated cause of failure of an automatic non-invasive blood pressure monitor. *J Clin Monit*, 2005, 8:4, pp. 291-294

[16] IEC TR 60721-4-7, *Classification of environmental conditions – Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 – Portable and non-stationary use*

[17] OSTCHEGA, Y., PHD, RN. Nurse consultant to the NHAMES project Hyattsville MD report to the AAMI/ISO Sphyg committee, May 9, 2013

[18] CELORIA, G., DAWSON, JA., and TERES, D. Compartment syndrome in a patient monitored with an automated pressure cuff. 1987, *J Clin Monit,* , 3, pp. 139-141

[19] LIN, C., et al. Blood Pressure Cuff Compression Injury of the Radial Nerve. *J of Clin Anesth*, 2001, 13, pp. 306–308

[20] GEDDES, ME., Whistler, SJ. The error in indirect blood pressure measurement with the incorrect size of cuff. *Am Heart J*, 1978, 96:1, pp. 1-8

[21] MARKS, LA., GROCH, A. Optimizing cuff width for non-invasive measurement of blood pressure. *Bld Press Mon*, 2000, 5:153, pp. 153-158

[22] PRINEAS, RJ., et al. US demographic trends in mid-arm circumference and recommended blood pressure cuffs for children and adolescents: data from the National Health and Nutrition Examination Survey 1988-2004. *Cl meth & pathphy*, 2007, 12:2, pp. 75-80

[23] ISO 9919:2005, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use*

[24] ISO 21647:2004, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors*

[25] IEC 60721-3-7, *Classification of environmental conditions – Part 3: Classification of groups of environmental parameters and their severities – Section 7: Portable and non-stationary use*

[26] ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements*

[27] ISO 594-2:1991, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

[28] CEN CR 13825:2000, *Luer connectors – A report to CEN CHeF from the CEN forum task group "Luer fittings"*

[29] *La prise de la pression artérielle au cabinet médical.* Société Française d'Hypertension Artérielle. 1998 (available in French only)

[30] 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*

Index of defined terms

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

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

AVANT-PROPOS

1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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La Norme internationale IEC 80601-2-30 a été établie par le groupe de travail commun du sous-comité 62D: Appareils électromédicaux, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale, et du sous-comité SC3: Ventilateurs pulmonaires et équipements connexes, du comité technique 121 de l'ISO: Matériel d'anesthésie et de réanimation respiratoire.

Cette deuxième édition annule et remplace la première édition parue en 2009 et son Amendement 1:2013. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) alignement avec l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1-8:2006/AMD1:2012 [1][1], et avec l'IEC 60601-1-2:2014 et l'IEC 60601-1-11:2015;

b) référence à l'IEC 60601-1-10:2007 et à l'IEC 60601-1-12;

c) modification d'un connecteur BRASSARD-sphygmomanomètre accessible à l'OPERATEUR non compatible avec la série ISO 594 en un connecteur compatible avec la série ISO 80369;

d) ajout d'exigences supplémentaires relatives aux sphygmomanomètres à usage autonome dans les zones publiques;

e) ajout d'une liste de FONCTIONS PRINCIPALES DE SERVICE.

La présente publication est une norme double logo.

Le texte de cette norme est issu des documents suivants de l'IEC:

FDIS	Rapport de vote
62D/1548/FDIS	62D/1560/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation du présent document. À l'ISO, la norme a été approuvée par 14 membres P sur un total de 15 votes exprimés.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;

– *modalités d'essais: caractères italiques;*

– indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;

– TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DANS LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);

– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif". Ainsi, un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité au présent document;

– "il convient" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité au présent document;

1 Les chiffres entre crochets font référence à la Bibliographie.

– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d'un titre d'alinéa ou de tableau, il indique l'existence d'un guide ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties de la Norme internationale 80601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de cette publication ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. À cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

NOTE L'attention des utilisateurs du présent document est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

INTRODUCTION

Les exigences minimales de sécurité spécifiées dans le présent document particulière sont considérées comme assurant un degré pratique de sécurité dans le fonctionnement des SPHYGMOMANOMETRES AUTOMATIQUES.

Les exigences sont suivies de spécifications relatives aux essais correspondants.

Conformément à la décision prise par le sous-comité 62D lors de sa réunion tenue à Washington DC en 1979, une section "Guide particulier et justifications" contenant, le cas échéant, des notes explicatives concernant les exigences les plus importantes figure en Annexe AA. La connaissance des raisons qui ont conduit à énoncer ces exigences est considérée non seulement comme facilitant l'application correcte de la norme mais aussi comme accélérant, en temps utile, toute révision rendue nécessaire par suite de modifications dans la pratique clinique ou d'évolutions technologiques. Cependant, les justifications contenues dans l'Annexe AA ne font pas partie des exigences du présent document.

APPAREILS ÉLECTROMÉDICAUX –

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

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale[2] s'applique avec les exceptions suivantes:

201.1.1 Domaine d'application

Remplacement:

La présente partie de la Norme internationale 80601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des SPHYGMOMANOMETRES AUTOMATIQUES, ci-après dénommés APPAREILS EM, qui, au moyen d'un BRASSARD gonflable, sont utilisés pour l'estimation indirecte non continue de la PRESSION ARTERIELLE sans ponction artérielle.

NOTE 1 Les appareils qui effectuent une DETERMINATION indirecte de la PRESSION ARTERIELLE sans ponction artérielle ne mesurent pas directement ladite PRESSION. Ils ne font qu'évaluer la PRESSION ARTERIELLE.

Le présent document spécifie les exigences pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES de ces APPAREILS EM et leurs ACCESSOIRES, y compris les exigences relatives à l'exactitude de la DETERMINATION de la PRESSION ARTERIELLE.

Le présent document couvre les APPAREILS EM automatiques à énergie électrique utilisés pour l'estimation indirecte intermittente de la PRESSION ARTERIELLE sans ponction artérielle, y compris les moniteurs de PRESSION ARTERIELLE pour l'ENVIRONNEMENT DES SOINS A DOMICILE.

Les exigences relatives aux APPAREILS EM d'estimation indirecte de la PRESSION ARTERIELLE sans ponction artérielle comportant un TRANSDUCTEUR DE PRESSION à énergie électrique et/ou des affichages utilisés conjointement avec un stéthoscope ou autres méthodes manuelles de détermination de la PRESSION ARTERIELLE (SPHYGMOMANOMETRES NON AUTOMATIQUES) sont spécifiées dans l'ISO 81060-1 [2].

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si tel n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des APPAREILS EM ou des SYSTEMES EM dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception de 201.11 et 201.105.3.3, ainsi que 7.2.13 et 8.4.1 de l'IEC 60601-1:2005.

NOTE 2 Voir également 4.2 de l'IEC 60601-1:2005 et de l'IEC 60601-1:2005/AMD1:2012.

201.1.2 Objet

Remplacement:

2 La norme générale est constituée de l'IEC 60601-1:2005 et de l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*.

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES d'un SPHYGMOMANOMETRE AUTOMATIQUE tel qu'il est défini en 201.3.201.

201.1.3 Normes collatérales

Addition:

La présente norme particulière fait référence aux normes collatérales applicables énumérées à l'Article 2 de la norme générale et à l'Article 201.2 de la présente norme particulière.

L'IEC 60601-1-2, l'IEC 60601-1-6, l'IEC 60601-1-10, l'IEC 60601-1-11 et l'IEC 60601-1-12 s'appliquent telles qu'elles sont modifiées respectivement aux Articles 202, 206, 210, 211 et 212. L'IEC 60601-1-3 [3] ne s'applique pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles qu'elles sont publiées [1] [4].

