Reverse Osmosis Unit AquaB

Technical Manual

Software Version: 2.0x

Edition: 1/08.04

Part no.: 634 104 1

CE 0123

Fresenius Medical Care

5.2 TSC and Maintenance Procedures Report

Manufacturer:	**Date:**
Serial number:	**Inventory no.:**
Machine type:	
Incl. option:	
The following inspections must be carried out every 12 months at the latest. The measurements may only be performed by skilled electricians with electrotechnical, device-related and medical technical expertise.	

TSC	No.	Description	Desired value / function	O.K.
	1	**Visual inspection**		
TSC	1.1	Labels and labelling	Must be present and legible.	❑
TSC	1.2	Mechanical condition	Must permit further safe use.	❑
TSC	1.2.1	Check connection cable incl. plug		❑
TSC	1.2.2	Check tube connection		❑
TSC	1.3	Damage or contaminations	There must be no signs of damage or contamination.	❑
TSC	1.4	Power cord	No signs of damage.	❑
TSC	1.5	Housing	No signs of damage.	❑
TSC	1.6	Display overlay/control panel	No signs of damage.	❑
TSC	1.7	Installation drawing	Must be present.	❑
TSC	1.8	Ring main flow diagram (in case of ring operation)	Must be present.	❑

TSC	No.	Description	Desired value / function	O.K.
	2	**Check of the electrical safety in Germany according to DIN VDE 0751-1; edition 10/2001. In other countries, observe the local regulations!**		
TSC	2.1	Visual inspection performed.	See item 1 Visual inspection	❑
TSC	2.2	Protective earth resistance	max. 0.3 ohms _____ Ω	❑
TSC	2.3	Permanent connection of power supply line	(Leakage current may be neglected)	❑
TSC	2.4	Direct measurement of the device leakage current according to figure C.5	The equivalent device leakage current may not exceed the limit specified below.	
		Nominal voltage of power supply:	_____ V	❑
		Device leakage current for mains polarity 1:	Measured value:_____ µA	❑
		With line voltage:	Measured value: _____ V	❑
		Scaled to nominal voltage:	max. 500 µA:_____ µA	❑
		Device leakage current for mains polarity 2:	Measured value:_____ µA	❑
		With line voltage:	Measured value: _____ V	❑
		Scaled to nominal voltage:	max. 500 µA:_____ µA	❑
		Test equipment used:	_____	❑
	3	**Feed water test**		
TSC	3.1	Activated carbon filter: Residual chlorine content (chlorine test strip)	Collect a sample; Chlorine:_____ mg/l Desired value: free chlorine < 0.1 mg/l	❑
TSC	3.2	Soft water test	Collect a sample; Desired value: 0° dH	❑
MA	3.3	SDI test	SDI:_____ Desired value: SDI < 3	❑
	4	**EMERGENCY STOP check**		
TSC	4.1	Emergency stop	Press EMERGENCY STOP in the Supply / Rinse mode: The pump stops.	❑
	5	**Operating parameters**		
TSC	5.1	Check set values / according to Settings report	Values are correct.	❑
TSC	5.2	Operating parameters	Check set values according to Settings report	❑

TSC	No.	Description	Desired value / function	O.K.
	6	**Sensor check**		
TSC	6.1	Permeate conductivity / temperature measurement cell LF_{PERM}	Compare the values with the external measuring instrument.	❑
TSC	6.2	Flow meter FL_{RW}, FL_{KONZ}	Check: Verify the waste water volume or measure the waste water and compare the result with the value displayed by the RO unit.	❑
TSC	6.3	Permeate volume	The total permeate flow displayed is equal to the system-specific desired rating.	❑
	7	**Alarms**		
TSC	7.1	Permeate conductivity alarm **SUPPLY** (step alarm)	Set the alarm limit to the minimum value. **0^{th} to 2^{nd} minute:** Yellow alarm **2^{nd} to 10^{th} minute:** Yellow + red alarms + audible signal **10^{th} minute and later:** Program aborted, only rinsing possible	❑
TSC	7.2	Permeate conductivity < 1 µS/cm	Turn the unit off; in the distributor board: disconnect the CD cell (brown); When starting SUPPLY mode: Red alarm	❑
TSC	7.3	Upper permeate temperature alarm	Set the alarm limit to be below the current value; yellow alarm In the Supply mode: V3 opens for a longer time	❑
TSC	7.4	Permeate conductivity alarm **RINSE**	Set the alarm limit to the minimum value. Yellow + red alarm + audible signal	❑
TSC	7.5	Water alarm	Interrupt water supply. Alarm message: WATER SUPPLY; red alarm (after 6 seconds) and restart within 3 minutes	❑
TSC	7.6	ERROR: Flow qC/qW !	In the Supply mode: Disconnect connector from V3.	❑
TSC	7.7	Disinfection connector	Loosen the connector: Red alarm	❑
TSC	7.8	Leakage sensor	Moisten the sensor or establish conductive contact connection. Red alarm	❑
TSC	7.9	Leakage connector	Disconnect the connector from the monitor: Red alarm	❑
TSC	7.10	Tank overfilled (with tank control)	Manually actuate the tank sensor. Red alarm	❑

TSC	No.	Description	Desired value / function	O.K.
	8	**Operating programs**		
TSC	8.1	SUPPLY AutoSTART / AutoSTOP	Set the appropriate values in the Settngs menu.	❑
TSC	8.2	Automatic RINSE	Set the appropriate values in the Settings menu.	❑
	10	**Remote control (optional)**		
TSC	10.1	Mechanical condition	Must permit further safe use.	❑
TSC	10.2	Alarm display	Alarms are indicated	❑
TSC	10.3	Switching between Standby / Supply	Check	❑

Technician's signature: _____, date _____	**Customer's signature:** _____, date _____
The system has been released for further use.	❑ Yes ❑ No
Remarks:	

The technical safety checks are to be entered in the Medical Device Register and the results of the check must be documented.

Corrective action must be taken to restore the safe function of any device which is not in proper or safe service and/or operating condition, or the operator is to be informed of the risk which the use of this device may present.

I herewith confirm proper performance of any procedure as specified above, and the data to be true and correct.