

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

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

Appareils électromédicaux –

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



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers**

FOREWORD

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

This first edition of IEC 80601-2-30 cancels and replaces the second edition of IEC 60601-2-30, published in 1999. This edition constitutes a major technical revision as well as an alignment with the third edition of IEC 60601-1. Specific technical changes include: expansion of the scope to include all AUTOMATED SPHYGMOMANOMETERS including those where the PATIENT is the OPERATOR, identification of ESSENTIAL PERFORMANCE, new clinical accuracy requirements, additional mechanical strength requirements and prohibition of OPERATOR accessible 'Luer' connectors in the PNEUMATIC SYSTEM.

This publication is published as a double logo standard.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/721/FDIS	62D/737/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 13 P-members out of 17 having cast a vote.

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

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

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

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

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this particular standard will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

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 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, this annex does not form part of the requirements of this standard.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 Scope

Replacement:

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

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

This standard 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 standard covers electrically-powered intermittent, indirect measurement of the BLOOD PRESSURE without arterial puncture, ME EQUIPMENT with automatic methods for estimating BLOOD PRESSURE, including BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT.

Requirements for indirect measurement 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.

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 standard are not covered by specific requirements in this standard except in 201.11 and 201.105.3.3, as well as 7.2.13 and 8.4.1 of IEC 60601-1.

NOTE 2 See also 4.2 of the general standard.

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.

¹⁾ The general standard is IEC 60601-1:2005, *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 IEC 60601-1 and Clause 2 of this particular standard.

IEC 60601-1-2 is amended by this particular standard. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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 its 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 is 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 standard 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 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

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

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

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

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures 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 standard" 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 49.

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

Amendment of the following reference:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

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

IEC 60068-2-31:2008, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens*

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

IEC 60601-2-2:2009, *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*

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

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

ISO 81060-2:____²⁾, *Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-8:2006, and IEC 60601-2-2:2009 apply, except as follows:

NOTE An index of defined terms is found beginning on page 51.

Addition:

²⁾ To be published.

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

201.3.202**BLADDER**

part of the CUFF that is inflatable

[ISO 81060-1:2007, definition 3.2]

201.3.203**BLOOD PRESSURE**

pressure in the systemic arterial system of the body

[ISO 81060-1:2007, definition 3.3]

201.3.204**CUFF**

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

NOTE 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).

[ISO 81060-1:2007, definition 3.5, modified]

201.3.205**DETERMINATION (value)**

result of the process of estimating BLOOD PRESSURE by the AUTOMATED SPHYGMOMANOMETER

201.3.206**DIASTOLIC BLOOD PRESSURE (value)**

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

NOTE Because of hydrostatic effects, this value should be determined with the CUFF at the level of the heart.

201.3.207**HOME HEALTHCARE ENVIRONMENT**

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

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

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

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

[IEC 60601-1-11____³], definition 3.2]

³ IEC 60601-1-11____, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* (in preparation).

201.3.208

LONG-TERM AUTOMATIC MODE

mode in which a timer, set by the OPERATOR, initiates multiple DETERMINATIONS

201.3.209

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 Because of hydrostatic effects, this value should be determined with the CUFF at the level of the heart.

201.3.210

NEONATAL MODE

mode of AUTOMATED SPHYGMOMANOMETER for use with neonates or infants

NOTE 1 The approximate age range for a newborn (neonate) is from birth to 1 month. [10]⁴

NOTE 2 The approximate age range for an infant is from 1 month to 2 years. [10] For the purposes of this standard, up to 3 years of age are considered infants (see ISO 81060-2, 6.1.3).

NOTE 3 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.

201.3.211

NON-AUTOMATED SPHYGMOMANOMETER

ME EQUIPMENT used for the non-invasive measurement 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 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.

[ISO 81060-1:2007, definition 3.11, modified]

201.3.212

PATIENT SIMULATOR

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

NOTE This equipment is not used for testing accuracy but is used in assessing stability of performance.

201.3.213

PNEUMATIC SYSTEM

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

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

[ISO 81060-1:2007, definition 3.16, modified]

201.3.214

PRESSURE TRANSDUCER

component that transforms sensed pressure into an electrical signal

201.3.215

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

⁴) Figures in square brackets refer to the Bibliography.

