BS EN 80601-2-30:2010+A1:2015

Incorporating corrigendum November 2010

BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN 80601-2-30:2010+A1:2015. It is identical to IEC 80601-2-30:2009, incorporating corrigendum January 2010 and amendment 1:2013. It supersedes BS EN 80601-2-30:2010 which will be withdrawn on 14 April 2018.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by IEC corrigendum January 2010 is indicated in the text by [AC] 〈AC].

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by [A1] 〈A1].

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Published by BSI Standards Limited 2015

ISBN 978 0 580 73897 5

ICS 11.040.55

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2010.

Amendments/corrigenda issued since publication

Date	Text affected
30 November 2010	Correction to supersession details
31 July 2015	Implementation of IEC amendment 1:2013 with CENELEC endorsement A1:2015. Annex ZA updated

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-30:2010+A1

May 2015

ICS 11.040

English version

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

(IEC 80601-2-30:2009 + corrigendum Jan. 2010)

Appareils électromédicaux - Partie 2-30: Exigences particulières pour la sécurité de base et les performances essentielles de sphygmomanomètres non invasifs automatiques (CEI 80601-2-30:2009 + corrigendum Jan. 2010)

Medizinische elektrische Geräte - Teil 2-30: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von nicht-invasiven Sphygmomanometern von automatisierten Typ (IEC 80601-2-30:2009 + corrigendum Jan. 2010)

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 80601-2-30:2010 E

Foreword

The text of document 62D/721/FDIS, future edition 1 of IEC 80601-2-30, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and SC 3, Lung ventilators and related equipment, of ISO TC 121, Anaesthetic and respiratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 80601-2-30 on 2010-09-01.

This European Standard supersedes EN 60601-2-30:2000.

EN 80601-2-30:2010 constitutes a major technical revision as well as an alignment with EN 60601-1:2006. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-06-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-09-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

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.

Annexes ZA and ZZ have been added by CENELEC.

_____

Endorsement notice

The text of the International Standard IEC 80601-2-30:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

[1] ISO 9919:2005 NOTE Harmonized as EN ISO 9919:2005 (not modified).

[3] ISO 21647:2004 NOTE Harmonized as EN ISO 21647:2004 (not modified).

_____

Foreword to amendment A1

The text of document 62D/1072/FDIS, future IEC 80601-2-30:2009/A1, prepared by SC 62D "Electrical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 80601-2-30:2010/A1:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-14

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 80601-2-30:2010.

Endorsement notice

The text of the International Standard IEC 80601-2-30:2009/A1:2013 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace *the reference to IEC 60601-1-2 by:*				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2007
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+A1	2013		+A1	2015
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8 + corr. March	2007 2010
+A1	2012		+A1 +A1/AC	2013 2014
Addition:				
IEC 60068-2-27	2008	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	EN 60068-2-27	2009
IEC 60068-2-31	2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	EN 60068-2-31	2008
IEC 60068-2-64	2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	EN 60068-2-64	2008
IEC 60601-1-11	2010	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	EN 60601-1-11	2010

Publication	Year	Title	EN/HD	Year
IEC 60601-2-2	2009	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2	2009
IEC 62366	2007	Medical devices - Application of usability engineering to medical devices	EN 62366	2008
ISO 594-1	1986	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	EN 20594-1	1993
ISO 594-2	1991	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings	-	-
ISO 81060-2	2013	Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC with the exception of ERs 3, 4, 7.1 and 12.1.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

_____

CONTENTS

FOREWORD 2
INTRODUCTION 10
201.1 Scope, object and related standards 11
201.2 Normative references 13
201.3 Terms and definitions 14
201.4 General requirements 16
201.5 General requirements for testing ME EQUIPMENT 16
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 17
201.7 ME EQUIPMENT identification, marking and documents 17
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 20
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 21
201.10 Protection against unwanted and excessive radiation HAZARDS 21
201.11 Protection against excessive temperatures and other HAZARDS 21
201.12 Accuracy of controls and instruments and protection against hazardous outputs 22
201.13 HAZARDOUS SITUATIONS and fault conditions 26
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 27
201.15 Construction of ME EQUIPMENT 27
201.16 ME SYSTEMS 29
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 29
201.101 Requirements for CUFFS 29
201.102 Connection tubing and CUFF connectors 29
201.103 Unauthorized access 29
201.104 * Maximum inflating time 30
201.105 * Automatic cycling modes 31
201.106 * Clinical accuracy 35
202 Electromagnetic compatibility – Requirements and tests 35
〈A1〉 206 Usability 38
211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT ..... 38 〈A1〉
Annexes 39
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 39
Annex AA (informative) Particular guidance and rationale 42
Annex BB (informative) Environmental aspects 50
Annex CC (informative) Reference to the essential principles 51
Bibliography 53
Index of defined terms 55

Figure 201.101 – CUFF pressure PROTECTION DEVICE, triggered by overpressure in SINGLE FAULT CONDITION 24
Figure 201.102 – CUFF pressure PROTECTION DEVICE, triggered by prolonged overpressure in SINGLE FAULT CONDITION 25
Figure 201.103 – CUFF pressure and maximum inflation time, NORMAL CONDITION and SINGLE FAULT CONDITION 31
Figure 201.104 – LONG-TERM AUTOMATIC MODE CUFF pressure in NORMAL CONDITION 32
Figure 201.105 – LONG-TERM AUTOMATIC MODE CUFF pressure in SINGLE FAULT CONDITION 32

Figure 201.106 – SHORT-TERM AUTOMATIC MODE CUFF pressure 33
Figure 201.107 – SELF-MEASUREMENT AUTOMATIC MODE CUFF pressure 34
Figure 202.101 – HF SURGICAL EQUIPMENT test layout 37
Figure 202.102 – Simulated PATIENT test set-up for HF SURGICAL EQUIPMENT 38

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements 16
Table 201.102 – CUFF deflation pressure 21
Table 201.103 – CUFF inflation pressure 30
Table 201.C.101 – Marking on the outside of AUTOMATED SPHYGMOMANOMETERS or their parts 39
Table 201.C.102 – Marking of controls and instruments of AUTOMATED SPHYGMOMANOMETERS or their parts 40
Table 201.C.103 – ACCOMPANYING DOCUMENTS, general information for AUTOMATED SPHYGMOMANOMETERS 40
Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED SPHYGMOMANOMETERS 40
Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description of AUTOMATED SPHYGMOMANOMETERS 41
Table AA.1 – Summary of requirements by mode 48
Table BB.1 – Environmental aspects addressed by clauses of this standard 50
Table CC.1 – Correspondence between this particular standard and the essential principles 51

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.

