PM Form_Haemodialysis Unit_FMC-5008

1	PASS	FAIL	N/A	QUALITY TEST	REMARKS
1.1				CHASSIS / HOUSING	
1.2				MOUNTS	
1.3				CASTERS/BRAKES	
1.4				AC PLUG/RECEPTACLES	
1.5				CIRCUIT BREAKERS / FUSES	
1.6				LINE CORD	
1.7				STRAIN RELIEFS	
1.8				INDICATORS / DISPLAYS	
1.9				CONTROLS / SWITCHES	Checking of concentrate level sensor and bicarbonate level sensor in the flow diagram
1.10				TUBE/HOSES	
1.11				FITTINGS/CONNECTORS	Checking of bicarbonate, concentrate flaps
1.12				MOTOR/ PUMP/FAN	
1.13				AIR DETECTOR/LINE CLAMP	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: –0.1 bar
1.14				BLOOD PRESSURE METER	Operating state: Service, DIAGNOSTICS 1. Connect the tubing and blood pressure cuff. 2. Wrap the blood pressure cuff around a rigid metal vessel. 3. In the SERVICE ☒ DIAGNOSTICS: BPM menu, press the Info / Test field. 4. Additionally with BPM version 1: Press the Preselected pressure field and set the value 250 mmHg. 5. Press the Leakage test field.
				IV POLE HANGER	1. Detach the IV pole hanger from the IV pole. 2. If the IV pole hanger has a marking • Ensure hexagon socket screw is tightly attached the IV pole hanger and the checking procedure finishes. Go to step 8 • If the IV pole hanger does not have a marking. Go to step 3. 3. Unscrew the hexagon socket screw from the IV pole hanger, wrench size 5 mm.

1.15					4. The hexagon socket screw and the threaded hole must be clean, dry and free from grease. 5. Apply the Loctite adhesive no. 2701 in the threaded hole on one side of the IV pole hanger. 6. Do not apply the adhesive on the hexagon socket screw, as in that case, a secure adhesive connection is not possible. 7. Screw the hexagon socket screw into the threaded hole and tighten by hand, wrench size 5 mm (ensure the thread-hole side of the hexagon socket screw is pointing outward of the hanger). ・ Wait 15 minutes for the adhesive completely dry. 8. Screw the IV pole hanger onto the IV pole.
1.16				BATTERY	
1.17				ACCESSORIES	
1.18				TIME/DATE SETTING	
1.19				AUDIBLE SIGNALS	
1.20				LABELING	
1.21				EQUIPMENT SELF-TEST	

2	PASS	FAIL	N/A	QUALITATIVE TEST	REMARKS
2.1				Electrical Safety Test (mm-st-01)	Refers to and record in the Electro-medical Equipment Safety Check Record Form.
IEC Standard					
Class					
Type					
2.2.1				LOADING PRESSURE	Operating state: Service, CALIBRATE 1. In the CALIBRATE > Degassing (A01/P01) menu, press the Loading pressure test button. 2. Check the loading pressure of the dosing chamber.
2.2.2				NEGATIVE PRESSURE	Operating state: Service, CALIBRATE 1. In the CALIBRATE > Degassing (A01/P01) menu, press the Negative pressure test button. 2. Check the degassing pressure of the degassing pump.
2.3.1				LOADING PRESSURE	Operating state: Service, CALIBRATE 1. In the CALIBRATE > Loading pump (A02/P02) menu, press the Loading pressure test button. 2. Check the loading pressure of the balancing chamber.
2.3.2				NEGATIVE PRESSURE	Operating state: Service, CALIBRATE 1. In the CALIBRATE > Flow pump (A03) menu, press the Start calibration button. 2. Calibrate the flow pump.
MAX WATER FLOW					Operating state: Service, CALIBRATE, Flow diagram 1. Check the Max. water inflow in the flow diagram. Target value: 1300 ml/min to 1550* ml/min 2. If necessary, correct the Max. water inflow using A04.
S03					
	Done				
	N/A				
S07					
	Done				

	N/A

S15

	Done
	N/A

S16

	Done
	N/A

BLOOD LEAK VOLTAGE

DIMNESS VOLTAGE

Operating state: Service, CALIBRATE
Basic requirements:
1. The device must be closed (avoid exposure to external light).
2. Flow on, flow 500 ml/min.
3. Temperature within a range from 34 °C to 39 °C.
4. Stable conductivity.
5. Check the blood leak voltage. Target value: 4.8 V to 5.2 V.
Operating state: Service, CALIBRATE
Basic requirements:
1. The device must be closed (avoid exposure to external light).
2. Flow on, flow 500 ml/min.
3. Temperature: specified value: 34 °C to 39 °C.
4. Stable conductivity.
5. Check the dimness voltage. Target value: 4.7 V to 5.3 V.

2.7 DIALYSATE TEMPERATUE

MEASURED (°C)	DISPLAY (°C)

Operating state: Service, CALIBRATE
Basic requirements:
– The device must be closed.
– Temperature: specified value 37.0 °C.
– Flow on, flow 500 ml/min.
1. Attach a reference meter to the lowest point of the IV pole.
2. Connect the dialyzer couplings to the reference meter.
3. Switch the flow on.
4. Wait until the values are stable within a range from 36.8 °C to 37.2 °C (on the display of the device).

Target value – difference: -0.5 °C to +0.2 °C

2.8 DIALYSATE CONDUCTIVITY

MEASURED (ms/cm)	DISPLAY (ms/cm)

2.8.1				CD7 and CD9 COMPARSION

Operating state: Service, CALIBRATE
Basic requirements:
– The device must be closed.
– If a bibag® is generally used, the test must be performed with a bibag®.
– Flow on.
1. Attach a reference meter to the lowest point of the IV pole.
2. Connect the dialyzer couplings to the reference meter.
3. Switch the flow on.
4. Wait until the values at CD7 are stable within a range from 13.5 mS/cm to 14.5 mS/cm.

