SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-16:2023

01-januar-2023

Medicinska električna oprema - 2-16. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za hemodializo, hemodiafiltracijo in hemofiltracijo

Medical electrical equipment - Part 2-16: Particular requirements for 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

Ta slovenski standard je istoveten z: **prEN IEC 60601-2-16:2022**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment

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62D/1988/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 60601-2-16 ED6**	
DATE OF CIRCULATION: **2022-11-11**	CLOSING DATE FOR VOTING: **2023-02-03**
SUPERSEDES DOCUMENTS: **62D/1912/CD, 62D/1937A/CC**	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

PROPOSED STABILITY DATE: 2028

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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 edition cancels and replaces the fifth edition of IEC 60601-2-16 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 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, 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/AMD2:2020and 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 subclause 201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT;

d) including withdrawn IEC PAS 63023 as Annex CC;

e) including SECURITY (CYBERSECURITY) requirements;

f) consideration of HAEMODIALYSIS EQUIPMENT using pre-manufactured DIALYSIS FLUID bags;

g) improvements for labeling;

h) other minor technical improvements;

i) editorial improvements.

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.

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;

– "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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 standard[1] 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, [5][2]);

– DIALYSERS (see ISO 8637-1, [4]);

– DIALYSIS FLUID CONCENTRATES (see ISO 23500-4, [11]);

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1 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

2 Numbers in square brackets refer to the Bibliography.

– pre-manufactured DIALYSIS FLUID bags;

– DIALYSIS WATER supply systems (see ISO 23500-2, [9]);

– CENTRAL DELIVERY SYSTEMS for DIALYSIS FLUID CONCENTRATES (see ISO 23500-4, [11]), described as systems for bulk mixing concentrate at a dialysis facility;

– equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39, [2]).

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Subclause 201.2 of this particular standard.

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 the general standard 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 the general standard.

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"*Addition*" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard 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 the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography.

Clause 2 of the general standard applies, except as follows:

Addition:

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*
Amendment 1:2013
Amendment 2:2020

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*.
Amendment 1:2020

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 method in an essentially free field over a reflecting plane*

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 terminological databases for use in standardization at the following addresses:

IEC Electropedia: available at http://www.electropedia.org/

ISO Online browsing platform: available at http://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.1 in Informative Annex 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 HAEMODIALYSIS EQUIPMENT used for online production of DIALYSIS FLUID bags and/or 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.

201.3.202

*** BLOOD LEAK**

leakage of blood from the blood compartment to the DIALYSIS FLUID compartment of the DIALYSER

Note 1 to entry: When performing an HF PROCESS, this involves the filtration fluid section.

201.3.203

CENTRAL DELIVERY SYSTEM

part of a ME SYSTEM which proportions DIALYSIS FLUID CONCENTRATE and DIALYSIS WATER for distribution as DIALYSIS FLUID to the HAEMODIALYSIS EQUIPMENT or distributes DIALYSIS FLUID CONCENTRATE

201.3.204

DIALYSER

device containing a semi-permeable membrane that is used to perform HD, HDF or HF

201.3.205
DIALYSIS FLUID
DIALYSATE
DIALYSIS SOLUTION
DIALYSING FLUID
aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during HAEMODIALYSIS

[SOURCE: ISO 23500-1:2019 [8], 3.15, modified – The word "dialysing fluid" has been added as synonym, and the notes have been deleted.]

Note 1 to entry: The DIALYSIS FLUID could be pre-manufactured in bags as pharmaceuticals according to the relevant pharmacopoeia monograph or be prepared by the HAEMODIALYSIS EQUIPMENT or be influenced in composition by the HAEMODIALYSIS EQUIPMENT.

201.3.206
DIALYSIS FLUID CONCENTRATE
substances which, when appropriately diluted or dissolved with DIALYSIS WATER, produce the DIALYSIS FLUID

201.3.207
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 23500-3:2019 [10] and which is suitable for use in HAEMODIALYSIS applications, including the preparation of DIALYSIS FLUID, reprocessing of DIALYSERS, preparation of DIALYSIS FLUID CONCENTRATE and preparation of SUBSTITUTION FLUID for online convective therapies

Note 1 to entry: The words "water for dialysis", "permeate", "reverse osmosis water" and "purified water" are commonly used as synonyms of DIALYSIS WATER.

[SOURCE: ISO 23500-1:2019 [8], 3.17, modified – The reference number "[10]" has been added in the definition, as well as the note.]

201.3.208
EXTRACORPOREAL CIRCUIT
blood lines, DIALYSER and any integral ACCESSORY

Note 1 to entry: An alternative for DIALYSER could be a HF-filter, adsorber or other device.

201.3.209
HAEMODIAFILTRATION
HDF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by a simultaneous combination of HD and HF

201.3.210
HAEMODIALYSIS
HD
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by bidirectional diffusive transport and ULTRAFILTRATION across a semi-permeable membrane separating the blood from the DIALYSIS FLUID

Note 1 to entry: This PROCESS typically includes fluid removal by filtration. This PROCESS is usually also accompanied by diffusion of substances from the DIALYSIS FLUID into the blood.

201.3.211
*** HAEMODIALYSIS EQUIPMENT**
ME EQUIPMENT or ME SYSTEM used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION

Note 1 to entry: When the term ME EQUIPMENT is used in headings, it is equivalent to HAEMODIALYSIS EQUIPMENT. When the term ME EQUIPMENT is used in the text, it is referring to a general ME EQUIPMENT.

201.3.212
HAEMOFILTRATION
HF
PROCESS whereby concentrations of water-soluble substances in a PATIENT'S blood and an excess of fluid of a PATIENT are corrected by convective transport via ULTRAFILTRATION and partial replacement by a SUBSTITUTION FLUID resulting in the required NET FLUID REMOVAL

201.3.213
NET FLUID REMOVAL
fluid loss from the PATIENT

Note 1 to entry: Historically, this term was "weight loss".

201.3.214
*** ONLINE HDF**
HAEMODIAFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT produces SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMODIAFILTRATION treatment

201.3.215
*** ONLINE HF**
HAEMOFILTRATION PROCEDURE where the HAEMODIALYSIS EQUIPMENT produces the SUBSTITUTION FLUID for infusion from DIALYSIS FLUID for the HAEMOFILTRATION treatment

201.3.216
*** PROTECTIVE SYSTEM**
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDOUS SITUATIONS

201.3.217
SUBSTITUTION FLUID
fluid used in HF and HDF treatments which is directly infused into the EXTRACORPOREAL CIRCUIT as a replacement for the fluid that is removed from the blood by filtration

[SOURCE:ISO 23500-1:2019 [8], 3.40, modified – The words "patient's blood" and "ultrafiltration" have been replaced respectively by "EXTRACORPOREAL CIRCUIT" and "filtration" in the definition, and the notes have been deleted.]

201.3.218
TRANSMEMBRANE PRESSURE
TMP
fluid pressure difference exerted across the semi-permeable membrane of the DIALYSER

Note 1 to entry: Generally, the mean TMP is used. In practice, the displayed TRANSMEMBRANE PRESSURE is usually estimated from the measured EXTRACORPOREAL CIRCUIT pressure minus the measured DIALYSIS FLUID pressure, each obtained at a single point.

Note 2 to entry: This note applies to the French language only.

201.3.219
*** ULTRAFILTRATION**
PROCESS of fluid removal from the PATIENT'S blood across the semi-permeable membrane of the DIALYSER

201.3.220
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT between the DIALYSER connection and PATIENT CONNECTION