

5008S



Service Manual

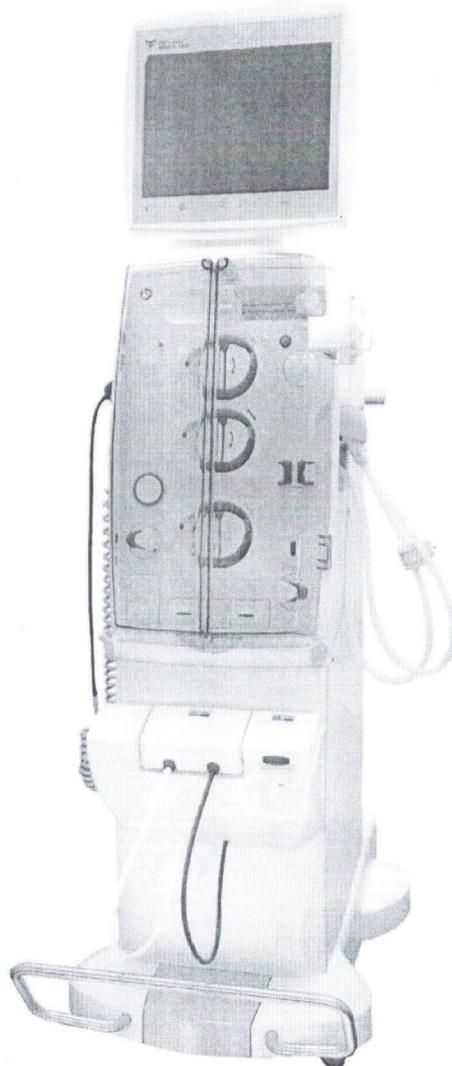
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CE⁰¹²³



**FRESENIUS
MEDICAL CARE**

6 Technical safety checks / maintenance procedures

6.1 Important information on TSCs and MAs

Considerations for working on the device	Read the information under "Considerations for working on the device" (see chapter 2.5 on page 19).
Technical safety checks (TSCs)	<p>The first TSCs are required before the end of the 24th month following initial start-up after delivery from the factory. All further TSCs are required before the end of the 24th month following the last TSC performed.</p> <p>The technical measurement checks (TMC) additionally required are country-specific and form part of the technical safety checks (TSC).</p> <p>The completion of the TSCs must be recorded in the Medical Device Register.</p>
Maintenance procedures (MAs)	The maintenance procedures (MAs) are a recommendation of the manufacturer. The maintenance procedures (MAs) help ensure trouble-free operation, and must be carried out for the first time before the end of the 24th month following initial start-up after delivery from the factory. All further maintenance procedures (MAs) should be performed before the end of the 24th month following the last maintenance procedure (MA) performed.
Qualification requirements of testers	<p>The checks must be performed by the manufacturer's service support organization or a person authorized by them.</p> <p>The checks must be performed by personnel qualified to perform them correctly, based on their education, training, knowledge and experience. Furthermore, the persons performing the checks must be permitted to do so independently and without outside interference.</p>
Processing the report	The report consists of inspection items and the corresponding explanatory notes. The inspection items and the corresponding explanations are related to each other and should be processed in chronological order.