201.3.216**SELF-MEASUREMENT AUTOMATIC MODE**

mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated by the OPERATOR and in which a limited number of DETERMINATIONS are made

201.3.217*** SHORT-TERM AUTOMATIC MODE**

mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated by the OPERATOR and in which repetitive automatic DETERMINATIONS are made rapidly within a specified time period

201.3.218**SYSTOLIC BLOOD PRESSURE (value)**

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

NOTE Because of hydrostatic effects, this value should be determined with the CUFF at the level of the heart.

201.4 General requirements

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

201.4.3 Essential performance

Additional subclause:

201.4.3.101 Additional essential performance requirements

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

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Electrosurgery interference recovery	202.6.2.101
Limits of the error of the manometer, or generation of a TECHNICAL ALARM CONDITION	201.12.1.102 201.11.8.102 201.12.1.101
Limits of the change in the error 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

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

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

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

201.7.2.4 * Accessories

Addition:

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

Additional subclauses:

201.7.2.101 Display of automated sphygmomanometers

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

- “S” or “SYS” for the value of SYSTOLIC BLOOD PRESSURE;
- “D” or “DIA” for the value of DIASTOLIC BLOOD PRESSURE;
- “M” or “MAP” for the value of MEAN ARTERIAL PRESSURE.

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

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

201.7.2.102 automated sphygmomanometers for home healthcare environment

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

- identification of the appropriate arm circumference;
- the operating and storage temperature and humidity ranges;
- any special requirements for a battery-powered AUTOMATED SPHYGMOMANOMETER.

201.7.2.103 * automated sphygmomanometers with neonatal mode

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

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

201.7.2.104 * automated sphygmomanometers for public use

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

- precautions for use, including a statement concerning the need to consult a physician for interpretation of BLOOD PRESSURE measurements;
- adequate operating instructions;
- this sphygmomanometer complies with IEC 80601-2-30.

EXAMPLE Self-measurement station in a pharmacy, fitness centre, workplace.

201.7.2.105 * Component replacement

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

EXAMPLES CUFF, microphone, connection tube, external power supply

201.7.2.106 Disposal

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

NOTE See also IEC 60601-1-9⁵⁾.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Replacement of the 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:

- for use with neonatal PATIENTS,
- 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;
- 5) intended conditions of use

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

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

201.7.9.2.2 Warning and safety notices

Addition, following the note:

The instructions for use shall include a warning:

⁵⁾ IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral standard: Requirements for environmentally conscious design*

- regarding the effect of blood flow interference and resulting harmful injury to the PATIENT caused by continuous CUFF pressure due to connection tubing kinking;
- indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference;
- regarding the application of the CUFF over a wound, as this can cause further injury;
- regarding the application of the CUFF and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury to the PATIENT;
- regarding the application of the CUFF and its pressurization on the arm on the side of a mastectomy;
- regarding the information that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb;
- 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;
- RATED ranges of the DETERMINATION.

201.7.9.2.9 Operating instructions

Addition:

The instructions for use shall contain the following information:

- a) an explanation of the selection of a suitably sized CUFF and the application of the CUFF to the PATIENT;
- b) an explanation of the operating steps needed to obtain accurate routine resting BLOOD PRESSURE measurements for the condition hypertension [20] including;
 - adjustment of the pressure reduction rate, if applicable,
 - PATIENT position in NORMAL USE, including
 - 1) comfortably seated
 - 2) legs uncrossed
 - 3) feet flat on the floor
 - 4) back and arm supported
 - 5) middle of the CUFF at the level of the right atrium of the heart
 - a recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE,
 - a recommendation that 5 min should elapse before the first reading is taken;
 - OPERATOR position in NORMAL USE,
- c) an explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT (standing, sitting, lying down), exercise, or the PATIENT'S physiologic condition;
- d) details of what the OPERATOR should do if unexpected readings are obtained;
- e) 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);

- f) a statement, if applicable, that the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude;
- g) if applicable, an explanation of the need to avoid compression or restriction of the connection tubing.
- h) the RATED range of CUFF pressure.

201.7.9.2.13 Maintenance

Addition, after the second paragraph:

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

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

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

Additional subclauses:

201.7.9.2.101 Compatibility with hf surgical equipment

If the AUTOMATED SPHYGMOMANOMETER complies with the requirements of 202.6.2.101, 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:

- the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in NEONATAL MODE;
- the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER can accommodate when in the NEONATAL MODE;
- 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 sphygmomanometer

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

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

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

Replacement:

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

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

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

201.11.8 Interruption of the power supply/supply mains to ME EQUIPMENT

Addition:

201.11.8.101 * Switching off

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

Table 201.102 – CUFF deflation pressure

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

Compliance is checked by functional testing.