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales, en fonction de ce qui est approprié à l'APPAREIL EM à l'étude. Elles peuvent également ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, dans la présente norme particulière, le terme "norme générale" désigne l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012. Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple, 201.1 dans le présent document aborde le contenu de l'Article 1 de la norme générale) ou de la norme collatérale applicable avec le préfixe "20x", où x est (sont) le (les) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple, 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale sont précisées en utilisant les termes suivants:

"Remplacement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

"Addition" signifie que le texte de la présente norme particulière vient s'ajouter aux exigences de la norme générale ou de la norme collatérale applicable.

"Modification" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué par le texte de la présente norme particulière.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées de 3.1 à 3.147, les définitions supplémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires sont notées AA, BB, etc., et les points supplémentaires aa), bb), etc.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour faire référence à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière, considérées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification. Lorsqu'il est demandé qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la bibliographie commençant à la page 114.

L'Article 2 de la norme générale s'applique, avec les exceptions suivantes:

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

IEC 60601-1-6:2010, *Appareils électromédicaux – Partie 1-6: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Aptitude à l'utilisation*
IEC 60601-1-6:2010/AMD 1:2013

Addition:

IEC 60068-2-27:2008, *Essais d'environnement – Partie 2-27: Essais – Essai Ea et guide: Chocs*

IEC 60068-2-64:2008, *Essais d'environnement – Partie 2-64: Essais – Essai Fh: Vibrations aléatoires à large bande et guide*

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD 1:2012

IEC 60601-1-10:2007, *Appareils électromédicaux – Partie 1-10: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour le développement des régulateurs physiologiques en boucle fermée*

IEC 60601-1-11:2015, *Appareils électromédicaux – Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles – Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile*

IEC 60601-1-12:2014, *Appareils électromédicaux – Partie 1-12: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux destinés à être utilisés dans l'environnement des services médicaux d'urgence*

IEC 60601-2-2:2017, *Appareils électromédicaux – Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence*

IEC 62366-1:2015, *Dispositifs médicaux – Partie 1: Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux*

IEC 80369-5:2016, *Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé – Partie 5: Raccords destinés à des applications au gonflage de brassard*

ISO 80369-1:—[3], *Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé – Partie 1: Exigences générales*

ISO 81060-2:2013, *Sphygmomanomètres non invasifs – Partie 2: Validation clinique pour type à mesurage automatique*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et les définitions de l'IEC 60601-1, l'IEC 60601-1-8, l'IEC 60601-2-2:2017 et l'IEC 62366-1:2015, ainsi que les suivants, s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

NOTE Un index des termes définis est donné à partir de la page 116.

Addition:

201.3.201
SPHYGMOMANOMETRE AUTOMATIQUE
APPAREIL EM utilisé pour l'estimation non invasive de la PRESSION ARTERIELLE en utilisant un BRASSARD gonflable, un TRANSDUCTEUR DE PRESSION, une valve de dégonflement, et/ou des affichages utilisés conjointement avec des méthodes automatiques pour déterminer la PRESSION ARTERIELLE

Note 1 à l'article: Les composants d'un SPHYGMOMANOMETRE AUTOMATIQUE comprennent un manomètre, un BRASSARD, une valve de dégonflement (souvent en combinaison avec la valve prévue pour évacuer rapidement le SYSTEME PNEUMATIQUE), la pompe pour le gonflement de la POCHE et les tuyaux de raccordement.

201.3.202
BRASSARD
composant du SPHYGMOMANOMETRE AUTOMATIQUE enroulé autour du bras du PATIENT

Note 1 à l'article: Un BRASSARD comprend habituellement une POCHE et un élément inélastique entourant la POCHE, ou est constitué d'une POCHE intégrale (c'est-à-dire que le BRASSARD, y compris la POCHE, est fait d'une seule pièce).

[SOURCE: ISO 81060-1:2007 [2], 3.5, modifié – Dans la définition, "non automatique" a été remplacé par "automatique", et dans la Note 1 à l'article, "peut comprendre" a été remplacé par "comprend habituellement".]

[3] En préparation. Stade au moment de la publication: ISO/FDIS 80369-1:2017.

201.3.203
DETERMINATION
VALEUR DE DETERMINATION
résultat du processus d'estimation de la PRESSION ARTERIELLE par le SPHYGMOMANOMETRE AUTOMATIQUE

201.3.204
PRESSION ARTERIELLE DIASTOLIQUE
VALEUR DE LA PRESSION ARTERIELLE DIASTOLIQUE
valeur minimale de la PRESSION ARTERIELLE par suite d'une relaxation du ventricule systémique

Note 1 à l'article: Du fait des effets hydrostatiques, il convient de déterminer cette valeur avec le BRASSARD placé au niveau du cœur.

201.3.205
MODE AUTOMATIQUE LONGUE DUREE
mode dans lequel une minuterie, réglée par l'OPERATEUR, procède au lancement de DETERMINATIONS multiples

201.3.206
PRESSION ARTERIELLE MOYENNE
VALEUR DE LA PRESSION ARTERIELLE MOYENNE
valeur de l'intégrale d'un cycle de battements de cœur de la courbe de la PRESSION ARTERIELLE divisée par la durée de ce cycle

Note 1 à l'article: Du fait des effets hydrostatiques, il convient de déterminer cette valeur avec le transducteur placé au niveau du cœur.

201.3.207
MODE POUR NOUVEAU-NES
mode de SPHYGMOMANOMETRE AUTOMATIQUE utilisé avec les nouveau-nés ou nourrissons

Note 1 à l'article: L'âge approximatif du nouveau-né se situe entre la naissance et 1 mois d'âge [5] [6].

Note 2 à l'article: L'âge approximatif du nourrisson se situe entre 1 mois et 2 ans d'âge [5] [6]. Pour les besoins du présent document, les enfants jusqu'à 3 ans sont considérés comme des nourrissons (voir ISO 81060-2:2013, 6.1.3).

Note 3 à l'article: Le MODE POUR NOUVEAU-NES est utilisé pour limiter la pression maximale à 150 mmHg et un algorithme différent des autres modes destinés à des PATIENTS plus âgés lui est fréquemment associé.

201.3.208
SPHYGMOMANOMETRE NON AUTOMATIQUE
APPAREIL EM utilisé pour l'estimation non invasive de la PRESSION ARTERIELLE au moyen d'un BRASSARD gonflable équipé d'un élément détecteur de pression, d'une valve de dégonflement et d'un affichage utilisés conjointement avec un stéthoscope ou toute autre méthode manuelle d'estimation de la PRESSION ARTERIELLE

Note 1 à l'article: Les composants de ces instruments comprennent un manomètre, un BRASSARD, une valve de dégonflement (souvent en combinaison avec la valve prévue pour évacuer rapidement le SYSTEME PNEUMATIQUE), une pompe à main ou une pompe électromécanique pour le gonflement de la POCHE et des tuyaux de raccordement. Un SPHYGMOMANOMETRE NON AUTOMATIQUE peut également renfermer des composants électromécaniques destinés à la régulation de la pression.

[SOURCE: ISO 81060-1:2007 [2], 3.11, modifié – La définition et la note à l'article ont été reformulées.]

201.3.209
SIMULATEUR DE PATIENT
appareil destiné à simuler les impulsions oscillométriques du BRASSARD et/ou les signes auscultatoires au cours du gonflement et du dégonflement

Note 1 à l'article: Cet appareil n'est pas utilisé pour vérifier l'exactitude mais il est utilisé en vue de l'évaluation de la stabilité de performance.

201.3.210
SYSTEME PNEUMATIQUE
composant du SPHYGMOMANOMETRE AUTOMATIQUE comprenant tous les composants sous pression et ceux permettant le contrôle de la pression

EXEMPLES Le BRASSARD, les tubes, les connecteurs, les valves, le TRANSDUCTEUR DE PRESSION et la pompe.

[SOURCE: ISO 81060-1:2007 [2], 3.16, modifié – Dans la définition, remplacement de "non automatique" par "automatique", et dans les exemples, ajout de "de pression".]