Service report number:			Serial number:		
Cat.	No.	Designation	Operating state	Measured value/correction	✓/NA
MA	3.3	Flow pump calibrated.	Service, CAL-IBRATE	–	<input type="checkbox"/> /✓
MA	3.4	Maximum water inflow when the reverse osmosis unit is running under its normal load checked. Target value: 1300 ml/min to 1550 ml/min (the target value may, under a specific condition, be 1300 ml/min to 1800 ml/min as described in the explanatory notes).	Service, CAL-IBRATE	____/____ ml/min	<input type="checkbox"/> /✓
MA	3.5	<i>Only if concentrate containers are used exclusively:</i> Level sensor (S17) checked.	Service, CAL-IBRATE	–	<input type="checkbox"/> /✓
MA	3.6	<i>Only if bicarbonate containers are used exclusively:</i> Level sensor (S19) checked.	Service, CAL-IBRATE	–	<input type="checkbox"/> /✓
MA	3.7	<i>Only if CDS (option) used exclusively:</i> Function of suction tube flap tested.	Service, CAL-IBRATE	–	<input type="checkbox"/> /✓
4 Dialysate pressure					
MA	4.1	Zero point S03/S07 checked. Reference meter: +0 mbar (±5 mbar) Check S03. Target value: S03 = Display of reference meter + (+11 mbar to +71 mbar) Check S07. Target value: S07 = Display of reference meter + (+11 mbar to +71 mbar)	Service, CAL-IBRATE	____/____ mbar ____/____ mbar ____/____ mbar	<input type="checkbox"/> /✓
MA	4.2	Slope S03/S07 (+) checked. Reference meter: +533 mbar (±26 mbar) Check S03. Target value: S03 = Display of reference meter + (+11 mbar to +71 mbar) Check S07. Target value: S07 = Display of reference meter + (+11 mbar to +71 mbar)	Service, CAL-IBRATE	____/____ mbar ____/____ mbar ____/____ mbar	<input type="checkbox"/> /✓
MA	4.3	Slope S03/S07 (–) checked. Reference meter: –533 mbar (±26 mbar) Check S03. Target value: S03 = Display of reference meter + (+11 mbar to +71 mbar) Check S07. Target value: S07 = Display of reference meter + (+11 mbar to +71 mbar)	Service, CAL-IBRATE	____/____ mbar ____/____ mbar ____/____ mbar	<input type="checkbox"/> /✓
5 Blood leak detector					
TSC	5.1	Blood leak detector checked. Target value for blood leak voltage: 4.8 Volt to 5.2 Volt Target value for dimness voltage: 4.7 Volt to 5.3 Volt	Service, CAL-IBRATE	____/____ Volt ____/____ Volt	<input type="checkbox"/>
6 Temperature/conductivity					
Information: Device set up for verifying temperature and conductivity. – Close the shunt interlock – no bypass – Dialysate flow: 500 ml/min – Dialysate temperature: 36.8 °C to 37.2 °C – Conductivity: 13.5 mS/cm to 14.5 mS/cm					
TSC	6.1	Temperature tested with reference meter. Display of temperature sensor PT7 Display of reference meter Target value for temperature difference (reference meter – PT7): –0.5 °C to +0.2 °C	Service, CAL-IBRATE	____/____ °C ____/____ °C ____/____ °C	<input type="checkbox"/>
TSC	6.2	Conductivity tested with reference meter. If a bibag is generally used, the test must be performed with a bibag. Display of conductivity sensor CD7 Display of reference meter Target value for conductivity difference (reference meter – CD7): ±0.15 mS/cm	Service, CAL-IBRATE	____/____ mS/cm ____/____ mS/cm ____/____ mS/cm	<input type="checkbox"/>
7 OCM					
TSC	7.1	Conductivity difference between CD7 and CD9 checked. Target value for conductivity difference (CD7 – CD9): ±0.05 mS/cm If the conductivity difference is > ±0.05 mS/cm: Calibrate conductivity and OCM.	Service, CAL-IBRATE	____/____ mS/cm	<input type="checkbox"/>
8 Error memory and data recorder					
MA	8.1	Clear error memory and data recorder.	Service, CAL-IBRATE	–	<input type="checkbox"/> /✓

