

DIN EN ISO 23500-1:2019-11 (English)

Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (ISO 23500-1:2019)

Contents	Page
European foreword	4
7.4.1 Surveillance of water storage tanks	30
7.4.2 Surveillance of the water distribution systems	30
7.4.3 Surveillance of bacterial control devices	31
7.5 Surveillance of concentrate preparation	31
7.5.1 Surveillance of mixing systems	31
7.5.2 Surveillance of additives	32
7.6 Surveillance of concentrate distribution	32
7.7 Surveillance of dialysis fluid proportioning	32
8 Strategies for microbiological control	32
8.1 General	32
8.2 Disinfection	33
8.2.1 General	33
8.2.2 Microbiological aspects of fluid system design	33
8.2.3 Disinfection frequency	34
8.3 Microbiological surveillance methods	35
8.3.1 General	35
8.3.2 Sample collection	35
8.3.3 Heterotrophic plate count	36
8.3.4 Bacterial endotoxin test	38
8.3.5 Determination of yeast and mould	38
9 Location of and access to the water treatment system	38
10 Personnel	38
Annex A (informative) Rationale for the development and provisions of this document	39
Annex B (informative) Equipment	44
Annex C (informative) Surveillance guidelines for water treatment equipment, distribution systems, and dialysis fluid	62
Annex D (informative) Strategies for microbiological control	67
Annex E (informative) Validation	74
Annex F (informative) Special considerations for home haemodialysis	77
Annex G (informative) Special considerations for acute haemodialysis	83
Bibliography	88
7.4 Surveillance of dialysis water storage and distribution	30