The contents of the corrigendum of January 2010 have been included in this copy.

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 standard[1)] 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 [A1] non-continuous [A1] 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* [A1] including Amendment 1:2012 [A1].

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:

〈A1〉 *Amendment of the following references:* 〈A1〉

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*

〈A1〉 IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
Amendment 1:2012 〈A1〉

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*

〈A1〉 IEC 60601-1-11:2010, *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* 〈A1〉

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*

〈A1〉 IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices* 〈A1〉

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*

〈A1〉 ISO 81060-2:2013, *Non-invasive sphygmomanometers – Part 2: Clinical investigation of automated measurement type* 〈A1〉

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2007, IEC 60601-1-8:2006+A1:2012, and IEC 60601-2-2:2009 apply, except as follows:

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

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 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 places where PATIENTS are present, 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 emergency medical services.

〈A1〉 NOTE 2 For the purpose of this particular standard, nursing homes are considered the HOME HEALTHCARE ENVIRONMENT.

NOTE 3 Other places where PATIENTS are present include the outdoor environment and in vehicles.

EXAMPLES In a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

[SOURCE: IEC 60601-1-11:2010, definition 3.2] 〈A1〉

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]2)

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]

2) Figures in square brackets refer to the Bibliography.

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

201.3.216
SELF-MEASUREMENT AUTOMATIC MODE
〈A1〉 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 limited period 〈A1〉

201.3.217
*** SHORT-TERM AUTOMATIC MODE**
〈A1〉 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 〈A1〉

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
〈A1〉 Reproducibility 〈A1〉 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 the HOME HEALTHCARE ENVIRONMENT

Vacant.

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 60601-1-9[3)].

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:

---

3) 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 〈A1〉 (see 201.12.1.106) 〈A1〉 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:

〈A1〉 201.8.5.5.101 * PATIENT CONNECTIONS of AUTOMATED SPHYGMOMANOMETERS 〈A1〉

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:

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

b) shall

- remain inoperative, and
- 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.

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 that the AUTOMATED SPHYGMOMANOMETER:

– *continues in the same mode of operation 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:

– 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 (± 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 A1 *40 mmHg (5,3 kPa)* A1 *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

A1 In any automatic cycling mode of operation, A1 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).

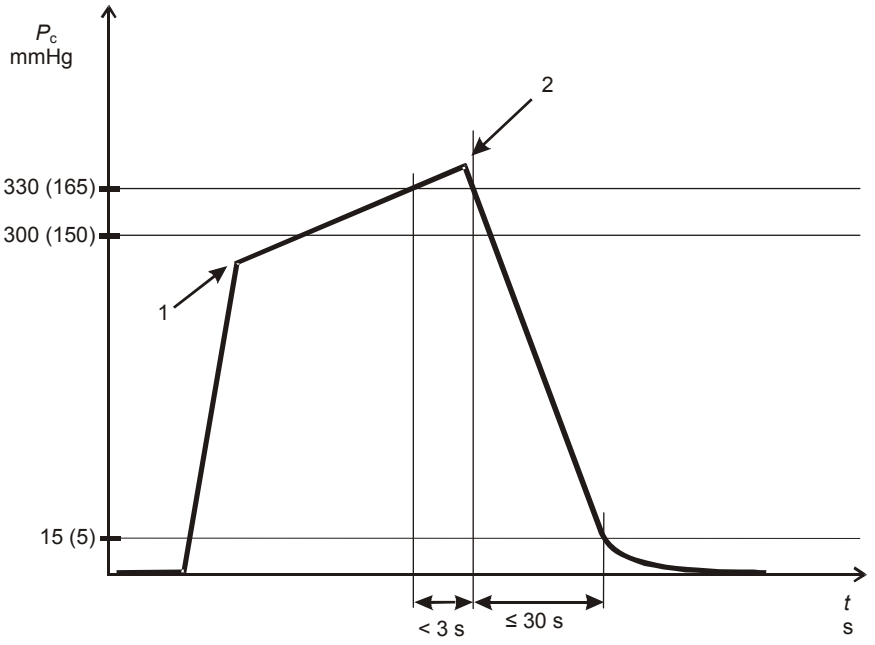
When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s to ≤ 15 mmHg (2,0 kPa) and to ≤ 5 mmHg (0,7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE.

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.

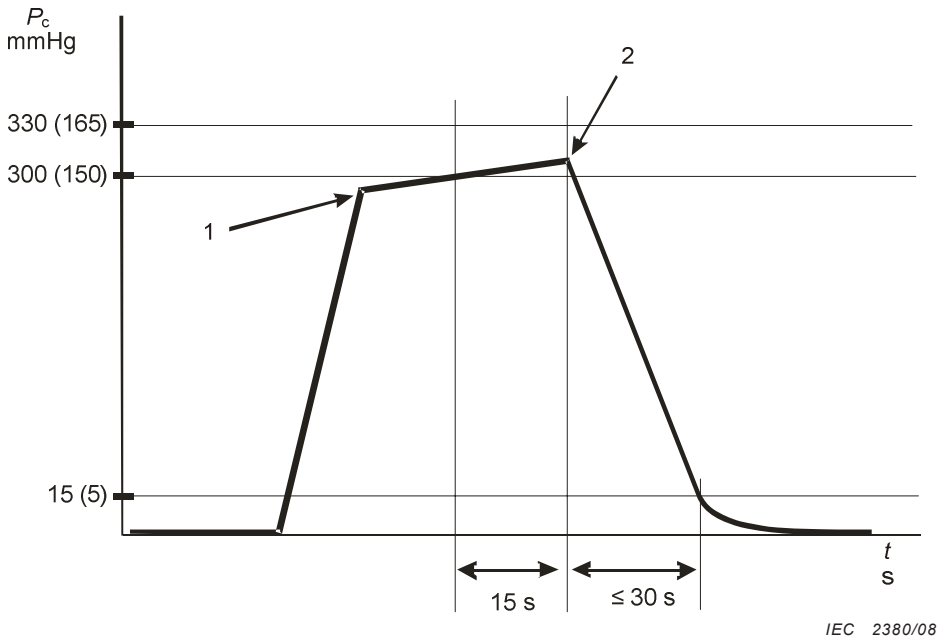
EXAMPLE 1 A port for connection to a pressure source so that the pressure can be measured by the AUTOMATED SPHYGMOMANOMETER in a test mode.

