



DPC: 16 / 30340380 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 30 March 2016

Origin: International

Latest date for receipt of comments: 25 May 2016

Project No. 2016/00975

Responsible committee: CH/62/4 Electromedical equipment

Interested committees:

Title: Draft BS EN 80601-2-30 Ed 2.0 Medical electrical equipment

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

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

**WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD.
THIS DRAFT IS NOT CURRENT BEYOND 25 May 2016**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <http://standardsdevelopment.bsigroup.com>

Responsible Committee Secretary: **Mrs Philippa Younas (BSI)**
Direct tel: **020 8996 7239**
E-mail: **philippa.younas@bsigroup.com**

 **Documents**
Document Sharing Hub

Introduction

This draft standard is based on international discussions in which the UK has taken an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent standard. There is a high probability that this text could be adopted by CENELEC as a reference document for harmonization or as a European Standard. Recipients of this draft are requested to comment on the text bearing in mind this possibility.

UK Vote

Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

Submission of Comments

- The guidance given below is intended to ensure that all comments receive efficient and appropriate attention by the responsible BSI committee. **Annotated drafts are not acceptable and will be rejected.**
- All comments must be submitted, preferably electronically, to the Responsible Committee Secretary at the address given on the front cover. Comments should be compatible with version 6.0 or version 97 of Microsoft Word for Windows, if possible; otherwise comments in ASCII text format are acceptable. **Any comments not submitted electronically should still adhere to these format requirements.**
- All comments submitted should be presented as given in the example below. Further information on submitting comments and how to obtain a blank electronic version of a comment form are available from the BSI website at:
<http://drafts.bsigroup.com/>

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	(7)
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/ Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

DRAFT INTERNATIONAL STANDARD

IEC/DIS 80601-2-30

ISO/TC 121/SC 3

Secretariat: ANSI

Voting begins on:
2016-03-25

Voting terminates on:
2016-06-25

Medical electrical equipment —

Part 2-30:

Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers

Appareils électromédicaux —

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

ICS: 11.040.10

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.



Reference number
IEC/DIS 80601-2-30:2016(E)
Documents
AVA Document Sharing Hub
© ISO 2016



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

CONTENTS

1		
2	201.1 Scope, object and related standards	8
3	201.2 Normative references	10
4	201.3 Terms and definitions	11
5	201.4 General requirements	13
6	201.5 General requirements for testing ME EQUIPMENT	14
7	201.6 Classification of ME EQUIPMENT and ME SYSTEMS	14
8	201.7 ME EQUIPMENT identification, marking and documents	14
9	201.8 Protection against electrical HAZARDS from ME EQUIPMENT	18
10	201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	18
11	201.10 Protection against unwanted and excessive radiation HAZARDS	18
12	201.11 Protection against excessive temperatures and other HAZARDS	18
13	201.12 Accuracy of controls and instruments and protection against hazardous outputs	19
14	201.13 HAZARDOUS SITUATIONS and fault conditions	23
15	201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	24
16	201.15 Construction of ME EQUIPMENT	24
17	201.16 ME SYSTEMS	25
18	201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	25
19	201.101 Requirements for CUFFS	25
20	201.102 Connection tubing and CUFF connectors	25
21	201.103 Unauthorized access	26
22	201.104 Maximum inflating time	26
23	201.105 Automatic cycling modes	27
24	201.106 Clinical accuracy	31
25	202 Electromagnetic disturbances – Requirements and tests	31
26	206 Usability	34
27	210 Requirements for the development of physiologic closed-loop controllers	34
28	211 Requirements for medical electrical equipment and medical electrical systems	
29	used in the home healthcare environment	35
30	212 Requirements for medical electrical equipment and medical electrical systems	
31	intended for use in the emergency medical services environment	35
32	Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT	
33	and ME SYSTEMS	37
34	Annex AA (informative) Particular guidance and rationale	41
35	Annex BB (informative) Environmental aspects	49
36	Annex CC (informative) Reference to the essential principles	50
37		
38	Figure 201.101 – CUFF pressure PROTECTION DEVICE, triggered by overpressure in	
39	SINGLE FAULT CONDITION	21
40	Figure 201.102 – CUFF pressure PROTECTION DEVICE, triggered by prolonged	
41	overpressure in SINGLE FAULT CONDITION	22
42	Figure 201.103 – CUFF pressure and maximum inflation time, NORMAL CONDITION and	
43	SINGLE FAULT CONDITION	27
44	Figure 201.104 – LONG-TERM AUTOMATIC MODE CUFF pressure in NORMAL CONDITION	28

