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TECHNICAL REPORT

Guideline for safe operation of medical equipment used for haemodialysis treatments

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

FOREWORD

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IEC 62653, which is a technical report, has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62D/976/DTR	62D/1006/RVC

Full information on the voting for the approval of this technical report 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.

The verbal forms used in this guideline are conform to usage described in Annex H of the ISO/IEC Directives, Part 2, 2011.

For the purpose of this informative guideline the auxiliary verb ”should“ means that this statement of the guideline is recommended for safe operation. This term is not to be interpreted as indicating requirements.

In this guideline the following print types are used:

– Requirements and definitions: roman type;
– Informative material, such as notes, examples and references: smaller type;
– TERMS DEFINED IN THIS GUIDELINE OR AS NOTED: SMALL CAPITALS.

An asterisk (*) as the first character of a title or at the beginning of a paragraph indicates that there is guidance or rationale related to that item in Annex A.

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- withdrawn,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.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

HAEMODIALYSIS is a therapeutic method for treating terminal renal insufficiency, in addition to peritoneal dialysis and renal transplantation. HAEMODIALYSIS is often used as a general term for related extracorporeal methods of renal replacement therapy. At present, HAEMODIALYSIS is a standard procedure in renal replacement therapy, which, when applied properly, yields high-quality results. The treatment is a complex procedure which is under the influence of medical-biological, physical-chemical and technical processes.

Numerous guidelines, agreements, codes, decrees and laws have been established with regard to HAEMODIALYSIS. They contain detailed regulations about the quality of structures, processes and results, laid down by the legislative body, executive bodies of self-government, and funding agencies.

Since the safety of PATIENT treatment and the legal provisions are highly important, it is reasonable to introduce a quality management system. This technical report may be an integral part of a quality management system of the ORGANIZATION. The ORGANIZATION should identify the residual risks, for example based on these guidelines. The ORGANIZATION should minimise such risks by the use of appropriate standard operating procedures. This document is intended to support the clinical management responsible for the quality management of HAEMODIALYSIS therapies.

GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

1 Scope

This technical report describes the technical requirements for use of equipment in HAEMODIALYSIS, HAEMOFILTRATION and HAEMODIAFILTRATION. These principles should be complied with to ensure safe, permissible and proper application.

The physician is responsible for the HAEMODIALYSIS treatment prescription. However, the ORGANIZATION administering the treatment is responsible for all resources, structures and processes used in connection with the treatment. These responsibilities will not be described here.

If applicable, the scope may be applicable to the use of the equipment in paediatrics, home HAEMODIALYSIS, acute and SORBENT DIALYSIS SYSTEMS.

The requirements of IEC 60601-2-16 ensure that equipment used for extracorporeal renal replacement therapy operates with a high level of safety. Despite that high level of safety, however, some residual risk remains, related to medical-biological, physical-chemical and technical HAZARDS. The ORGANIZATION administering the treatment is responsible for managing the residual risk.

This technical report is not intended to be used as the basis of regulatory inspection or certification assessment activities.

2 Normative references

None.

NOTE Informative references including IEC and ISO standards are listed in the Bibliography on page 28.

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

NOTE An index of defined terms is found on page 30.

3.1
ACCESSORY
additional part for use with equipment in order to:

– achieve the INTENDED USE,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other equipment

Note 1 to entry: Accessories can be objects, substances, preparations of substances and software which do not constitute any medical devices themselves.

[SOURCE: IEC 60601-1:2005, 3.3, modified – a note to entry has been added.]

3.2
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.

[SOURCE: IEC 60601-2-16:2012, 201.3.201]

3.3
BLOOD LEAK
leakage of blood from the blood compartment to the DIALYSIS FLUID compartment of the DIALYSER

Note 1 to entry: Not to be mistaken for blood loss to the environment.

[SOURCE: IEC 60601-2-16:2012, 201.3.202, modified – the original note to entry has been replaced.]

