

Dialog+ Evolution HDF Online Technical Specification

1. General Technical Specifications

Description	Value
Nominal voltage	230 V~ ± 10%
Nominal frequency	50/60 Hz ± 5%
Nominal current	max. 11 A
Connected load	2,5 kW
Main Cord	
Current voltage rating	16 A
Minimum cross section of single strand	1.5 mm ² for 230 V~
Withstand voltage of single strand (L-N, L-PN, N-PE)	min. 2 kV~, 50 Hz, ≥ 1 min
Average energy consumption	approx. 1.5 kW/h
Heat emission	approx. 230 W/h
Categorization	II b according to EC Directive for Medical Devices 93/42/EEC
Classification	Type B, IEC 60601-1
Device leakage current	< 500 µA
Patient leakage current	< 10 µA
Protection class	IP21 (Protection against foreign bodies > 12 mm and certically falling drip water) DIN EN 60529
Electrical ground	via optional cable
Dimensions (WxHxD)	approx. 510 x 1678 x 637 mm
Housing material	Aluminum, corrosion-proof
Empty weight	approx. 85 kg
Water supply	
Pressure range	0,5 - 6 bar
Temperature range	10 - 30 °C Heat exchanger recommended at < 10 °C
Water inlet temperature for disinfection	max. 95 °C
Alarm "No Water"	from separate monitoring device
Concentrate supply	from container or central supply 0-1 bar

2. Ambient conditions

Description	Value
Operation	
Temperature	+10 to +40 °C
Relative humidity	15% - 70 %
Atmospheric pressure	700 - 1060 mbar
Tranportation and storage (dry)	
Temperature	-20 to +60 °C
Relative humidity	15% - 80%
Atmospheric pressure	700 - 1060 mbar

3. Dialysate system

Description	Value
Temperature operating range	33 - 40 °C
Tolerance	+0,5 °C to -1,5 °C
Limits	± 1 °C (of set specified value)
Excessive temperature protection	41 °C
Protection system	temperature sensor
Bridging time of protection system	cannot be bridged during dialysis
Deactivation of acoustic alarm	120 s
Heating power	1800 W
Conditioning	Conductivity regulated
Operating regime	Conductivity bicarbonate 2-4 mS/cm, 4-7 mS/cm
	Overall conductivity 12,5 to 16,0 mS/cm
Tolerance	± 0,2 mS/cm
Measurement	temperature-compensated (reference temperature 25 °C)
Protection system	monitoring through second conductivity sensor with different geometry
Limits	± 5% (of set value)
Bridging time of protection system	cannot be bridged during dialysis
Deactivation of acoustic alarm	180 s
Flow	300 - 800 ml/min
DF tolerance at dialysis machine	± 5 % (of specified value) at 300-800 ml/min
Bridging time of protection system	not bridgeable via balance chamber filling times during dialysis
Deactivation of acoustic alarm	300 s
Dialysate pressure range	+400 to -450 mmHg
Tolerance (PDA)	± 10 mmHg
Upper limit	+400 mmHg
Lower limit	-450 mmHg
Deactivation of acoustic alarm	120 s
Blood leak detector	red sensitive
Tolerance	10%
Alarm threshold	> 0,5 ml/min blood at HKT 45% > 0,35 ml/min blood at HKT 25% (AAMI)
Bridging time of protection system	cannot be bridged during dialysis
Deactivation of acoustic alarm	120 s
Ultrafiltration	Volume-controlled via balance chambers, ultrafiltration through ultrafiltration pump Sequential ultrafiltration (Bergström)
Operating range	0 - 4.000 ml/h
Overall Accuracy	$F = F_{bal} + F_{UF}$
F_{bal}	± 0,2 ml/chamber cycle
F_{UF}	Ultrafiltration pump tolerance < 1%
Protection system	Speed monitoring of ultrafiltration pump with an accuracy of < 1%