Service report number:			Serial number:		
Cat.	No.	Designation	Operating state	Measured value/correction	✓/NA
	9	Options			
	9.1	BPM (option): The technical measurement checks (TMCs) additionally required are country-specific and form part of the technical safety checks (TSCs).			<input type="checkbox"/>
TSC TMC	9.1.1	BPM (option) checked against the required pressures. Test pressure to be set on the reference meter: +250 mmHg (±3 mmHg) Set point BPM: reference meter value (±3 mmHg) Test pressure to be set on the reference meter: +200 mmHg (±3 mmHg) Set point BPM: reference meter value (±3 mmHg) Test pressure to be set on the reference meter: +150 mmHg (±3 mmHg) Set point BPM: reference meter value (±3 mmHg) Test pressure to be set on the reference meter: +100 mmHg (±3 mmHg) Set point BPM: reference meter value (±3 mmHg) Test pressure to be set on the reference meter: +50 mmHg (±3 mmHg) Set point BPM: reference meter value (±3 mmHg)	Service, DI-AGNOSTICS	____/____ mmHg ____/____ mmHg ____/____ mmHg ____/____ mmHg ____/____ mmHg ____/____ mmHg ____/____ mmHg ____/____ mmHg	<input type="checkbox"/>
MA	9.1.2	Blood pressure cuff and pressure tubing checked for damage. Damaged parts replaced.	Service, DI-AGNOSTICS	–	<input type="checkbox"/>
MA	9.1.3	Blood pressure cuff and pressure tubing are correctly connected to the BPM (option).	Service, DI-AGNOSTICS	–	<input type="checkbox"/>
TSC TMC	9.1.4	BPM (option) checked for leaks. Target value Maximum leakage rate: ≤ 6 mmHg/min	Service, DI-AGNOSTICS	____/____ mmHg/ min	<input type="checkbox"/>
TSC TMC	9.1.5	Safety valve of BPM (option) checked. Target value: The cuff deflates when the safety valve is opened.	Standby	–	<input type="checkbox"/>
TSC TMC	9.1.6	Blood pressure measurement performed with the BPM (option). Target value: The measured values are plausible.	Standby	–	<input type="checkbox"/>
	9.2	BTM (option): There are no additional technical safety checks and maintenance procedures to be performed (exception: measurement of the protective earth resistance).			
	10	Electrical safety check according to (DIN) EN 62353:2015, IEC 62353:2014, and functional test			
	Information: Switch off the device with the key On/Off.				
TSC	10.1	Protective earth resistance measured and checked. Target value: ≤ 0.3 Ω with power supply cord	Off	____/____ Ω	<input type="checkbox"/>
	Information: Switch on the device with the key On/Off. Prepare and fill in service report and documents.				
TSC	10.2	Zero point of the arterial and venous pressure displays checked. Target value for arterial pressure: 0 mmHg ±5 mmHg Target value for venous pressure: 0 mmHg ±5 mmHg	Standby	____/____ mmHg ____/____ mmHg	<input type="checkbox"/>
	Information: Start T1 test. Perform further steps in T1 test operating state.				
TSC	10.3	Slope of the arterial and venous pressure displays checked with a built-up pressure of approx. 280 mmHg. Target value for arterial pressure: built-up pressure ±5 mmHg Target value for venous pressure: built-up pressure ±5 mmHg	T1 test	____/____ mmHg ____/____ mmHg	<input type="checkbox"/>
TSC	10.4	Venous occlusion clamp checked. A change in pressure must not exceed the following values within 3 minutes: Arterial pressure display, maximum change in pressure: ±5 mmHg Pressure display of reference meter, maximum pressure drop: –75 mmHg	T1 test	–	<input type="checkbox"/>
TSC/ MA	10.5	T1 test completed successfully. (Perform further checks only after completion of the T1 test.)	T1 test	–	<input type="checkbox"/>
TSC	10.6	Applied part type: type B Device leakage currents of applied part type B measured, measurement value scaled to nominal line voltage and checked against "Additional condition". Target value: $I_N \leq 500 \mu A$ <input type="checkbox"/> Differential current measurement according to figure 8 <input type="checkbox"/> Direct measurement according to figure 7 Nominal voltage of the power supply (U_0) AC polarity L – N: Maximum device leakage current (I_{Bmax}) Actual line voltage measured (U_{Bmax}) Device leakage current scaled to nominal line voltage ($I_N = (U_0 \times I_{Bmax}) : U_{Bmax}$) AC polarity N – L: Maximum device leakage current (I_{Bmax}) Actual line voltage measured (U_{Bmax}) Device leakage current scaled to nominal line voltage ($I_N = (U_0 \times I_{Bmax}) : U_{Bmax}$)	Preparation	____ V ____/____ μA ____/____ V ____/____ μA ____/____ μA ____/____ μA	<input type="checkbox"/>
TSC	10.7	Equipotential bonding line connected.	Preparation	–	<input type="checkbox"/>
	11	Final tasks			
TSC/ MA	11.1	Disinfection program with Puristeril 340, Puristeril plus, Diasteril, or Citrosteril started. Disinfectant drawn in.	Cleaning	–	<input type="checkbox"/>
MA	11.2	Residual-current device (option) checked.	Cleaning	–	<input type="checkbox"/>

Service report number:			Serial number:		
Cat.	No.	Designation	Operating state	Measured value/correction	✓/NA
TSC	11.3	<i>During disinfection: Power failure alarm checked. Audible alarm, message: Power failure Device is battery-operated. – Confirm</i>	Cleaning	–	<input type="checkbox"/>
–	11.4	Procedure recorded on the machine card and in the Medical Device Register.	Cleaning	–	<input type="checkbox"/> /NA
–	11.5	All waste properly disposed of.	Cleaning	–	<input type="checkbox"/>
–	11.6	All documents created.	Cleaning	–	<input type="checkbox"/>
TSC/MA	11.7	<i>Only with USER SETUP ⇒ Cleaning ⇒ Check for residual disinfectant = Manual and disinfection program with Puristeril 340, Puristeril plus or Diasteril: Disinfection program completed successfully. Absence of residual disinfectant verified by means of test strips after disinfection program.</i>	Standby	–	<input type="checkbox"/> /NA
Confirmation of the inspection					
Service report number:			Serial number:		
Test equipment used (type and serial number):					
Inspection comments:					
Date of inspection:		Tester's signature:		Tester's name:	
Assessment of the inspection					
The device is released for its intended use.			<input type="checkbox"/> Yes <input type="checkbox"/> No		Date of next inspection:
The inspection label has been attached to the device.					
Comments on the assessment:					
Date of assessment:		Signature of representative of the responsible organization:		Name of representative of the responsible organization:	

4008 B / 4008 H / 4008 S Hemodialysis Device

Technical Manual

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**FRESENIUS
MEDICAL CARE**

3.2 Technical Safety Checks / maintenance procedures

3.2.1 Important information on TSC / MA

This chapter lists all necessary Technical Safety Checks (**TSC**) and Maintenance procedures (**MA**). The Technical Measurement Checks (TMC) additionally stipulated for specific countries form part of the Technical Safety Checks (TSC).