Target value – difference: ±0.2 mS/cm
Operating state: Service, CALIBRATE
Basic requirements:
– The device must be closed.
– If a bibag® is generally used, the test must be performed with a bibag®.
1. Switch the flow on.
2. Wait until the values at CD7 and CD9 are stable within a range from 13.5 mS/cm to 14.5 mS/cm.
3. Compare sensors CD7 and CD9:
Difference (CD7 – CD9)
Target value – difference: ±0.05 mS/cm

2.9 ARTERIAL PRESSURE TARGET (mmHg) / MEASURED (mmHg) 0 / 280 /	Operating state: Standby 1. Insert start-up tubing set. 2. Connect the arterial pressure dome. 3. Open the start-up tubing set to the atmosphere. 4. Check the arterial pressure display. Target value: 0 mmHg ±5 mmHg Operating state: Standby 1. Insert start-up tubing set. 2. Connect the arterial pressure dome. 3. Connect reference meter. 4. Close start-up tubing set. 5. Using a syringe, build up a pressure of approximately 280 mmHg. 6. Check the arterial pressure display. Target value: built-up pressure ±5 mmHg
2.10 VENUS PRESSURE TARGET (mmHg) / MEASURED (mmHg) 0 / 280 /	Operating state: Standby 1. Insert start-up tubing set. 2. Connect the arterial pressure dome. 3. Open the start-up tubing set to the atmosphere. 4. Check the arterial pressure display. Target value: 0 mmHg ±5 mmHg Operating state: Standby 1. Insert start-up tubing set. 2. Connect the arterial pressure dome. 3. Connect reference meter. 4. Close start-up tubing set. 5. Using a syringe, build up a pressure of approximately 280 mmHg. 6. Check the arterial pressure display. Target value: built-up pressure ±5 mmHg
SINGLE NEEDLE MODEL ☐ Yes ☐ No 2.11.2 SINGLE NEEDLE PRESSURE TARGET (mmHg) / MEASURED (mmHg) 0 / 280 /	Operating state: Standby 1. Connect tubing set to single needle pressure transducer. 2. Open the tubing set to the atmosphere. 3. Check the venous pressure display. Target value: 0 mmHg ±5 mmHg Operating state: Standby 1. Connect tubing set to single needle pressure transducer. 2. Connect reference meter. 3. Close tubing set. 4. Using a syringe, build up a pressure of approximately 280 mmHg. 5. Check the venous pressure display. Target value: built-up pressure ±5 mmHg

3	DONE	N/A	MISCELLANEOUS	REMARKS
CLEANING ☐ Yes ☐ No				
DISINFECTION ☐ Yes ☐ No				
UPDATE PM LABEL ☐ Yes ☐ No				
3.4.1	☐	☐	FAN FILTER	Replace the fan filter on the rear of the device. Refer to F01 filter in the manual.

3.4.2			WATER INLET FILTER	Refer to F07 filter in the manual.
3.4.3			DIALYSATE FILTER	Greased and replaced
3.4.4			O-RING IN DIALYZER COUPLINGS	Greased and replaced
3.4.5			O-RING OF BI-BAG CONNECTOR	Greased and replaced
3.4.6			SUBSTITUTE PORT	Greased and replaced
3.4.7			RINSE PORT LIP	Refer to F06 filter in the manual.
3.4.8			SEAL OF RINSE CHAMBERS	Refer to F08 filter in the manual.
3.4.9			HYDROPHOBIC COMPRESSOR FILTER	Refer to F10 & F16 filters in the manual.
3.4.10			UF PUMP FILTER	Refer to F11 (concentrate) & F12 (bicarbonate) filters in the manual.
3.4.11			DISINFECTANT FILTER	Refer to F13 (BIC) & F14 (CDS1) & F15 (CDS2) filters in the manual.
3.4.12			SUCTION TUBE FILTER	Refer to F17 (bibag inlet) & F18 (bibag outlet) filters in the manual.
3.4.13			CDS FILTER	Refer to V20 & V34 filters in the manual.
3.4.14			BIBAG FILTER	v20: Only applicable when using Puristeril 340.
3.4.15			DISINFECTANT VALVE	V34_Only applicable when using Sporotal 100.
3.4.16			TUBING IN SUBSTITUATE VALVE (EVERY 6 YRS)	Battery – monitor (1) CR 2032
TUBING IN SUBSTITUATE VALVE REPLACEMENT DATE				Battery – monitor (2) CR 2032
TUBING IN SUBSTITUATE VALVE LAST REPLACED AT				Battery – power supply unit (3) CR 1225
3.4.19			BATTERY (EVERY 4 YRS)	Rechargeable battery – battery pack (4)
BATTERY REPLACEMENT DATE				
BATTERY LAST REPLACED AT				

4 REMARK ON PHYSICAL CONDITION

	No observable deterioration or defect. Normal and efficient.
	Minor observable deterioration or defects which do not pose a potential threat to failure or malfunction. Minor signs of inefficiency observed, but condition is acceptable.
	Major observable deterioration or defect which can eventually lead to failure or malfunction. Signs of inefficiency observed. (NOTE1)

5 REMARK ON SUPPORTABILITY (TECHNICAL ASSISTANCE AND SPARE PARTS SUPPLY)

	Good support
	Poor support
	No support in the coming future
	No support already (NOTE1,2)

6 COMMENTS / DESCRIPTION

COMMENTS / DESCRIPTION

N/A