201.3.211
TRANSDUCTEUR DE PRESSION
composant qui transforme la pression observée en un signal électrique

201.3.212
DISPOSITIF DE PROTECTION
partie de L'APPAREIL EM, qui, sans l'intervention de l'OPERATEUR, protège le PATIENT contre les caractéristiques de sortie dangereuses dues à une administration incorrecte d'énergie ou de substances

201.3.213
MODE AUTOMATIQUE D'AUTOMESURE
mode de SPHYGMOMANOMETRE AUTOMATIQUE déclenché manuellement et supervisé par l'OPERATEUR et permettant d'effectuer un nombre limité de DETERMINATIONS répétées sur une période finie

201.3.214
*** MODE AUTOMATIQUE COURTE DUREE**
mode de SPHYGMOMANOMETRE AUTOMATIQUE déclenché manuellement par l'OPERATEUR et permettant d'effectuer des DETERMINATIONS automatiques répétitives rapides dans un délai spécifié

201.3.215
PRESSION ARTERIELLE SYSTOLIQUE
VALEUR DE LA PRESSION ARTERIELLE SYSTOLIQUE
valeur maximale de la PRESSION ARTERIELLE par suite de la contraction du ventricule systémique

Note 1 à l'article: Du fait des effets hydrostatiques, il convient de déterminer cette valeur avec le BRASSARD placé au niveau du cœur.

201.4 Exigences générales

L'Article 4 de la norme générale s'applique avec les exceptions suivantes:

201.4.3 PERFORMANCE ESSENTIELLE

Paragraphe complémentaire:

201.4.3.101 Exigences supplémentaires de PERFORMANCES ESSENTIELLES

Des exigences supplémentaires de PERFORMANCES ESSENTIELLES sont données pour un SPHYGMOMANOMETRE AUTOMATIQUE dans les paragraphes énumérés dans le Tableau 201.101.

Tableau 201.101 – Répartition des exigences DE PERFORMANCES ESSENTIELLES

Exigence	Paragraphe
Récupération liée aux perturbations de l'électrochirurgie	202.8.101
Limites de l'erreur du manomètre [a], ou production d'une CONDITION D'ALARME TECHNIQUE	201.12.1.102 201.11.8.102 201.12.1.101
Reproductibilité de la DETERMINATION de la PRESSION ARTERIELLE et des CONDITIONS D'ALARME PHYSIOLOGIQUE pour la PRESSION ARTERIELLE basse et élevée (le cas échéant), ou production d'une CONDITION D'ALARME TECHNIQUE	201.12.1.107 201.12.3.101 201.11.8.102 201.12.1.101
[a] 202.8.1.101 d) spécifie des méthodes d'évaluation des limites de l'erreur du manomètre comme critères d'acceptation par suite des essais spécifiques exigés par le présent document.	

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique avec les exceptions suivantes:

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM

201.7.2.4 * ACCESSOIRES

Addition:

Un BRASSARD doit porter l'indication de sa position correcte au-dessus de l'artère sur le membre désigné.

Paragraphes complémentaires:

201.7.2.101 Dispositif d'affichage des SPHYGMOMANOMETRES AUTOMATIQUES

Si des abréviations sont utilisées sur le dispositif d'affichage, il doit s'agir des suivantes:

– « S » ou « SYS » pour la valeur de la PRESSION ARTERIELLE SYSTOLIQUE;
– « D » ou « DIA » pour la valeur de la PRESSION ARTERIELLE DIASTOLIQUE;
– « M » ou « MAP » pour la valeur de la PRESSION ARTERIELLE MOYENNE.

Les abréviations à une seule lettre doivent être placées de manière à éviter une confusion avec les unités SI.

L'étape numérique des lectures de la PRESSION ARTERIELLE doit être 1 mmHg ou 0,1 kPa.

201.7.2.102 * SPHYGMOMANOMETRE AUTOMATIQUE avec MODE POUR NOUVEAU-NES

Si un SPHYGMOMANOMETRE AUTOMATIQUE est prévu pour être utilisé avec des PATIENTS nouveau-nés et d'autres PATIENTS, il convient de l'équiper d'un dispositif permettant de détecter qu'un BRASSARD destiné à être utilisé avec un PATIENT nouveau-né est relié au SPHYGMOMANOMETRE AUTOMATIQUE, ainsi que d'un dispositif de réglage automatique de ce dernier en MODE POUR NOUVEAU-NES lorsque ce BRASSARD existe. En l'absence de ces dispositifs, les instructions d'utilisation doivent décrire la méthode de réglage du SPHYGMOMANOMETRE AUTOMATIQUE en MODE POUR NOUVEAU-NES et inclure un avertissement qui détaille les RISQUES associés à l'utilisation de modes autres que le MODE POUR NOUVEAU-NES sur un PATIENT nouveau-né.

Tous les ACCESSOIRES destinés à être utilisés uniquement en MODE POUR NOUVEAU-NES, et dont l'utilisation en d'autres modes génère un RISQUE inacceptable, doivent porter un marquage spécifiant une utilisation en mode pour nouveau-nés uniquement.

201.7.2.103 * SPHYGMOMANOMETRE AUTOMATIQUE destiné à un usage autonome dans les zones publiques

Si le SPHYGMOMANOMETRE AUTOMATIQUE est destiné à un usage autonome dans des zones publiques, son INTERFACE UTILISATEUR doit porter les indications suivantes:

a) les précautions d'emploi, y compris une mention de la nécessité de consulter un médecin pour l'interprétation des valeurs de la PRESSION ARTERIELLE;

b) des instructions appropriées d'utilisation; et

c) une mention indiquant "ce sphygmomanomètre est conforme à l'IEC 80601-2-30:2017".

EXEMPLES Poste d'automesure en libre-service dans une pharmacie, club sportif (de remise en forme) ou sur le lieu de travail, prévu pour être utilisé par le grand public sans assistance qualifiée.

Si le SPHYGMOMANOMETRE AUTOMATIQUE est destiné à un usage avec un brassard unique, son INTERFACE UTILISATEUR doit porter les indications suivantes:

d) la plage de circonférences de bras pour laquelle le BRASSARD est prévu – en particulier les seuils minimal et maximal de circonférence de la partie supérieure du bras (au milieu), en centimètres et en pouces; et

e) une mention indiquant que les résultats peuvent ne pas être exacts si la taille de circonférence de bras ne s'inscrit pas dans la plage spécifiée.

201.7.2.104 * Remplacement de composants

Si un composant peut être remplacé par l'OPERATEUR ou le PERSONNEL DE SERVICE, et si ce remplacement peut affecter la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES du SPHYGMOMANOMETRE AUTOMATIQUE, le SPHYGMOMANOMETRE AUTOMATIQUE ou le composant doit comporter soit une mise en garde selon laquelle le remplacement par un composant différent de celui qui est fourni peut donner lieu à une erreur de mesure, soit le signe de sécurité ISO 7010-M002 (voir l'IEC 60601-1:2005, Tableau D.2, signe de sécurité 10).

EXEMPLES BRASSARD, microphone, tuyau de raccordement, alimentation externe.

201.7.2.105 Mise au rebut

Le SPHYGMOMANOMETRE AUTOMATIQUE et ses éléments doivent comporter des informations appropriées relatives à la mise au rebut, conformément à la réglementation nationale ou régionale.

NOTE Voir aussi l'IEC 60601-1-9 [4].

201.7.9.2 Instructions d'utilisation

201.7.9.2.1 Généralités

Remplacement des trois premiers tirets:

– l'utilisation du SPHYGMOMANOMETRE AUTOMATIQUE comme prévu par le FABRICANT, et en particulier:

1) l'indication médicale prévue;

EXEMPLE 1 État(s) ou maladie(s) à dépister, à surveiller, à traiter, à diagnostiquer ou à prévenir.