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**.

Performance of the Technical Safety Checks must be recorded in the Medical Device Register.

● Precautions for working on the device



Warning

Start-up, extensions, adjustments, calibrations, maintenance procedures, modifications, or repairs may only be carried out by the manufacturer or persons authorized by the manufacturer.

The activities described in the Technical Manual require the availability of the necessary technical test equipment and accessories.

When working on the open device, the following precautions must be respected:

- Protect the components against ingress of fluids.
- Do not touch live parts (e.g., connectors on the power cable or heater).

When repairing and replacing spare parts, observe the applicable ESD precautions (e.g., EN 100 015-1).

3.2.2 TSC / MA report

TSC / MA report TSC report

The TSC / MA report (see **TSC / MA report** on page 3-25) and the TSC report (see **TSC report** on page 3-42) differ in the following points:

- Maintenance procedures (MA)
- Category TSC or MA in first column

4008 B / 4008 H / 4008 S	TSC / MA report	FRESENIUS MEDICAL CARE
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<p>These checks must be performed every 24 months if all of the following requirements have been met:</p> <p><input type="checkbox"/> Unique assignment of the rotors to the appropriate tube roller pumps</p> <p><input type="checkbox"/> 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</p> <p><input type="checkbox"/> DIP switch PCB LP632 array 2 SW 5 set to OFF.</p> <p><input type="checkbox"/> DIP switch PCB LP631 array 2 SW 7 set to ON.</p> <p><input type="checkbox"/> DIP switch PCB LP631 array 2 SW 8 set to ON. (With CDS option only)</p> <p><input type="checkbox"/> Heater rod made of Titanium</p> <p>If one of the requirements mentioned above has not been met, the checks have to be performed every 12 months.</p>	<p>Interval:</p> <p><input type="checkbox"/> 24 months</p> <p><input type="checkbox"/> 12 months (Please check)</p>
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Name of technician	Service report no.:	
Customer / Customer no.:		
Serial number:	Inventory no.:	Operating hours:
Device type:	<input type="checkbox"/> 4008 B <input type="checkbox"/> 4008 H <input type="checkbox"/> 4008 S	
With option:	<input type="checkbox"/> DIASAFE [®] plus <input type="checkbox"/> OCM <input type="checkbox"/> ONLINEplus™ <input type="checkbox"/> SN <input type="checkbox"/> bibag [®]	
<input type="checkbox"/> BPM	<input type="checkbox"/> BTM <input type="checkbox"/> BVM <input type="checkbox"/> DIASAFE <input type="checkbox"/> ONLINE HDF <input type="checkbox"/> 4008 HDF	

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

	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	-	<input type="checkbox"/>
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.	-	<input type="checkbox"/>
3 Check of the hydraulics				
MA	3.1	Water inlet pressure (reduced) 0.9 bar to 1.4 bar	_____	<input type="checkbox"/>
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	_____	<input type="checkbox"/>
MA	3.3	Degassing pressure: -0.81 to -0.85 bar	_____	<input type="checkbox"/>
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	_____	<input type="checkbox"/>
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)	_____	<input type="checkbox"/>
MA	4.2	Concentrate pump calibration volume removal / number of strokes	_____	<input type="checkbox"/>
MA	4.3	Bicarbonate pump calibration volume removal / number of strokes	_____	<input type="checkbox"/>
5 Treatment				
MA	5.1	Desired temperature 37 °C ±0.5 °C	_____	<input type="checkbox"/>
MA	5.2	Temperature display 37 °C ±0.5 °C	_____	<input type="checkbox"/>
MA	5.3	Dialysate pressure - Flow off zero point checked - Slope checked	_____	<input type="checkbox"/>
TSC	5.4	Conductivity display checked with reference meter If the bibag [®] option is used, connect a bibag [®] ! - CD device - CD ref.	_____	<input type="checkbox"/>
6 Extracorporeal components				
MA	6.1	Arterial pressure display checked with reference meter	-	<input type="checkbox"/>
MA	6.2	Venous pressure display checked with reference meter	-	<input type="checkbox"/>
TSC	6.3	Blood pumps: Check of blood pump rate (calibration program: BP rate TEST)	-	<input type="checkbox"/>
TSC	6.4	SN switching pressure checked according to table in the Technical Manual	-	<input type="checkbox"/>
TSC	6.5	Blood pump stop alarm checked	-	<input type="checkbox"/>
TSC	6.6	Venous tube clamp closes after blood alarm	-	<input type="checkbox"/>
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	-	<input type="checkbox"/>
7 Options				
7.1 bibag[®]				
MA	7.1.1	bibag [®] connector, O-rings replaced	-	<input type="checkbox"/>
MA	7.1.2	Switching pressure of PSW 134 checked, 130 mbar, + 30 mbar	_____	<input type="checkbox"/>
7.2 DIASAFE				
MA	7.2.1	DIASAFE filter life checked	-	<input type="checkbox"/>
MA	7.2.2	Hydrophobic filter 111 replaced	-	<input type="checkbox"/>
MA	7.2.3	O-rings in the DIASAFE's dialysate couplings checked	-	<input type="checkbox"/>
7.3 DIASAFE^{® plus}				
MA	7.3.1	DIASAFE ^{® plus} filter life checked	-	<input type="checkbox"/>
MA	7.3.2	Hydrophobic filter 111 replaced	-	<input type="checkbox"/>
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)	_____	<input type="checkbox"/>
7.5 ONLINE-HDF (and DIASAFE)				
MA	7.5.1	Filter life of DIASAFE and ONLINE filter checked	-	<input type="checkbox"/>
MA	7.5.2	Hydrophobic filter 111 replaced	-	<input type="checkbox"/>
MA	7.5.3	O-rings in the DIASAFE's dialysate couplings checked	-	<input type="checkbox"/>
MA	7.5.4	HDF pump rotor checked (smooth running, wear)	-	<input type="checkbox"/>
MA	7.5.5	Fastening strap for Luer-lock checked	-	<input type="checkbox"/>
TSC	7.5.6	Substitute pump <input type="checkbox"/> with DC motor: Pump adjusted or <input type="checkbox"/> with stepper motor: Pump rate checked (calibration program: HDF-Pump-Rate Check)	- Desired / actual: ____ / ____	<input type="checkbox"/>

