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Date: 10 February 2025

Origin: International

Latest date for receipt of comments: 2 April 2025

Project No. 2022/00639

Responsible committee: CH/62/4 Particular medical equipment, software, and systems

Interested committees:

Title: BS EN IEC 80601-2-30 Medical electrical equipment

Part 2-30: Particular requirements for the 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

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THIS DRAFT IS NOT CURRENT BEYOND 2 April 2025**

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.**

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (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.	



PROJECT NUMBER: IEC 80601-2-30 ED3	
DATE OF CIRCULATION: 2025-02-07	CLOSING DATE FOR VOTING: 2025-05-02
SUPERSEDES DOCUMENTS: 62D/1946/RR	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: Safety	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant "In Some Countries" clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

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

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

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

- a) a clarified definition of neonate and infant and associated modes;

- b) relabeling of some primary operating functions;
- c) additional requirements for monitoring equipment to avoid the misuse of misleading or “stale” data;
- d) updated normative references to the current versions where applicable.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 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) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. 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: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and of subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This third edition cancels and replaces the second edition published in 2018. This edition constitutes a technical revision.

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

- a) a clarified definition of neonate and infant and associated modes;
- b) relabeling of some primary operating functions;
- c) additional requirements for monitoring equipment to avoid the misuse of misleading or "stale" data;
- d) updated normative references to the current versions where applicable.

This publication is published as a double logo standard.

The text of this document is based on the following documents of IEC:

FDIS	Report on voting
62D/1548/FDIS	62D/1560/RVD

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 14 P members out of 15 having cast a vote.

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

In this document, the following print types are used:

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

In referring to the structure of this document, the term

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

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

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

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
- "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 D (informative)

Application Programming Interface Framework

D.1 General guidance

This annex provides a minimal informative framework for Electronic Automated Blood Pressure device digital connectivity. It is common for health monitoring devices that are being used at all levels of patient acuity to be "connected" for the purpose of direct transmission of device data to a distant dashboard, electronic medical record and even from the patient's home to their health provider. In this annex, the term Application Programming Interface (API) is used in its most generic sense, representing the flow of data and commands to and from a device that provides connectivity and has NIBP determination capability. A conceptual API is presented without specifics of data structures or communication protocols. The annex is intended to serve as a starting point for discussion about the design of an API for an NIBP device. It is by no means a comprehensive or required framework but a starting point, listing basic functionality that an NIBP API should consider. There is no intention to provide a comprehensive model for an API that meets all the needs of all server/client interactions. Nor is there any intention to imply that the implementation of this API framework will provide any level of market acceptance or interoperability of NIBP devices.

The committee presents the following minimum set of API functionality for your consideration in the development of connected NIBP devices:

API shall include

- Start BP reading
- Stop BP reading
- Abort an NIBP cycle
- Get NIBP results - sys, dia, HR ,MAP, Error code
- Set BP mode to Neonate
- Set BP mode to Pediatric (if applicable)
- Set BP mode to Adult
- Set BP mode to special.
- Reset the API
- Set API Parameters (protocol, Baud ...)
- Control Pump
- Control valve
- Calibrate or cal-check pressure transducers
- Capability to support testing of single-fault failsafe components and controls

Annex AA.

A list of all parts of the 80601 International standard, published under the general title *Medical electrical equipment*, can be found on the IEC website.

209 The committee has decided that the contents of this publication will remain unchanged until
210 the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data
211 related to the specific publication. At this date, the publication will be

- 212 • reconfirmed,
- 213 • withdrawn,
- 214 • replaced by a revised edition, or
- 215 • amended.

216

217 NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing
218 organizations may need a transitional period following publication of a new, amended or revised IEC publication in
219 which to make products in accordance with the new requirements and to equip themselves for conducting new or
220 revised tests. It is the recommendation of the committees that the content of this publication be adopted for
221 implementation nationally not earlier than 3 years from the date of publication.

222

223

224

INTRODUCTION

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

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

228 Following the decision taken by subcommittee 62D at the meeting in Washington DC in 1979,
229 a "General guidance and rationale" section giving some explanatory notes, where appropriate,
230 about the more important requirements is included in Annex AA. It is considered that
231 knowledge of the reasons for these requirements will not only facilitate the proper application
232 of the standard but will, in due course, expedite any revision necessitated by changes in
233 clinical practice or because of developments in technology. However, the Annex AA does not
234 form part of the requirements of this document.

