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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- withdrawn,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.