

TECHNICAL REPORT

Guideline for safe operation of medical equipment used for haemodialysis treatments





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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 A (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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

FOREWORD

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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.

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.