235

236

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 applies, except as follows:

201.1.1 Scope

Replacement:

This part of the 80601 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of AUTOMATED SPHYGMOMANOMETERS, hereafter referred to as ME EQUIPMENT, which by means of an inflatable CUFF, are used for non-continuous indirect estimation of the BLOOD PRESSURE without arterial puncture.

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

This document specifies requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE for this ME EQUIPMENT and its ACCESSORIES, including the requirements for the accuracy of BLOOD PRESSURE DETERMINATION.

This document covers automatic electrically-powered ME EQUIPMENT used for the intermittent, indirect estimation of the BLOOD PRESSURE without arterial puncture, including BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT.

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

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

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 201.11 and 201.105.3.3, as well as 7.2.13 and 8.4.1 of IEC 60601-1:2022.

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.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

278 IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 apply
279 as modified in Clauses 202, 206, 210, 211 and 212 respectively. IEC 60601-1-3 [3] does not
280 apply. All other published collateral standards in the IEC 60601-1 series apply as
281 published [1] [4].

282 **201.1.4 Particular standards**

283 *Replacement:*

284 In the IEC 60601 series, particular standards may modify, replace or delete requirements
285 contained in the general standard and collateral standards as appropriate for the particular
286 ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL
287 PERFORMANCE requirements.

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

289 For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this
290 particular standard as the general standard. Collateral standards are referred to by their
291 document number.

292 The numbering of clauses and subclauses of this particular standard correspond to that of the
293 general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of
294 Clause 1 of the general standard) or applicable collateral standard with the prefix "20x",
295 where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this
296 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral
297 standard, 203.4 in this particular standard addresses the content of Clause 4 of the
298 IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are
299 specified by the use of the following words:

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

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

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

306 Subclauses, figures or tables which are additional to those of the general standard are
307 numbered starting from 201.101. However, due to the fact that definitions in the general
308 standard are numbered 3.1 through 3.147, additional definitions in this document are
309 numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and
310 additional items aa), bb), etc.

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

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

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

321 **201.2 Normative references**

322 NOTE Informative references are listed in the bibliography beginning on page 56.

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

324 *Replacement:*

325 IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic*
326 *safety and essential performance – Collateral Standard: Electromagnetic disturbances –*
327 *Requirements and tests*
328 IEC 60601-1-2:2014/AMD 1:2020

329 IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic*
330 *safety and essential performance – Collateral standard: Usability*
331 IEC 60601-1-6:2010/AMD 1:2013
332 IEC 60601-1-6:2010/AMD 2:2020

333 *Addition:*

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

336 IEC 60068-2-64:2008+AMD1:2019, *Environmental testing – Part 2-64: Tests – Test Fh:*
337 *Vibration, broad-band random and guidance*

338 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic*
339 *safety and essential performance*
340 IEC 60601-1:2005/AMD 1:2012

341 IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for*
342 *basic safety and essential performance – Collateral Standard: Requirements for the*
343 *development of physiologic closed-loop controllers*
344 IEC 60601-1-10:2007/AMD1:2013
345 IEC 60601-1-10:2007/AMD2:2020

346 IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for*
347 *basic safety and essential performance – Collateral Standard: Requirements for medical*
348 *electrical equipment and medical electrical systems used in the home healthcare environment*
349 IEC 60601-1-11:2015/AMD1:2020

350 IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for*
351 *basic safety and essential performance – Collateral Standard: Requirements for medical*
352 *electrical equipment and medical electrical systems intended for use in the emergency*
353 *medical services environment*
354 IEC 60601-1-12:2014/AMD1:2020

355 IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the*
356 *basic safety and essential performance of high frequency surgical equipment and high*
357 *frequency surgical accessories*
358 IEC 60601-2-2:2017/AMD1:2023

359 IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical*
360 *devices*
361 IEC 62366-1:2015/AMD1:2020

362 IEC 80369-5:2016, *Small-bore connectors for liquids and gases in healthcare applications –*
363 *Part 5: Connectors for limb cuff inflation applications*

364 ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications –*
365 *Part 1: General requirements*

366 ISO 81060-2:—¹, *Non-invasive sphygmomanometers – Part 2: Clinical investigation of*
367 *automated measurement type*

368 **201.3 Terms and definitions**

369 For the purposes of this document, the terms and definitions given in IEC 60601-1,
370 IEC 60601-1-8, IEC 60601-2-2:2017, IEC 60601-2-2:2017/AMD1:2023, IEC 62366-1:2015 and
371 IEC 62366-1:2015/AMD1:2020 and the following apply.

