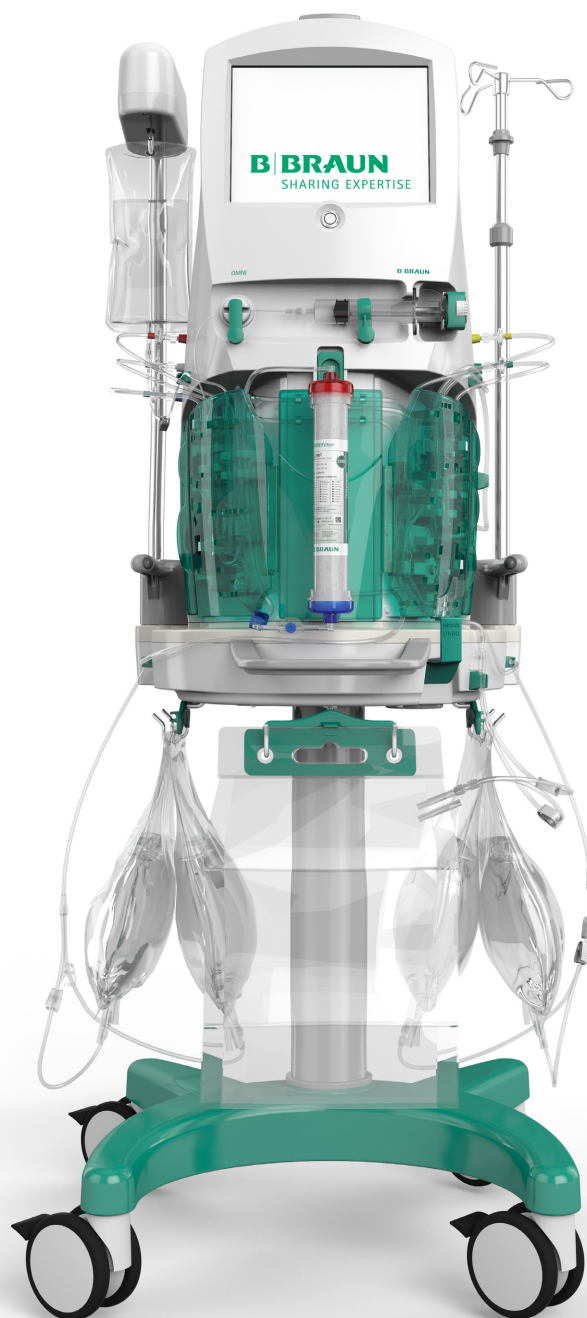


OMNI[®]

Acute Blood Purification System

Service Protocol Commissioning, Rev. 1.03.00

SW ≥ 1.75.10





OMNI Service Protocol Commissioning EN / 1.03.00 /
2025-11

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This service protocol is a supplement to the latest valid OMNI service manual and is part of chapter 3 *Commissioning*.

1 Commissioning

1.1 Commissioning Check List

The commissioning (putting into service) must be performed and documented according to the following checklist and with reference to the service manual and instructions for use before the machine is handed over to the responsible organization (user). This requirement also applies after any relocation of the machine.

In the *Execution Protocol Commissioning Check List* (see p. 8), every step is explained in detail.

REF (reference No./Nr.)	<input type="text"/>
Responsible organization (user)	<input type="text"/>
Operating hours [h]	<input type="text"/>
Internal number (if available)	<input type="text"/>
SW version	<input type="text"/>
Workorder number (if available)	<input type="text"/>

1	Unpacking and initial checks	OK
1.1	Unpack the machine and retain the packaging	<input type="checkbox"/>
1.2	Visual inspection (exterior)	<input type="checkbox"/>
1.3	Visual inspection (interior) <ul style="list-style-type: none"> Open the machine Connect the <i>power input</i> connector to the main board (J18) 	<input type="checkbox"/>
1.4	Measure the protective earth resistance Ensure that the OMNI is used only with a mains cord intended for it. Measurement points: <ul style="list-style-type: none"> Potential equalization bolt (connector panel) Screw on the bottom of the lower housing Interior: base plate (free position) Note the highest value	<input type="checkbox"/>
	Max. Value: ≤ 0.2 [Ω]	
	Actual Value: <input type="text"/> [Ω]	
1.5	Staff call Set the hospital system configuration on the staff call board: STAT (default) DYN DYN OFF	<input type="radio"/> <input type="radio"/> <input type="radio"/>

