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TECHNICAL REPORT

Guideline for safe operation of medical equipment used for haemodialysis treatments

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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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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- withdrawn,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.

3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

NOTE An index of defined terms is found on page 30.

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 themselves.

[SOURCE: IEC 60601-1:2005, 3.3, modified – a note to entry has been added.]