

DIN EN ISO 23500-1:2025-03 (E)

Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (ISO 23500-1:2024)

| Contents | Page |
|---|-------------|
| European foreword | 4 |
| Foreword | 5 |
| Introduction | 7 |
| 1 Scope | 8 |
| 2 Normative references | 8 |
| 3 Terms and definitions | 9 |
| 4 Quality requirements | 16 |
| 4.1 General | 16 |
| 4.2 Dialysis water | 17 |
| 4.2.1 General | 17 |
| 4.2.2 Chemical contaminants in dialysis water | 17 |
| 4.2.3 Organic carbon, pesticides and other chemicals | 19 |
| 4.2.4 Microbiological contaminants in dialysis water | 19 |
| 4.3 Requirements for concentrate | 19 |
| 4.3.1 Chemical and microbiological contaminants in concentrate | 19 |
| 4.3.2 Water used to prepare concentrate | 20 |
| 4.4 Requirements for dialysis fluid | 20 |
| 4.4.1 General | 20 |
| 4.4.2 Microbiological requirements for standard dialysis fluid | 20 |
| 4.4.3 Microbiological requirements for ultrapure dialysis fluid | 20 |
| 4.4.4 Microbiological requirements for online-prepared substitution fluid | 21 |
| 4.5 Record retention | 21 |
| 5 System design and technical considerations | 21 |
| 5.1 General | 21 |
| 5.2 Technical aspects | 22 |
| 5.3 Microbiological aspects | 23 |
| 5.4 Environmental impact | 23 |
| 6 Validation of system performance | 23 |
| 6.1 General | 23 |
| 6.2 Validation plan | 25 |
| 6.3 Installation and operational qualification | 25 |
| 6.4 Performance qualification | 25 |
| 6.5 Validation | 26 |
| 6.5.1 General | 26 |
| 6.5.2 Initial validation | 26 |
| 6.5.3 Retrospective (annual) validation | 26 |
| 6.5.4 Revalidation | 26 |
| 6.6 Monitoring and surveillance | 27 |
| 7 Quality management | 27 |
| 7.1 General | 27 |
| 7.2 Surveillance of fluid quality | 28 |
| 7.2.1 Surveillance of dialysis water quality | 28 |
| 7.2.2 Surveillance of concentrate quality | 28 |
| 7.2.3 Surveillance of dialysis fluid quality | 28 |

| | | |
|------------------------------|--|------------|
| 7.3 | Surveillance of water treatment equipment..... | 28 |
| 7.3.1 | General..... | 28 |
| 7.3.2 | Surveillance of sediment filters..... | 28 |
| 7.3.3 | Surveillance of cartridge filters..... | 29 |
| 7.3.4 | Surveillance of softeners..... | 29 |
| 7.3.5 | Surveillance of carbon media..... | 30 |
| 7.3.6 | Surveillance of chemical injection systems..... | 30 |
| 7.3.7 | Surveillance of reverse osmosis..... | 31 |
| 7.3.8 | Surveillance of deionization..... | 32 |
| 7.3.9 | Surveillance of bacteria and endotoxin-retentive filters..... | 32 |
| 7.3.10 | Surveillance of dialysis water storage and distribution..... | 32 |
| 7.3.11 | Surveillance of bacterial control devices..... | 33 |
| 7.4 | Surveillance of concentrate preparation..... | 34 |
| 7.4.1 | Surveillance of mixing systems..... | 34 |
| 7.4.2 | Surveillance of additives..... | 34 |
| 7.5 | Surveillance of concentrate distribution..... | 34 |
| 7.6 | Surveillance of dialysis fluid proportioning..... | 34 |
| 8 | Strategies for microbiological control..... | 35 |
| 8.1 | General..... | 35 |
| 8.2 | Disinfection..... | 35 |
| 8.2.1 | General..... | 35 |
| 8.2.2 | Microbiological aspects of fluid system design..... | 35 |
| 8.2.3 | Disinfection frequency..... | 36 |
| 8.3 | Microbiological surveillance methods..... | 37 |
| 8.3.1 | General..... | 37 |
| 8.3.2 | Sample collection..... | 38 |
| 8.3.3 | Heterotrophic plate count..... | 39 |
| 8.3.4 | Bacterial endotoxin test..... | 41 |
| 8.3.5 | Determination of yeast and mould..... | 41 |
| 9 | Location of and access to the water treatment system..... | 42 |
| 10 | Personnel..... | 42 |
| Annex A (informative) | Rationale for the development and provisions of this document..... | 43 |
| Annex B (informative) | Equipment..... | 49 |
| Annex C (informative) | Surveillance guidelines for water treatment equipment, distribution systems and dialysis fluid..... | 68 |
| Annex D (informative) | Strategies for microbiological control..... | 72 |
| Annex E (informative) | Validation..... | 82 |
| Annex F (informative) | Special considerations for home haemodialysis..... | 90 |
| Annex G (informative) | Special considerations for acute haemodialysis..... | 97 |
| Annex H (informative) | Further considerations for different water quality monitoring approaches..... | 102 |
| Annex I (informative) | Additional considerations for risk assessment..... | 104 |
| Bibliography | | 107 |