1	Unpacking and initial checks	OK
1.6	Close the machine	<input type="checkbox"/>
1.7	Printed instructions for use (IFU) available for installed software version in required language	<input type="checkbox"/>

2	Preparation for the function inspection	OK
2.1	Language installation Language installation required: Yes, installed language (and version): <input type="text"/> No	<input type="checkbox"/> <input type="checkbox"/>
2.2	Start machine in TSM mode	<input type="checkbox"/>
2.3	Check the machine's date and time (reboot required after adjustment)	<input type="checkbox"/>

3	Function inspection: Pressures	OK
3.1	Pressure sensors AP, FP, VP, SP, EP (0 mmHg) (permissible tolerance +/-10 mmHg) Set value¹: 0 mmHg	<input type="checkbox"/>
3.2	Pressure sensors AP, FP, VP, SP, EP (approx.:+600 mmHg) (permissible tolerance +/-10 mmHg) Set value¹: <input type="text"/> mmHg	<input type="checkbox"/>
3.3	Pressure sensors AP, FP, VP, SP, EP (approx.: -450 mmHg) (permissible tolerance +/-10 mmHg) Set value¹: <input type="text"/> mmHg	<input type="checkbox"/>
3.4	Pressure leak test	<input type="checkbox"/>

¹The *set value* is the pressure applied to the pressure sensors according to the calibrated reference device. To pass the test, the machine must display a value within the permissible tolerance of the set value.

4	Function inspection: Syringe Pump and SAD	OK
4.1	Check the syringe pump	<input type="checkbox"/>
4.2	Check the safety air detectors	<input type="checkbox"/>

5	Function inspection: BLD and Warmer	OK
5.1	Check the blood leak detector (BLD)	<input type="checkbox"/>
5.2	Check the warmer and the temperature sensors	<input type="checkbox"/>

6	Function inspection: Load Cell Calibration	OK
6.1	Calibrate the citrate load cell	<input type="checkbox"/>
6.2	Calibrate the left load cell	<input type="checkbox"/>
6.3	Calibrate the center load cell	<input type="checkbox"/>
6.4	Calibrate the right load cell	<input type="checkbox"/>

7	Function inspection: Detectors and Voltages	OK
7.1	Check door detector sensitivity	<input type="checkbox"/>
7.2	Check the staff call	<input type="checkbox"/>

8	Option Handling and User Configuration	OK
8.1	Option Handling The following option/s is/are activated (if no option is activated, enter <i>N/A</i>): <input type="text"/>	<input type="checkbox"/>
8.2	Set and confirm user configuration parameters Fill in the user configuration protocol for the respective software version - see chapter 3.2 Protocol User Configuration Parameters of the latest valid OMNI service manual.	<input type="checkbox"/>

9	Preparation and Test Therapy	OK
9.1	Start the preparation	<input type="checkbox"/>
9.2	No weights are present on the load cells	<input type="checkbox"/>
9.3	Scan disposable kit and select therapy	<input type="checkbox"/>
9.4	Prepare and set up disposables	<input type="checkbox"/>
9.5	Machine passed self tests successfully and is ready for therapy	<input type="checkbox"/>
9.6	Enter the parameters for the test therapy <ul style="list-style-type: none"> • Patient ID: 12345 • Patient Weight: 80 kg • Net Fluid Removal: 2000 mL/h • Substitution: 5000 mL/h • Dialysate: 1000 mL/h • Heparin Flow Rate: 1 mL/h 	<input type="checkbox"/>
9.7	Start the therapy Set the blood flow to 500 mL/min and press the <i>Therapy</i> button. Wait until all parameters are reached.	<input type="checkbox"/>
9.8	Check the alarm function of the blood side door and the fluid side door	<input type="checkbox"/>
9.9	Check the battery function and the function of the charge indicator light	<input type="checkbox"/>
9.10	Check the stop key function	<input type="checkbox"/>

10	Electrical safety check according to EN 62353 / EN 60601-1			OK
10.1	Wait until all set parameters are reached			<input type="checkbox"/>
10.2	Measure the equipment leakage current			<input type="checkbox"/>
	Max. Value:	≤ 0.5	[mA]	
	Actual Value:	<input type="text"/>	[mA]	
10.3	Measure the patient leakage current			<input type="checkbox"/>
	Max. Value:	< 10	[µA] AC	
	Actual Value:	<input type="text"/>	[µA] AC	