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.



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

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

d) Record these results as the AUTOMATED SPHYGMOMANOMETER B starting values. 〈A1〉

A1 *e) Verify that the standard deviation of the DIASTOLIC BLOOD PRESSURE and of the SYSTOLIC BLOOD PRESSURE are ≤ 2,0 mmHg (≤ 0,27 kPa) for the AUTOMATED SPHYGMOMANOMETER B starting values. If either one of these criterion 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 mean and standard deviation for both the DIASTOLIC BLOOD PRESSURE and the SYSTOLIC BLOOD PRESSURE.

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

h) Using AUTOMATED SPHYGMOMANOMETER A, perform at least the following tests, without the simulation of SINGLE FAULT CONDITIONS, of this particular standard: 201.11.6.5, 201.12.1.102, 201.15.3.5.101, and 201.15.3.5.102 as well as IEC 60601-1:2005, 15.3.2, 15.3.3 and 15.3.4.

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

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

o) For AUTOMATED SPHYGMOMANOMETER A, verify that the absolute value of the difference between the mean starting values calculated in f) and ending values calculated in i) are ≤ 5,0 mmHg (≤ 0,67 kPa). A1

201.12.3 Alarm systems

Addition:

A1 201.12.3.101 Additional ALARM SYSTEM requirements A1

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:

[A1] – *peak acceleration: 150 m/s^2 (15 g);* [A1]

– *duration: 11 ms;*

– *pulse shape: half sine;*

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

2) test type: Type 2:

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

– *duration: 6 ms;*

– *pulse shape: half sine;*

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

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

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

NOTE 2 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 [A1] in any automatic cycling mode of operation 〈A1〉, 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

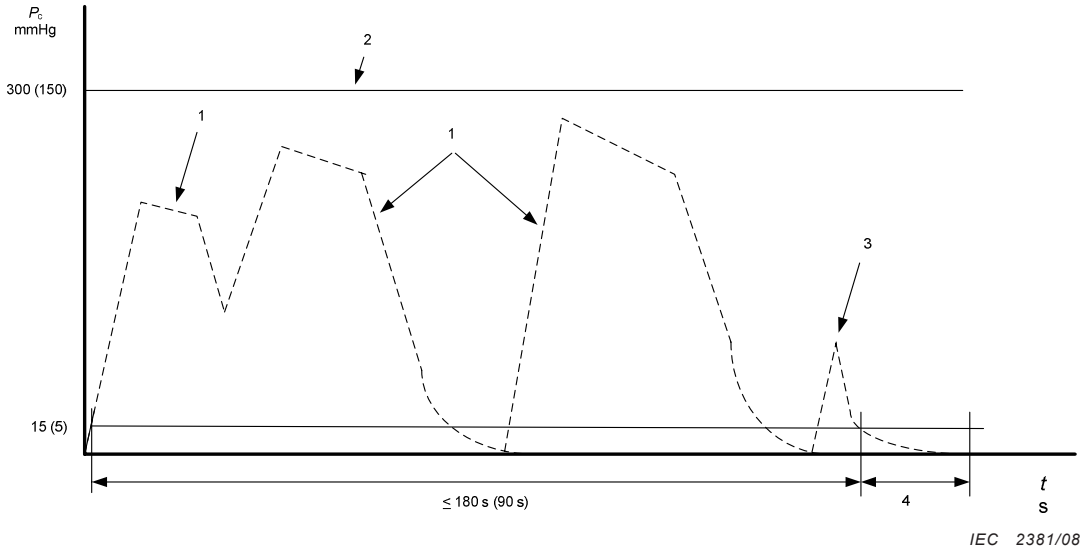
Mode	CUFF pressure
NEONATAL MODE	> 5 mmHg (0,7 kPa)
Any other mode	> 15 mmHg (2,0 kPa)

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) 〖AC〗 in NORMAL CONDITION:

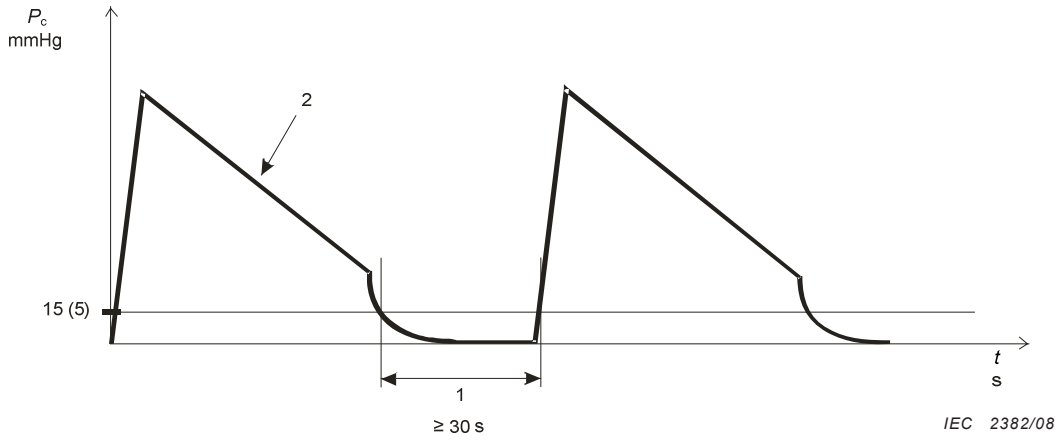
- the total duration of the alternating inflation/deflation periods in an unsuccessful DETERMINATION (see Figure 201.103) shall not exceed the maximum inflation time specified in 201.104; and 〖AC〗
- after each successful DETERMINATION;