201.11.8.102 SUPPLY MAINS

When 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 SUPPLY MAINS is restored the AUTOMATED SPHYGMOMANOMETER shall:

- a) continue in the same mode of operation and with all OPERATOR settings unchanged, or
- b) remain inoperative and, if equipped 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.

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

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

Restore the SUPPLY MAINS and determine either that the AUTOMATED SPHYGMOMANOMETER continues in the same mode of operation and with all OPERATOR settings unchanged, or 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:

- 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 standard
 - 1) for protective shutdown, and
 - 2) for cancelling the indicated BLOOD PRESSURE;
- of determining the state of the power supply.

Compliance is checked by functional testing.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

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

Replacement:

201.12.1 Accuracy of controls and instruments

201.12.1.101 Measuring and display ranges

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

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

Compliance is checked by functional testing.

201.12.1.102 Limits of the error of the manometer from environmental conditions

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

Compliance is checked by functional testing.

201.12.1.103 * Nominal blood pressure indication range

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

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

Compliance is checked with the following test:

Connect the AUTOMATED SPHYGMOMANOMETER to a PATIENT SIMULATOR.

Adjust the PATIENT SIMULATOR to generate signals in such a way that the AUTOMATED SPHYGMOMANOMETER displays DIASTOLIC BLOOD PRESSURE values of 20 mmHg (2,7 kPa) or less and SYSTOLIC BLOOD PRESSURE values of 110 mmHg (14,7 kPa) or more in NEONATAL MODE and DIASTOLIC BLOOD PRESSURE values of 60 mmHg (8,0 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

A PROTECTION DEVICE shall be provided, functioning independently of the normal PNEUMATIC SYSTEM control, which in any SINGLE FAULT CONDITION, shall:

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

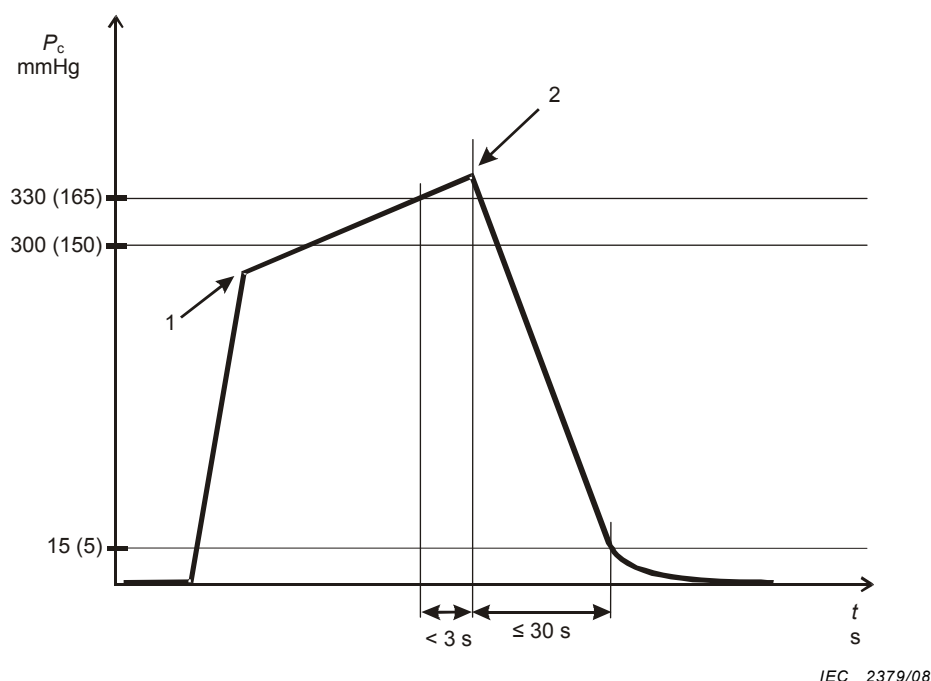
When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s to ≤ 15 mmHg (2,0 kPa) and to ≤ 5 mmHg (0,7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE.

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

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

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

Compliance is checked by functional testing in SINGLE FAULT CONDITION.



