IEC 60601-2-16

Edition 4.0 2012-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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 fourth edition cancels and replaces the third edition of IEC 60601-2-16, published in 2008. This edition constitutes a technical revision. Changes since the previous edition include, among others, better adaptation of IEC 60601-1-8 and improvement of subclause 201.8.3.

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

FDIS	Report on voting
62D/972/FDIS	62D/987/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 standard, 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 standard, 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 standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– "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 web site 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.

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

Addition:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT, hereafter referred to as HAEMODIALYSIS EQUIPMENT.

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

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

This International Standard includes all ME EQUIPMENT that is intended to deliver a HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION treatment to a PATIENT suffering from kidney failure.

The particular requirements in this international standard do not apply to:

– EXTRACORPOREAL CIRCUITS;
– DIALYSERS;
– DIALYSIS FLUID CONCENTRATES;
– water treatment equipment;
– equipment used to perform PERITONEAL DIALYSIS (see IEC 60601-2-39).

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.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of IEC 60601-1.

NOTE See also 4.2 of IEC 60601-1:2005.

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[1] The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

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 IEC 60601-1, and Clause 201.2 of this International Standard.

IEC 60601-1-2, IEC 60601-1-8, IEC 60601-1-10 and IEC 60601-1-11 apply as modified in Clauses 202, 208, 210 and 211 respectively. IEC 60601-1-3 does not apply. 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 IEC 60601-1.

For brevity, IEC 60601-1 is 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 standard 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 3.139, additional definitions in this standard 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, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" 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 beginning on page 63.

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

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 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.*

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*

IEC 60601-1-11:2010, *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 62366:2007, *Medical devices – Application of usability engineering to medical devices*

ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

ISO 3744, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Engineering method in an essentially free field over a reflecting plane*

ISO 8638, *Cardiovascular implants and artificial organs – Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, and IEC 60601-1-10:2007 apply, except as follows:

NOTE An index of defined terms is found beginning on page 64.

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 Annex AA.

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 current can flow between the PATIENT and the HAEMODIALYSIS EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION.

Additions:

201.3.201
ARTERIAL PRESSURE
pressure measured in the blood withdrawal line of the EXTRACORPOREAL CIRCUIT

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 water for distribution as DIALYSIS FLUID to the HAEMODIALYSIS EQUIPMENT or distributes DIALYSIS FLUID CONCENTRATE

201.3.204
DIALYSER
a device containing a semi-permeable membrane that is used to perform HD, HDF or HF

201.3.205
DIALYSIS FLUID
solution intended to exchange solutes and/or water with blood during HD or HDF

Note 1 to entry: The words "dialysate", “dialysis solution” and "dialysing fluid" are commonly used as synonyms of DIALYSIS FLUID.

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

201.3.207
EXTRACORPOREAL CIRCUIT
blood lines and any integral ACCESSORY thereof

201.3.208
HAEMODIAFILTRATION
HDF
process whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT with renal insufficiency are corrected by a simultaneous combination of HD and HF

201.3.209
HAEMODIALYSIS
HD
process whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT with renal insufficiency 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 normally includes fluid removal by filtration. This process is usually also accompanied by diffusion of substances from the DIALYSIS FLUID into the blood.

201.3.210
*** 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.

201.3.211
HAEMOFILTRATION
HF
process whereby concentrations of water-soluble substances in a PATIENT's blood and an excess of fluid of a PATIENT with renal insufficiency are corrected by unidirectional convective transport via ULTRAFILTRATION across a semi-permeable membrane separating the blood from the DIALYSIS FLUID AND ultrafiltrate is simultaneously replaced by an approximately isoosmolar SUBSTITUTION FLUID at a rate such that the difference between the ULTRAFILTRATION rate and the rate of SUBSTITUTION FLUID addition will lead to removal of the excess fluid over the course of the treatment

201.3.212
NET FLUID REMOVAL
fluid loss from the PATIENT

Note 1 to entry: Historically this term was “weight loss”.

201.3.213
***ONLINE HDF**
HAEMODIAFILTRATION procedure where the HAEMODIALYSIS EQUIPMENT, based on the DIALYSIS FLUID, produces the SUBSTITUTION FLUID for the HDF treatment, suitable for injection

201.3.214
***ONLINE HF**
HAEMOFILTRATION procedure where the HAEMODIALYSIS EQUIPMENT, based on the DIALYSIS FLUID, produces the SUBSTITUTION FLUID for the HF treatment, suitable for injection

201.3.215
***PROTECTIVE SYSTEM**
automatic system, or a constructional feature, specifically designed to protect the PATIENT against HAZARDS which can arise

201.3.216
SUBSTITUTION FLUID
a fluid administered to the PATIENT via the EXTRACORPOREAL CIRCUIT during HF or HDF

201.3.217
TRANSMEMBRANE PRESSURE
TMP
fluid pressure difference exerted across a semi-permeable membrane

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 and the measured DIALYSIS FLUID pressure, each obtained at a single point.

