

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**

IEC 80601-2-30:2018

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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

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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]¹, 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.

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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.

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¹ Figures in square brackets refer to the Bibliography.