



**NSAI**  
Standards

Irish Standard  
I.S. EN IEC 80601-2-30:2019

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

**I.S. EN IEC 80601-2-30:2019**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

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## National Foreword

I.S. EN IEC 80601-2-30:2019 is the adopted Irish version of the European Document EN IEC 80601-2-30:2019, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN IEC 80601-2-30**

May 2019

ICS 11.040

Supersedes EN 80601-2-30:2010

English Version

**Medical electrical equipment - Part 2-30: Particular requirements  
for the basic safety and essential performance of automated  
non-invasive sphygmomanometers  
(IEC 80601-2-30:2018)**

Appareils électromédicaux - Partie 2-30: Exigences  
particulières pour la sécurité de base et les performances  
essentielle de sphymomanomètres non invasifs  
automatiques  
(IEC 80601-2-30:2018)

Medizinische elektrische Geräte - Teil 2-30: Besondere  
Festlegungen für die Sicherheit einschließlich der  
wesentlichen Leistungsmerkmale von automatisierten nicht-  
invasiven Blutdruckmessgeräten  
(IEC 80601-2-30:2018)

This European Standard was approved by CENELEC on 2018-04-26. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

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Comité Européen de Normalisation Electrotechnique  
Europäisches Komitee für Elektrotechnische Normung

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

## **EN IEC 80601-2-30:2019 (E)**

### **European foreword**

The text of document 62D/1548/FDIS, future edition 2 of IEC 80601-2-30, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-30:2019.

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) 2019-11-24
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-05-24

This document supersedes EN 80601-2-30:2010.

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

IEC 60601-1-8:2006 NOTE Harmonized as EN 60601-1-8:2007 (not modified)  
ISO 81060-1:2007 NOTE Harmonized as EN ISO 81060-1:2012 (not modified)  
IEC 60601-1-3 NOTE Harmonized as EN 60601-1-3  
IEC 60601-1-9:2007 NOTE Harmonized as EN 60601-1-9:2008 (not modified)  
IEC 60721-3-7 NOTE Harmonized as EN 60721-3-7

## Annex ZA

(normative)

### Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where 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](http://www.cenelec.eu).

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

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replacement</i>				
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2:EN 60601-1-2 General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests		2015
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6:EN 60601-1-6 General requirements for basic safety and essential performance - Collateral standard: Usability		2010
+ A1	2013		+ A1	2015
<i>Addition</i>				
IEC 60068-2-27	2008	Environmental testing - Part 2-27: Tests -EN 60068-2-27 Test Ea and guidance: Shock		2009
IEC 60068-2-64	2008	Environmental testing - Part 2-64: Tests -EN 60068-2-64 Test Fh: Vibration, broadband random and guidance		2008
IEC 60601-1	2005	Medical electrical equipment - Part 1:EN 60601-1 General requirements for basic safety and essential performance		2006
-	-		+ corrigendum Mar. 2010	
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60601-1-10	2007	Medical electrical equipment - Part 1-10:EN 60601-1-10 General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers		2008

## EN IEC 80601-2-30:2019 (E)

IEC 60601-1-11	2015	Medical electrical equipment - Part 1-11:EN 60601-1-11	2015
		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	
IEC 60601-1-12	2014	Medical electrical equipment - Part 1-12:- General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	-
IEC 60601-2-2	2017	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	-
IEC 62366-1	2015	Medical devices - Part 1: Application ofEN 62366-1 usability engineering to medical devices	2015
-	-	+ AC	2015
IEC 80369-5	2016	Small-bore connectors for liquids and-gases in healthcare applications_- Part_5: Connectors for limb cuff inflation applications	-
ISO 80369-1	2018	Small-bore connectors for liquids and-gases in healthcare applications -- Part 1: General requirements	-
ISO 81060-2	2013	Non-invasive sphygmomanometers – PartEN ISO 81060-2 2: Clinical validation investigation of automated measurement type	2014





**IEC 80601-2-30**

Edition 2.0 2018-03

# **INTERNATIONAL STANDARD**

## **NORME INTERNATIONALE**

**Medical electrical equipment –**

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

**Appareils électromédicaux –**

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



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**IEC 80601-2-30**

Edition 2.0 2018-03

# **INTERNATIONAL STANDARD**

## **NORME INTERNATIONALE**

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**Medical electrical equipment –**

