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Guidance for the preparation and quality management of fluids for haemodialysis and related therapies

*Directives concernant la préparation et le management de la qualité
des fluides d'hémodialyse et de thérapies annexes*



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Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
1.1 General.....	1
1.2 Inclusions.....	1
1.3 Exclusions.....	1
2 Normative references	1
3 Terms and definitions	2
4 Summary of quality requirements of ISO 13958, ISO 13959 and ISO 11663	9
4.1 Dialysis water.....	9
4.2 Requirements for concentrate.....	11
4.3 Requirements for dialysis fluid.....	11
4.4 Record retention.....	12
5 Critical aspects of system design	12
5.1 Technical aspects.....	13
5.2 Microbiological aspects.....	13
6 Validation of system performance	14
6.1 Validation plan.....	14
6.2 Installation and operational qualification.....	15
6.3 Performance qualification.....	16
6.4 Routine monitoring and revalidation.....	16
7 Quality management	17
7.1 General.....	17
7.2 Monitoring of fluid quality.....	17
7.3 Monitoring of water treatment equipment.....	18
7.4 Monitoring of dialysis water storage and distribution.....	21
7.5 Monitoring of concentrate preparation.....	23
7.6 Monitoring of concentrate distribution.....	23
7.7 Monitoring of dialysis fluid proportioning.....	23
8 Strategies for microbiological control	24
8.1 General.....	24
8.2 Disinfection.....	24
8.3 Microbiological monitoring methods.....	26
9 Environment	28
10 Personnel	29
Annex A (informative) Rationale for the development and provisions of this International Standard	30
Annex B (informative) Equipment	34
Annex C (informative) Monitoring guidelines for water treatment equipment, distribution systems, and dialysis fluid	52
Annex D (informative) Strategies for microbiological control	57
Annex E (informative) Validation	62
Annex F (informative) Special considerations for home haemodialysis	65
Annex G (informative) Special considerations for acute haemodialysis	71
Bibliography	76

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 23500:2011), which has been technically revised.

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Introduction

This International Standard was developed by ISO/TC 150/SC 2. The objective was to provide users with guidance for handling water and concentrates and for the production and monitoring of dialysis fluid used for haemodialysis. The need for such guidance is based on the critical role of dialysis fluid quality in providing safe and effective haemodialysis, and the recognition that day-to-day dialysis fluid quality is under the control of the healthcare professionals who deliver dialysis therapy.

Quality requirements for the water and concentrates used to prepare dialysis fluid, and for that dialysis fluid, are provided in ISO 13959, ISO 13958, and ISO 11663, respectively. This International Standard does not address clinical issues that might be associated with inappropriate usage of the water, dialysis water, concentrates, or dialysis fluid. Healthcare professionals involved in the provision of treatment for kidney failure should make the final decision regarding the applications with which these fluids are used, for example, haemodialysis, haemodiafiltration, high-flux haemodialysis, and the reprocessing of dialysers, and need to be aware of the issues that the use of inappropriate fluid quality raises in each of the therapies.

The equipment used in the various stages of dialysis fluid preparation is generally obtained from specialized vendors. Dialysis practitioners are generally responsible for maintaining that equipment following its installation. Therefore, this International Standard provides guidance on monitoring and maintenance of the equipment to ensure that dialysis fluid quality is acceptable at all times. At various places throughout this International Standard, the user is advised to follow the manufacturer's instructions regarding the operation and maintenance of equipment. In those instances in which the equipment is not obtained from a specialized vendor, it is the responsibility of the user to validate the performance of the equipment in the haemodialysis setting and to ensure that appropriate operating and maintenance manuals are available. [Annex B](#) provides a general description of the system components that are used for water treatment, concentrate, and dialysis fluid preparation at a dialysis facility. These descriptions are intended to provide the user with a basis for understanding why certain equipment might be required and how it should be configured; they are not intended as detailed design standards. Requirements for water treatment equipment are provided in ISO 26722.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2:2004. For the purposes of this International standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this International Standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

This International Standard reflects the conscientious efforts of healthcare professionals, patients, and medical device manufacturers to develop recommendations for handling water and concentrates and for the production and monitoring of dialysis fluid for haemodialysis. This International Standard is directed towards the healthcare professionals involved in the management or routine care of haemodialysis patients and responsible for the quality of dialysis fluid. The recommendations contained in this International Standard might not be applicable in all circumstances and they are not intended for regulatory application.

The guidance provided by this International Standard should help protect haemodialysis patients from adverse effects arising from known chemical and microbial contaminants that might be found in improperly prepared dialysis fluid. However, the physician in charge of dialysis has the ultimate responsibility for ensuring that the dialysis fluid is correctly formulated and meets the requirements of all applicable quality standards.

The concepts incorporated in this International Standard should not be considered inflexible or static. The recommendations presented here should be reviewed periodically in order to assimilate increased understanding of the role of dialysis fluid purity in patient outcomes and technological developments.