	No.	Description	Meas. value	✓
TSC	7.5.7	Substitute pump stop – Following blood alarm – After triggering the bypass function – After opening the blood pump door	– – –	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
TSC	7.5.8	Check substitute 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	– – –	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	7.6	ONLINEplus™ (and DIASAFE® plus)		
MA	7.6.1	Filter life of DIASAFE® plus and ONLINEplus™ checked	–	<input type="checkbox"/>
MA	7.6.2	Hydrophobic filters 111 and 184 replaced	–	<input type="checkbox"/>
MA	7.6.3	O-rings at substitute port 195 and rinse port 194 replaced. O-rings lubricated with Unisilikon grease before installation	–	<input type="checkbox"/>
TSC	7.6.4	Tube in the tube pinch valve 193 (ONL1) replaced	–	<input type="checkbox"/>
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)	–	<input type="checkbox"/>
	7.7	OCM		
MA	7.7.1	OCM temperature / conductivity compensation test completed – CD cell 7 – CD cell 110 – OCM PULSE calibration required?	– _____ _____ <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
	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	–	<input type="checkbox"/>
MA	7.8.2	Mechanical condition permits further safe use	–	<input type="checkbox"/>
MA	7.8.2.1	Tube connection correctly connected to device	–	<input type="checkbox"/>
MA	7.8.2.2	Internal blood pressure module, printed circuit boards, cable connections properly attached	–	<input type="checkbox"/>
MA	7.8.2.3	Damaged tubes or cuffs have been replaced	–	<input type="checkbox"/>
MA	7.8.2.4	Indicating elements checked	–	<input type="checkbox"/>
MA	7.8.2.5	Touch panel checked	–	<input type="checkbox"/>
TSC TMC	7.8.3	Leakage test: Pressure leakage rate less than 6 mmHg/min	–	<input type="checkbox"/>
TSC TMC	7.8.4	Calibration: Pressure values Tolerance 250 mmHg ±3 mmHg 200 mmHg ±3 mmHg 150 mmHg ±3 mmHg 100 mmHg ±3 mmHg 050 mmHg ±3 mmHg	_____ _____ _____ _____ _____	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
TSC TMC	7.8.5	Safety valve: Drained at 320 mmHg, ±10 mmHg	–	<input type="checkbox"/>
TSC TMC	7.8.6	Blood pressure measurement performed	–	<input type="checkbox"/>
	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	-	<input type="checkbox"/>
TSC 8.2	Protective earth resistance, maximum 0.3 Ω (with power cable)	_____ Ω	<input type="checkbox"/>
TSC 8.3	Device leakage current measured <input type="checkbox"/> Device leakage current – differential current measurement according to fig. 5 or <input type="checkbox"/> Device leakage current – direct measurement according to fig. 4 Nominal voltage of power supply: _____ V Device leakage current, mains polarity 1 For line voltage _____ μA _____ V Normalized to nominal voltage (maximum 500 μA, see Additional conditions) _____ μA Device leakage current, mains polarity 2 For line voltage _____ μA _____ V Normalized to nominal voltage (maximum 500 μA, see Additional conditions) _____ μA		<input type="checkbox"/>
9	Functional checks		
TSC 9.1	T1 Test completed	-	<input type="checkbox"/>