201.3.218
***ULTRAFILTRATION**
process of fluid removal from the PATIENT'S blood across the DIALYSER

201.3.219
VENOUS PRESSURE
pressure measured in the blood return line of the EXTRACORPOREAL CIRCUIT

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Additional subclauses:

201.4.3.101 * Additional ESSENTIAL PERFORMANCE requirements

ESSENTIAL PERFORMANCE of HAEMODIALYSIS EQUIPMENT includes, but is not limited to the functions found in the subclauses listed in Table 201.101, which shall be met within the tolerances specified by the MANUFACTURER under NORMAL CONDITION, if applicable:

Table 201.101 – ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Blood flow	201.4.3.102
DIALYSIS FLUID flow	201.4.3.103
NET FLUID REMOVAL	201.4.3.104
SUBSTITUTION FLUID flow	201.4.3.105
Dialysis time	201.4.3.106
DIALYSIS FLUID composition	201.4.3.107
DIALYSIS FLUID temperature	201.4.3.108
SUBSTITUTION FLUID temperature	201.4.3.109

NOTE Some ESSENTIAL PERFORMANCES listed in Table 201.101 are dependent on the characteristics of the disposable used (e.g. blood flow is dependent upon the pump segment inner diameter in rotary peristaltic pumps).

201.4.3.102 Blood flow

The blood flow for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

NOTE 1 Only a blood flow lower than the set value is considered as negative for the treatment. Therefore the goal of testing is to find the highest negative blood flow error.

Compliance is checked under the following test conditions for typical peristaltic pumps.

– *Apply a pump segment to the HAEMODIALYSIS EQUIPMENT and let it run for at least 30 min.*
– *Apply a fluid (e.g. water) with a temperature of 37 °C in the EXTRACORPOREAL CIRCUIT.*
– *Set the blood flow of the HAEMODIALYSIS EQUIPMENT to 400 ml/min or – if not possible - to the highest possible blood flow.*
– *Set the ARTERIAL PRESSURE to -200 mmHg.*
– *Measure the blood flow.*

The values of the measured blood flow shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

NOTE 2 Pump segment fatigue can reduce the blood flow rate.

NOTE 3 The blood flow rate in peristaltic pumps can be affected by negative input pressures

201.4.3.103 DIALYSIS FLUID flow

The DIALYSIS FLUID flow for the DIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

NOTE Only a DIALYSIS FLUID flow lower than the set value is considered as negative for the treatment.

Compliance is checked under the following test conditions.:

– *Set the HAEMODIALYSIS EQUIPMENT to the HAEMODIALYSIS mode as specified by the MANUFACTURER.*
– *Set the HAEMODIALYSIS EQUIPMENT to maximum DIALYSIS FLUID flow.*
  Measure the DIALYSIS FLUID flow during 30 min.
– *Set the HAEMODIALYSIS EQUIPMENT to minimum DIALYSIS FLUID flow.*
– *Measure the DIALYSIS FLUID flow during 30 min.*

The values of the DIALYSIS FLUID flow shall be within the tolerances specified by the MANUFACTURER in the instructions for use.

201.4.3.104 NET FLUID REMOVAL

The NET FLUID REMOVAL for the HAEMODIALYSIS EQUIPMENT shall be as specified by the MANUFACTURER.

Compliance is checked under the following test conditions.

Test 1 for the balancing part of the HAEMODIALYSIS EQUIPMENT only:

– *Set the HAEMODIALYSIS EQUIPMENT in the HAEMODIALYSIS mode, if applicable, with a DIALYSER according to the MANUFACTURER's recommendation.*
– *Apply fluid (e.g. water) in THE EXTRACORPOREAL CIRCUIT.*
– *Set the highest DIALYSIS FLUID flow, if applicable.*
– *Set the DIALYSIS FLUID temperature to 37 °C, if applicable.*
– *Set the NET FLUID REMOVAL rate to 0 ml/h or the lowest adjustable value.*
– *Create a blood outlet pressure of 50 mmHg below the highest pressure specified by the MANUFACTURER.*
– *Measure the NET FLUID REMOVAL during an appropriate time interval.*

Continue with test 2:

– *Set the NET FLUID REMOVAL rate to the maximum value.*