  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

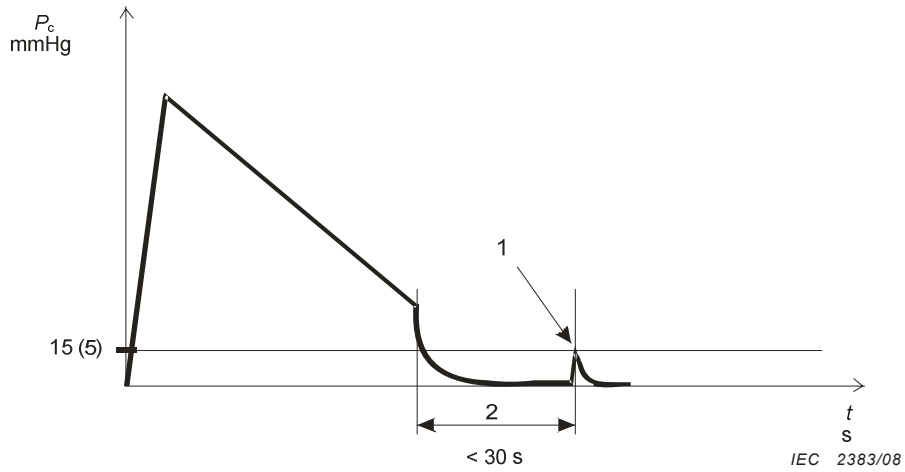
1 Deflated time

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

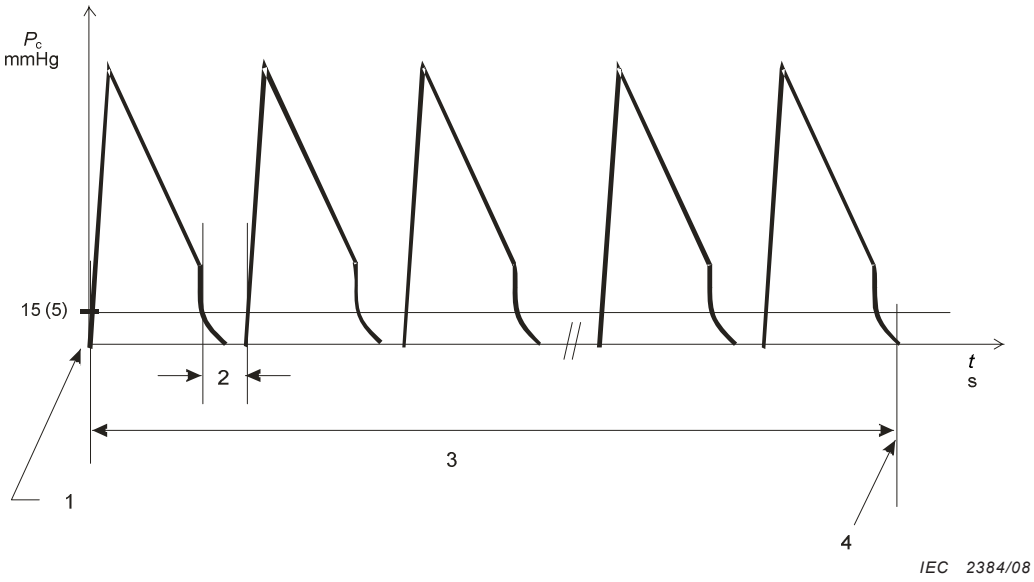
201.105.2 * SHORT-TERM AUTOMATIC MODE

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). [A1] The maximum duration of SELF-MEASUREMENT AUTOMATIC MODE shall not exceed 30 min. [A1] 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.

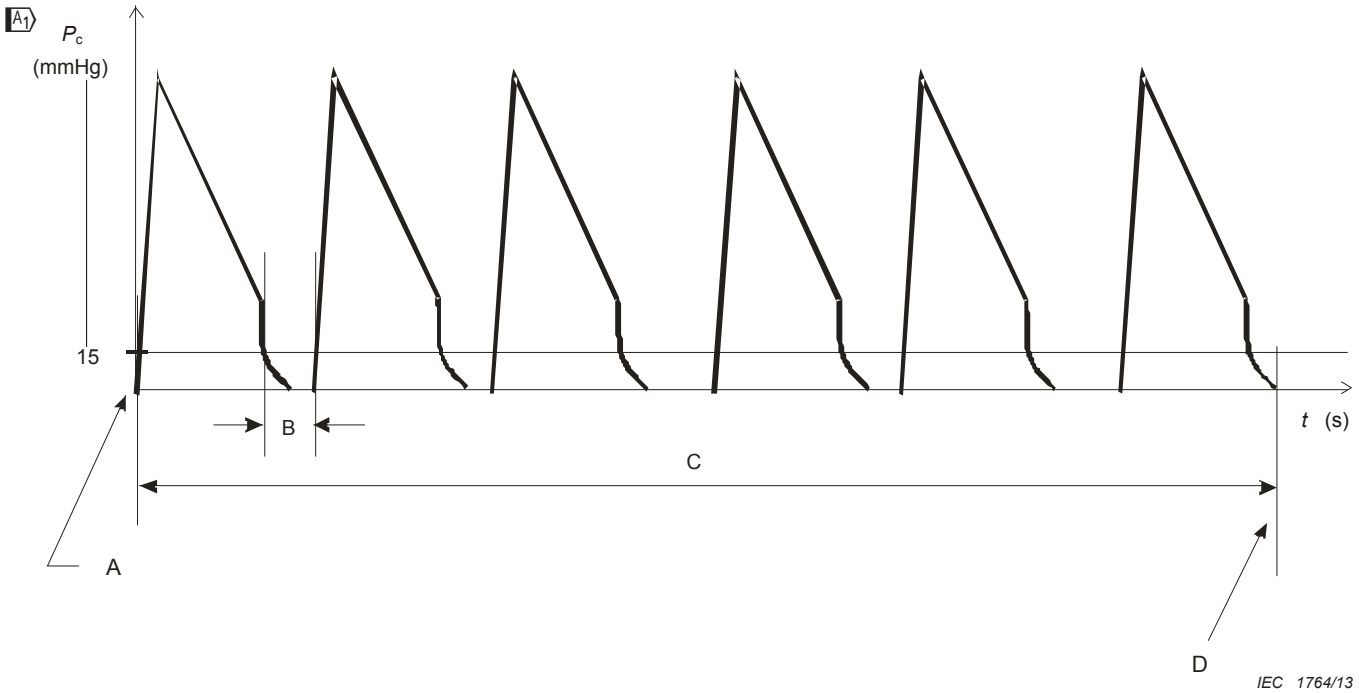
An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall not be intended for use with neonatal or infant PATIENTS. An AUTOMATED SPHYGMOMANOMETER that operates in a SELF-MEASUREMENT AUTOMATIC MODE shall be intended for use where:

– 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

A OPERATOR starts SELF-MEASUREMENT MODE

B Deflated time ≥ 5 s after each DETERMINATION

C SELF-MEASUREMENT MODE limited to 6 DETERMINATIONS

D SELF-MEASUREMENT MODE ends

CUFF pressure, P_c, as a function of time [A1]

Figure 201.107 – SELF-MEASUREMENT AUTOMATIC MODE CUFF pressure

201.105.3.2 NORMAL CONDITION

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

– 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; [AC] and [AC]

[A1] – after each successful DETERMINATION, the CUFF pressure shall be released and shall remain below the pressure values in Table 201.102 for at least 5 s (see Figure 201.107). [A1]

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:

[A1] – if the duration of deflation below the pressure values in Table 201.102 is less than 5 s (see Figure 201.107), then a pressure relief PROTECTION DEVICE functioning independently of the NORMAL CONDITION PROTECTION DEVICE shall release the CUFF pressure to the values in Table 201.102;

– 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). [A1]

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

201.106 * Clinical accuracy

[A1] 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. [A1]

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 ± 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 ± 10 mmHg (13,3/9,3 kPa ± 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 ± 10 mmHg (13,3/9,3 kPa ± 1,3 kPa). On the HF SURGICAL EQUIPMENT select the coagulation mode at 100 W.

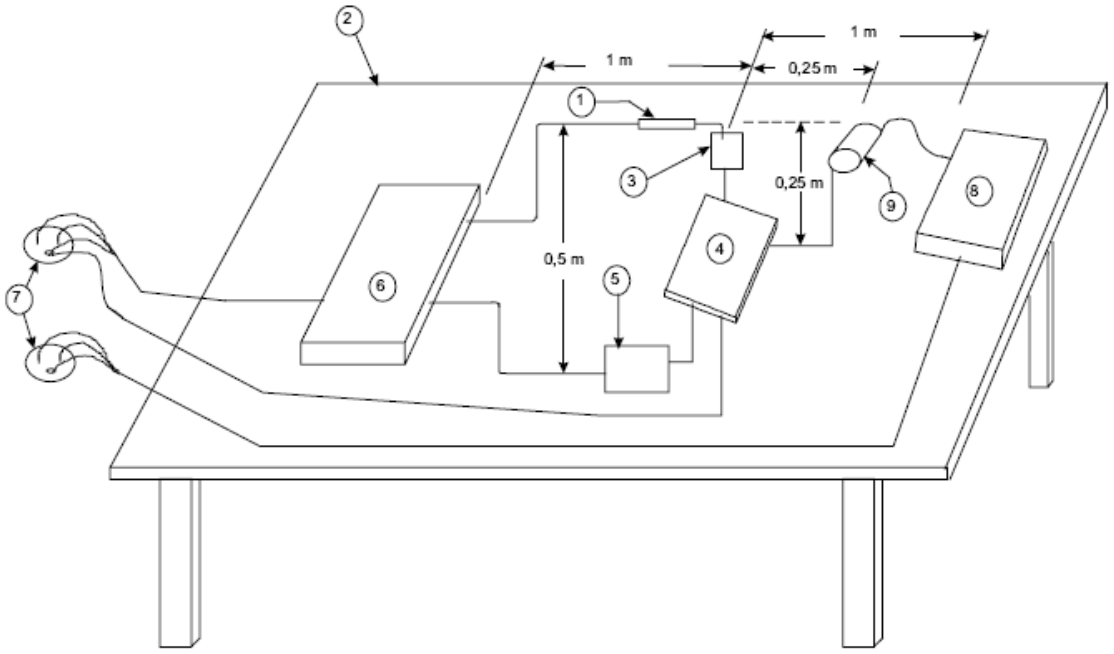
Touch the metal plate in the test setup (see Figure 202.101) with the active electrode and remove the electrode slowly to produce a spark (generate high-frequency interference).

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.



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

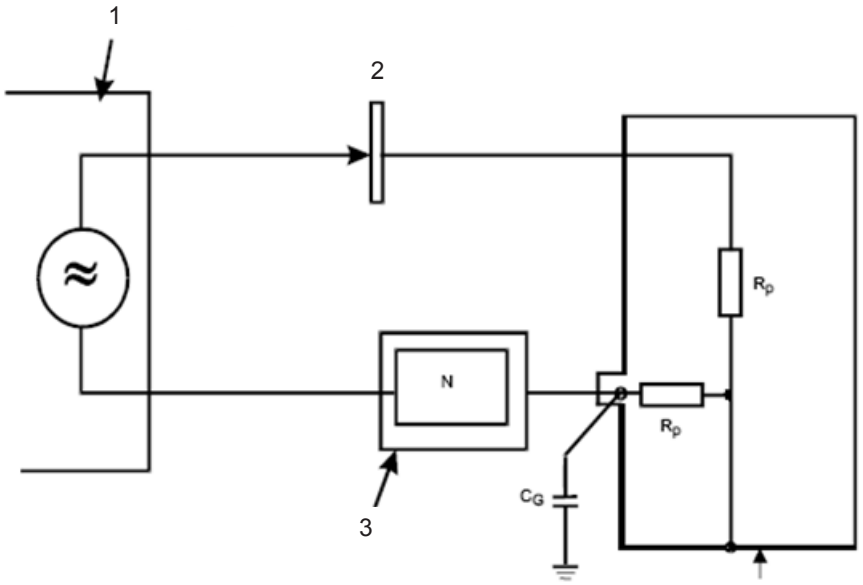
7 SUPPLY MAINS

8 AUTOMATED SPHYGMOMANOMETER under test

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

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

Figure 202.101 – HF SURGICAL EQUIPMENT test layout



Key

1 HF SURGICAL EQUIPMENT

2 Metal plate

3 Metal plate

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

206 USABILITY

IEC 60601-1-6:2010+A1:2013 applies.

