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# American National Standard



ANSI/AAMI/  
IEC 80601-2-

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30:2018

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Medical electrical  
equipment—Part 2-30:  
Particular requirements for  
basic safety and essential  
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American National Standard

**ANSI/AAMI/IEC 80601-2-30:2018**  
(Revision to ANSI/AAMI/IEC 80601-2-30:2009 + A1:2013)



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

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Approved 21 November 2018 by  
**AAMI**

Approved 11 January 2019 by  
**American National Standards Institute, Inc.**

**Abstract:** Applies to basic safety and essential performance of automated sphygmomanometers which are used for the non-invasive blood pressure measurement.

**Keywords:** automated sphygmomanometer, blood pressure, non-automated sphygmomanometer, non-invasive blood pressure measurement

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## Committee representation

### Association for the Advancement of Medical Instrumentation Sphygmomanometers Device Committee

The adoption of IEC 80601-2-30 as a revision to an existing national standard, ANSI/AAMI/IEC 80601-2-30:2009/A1:2013, was initiated by the AAMI Sphygmomanometer Committee. U.S. representatives played an active role in developing the IEC standard.

Committee approval of the standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Sphygmomanometer Committee** had the following members:

**Cochairs:** Tammy Brady, MD, PhD  
David Quinn

**Members:** Bruce Alpert, MD  
Kristen Bean, Draeger Inc  
Tony Boonyasai, MD, Johns Hopkins Hospital  
Tammy Brady, MD, PhD, Johns Hopkins Hospital  
Steve Briol, Nonin Medical Inc  
Jim Brown, Colson Products Company  
Stephanie Cadorette, Intertek  
Richard Dart, MD, Marshfield Clinic  
Susan Dorsch, MD  
David Feinstein, MD, Beth Israel Deaconess Medical Center  
Gerhard Frick, Microlife AG  
Bruce Friedman, GE Healthcare  
Jeff Gilham, Spacelabs Healthcare  
Clarence Grim, MD, Medical College of Wisconsin  
John Hedley-Whyte, MD  
Charles Ho, PhD, FDA/CDRH  
Tsutomu Ichikawa, Omron Healthcare, Inc  
Jiri Jilek  
Aaron Macan, Medtronic  
Christopher McFadden, MD, Cooper Medical School of Rowan University  
Charles Monroe, Philips  
Bruce Morgenstern, MD, Phoenix Childrens Hospital  
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Raj Padwal, MD  
David Quinn, Hill-Rom  
Cadathur Rajagopalan, PhD, Mindray  
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Joseph Rebot, Clinical Dynamics Corporation  
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Joshua Kim, Hill-Rom

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Andrew Provencher, Draeger  
Binyam Taddese, FDA/CDRH

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

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## Background of ANSI/AAMI adoption of IEC 80601-2-30:2018

As indicated in the foreword to the main body of this document (page vii), the International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising of all national electrotechnical committees. The United States is one of the IEC members that took an active role in the development of this amendment, which was developed by the IEC Technical Subcommittee 62D, Electromedical equipment.

U.S. participation in IEC/SC 62D is organized through the U.S. Technical Advisory Group (TAG) for IEC/SC 62D, administered by AAMI on behalf of the U.S. National Committee of the American National Standards Institute. The U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the final draft of IEC 80601-2-30, the AAMI SP, Sphygmomanometer Committee decided to adopt it verbatim.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other IEC and ISO standards. See the Glossary of Equivalent Standards for a list of IEC and ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the IEC and ISO standard.

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NOTE Users of this standard are advised that this document is an AAMI identical adoption of an IEC document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as advances are made in technology and as new data come to light.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 901 N. Glebe Road, Suite 500, Arlington, VA 22203.

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NOTE-This background does not contain provisions of the American National Standard, *Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated type non-invasive sphygmomanometers*, (ANSI/AAMI/IEC 80601-2-30), but it does provide important information about the development and intended use of the document.

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NOTE-Beginning with the foreword on page vii, this American National Standard is identical to IEC 80601-2-30.

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## 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.
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- 6) All users should ensure that they have the latest edition of this publication.
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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) 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: 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 second edition cancels and replaces the first edition published in 2009 and Amendment 1:2013. This edition constitutes a technical revision.

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

- a) alignment with IEC 60601-1:2005/AMD1:2012 and IEC 60601-1-8:2006/AMD1:2012 [1]<sup>1</sup>, and with IEC 60601-1-2:2014 and IEC 60601-1-11:2015;
- b) referencing IEC 60601-1-10:2007 and IEC 60601-1-12;
- c) changing an OPERATOR-accessible CUFF-sphygmomanometer connector from not compatible with the ISO 594 series to compatible with the ISO 80369 series;

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<sup>1</sup> Figures in square brackets refer to the Bibliography.

- d) added additional requirements for public self-use sphygmomanometers;
- e) added a list of PRIMARY OPERATING FUNCTIONS.

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 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.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website 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 users of this document 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.



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## Introduction

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

The requirements are followed by specifications for the relevant tests.

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



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

## 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>2</sup> applies, except as follows:

### 201.1.1 Scope

#### Replacement:

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

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

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

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

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

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

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 201.11 and 201.105.3.3, as well as 7.2.13 and 8.4.1 of IEC 60601-1:2005.

NOTE 2 See also 4.2 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012.

<sup>2</sup> The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.