

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Medical electrical equipment –
Part 2-16: Particular requirements for the basic safety and essential performance
of haemodialysis, haemodiafiltration and haemofiltration equipment**

**Appareils électromédicaux –
Partie 2-16: Exigences particulières pour la sécurité de base et les performances
essentielles des appareils d'hémodialyse, d'hémodiafiltration et d'hémofiltration**





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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment**

FOREWORD

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International standard IEC 60601-2-16 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This fifth edition cancels and replaces the fourth edition of IEC 60601-2-16 published in 2012. This edition constitutes a technical revision.

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

- a) update of references to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, of references and requirements to IEC 60601-1-2:2014, of references to IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013, of references and requirements to IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, of references to

IEC 60601-1-9:2007 and IEC 60601-1-9:2007/AMD1:2013, of references to IEC 60601-1-10:2007 and IEC 60601-1-10:2007/AMD1:2013 and of references to IEC 60601-1-11:2015;

- b) widening of the scope;
- c) editorial improvements;
- d) addition of requirements for anticoagulant delivery means;
- e) other few small technical changes.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/1557/FDIS	62D/1585/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

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

In this document, the following print types are used:

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- *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;
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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.

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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 HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.