

# DIN EN ISO 8637-2:2024-09 (E)

## Extracorporeal systems for blood purification - Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (ISO 8637-2:2024)

---

<b>Contents</b>		<b>Page</b>
European foreword .....		4
Foreword.....		5
Introduction.....		6
<b>1</b>	<b>Scope</b> .....	<b>7</b>
<b>2</b>	<b>Normative references</b> .....	<b>7</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>8</b>
<b>4</b>	<b>Requirements</b> .....	<b>12</b>
4.1	General.....	12
4.2	Biological safety and haemocompatibility.....	12
4.3	Sterility.....	12
4.4	Non-pyrogenicity.....	13
4.5	Mechanical characteristics.....	13
4.5.1	Structural integrity.....	13
4.5.2	Connectors to haemodialyser, haemodiafilter or haemofilter.....	13
4.5.3	Connectors to vascular access device.....	16
4.5.4	Connectors to ancillary components.....	16
4.5.5	Colour coding.....	16
4.5.6	Access ports.....	16
4.5.7	Blood pathway volume.....	17
4.5.8	Air capture chamber fill level.....	17
4.5.9	Transducer protectors.....	17
4.6	Functional characteristics.....	17
4.6.1	General.....	17
4.6.2	Blood pump system performance.....	17
4.6.3	Dialysis fluid pump performance.....	18
4.6.4	Net fluid removal.....	18
4.6.5	Substitution fluid flow rate.....	18
4.6.6	Dialysis fluid composition.....	18
4.6.7	Dialysis fluid temperature.....	18
4.6.8	Substitution fluid temperature.....	18
4.6.9	Fluid path occlusion.....	18
4.6.10	Prevention of air infusion.....	19
4.6.11	Pressure monitoring.....	19
4.6.12	Blood leak detection.....	19
4.7	Expiry date.....	19
<b>5</b>	<b>Test methods</b> .....	<b>19</b>
5.1	General.....	19
5.2	Biological safety and haemocompatibility.....	20
5.3	Sterility.....	20
5.4	Non-pyrogenicity.....	20
5.5	Mechanical characteristics.....	20
5.5.1	Structural integrity.....	20
5.5.2	Connectors to haemodialyser, haemodiafilter or haemofilter.....	21
5.5.3	Connectors to vascular access device.....	26
5.5.4	Connectors to ancillary components.....	26
5.5.5	Colour coding.....	26
5.5.6	Access ports.....	27
5.5.7	Blood pathway volume.....	27
5.5.8	Air capture chamber fill level.....	27
5.5.9	Transducer protectors.....	27

5.6	Functional characteristics .....	28
5.6.1	General .....	28
5.6.2	Blood pump system performance .....	28
5.6.3	Dialysis fluid pump performance .....	28
5.6.4	Net fluid removal .....	28
5.6.5	Substitution fluid flow rate .....	28
5.6.6	Dialysis fluid composition .....	28
5.6.7	Dialysis fluid temperature .....	28
5.6.8	Substitution fluid temperature .....	28
5.6.9	Fluid path occlusion .....	29
5.6.10	Prevention of air infusion .....	29
5.6.11	Pressure monitoring .....	29
5.6.12	Blood leak detection .....	29
5.7	Expiry date .....	29
<b>6</b>	<b>Labelling .....</b>	<b>29</b>
6.1	Labelling on the device .....	29
6.2	Labelling on unit protective packaging .....	29
6.3	Labelling on the outer shipping container .....	30
6.4	Information to be given in the accompanying documentation .....	30
<b>7</b>	<b>Packaging .....</b>	<b>32</b>
	<b>Bibliography .....</b>	<b>33</b>