4008 B / 4008 H / 4008 S Hemodialysis Device

Technical Manual

Software version: ≥ 4.5 / ≥ 5.3
Edition: 12A-2016
Part no.: F40003413
CE 0123

FRESENIUS MEDICAL CARE

4008 B / 4008 H / 4008 S	**TSC / MA report**	FRESENIUS MEDICAL CARE

These checks must be performed every **24 months** if all of the following requirements have been met: ❑ Unique assignment of the rotors to the appropriate tube roller pumps ❑ Software: 4008 B system: from 4.951 to < 5.00 or with 5.201 or higher 4008 H/S systems: from 2.951 to < 3.00 or from 4.311 to < 10.00 ❑ DIP switch PCB LP632 array 2 SW 5 set to OFF. ❑ DIP switch PCB LP631 array 2 SW 7 set to ON. ❑ DIP switch PCB LP631 array 2 SW 8 set to ON. (With CDS option only) ❑ Heater rod made of Titanium If one of the requirements mentioned above has not been met, the checks have to be performed every **12 months**.	Interval: ❑ 24 months ❑ 12 months (Please check)

Name of technician			**Service report no.:**
Customer / Customer no.:			
Serial number:	**Inventory no.:**		**Operating hours:**
Device type:	❑ 4008 B	❑ 4008 H	❑ 4008 S
With option:	❑ DIASAFE® *plus*	❑ OCM	❑ ONLINE*plus*™
❑ BPM	❑ BTM	❑ BVM	❑ DIASAFE
			❑ SN
			❑ ONLINE HDF
			❑ bibag®
			❑ 4008 HDF

	No.	Description	Meas. value	✓
	1	**Visual inspections**		
TSC	1.1	Fuses accessible from the outside comply with the specified values	–	❑
TSC	1.2	Labels and inscriptions are present and legible	–	❑
TSC	1.3	Mechanical condition permits further safe use	–	❑
TSC	1.4	There are no signs of damage or contamination	–	❑
TSC	1.4.1	No signs of damage on the tube roller pump rotors	–	❑
TSC	1.4.2	PCB LP 928 (CAN bus distributor) with covering checked (only 4008 S with E-Code 905 and lower)	–	❑
TSC	1.5	Power cable not damaged	–	❑
MA	1.6	Preventive measures		
MA	1.6.1	Sealing plungers in suction tubes replaced and lubricated; rivets replaced	–	❑
MA	1.6.2	Rubber in the rinse chambers checked for proper function	–	❑
MA	1.6.3	Rinse chamber screws are tight	–	❑
MA	1.6.4	Check valve replaced and, if required, CDS check valves 117/118 and filter 119/120 replaced	–	❑
MA	1.6.5	Pre-UF pump filter, filter downstream of MV 43, filter between rinse chambers and on MV 99, MV 100 replaced	–	❑
MA	1.6.6	Dialysate filter replaced or sieve changed	–	❑
MA	1.6.7	O-rings in dialyzer couplings replaced	–	❑
MA	1.6.8	Sampling valve is functional	–	❑
MA	1.6.9	Fan filter replaced	–	❑
MA	1.6.10	Running band and tube segment of air separation pump replaced	–	❑
MA	1.6.11	MV 84 (yellow label), replaced after 2 years. (Only applicable when using Puristeril 340, Puristeril *plus*)	–	❑
MA	1.6.12	Connecting piece or equilibration chamber replaced. (Only when ONLINE*plus*™ and DIASAFE® *plus* options are not used)	–	❑
MA	1.6.13	Filter 210 (if present) replaced	–	❑
MA	1.6.14	Disinfectant filter replaced	–	❑
MA	1.6.15	There are no dirty or worn tubes	–	❑
MA	1.6.16	*Every 4 years only*: Battery replaced (ensure correct polarity!)		
	2	**General checks**		
TSC	2.1	Power failure alarm – continuous sound – text displayed: Emergency operation	–	❑