45	Figure 201.105 – LONG-TERM AUTOMATIC MODE CUFF pressure in SINGLE FAULT CONDITION	28
46	Figure 201.106 – SHORT-TERM AUTOMATIC MODE CUFF pressure	29
47	Figure 201.107 – SELF-MEASUREMENT AUTOMATIC MODE CUFF pressure.....	30
48	Figure 202.101 – HF SURGICAL EQUIPMENT test layout	33
49	Figure 202.102 – Simulated PATIENT test set-up for HF SURGICAL EQUIPMENT	34
50		
51	Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements	13
52	Table 201.102 – CUFF deflation pressure	18
53	Table 201.103 – CUFF inflation pressure	26
54	Table 201.C.101 – Marking on the outside of AUTOMATED SPHYGMOMANOMETERS or their	
55	parts	37
56	Table 201.C.102 – Marking of controls and instruments of AUTOMATED	
57	SPHYGMOMANOMETERS or their parts	38
58	Table 201.C.103 – ACCOMPANYING DOCUMENTS, general information for AUTOMATED	
59	SPHYGMOMANOMETERS	38
60	Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED	
61	SPHYGMOMANOMETERS	38
62	Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description of AUTOMATED	
63	SPHYGMOMANOMETERS	40
64	Table AA.1 – Summary of requirements by mode.....	47
65	Table BB.1 – Environmental aspects addressed by clauses of this standard	49
66	Table CC.1 – Correspondence between this particular standard and the essential	
67	principles	50
68		
69		

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

This edition constitutes a technical revision as well as an alignment with Amendment 1 of both the third edition of IEC 60601-1 and IEC 60601-1-8 and the fourth edition of IEC 60601-1-2.

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

- a) un-dating the references to the general standard and collateral standards and updates, as appropriate, for the newest versions of these standards;
- b) referencing IEC 60601-1-10 and IEC 60601-1-12;

- 126 c) changing an OPERATOR-accessible CUFF-sphygmomanometer connector from not
 127 compatible with the ISO 594 series to compatible with the ISO 80369 series;
 128 d) added additional requirements for public self-use sphygmomanometers; and
 129 e) added a list of PRIMARY OPERATING FUNCTIONS.

130 This publication is published as a double logo standard.

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

132 In this standard, the following print types are used:

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

139 In referring to the structure of this standard, the term

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

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

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

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

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

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

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

160

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability 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.

The National Committees are requested to note that for this publication the stability date is 2022.

THIS TEXT IS INCLUDED FOR THE INFORMATION OF THE NATIONAL COMMITTEES AND WILL BE DELETED AT THE PUBLICATION STAGE.

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

183

INTRODUCTION

184 The minimum safety requirements specified in this particular standard are considered to
185 provide for a practical degree of safety in the operation of an AUTOMATED
186 SPHYGMOMANOMETER.

187 The requirements are followed by specifications for the relevant tests.

188 Following the decision taken by subcommittee 62D at the meeting in Washington DC in 1979,
189 a "General guidance and rationale" section giving some explanatory notes, where appropriate,
190 about the more important requirements is included in Annex AA.

191 It is considered that knowledge of the reasons for these requirements will not only facilitate
192 the proper application of the standard but will, in due course, expedite any revision
193 necessitated by changes in clinical practice or as a result of developments in technology.
194 However, this annex does not form part of the requirements of this standard.

195

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

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

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

This 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 estimation of the BLOOD PRESSURE without arterial puncture ME EQUIPMENT with an electrically-powered PRESSURE TRANSDUCER and/or displays used in conjunction with a stethoscope or other manual methods for determining BLOOD PRESSURE (NON-AUTOMATED SPHYGMOMANOMETERS) are specified in document ISO 81060-1. [1]²⁾

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this 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:

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

²⁾ Figures in square brackets refer to the Bibliography.

232 The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL
233 PERFORMANCE requirements for an AUTOMATED SPHYGMOMANOMETER as defined in 201.3.201.

234 **201.1.3 Collateral standards**

235 *Addition:*

236 This particular standard refers to those applicable collateral standards that are listed in
237 Clause 2 of IEC 60601-1 and Clause 2 of this particular standard.

238 IEC 60601-1-2, IEC 60601-1-11 and IEC 60601-1-12 apply as modified in Clauses 202, 211
239 and 212 respectively. IEC 60601-1-3 does not apply. All other published collateral standards
240 in the IEC 60601-1 series apply as published.

