

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN IEC 60601-2-16:2025 sisaldab Euroopa standardi EN IEC 60601-2-16:2025 ingliskeelset teksti. Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.02.2025. Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	This Estonian standard EVS-EN IEC 60601-2-16:2025 consists of the English text of the European standard EN IEC 60601-2-16:2025. This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 21.02.2025. The standard is available from the Estonian Centre for Standardisation and Accreditation.
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English Version

**Medical electrical equipment - Part 2-16: Particular requirements
for the basic safety and essential performance of haemodialysis,
haemodiafiltration and haemofiltration equipment
(IEC 60601-2-16:2025)**

Appareils électromédicaux - Partie 2-16 : Exigences
particulières pour la sécurité de base et les performances
essentiels des appareils d'hémodialyse,
d'hémodiafiltration et d'hémofiltration
(IEC 60601-2-16:2025)

Medizinische elektrische Geräte - Teil 2-16: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Hämodialyse-,
Hämodiafiltrations- und Hämofiltrationsgeräten
(IEC 60601-2-16:2025)

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

European foreword

The text of document 62D/2163/FDIS, future edition 6 of IEC 60601-2-16, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-16:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2026-02-28 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-02-29 document have to be withdrawn

This document supersedes EN IEC 60601-2-16:2019 and all of its amendments and corrigenda (if any).

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The text of the International Standard IEC 60601-2-16:2025 was approved by CENELEC as a European Standard without any modification.

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

ISO 8637-2:2024	NOTE	Approved as EN ISO 8637-2:2024 (not modified)
ISO 23500-4:2024	NOTE	Approved as EN ISO 23500-4:2024 (not modified)
IEC 60601-2-39:2018	NOTE	Approved as EN IEC 60601-2-39:2019 (not modified)
ISO 23500-1:2024	NOTE	Approved as EN ISO 23500-1:2024 (not modified)
ISO 23500-5:2024	NOTE	Approved as EN ISO 23500-5:2024 (not modified)
IEC 80001-1:2021	NOTE	Approved as EN IEC 80001-1:2021 (not modified)
ISO 80369-1:2018	NOTE	Approved as EN ISO 80369-1:2018 (not modified)
ISO 11197:2019	NOTE	Approved as EN ISO 11197:2019 (not modified)
ISO 17664-1:2021	NOTE	Approved as EN ISO 17664-1:2021 (not modified)
ISO 15883 series	NOTE	Approved as EN ISO 15883 series
IEC 60601-2-24:2012	NOTE	Approved as EN 60601-2-24:2015 (not modified)
ISO 17664-2:2021	NOTE	Approved as EN ISO 17664-2:2023 (not modified)

ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) +A11:2021
IEC 60601-1-9:2007	NOTE	Approved as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Approved as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-9:2007/A2:2020	NOTE	Approved as EN 60601-1-9:2008/A2:2020 (not modified)
IEC 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (not modified)

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 STANDARD

NORME INTERNATIONALE



**Medical electrical equipment –
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of haemodialysis, haemodiafiltration and haemofiltration equipment**

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Partie 2-16 : Exigences particulières pour la sécurité de base et les performances
essentiels 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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IEC 60601-2-16 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This sixth edition cancels and replaces the fifth edition published in 2018. 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, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, of references to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, of references to IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, of references to IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020, of references to IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 and of references to IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020;
- b) consideration of ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION regarding IEC 60601-1:2005/AMD1:2012/ISH1:2021;
- c) including the information given in the document 62D/1771A/INF regarding 201.11.8;
- d) including withdrawn IEC PAS 63023[17] as Annex CC;
- e) including SECURITY (CYBERSECURITY) requirements;
- f) consideration of HAEMODIALYSIS EQUIPMENT using pre-manufactured DIALYSIS FLUID bags;
- g) improvements for labelling;
- h) other minor technical improvements;
- i) editorial improvements.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2163/FDIS	62D/2184/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT 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 document 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:

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- "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 IEC 60601 and IEC 80601 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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INTRODUCTION

The minimum safety requirements specified in this document are considered to provide for a practical degree of safety in the operation of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.

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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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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. It applies to HAEMODIALYSIS EQUIPMENT intended for use either by medical staff or under the supervision of medical experts, including HAEMODIALYSIS EQUIPMENT operated by the PATIENT, regardless of whether the HAEMODIALYSIS EQUIPMENT is used in a hospital or domestic environment.

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.

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 [1]¹),
- DIALYSERS (see ISO 8637-1 [2]),
- DIALYSIS FLUID CONCENTRATES (see ISO 23500-4 [3]),
- pre-manufactured DIALYSIS FLUID bags,
- DIALYSIS WATER supply systems (see ISO 23500-2 [4]),

¹ Numbers in square brackets refer to the Bibliography.

- CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES (see ISO 23500-4 [3]), described as systems for bulk mixing concentrate at a dialysis facility,
- equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39 [5]).

201.1.2 Object

Replacement:

The object of this document is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for HAEMODIALYSIS EQUIPMENT.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020 apply as modified in Clauses 202, 208, 210 and 211.

IEC 60601-1-3 does not apply. IEC 60601-1-9:2007, IEC 60601-1-9:2007/AMD1:2013 and IEC 60601-1-9:2007/AMD2:2020 does not apply as noted in Clause 209.

All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-10:2007/AMD1:2013

IEC 60601-1-10:2007/AMD2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: 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 60601-1-11:2015/AMD1:2020

IEC 61672-1:2013, *Electroacoustics – Sound level meters – Part 1: Specifications*

ISO 3744:2010, *Acoustics – Determination of sound power levels and sound energy levels of noise sources using sound pressure – Engineering methods for an essentially free field over a reflecting plane*

ISO 23500-3:2024, *Preparation and quality management of fluids for haemodialysis and related therapies – Part 3: Water for haemodialysis and related therapies*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

NOTE Refer to section "Index of defined terms used in this particular standard" for the index of defined terms.

201.3.8

* APPLIED PART

Replacement:

EXTRACORPOREAL CIRCUIT and all parts permanently and conductively connected to it (e.g. DIALYSIS FLUID circuit)

Note 1 to entry: See Figure AA.8 in Informative Annex AA Subclause 201.16 and see 201.16.6.3.

Note 2 to entry: One example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including any pre-manufactured DIALYSIS FLUID bags, extension lines, and drain bags in a stand-alone system connected during treatment.

Note 3 to entry: Another example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including connected DIALYSIS FLUID bags, that are online prepared before treatment without the patient connected and drain bags. During treatment the online preparation part of the HAEMODIALYSIS EQUIPMENT is conductively disconnected.

Note 4 to entry: Another example of an APPLIED PART is the EXTRACORPOREAL CIRCUIT including all connected fluid paths of the HAEMODIALYSIS EQUIPMENT and the connection to a drain during the treatment.

201.3.78

PATIENT CONNECTION

Addition:

Note 1 to entry: The PATIENT blood lines connectors are the individual points on the APPLIED PART through which a current can flow between the PATIENT and the HAEMODIALYSIS EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

Additional terms and definitions:

201.3.201

ARTERIAL PRESSURE

pressure measured in the blood withdrawal line of the EXTRACORPOREAL CIRCUIT between the PATIENT CONNECTION and DIALYSER connection

Note 1 to entry: A difference can be made between the pre-pump pressure, which is upstream of the blood pump, and post-pump pressure, which is downstream of the blood pump.