

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