

# ISO 8637-2:2024-04 (E)

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

<b>Contents</b>		<b>Page</b>
<b>Foreword</b>		<b>v</b>
<b>Introduction</b>		<b>vi</b>
<b>1</b>	<b>Scope</b>	<b>1</b>
<b>2</b>	<b>Normative references</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions</b>	<b>2</b>
<b>4</b>	<b>Requirements</b>	<b>6</b>
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
<b>5</b>	<b>Test methods</b>	<b>13</b>
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
<b>6</b>	<b>Labelling</b> .....	<b>23</b>
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
<b>7</b>	<b>Packaging</b> .....	<b>26</b>
	<b>Bibliography</b> .....	<b>27</b>