

ISO 8637-2:2018 (E)

Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Requirements
4.1	Biological safety
4.2	Sterility
4.3	Non-pyrogenicity
4.4	Mechanical characteristics
4.4.1	Structural integrity
4.4.2	Connectors to haemodialyser, haemodiafilter or haemofilter
4.4.3	Connectors to vascular access device
4.4.4	Connectors to ancillary components
4.4.5	Colour coding
4.4.6	Access ports
4.4.6.1	Needle access ports
4.4.6.2	Needleless access ports
4.4.7	Blood pathway volume
4.4.8	Air capture chamber fill level
4.4.9	Transducer protectors
4.4.9.1	Integral transducer protectors
4.4.9.2	Non-integral transducer protectors
4.4.10	Blood pathway flow dynamics
4.4.11	Pump segment performance
4.5	Expiry date
4.6	Tubing compliance
5	Test methods
5.1	General
5.2	Biological safety
5.3	Sterility
5.4	Non-pyrogenicity
5.5	Mechanical characteristics
5.5.1	Structural integrity
5.5.1.1	Positive pressure
5.5.1.2	Negative pressure
5.5.2	Connectors to haemodialyser, haemodiafilter or haemofilter
5.5.3	Connector to vascular access device
5.5.4	Connectors to ancillary components
5.5.5	Colour coding
5.5.6	Access ports
5.5.6.1	Needle access ports
5.5.6.2	Needleless access ports
5.5.7	Blood pathway volume
5.5.8	Air capture chamber fill level
5.5.9	Transducer protectors
5.5.10	Blood pathway flow dynamics

- 5.5.11 Pump segment performance
- 5.6 Expiry date
- 5.7 Tubing compliance
- 6 Labelling
 - 6.1 Labelling on the device
 - 6.2 Labelling on unit containers
 - 6.3 Labelling on the outer containers
 - 6.4 Information to be given in the accompanying documentation

Page count: 14