2) toutes restrictions connues d'utilisation ou contre-indication(s) connues à l'utilisation du SPHYGMOMANOMETRE AUTOMATIQUE;

EXEMPLE 2 SPHYGMOMANOMETRE AUTOMATIQUE destiné à être utilisé dans une ambulance ou un hélicoptère, dans l'ENVIRONNEMENT DES SOINS A DOMICILE, ou avec des PATIENTS nouveau-nés ou prééclamptiques.

3) population prévue de PATIENTS, que le SPHYGMOMANOMETRE AUTOMATIQUE soit prévu ou non:

i) pour utilisation avec des PATIENTS nouveau-nés,

ii) pour utilisation avec des PATIENTES enceintes, y compris prééclamptiques;

EXEMPLE 3 Âge, poids, région du corps, état de santé ou diagnostic.

4) position prévue du BRASSARD; et

5) conditions d'utilisation prévues;

EXEMPLE 4 Exigences d'environnement, y compris d'hygiène, fréquence d'utilisation, emplacement, mobilité.

– les fonctions utilisées fréquemment;

– les conditions ambiantes admissibles d'utilisation, comprenant au moins une plage de températures de 10 °C à 40 °C avec une plage d'humidité relative comprise entre 15 % et 85 % (sans condensation).

201.7.9.2.2 Avertissement et consignes de sécurité

Addition, après la note:

Les instructions d'utilisation doivent comprendre un avertissement:

aa) relatif à l'effet de l'interférence sur le flux sanguin et aux blessures subséquentes au PATIENT provoquées par une pression continue du BRASSARD en raison du pliage du tuyau de raccordement;

bb) indiquant que des mesurages trop fréquents peuvent provoquer des blessures au PATIENT en raison de l'interférence sur le flux sanguin;

cc) relatif à l'application du BRASSARD sur une plaie, sachant qu'il peut s'ensuivre une blessure supplémentaire;

dd) concernant l'application du BRASSARD et sa pressurisation sur le membre où est présent un accès ou une thérapie intravasculaire ou encore un shunt artérioveineux (A-V) du fait de l'interférence temporaire avec le flux sanguin, qui peut entraîner une blessure du PATIENT;

ee) relatif à l'application du BRASSARD et sa pressurisation sur le bras dans le cas d'une mastectomie ou d'un curage des ganglions lymphatiques;

ff) concernant les informations selon lesquelles la pressurisation du BRASSARD peut provoquer temporairement un arrêt de fonctionnement de l'APPAREIL EM de surveillance utilisé simultanément sur le même membre;

gg) concernant la nécessité de vérifier (par exemple, par l'observation du membre concerné) que le fonctionnement du SPHYGMOMANOMETRE AUTOMATIQUE n'entraîne pas une dégradation prolongée de la circulation sanguine du PATIENT.

201.7.9.2.5 Description de l'APPAREIL EM

Addition, après le troisième tiret du premier alinéa:

– une description des principes de fonctionnement du SPHYGMOMANOMETRE AUTOMATIQUE; et

– les plages ASSIGNEES de la DETERMINATION.

201.7.9.2.9 Instructions de fonctionnement

Addition:

Les instructions d'utilisation doivent contenir les informations suivantes:

aa) une explication du choix d'une taille de BRASSARD appropriée et de l'application du BRASSARD au PATIENT;

bb) une explication des étapes de fonctionnement nécessaires pour obtenir des valeurs périodiques exactes de la PRESSION ARTERIELLE au repos en vue du diagnostic d'hypertension [7] [8] [9] [10] [11], y compris:

1) réglage du taux de réduction de la pression, le cas échéant;
2) position du PATIENT en UTILISATION NORMALE, y compris:
   i) une position assise confortable,
   ii) les jambes décroisées,
   iii) les pieds à plat sur le sol,
   iv) le dos et le bras soutenus, et
   v) le milieu du BRASSARD au niveau de l'atrium droit du cœur;
3) une recommandation faite au PATIENT de se détendre le plus possible et de ne pas parler au cours de la PROCEDURE de mesure;
4) une recommandation selon laquelle il convient d'attendre 5 min avant d'effectuer la première lecture;
5) position de L'OPERATEUR en UTILISATION NORMALE;

cc) l'explication concernant toute valeur lue de la PRESSION ARTERIELLE susceptible d'être affectée par le lieu de la mesure, la position du PATIENT (debout, assis, couché) [12], l'exercice, ou l'état physiologique du PATIENT;

dd) des informations détaillées sur ce qu'il convient que l'OPERATEUR fasse s'il obtient des valeurs lues inattendues;

ee) des informations détaillées sur les facteurs ambiants et fonctionnels pouvant affecter les performances du SPHYGMOMANOMETRE AUTOMATIQUE et/ou la valeur lue sur celui-ci de la PRESSION ARTERIELLE (par exemple, des arythmies cardiaques communes telles que des battements auriculaires et ventriculaires prématurés ou une fibrillation auriculaire, une sclérose artérielle, une mauvaise perfusion, le diabète, l'âge, la grossesse, la prééclampsie, les maladies rénales, des mouvements, tremblements, grelottements du PATIENT); [13] [14] [15]

ff) une mention, le cas échéant, selon laquelle les performances du SPHYGMOMANOMETRE AUTOMATIQUE peuvent être affectées par des valeurs extrêmes de température, d'humidité et d'altitude;

gg) le cas échéant, une explication de la nécessité d'éviter la compression ou la restriction des tuyaux de raccordement; et

hh) la plage ASSIGNEE de la pression du BRASSARD.

201.7.9.2.13 * Maintenance

Addition, après le deuxième alinéa:

Si le SPHYGMOMANOMETRE AUTOMATIQUE est prévu pour être démonté par l'OPERATEUR, les instructions d'utilisation doivent indiquer la méthode correcte de réassemblage.

Si la POCHE peut être insérée de manière incorrecte dans la partie inélastique du BRASSARD (par exemple, après nettoyage), le BRASSARD ou les instructions d'utilisation doivent comprendre une description détaillée de la manière correcte d'insérer la POCHE dans la partie inélastique du BRASSARD.

Paragraphes complémentaires:

201.7.9.2.101 Compatibilité avec les APPAREILS D'ELECTROCHIRURGIE HF

Si le SPHYGMOMANOMETRE AUTOMATIQUE est conforme aux exigences du 202.8.101, les instructions d'utilisation doivent comprendre une mention selon laquelle cet APPAREIL EM convient à une utilisation en présence d'électrochirurgie.

Si des parties des TRANSDUCTEURS DE PRESSION ou du SPHYGMOMANOMETRE AUTOMATIQUE comportent des moyens de protection du PATIENT contre les brûlures en cas d'utilisation avec des APPAREILS D'ELECTROCHIRURGIE HF, de tels moyens doivent être signalés à l'OPERATEUR dans les instructions d'utilisation. Si ces moyens n'existent pas, de telles parties doivent être identifiées dans les instructions d'utilisation.

201.7.9.2.102 SPHYGMOMANOMETRES AUTOMATIQUES utilisés en MODE POUR NOUVEAU-NES

Si le SPHYGMOMANOMETRE AUTOMATIQUE est équipé d'un MODE POUR NOUVEAU-NES, les instructions d'utilisation doivent comprendre les informations suivantes:

a) la pression maximale qui peut être appliquée par le SPHYGMOMANOMETRE AUTOMATIQUE au BRASSARD lorsqu'il se trouve en MODE POUR NOUVEAU-NES;

b) la plage de PRESSIONS ARTERIELLES que le SPHYGMOMANOMETRE AUTOMATIQUE peut prendre en charge lorsqu'il est en MODE POUR NOUVEAU-NES; et

c) les ACCESSOIRES que le FABRICANT recommande pour un usage en MODE POUR NOUVEAU-NES pour éviter des erreurs et une pression excessive.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de la norme générale s'applique avec les exceptions suivantes:

201.8.5.5 PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION

Paragraphe complémentaire:

201.8.5.5.101 * CONTACTS PATIENT des SPHYGMOMANOMETRES AUTOMATIQUES

Si la PARTIE APPLIQUEE d'un SPHYGMOMANOMETRE AUTOMATIQUE comporte des CONTACTS PATIENT, elle doit être classée comme une PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION.