11	Setting into service			OK
11.1	Stop the therapy			<input type="checkbox"/>
11.2	Remove disposables and test equipment from the machine			<input type="checkbox"/>
11.3	Attach the USB port protector			<input type="checkbox"/>
11.4	Document the applied measurement equipment in the table below. Applied disposable kit:			<input type="checkbox"/>
	<input type="text"/>			
11.5	Clean the outer surface of the machine according to the IFU			<input type="checkbox"/>
11.6	Machine is released for patient use			<input type="checkbox"/>

Applied Measurement Equipment	Due Date of next Calibration	Description	ID/Serial No.
Electrical safety analyzer	<input type="text"/>	<input type="text"/>	<input type="text"/>
Reference weight 5,000 g	<input type="text"/>	<input type="text"/>	<input type="text"/>
Reference weight 5,000 g	<input type="text"/>	<input type="text"/>	<input type="text"/>
Reference weight 2,000 g	<input type="text"/>	<input type="text"/>	<input type="text"/>
Warmer Test and Calibration Board	<input type="text"/>	<input type="text"/>	<input type="text"/>
Pressure measurement instrument	<input type="text"/>	<input type="text"/>	<input type="text"/>
Template 1.4/1.5 mm for venous clamp	<input type="text"/>	<input type="text"/>	<input type="text"/>
Other measurement device	<input type="text"/>	<input type="text"/>	<input type="text"/>

For measurement equipment not required for the service activity, enter *N/A* in the corresponding fields.

The commissioning was performed and the machine is released for patient use. The machine was handed over to the responsible organization (user). <i>Comment below if ticked "No" and mark the machine accordingly.</i>	Yes <input type="radio"/>	No <input type="radio"/>
Comments: <input type="text"/>		
Next inspection date:	<input type="text"/>	

Signatures	
The commissioning was performed by: <input type="text"/>	
<i>Name Service Technician / Company</i>	
<input type="text"/>	<input type="text"/>
<i>Date (yyyy-mm-dd)</i>	<i>Signature</i>
Responsible Organization (User):	
<input type="text"/>	
<i>Name</i>	
<input type="text"/>	<input type="text"/>
<i>Date (yyyy-mm-dd)</i>	<i>Signature</i>

1.2 Execution Protocol Commissioning Check List

1 Unpacking and initial checks

1.1 Unpack the machine and retain the packaging

- Check the packaging for damages. In case of any damages please note on the service report.
- Remove packaging from the machine and retain the packaging for transportation or relocation of the machine.

1.2 Visual inspection (exterior)

- Machine exterior: Machine is clean/complete; no damages/moisture influences; casters are movable; type plate and warning for max. load on the load cells are legible.
- Labels to check:
 - Device max. weight
 - Pressure labels are legible (AP,FP,VP,EP,SP)
 - Load cells symbols are present (each load cell (4pieces) has unique symbol)
 - B. Braun Avitum AG logo and the name of the machine is legible
 - Type plate and consult accompanying documentation symbol is present
 - Stop key text legible
 - Barcode scanner safety symbol is present
 - Color code of the tubing guides is present (green = dialysate / yellow = effluent / purple = substitution / red = blood pump / black = citrate pump)
 - Symbols on the connector panel are legible
 - Warmer door warning is legible
- Check housing gap between front housing and rear housing.
- Check housing gap between lower housing and base plate housing.

1.3 Visual inspection (interior)

- Remove the rear housing
 - Remove the ten screws from the rear housing.

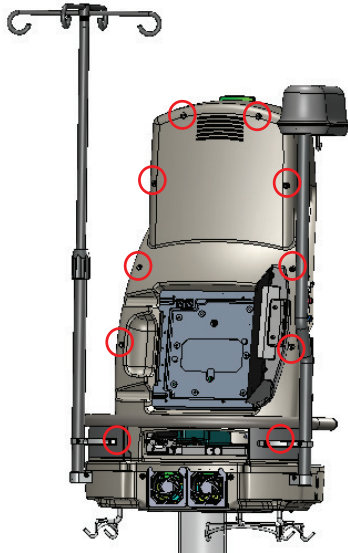


Fig. 1-1 Rear housing screws

- Connect power supply connector to the main board (J18).
- Tilt the warmer assembly from the machine.
- Machine interior: Machine is clean/complete; no damages/moisture influences or loose assemblies; no moveable parts are touching tubings and wires.
- Check the fixed position of boards, connectors, mains supply parts and tubings.
- Check the fixed position of potential equalization cable and the staff call.
- Check the integrity of the conductive coating.
- Check the gasket between the touch screen and the front housing for damages.
- Check the gasket between the front and the rear housing for damages.