372 ISO and IEC maintain terminological databases for use in standardization at the following
373 addresses:

- 374 • IEC Electropedia: available at <http://www.electropedia.org/>
- 375 • ISO Online browsing platform: available at <http://www.iso.org/obp>

376 NOTE An index of defined terms is found beginning on page 59.

377 *Addition:*

378 **201.3.201**

379 **AUTOMATED SPHYGMOMANOMETER**

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

383 Note 1 to entry: Components of an AUTOMATED SPHYGMOMANOMETER include manometer, CUFF, valve for deflation
384 (often in combination with the valve for rapidly exhausting the PNEUMATIC SYSTEM), pump for inflation of the
385 BLADDER, and connection tubing.

386 **201.3.202**

387 **CUFF**

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

389 Note 1 to entry: A CUFF usually comprises a BLADDER and an inelastic part that encloses the BLADDER, or has an
390 integral BLADDER (i.e., the CUFF, including the BLADDER, is one piece).

391 [SOURCE: ISO 81060-1:2007 [2], 3.5, modified – In the definition, "non-automated" has been
392 replaced by "automated", and in the Note 1 to entry "might comprise" has been replaced by
393 "usually comprises".]

394 **201.3.203**

395 **DETERMINATION**

396 **DETERMINATION VALUE**

397 result of the PROCESS of estimating BLOOD PRESSURE by the AUTOMATED SPHYGMOMANOMETER

398 **201.3.204**

399 **DIASTOLIC BLOOD PRESSURE**

400 **DIASTOLIC BLOOD PRESSURE VALUE**

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

402 Note 1 to entry: Because of hydrostatic effects, this value should be determined with the CUFF at the same
403 elevation as the heart (phlebostatic axis).

¹ New revision under preparation. Stage at the time of publication: ISO/xx 80601-2:20xx.

404 201.3.205**405 LONG-TERM AUTOMATIC MODE**

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

407 201.3.206**408 MEAN ARTERIAL PRESSURE****409 MEAN ARTERIAL PRESSURE VALUE**

410 value of the integral of one heartbeat cycle of the BLOOD PRESSURE curve divided by the time
411 of that cycle

412 Note 1 to entry: Because of hydrostatic effects, this value should be determined with the transducer at the same
413 elevation as the heart (phlebostatic axis).

414 201.3.207**415 NEONATAL MODE**

416 mode of an AUTOMATED SPHYGMOMANOMETER intended for use on neonate patients

417 Note 1 to entry: Some devices are designed to utilise a mode called "Neonatal Mode" that includes infants as well
418 as neonates.

419 Note 2 to entry: The approximate age range for a newborn (neonate) is from birth to 1 month [5] [6].

420 Note 3 to entry: The approximate age range for an infant is commonly from 1 month to 2 years [5] [6]. For the
421 purposes of this document, up to 3 years of age are considered infants (see ISO 81060-2:20xx, 6.1.3).

422 Note 4 to entry: The NEONATAL MODE is used to limit the maximum pressure to 150 mmHg and often has a
423 neonate-specific algorithm that is different than algorithms intended for older PATIENTS.

424 201.3.208**425 NON-AUTOMATED SPHYGMOMANOMETER**

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

429 Note 1 to entry: Components of these instruments include a manometer, CUFF, valve for deflation (often in
430 combination with the valve for rapidly exhausting the PNEUMATIC SYSTEM), hand pump or electro-mechanical pump
431 for inflation of the BLADDER, and connection tubing. A NON-AUTOMATED SPHYGMOMANOMETER can also contain
432 electro-mechanical components for cuff pressure control.

433 [SOURCE: ISO 81060-1:2007 [2], 3.11, modified – The definition and the note to entry have
434 been rephrased.]

435 201.3.209**436 PATIENT SIMULATOR**

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

439 Note 1 to entry: This equipment is not used for testing clinical accuracy but is used in assessing stability of
440 performance.

441 201.3.210**442 PNEUMATIC SYSTEM**

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

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

446 [SOURCE: ISO 81060-1:2007 [2], 3.16, modified – In the definition, replacement of "non
447 automated" by "automated", and in the examples, addition of "pressure".]

