

ISO 8637-1:2024-05 (E)

Extracorporeal systems for blood purification - Part 1: 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	5
4.1	Biological safety and haemocompatibility	5
4.2	Sterility	5
4.3	Non-pyrogenicity	5
4.4	Mechanical characteristics	6
4.4.1	Structural integrity	6
4.4.2	Blood compartment integrity	6
4.4.3	Blood compartment connectors of haemodialysers, haemodiafilters and haemofilters	6
4.4.4	Dialysis fluid compartment connectors of haemodialysers and haemodiafilters	7
4.4.5	Filtrate connectors of haemofilters	8
4.4.6	Blood and filtrate connectors of haemoconcentrators	8
4.5	Performance characteristics	9
4.5.1	Solute clearance for haemodialysers and haemodiafilters	9
4.5.2	Sieving coefficients for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators	9
4.5.3	Ultrafiltration rate	9
4.5.4	Ultrafiltration coefficient	9
4.5.5	Blood compartment volume	9
4.5.6	Blood compartment pressure drop	10
4.5.7	Endotoxin transfer of haemodialysers and haemodiafilters	10
4.6	Expiry date	10
5	Test methods	10
5.1	General	10
5.2	Biological safety and haemocompatibility	11
5.3	Sterility	11
5.4	Non-pyrogenicity	11
5.5	Mechanical characteristics	11
5.5.1	Structural integrity	11
5.5.2	Blood compartment integrity	12
5.5.3	Connectors	12
5.6	Performance characteristics	16
5.6.1	Solute clearance of haemodialysers and haemodiafilters	16
5.6.2	Sieving coefficient of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators	19
5.6.3	Ultrafiltration rate	21
5.6.4	Ultrafiltration coefficient	21
5.6.5	Blood compartment volume	21
5.6.6	Blood compartment pressure drop	22
5.6.7	Endotoxin transfer of haemodialysers and haemodiafilters	22
6	Expiry date	22

7	Labelling	22
7.1	Labelling on the device.....	22
7.2	Labelling on unit containers.....	23
7.3	Labelling on the outer containers.....	23
7.4	Information to be given in the accompanying documentation	24
8	Packaging	26
Annex A (informative)	Endotoxin transfer assessment	27
Bibliography		30