211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

IEC 60601-1-11:2010 applies, except as follows:

211.4.2.1 Environmental conditions of transport and storage between uses

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

211.4.2.2 Environmental operating conditions

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

211.7.4.5 Additional requirements for operating instructions

Add the following sentence to the existing text:

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

211.8.3.1 Ingress of water or particulate matter into ME EQUIPMENT

In the second sentence, replace "IP21*" with: "*IP20*".*

Annexes

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

Annex C
(informative)

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

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

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

Addition:

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

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

Description of marking	Subclause
As appropriate, proper disposal methods	201.7.2.106
Correct positioning for the CUFF on the designated limb over the artery	201.7.2.4
〈A1〉 *Text deleted* 〈A1〉	
For public use, adequate operating instructions	201.7.2.104
For public use, the measurement accuracy of the AUTOMATED SPHYGMOMANOMETER	201.7.2.104
For public use, the need to consult a physician for interpretation of BLOOD PRESSURE measurements	201.7.2.104
For public use, precautions for use	201.7.2.104
If applicable, ACCESSORIES intended for use only in the NEONATAL MODE	201.7.2.103
If applicable, caution to the effect that substitution of a component different from that supplied might result in measurement error, or with symbol ISO 7010-M002	201.7.2.105
If applicable, a detailed description of correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2.13
An indication of whether the CUFF is the correct size	201.101.1
The range of limb circumference for which the CUFF is appropriate	201.101.1

201.C.3 Marking of controls and instruments

Addition:

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

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

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

201.C.4 ACCOMPANYING DOCUMENTS, general

Addition:

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

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

Description of disclosure	Subclause
Additional requirements can be found in ISO 81060-2.	201.106

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Addition:

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

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

Description of disclosure	Subclause
An explanation of the operating steps of the AUTOMATED SPHYGMOMANOMETER needed to obtain routine resting BLOOD PRESSURE measurements for the diagnosis of hypertension	201.7.9.2.9 b)
An explanation of the selection of a suitable size and application of the CUFF to the PATIENT	201.7.9.2.9 a)
An explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition	201.7.9.2.9 c)
Details of the environmental or operation factors which can affect the performance of the AUTOMATED SPHYGMOMANOMETER and/or its BLOOD PRESSURE reading	201.7.9.2.9 e)
Details of what the OPERATOR should do if unexpected readings are obtained	201.7.9.2.9 d)
Frequently used functions	201.7.9.2.1
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)
Method for placing into the NEONATAL MODE	201.7.2.103
Permissible environmental conditions of use	201.7.9.2.1
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

Table 201.C.104 *(continued)*

Description of disclosure	Subclause
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 of blood flow and resulting injury to the PATIENT	201.7.9.2.2
Warning regarding applying the CUFF over a wound, as this can cause further injury	201.7.9.2.2
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
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
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
Warning regarding the RISKS of not using the NEONATAL MODE on a neonatal PATIENT	201.7.2.103
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 f)
An explanation of the need to avoid compression or restriction of the connection tubing	201.7.9.2.9 g)
RATED ranges of the DETERMINATION	201.7.9.2.5
RATED range of CUFF pressure	201.7.9.2.9 h)
If applicable, the correct method of reassembly	201.7.9.2.13
If applicable, a detailed description of the correct insertion of the BLADDER into the inelastic part of the CUFF	201.7.9.2.13
If applicable, that the ME EQUIPMENT is suitable for use in the presence of electrosurgery	201.7.9.2.101
If applicable, the protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2.101
If applicable, the absence of protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT	201.7.9.2.101
If applicable, the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in the NEONATAL MODE	201.7.9.2.102
If applicable, the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER can accommodate when in the NEONATAL MODE	201.7.9.2.102
If applicable, recommended ACCESSORIES to avoid errors and excessive pressure	201.7.9.2.102
Description of the operating principles	201.7.9.2.5

201.C.6 ACCOMPANYING DOCUMENTS, technical description

Addition:

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

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

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

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

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

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

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

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

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

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

AA.2 Rationale for particular clauses and subclauses

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

Subclause 201.3.217 – SHORT-TERM AUTOMATIC MODE

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

Subclause 201.7.2.4 – ACCESSORIES

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

Subclause 201.7.2.103 – AUTOMATED SPHYGMOMANOMETERS with NEONATAL MODE

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

Subclause 201.7.2.104 – AUTOMATED SPHYGMOMANOMETERS for public use

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

Subclause 201.7.2.105 – 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, e.g. re-calibration, should occur following such replacements. The marking requirement is intended to give this awareness.

Subclause 201.8.5.5.101 – PATIENT CONNECTIONS of AUTOMATED SPHYGMOMANOMETER

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 Subclause 201.12.1.105 for a discussion of pressure levels and deflation acceptance criterion.

Subclause 201.11.8.103 – INTERNAL ELECTRICAL POWER SOURCE

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

Subclause 201.12.1.103 – NOMINAL BLOOD PRESSURE indication range

This test is a compromise as it is not practicable to perform this test in human subjects since these BLOOD PRESSURE values are extremely rare in clinical care. It is important for AUTOMATED SPHYGMOMANOMETERS to be able to indicate BLOOD PRESSURES above the range over which

they are ⟦A1⟩ clinically investigated ⟨A1⟧. An AUTOMATED SPHYGMOMANOMETER that either blanks or artificially limits the value of the display above that range would 'hide' the condition of the PATIENT from the OPERATOR.