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

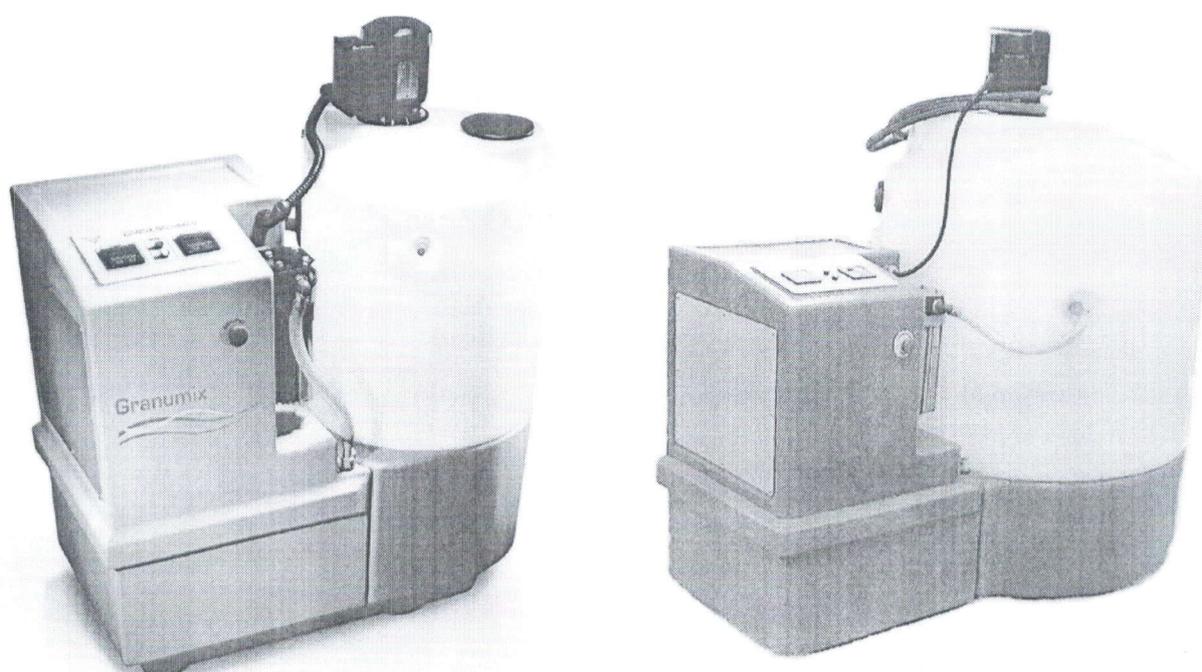
A disinfection must be performed on completion of the checks.

GRANUMIX 107S / GRANUMIX 507S Concentrate Preparation Device

Service Manual

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**FRESENIUS
MEDICAL CARE**

6 Technical Safety Checks / Maintenance Procedures

6.1 Important information on TSC/MA

Considerations for working on the device	Read the information under "Considerations for working on the device" (see chapter 2.5 on page 9).
Technical safety checks (TSCs)	<p>The first TSCs are required before the end of the 24th month following initial start-up after delivery from the factory. All further TSCs are required before the end of the 24th month following the last TSC performed.</p> <p>The completion of the TSCs must be recorded in the Medical Device Register.</p>
Maintenance procedures (MAs)	The maintenance procedures (MAs) are a recommendation of the manufacturer. The maintenance procedures (MAs) help ensure trouble-free operation, and must be carried out for the first time before the end of the 24th month following initial start-up after delivery from the factory. All further maintenance procedures (MAs) should be performed before the end of the 24th month following the last maintenance procedure (MA) performed.
Qualification requirements of testers	<p>The checks must be performed by the manufacturer's service support organization or a person authorized by them.</p> <p>The checks must be performed by personnel qualified to perform them correctly, based on their education, training, knowledge and experience. Furthermore, the persons performing the checks must be permitted to do so independently and without outside interference.</p>

6.2 Articles required to perform the TSCs/MAs

No special items are necessary for performing the TSCs/MAs.

6.3 TSC/MA report

Explanations for the report The explanatory notes on the report can be found in a separate chapter (see chapter 6.4 on page 48).