241 **201.1.4 Particular standards**

242 *Replacement:*

243 In the IEC 60601 series, particular standards may modify, replace or delete requirements
244 contained in the general standard and its collateral standards as appropriate for the particular
245 ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL
246 PERFORMANCE requirements.

247 A requirement of a particular standard takes priority over the general standard.

248 For brevity, IEC 60601-1 is referred to in this particular standard as the general standard.
249 Collateral standards are referred to by their document number.

250 The numbering of clauses and subclauses of this particular standard corresponds to that of
251 the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content
252 of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x"
253 where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this
254 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard,
255 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral
256 standard, etc.). The changes to the text of the general standard are specified by the use of
257 the following words:

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

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

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

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

269 Subclauses or figures which are additional to those of a collateral standard are numbered
270 starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-
271 1-2, 203 for IEC 60601-1-3, etc.

272 The term "this standard" is used to make reference to the general standard, any applicable
273 collateral standards and this particular standard taken together.

274 Where there is no corresponding clause or subclause in this particular standard, the clause or
275 subclause of the general standard or applicable collateral standard, although possibly not
276 relevant, applies without modification; where it is intended that any part of the general
277 standard or applicable collateral standard, although possibly relevant, is not to be applied, a
278 statement to that effect is given in this particular standard.

279 **201.2 Normative references**

280 NOTE Informative references are listed in the bibliography beginning on page 52.

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

282 *Addition:*

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

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

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

289 IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic*
290 *safety and essential performance – Collateral standard: Requirements for the development of*
291 *physiologic closed-loop controllers*

292 IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic*
293 *safety and essential performance – Collateral standard: Requirements for medical electrical*
294 *equipment and medical electrical systems used in the home healthcare environment*

295 IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic*
296 *safety and essential performance – Collateral standard: Requirements for medical electrical*
297 *equipment and medical electrical systems used in the emergency medical services*
298 *environment*

299 IEC 60601-2-2:2009, *Medical electrical equipment – Part 2-2: Particular requirements for the*
300 *basic safety and essential performance of high frequency surgical equipment and high*
301 *frequency surgical accessories*

302 IEC 62366-1:2015, *Medical devices – Application of usability engineering to medical devices*

303 IEC 80369-1:2016³⁾, *Small-bore connectors for liquids and gases in healthcare applications --*
304 *Part 1: General requirements*

305 IEC 80369-5:2016⁴⁾, *Small-bore connectors for liquids and gases in healthcare applications --*
306 *Part 5: Connectors for limb cuff inflation applications*

3) To be published.

4) To be published.

307 ISO 81060-2:2013, *Non-invasive sphygmomanometers – Part 2: Clinical investigation of*
 308 *automated measurement type*

309 **201.3 Terms and definitions**

310 For the purposes of this document, the terms and definitions given in IEC 60601-1,
 311 IEC 60601-1-8, IEC 60601-2-2:2009 and IEC 62366-1:2015 apply, except as follows:

312 NOTE An index of defined terms is found beginning on page 54.

313 *Addition:*

314 **201.3.201**

315 **AUTOMATED SPHYGMOMANOMETER**

316 ME EQUIPMENT used for the non-invasive estimation of the BLOOD PRESSURE by utilizing an
 317 inflatable CUFF, a PRESSURE TRANSDUCER, a valve for deflation, and/or displays used in
 318 conjunction with automatic methods for determining BLOOD PRESSURE

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

322 **201.3.202**

323 **BLADDER**

324 part of the CUFF that is inflatable

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

326 **201.3.203**

327 **BLOOD PRESSURE**

328 pressure in the systemic arterial system of the body

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

330 **201.3.204**

331 **CUFF**

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

333 NOTE A CUFF usually comprises a BLADDER and an inelastic part that encloses the BLADDER, or has an integral
 334 BLADDER (i.e., the CUFF, including the BLADDER, is one piece).

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

336 **201.3.205**

337 **DETERMINATION (value)**

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

339 **201.3.206**

340 **DIASTOLIC BLOOD PRESSURE (value)**

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

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

343 **201.3.207**

344 **HOME HEALTHCARE ENVIRONMENT**

345 dwelling place in which a PATIENT lives or other places where PATIENTS are present, excluding
 346 professional healthcare facility environments where OPERATORS with medical training are
 347 continually available when PATIENTS are present

348 NOTE 1 Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental
 349 offices, freestanding birthing centres, limited care facilities, multiple treatment facilities and emergency medical
 350 services.

351 NOTE 2 For the purpose of this particular standard, nursing homes are considered the HOME HEALTHCARE
 352 ENVIRONMENT.

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

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

355 [SOURCE: IEC 60601-1-11:2015), definition 3.1]

356 **201.3.208**

357 **LONG-TERM AUTOMATIC MODE**

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

359 **201.3.209**

360 **MEAN ARTERIAL PRESSURE (value)**

361 value of the integral of one heartbeat cycle of the BLOOD PRESSURE curve divided by the time
 362 of that cycle

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

364 **201.3.210**

365 **NEONATAL MODE**

366 mode of AUTOMATED SPHYGMOMANOMETER for use with neonates or infants

367 NOTE 1 The approximate age range for a newborn (neonate) is from birth to 1 month. [2][3]

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

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

372 **201.3.211**

373 **NON-AUTOMATED SPHYGMOMANOMETER**

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

377 NOTE Components of these instruments include manometer, CUFF, valve for deflation (often in combination with
 378 the valve for rapidly exhausting the PNEUMATIC SYSTEM), hand pump or electro-mechanical pump for inflation of the
 379 BLADDER, and connection tubing. A NON-AUTOMATED SPHYGMOMANOMETER can also contain electro-mechanical
 380 components for pressure control.

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

382 **201.3.212**

383 **PATIENT SIMULATOR**

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

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

387 **201.3.213**

388 **PNEUMATIC SYSTEM**

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

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

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

393 **201.3.214**
 394 **PRESSURE TRANSDUCER**
 395 component that transforms sensed pressure into an electrical signal

396 **201.3.215**
 397 **PROTECTION DEVICE**
 398 part of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from
 399 hazardous output due to incorrect delivery of energy or substances

400 **201.3.216**
 401 **SELF-MEASUREMENT AUTOMATIC MODE**
 402 mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated and overseen by the
 403 OPERATOR and in which a limited number of repeated DETERMINATIONS are made over a finite
 404 period

405 **201.3.217**
 406 *** SHORT-TERM AUTOMATIC MODE**
 407 mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated by the OPERATOR and in
 408 which rapid repetitive automatic DETERMINATIONS are made within a specified time period

409 **201.3.218**
 410 **SYSTOLIC BLOOD PRESSURE** (value)
 411 maximum value of the BLOOD PRESSURE as a result of the contraction of the systemic ventricle

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

413 **201.4 General requirements**

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

415 **201.4.3 ESSENTIAL PERFORMANCE**

416 *Additional subclause:*

417 **201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements**

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

420 **Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements**

Requirement	Subclause
Electrosurgery interference recovery	202.8.101
Limits of the error of the manometer ^a , or generation of a TECHNICAL ALARM CONDITION	201.12.1.102 201.11.8.102 201.12.1.101
Reproducibility of the BLOOD PRESSURE DETERMINATION and low and high BLOOD PRESSURE PHYSIOLOGICAL ALARM CONDITIONS (if provided), or generation of a TECHNICAL ALARM CONDITION	201.12.1.107 201.12.3.101 201.11.8.102 201.12.1.101
^a 202.8.1.101 indicates methods of evaluating limits of the error of the manometer as acceptance criteria following specific tests required by ISO 80601 series.	

421 **201.5 General requirements for testing ME EQUIPMENT**

422 Clause 5 of the general standard applies.

423 **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

424 Clause 6 of the general standard applies.

425 **201.7 ME EQUIPMENT identification, marking and documents**

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

427 **201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**

428 **201.7.2.4 * ACCESSORIES**

429 *Addition:*

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

432 *Additional subclauses:*

433 **201.7.2.101 Display of AUTOMATED SPHYGMOMANOMETERS**

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

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

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

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

441 **201.7.2.102 * AUTOMATED SPHYGMOMANOMETERS with NEONATAL MODE**

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

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

452 **201.7.2.103 * AUTOMATED SPHYGMOMANOMETERS intended for self-use in public areas**

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

- a) precautions for use, including a statement concerning the need to consult a physician for interpretation of BLOOD PRESSURE values;
- b) adequate operating instructions; and
- c) this sphygmomanometer complies with IEC 80601-2-30:2016.

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

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

- d) the range of arm circumference for which the CUFF is intended – specifically minimum and maximum upper arm (midpoint) circumference thresholds in centimetres and in inches; and
- e) a statement to the effect that results might not be accurate if your arm is outside specified circumference range.

201.7.2.104 * Component replacement

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

EXAMPLES CUFF, microphone, connection tube, external power supply

201.7.2.105 Disposal

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

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

201.7.9.2 Instructions for use

201.7.9.2.1 General

Replacement of the 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; and

- 5) intended conditions of use

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