448 201.3.211**449 PRESSURE TRANSDUCER**

450 component that transforms sensed pressure into an electrical signal

451 **201.3.212**
 452 **PROTECTION DEVICE**
 453 part of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from
 454 hazardous output due to incorrect delivery of energy or substances

455 **201.3.213**
 456 *** SELF-MEASUREMENT AUTOMATIC MODE**
 457 mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated and overseen by the
 458 OPERATOR and in which a limited number of repeated DETERMINATIONS are made over a finite
 459 period of time

460 Note 1 to entry: This mode is also referred to as "blood pressure averaging mode".

461 **201.3.214**
 462 *** SHORT-TERM AUTOMATIC MODE**
 463 mode of AUTOMATED SPHYGMOMANOMETER that is manually initiated by the OPERATOR and in
 464 which rapid repetitive, automatic DETERMINATIONS are made within a specified time period

465 **201.3.215**
 466 *** STALE DATA**
 467 data status where too much time has elapsed since the displayed determination was
 468 performed for it to be relevant or reliable for use in the clinical circumstance

469 Note 1 to entry: A stale data indication alerts the user that stale data is being displayed.

470 **201.3.216**
 471 **SYSTOLIC BLOOD PRESSURE**
 472 **SYSTOLIC BLOOD PRESSURE VALUE**
 473 maximum value of the BLOOD PRESSURE as a result of the contraction of the systemic ventricle

474 Note 1 to entry: Because of hydrostatic effects, this value should be determined with the CUFF at the level of the
 475 heart.

476 **201.4 General requirements**

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

478 **201.4.3 ESSENTIAL PERFORMANCE**

479 *Additional subclause:*

480 **201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements**

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

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

Requirement	Subclause
Electrosurgery interference recovery	202.8.101
Limits of the error of the manometer ^a , or generation of a TECHNICAL ALARM CONDITION	201.12.1.102 201.11.8.102 201.12.1.101
Reproducibility of the BLOOD PRESSURE DETERMINATION and low and high BLOOD PRESSURE PHYSIOLOGICAL ALARM CONDITIONS (if provided), or generation of a TECHNICAL ALARM CONDITION	201.12.1.107 201.12.3.101 201.11.8.102 201.12.1.101

^a 202.8.1.101 d) indicates methods of evaluating limits of the error of the manometer as acceptance criteria following specific tests required by this document.

484

485 **201.5 General requirements for testing ME EQUIPMENT**

486 Clause 5 of the general standard applies.

487 **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

488 Clause 6 of the general standard applies.

489 **201.7 ME EQUIPMENT identification, marking and documents**

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

491 **201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**

492 **201.7.2.4 * ACCESSORIES**

493 *Addition:*

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

496 *Additional subclauses:*

497 **201.7.2.101 Display of AUTOMATED SPHYGMOMANOMETERS**

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

- 499 – "S" or "SYS" for the value of SYSTOLIC BLOOD PRESSURE;
- 500 – "D" or "DIA" for the value of DIASTOLIC BLOOD PRESSURE;
- 501 – "M" or "MAP" for the value of MEAN ARTERIAL PRESSURE.

502 Single letter abbreviations shall be positioned in such a way as to avoid confusion with
503 SI units.

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

505 **201.7.2.102 * AUTOMATED SPHYGMOMANOMETER with NEONATAL MODE**

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

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

516 201.7.2.103 * AUTOMATED SPHYGMOMANOMETER intended for self-use in public areas

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

- 519 a) precautions for use, including a statement concerning the need to consult a physician for
520 interpretation of BLOOD PRESSURE values;
- 521 b) adequate operating instructions; and
- 522 c) this sphygmomanometer complies with IEC 80601-2-30:2017.

523 EXAMPLES Self-measurement station in a pharmacy, fitness centre, workplace intended for use by the general
524 population without professional assistance.

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

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

532 201.7.2.104 * Component replacement

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

539 EXAMPLES CUFF, microphone, connection tube, external power supply

540 201.7.2.105 Disposal

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

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

544 201.7.9.2 Instructions for use**545 201.7.9.2.1 General**

546 *Replacement of the first three dashed items:*

- 547 – the use of the AUTOMATED SPHYGMOMANOMETER as intended by the MANUFACTURER, and in
548 particular:

- 549 1) intended medical indication;

550 EXAMPLE 1 Condition(s) or disease(s) to be screened for, monitored, treated, diagnosed, or prevented.

- 551 2) any known restrictions on use or contraindication(s) to the use of the AUTOMATED
552 SPHYGMOMANOMETER;

553 EXAMPLE 2 AUTOMATED SPHYGMOMANOMETER for use in an ambulance or helicopter, for use in the HOME
554 HEALTHCARE ENVIRONMENT, for use with neonatal or pre-eclamptic PATIENTS.

- 555 3) intended PATIENT population, including whether or not the AUTOMATED
556 SPHYGMOMANOMETER is intended:

- 557 i) for use with neonatal PATIENTS,

- 558 ii) for use with pregnant, including pre-eclamptic, PATIENTS;