 FRESENIUS MEDICAL CARE		TSC/MA report		GRANUMIX 107S/ GRANUMIX 507S		
Customer number/Customer name:				Inventory number:		
Name of tester:				Operating hours:		
Software version:				Equipment code:		
Service report number:				Serial number:		
Cat.	No.	Description	Operating state	Measured value/ Correction value	✓/NA	
Information: ✓ = successful inspection item / NA = non-applicable inspection item						
1 Checks/procedures with device switched off and power plug unplugged						
TSC	1.1	Power supply cord checked for signs of damage.	Off	-	<input type="checkbox"/>	
TSC	1.2	Checked that the fuse accessible on the outside has the correct rating. If present, checked seal for damage.	Off	-	<input type="checkbox"/>	
TSC	1.3	Checked that all labels and inscriptions are present and legible.	Off	-	<input type="checkbox"/>	
TSC	1.4	Device checked for damage and dirt. Target value: The device's mechanical condition allows continued safe use of the device as intended.	Off	-	<input type="checkbox"/>	
MA	1.5	When using a power supply via a transformer: Transformer and cooling ducts checked for contamination.	Off	-	<input type="checkbox"/>	
2 Electrical safety check according to (DIN) EN 62353, IEC 62353, and functional test						
TSC	2.1	Protective earth resistance measured and checked. Target value: $\leq 0.3 \Omega$ with power supply cord	Off	____ / ____ Ω	<input type="checkbox"/>	
Information: Connect the power plug and switch the device on. Prepare and fill in service report and documents.						
TSC	2.2	Device leakage currents measured, scaled to nominal line voltage, and checked taking the "Additional condition" into account. Target value: $I_N \leq 500 \mu A$ Differential current measurement according to Figure 8 Nominal voltage of the power supply (U_0) AC polarity L – N: Maximum device leakage current (I_{Bmax}) Actual line voltage measured (U_{Bmax}) Device leakage current scaled to nominal line voltage ($I_N = (U_0 \times I_{Bmax}) : U_{Bmax}$) AC polarity N – L: Maximum device leakage current (I_{Bmax}) Actual line voltage measured (U_{Bmax}) Device leakage current scaled to nominal line voltage ($I_N = (U_0 \times I_{Bmax}) : U_{Bmax}$)	On	____ V ____ / ____ μA ____ / ____ V ____ / ____ μA ____ / ____ μA ____ / ____ V ____ / ____ μA	<input type="checkbox"/>	
3 Level sensor						
TSC	3.1	No leakages.	On	-	<input type="checkbox"/>	
TSC	3.2	Correct operation of the sensor.	On	-	<input type="checkbox"/>	
TSC	3.3	Inlet valve checked.	On	-	<input type="checkbox"/>	
TSC	3.4	Check valve checked.	On	-	<input type="checkbox"/>	
4 Functional test						
MA	4.1	Correct functioning of mixer and circulation pump tested using the timer.	On	-	<input type="checkbox"/>	
TSC	4.2	Motor protection switch checked.	On	-	<input type="checkbox"/>	
MA	4.3	Pump is not showing any signs of leakage.	On	-	<input type="checkbox"/>	
5 Timer						
MA	5.1	Displays/indicators and counting processes are OK and easily legible under the environmental conditions.	On	-	<input type="checkbox"/>	
MA	5.2	Counting process continues after the GRANUMIX 107S / GRANUMIX 507S is turned off and on.	On	-	<input type="checkbox"/>	
6 EMERGENCY STOP switch						
TSC	6.1	Correct operation of the EMERGENCY STOP switch.	On	-	<input type="checkbox"/>	
7 Final tasks						
TSC	7.1	Procedure recorded on the machine card and in the Medical Device Register.	On	-	<input type="checkbox"/>	
TSC	7.2	All waste properly disposed of.	On	-	<input type="checkbox"/>	
TSC	7.3	All documents created.	On	-	<input type="checkbox"/>	

Confirmation of the inspection		
Service report number:		Serial number:
Test equipment used (type and serial number):		
Inspection comments:		
Date of inspection:	Tester's signature:	Tester's stamp:
Assessment of the inspection		
The device is released for its intended use.		Date of next inspection:
The inspection label has been attached to the device. <input type="checkbox"/> Yes <input type="checkbox"/> No		
Assessment comments:		
Assessment date:	Signature of representative of the responsible organization:	Stamp of the responsible organization:

AquaUNO Single Station Reverse Osmosis System

Service Manual

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**FRESENIUS
MEDICAL CARE**

6 Technical Safety Checks/Maintenance Procedures

6.1 Important information on TSCs/MAs

Precautions for working on the device	Observe the information about working on the device (see Chapter 2.5 on page 2-3).
Technical Safety Checks (TSCs)	<p>The first TSCs are required before the end of the 24th consecutive month after initial start-up following delivery from the factory. All other TSCs are required before the end of the 24th consecutive month after the last TSC performed.</p> <p>Completion of the TSCs must be recorded in the Medical Device Register.</p>
Maintenance procedures (MAs)	Maintenance procedures (MAs) are recommended by the manufacturer. They serve to prevent malfunctions and should be carried out for the first time before the end of the 24th consecutive month after initial start-up following delivery from the factory. All other MAs should be performed before the end of the 24th consecutive month after the last maintenance procedures performed.
Tester's qualification	<p>The checks must be performed by the manufacturer's service department or a person authorised by them.</p> <p>The checks may only be performed by persons qualified to properly perform the specified checks owing to their educational background, training, knowledge, and experience. Furthermore, the persons performing the checks must not be bound by any directives when performing this activity.</p>

6.2 Required items for performing TSCs/MAs

No special items are necessary for performing the TSCs/MAs.

