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भारतीय मानक
Indian Standard

IS/IEC 80601-2-30 : 2018



चिकित्सीय विद्युत उपस्कर

भाग 2-30 स्वचालित नॉन-इनवेसिव इस्फिगमोमैओमीटर
की बुनियादी सुरक्षा और आवश्यक कार्य निष्पादन
के लिए विशेष आवश्यकताएं

Medical Electrical Equipment

Part 2-30 Particular Requirements for Basic Safety
and Essential Performance of Automated
Non-Invasive Sphygmomanometers

ICS 11.040.01

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Anaesthetic, Resuscitation and Allied equipment Sectional Committee MHD 11

NATIONAL FOREWORD

This Indian Standard (Part 2/Sec 30) which is identical with IEC80601-2-30 : 2018 'Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers' issued by the International Electrotechnical Commission (IEC) was adopted by the Bureau of Indian Standards on recommendation of the Anaesthetic, Resuscitation and Allied equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of the ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain terminologies and conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appears referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker, while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
IEC 60601-1 : 2005 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance IEC 60601-1 : 2005/AMD 1 : 2012	IS 13450 (Part 1) : 2018 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance (<i>second revision</i>)	Identical with IEC 60601-1 : 2012 (Ed. 3.1)
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	IS 13450 (Part 1/Sec 2) : 2018 Medical electrical equipment: Part 1 General requirements for basic safety and essential performance, Section 2 Collateral standard: Electromagnetic disturbances — Requirements and tests (<i>first revision</i>)	Identical

The technical committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard</i>	<i>Title</i>
ISO 80369-1	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
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, broadband random and guidance
IEC 60601-1-6 : 2010	Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability

(Continued on third cover)

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.

Indian Standard

MEDICAL ELECTRICAL EQUIPMENT

PART 2-30 PARTICULAR REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE OF AUTOMATED NON-INVASIVE SPHYGMOMANOMETERS

201.1 Scope, object and related standards

Clause 1 of the general standard² 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

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 , or generation of a TECHNICAL ALARM CONDITION	201.12.1.102 201.11.8.102 201.12.1.101
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

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

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;
- 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, where 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;

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;

- 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 reading, whichever is greater,

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).

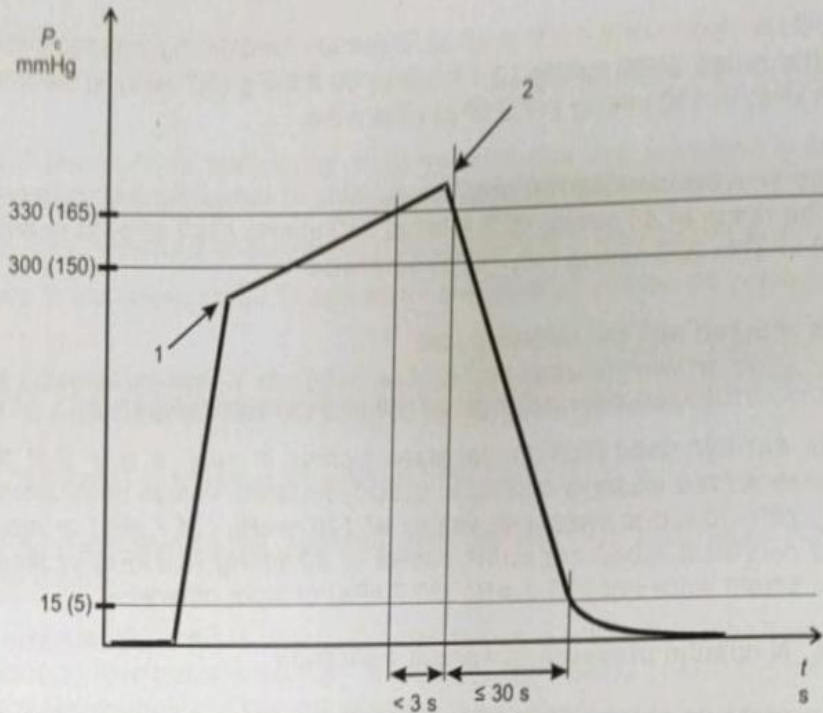
When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s to ≤ 15 mmHg (2,0 kPa) and to ≤ 5 mmHg (0,7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE.

