ISO 8637-2:2024-04 (E)

Extracorporeal systems for blood purification - Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

Contents

Page

Foreword ..... **v**

Introduction ..... **vi**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **2**

4 Requirements **6**

4.1 General 6

4.2 Biological safety and haemocompatibility 6

4.3 Sterility 6

4.4 Non-pyrogenicity 7

4.5 Mechanical characteristics 7

4.5.1 Structural integrity 7

4.5.2 Connectors to haemodialyser, haemodiafilter or haemofilter 7

4.5.3 Connectors to vascular access device 10

4.5.4 Connectors to ancillary components 10

4.5.5 Colour coding 10

4.5.6 Access ports 10

4.5.7 Blood pathway volume 11

4.5.8 Air capture chamber fill level 11

4.5.9 Transducer protectors 11

4.6 Functional characteristics 11

4.6.1 General 11

4.6.2 Blood pump system performance 11

4.6.3 Dialysis fluid pump performance 12

4.6.4 Net fluid removal 12

4.6.5 Substitution fluid flow rate 12

4.6.6 Dialysis fluid composition 12

4.6.7 Dialysis fluid temperature 12

4.6.8 Substitution fluid temperature 12

4.6.9 Fluid path occlusion 12

4.6.10 Prevention of air infusion 13

4.6.11 Pressure monitoring 13

4.6.12 Blood leak detection 13

4.7 Expiry date 13

5 Test methods **13**

5.1 General 13

5.2 Biological safety and haemocompatibility 14

5.3 Sterility 14

5.4 Non-pyrogenicity 14

5.5 Mechanical characteristics 14

5.5.1 Structural integrity 14

5.5.2 Connectors to haemodialyser, haemodiafilter or haemofilter 15

5.5.3 Connectors to vascular access device 20

5.5.4 Connectors to ancillary components 20

5.5.5 Colour coding 20

5.5.6 Access ports 21

5.5.7 Blood pathway volume 21

5.5.8 Air capture chamber fill level 21
5.5.9 Transducer protectors 21
5.6 Functional characteristics 22
5.6.1 General 22
5.6.2 Blood pump system performance 22
5.6.3 Dialysis fluid pump performance 22
5.6.4 Net fluid removal 22
5.6.5 Substitution fluid flow rate 22
5.6.6 Dialysis fluid composition 22
5.6.7 Dialysis fluid temperature 22
5.6.8 Substitution fluid temperature 22
5.6.9 Fluid path occlusion 23
5.6.10 Prevention of air infusion 23
5.6.11 Pressure monitoring 23
5.6.12 Blood leak detection 23
5.7 Expiry date 23
6 Labelling 23
6.1 Labelling on the device 23
6.2 Labelling on unit protective packaging 23
6.3 Labelling on the outer shipping container 24
6.4 Information to be given in the accompanying documentation 24
7 Packaging 26
Bibliography 27