Key

- 1 SINGLE FAULT CONDITION occurs
- 2 PROTECTION DEVICE activates due to overpressure

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

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

201.12.1.106 * Manometer test mode

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

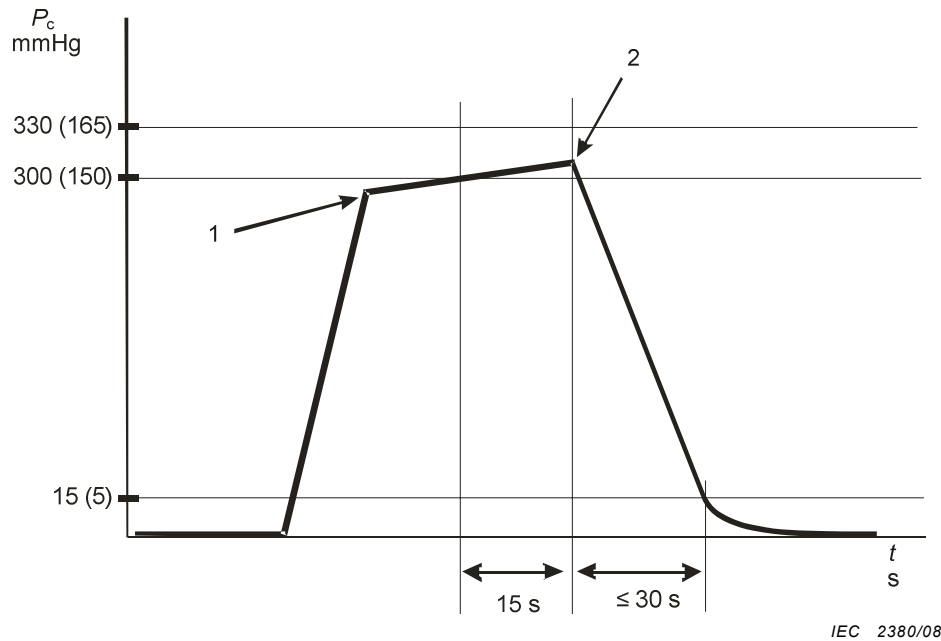
EXAMPLE 1 A port for connection to a pressure source so that the pressure can be measured by the AUTOMATED SPHYGMOMANOMETER in a test mode.

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

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

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

Compliance is checked by inspection and functional testing.



IEC 2380/08

Key

- 1 SINGLE FAULT CONDITION occurs
- 2 PROTECTION DEVICE activates due to prolonged overpressure

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

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

201.12.1.107 Limits of the change in error of the blood pressure determination

The laboratory limits of the change in error of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER shall be less than 3 mmHg (0,4 kPa).

Compliance is checked with the following test:

- a) *Prior to performing the other tests of this standard, adjust the PATIENT SIMULATOR to generate signals in such a way that the AUTOMATED SPHYGMOMANOMETER displays approximately a DIASTOLIC BLOOD PRESSURE value of 40 mmHg (2,7 kPa) and a SYSTOLIC BLOOD PRESSURE value of 70 mmHg (18,0 kPa) at a pulse rate of 140 beats/min in NEONATAL MODE and a DIASTOLIC BLOOD PRESSURE value of 80 mmHg (5,3 kPa) and a SYSTOLIC BLOOD PRESSURE value of 120 mmHg (30,7 kPa) at a pulse rate of 80 beats/min otherwise.*
- b) *Perform 20 DETERMINATIONS and calculate the mean DIASTOLIC BLOOD PRESSURE and SYSTOLIC BLOOD PRESSURE.*
- c) *Perform all the tests of this standard, except 201.106.*
- d) *Using the same PATIENT SIMULATOR settings as in a), perform 20 DETERMINATIONS and calculate the mean DIASTOLIC BLOOD PRESSURE and SYSTOLIC BLOOD PRESSURE.*
- e) *Calculate the difference of the means calculated in b) and d)*
- f) *Ensure that the difference is below the limit.*

201.12.3 Alarm systems

Addition:

201.12.3.101 Alarm systems

If an AUTOMATED SPHYGMOMANOMETER has an ALARM SYSTEM that includes PHYSIOLOGICAL ALARM CONDITIONS, it shall have both a PHYSIOLOGICAL ALARM CONDITION for low BLOOD PRESSURE and a PHYSIOLOGICAL ALARM CONDITION for high BLOOD PRESSURE of at least MEDIUM PRIORITY. These ALARM CONDITIONS may be for SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE, or MEAN ARTERIAL PRESSURE.