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.



IEC

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.

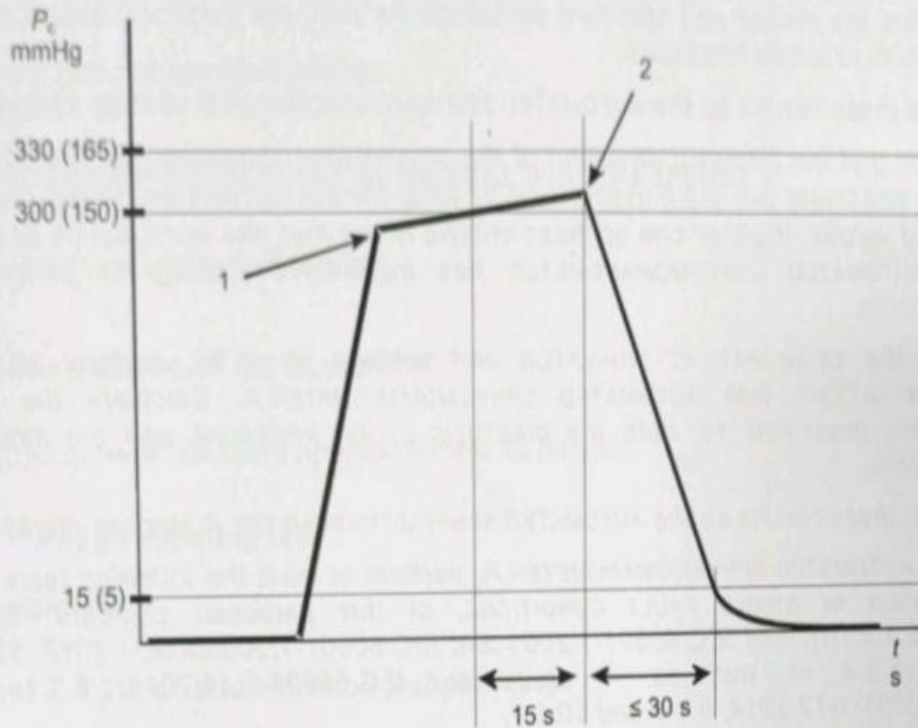
EXAMPLE 1 A port for connection to a pressure source so that the pressure can be measured by the AUTOMATED SPHYGMOMANOMETER in a test mode.

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.



IEC

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.

- 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 $\leq 2,0$ mmHg ($\leq 0,27$ 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 simulation of SINGLE FAULT CONDITIONS, of this particular standard: 201.12.1.10, 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 $\leq 2,0$ mmHg ($\leq 0,27$ 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 $\leq 2,0$ mmHg ($\leq 0,27$ 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 $\leq 5,0$ mmHg ($\leq 0,67$ 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.

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

- 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 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.

2 * Connection tubing and CUFF connectors

FOR-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 80369-14 or IEC 80369-5.

Compliance is checked by inspection.

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.

104 * Maximum inflating time

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.

