

TECHNICAL REPORT

Guideline for safe operation of medical equipment used for haemodialysis treatments

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE

U

ICS 11.040.20; 11.040.25

ISBN 978-2-83220-133-6

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

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	5
1 Scope.....	6
2 Normative references	6
3 Terms and definitions	6
4 Requirements	12
4.1 Personnel, qualification	12
4.2 Training.....	12
4.3 Infrastructure.....	12
4.3.1 General	12
4.3.2 Infrastructure requirements.....	13
5 Treatment.....	15
5.1 General.....	15
5.2 Preparation	15
5.2.1 DIALYSIS MACHINE	15
5.2.2 * DIALYSIS FLUID PREPARATION.....	15
5.2.3 * EXTRACORPOREAL CIRCUIT	16
5.2.4 DIALYSIS FLUID compartment	16
5.2.5 PATIENT	16
5.3 Treatment.....	17
5.3.1 Preparing the vascular access	17
5.3.2 * Connection to the EXTRACORPOREAL CIRCUIT	17
5.3.3 Initiation of treatment.....	17
5.3.4 Checks to be repeated during the treatment	18
5.3.5 * HAZARDS during the treatment	19
5.3.6 Deviations from the treatment parameters prescribed or treatment interruption.....	19
5.3.7 Terminating the DIALYSIS treatment	20
5.3.8 * After completion of the dialysis treatment	20
6 Notification of INCIDENTS	20
7 Handling medical devices	20
7.1 Technical service, SERVICING and checks of equipment and plants	20
7.2 * Equipment safety and device combinations	21
7.3 Non-INTENDED USE	21
Annex A (informative) Explanatory technical remarks.....	22
Bibliography.....	28
Index of defined terms used in this guideline.....	30
Figure 1 – Example PATIENT ENVIRONMENT.....	10
Figure A.1 – Typical central DIALYSIS FLUID delivery system, CDDS.....	26

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 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.