

DIN EN ISO 8637-1:2020-10 (Englisch)

Extracorporeal systems for blood purification - Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (ISO 8637-1:2017)

Contents		Page
	European foreword.....	3
	Foreword.....	4
	Introduction.....	5
1	Scope	6
2	Normative references	6
3	Terms and definitions	7
4	Requirements	9
4.1	Biological safety.....	9
4.2	Sterility.....	9
4.3	Non-pyrogenicity.....	9
4.4	Mechanical characteristics.....	9
4.4.1	Structural integrity.....	9
4.4.2	Blood compartment integrity.....	9
4.4.3	Haemodialyser, haemodiafilter and haemofilter blood compartment ports.....	10
4.4.4	Haemodialyser and haemodiafilter dialysis fluid compartment ports.....	12
4.4.5	Haemofilter filtrate ports.....	12
4.4.6	Haemoconcentrator blood and filtrate ports.....	12
4.5	Performance characteristics.....	12
4.5.1	Solute clearance of haemodialysers and haemodiafilters.....	12
4.5.2	Sieving coefficient of haemodiafilters, haemofilters and haemoconcentrators.....	13
4.5.3	Ultrafiltration coefficient.....	13
4.5.4	Volume of the blood compartment.....	13
4.5.5	Pressure drop of the blood compartment.....	13
4.6	Expiry date.....	13
5	Test methods	13
5.1	General.....	13
5.2	Biological safety.....	14
5.3	Sterility.....	14
5.4	Non-pyrogenicity.....	14
5.5	Mechanical characteristics.....	14
5.5.1	Structural integrity.....	14
5.5.2	Blood compartment integrity.....	15
5.5.3	Haemodialyser, haemodiafilter and haemofilter blood compartment ports.....	15
5.5.4	Haemodialyser and haemodiafilter dialysis fluid compartment ports.....	15
5.5.5	Haemofilter filtrate ports.....	15
5.5.6	Haemoconcentrator blood and filtrate ports.....	15
5.6	Performance characteristics.....	17
5.6.1	Clearance.....	17
5.6.2	Sieving coefficient of haemodiafilters, haemofilters and haemoconcentrators.....	19
5.6.3	Ultrafiltration coefficient.....	20
5.6.4	Volume of the blood compartment.....	21
5.6.5	Pressure drop of the blood compartment.....	21
5.7	Expiry date.....	21
6	Labelling	21
6.1	Labelling on the device.....	21
6.2	Labelling on unit containers.....	22
6.3	Labelling on the outer containers.....	22
6.4	Information to be given in the accompanying documentation.....	23
	Bibliography	26