3.4
DIALYSER
a device containing a semi-permeable membrane that is used to perform HAEMODIALYSIS, HAEMODIAFILTRATION or HAEMOFILTRATION

[SOURCE: IEC 60601-2-16:2012, 201.3.204]

*** 3.5**
DIALYSIS FLUID
aqueous fluid containing electrolytes and usually buffer and glucose, which is intended to exchange solutes with blood during HAEMODIALYSIS

Note 1 to entry: The term "DIALYSIS FLUID" is used throughout this document to mean the fluid made from DIALYSIS WATER and concentrates which is delivered to the DIALYSER by the DIALYSIS FLUID delivery system. Such phrases as "dialysate", "dialysis solution" or "dialysing fluid" may be used in place of DIALYSIS FLUID.

Note 2 to entry: The DIALYSIS FLUID entering the DIALYSER is referred to as "fresh DIALYSIS FLUID", while the fluid leaving the DIALYSER is referred to as "spent DIALYSIS FLUID".

Note 3 to entry: DIALYSIS FLUID does not include prepackaged parenteral fluids used in some renal replacement therapies, such as HAEMODIAFILTRATION and HAEMOFILTRATION.

[SOURCE: ISO 11663:2009, 3.7]

*** 3.6**
DIALYSIS MACHINE
HAEMODIALYSIS MACHINE
HAEMODIAFILTRATION MACHINE
HAEMOFILTRATION MACHINE
system or combination of units used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION

Note 1 to entry: The DIALYSIS MACHINE can be a batch DIALYSIS MACHINE filled with the entire DIALYSIS FLUID prior to treatment (see Clause A.6).

Note 2 to entry: The DIALYSIS MACHINE can be supplied with DIALYSIS FLUID from a central DIALYSIS FLUID delivery system (see Clause A.7).

3.7
DIALYSIS WATER
water that has been treated to meet the requirements of ISO 13959 and which is suitable for use in HAEMODIALYSIS applications, including the preparation of DIALYSIS FLUID, reprocessing of DIALYSERS, preparation of concentrates and preparation of substitution fluid for online convective therapies

[SOURCE: ISO 13959:2009, 2.5]

3.8
ENCLOSURE
exterior surface of electrical equipment or parts thereof

Note 1 to entry: Including all touchable parts, such as rotary knobs, handles, and the like.

[SOURCE: IEC 60601-1:2005, 3.26, modified – the original note to entry has been replaced.]

*** 3.9**
EXTRACORPOREAL CIRCUIT
blood lines and any integral ACCESSORY thereof

[SOURCE: IEC 60601-2-16:2012, 201.3.207]

3.10
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

[SOURCE: IEC 60601-2-16:2012, 201.3.208]

3.11
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: Usually, this process includes bidirectional filtration, with fluid removal normally being predominant.

[SOURCE: IEC 60601-2-16:2012, 201.3.209, modified – the original note to entry has been replaced.]

3.12
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 ultrafiltrate and ultrafiltrate is simultaneously replaced by an approximately iso-osmolar 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

[SOURCE: IEC 60601-2-16:2012, 201.3.211, modified – an error has been corrected]

3.13
HAZARD
potential source of harm

[SOURCE: ISO 14971:2007, 2.3]

3.14
HAZARDOUS SITUATION
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[SOURCE: IEC 60601-1:2005, 3.40]

3.15
INCIDENT
malfunction, failure or modification of the features or the performance, or an inadequate or incorrect labeling or instructions for use of a medical device, which directly or indirectly resulted in, could have resulted in or might result in the death or a severe deterioration of the state of health of a patient, an OPERATOR or another person

3.16
INTENDED USE
INTENDED PURPOSE
use for which a product, process or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[SOURCE: ISO 14971:2007, 2.5]

3.17
MAINTENANCE
combination of all technical and administrative means, including supervising ones, to keep or restore a unit in working condition

Note 1 to entry: Unit can be a device or a system.

[SOURCE: IEC 62353:2007, 3.19, modified – a note to entry has been added.]