	No.	Description	Meas. value	✓
TSC	2.2	Air separation by air separation pump activated; text displayed if more air must be separated and OD senses blood: Fill program	–	☐
TSC	2.3	Check DIP switches PCB LP 631 (CPU1) DIP switch array 2 SW7 is set to ON. With Central Delivery System: PCB LP 631 (CPU1) DIP switch array 2 SW8 is set to ON.	–	☐
	3	**Check of the hydraulics**		
MA	3.1	Water inlet pressure (reduced) 0.9 bar to 1.4 bar	_____	☐
MA	3.2	Loading pressure 1.25 bar ±0.05 bar From EC495 (4008 B); EC295 (4008 H) and EC275 (4008 S) Loading pressure 1.45 bar ±0.05 bar	_____	☐
MA	3.3	Degassing pressure: –0.81 to –0.85 bar	_____	☐
MA	3.4	Relief pressure of balancing chamber at 800 ml/min Loading pressure: Relief pressure: 1.2 to 1.3 bar 1.9 to 2.1 bar 1.45 ±0.05 bar 2.2 ±0.05 bar	_____	☐
	4	**Ultrafiltration system and membrane pumps**		
TSC	4.1	UF pump, 1 stroke = 1 ml, 60 strokes = 60 ml ±0.5 ml (59.6 g ±0.5 g dialysis water)	_____	☐
MA	4.2	Concentrate pump calibration volume removal / number of strokes	_____	☐
MA	4.3	Bicarbonate pump calibration volume removal / number of strokes	_____	☐
	5	**Treatment**		
MA	5.1	Desired temperature 37 °C ±0.5 °C	_____	☐
MA	5.2	Temperature display 37 °C ±0.5 °C	_____	☐
MA	5.3	Dialysate pressure – Flow off zero point checked – Slope checked	_____ _____	☐ ☐
TSC	5.4	Conductivity display checked with reference meter If the bibag® option is used, connect a bibag®! – CD device – CD ref.	_____ _____	☐ ☐
	6	**Extracorporeal components**		
MA	6.1	Arterial pressure display checked with reference meter	–	☐
MA	6.2	Venous pressure display checked with reference meter	–	☐
TSC	6.3	Blood pumps: Check of blood pump rate (calibration program: BP rate TEST)	–	☐
TSC	6.4	SN switching pressure checked according to table in the Technical Manual	–	☐
TSC	6.5	Blood pump stop alarm checked	–	☐
TSC	6.6	Venous tube clamp closes after blood alarm	–	☐
TSC	6.7	Pressure of approx. 2 bar in the venous bubble catcher. Pressure must not drop by more than 0.1 bar within 3 minutes	–	☐
	7	**Options**		
	7.1	**bibag®**		
MA	7.1.1	bibag® connector, O-rings replaced	–	☐
MA	7.1.2	Switching pressure of PSW 134 checked, 130 mbar, + 30 mbar	_____	☐
	7.2	**DIASAFE**		
MA	7.2.1	DIASAFE filter life checked	–	☐
MA	7.2.2	Hydrophobic filter 111 replaced	–	☐
MA	7.2.3	O-rings in the DIASAFE's dialysate couplings checked	–	☐
	7.3	**DIASAFE® *plus***		
MA	7.3.1	DIASAFE® *plus* filter life checked	–	☐
MA	7.3.2	Hydrophobic filter 111 replaced	–	☐
	7.4	**4008 HDF**		
TSC	7.4.1	2nd UF pump, 1 stroke = 1 ml, 60 strokes = 60 ml ±0.5 ml (59.6 g ±0.5 g dialysis water)	_____	☐
	7.5	**ONLINE-HDF (and DIASAFE)**		
MA	7.5.1	Filter life of DIASAFE and ONLINE filter checked	–	☐
MA	7.5.2	Hydrophobic filter 111 replaced	–	☐
MA	7.5.3	O-rings in the DIASAFE's dialysate couplings checked	–	☐
MA	7.5.4	HDF pump rotor checked (smooth running, wear)	–	☐
MA	7.5.5	Fastening strap for Luer-lock checked	–	☐
TSC	7.5.6	Substitute pump ☐ with DC motor: Pump adjusted *or* ☐ with stepper motor: Pump rate checked (calibration program: HDF-Pump-Rate Check)	– Desired / actual: ____ / ____	☐