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM

L'Article 9 de la norme générale s'applique.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs

L'Article 10 de la norme générale s'applique.

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 de la norme générale s'applique.

201.11.8 Coupure de l'alimentation/du RESEAU D'ALIMENTATION vers l'APPAREIL EM

Addition:

201.11.8.101 * Mise à l'arrêt

Lorsque le SPHYGMOMANOMETRE AUTOMATIQUE est mis hors tension par l'OPERATEUR, le BRASSARD étant gonflé, ledit BRASSARD doit être dégonflé en 30 s dans la limite des valeurs indiquées dans le Tableau 201.102.

Tableau 201.102 – Pression de dégonflement du BRASSARD

Mode	Pression du BRASSARD
MODE POUR NOUVEAU-NES	≤ 5 mmHg (0,7 kPa)
Tout autre mode	≤ 15 mmHg (2,0 kPa)

La conformité est vérifiée par des essais fonctionnels.

201.11.8.102 Coupure du RESEAU D'ALIMENTATION

Lorsque le RESEAU D'ALIMENTATION pour le SPHYGMOMANOMETRE AUTOMATIQUE est coupé, le BRASSARD doit être dégonflé en 30 s dans la limite des valeurs indiquées dans le Tableau 201.102, et toute indication de PRESSION ARTERIELLE doit être annulée.

Lorsque le RESEAU D'ALIMENTATION est rétabli, le SPHYGMOMANOMETRE AUTOMATIQUE:

a) doit continuer dans le même mode de fonctionnement et sans modification d'aucun réglage de l'OPERATEUR, ou

b) doit

   1) demeurer non opérationnel, et

   2) s'il comporte un MODE AUTOMATIQUE COURTE DUREE ou un MODE AUTOMATIQUE LONGUE DUREE, être équipé d'un SYSTEME D'ALARME comprenant une CONDITION D'ALARME TECHNIQUE indiquant que le SPHYGMOMANOMETRE AUTOMATIQUE est non opérationnel.

Un SPHYGMOMANOMETRE AUTOMATIQUE qui passe automatiquement en fonctionnement à partir d'une SOURCE ELECTRIQUE INTERNE et continue à fonctionner normalement ne doit pas être soumis à ces exigences.

La conformité est vérifiée par l'essai suivant.

c) Effectuer une DETERMINATION en utilisant un SIMULATEUR DE PATIENT et observer le mode de fonctionnement du SPHYGMOMANOMETRE AUTOMATIQUE. Couper le RESEAU D'ALIMENTATION pendant un laps de temps supérieur à 30 s.

d) Confirmer que le BRASSARD est suffisamment dégonflé et que la PRESSION ARTERIELLE indiquée disparaît en 30 s.

e) Rétablir le RESEAU D'ALIMENTATION et confirmer que le SPHYGMOMANOMETRE AUTOMATIQUE:

– *continue dans le même mode de fonctionnement et sans modification d'aucun réglage de l'OPERATEUR, ou*

– *reste non opérationnel et, s'il est équipé d'un MODE AUTOMATIQUE COURTE DUREE ou d'un MODE AUTOMATIQUE LONGUE DUREE, qu'une CONDITION D'ALARME TECHNIQUE est générée.*

201.11.8.103 * SOURCE ELECTRIQUE INTERNE

Un SPHYGMOMANOMETRE AUTOMATIQUE alimenté par une SOURCE ELECTRIQUE INTERNE doit incorporer des dispositifs:

a) en cas de défaillance ou d'épuisement de la SOURCE ELECTRIQUE INTERNE, ce qui ne permet plus au SPHYGMOMANOMETRE AUTOMATIQUE de satisfaire aux exigences relatives à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES du présent document,

   1) en vue d'un arrêt de protection, et

   2) en vue d'annuler l'indication de la PRESSION ARTERIELLE;

b) pour déterminer l'état de l'alimentation.

La conformité est vérifiée par des essais fonctionnels.

201.12 Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques

L'Article 12 de la norme générale s'applique avec les exceptions suivantes:

201.12.1 Précision des commandes et des instruments

Addition:

201.12.1.101 Plages de mesure et d'affichage

Les plages de mesure et d'affichage de la pression du BRASSARD doivent correspondre à la plage ASSIGNEE pour la pression du BRASSARD.

Les valeurs de la PRESSION ARTERIELLE en dehors de la plage ASSIGNEE pour la PRESSION ARTERIELLE ne doivent pas être affichées, et le SPHYGMOMANOMETRE AUTOMATIQUE doit être équipé d'un SYSTEME D'ALARME comprenant une CONDITION D'ALARME TECHNIQUE qui indique lorsque la PRESSION ARTERIELLE déterminée est en dehors de la plage ASSIGNEE.

La conformité est vérifiée par des essais fonctionnels.

201.12.1.102 Limites de l'erreur du manomètre du fait des conditions d'environnement

Sur la plage de températures comprises entre 10 °C et 40 °C et la plage d'humidité relative de 15 % à 85 % (sans condensation), l'erreur maximale de mesure de la pression du BRASSARD à un point quelconque de la plage NOMINALE de mesure doit être inférieure ou égale à ±3 mmHg (±0,4 kPa) ou 2 % de la valeur lue, en prenant celle des deux valeurs qui est la plus élevée.

La conformité est vérifiée par des essais fonctionnels.

201.12.1.103 * Plage d'indication de la PRESSION ARTERIELLE NOMINALE

Le SPHYGMOMANOMETRE AUTOMATIQUE doit être capable d'indiquer la PRESSION ARTERIELLE DIASTOLIQUE au minimum sur la plage comprise entre 20 mmHg (2,7 kPa) et 60 mmHg (8,0 kPa) en MODE POUR NOUVEAU-NES et, par ailleurs, entre 40 mmHg (5,3 kPa) et 130 mmHg (17,3 kPa).

Le SPHYGMOMANOMETRE AUTOMATIQUE doit être capable d'indiquer la PRESSION ARTERIELLE SYSTOLIQUE au minimum sur la plage comprise entre 40 mmHg (5,3 kPa) et 110 mmHg (14,7 kPa) en MODE POUR NOUVEAU-NES et, par ailleurs, entre 60 mmHg (8,0 kPa) et 230 mmHg (30,7 kPa).

La conformité est vérifiée par l'essai suivant:

a) Raccorder le SPHYGMOMANOMETRE AUTOMATIQUE à un SIMULATEUR DE PATIENT.

b) Régler le SIMULATEUR DE PATIENT pour générer des signaux de sorte que le SPHYGMOMANOMETRE AUTOMATIQUE affiche les valeurs de PRESSION ARTERIELLE DIASTOLIQUE de 20 mmHg (2,7 kPa) ou inférieures et les valeurs de PRESSION ARTERIELLE SYSTOLIQUE de 110 mmHg (14,7 kPa) ou supérieures en MODE POUR NOUVEAU-NES, ainsi que les valeurs de PRESSION ARTERIELLE DIASTOLIQUE de 40 mmHg (5,3 kPa) ou inférieures et les valeurs de PRESSION ARTERIELLE SYSTOLIQUE de 230 mmHg (30,7 kPa) ou supérieures par ailleurs.

201.12.1.104 Pression maximale en CONDITION NORMALE

La pression maximale qui peut être obtenue en CONDITION NORMALE ne doit pas dépasser 150 mmHg (20 kPa) pour un SPHYGMOMANOMETRE AUTOMATIQUE en MODE POUR NOUVEAU-NES et 300 mmHg (40 kPa) par ailleurs. Un SPHYGMOMANOMETRE AUTOMATIQUE peut comporter un ou plusieurs modes.

La conformité est vérifiée par des essais fonctionnels en CONDITION NORMALE.