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

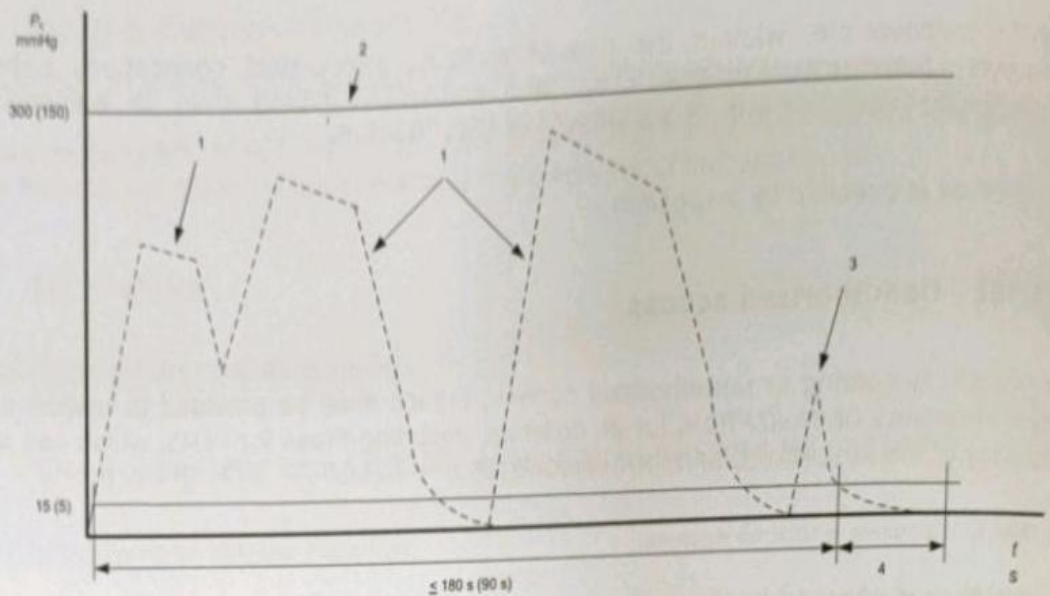
Mode	CUFF pressure
NEONATAL MODE	> 5 mmHg (0,7 kPa)
Any other mode	> 15 mmHg (2,0 kPa)

For 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.



IEC

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.

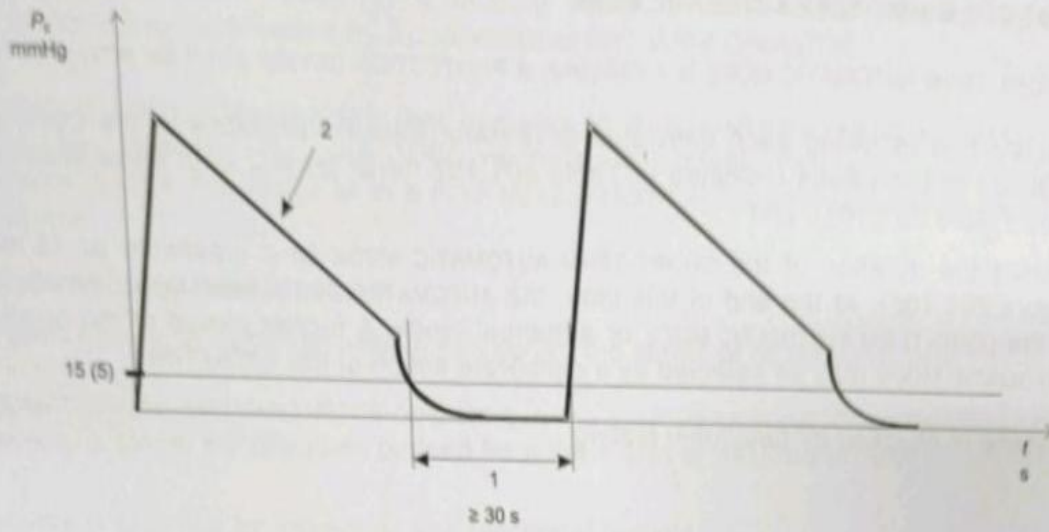
Figure 201.103 – CUFF pressure and maximum inflation time, NORMAL CONDITION and SINGLE FAULT CONDITION

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 values in Table 201.102.



