



BSI Standards Publication

Guideline for safe operation of medical equipment used for haemodialysis treatments

National foreword

This Published Document is the UK implementation of IEC TR 62653:2020.

The UK participation in its preparation was entrusted to Technical Committee CH/62, Electrical Equipment in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2020
Published by BSI Standards Limited 2020

ISBN 978 0 539 03014 3

ICS 11.040.20; 11.040.25

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 April 2020.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------



TECHNICAL REPORT

Guideline for safe operation of medical equipment used for haemodialysis treatments

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.20; 11.040.25

ISBN 978-2-8322-8143-7

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD	4
INTRODUCTION	6
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 Recommendations	13
4.1 Personnel, qualification	13
4.2 Training	13
4.3 Infrastructure	14
4.3.1 General	14
4.3.2 Infrastructure recommendations	14
5 Treatment	17
5.1 General	17
5.2 Preparation	17
5.2.1 DIALYSIS MACHINE	17
5.2.2 DIALYSIS FLUID preparation by DIALYSIS MACHINE	18
5.2.3 EXTRACORPOREAL CIRCUIT	18
5.2.4 DIALYSIS FLUID compartment	19
5.2.5 PATIENT	19
5.3 Treatment	19
5.3.1 Preparing the vascular access	19
5.3.2 Connection to the EXTRACORPOREAL CIRCUIT	20
5.3.3 Initiation of treatment	20
5.3.4 Checks to be repeated during the treatment	21
5.3.5 HAZARDS during the treatment	22
5.3.6 Deviations from the prescribed treatment parameters	23
5.3.7 Terminating the DIALYSIS treatment	23
5.3.8 After completion of the dialysis treatment	23
6 Notification of INCIDENTS	23
7 Handling medical electrical equipment and medical devices	24
7.1 Technical service, SERVICING and checks of medical electrical equipment and infrastructure	24
7.2 Medical electrical equipment safety and medical electrical equipment combinations	24
7.3 Non-INTENDED USE	25
Annex (informative) Explanatory technical remarks	26
A.1 Overview	26
A.2 DIALYSIS FLUID	26
A.3 Blood loss to the environment	27
A.4 Air infusion	28
A.5 Electrical safety	28
A.6 Proportioning type and batch DIALYSIS MACHINES	29
A.7 CENTRAL DIALYSIS FLUID DELIVERY SYSTEM (CDDS)	30
A.8 Microbiological contamination of the DIALYSIS FLUID	30
A.9 Bloodline INTENDED USE and potential risks	31
Bibliography	32

Index of defined terms used in this document	36
Figure 1 – Example PATIENT ENVIRONMENT	12
Figure A.1 – Typical CENTRAL DIALYSIS FLUID DELIVERY SYSTEM (CDDS)	30

Currently in preview, click buy full version

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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: small type;
- TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITAL

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 content 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.

INTRODUCTION

HAEMODIALYSIS is a therapeutic method for treating 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 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 recommendations for use of medical equipment in chronic HAEMODIALYSIS, HAEMOFILTRATION and HAEMODIAFILTRATION. These principles are important to be complied with to ensure safe, permissible and 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 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.

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

There are no normative references in this document.

NOTE Informative references including IEC and ISO standards are listed in the Bibliography starting on page 32.

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 36.

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,