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

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

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## CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards .....	8
201.2 Normative references.....	10
201.3 Terms and definitions.....	11
201.4 General requirements .....	13
201.5 General requirements for testing ME EQUIPMENT .....	13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	14
201.7 ME EQUIPMENT identification, marking and documents .....	14
201.8 Protection against electrical HAZARDS from ME EQUIPMENT .....	17
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	18
201.10 Protection against unwanted and excessive radiation HAZARDS .....	18
201.11 Protection against excessive temperatures and other HAZARDS .....	18
201.12 Accuracy of controls and instruments and protection against hazardous outputs .....	19
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT .....	24
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	24
201.15 Construction of ME EQUIPMENT .....	24
201.16 ME SYSTEMS .....	25
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS .....	25
201.101 Requirements for CUFFS .....	25
201.102 * Connection tubing and CUFF connectors .....	26
201.103 Unauthorized access.....	26
201.104 * Maximum inflating time .....	26
201.105 * Automatic cycling modes .....	27
201.106 * Clinical accuracy .....	31
202 Electromagnetic disturbances – Requirements and tests.....	31
206 Usability.....	34
210 Requirements for the development of physiologic closed-loop controllers .....	35
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment .....	35
212 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.....	35
Annexes .....	37
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	38
Annex AA (informative) Particular guidance and rationale .....	41
Annex BB (informative) Environmental aspects .....	50
Annex CC (informative) Reference to the ESSENTIAL PRINCIPLES .....	51
Bibliography.....	54
Index of defined terms .....	56

Figure 201.101 – CUFF pressure PROTECTION DEVICE, triggered by overpressure in SINGLE FAULT CONDITION.....	21
Figure 201.102 – CUFF pressure PROTECTION DEVICE, triggered by prolonged overpressure in SINGLE FAULT CONDITION.....	22
Figure 201.103 – CUFF pressure and maximum inflation time, NORMAL CONDITION and SINGLE FAULT CONDITION.....	27
Figure 201.104 – LONG-TERM AUTOMATIC MODE CUFF pressure in NORMAL CONDITION .....	28
Figure 201.105 – LONG-TERM AUTOMATIC MODE CUFF pressure in SINGLE FAULT CONDITION .....	28
Figure 201.106 – SHORT-TERM AUTOMATIC MODE CUFF pressure .....	29
Figure 201.107 – SELF-MEASUREMENT AUTOMATIC MODE CUFF pressure.....	30
Figure 202.101 – HF SURGICAL EQUIPMENT test layout .....	33
Figure 202.102 – Simulated PATIENT test set-up for HF SURGICAL EQUIPMENT .....	34
Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements .....	13
Table 201.102 – CUFF deflation pressure .....	18
Table 201.103 – CUFF inflation pressure .....	26
Table 201.C.101 – Marking on the outside of AUTOMATED SPHYGMOMANOMETERS or their parts .....	38
Table 201.C.102 – Marking of controls and instruments of AUTOMATED SPHYGMOMANOMETERS or their parts .....	38
Table 201.C.103 – ACCOMPANYING DOCUMENTS, general information for AUTOMATED SPHYGMOMANOMETERS .....	39
Table 201.C.104 – ACCOMPANYING DOCUMENTS, instructions for use of AUTOMATED SPHYGMOMANOMETERS .....	39
Table 201.C.105 – ACCOMPANYING DOCUMENTS, technical description of AUTOMATED SPHYGMOMANOMETERS .....	40
Table AA.1 – Summary of requirements by mode.....	47
Table BB.1 – Environmental aspects addressed by clauses of this document .....	50
Table CC.1 – Correspondence between this particular standard and the ESSENTIAL PRINCIPLES .....	51

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

### MEDICAL ELECTRICAL EQUIPMENT –

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

### FOREWORD

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International standard IEC 80601-2-30 has been prepared by a Joint Working Group of 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;
- 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;

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

- "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.

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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.

## 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<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.

##### 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.

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<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*.

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