IEC

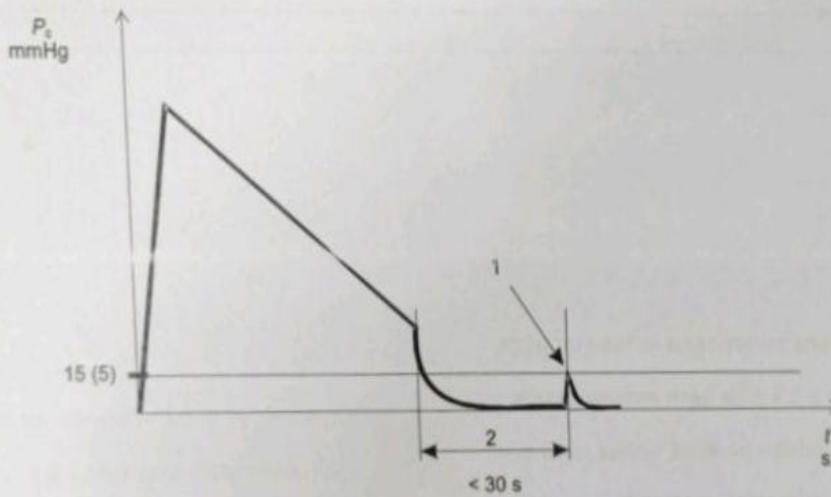
Key

- 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



IEC

Key

- 1 Pressure relief PROTECTION DEVICE activates
- 2 Deflated time

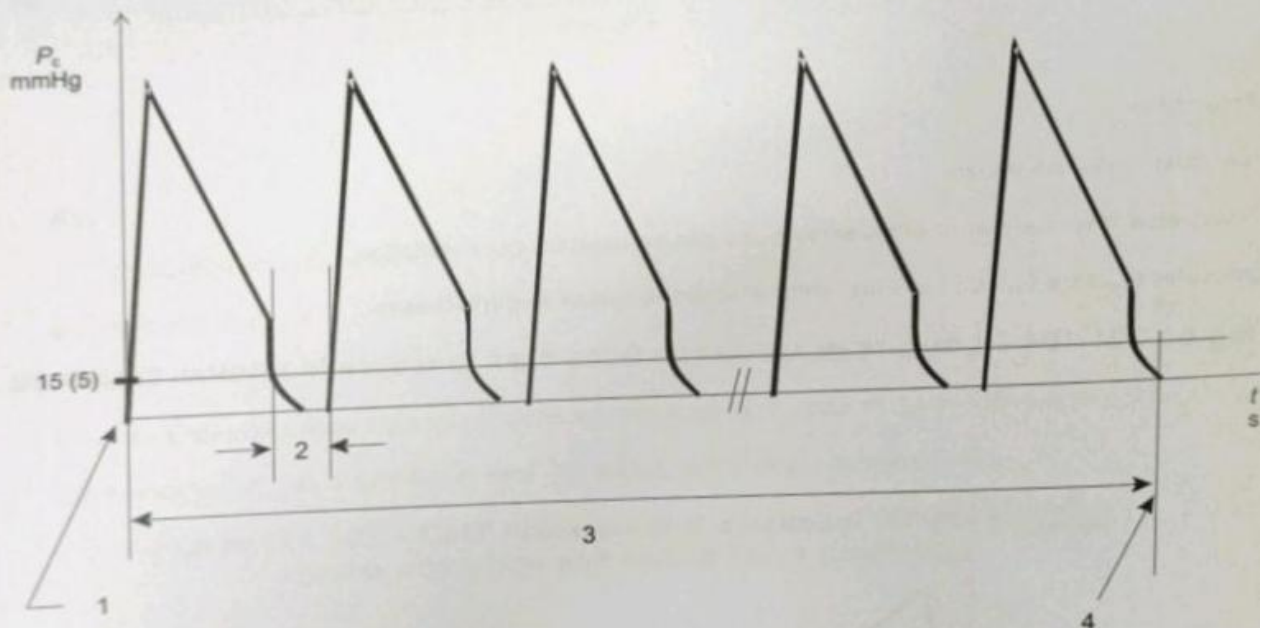
CUFF pressure, P_c , as a function of time. NEONATAL MODE values in parentheses.