FRESENIUS MEDICAL CARE		TSC/MA report		AquaUNO	
Customer number/customer name:			Inventory number:		
Tester's name:			Operating hours:		
Software version:			Equipment code:		
Service report number:			Serial number:		
Cat.	No.	Description	Operating mode	Measured value/correction	✓/NA
Information: ✓ = successful inspection item / NA = non-applicable inspection item					
1 Checks/procedures with device switched off and power plug unplugged					
TSC	1.1	Power supply cord checked for signs of damage.	Off	--	<input type="checkbox"/>
TSC	1.2	Externally accessible fuse checked for specified rating. Seal checked for signs of damage, where applicable.	Off	--	<input type="checkbox"/>
TSC	1.3	Presence and legibility of labels and inscriptions checked.	Off	--	<input type="checkbox"/>
TSC	1.4	Device checked for damage and contamination. Target value: The device's mechanical condition allows continued safe use of the device as intended.	Off	--	<input type="checkbox"/>
2 Electrical safety check following (DIN) EN 62353:2015, IEC 62353:2014, and functional test					
TSC	2.1	Protective earth resistance measured and checked. Target value: $\leq 0.3 \Omega$ with power supply cord	Off	____/____ Ω	<input type="checkbox"/>
TSC	2.2	Measurement of protective earth resistance on Porter model completed. Maximum of 0.3Ω (with power supply cord) at additional measurement points according to Figure 1.	Off	____/____ Ω	<input type="checkbox"/>
Information: Switch on the device. Prepare and fill out service report and documents.					
TSC	2.3	Type of applied part: Type B Device leakage currents for Type B applied part measured, scaled to nominal line voltage, and checked taking the "Additional condition" into account. Target value: $I_N \leq 500 \mu A$ Differential current measurement according to Figure 8 Nominal voltage of power supply (U_0) Power supply polarity L – N: Maximum device leakage current: (I_{Bmax}) Associated line voltage (U_{Bmax}) Device leakage current scaled to nominal line voltage ($I_N = (U_0 \times I_{Bmax}) : U_{Bmax}$) Power supply polarity N – L: Maximum device leakage current: (I_{Bmax}) Associated line voltage (U_{Bmax}) Device leakage current scaled to nominal line voltage ($I_N = (U_0 \times I_{Bmax}) : U_{Bmax}$)	On	____ V ____/____ μA ____/____ V ____/____ μA ____/____ μA ____/____ V ____/____ μA	<input type="checkbox"/>
3 Checking the sensors					
TSC	3.1	Permeate conductivity sensor CD_{PERM} is functional. Values compared with the external measuring instrument (not temperature-compensated). Allowable deviation $\pm 2 \mu S$		____/____ μS	<input type="checkbox"/>
TSC	3.2	Feed water conductivity cell CD_{RW} is functional. Values compared with the external measuring instrument (not temperature-compensated). Allowable deviation $\pm 50 \mu S$		____/____ μS	<input type="checkbox"/>
4 Alarms					
TSC	4.1	Run-dry protection is functional.		--	<input type="checkbox"/>
TSC	4.2	FAULT CDP MAX is functional.		--	<input type="checkbox"/>
TSC	4.3	Overflow protection is functional.	STANDBY	--	<input type="checkbox"/>
5 Checking the functions					
MA	5.1	Service keyboard is functional (not applicable for systems with EC 15 and higher).		--	<input type="checkbox"/>
MA	5.2	Permeate output checked. Target value: 60 L/h at feed water hardness $< 1^\circ dH$		____/____ L/h	<input type="checkbox"/>
6 Checking the options					
MA	6.1	Cartridge on prefilter replaced.		--	<input type="checkbox"/>
TSC	6.2	AquaSTOP is functional.		--	<input type="checkbox"/>
MA	6.3	Pressure switch is functional.		--	<input type="checkbox"/>
7 Final tasks					
TSC	7.1	Procedure recorded in the Medical Device Register.		--	<input type="checkbox"/>
TSC	7.2	All waste properly disposed of.		--	<input type="checkbox"/>
TSC	7.3	All documents completed.		--	<input type="checkbox"/>

Confirmation of the inspection		
Service report number:		Serial number:
Test equipment used (type and serial number):		
Inspection comments:		
Date of inspection:	Tester's signature:	Tester's stamp:
Assessment of the inspection		
The device is released for its intended use. <input type="checkbox"/> Yes <input type="checkbox"/> No		Date of next inspection:
The inspection label has been attached to the device.		
Assessment comments:		
Date of assessment:	Signature of representative of the responsible organization:	Stamp of the responsible organization: