Medtronic

Technical Data Sheet

FLEXYA hemodialysis system

Device description

The FLEXYA haemodialysis system is intended for extracorporeal dialysis treatments and haemodiafiltration.

The FLEXYA hemodialysis system is equipped with:

- Three peristaltic pumps for control of the extracorporeal blood circuit (arterial line and venous line) and administration of the infusion solution.
- A "cassette" system for automatic loading and optical recognition (by reading a barcode) of the preassembled Automatica BL 500 bloodlines.
- Three automatically-driven electroclamps that act on the arterial, venous and infusion lines.
- Two independently operated syringe pumps for the administration of heparin into the extracorporeal blood circuit.
- Electronic multiprocessor architecture consisting of control and protection systems that control functioning of all the actuators/detectors/transducers in the various treatment phases.
- A set of cutting-edge sensors (Sphygmo, Hemox, Natrium) for real-time monitoring of dialysis progress and patient status.
- A large orientable touchscreen display.
- A dialysis fluid preparation system with powder bicarbonate and liquid acid concentrate with or without acetate (Lympha).
- A double dialysis fluid ultrafiltration system for preparation of the ultrapure solution that can be used as both dialysis fluid and infusion fluid in online treatments.
- A single-pass and hydraulic circuit that can be completely disinfected.
- Four pivoting wheels with a braking system.

The three-pump design of the FLEXYA hemodialysis system allows you to perform multiple dialysis treatments:

- Double-needle haemodialysis (DN)
- Single-needle single-pump haemodialysis (SNsp)
- Single-needle double-pump haemodialysis (SNdp)
- Sequential DN, SNsp and SNdp haemodialysis by means of manual activation of isolated ultrafiltration

- Double-needle online haemodiafiltration in pre-dilution (HDF PRE)
- Double-needle online haemodiafiltration in post-dilution (HDF POST)
- Double-needle online haemodiafiltration in pre- and post-dilution (HDF PRE+POST)
- Double-needle online haemodiafiltration with mid-dilution (Mid-dilution HDF)
- Double-needle online haemodiafiltration in pre/post/pre+post dilution or mid-dilution with isolated ultrafiltration (technically, haemofiltration is performed in the various infusion methods)
- Haemodiafiltration with endogenous reinfusion (HFR and SUPRA therapies).

The following **FLEXYA** models are manufactured:

- Code **IBN03X700** [220-240V, Bidry]
- Code **IBN03X300** [110-120V, Bidry]
- Code **IBN03X701** [220-240V, Biflexy]
- Code **IBN03X301** [110-120V, Biflexy]

FLEXYA system

Device classification		
93/42/EEC	Class IIb	
CND	Z12090201	Haemodialysis machines
GMDN	35453	Haemofiltration system
	58130	Haemodialysis system, institutional
IEC 60601-1	Class I - Type B	

Intended use

System for extracorporeal dialysis treatments and haemodiafiltration.

Field of application

The FLEXYA system is designed for execution and monitoring of individual dialysis treatments in patients affected by chronic and acute renal failure and water overload or for removal of harmful molecules and substances for whom an extracorporeal blood treatment has been prescribed.

It allows performing haemodialysis, haemofiltration and haemodiafiltration treatments in single or double vascular access mode.

It can be used in a hospital environment, dialysis centres (also with limited assistance) and clinics under the supervision of medical and/or nursing staff trained for the purpose.

Materials in contact with the dialysate

Metallic materials
Stainless steel AISI 316
Stainless steel UHB 904L/R 840
Stainless steel AISI 302
Stainless steel AISI 316L
Titanium grade 1
Ceramic materials
Pure alumina 98.5%
Zirconium
Glass
Borosilicated glass 3.3 DIN-ISO 3585

Plastic materials
Polyoxymethylene (POM)
Polyvinylidene difluoride (PVDF)
Polyetherimide (PEI)
Polytetrafluoroethylene (PTFE)
Polysulfone (PSU)
Polyarylether (PEEK)
Polyphenylsulfide (PPS)
Polyethersulfone
Polycarbonate
Polyurethane
Polyphthalamide (PPA)
Polyphenylsulfone (PPSU)
Polypropylene reinforced with glass fibres (PP/GF)

Elastomeric materials
Silicone VMQ-FG
Silicone VMQ-FG + fabric
Fluorosilicone (MVSQ)
Ethylene-propylene-diene (EPDM)
Medical-grade silicone Si
Red silicone Si

Tubes
Silicone VMQ-FG
Silicone VMQ-FG + fabric
Medical-grade silicone Si
Lubricants
Medical-grade silicone spray
Colourless ethanol

Disposal

At the end of its useful lifetime the machine must be disposed of as special waste and be collected separately in accordance with the national regulations in force. The machine to be disposed of must be returned to the manufacturer appropriately disinfected and accompanied by a declaration stating that the machine is NOT infected.