3.18
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging or labelling of medical electrical equipment, assembling a medical electrical system, or adapting medical electrical equipment or a medical electrical system, regardless of whether these operations are performed by that person or on that person's behalf by a third party

[SOURCE: IEC 60601-1:2005, 3.55, modified – the original notes to entry have been deleted.]

3.19
MODIFICATION
changing constructional or functional features of medical electrical equipment or a medical electrical system in a way not described in its accompanying documents (instructions for use)

[SOURCE: IEC 62353:2007, 3.23, modified – a note to entry has been deleted and a reference to instructions for use has been added.]

3.20
OPERATOR
person handling equipment

[SOURCE: IEC 60601-1:2005, 3.73, modified – the original note to entry has been deleted because not relevant in the context of the present document.]

3.21
ORGANIZATION
entity of the persons and/or institutions responsible for the use and MAINTENANCE of systems for extracorporeal renal replacement therapy

EXAMPLES Doctor's office, dialysis center and dialysis clinic.

3.22
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

[SOURCE: IEC 60601-1:2005, 3.76]

3.23
PATIENT ENVIRONMENT
any volume in which intentional or unintentional contact can occur between a PATIENT and parts of the medical electrical equipment or medical electrical system or between a PATIENT and other persons touching parts of the medical electrical equipment or medical electrical system

Note 1 to entry: Volume here means room area.

Note 2 to entry: An example of PATIENT ENVIRONMENT is shown in Figure 1.

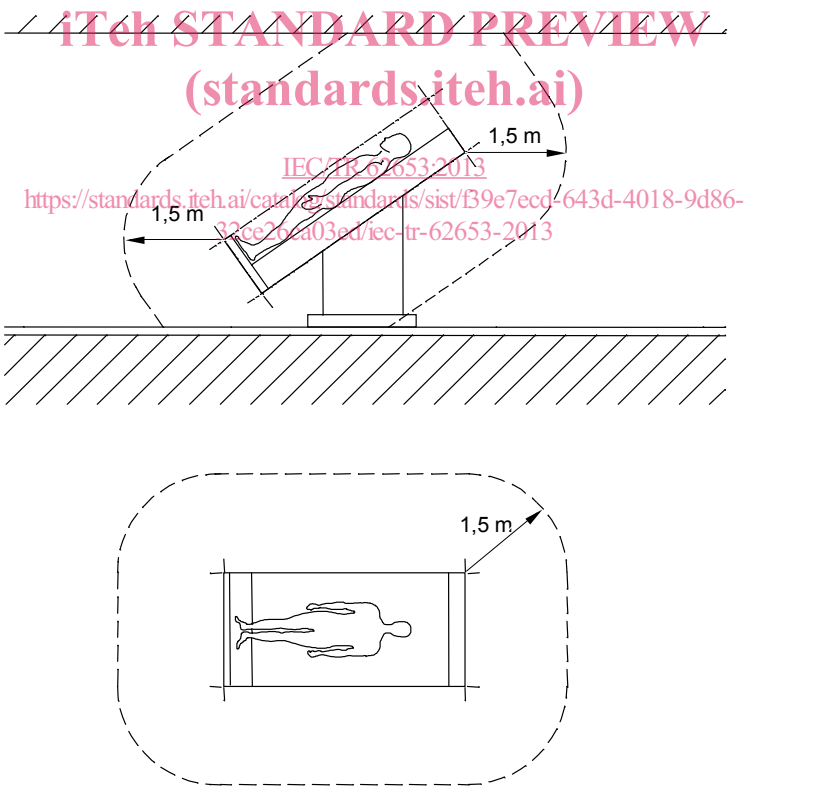

Figure 1 – Example PATIENT ENVIRONMENT

[SOURCE: IEC 60601-1:2005, 3.79, modified – two notes to entry have been added, including a figure illustrating the term.]

*** 3.24**
PATIENT LEAKAGE CURRENT
current coming from an electric device and flowing through the PATIENT to the ground