

Clinical Evaluation Report

Based on MEDDEV 2.7.1:2016 Rev.4 and MEDDEV 2.12-2:2012 Rev.2

Risk Management File, TF 45 Chap 07 RMF
 Biocompatibility studies, TF 45 Chap 10 Biocompatibility Data
 Sterilization Process documentation, TF 45 Chap 14 Sterilization Process

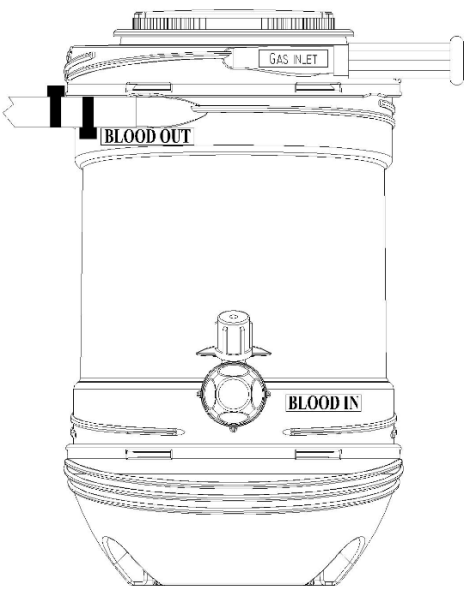
Technical Specifications of ECCO2R		
Technical Data		
	Recommended maximum blood flow	500 ml/min
	Recommended minimum blood flow	100 ml/min
	Recommended minimum gas flow rate	100 ml/min
	Recommended maximum gas flow rate	7.5 l/min
	Recommended maximum gas/blood flow ratio	15:1
	Maximum blood pressure	600 mmHg
	Maximum gas pressure	600 mmHg
	Membrane type	Microporous polymethylpentene (PMP)
	Membrane surface area	1.81 m ²
	Static priming volume oxygenator module + blood lines	148 ml +/- 10%
	Connections:	
	Oxygenator blood inlet	Male Dialyser Connector ISO 8638
Oxygenator blood outlet	Female Dialyser connector ISO 8638	

Table 2. Technical data of ECCO2R

Main materials of ECCO2R	
Materials	
Housing	Polycarbonate (PC)
Microporous hollow fiber membrane	Polymethyl pentene (PMP)
Potting	Polyurethane resin
Contact surface treatment	Phosphorylcholine (PC)
Blood in line	PolyVinyl Chloride (PVC)
Blood out line	PolyVinyl Chloride (PVC)

Table 3. main material of ECCO2R.

4.2 DEVICE DESCRIPTION**4.2.1 The concept**