Compliance is checked by inspection and functional testing.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

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

201.15.3.5 Rough handling test

Additional subclauses:

201.15. 3.5.101 * Shock and vibration for other than transport

An AUTOMATED SPHYGMOMANOMETER or its parts not intended for use during PATIENT transport outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping, and rough handling. A FIXED AUTOMATED SPHYGMOMANOMETER is exempt from the requirements of this subclause.

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

Compliance is checked by the following tests:

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

NOTE 1 This represents IEC 60721-4-7:1995, Class 7M2.

1) test type: Type 1:

- peak acceleration: 100 m/s² (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/s² (30 g);
- duration: 6 ms;
- pulse shape: half sine;
- number of shocks: 3 shocks per direction per axis (18 total).

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

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

NOTE 2 This represents IEC 60721-4-7:1995, Classes 7M1 and 7M2

- 1) *acceleration amplitude:*

- 10 Hz to 100 Hz: $1,0 (m/s^2)^2/Hz$;
- 100 Hz to 200 Hz: -3 db/octave ;
- 200 Hz to 2 000 Hz: $0,5 (m/s^2)^2/Hz$;

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

The requirements in 201.15.3.5.102 in total or in part, may be substituted for the corresponding requirements of this subclause.

201.15.3.5.102 * Shock and vibration for transport

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

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

Compliance is checked by the following tests:

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

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

- 1) *test type: Type 1:*

- *peak acceleration: $300 m/s^2$ (30 g);*
- *duration: 11 ms;*
- *pulse shape: half sine;*
- *number of shocks: 3 shocks per direction per axis (18 total);*

- 2) *test type: Type 2:*

- *peak acceleration: $1\,000 m/s^2$ (100 g);*
- *duration: 6 ms;*
- *pulse shape: half sine;*
- *number of shocks: 3 shocks per direction per axis (18 total).*

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

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

- 1) *acceleration amplitude:*

- 10 Hz to 100 Hz: $5,0 (m/s^2)^2/Hz$;
- 100 Hz to 200 Hz: -7 db/octave ;
- 200 Hz to 1 000 Hz: $1,0 (m/s^2)^2/Hz$;

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

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

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

1) *fall height:*

- *for mass < 1 kg, 0,25 m;*
- *for mass between 1 kg and < 10 kg, 0,1 m;*
- *for mass between 10 kg and < 50 kg, 0,05 m;*
- *for mass ≥ 50 kg, 0,01 m;*

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

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

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

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies, except as follows:

Addition:

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

New 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.

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.

201.102 Connection tubing and CUFF connectors

The connections between the AUTOMATED SPHYGMOMANOMETER, CUFF, and connection tubing shall not be equipped with a connector that couples with a connector complying with ISO 594-1 or ISO 594-2.

Compliance is checked by inspection.

201.103 Unauthorized access

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

EXAMPLE Requiring a TOOL for opening.

Compliance is checked by inspection.

201.104 * Maximum inflating time

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

In SINGLE FAULT CONDITION, a pressure relief PROTECTION DEVICE, functioning independently of the NORMAL CONDITION PROTECTION DEVICE, shall ensure that the CUFF shall not inflate above the values in Table 201.103 for more than 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and otherwise for more than 180 s, see Figure 201.103.