201.12.1.105 * Pression maximale en CONDITION DE PREMIER DEFAUT

Dans tout mode cyclique automatique de fonctionnement, dans toute CONDITION DE PREMIER DEFAUT, un DISPOSITIF DE PROTECTION doit être prévu, fonctionnant indépendamment de la commande normale du SYSTEME PNEUMATIQUE. Ce DISPOSITIF DE PROTECTION doit:

a) empêcher la pression du SYSTEME PNEUMATIQUE de dépasser de plus de 10 % la valeur ASSIGNEE maximale spécifiée en 201.12.1.104 pendant plus de 3 s (voir Figure 201.101); et

b) se déclencher si la pression dans le SYSTEME PNEUMATIQUE dépasse la valeur ASSIGNEE maximale spécifiée en 201.12.1.104 pendant 15 s (voir Figure 201.102).

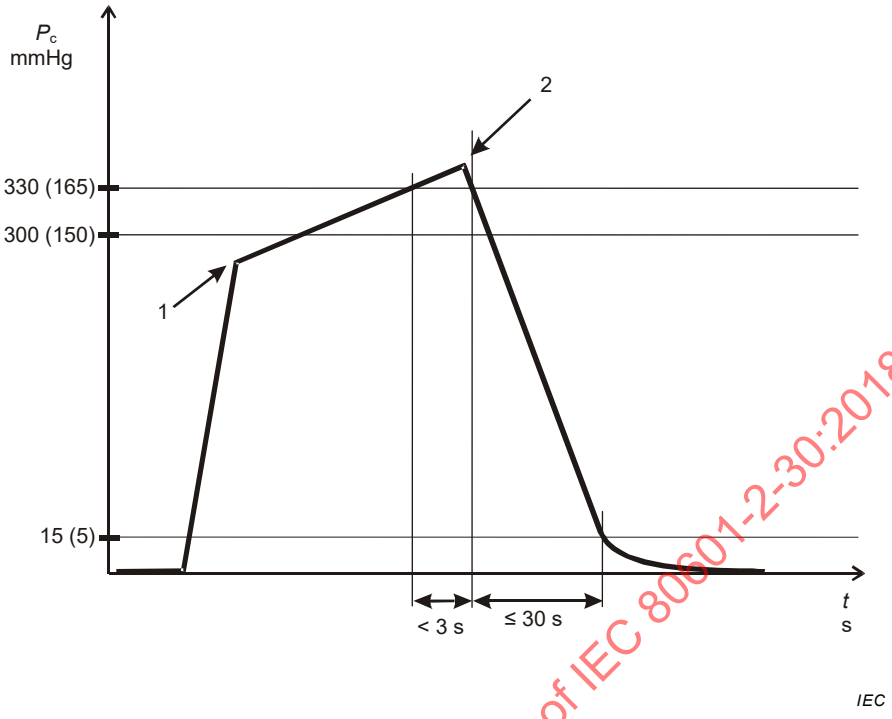
Lorsqu'il est actionné, le DISPOSITIF DE PROTECTION doit dégonfler le SYSTEME PNEUMATIQUE en 30 s à ≤ 15 mmHg (2,0 kPa) et à ≤ 5 mmHg (0,7 kPa) pour un SPHYGMOMANOMETRE AUTOMATIQUE en MODE POUR NOUVEAU-NES.

Un SPHYGMOMANOMETRE AUTOMATIQUE qui fonctionne uniquement en MODE AUTOMATIQUE D'AUTOMESURE, dans lequel le PATIENT est l'OPERATEUR ou l'OPERATEUR est censé être présent en permanence, et avec lequel la pression du BRASSARD peut être relâchée par l'OPERATEUR, n'est pas soumis à cette exigence.

EXEMPLE 1 Pression relâchée en déconnectant le BRASSARD du SPHYGMOMANOMETRE AUTOMATIQUE.

EXEMPLE 2 Pression relâchée en retirant le BRASSARD du membre.

La conformité est vérifiée par des essais fonctionnels en CONDITION DE PREMIER DEFAUT.



Légende

1 Une CONDITION DE PREMIER DEFAUT a lieu

2 Un DISPOSITIF DE PROTECTION se déclenche en raison d'une surpression

Pression du BRASSARD, P_c, en fonction du temps. Les valeurs relatives au MODE POUR NOUVEAU-NES sont données entre parenthèses.

Figure 201.101 – DISPOSITIF DE PROTECTION pour la pression du BRASSARD, déclenché par une surpression en CONDITION DE PREMIER DEFAUT

201.12.1.106 * Mode d'essai manomètre

Le SPHYGMOMANOMETRE AUTOMATIQUE doit comporter un mode d'essai manomètre permettant de mesurer la pression statique, au minimum, dans la plage d'indication de la PRESSION ARTERIELLE NOMINALE (voir 201.12.1.103). Ce mode ne doit pas pouvoir être utilisé en UTILISATION NORMALE, mais limité au PERSONNEL DE SERVICE.

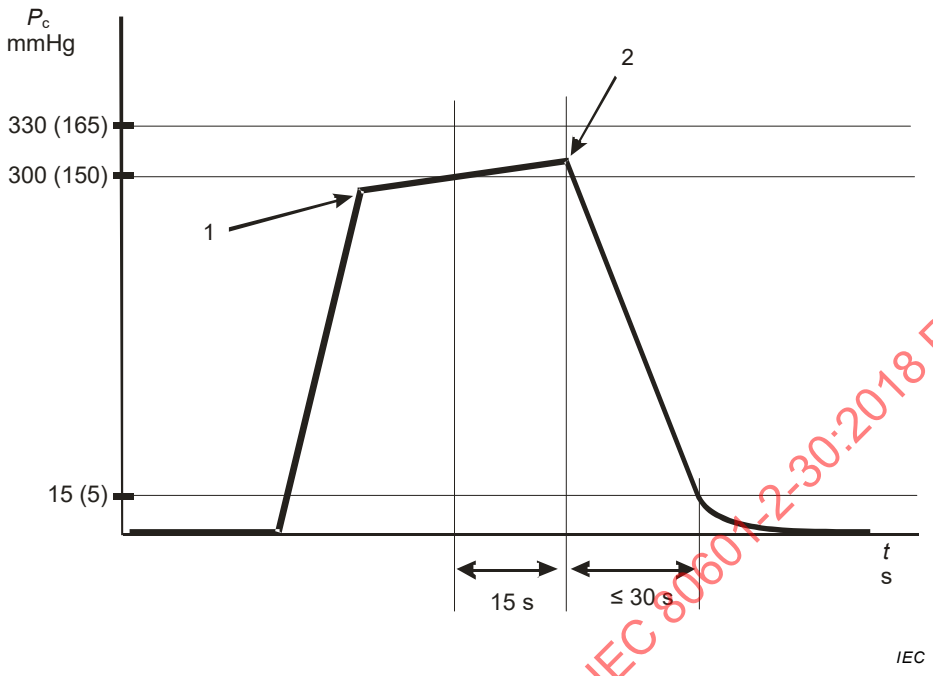
EXEMPLE 1 Un orifice de raccordement à une source de pression de manière à ce que le SPHYGMOMANOMETRE AUTOMATIQUE puisse mesurer la pression en mode d'essai.

EXEMPLE 2 Un orifice de raccordement à un manomètre de référence pouvant être mis sous pression par le SPHYGMOMANOMETRE AUTOMATIQUE en mode d'essai.

NOTE Ce mode peut être utilisé pour vérifier l'exactitude de pression du manomètre.

La description technique doit comprendre une méthode d'essai pouvant être utilisée pour vérifier l'étalonnage du SPHYGMOMANOMETRE AUTOMATIQUE.

La conformité est vérifiée par examen et par des essais fonctionnels.



Légende

1 Une CONDITION DE PREMIER DEFAUT a lieu

2 Un DISPOSITIF DE PROTECTION se déclenche en raison d'une surpression prolongée

Pression du BRASSARD, P_c, en fonction du temps. Les valeurs relatives au MODE POUR NOUVEAU-NES sont données entre parenthèses.

Figure 201.102 – DISPOSITIF DE PROTECTION pour la pression du BRASSARD, déclenché par une surpression prolongée en CONDITION DE PREMIER DEFAUT

201.12.1.107 * Reproductibilité de la DETERMINATION de la PRESSION ARTERIELLE

La reproductibilité en laboratoire de la DETERMINATION de la PRESSION ARTERIELLE du SPHYGMOMANOMETRE AUTOMATIQUE doit être inférieure ou égale à 3,0 mmHg (0,4 kPa).

La conformité est vérifiée par l'essai suivant:

Deux échantillons du SPHYGMOMANOMETRE AUTOMATIQUE de même REFERENCE DU MODELE OU DU TYPE sont nécessaires pour réaliser cette PROCEDURE d'essai.

NOTE Au début de cet essai de conformité, aucun des deux échantillons n'a été soumis aux essais de contraintes mécaniques présentés dans la norme générale et les normes collatérales. L'étape h) soumet le SPHYGMOMANOMETRE AUTOMATIQUE A aux essais de contraintes, et les limites obtenues par le laboratoire de la variation de l'erreur dans la DETERMINATION de la PRESSION ARTERIELLE sont comparées avant et après l'application de ces contraintes mécaniques.

a) Étiqueter l'un des échantillons du SPHYGMOMANOMETRE AUTOMATIQUE sous la lettre A et l'autre échantillon sous la lettre B.

b) Avant d'effectuer les autres essais mentionnés dans le présent document, régler le SIMULATEUR DE PATIENT pour générer des signaux de sorte que le SPHYGMOMANOMETRE AUTOMATIQUE affiche approximativement une valeur de PRESSION ARTERIELLE DIASTOLIQUE de 40 mmHg (5,3 kPa) et une valeur de PRESSION ARTERIELLE SYSTOLIQUE de 70 mmHg (9,33 kPa) à un taux de pulsation de 140 battements/min en MODE POUR NOUVEAU-NES, et une valeur de PRESSION ARTERIELLE DIASTOLIQUE de 80 mmHg (10,67 kPa), ainsi qu'une valeur de PRESSION ARTERIELLE SYSTOLIQUE de 120 mmHg (16,0 kPa) à un taux de

pulsation de 80 battements/min par ailleurs. L'un ou l'autre des échantillons du SPHYGMOMANOMETRE AUTOMATIQUE peut être utilisé pour cette étape.

c) *Effectuer 20 DETERMINATIONS consécutives avec le SPHYGMOMANOMETRE AUTOMATIQUE B. Calculer les moyennes et les écarts-types à la fois pour la PRESSION ARTERIELLE DIASTOLIQUE et pour la PRESSION ARTERIELLE SYSTOLIQUE.*

d) *Enregistrer ces résultats en tant que valeurs initiales du SPHYGMOMANOMETRE AUTOMATIQUE B.*

e) *Confirmer que l'écart-type de la PRESSION ARTERIELLE DIASTOLIQUE et celui de la PRESSION ARTERIELLE SYSTOLIQUE sont ≤ 2,0 mmHg (≤ 0,27 kPa) pour les valeurs initiales du SPHYGMOMANOMETRE AUTOMATIQUE B. Si l'un ou l'autre de ces critères n'est pas respecté, la combinaison du simulateur et du SPHYGMOMANOMETRE AUTOMATIQUE présente une stabilité insuffisante pour effectuer cette PROCEDURE d'essai.*

f) *En utilisant le même SIMULATEUR DE PATIENT et les mêmes réglages que ceux définis en b), effectuer 20 DETERMINATIONS consécutives avec le SPHYGMOMANOMETRE AUTOMATIQUE A. Calculer les moyennes et les écarts-types à la fois pour la PRESSION ARTERIELLE DIASTOLIQUE et pour la PRESSION ARTERIELLE SYSTOLIQUE.*

g) *Enregistrer ces résultats en tant que valeurs initiales du SPHYGMOMANOMETRE AUTOMATIQUE A.*

h) *En utilisant le SPHYGMOMANOMETRE AUTOMATIQUE A, réaliser au minimum, sans simulation des CONDITIONS DE PREMIER DEFAUT, les essais suivants de la présente norme particulière: 201.12.1.102, 201.15.3.5.101, et IEC 60601-1:2005 et IEC 60601-1:2005/AMD1:2012, 15.3.2, 15.3.3 et 15.3.4 ainsi que, s'il y a lieu, IEC 60601-1-11:2015, 8.3.1, 10.1, et IEC 60601-1-12:2014, 8.1.1 et 10.1.1.*

i) *En utilisant le même SIMULATEUR DE PATIENT et les mêmes réglages que ceux définis en b), effectuer 20 DETERMINATIONS avec le SPHYGMOMANOMETRE AUTOMATIQUE A. Calculer les valeurs moyennes de la PRESSION ARTERIELLE DIASTOLIQUE et de la PRESSION ARTERIELLE SYSTOLIQUE.*

j) *Enregistrer ces résultats en tant que valeurs finales du SPHYGMOMANOMETRE AUTOMATIQUE A.*

k) *En utilisant le même SIMULATEUR DE PATIENT et les mêmes réglages que ceux définis en b), effectuer 20 DETERMINATIONS avec le SPHYGMOMANOMETRE AUTOMATIQUE B. Calculer les valeurs moyennes de la PRESSION ARTERIELLE DIASTOLIQUE et de la PRESSION ARTERIELLE SYSTOLIQUE.*

l) *Enregistrer ces résultats en tant que valeurs finales du SPHYGMOMANOMETRE AUTOMATIQUE B.*

m) *Pour les valeurs finales du SPHYGMOMANOMETRE AUTOMATIQUE B, confirmer que l'écart-type de la PRESSION ARTERIELLE DIASTOLIQUE et celui de la PRESSION ARTERIELLE SYSTOLIQUE sont ≤ 2,0 mmHg (≤ 0,27 kPa). Si l'un ou l'autre de ces critères n'est pas respecté, la combinaison du simulateur et du SPHYGMOMANOMETRE AUTOMATIQUE présente une stabilité insuffisante pour effectuer cette PROCEDURE d'essai.*

n) *Pour le SPHYGMOMANOMETRE AUTOMATIQUE B, confirmer que la valeur absolue de la différence entre les valeurs initiales moyennes calculées en c) et les valeurs finales calculées en m) est ≤ 2,0 mmHg (≤ 0,27 kPa). Si l'un ou l'autre de ces critères n'est pas respecté, la combinaison du simulateur et du SPHYGMOMANOMETRE AUTOMATIQUE présente une stabilité insuffisante pour effectuer cette PROCEDURE d'essai.*

o) *Pour le SPHYGMOMANOMETRE AUTOMATIQUE A, confirmer que la valeur absolue de la différence entre les valeurs initiales moyennes calculées en f) et les valeurs finales calculées en i) est ≤ 5,0 mmHg (≤ 0,67 kPa).*

201.12.3 SYSTEMES D'ALARME

Addition:

201.12.3.101 Exigences supplémentaires pour les SYSTEMES D'ALARME

Si un SPHYGMOMANOMETRE AUTOMATIQUE comporte un SYSTEME D'ALARME comprenant des CONDITIONS D'ALARME PHYSIOLOGIQUES, il doit être équipé d'un SYSTEME D'ALARME capable de détecter une CONDITION D'ALARME pour indiquer à la fois une CONDITION D'ALARME PHYSIOLOGIQUE pour une PRESSION ARTERIELLE faible et une CONDITION D'ALARME PHYSIOLOGIQUE pour une PRESSION ARTERIELLE élevée. Ces CONDITIONS D'ALARME doivent être au minimum de PRIORITE MOYENNE, sauf si un SYSTEME D'ALARME INTELLIGENT utilisant des informations physiologiques complémentaires est utilisé pour déterminer que ces CONDITIONS D'ALARME ne sont pas vraies. Ces CONDITIONS D'ALARME peuvent concerner une PRESSION ARTERIELLE SYSTOLIQUE, une PRESSION ARTERIELLE DIASTOLIQUE ou une PRESSION ARTERIELLE MOYENNE.

La conformité est vérifiée par des essais fonctionnels.

201.13 SITUATIONS DANGEREUSES et conditions de défaut pour APPAREILS EM

L'Article 13 de la norme générale s'applique.

201.14 SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP)

L'Article 14 de la norme générale s'applique.

201.15 Construction de l'APPAREIL EM

L'Article 15 de la norme générale s'applique avec les exceptions suivantes:

201.15.3.5 Essai de manipulations brutales

Paragraphes complémentaires:

201.15.3.5.101 * Chocs et vibrations (robustesse)

Un SPHYGMOMANOMETRE AUTOMATIQUE ou ses parties doivent avoir une résistance mécanique adéquate lorsqu'ils sont soumis à des contraintes mécaniques en UTILISATION NORMALE, lorsqu'ils sont poussés, qu'ils subissent des impacts, des chutes et une manipulation brutale. Un SPHYGMOMANOMETRE AUTOMATIQUE FIXE n'est pas soumis aux exigences du présent paragraphe.

Après les essais suivants, le SPHYGMOMANOMETRE AUTOMATIQUE ne doit pas provoquer de RISQUE inacceptable et doit fonctionner normalement.

NOTE 1 Des exigences supplémentaires figurent dans l'IEC 60601-1-11 et dans l'IEC 60601-1-12.

La conformité est vérifiée par les essais suivants:

a) Essai de chocs, selon l'IEC 60068-2-27:2008, en appliquant les conditions du type d'essai 1 ou 2:

NOTE 2 Ceci correspond à l'IEC TR 60721-4-7 [16], Classe 7M2.

1) type d'essai: Type 1:

- *accélération de crête: 150 m/s^2 (15 g);*
- *durée: 11 ms;*
- *forme d'impulsion: semi-sinusoïdale;*
- *nombre de chocs: 3 chocs par direction par axe (18 au total).*

2) *type d'essai: Type 2:*
   - *accélération de crête: 300 m/s^2 (30 g);*
   - *durée: 6 ms;*
   - *forme d'impulsion: semi-sinusoïdale;*
   - *nombre de chocs: 3 chocs par direction par axe (18 au total).*

Pour un SPHYGMOMANOMETRE AUTOMATIQUE PORTATIF, les exigences spécifiées en 15.3.4.1 de la norme générale peuvent être remplacées par cette exigence.

b) Vibrations aléatoires à large bande, selon l'IEC 60068-2-64:2008, en appliquant les conditions suivantes:

NOTE 3 Ceci correspond à l'IEC TR 60721-4-7 [16], Classe 7M1 et 7M2.

1) *amplitude d'accélération:*
   - *10 Hz à 100 Hz: 1,0 (m/s^2)^2/Hz;*
   - *100 Hz à 200 Hz: −3 db/octave;*
   - *200 Hz à 2 000 Hz: 0,5 (m/s^2)^2/Hz;*

2) *durée: 30 min pour chaque axe perpendiculaire (3 au total).*

Les exigences spécifiées dans l'IEC 60601-1-11:2015, 10.1 ou dans l'IEC 60601-1-12:2014, 10.1.1, en totalité ou en partie, peuvent être remplacées par les exigences correspondantes spécifiées dans le présent paragraphe.

201.16 SYSTEMES EM

L'Article 16 de la norme générale s'applique.

201.17 Compatibilité électromagnétique des APPAREILS et des SYSTEMES EM

L'Article 17 de la norme générale s'applique.

Articles complémentaires:

201.101 Exigences pour les BRASSARDS

201.101.1 * Construction

Le BRASSARD doit comporter ou intégrer une POCHE.

Le BRASSARD doit être construit de sorte que lorsqu'il est appliqué sur un membre, sa construction permet de s'assurer que sa taille est appropriée, ou il doit porter un marquage indiquant la plage de circonférences du membre pour laquelle le BRASSARD est approprié.

NOTE Des exigences supplémentaires relatives au marquage des SPHYGMOMANOMETRES AUTOMATIQUES prévus pour un usage autonome dans les zones publiques sont données en 201.7.2.104.

La conformité est vérifiée par examen.

201.101.2 * Pressurisation

Le BRASSARD et la POCHE ainsi que le tuyau de raccordement doivent être capables de résister à une pression interne égale à 180 mmHg (24 kPa) pour un SPHYGMOMANOMETRE AUTOMATIQUE en MODE POUR NOUVEAU-NES et à une pression interne égale à 360 mmHg (48 kPa) par ailleurs. La POCHE doit être complètement maintenue dans le BRASSARD au cours de cette pressurisation.

La conformité est vérifiée par des essais fonctionnels. Utiliser un mandrin pour ces essais.

201.101.3 * SPHYGMOMANOMETRE AUTOMATIQUE destiné à un usage autonome dans les zones publiques avec un BRASSARD unique

Pour un SPHYGMOMANOMETRE AUTOMATIQUE destiné à un usage autonome par un adulte dans les zones publiques avec un BRASSARD unique:

a) les tailles de membres (voir ISO 81060-2:2013, 5.1.4) compatibles avec le BRASSARD doivent correspondre à une plage ASSIGNEE de circonférences de milieu de bras qui comprend au minimum 22 cm à 42 cm [17]; ou

b) le SPHYGMOMANOMETRE AUTOMATIQUE ne doit pas afficher de valeur de PRESSION ARTERIELLE dans le cas où la circonférence de milieu de bras ne rentre pas dans la plage ASSIGNEE du BRASSARD.

La conformité est vérifiée par examen.

201.102 * Tuyaux de raccordement et connecteurs de BRASSARDS

Accessibles à l'OPERATEUR sans l'utilisation d'un OUTIL, les raccordements DE PETITE TAILLE entre le SPHYGMOMANOMETRE AUTOMATIQUE, le BRASSARD et les tuyaux de raccordement doivent être équipés d'un connecteur conforme à l'ISO 80369-14 ou à l'IEC 80369-5.

La conformité est vérifiée par examen.

201.103 Accès non autorisé

Pour empêcher toute tentative d'altération ou un accès non autorisé, un dispositif doit être prévu pour limiter l'accès à toutes les commandes, y compris celles pour les SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP), pouvant affecter l'exactitude du SPHYGMOMANOMETRE AUTOMATIQUE, à l'ORGANISME RESPONSABLE.

EXEMPLE Un OUTIL est exigé pour l'ouverture.

La conformité est vérifiée par examen.

201.104 * Temps maximal de gonflement

En CONDITION NORMALE et dans tout mode cyclique automatique de fonctionnement, un DISPOSITIF DE PROTECTION limiteur de pression doit permettre de s'assurer que le BRASSARD ne doit pas gonfler au-dessus des valeurs données dans le Tableau 201.103 pendant plus de 180 s, ou pendant plus de 90 s en MODE POUR NOUVEAU-NES. Voir Figure 201.103.

En CONDITION DE PREMIER DEFAUT et dans tout mode cyclique automatique de fonctionnement, un DISPOSITIF DE PROTECTION limiteur de pression, fonctionnant indépendamment du DISPOSITIF DE PROTECTION EN CONDITION NORMALE, doit permettre de s'assurer que le BRASSARD ne gonfle pas au-dessus des valeurs données dans le Tableau 201.103 pendant plus de 180 s, ou pendant plus de 90 s en MODE POUR NOUVEAU-NES. Voir Figure 201.103.

4 En préparation. Stade au moment de la publication: ISO/FDIS 80369-1:2017.