# IEC TR 62653

Edition 2.0 2020-04
REDLINE VERSION

# TECHNICAL REPORT

colour inside

## 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
info@iec.ch
www.iec.ch

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# CONTENTS

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# GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

## FOREWORD

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The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example "state of the art".

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

This second edition cancels and replaces the first edition 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 the relevant references to the new numbering scheme of the ISO 23500 family;
b) alignment with IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 62353:2014 and 60601-2-16:2018;
c) technical additions in several sections.

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

| Enquiry draft | Report on voting |
|---|---|
| 62D/1698/DTR | 62D/1744/RVDTR |



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 document has been drafted in accordance with the ISO/IEC Directives, Part 2.



The verbal forms used in this document are conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2, 2018.

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

In this document the following print types are used:

– requirements and definitions: roman type;
– informative material, such as notes, examples and references: smaller type;
– TERMS DEFINED IN CLAUSE 3 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 document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document 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

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 document may be an integral part of a quality management system of the ORGANIZATION. The ORGANIZATION should ~~identify~~ be aware of the residual risks and identify appropriate measures, 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 document describes the technical ~~requirements~~ recommendations for use of medical equipment in chronic HAEMODIALYSIS, HAEMOFILTRATION and HAEMODIAFILTRATION. These principles ~~should~~ are important to be complied with to ensure safe, permissible and ~~proper~~ appropriate application.

The term HAEMODIALYSIS is used in this document as synonym for all therapy modalities.

The scope can be applicable to the use of the medical equipment in home, acute and pediatrics environment. The scope may also be applicable to SORBENT DIALYSIS SYSTEMS.

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 medical electrical 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 document is not intended to be used as the basis of regulatory inspection or certification assessment activities.

## 2 Normative references

~~None.~~

There are no normative references in this document.

NOTE Informative references including IEC and ISO standards are listed in the Bibliography starting on page 30.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions 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 An index of defined terms is found on page 34.

**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~~ equipment 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 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 (typically negative), and post-pump pressure (typical positive), which is downstream of the blood pump.

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.201, modified – Direction of pressure added.]



**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~~2018, 201.3.202, modified – The original note to entry has been replaced.]



**3.4**
**CENTRAL CONCENTRATE SYSTEM**
system that prepares and/or stores concentrate at a central point for subsequent distribution to its points of use

**3.5**
**CENTRAL DIALYSIS FLUID DELIVERY SYSTEM**
system that produces DIALYSIS FLUID from DIALYSIS WATER and concentrate or powder at a central point and distributes the DIALYSIS FLUID from the central point to individual dialysis consoles

**3.6**
**DIALYSER**
device containing a semi-permeable membrane that is used to perform HAEMODIALYSIS, HAEMODIAFILTRATION or HAEMOFILTRATION

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.204]

*** 3.7**
**DIALYSIS FLUID**
aqueous fluid containing electrolytes and usually buffer and glucose, which is intended to exchange solutes with blood during HAEMODIALYSIS and HEMODIAFILTRATION

Note 1 to entry: The term "DIALYSIS FLUID" is used throughout this document to mean the fluid made from DIALYSIS WATER and concentrates that is delivered to the DIALYSER by the DIALYSIS FLUID delivery system. Such phrases as "dialysate" or "dialysis solution" ~~or "dialysing fluid" may be~~ are used in place of DIALYSIS FLUID in some countries; however, that usage is discouraged to avoid confusion.

Note 2 to entry: ISO 23500-5 defines three levels of DIALYSIS FLUID: standard DIALYSIS FLUID, ultrapure DIALYSIS FLUID, and online-prepared substitution fluid used for HAEMODIAFILTRATION.

Note 3 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 4 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~~ ISO 23500-1:2019, 3.15, modified – The terms "dialysate" and "dialysis solution" were deleted.]

*** 3.8**
**DIALYSIS MACHINE**
**HAEMODIALYSIS MACHINE**
**HAEMODIAFILTRATION MACHINE**
**HAEMOFILTRATION MACHINE**
~~system or combination of units~~ medical electrical equipment 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 A.6).

Note 2 to entry: The DIALYSIS MACHINE can be supplied with DIALYSIS FLUID from a CENTRAL DIALYSIS FLUID DELIVERY SYSTEM and synonymously named individual dialysis console in this context (see A.7).



**3.9**
**DIALYSIS WATER**
water that has been treated to meet the requirements of ~~ISO 13959~~ ISO 23500-3 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~~ ISO 23500-1:2019, 3.17]

**3.10**
**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.]

*** 3.11**
**EXTRACORPOREAL CIRCUIT**
blood lines, DIALYSER and any integral ACCESSORY ~~thereof~~

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.207, modified – Deletion of Note to entry.]

**3.12**
**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~~2018, 201.3.208]

**3.13**
**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.~~ 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.

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.209~~, modified – the original note to entry has been replaced~~]

**3.14**
**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~~
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

[SOURCE: IEC 60601-2-16:~~2012~~2018, 201.3.211~~, modified – an error has been corrected~~]

**3.15**
**HAZARD**
potential source of harm

[SOURCE: ISO 14971:~~2007, 2.3~~ 2019, 3.4]

**3.16**
**HAZARDOUS SITUATION**
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.40]

**3.17**
**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~~ equipment, 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

**3.18**
**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~~ 2019, 3.6, modified – Deletion of the Note.]

**3.19**
**MAINTENANCE**
combination of all technical and administrative means, including supervising ones, to keep ~~or restore a unit in working condition~~ medical electrical equipment or a medical electrical system in a normal working condition or restored to normal working condition

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

[SOURCE: IEC 62353:~~2007~~2014, ~~3.19, modified – a note to entry has been added~~ 3.21]

**3.20**
**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

Note 1 to entry: In the context of this document the term medical equipment is used as umbrella term for medical electrical equipment and non-active medical devices.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.55, modified – The original notes to entry have been deleted.]

**3.21**
**MODIFICATION**
changing constructional or functional features of medical ~~electrical~~ equipment or a medical ~~electrical~~ system in a way not described in its instruction for use or other accompanying documents ~~(instructions for use)~~

[SOURCE: IEC 62353:~~2007~~2014, ~~3.23~~ 3.25, modified – A note to entry has been deleted and a reference to instructions for use has been added.]

**3.22**
**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~~.]

**3.23**
**ORGANIZATION**
entity of the persons and/or institutions responsible for the ~~use~~ application and MAINTENANCE of systems for extracorporeal renal replacement therapy

EXAMPLES ~~Doctor's office~~ Medical doctors, dialysis centers and dialysis clinics and their responsible parties.

**3.24**
**PATIENT**
living being (person or animal) undergoing a medical, surgical or dental procedure

Note 1 to entry: A PATIENT can be an OPERATOR.

Note 2 to entry: For the purpose of this document PATIENT is a human being

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.76, modified – Addition of a new Note 2 to entry.]