	No.	Description	Meas. value	✓
TSC	7.5.7	Substituate pump stop – Following blood alarm – After triggering the bypass function – After opening the blood pump door	– – –	☐ ☐ ☐
TSC	7.5.8	Check substituate pump for proper function: – Rinse program, delivery rate: 400 ml/min – Hot rinse program, delivery rate: 150 ml/min – Disinfection program, delivery rate: 400 ml/min	– – –	☐ ☐ ☐
	7.6	**ONLINE*plus*™ (and DIASAFE® *plus*)**		
MA	7.6.1	Filter life of DIASAFE® *plus* and ONLINE*plus*™ checked	–	☐
MA	7.6.2	Hydrophobic filters 111 and 184 replaced	–	☐
MA	7.6.3	O-rings at substituate port 195 and rinse port 194 replaced. O-rings lubricated with Unisilkon grease before installation	–	☐
TSC	7.6.4	Tube in the tube pinch valve 193 (ONL1) replaced	–	☐
TSC	7.6.5	Check of DIP switch PCB LP632 (CPU2) DIP switch array 2 switch 5 is set to OFF in HPU (hydraulics processing unit)	–	☐
	7.7	**OCM**		
MA	7.7.1	OCM temperature / conductivity compensation test completed – CD cell 7 – CD cell 110 – OCM PULSE calibration required?	– _____ _____ ☐ Yes ☐ No	☐ ☐ ☐
	7.8	**BPM 4008** **The Technical Measurement Checks (TMC) additionally stipulated for specific countries form part of the Technical Safety Checks (TSC).**		
MA	7.8.1	Labels and inscriptions are present and legible	–	☐
MA	7.8.2	Mechanical condition permits further safe use	–	☐
MA	7.8.2.1	Tube connection correctly connected to device	–	☐
MA	7.8.2.2	Internal blood pressure module, printed circuit boards, cable connections properly attached	–	☐
MA	7.8.2.3	Damaged tubes or cuffs have been replaced	–	☐
MA	7.8.2.4	Indicating elements checked	–	☐
MA	7.8.2.5	Touch panel checked	–	☐
TSC TMC	7.8.3	Leakage test: Pressure leakage rate less than 6 mmHg/min	–	☐
TSC TMC	7.8.4	Calibration: Pressure valuesTolerance 250 mmHg ±3 mmHg 200 mmHg ±3 mmHg 150 mmHg ±3 mmHg 100 mmHg ±3 mmHg 050 mmHg ±3 mmHg	 _____ _____ _____ _____ _____	 ☐ ☐ ☐ ☐ ☐
TSC TMC	7.8.5	Safety valve: Drained at 320 mmHg, ±10 mmHg	–	☐
TSC TMC	7.8.6	Blood pressure measurement performed	–	☐
	7.9	**BTM 4008**		
		No further Technical Safety Checks and maintenance procedures must be performed		
	7.10	**BVM 4008**		
		No further Technical Safety Checks and maintenance procedures must be performed		

	No.	Description	Meas. value	✓
	8	**Check of the electrical safety** **According to (DIN) EN 62353:2008, IEC 62353:2007** **Measurement points: (see Chapter 3.2.3.1 on page 3-39)** **For 4008 HDF option, check additional measuring point!**		
TSC	8.1	Visual inspections performed according to item 1	–	❑
TSC	8.2	Protective earth resistance, maximum 0.3 Ω (with power cable)	_____ Ω	❑
TSC	8.3	Device leakage current measured ❑ Device leakage current – differential current measurement according to fig. 5 *or* ❑ Device leakage current – direct measurement according to fig. 4	–	❑
		Nominal voltage of power supply: _____ V		
		Device leakage current, mains polarity 1	_____ µA	
		For line voltage	_____ V	
		Normalized to nominal voltage (maximum 500 µA, see Additional conditions)	_____ µA	
		Device leakage current, mains polarity 2	_____ µA	
		For line voltage	_____ V	
		Normalized to nominal voltage (maximum 500 µA, see Additional conditions)	_____ µA	
	9	**Functional checks**		
TSC	9.1	T1 Test completed	–	❑

Test equipment used:

Temperature, conductivity, pressure
(type, serial number):

Protective earth resistance, leakage current
(type, serial number):

Remarks:

Date:	**Signature:**	**Stamp:**

The device is released for its intended use **(attach inspection label)**	❑ Yes ❑ No
Date of next check:	
Remarks:	

Date:	**Signature:**	**Stamp:**

Warning

A disinfection must be performed on completion of the checks.