	System will alarm 200 ml beyond given value or 10% beyond preset UF rate
Bridging time of protection system	cannot be bridged during dialysis
Deactivation of acoustic alarm	120 s
Trans membrane pressure	
Limit setting range (max. TMP)	300 - 700 mmHg
Absolute alarm limit	-100 mmHg
Limit window	adjustable (2% - 99%)
Tolerance	Calculator through PBE, PDA and PV
Bridging time of protection system	cannot be bridged during dialysis
Deactivation of acoustic alarm	120 s
Degassing system	pump
Tolerance	± 50 mmHg
Disinfection	
During disinfection processes, dialysis is blocked	
manufacturer	
	Automatic program with enforced rinse-out The parameters for the disinfectant used can be set in the service program HDF-online and dialysis fluid filter option : Only disinfectants cleared for the dialysis fluid filter can be used.
Disinfection/cleaning	
Thermal disinfection	Automatic program cycle at approx. 85 °C at the dialyzer couplings

4. Extracorporeal circulation

Description	Value
Blood pump	2-roller pump with automatic motor switch-off when lid is opened, backstop, low hemolysis
Pumping rate	50 - 600 ml/min Adjustable in 10 ml steps
Tolerance interval	< 10%
Working pressure range	Intake pressure up to -390 mmHg Pumping pressure 0 - 1725 mmHg
Heparin pump	Syringe pump for 10-30 ml syringes
Pumping rate	0,1 - 10 ml/h in steps of 0,5 ml/h or 0,1 ml/h, can be turned off, bolus : 600 ml/h
Tolerance interval	< ± 10%
Pressure range	0 to +480 mmHg
Safety air detector	SAD (Safety air detector), based on ultrasound
	Air bubbles at > 50 µl, micro foam with cumulated volume
	Limit value double needle:
	0,2 ml at 0-200 ml/min SAD flow
	0,3 ml at 200-400 ml/min SAD flow
	0,5 ml at > 400 ml/min SAD flow
	Limit value single needle:
Sensitivity	0,7 ml at 1200 ml/min constant SAD flow
Protection system	Ultrasound detector, automatic cyclical check during entire operating phase

Bridging time of protection system	cannot be bridged during dialysis
Red sensor	in SAD housing
Function	Detects blood in tube system
Functions	1st mode of operation: The blood pump is stopped as soon as the red sensor detects blood when connected at this site 2nd mode of operation: If the red sensor detects blood at this point, a heparin bolus is administered 3rd mode of operation: If no blood is detected at this site in the End Therapy mode, the blood pump is stopped 4th mode of operation: if blood is detected during preparation or disinfection, the blood pump is stopped --> Alarm caused
Pressure measurement at arterial inlet of dialyzer (PBE)	Electronic pressure sensor
Operating range	0 - 700 mmHg
Tolerance interval	± 10 mmHg
Limit	Adjustable within operating range
Protection system	Test prior to start of therapy
Arterial inlet pressure (PA) measurement	Electronic pressure sensor with digital quasi-analogue display
Operating range	-400 to +400 mmHg
Tolerance	± 10 mmHg
Limit	-400 to +400 mmHg Adjustable within operating range, adjustable interval width for dynamic limits window
Protection system	Electronic pressure sensor, test prior to start of therapy
Deactivation of acoustic alarm	120 s
Venous return pressure (PV) measurement	Electronic pressure sensor with digital quasi-analogue display
Operating range	20 - 390 mmHg
Tolerance	± 10 mmHg
Limit	Alarm window around operating value Configurable alarm window (20-200 mmHg) After blood pump adjustment, the alarm window is re-centered
Protection system	Test prior to start of therapy Venous window of 20-390 mmHg. Venous limits are monitored by the function and control systems
Bridging time of protection system	cannot be bridged during dialysis
Deactivation of acoustic alarm	120 s

5. HDF/HF-online

Description	Value
HDF (Haemodiafiltration)	
Substitution rate	20 - 400 ml/min ± 10%
Dialysate processing	500 - 800 ml/min ± 10%
Infusion bolus	50 - 250 ml/min ± 10%
HF (Haemofiltration)	

Substitution rate	20 - 400 ml/min \pm 10%
Infusion bolus	50 - 250 ml/min \pm 10%
Online Filter	
Operating time	150 treatments (900 h), see filter instructions for use