Guideline for safe operation of medical equipment used for haemodialysis treatments
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This Redline version is not an official Standard and is intended to provide the user with an indication of what changes have been made to the previous version. Only the IEC International Standard provided in this package is to be considered the official Standard.

This Redline version provides you with a quick and easy way to compare all the changes between this standard and its previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.
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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 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.
GUIDELINE FOR SAFE OPERATION OF MEDICAL EQUIPMENT USED FOR HAEMODIALYSIS TREATMENTS

1 Scope

This document describes the technical requirements recommendations for use of medical equipment in chronic HAEMODIALYSIS, HAEMOFILTRATION and HAEMODIAFILTRATION. These principles should be 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 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 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

None.

There are no normative references in this document.

NOTE Informative references including IEC and ISO standards are listed in the Bibliography starting on page 30.
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