201.105.2 * SHORT-TERM AUTOMATIC MODE

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

- 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 flow (see Figure 201.106), and
- 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 return 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

- OPERATOR starts SHORT-TERM AUTOMATIC MODE
- Deflated time ≥ 2 s after each DETERMINATION
- SHORT-TERM AUTOMATIC MODE limited to 15 min
- 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

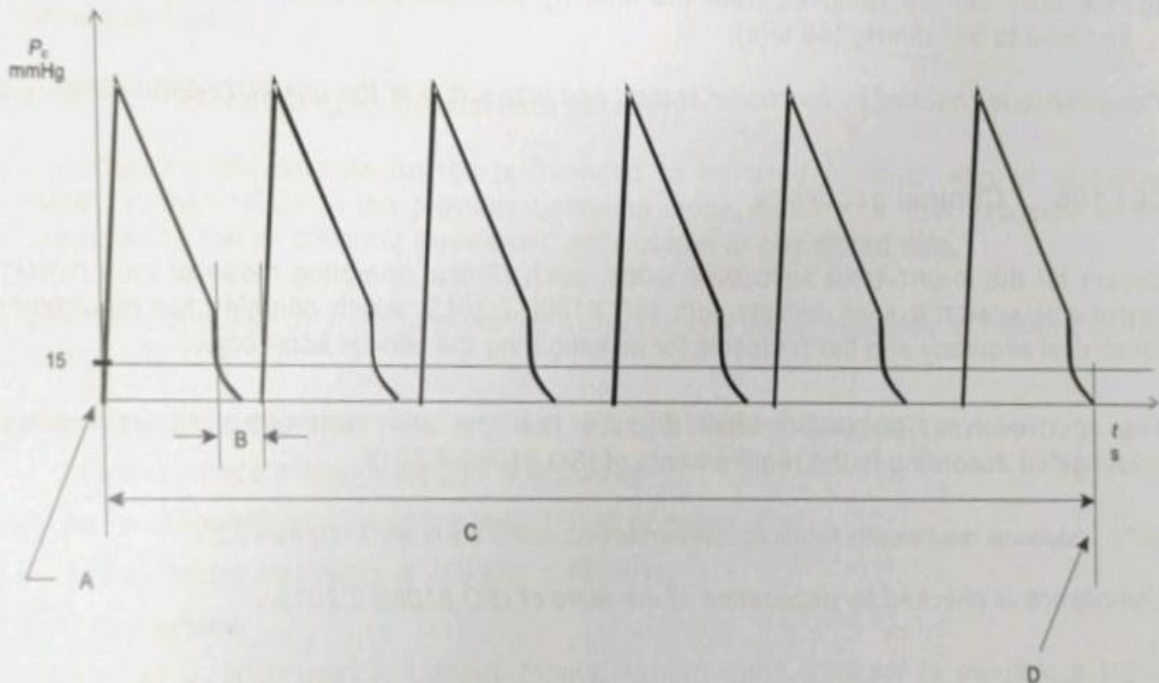
SPHYGMOMANOMETER shall revert to a manual mode. A subsequent SELF-MEASUREMENT AUTOMATIC MODE may be selected by a deliberate action of the OPERATOR.

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.



IEC

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) the total duration of the alternating inflation/deflation periods in an unusual DETERMINATION (see Figure 201.103) shall not exceed the maximum inflation specified in 201.104; and
- b) after each successful DETERMINATION, the CUFF pressure shall be released and 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 independent 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 DOCUMENTATION.

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

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 \pm 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 \pm 10 mmHg (13,3/9,3 kPa \pm 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.

