ISO 23500-2:2024-07 (E)

Preparation and quality management of fluids for haemodialysis and related therapies - Part 2: Water treatment equipment for haemodialysis applications and related therapies

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms and definitions 2

4 Requirements 2
4.1 Dialysis water quality requirements 2
4.1.1 General 2
4.1.2 Chemical contaminant requirements 2
4.1.3 Organic carbon, pesticides and other chemicals 3
4.1.4 Microbiology of dialysis water 3
4.2 Water treatment equipment requirements 3
4.2.1 General 3
4.2.2 Backflow prevention 5
4.2.3 Tempering valves 5
4.2.4 Sediment filters 5
4.2.5 Cartridge filters 5
4.2.6 Softeners 5
4.2.7 Anion exchange resin tank 5
4.2.8 Carbon media 5
4.2.9 Chemical injection systems 7
4.2.10 Reverse osmosis 7
4.2.11 Deionization 8
4.2.12 Bacteria and endotoxin retentive filters 8
4.2.13 Storage and distribution of dialysis water 8
4.3 Electrical safety of water treatment equipment for haemodialysis applications and related therapies 10

5 Testing 10
5.1 Conformity with dialysis water quality requirements 10
5.1.1 General 10
5.1.2 Microbiology of dialysis water 11
5.1.3 Maximum level of chemical contaminants 12
5.2 Conformity with water treatment equipment requirements 12
5.2.1 General 12
5.2.2 Backflow prevention 13
5.2.3 Tempering valves 13
5.2.4 Sediment filters 13
5.2.5 Cartridge filters 13
5.2.6 Softeners 13
5.2.7 Anion exchange resin tanks 13
5.2.8 Carbon media 14
5.2.9 Chemical injection systems 14
5.2.10 Reverse osmosis 14

5.2.11 Deionization 14
5.2.12 Endotoxin retentive filters 14
5.2.13 Storage and distribution of dialysis water 14

6 Labelling 15
6.1 General 15
6.2 Device or system markings 15
6.3 Product literature 15

Annex A (informative) Rationale for the development and provisions of this document 18

Annex B (informative) Reference tables 29

Bibliography 31