Subclause 201.12.1.105 – Maximum pressure in SINGLE FAULT CONDITION

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

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

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

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

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

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

Subclause 201.12.1.106 – Manometer test mode

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

Subclause 201.12.1.107 – Reproducibility of the BLOOD PRESSURE DETERMINATION

This requirement is designed to demonstrate that an AUTOMATED SPHYGMOMANOMETER continues to have acceptable reproducibility following the environmental stresses of this particular standard. During the development of this particular standard, concern was raised that the simulator used might not have sufficient reproducibility to successfully perform this test. This test PROCEDURE was developed to address this concern. The PROCEDURE allows one to determine 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 for 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 simulator works 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 determine when the test set-up is inadequate.

Steps b) to e) are used to determine 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 criterion is not met, the combination of the simulator and AUTOMATED SPHYGMOMANOMETER has insufficient long-term stability to perform this test PROCEDURE.

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

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

Subclause 201.15.3.5.101 – Shock and vibration for other than transport

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

These tests were chosen by first reviewing the results of the work published in other PATIENT monitoring standards where those committees [1][3] qualitatively assessed the relative severity of the scenarios within various environments (i.e., HOME HEALTHCARE ENVIRONMENT, healthcare institution and professional transport (wings and wheels)), by various sizes and types of ME EQUIPMENT (i.e., HAND-HELD, PORTABLE and MOBILE ME EQUIPMENT).

After that qualitative assessment, those committees assessed the relevant particular standards for environmental testing in the IEC 60068 series and their respective rationales, as well as the IEC 60721 series of guidance documents. In selecting the requirements, those committees reviewed other sources for material related to these tests (e.g., FDA Reviewers Guidance for premarket notification submissions, Mil Std 810, etc) but found the best fit was with the standard IEC 60721-3-7:1995[4)]. There is also a guidance document, IEC TR 60721-4-7:2001[5)], that helps to correlate environmental condition classes of IEC 60721-3 to environmental tests according the IEC 60068 series. The aforementioned standards specify 3 classes of mechanical conditions, 7M1, 7M2 and 7M3. Those committees found that classes 7M1 and 7M3 best represent the conditions seen during PATIENT transport within healthcare facilities and PATIENT transport outside healthcare facilities, respectively. Those committees agreed that different tests and test levels should be applied to ME EQUIMENT intended for use in a healthcare facility versus ME EQUIMENT intended for use during PATIENT transport outside the healthcare facility.

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

Subclause 201.15.3.5.102 – Shock and vibration for transport

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

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

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

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

---

4) IEC 60721-3-7:1995, *Classification of environmental conditions – Part 3: Classification of groups of environmental parameters and their severities – Section 7: Portable and non-stationary use*

5) IEC/TR 60721-4-7:2001, *Classification of environmental conditions – Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 – Portable and non-stationary use*

Subclause 201.101.1 – Construction

This standard does not specify the details of the construction of CUFFS and BLADDERS. Studies [13] [17] [21] have suggested that the appropriate BLADDER size for the placement at the upper arm for auscultatory estimates of BLOOD PRESSURE is one with dimensions such that its width is 40 % of the limb circumference at the maximum range for each CUFF size and its length is 80 % to 100 % of the limb circumference at the centre of the range for each CUFF size. In auscultation, use of the wrong size CUFF can affect the accuracy of the estimates of BLOOD PRESSURE. These recommended dimensions are subject to ongoing consideration. AUTOMATED SPHYGMOMANOMETERS can be designed with different CUFF dimensions.

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

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

Subclause 201.101.2 – Pressurization

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

Subclause 201.104 – Maximum inflating time

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

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

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

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

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

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	[A1] ≤30 min [A1] [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]
[A1] Clinical investigation [A1] (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 [A1] with a 30 min [A1] 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.

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 standard.

Subclause 201.105.2 – SHORT-TERM AUTOMATIC MODE

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

Subclause 201.105.3 – SELF-MEASUREMENT AUTOMATIC MODE

SELF-MEASUREMENTAUTOMATIC 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 [20] recommend that at least 2 DETERMINATIONS should be taken at intervals of at least 1 min, and the average of those DETERMINATIONS should be taken as the PATIENT'S BLOOD PRESSURE.

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

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

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

Subclause 201.105.3.3 – SINGLE FAULT CONDITION

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

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

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

Subclause 201.106 – Clinical accuracy

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

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

Subclause 202.6.2.101 – Electrosurgery interference recovery

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

Annex BB
(informative)

Environmental aspects

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

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

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

– scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this standard 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 standard

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

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

Annex CC
(informative)

Reference to the essential principles

This particular standard has been prepared to support the essential principles of safety and performance of AUTOMATED SPHYGMOMANOMETERS as medical devices according to ISO/TR 16142. This particular standard is intended to be acceptable for conformity assessment purposes.

Compliance with this particular standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible.

See Table CC.1 for a mapping of the clauses and subclauses of this standard to essential principles of ISO/TR 16142:2006.

Table CC.1 – Correspondence between this particular standard and the essential principles

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

Table CC.1 *(continued)*

Corresponding essential principle of ISO/TR 16142:2006	Clause(s)/sub-clause(s) of this International Standard	Qualifying remarks/Notes
A.11.1	201.4, 201.10, 201.12, 201.17, 202	
A.11.2.1	201.4, 201.10, 201.12	
A.11.2.2	201.4, 201.12	
A.11.3	201.4, 201.10, 201.12	
A.11.4	201.4, 201.7	
A.11.5.1	201.4, 201.10, 201.12	
A.11.5.2	201.4, 201.10, 201.12	
A.11.5.3	201.4, 201.10, 201.12	
A.12.1	201.4, 201.14	
A.12.2	201.11.8	
A.12.3	201.4, 201.7, 201.12, 201.11.8	
A.12.4	201.4, 201.7, 201.12	
A.12.5	201.4, 201.17, 202	
A.12.6	201.4, 201.8	
A.12.7.1	201.4, 201.9, 201.15	
A.12.7.2	201.4, 201.9	
A.12.7.3	201.4, 201.9	
A.12.7.4	201.4, 201.8	
A.12.7.5	201.4, 201.8, 201.11, 201.15, 201.16	
A.12.8.1	201.4, 201.12, 201.105	
A.12.8.2	201.4, 201.7, 201.12	
A.12.8.3	201.4, 201.7, 201.12	
A.13.1	201.7, 201.16	
A.14.1	201.4, 201.11, 19	