Table 201.103 – CUFF inflation pressure

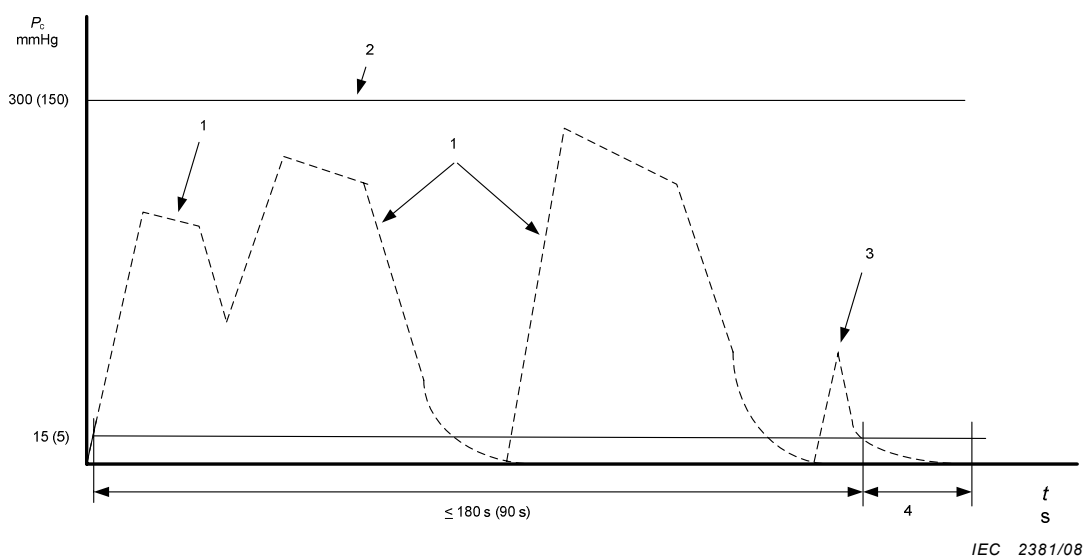
Mode	CUFF pressure
NEONATAL MODE	> 5 mmHg (0,7 kPa)
Any other mode	> 15 mmHg (2,0 kPa)

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

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

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

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

**Key**

- 1 Unsuccessful DETERMINATION
- 2 Pressure limit, NEONATAL MODE values in parentheses
- 3 Aborted DETERMINATION
- 4 ≥ 30 s for LONG-TERM AUTOMATIC MODE and ≥ 5 s 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

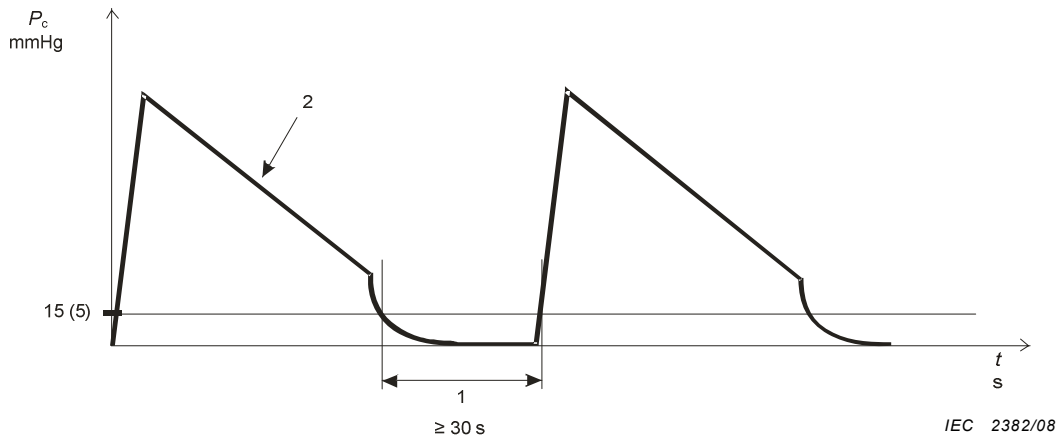
If an AUTOMATED SPHYGMOMANOMETER is equipped with a LONG-TERM AUTOMATIC MODE, a PROTECTION DEVICE shall be provided to ensure that:

- a) in NORMAL CONDITION either:
 - 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; or
 - after each successful DETERMINATION;

the CUFF pressure shall be released and shall remain below the values in Table 201.102 for at least 30 s (see Figure 201.104); and
- b) in SINGLE FAULT CONDITION:

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

Compliance is checked by functional testing.