Technical and functional characteristics

Dimensions and weight	
Height, depth, width	1750 × 690 × 520 mm
Weight	128 kg
Maximum weight in condition of use	163 kg

Ambient and storage conditions	
Operation	
Temperature	between +10°C and +30°C
Relative humidity	0-95% non-condensing
Pressure	70-106 kPa (atmospheric)
Storage and transport (without liquids)	
Temperature	between -29°C and +60°C
Relative humidity	0-95% non-condensing
Pressure	70-106 kPa (atmospheric)

Water system requirements	
Water	Suitable for dialysis treatments in compliance with the American AAMI standards or the European Pharmacopoeia in force
Temperature (min-max)	between 5°C and 32°C during dialysis between 5°C and 94°C during centralised heat disinfection
Input pressure	2 - 7 bar
Flow (minimum at inlet)	1200 ml/min

Consumption (4h treatment time)	500 ml/min (120 l) 800 ml/min (192 l) 1200 ml/min (288 l)
Drain	At atmospheric pressure to prevent siphon effects
Height of drain from ground	max. 800 mm
Flow	max 76 l/h
Temperature	~15°C during dialysis ~70°C during heat disinfection

Electrical data	
Nominal voltage	220-240V~ ± 10% 110-120V~ ± 10%
Nominal frequency	50/60 Hz
Average power absorbed during dialysis	1.0 kW (T**in** water = 17.5°C, T**dial** = 37°C, T**amb** = 20°C, Dialysate flow = 800 ml/min)
Energy exchanged with the environment	~547 W (T**dial** = 39°C, T**amb** = 20°C, Dialysate flow = 500 ml/min)
Max. absorption	8A (220-240V~) 16A (110-120V~)
Leakage current to earth	≤ 5 mA
Leakage current to patient	≤ 0.1 mA in compliance with IEC 60601-1
Applied part	Extracorporeal circuit including needles, dialysis fluid and all the conductive parts connected to it (type B), and the BPM (type BF).
Type of protection against electric shock	Class I
Degree of protection against infiltration of water (IP code)	IP21
Electromagnetic compatibility	In compliance with IEC 60601-1-2:2014
Power failure	The system is capable of keeping the current dialysis parameters (including the alarm system parameters) in memory for a maximum of 2 minutes. An acoustic alarm is instantly sounded and cannot be silenced. When the power is restored, the system automatically restarts from the same values.
Battery operation	Lead battery 12V, 7.2Ah

Settable dialysis parameters	
Blood flow	30-700 ml/min (depending on the treatment and phase)
Resolution	1 ml/min
Accuracy	±10% for AP >-130 mmHg ±25% for -250 mmHg < AP < -130 mmHg in compliance with IEC 60601-2-16
Infusion flow	1-24 l/h (depending on the treatment)
Resolution	0.1 l/h
Accuracy	±10%
Heparin flow (with syringe)	0.0-10 ml/h (increments of 0.1 ml/h) - Syringe capacity 10, 20, 30 ml
Dialysis fluid	
Flow	300-1200 ml/min
Resolution	1 ml/min
Accuracy	-10% to +15%
Temperature	35-39°C
Resolution	0.1°C
Accuracy	± 0.5°C
Conductivity	
Total	12.1-16.0 mS/cm – Resolution: 0.1 mS/cm
Bicarbonate solution	2.4-3.6 mS/cm – Resolution: 0.1 mS/cm
Accuracy	± 0.1 mS/cm
Hourly weight loss	0.0-4.0 kg/h
Accuracy	± 1 g/min, ± 1% of hourly weight loss

Hydraulic circuit disinfection/cleaning programs

- Oxagal chemical disinfection
- Oxagal Deep chemical disinfection (also with dwell time)
- User chemical cleaning
- User Deep chemical cleaning
- Heat + Citric Acid disinfection (concentration configurable from 12 to 50%)
- Standard heat disinfection with water
- Centralised heat disinfection with water
- Centralised chemical cleaning (active chlorine or peracetic acid)
- Centralised heat rinsing

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.

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