



NSAI
Standards

Irish Standard
I.S. EN IEC 60601-2-16:2019

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

I.S. EN IEC 60601-2-16:2019

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National Foreword

I.S. EN IEC 60601-2-16:2019 is the adopted Irish version of the European Document EN IEC 60601-2-16:2019, Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 60601-2-16

May 2019

ICS 11.040.20; 11.040.25

Supersedes EN 60601-2-16:2015

English Version

**Medical electrical equipment - Part 2-16: Particular requirements
for the basic safety and essential performance of haemodialysis,
haemodiafiltration and haemofiltration equipment
(IEC 60601-2-16:2018)**

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
(IEC 60601-2-16:2018)

Medizinische elektrische Geräte - Teil 2-16: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Hämodialyse-,
Hämodiafiltrations- und Hämofiltrationsgeräten
(IEC 60601-2-16:2018)

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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 60601-2-16:2019 (E)

European foreword

The text of document 62D/1557/FDIS, future edition 5 of IEC 60601-2-16, 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 60601-2-16:2019.

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-05-24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 60601-2-16:2015.

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

IEC 60601-2-24	NOTE Harmonized as EN 60601-2-24
IEC 60601-2-39	NOTE Harmonized as EN 60601-2-39
IEC 80001-1:2010	NOTE Harmonized as EN 80001-1:2011 (not modified)
ISO 8637-2	NOTE Harmonized as EN ISO 8637-2
ISO 11197	NOTE Harmonized as EN ISO 11197
ISO 23500-1	NOTE Harmonized as EN ISO 23500-1
ISO 23500-2	NOTE Harmonized as EN ISO 23500-2
ISO 23500-3	NOTE Harmonized as EN ISO 23500-3
ISO 23500-4	NOTE Harmonized as EN ISO 23500-4
ISO 23500-5	NOTE Harmonized as EN ISO 23500-5
ISO 14971:2007	NOTE Harmonized as EN ISO 14971:2012 (not modified)

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.

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
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8:EN 60601-1-8 General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems		2007
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2017
<i>Addition</i>				
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
+ A1	2013		+ A1	2015

EN IEC 60601-2-16:2019 (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 61672-1	-	Electroacoustics - Sound level meters -EN 61672-1	-
		Part 1: Specifications	
ISO 3744	-	Acoustics - Determination of sound powerEN ISO 3744	-
		levels and sound energy levels of noise sources using sound pressure - Engineering methods for an essentially free field over a reflecting plane	



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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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IEC 60601-2-16

Edition 5.0 2018-04

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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ELECTROTECHNICAL
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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:

- 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.

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- "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 IEC 60601 series, 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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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.

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.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT, hereafter referred to as HAEMODIALYSIS EQUIPMENT.

This document does not take into consideration specific safety details of the DIALYSIS FLUID control system of HAEMODIALYSIS EQUIPMENT using regeneration of DIALYSIS FLUID or CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID. It does, however, take into consideration the specific safety requirements of such HAEMODIALYSIS EQUIPMENT concerning electrical safety and PATIENT safety.

This document specifies the minimum safety requirements for HAEMODIALYSIS EQUIPMENT. These HAEMODIALYSIS EQUIPMENT are intended for use either by medical staff or for use by the PATIENT or other trained personnel under medical supervision.

This document includes all ME EQUIPMENT that is intended to deliver a HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION treatment to a PATIENT, independent of the treatment duration and location.

If applicable, this document applies to the relevant parts of ME EQUIPMENT intended for other extracorporeal blood purification treatments.

The particular requirements in this document do not apply to:

- EXTRACORPOREAL CIRCUITS (see ISO 8637-2, [12]²);
- DIALYSERS (see ISO 8637-1, [11]);
- DIALYSIS FLUID CONCENTRATES (see ISO 23500-4, [18]);
- DIALYSIS WATER supply systems (see ISO 23500-2, [16]);
- CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES (see ISO 23500-4, [18]), described as systems for bulk mixing concentrate at a dialysis facility;
- equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39, [8]).

¹ 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*.

² Numbers in square brackets refer to the Bibliography.

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