

ISO 8637-3:2018 (E)

Extracorporeal systems for blood purification — Part 3: Plasmafilters

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	Blood compartment integrity
4.4.3	Connectors and ports
4.4.3.1	Blood Compartment Ports
4.4.3.2	Connection to the plasma filtrate compartment
4.4.4	Volume of the blood compartment
4.4.5	Pressure drop of the blood compartment
4.5	Performance characteristics
4.5.1	Filtration rate
4.5.2	Sieving coefficient
4.5.3	Haemolytic characteristics
4.6	Expiry date
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
5.5.2	Blood compartment integrity
5.5.3	Blood compartment ports
5.5.4	Blood compartment volume
5.6	Plasma filtrate port
5.7	Pressure drop
5.7.1	Test solution
5.7.2	Pressure drop test procedure
5.8	Performance characteristics
5.8.1	Filtration rate
5.8.1.1	Test solution
5.8.1.2	Filtration rate test procedure
5.8.2	Sieving coefficient
5.8.2.1	Test solution
5.8.2.2	Sieving coefficient test procedure
5.8.3	Haemolytic characteristics
5.8.3.1	Test solution
5.8.3.2	Haemolytic characteristics test procedure
5.9	Expiry date
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