Bibliography

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

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

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

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

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

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

[7] CELORIA, G., DAWSON, JA., and TERES, D. Compartment syndrome in a patient monitored with an automated pressure cuff. *J Clin Monit*, 1987, 3, pp. 149-141

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

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

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

[11] FDA, *Guidance for Industry and FDA Staff - Premarket Assessment of Pediatric Medical Devices*. May 14, 2004 [6)]

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

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

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

[15] *La prise de la pression artérielle au cabinet médical*. Société Française d'Hypertension Artérielle. 1998

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

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

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

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

6) Available from FDA at http://www.fda.gov/cdrh/ode/1220.pdf

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

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

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

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

Index of defined terms

ACCESSORY ..... IEC 60601-1:2005, 3.3
ALARM CONDITION ..... IEC 60601-1-8:2006, 3.1
ALARM SYSTEM ..... IEC 60601-1-8:2006, 3.11
APPLIED PART ..... IEC 60601-1:2005, 3.8
AUTOMATED SPHYGMOMANOMETER 201.3.201
BASIC SAFETY ..... IEC 60601-1:2005, 3.10
BLADDER 201.3.202
BLOOD PRESSURE 201.3.203
CUFF 201.3.204
DEFIBRILLATION-PROOF APPLIED PART ..... IEC 60601-1:2005, 3.20
DETERMINATION 201.3.205
DIASTOLIC BLOOD PRESSURE (value) 201.3.206
ENCLOSURE ..... IEC 60601-1:2005, 3.26
ESSENTIAL PERFORMANCE ..... IEC 60601-1:2005, 3.27
EXCLUSION BAND ..... IEC 60601-1-2:2007, 3.10
FIXED ..... IEC 60601-1:2005, 3.30
HAND-HELD ..... IEC 60601-1:2005, 3.37
HAZARD ..... IEC 60601-1:2005, 3.39
HAZARDOUS SITUATION ..... IEC 60601-1:2005, 3.40
HF SURGICAL EQUIPMENT ..... IEC 60601-2-2:2009, 201.3.222
HOME HEALTHCARE ENVIRONMENT 201.3.207
IMMUNITY TEST LEVEL ..... IEC 60601-1-2:2007, 3.15
INTERNAL ELECTRICAL POWER SOURCE ..... IEC 60601-1:2005, 3.45
LEAKAGE CURRENT ..... IEC 60601-1:2005, 3.47
LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM ..... IEC 60601-1-2:2007, 3.18
LONG-TERM AUTOMATIC MODE 201.3.208
MANUFACTURER ..... IEC 60601-1:2005, 3.55
MEAN ARTERIAL PRESSURE (value) 201.3.209
MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT) ..... IEC 60601-1:2005, 3.63
MEDICAL ELECTRICAL SYSTEM (ME SYSTEM) ..... IEC 60601-1:2005, 3.64
MEDIUM PRIORITY ..... IEC 60601-1-8:2006, 3.28
MOBILE ..... IEC 60601-1:2005, 3.65
〈A1〉 MODEL OR TYPE REFERENCE ..... IEC 60601-1:2005, 3.66 〈A1〉
NEONATAL MODE 201.3.210
NOMINAL (value) ..... IEC 60601-1:2005, 3.69
NON-AUTOMATED SPHYGMOMANOMETER 201.3.211
NORMAL CONDITION ..... IEC 60601-1:2005, 3.70
NORMAL USE ..... IEC 60601-1:2005, 3.71
OPERATOR ..... IEC 60601-1:2005, 3.73
PATIENT ..... IEC 60601-1:2005, 3.76
PATIENT CONNECTION ..... IEC 60601-1:2005, 3.78

PATIENT SIMULATOR 201.3.212
PHYSIOLOGICAL ALARM CONDITION ..... IEC 60601-1-8:2006, 3.31
PNEUMATIC SYSTEM 201.3.213
PORTABLE ..... IEC 60601-1:2005, 3.85
PRESSURE TRANSDUCER 201.3.214
PROCEDURE ..... IEC 60601-1:2005, 3.88
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS) ..... IEC 60601-1:2005, 3.90
PROTECTION DEVICE 201.3.215
RATED (value) ..... IEC 60601-1:2005, 3.97
RESIDUAL RISK ..... IEC 60601-1:2005, 3.100
RESPONSIBLE ORGANIZATION ..... IEC 60601-1:2005, 3.101
RISK ..... IEC 60601-1:2005, 3.102
RISK CONTROL ..... IEC 60601-1:2005, 3.105
SELF-MEASUREMENT AUTOMATIC MODE 201.3.216
SERVICE PERSONNEL ..... IEC 60601-1:2005, 3.113
SHORT-TERM AUTOMATIC MODE 201.3.217
SINGLE FAULT CONDITION ..... IEC 60601-1:2005, 3.116
SUPPLY MAINS ..... IEC 60601-1:2005, 3.120
SYSTOLIC BLOOD PRESSURE (value) 201.3.218
TECHNICAL ALARM CONDITION ..... IEC 60601-1-8:2006, 3.36
TOOL ..... IEC 60601-1:2005, 3.127
A1 USABILITY ..... IEC 62366:2007, 3.17
USABILITY ENGINEERING FILE ..... IEC 62366:2007, 3.19 A1

This page deliberately left blank

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards -based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email bsmusales@bsigroup.com.

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Copyright

Useful Contacts:

Customer Services
Tel: +44 845 086 9001
Email (orders): orders@bsigroup.com
Email (enquiries): cservices@bsigroup.com

Subscriptions
Tel: +44 845 086 9001
Email: subscriptions@bsigroup.com

Knowledge Centre
Tel: +44 20 8996 7004
Email: knowledgecentre@bsigroup.com

Copyright & Licensing
Tel: +44 20 8996 7070
Email: copyright@bsigroup.com

bsi.

...making excellence a habit.™