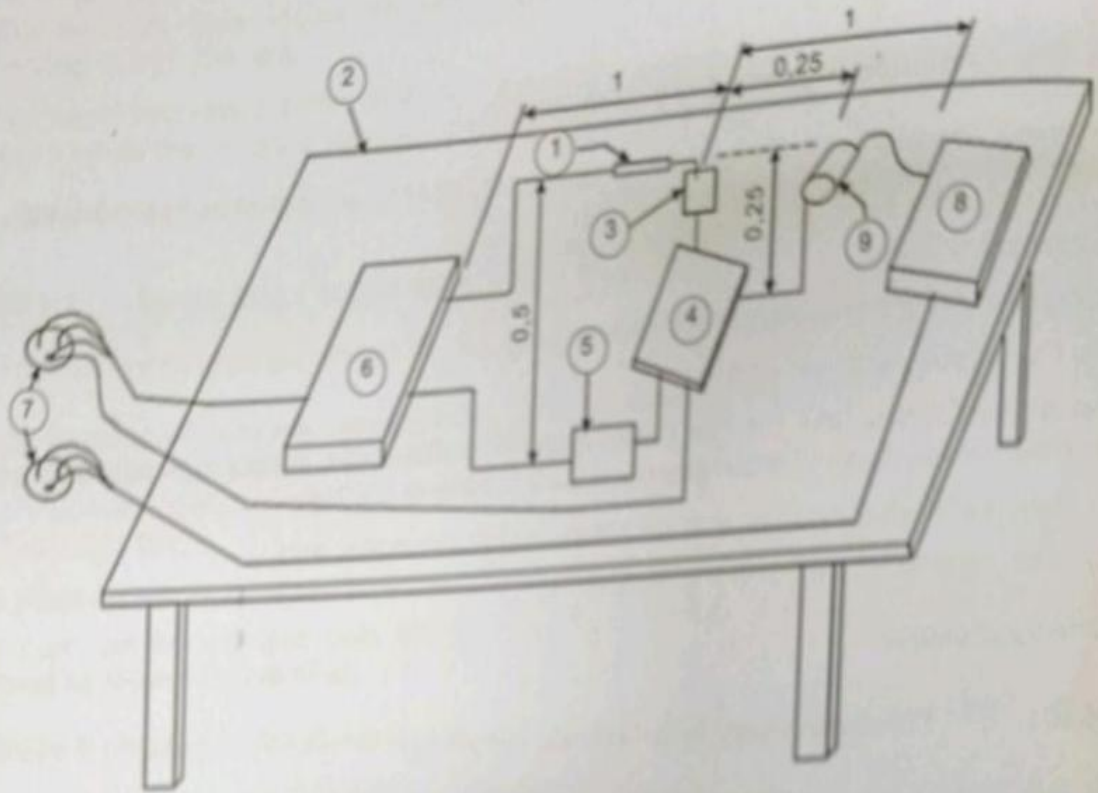
c) Test in coagulation mode:

Set up the ME EQUIPMENT to operate from a PATIENT SIMULATOR set to simulate a BLOOD PRESSURE of about 100/70 mmHg \pm 10 mmHg (13,3/9,3 kPa \pm 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.