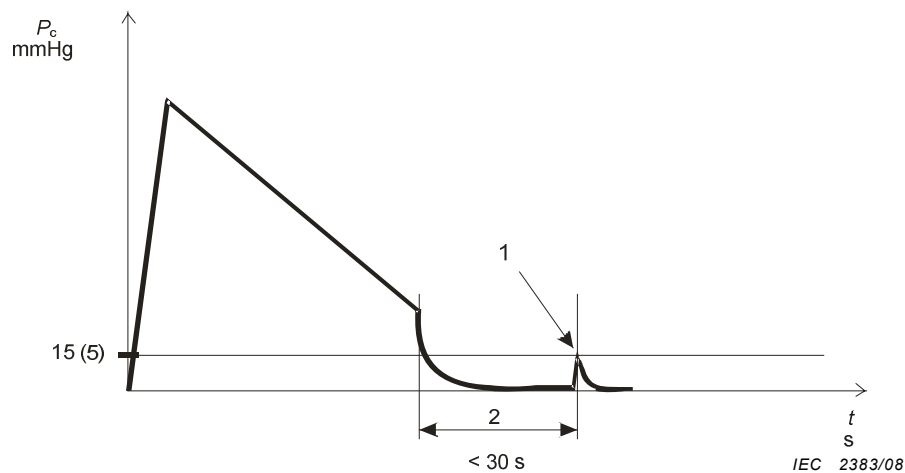
Key

- 1 Deflated time
- 2 Linear CUFF deflation shown

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

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

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



Key

- 1 Pressure relief PROTECTION DEVICE activates
- 2 Deflated time

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

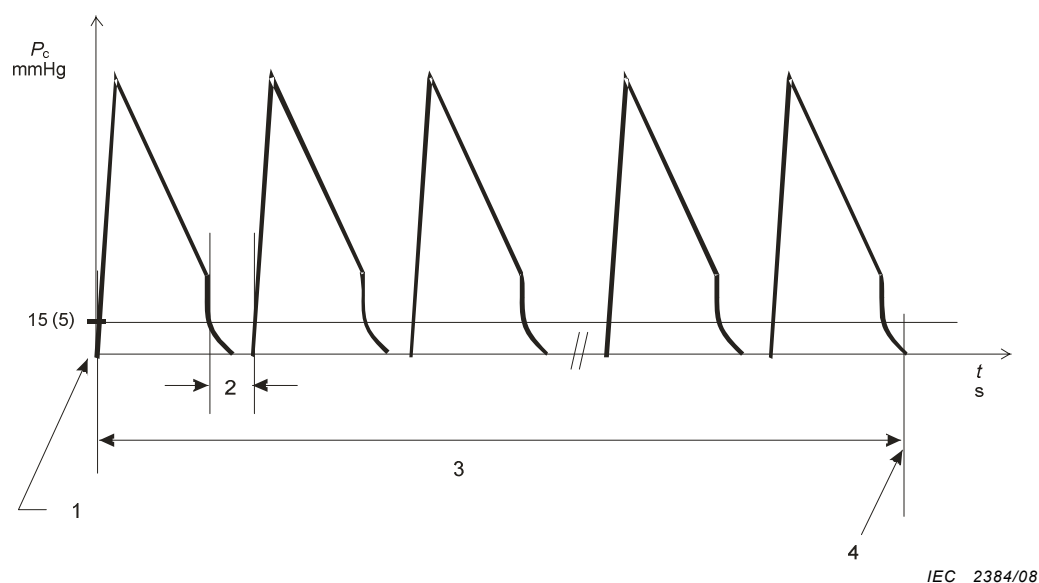
Figure 201.105 – LONG-TERM AUTOMATIC MODE CUFF pressure in SINGLE FAULT CONDITION

201.105.2 * SHORT-TERM AUTOMATIC MODE

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

- ensure that following each individual DETERMINATION, the pressure in the CUFF shall be reduced to the values indicated in Table 201.102 for at least 2 s, to allow venous return (see Figure 201.106), and
- restrict the duration of the SHORT-TERM AUTOMATIC MODE to a maximum of 15 min (see Figure 201.106). At the end of this time, the AUTOMATED SPHYGMOMANOMETER shall revert to the LONG-TERM AUTOMATIC MODE or a manual mode. A further period of the SHORT-TERM AUTOMATIC MODE may be selected by a deliberate action of the OPERATOR.

Compliance is checked by functional testing.

**Key**

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

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

Figure 201.106 – SHORT-TERM AUTOMATIC MODE CUFF pressure

201.105.3 * SELF-MEASUREMENT AUTOMATIC MODE

201.105.3.1 General

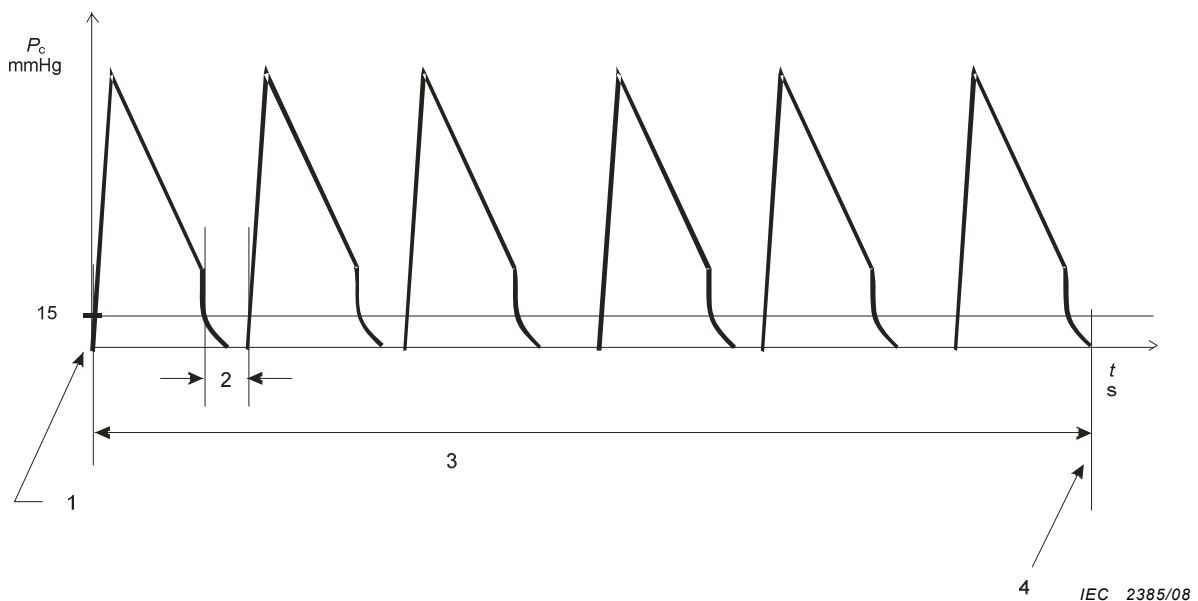
If a SELF-MEASUREMENT AUTOMATIC MODE is available, the AUTOMATED SPHYGMOMANOMETER shall perform only a manually-initiated series of less than 7 DETERMINATIONS (see Figure 201.107). After the completion of this series of DETERMINATIONS, the AUTOMATED SPHYGMOMANOMETER shall revert to a manual mode. A subsequent 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:

- the PATIENT is the OPERATOR; or
- the OPERATOR is in continual attendance during the series of DETERMINATIONS.

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

Compliance is checked by inspection and functional testing.



Key

- 1 OPERATOR starts SELF-MEASUREMENT MODE
- 2 Deflated time ≥ 5 s after each DETERMINATION
- 3 SELF-MEASUREMENT MODE limited to 6 DETERMINATIONS
- 4 SELF-MEASUREMENT MODE ends

CUFF pressure, P_c , as a function of time

Figure 201.107 – SELF-MEASUREMENT AUTOMATIC MODE CUFF pressure

201.105.3.2 NORMAL CONDITION

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

- 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; or
- after each successful DETERMINATION, the CUFF pressure shall be released and shall remain below the values in Table 201.102 for at least 5 s (see Figure 201.104).

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:

- if the duration of deflation below the values in Table 201.102 is less than 30 s (see Figure 201.105), then a pressure relief PROTECTION DEVICE functioning independently of the NORMAL CONDITION PROTECTION DEVICE shall release the CUFF pressure to the values in Table 201.102; or
- where:
 - the pressure can be released from the CUFF by the OPERATOR; or
 - the CUFF can be removed from the limb by the intended OPERATOR when the CUFF is inflated to 360 mmHg (48 kPa).

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

201.106 * Clinical accuracy

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

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.

202 Electromagnetic compatibility – Requirements and tests

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

202.4 General requirements

Additional subclause:

202.4.101 Classification

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

202.6.2 Immunity

202.6.2.1.10 Compliance criteria

Replacement:

Under the test conditions specified in IEC 60601-1-2:2007, 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE. Under these conditions, the maximum change in the reading for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to 2 mmHg (0.3 kPa).

202.6.2.3.1 Requirements

a) General

Replacement:

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

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

Additional subclause:

202.6.2.101 * 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 $\pm$ 100 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 select the cut mode at 300 W.

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

Terminate the interference. Wait 10 s. Determine whether 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 select the coagulation mode at 100 W.

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

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

Repeat this PROCEDURE as described, five times.

NOTE 1 Test of the spray coagulation is not required.

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