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Edition 2.0 2020-04

TECHNICAL REPORT

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Guideline for safe operation of medical equipment used for haemodialysis treatments



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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 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;

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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.

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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.

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GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

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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,