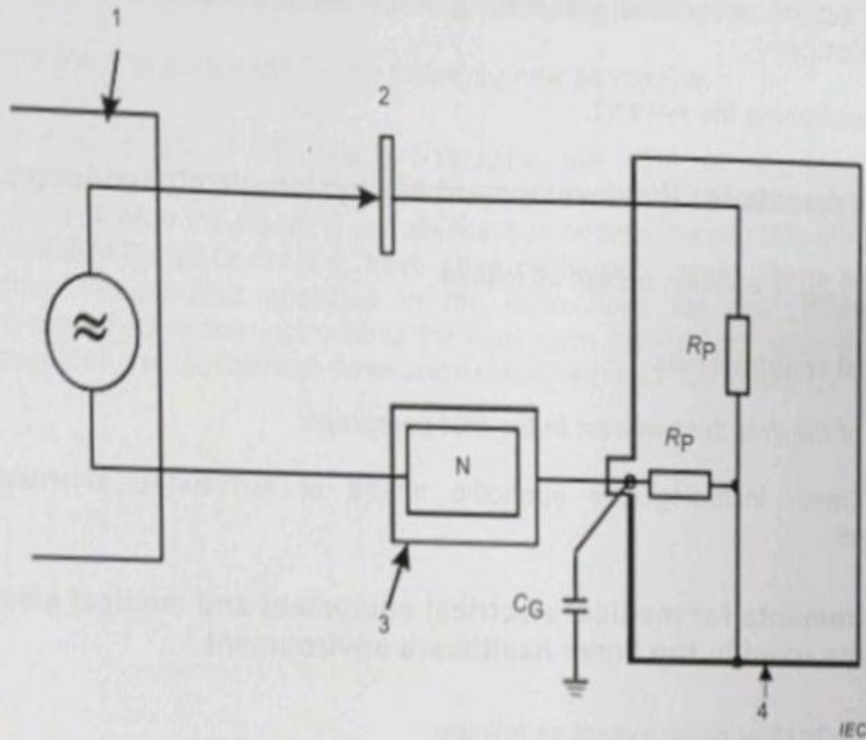
REC

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

$R_p = 220 \Omega, 200 \text{ W}$ (low inductance, simulates PATIENT impedance)

$C_G = 47 \text{ nF}$ (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

OPERATING FUNCTION:

h) properly positioning the PATIENT.

210 Requirements for the development of physiologic closed-loop co

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 SPHYGMOMA
DETERMINATIONS;

211 Requirements for medical electrical equipment and medical electric 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 word
the sales packaging".*

211.4.2.3.1 Continuous operating conditions

*Addition, in the first sentence after the phrase "The instructions for use", of the word
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
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 environme

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.

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 SLABBER into the inelastic part of the CUFF	201.7.2.13
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	Subclass
Additional requirements can be found in ISO 81060-2.	201
Disclosure that the AUTOMATED SPHYGMOMANOMETER was clinically investigated according to ISO 81060-2:2013.	201

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	Subclass
An explanation of the need to avoid compression or restriction of the connection tubing	201.7.9.2
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
An explanation of the selection of a suitable size and application of the CUFF to the PATIENT	201.7.9.2
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
Description of the operating principles	201.7.9.
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
Details of what the OPERATOR should do if unexpected readings are obtained	201.7.9.2
For the sales packaging, conditions of transport and storage between uses	211.4.2
For the sales packaging, continuous operating conditions	211.4.2
For the sales packaging, RATED range of arm circumferences of the CUFF	211.7.4
Frequently used functions	201.7.9.2
If applicable, the correct method of reassembly	201.7.9.2
If applicable, a detailed description of the correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2
If applicable, that the ME EQUIPMENT is suitable for use in the presence of electrosurgery	201.7.9.2
If applicable, the protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2
If applicable, the absence of protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2

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 health care. As such, BLOOD PRESSURE monitoring is used on almost all PATIENTS when they encounter a healthcare system. They are increasingly being used by PATIENTS in the HOME HEALTH CARE ENVIRONMENT.

Faults in the inflation and deflation cycles of AUTOMATED SPHYGMOMANOMETERS are considered to be 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 or 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 monitor 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 the 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

Subclause 201.11.8.103 – INTERNAL ELECTRICAL

Failure to deflate the CUFF within 30 s to the values indicated in Table 201.102 is 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. These BLOOD PRESSURE values are extremely rare in clinical care. It is important for SPHYGMOMANOMETERS to be able to indicate BLOOD PRESSURES above the range they are clinically investigated. An AUTOMATED SPHYGMOMANOMETER that either artificially limits the value of the display above that range would "hide" the condition 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 from excessive pressure applied to the limb when the primary pressure sensing and 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 OPERATOR is unable to remove the CUFF in the case of overpressure and there is no OPERATOR intervention present. In these cases, it is necessary to provide a PROTECTION DEVICE to release 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 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 to 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 the 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 and the volume of the CUFF. The initial pressure chosen for the test should represent the maximum pressure expected in NORMAL USE, which occurs at the end of the inflation cycle. For 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 ± 25 ml for NEONATAL MODE or for wrist AUTOMATED SPHYGMOMANOMETERS and 500 ml ± 25 ml for other AUTOMATED SPHYGMOMANOMETERS). An alternative method is to utilize the largest CUFF specified in the instructions for use. The CUFF should be wrapped around a rigid mandrel that represents the limb.

