

Medtronic

FLEXYA hemodialysis system

Product specifications related to Flexya equipment

Treatment modes

Haemodialysis

- Double-needle dialysis
- Single-needle dialysis (single pump)
- Single-needle dialysis (double pump)
- Isolated ultrafiltration

Online haemodiafiltration

- HDF Pre-dilution
- HDF Post-dilution
- HDF Pre + Post dilution
- Mid-HDF Intermediate dilution

Haemodiafiltration with endogenous reinfusion

- HFR
- HFR Aequilibrium
- SUPRA HFR
- SUPRA HFR Aequilibrium

Treatment technical data

Sensors	
Sphygmo, Hemox, Natrium	

Blood flow control	
Double-needle dialysis	30 ÷ 700 mL/min
Single-needle dialysis (single pump)	30 ÷ 700 mL/min with "stroke-pressure" control
Single-needle dialysis (double pump)	30 ÷ 700 mL/min with "pressure-stroke" control and automatic adaptive control system of the efficiency and switching pressure

Extracorporeal circuit pressure monitoring	
Venous pressure	- 400 ÷ 800 mmHg
Arterial pressure	- 400 ÷ 300 mmHg
Infusion pressure	- 400 ÷ 800 mmHg
Prefilter pressure	0 ÷ 800 mmHg



Online haemofiltration

Treatment available in online HDF and Mid-HDF enabling the isolated UF

Profiles

Applicable to all treatments:

- Partial conductivity
- Total conductivity
- Hourly ultrafiltration

Dialysis fluid types

Usable with all the treatments:

- Powder bicarbonate and standard acid concentrate
- Powder bicarbonate and Lympha acetate-free acid concentrate

Applications
Kt/V, Aequilibrium, Soglia, Blood Volume Reduction (BVR)%, thermal balance, arteriovenous recirculation evaluation, Patient Card

Infusion flow	
Online HDF (Pre, Post, Pre+Post)	1 to 24 L/h
HFR, SUPRA HFR	1 to 8 L/h
Resolution	0.1 L/h
Accuracy	± 10%

Dimensions and weight	
Height	1750 mm
Depth	690 mm
Width	520 mm
Weight	128 kg

Heparin pumps	
Syringe capacity	10, 20, 30 mL
Infusion flow	0.0 ÷ 10 mL/h in step of 0.1 mL/h

Air detector	
Detection method	ultrasound
Detection	on venous line
Sensitivity	bubbles ≥ 40 µL

Ultrafiltration control	
Type of control	single pass through Coriolis flowmeter
Hourly weight loss	0.0 ÷ 4 kg/h
Accuracy	± 1 g/min, ± 1% total UF

Blood leak detector	
Detection method	optical
Accuracy	0.35 mL/min (Hct 32%)

Disinfection / Cleaning	
Chemical disinfection	Oxagal (40°C)
Chemical disinfection with dwell time (deep)	Oxagal (40°C) time < 80 h
User chemical cleaning	
User deep chemical cleaning	
Heat + citric acid disinfection	Citric acid 12-50% T _{med} 65°C - T _{max} 98°C
Standard heat disinfection	Water T _{med} 65°C - T _{max} 98°C
Centralised heat disinfection	Water T _{med} 65°C - T _{max} 98°C
Centralised chemical cleaning	Active chlorine or peracetic acid
Centralised heat rinsing	

Water supply	
Quality	In compliance with national and international standards, e.g. AAMI, European Pharmacopoeia
Inlet temperature	5°C ÷ 32°C in dialysis 5°C ÷ 94°C in centralised heat disinfection
Inlet pressure	2 ÷ 7 bar
Water filter	H ₂ Oclean ultrafilter

Blood detector	
Detection method	optical
Venous chamber	optical (camera)

Dialysis fluid preparation and monitoring	
Dialysis fluid flow	300 ÷ 1200 mL/min
Total flow	300 ÷ 1200 mL/min
Double ultrafiltration	2 Diallyclean ultrafilters

Dialysis fluid conductivity	
Total	12.1 ÷ 16.0 mS/cm
Bicarbonate solution	2.4 ÷ 3.6 mS/cm

Power supply	
Voltage	(220 - 240 V~) ± 10% (110 - 120 V~) ± 10%
Frequency	50/60 Hz
Avg. power absorbed during dialysis	1.0 kW (T _{in} 17.5°C - T _{dial} 37°C - T _{amb} 20°C - Dialysate flow 800 mL/min)
Max. absorption	8A (220 - 240 V~) 16A (110 - 120 V~)

Ambient operating conditions	
Temperature	10°C ÷ 30°C
Relative humidity	0 ÷ 95% non-condensing
Pressure	70-106 kPa (atmospheric)

External connections	
RJ - 45, Ethernet - USB	

Safety standards	
General standards	IEC 60601-1
Collateral standards	IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-8 IEC 60601-1-10
Particular standards	IEC 60601-2-16 IEC 80601-2-30
Other standards	IEC 62304 IEC 62366-1 EN ISO 14971

IMPORTANT: Flexya is an active, non-invasive, class IIb medical device CE0123. Please refer to the Instructions for Use for complete instructions, contraindications, warnings and precautions.