Subclause 201.12.1.106 – Manometer test mode

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 $\leq 5,0$ 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 $\leq 3,0$ mmHg (0,4 kPa) criterion permitted for the AUTOMATED SPHYGMOMANOMETER undergoing the TYPE TEST.

AUTOMATED SPHYGMOMANOMETERS in NORMAL USE will be subjected to mechanical (e.g. vibration, shock) and could randomly be subjected to additional stresses. The **AUTOMATED SPHYGMOMANOMETER** needs to be robust enough to withstand the vibration 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 monitoring standards where those committees qualitatively assessed the relative severity of the scenarios within various environments (i.e., HOME HEALTHCARE ENVIRONMENT, hospital 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 performance 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, the committees reviewed other sources for material related to these tests (e.g., FDA Regulatory Guidance for premarket notification submissions, Mil Std 810, etc.) but found the best fit 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 conditions according to 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 concluded 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 a healthcare facility.

Verifying that the instrument is functioning within the MANUFACTURER'S specifications when vibration (random and sinusoidal) tests are being conducted was not believed necessary. A 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 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 on 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 size. In auscultation, use of the wrong size CUFF can affect the accuracy of the estimated 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 DETERMINATIONS. For example CUFFS that are too small can result in erroneously high DETERMINATIONS. This 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 permissible range 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 10 cm to 14 cm for a wrist circumference of 15 cm to 20 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

cause more readings to be taken.

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

An alternative RISK CONTROL method is provided for AUTOMATED SPHYGMOMANOMETERS 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 cycle should not exceed 15 minutes.

Clause 201.105.3 – SELF-MEASUREMENT AUTOMATIC MODE

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 three 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.

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].

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

When 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 operate in the SELF-MEASUREMENT AUTOMATIC MODE. In this mode, it is assumed that the duration 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.

This alternative RISK CONTROL method is intended to provide an acceptable RESIDUAL RISK by reducing the cost of a PROTECTION DEVICE with OPERATOR action when OPERATOR/PATIENT intervention 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.

Clause 201.106 – Clinical accuracy

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

Subclause 202.8.1.101 – Additional general

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

Subclause 202.8.101 – Electrosurgery interference recovery

If an AUTOMATED SPHYGMOMANOMETER is intended to be used together or in the presence of 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, a 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 would be an unacceptable RISK to a PATIENT if an AUTOMATED SPHYGMOMANOMETER is 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	Distribution (including packaging)	Use	End of life
		Stage A	Stage B	Stage C	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.

Reference to the ESSENTIAL PRINCIPLES

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

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

See Table CC.1 for a mapping of the clauses and subclauses of this document to the 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
1	All	The part relating to manufacturing is addressed.
a)	206	
b)	206	
2	201.4	The part relating to manufacturing is addressed.
a)	All	
b)	201.4	The part relating to manufacturing is addressed.
c)	201.7, 201.11, 201.12, 201.13, 208	
d)	201.7	
3	All	The part relating to manufacturing is 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	

ESSENTIAL PRINCIPLE of 16142-1:2016, Tables B.1 and B.2 [30]	Corresponding clause(s)/subclause(s) of this document	Qualifying remarks/Notes
	201.14, 201.16	
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	201.11	
	201.7, 201.8, 201.12.1.106	
	201.1.3, 201.7.2.105	
	201.7.2.101, 201.12.1, 201.101, 201.105, 201.106	
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and B.2 [30]		
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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	
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21.9	—	
b)	211	
d)	211	
f)	201.7	

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A-1 BIS CERTIFICATION MARKING

The product may also be marked with the Standard Mark.

A-1.1 The use of Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations made there under. The details of the conditions under which the licence for use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

(Continued from second cover)

<i>International Standard</i>	<i>Title</i>
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

Only the English language text has been retained while adopting it in this Indian Standard, and as such, the page numbers given here are not the same as in the IEC Publication.

The standard also makes a reference to the BIS Certification Marking on the product. Details of which are given in National Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

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