1.4 Protective Earth Resistance



Ensure that the OMNI is used only with a mains cord intended for it.

1. Connect and secure the mains cord to the machine.
2. Connect the machine's plug to the electrical safety analyzer as shown in the scheme below and set the measurement device to protective earth measurement setup (test current ≥ 200 mA).
3. Move the mains cord during the check, so that possible loose connections can be detected. The potential equalization cable must not be connected during the check of the protective earth resistance. Measurement points:
 - Exterior: Potential equalization (connector panel); One of the screws below the machine body
 - Interior: Base plate (free position)
4. Note the highest value in the check list.

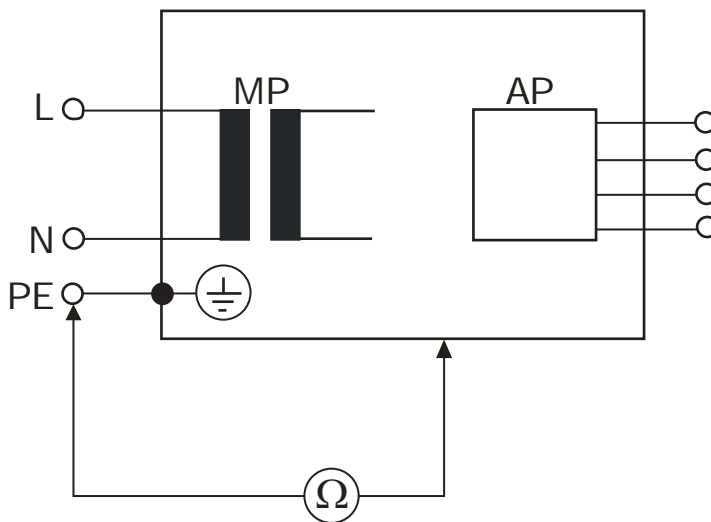


Fig. 1-2 Protective earth resistance measurement

1.5 Staff call setting

1. Remove the warmer assembly from the machine.
2. Disassemble the staff call board from the connector panel by removing the nut.
3. Set the staff call parameters according to the hospital system.

The dip switches are located on the staff call board behind the connector panel. Only one operation mode can be selected.

Dip switch positions:

Operating Mode	Dip switch 1	Dip switch 2	Dip switch 3
STAT	On	Off	Off
DYN	Off	On	Off
DYNOFF	Off	Off	On

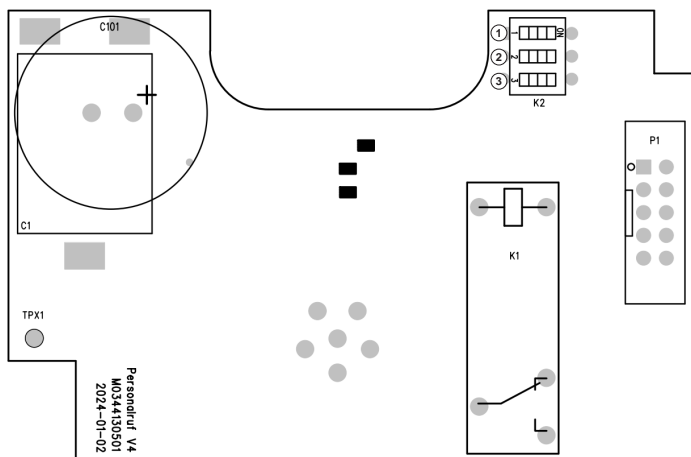


Fig. 1-3 Staff call board with dip switches

- 1 Dip switch 1
- 2 Dip switch 2
- 3 Dip switch 3

Reassembly of the staff call board

1. Install the staff call board onto the connector panel and secure it by tightening the nut.
2. Install the warmer assembly onto the machine, ensuring both connectors are properly connected and the unit is securely fixed.

1.6 Close the machine

Attach the rear housing to the machine.

1.7 Printed instructions for use (IFU) available for installed software version in required language

Printed instructions for use (IFU) is available in the required language for the installed software version.

The printable PDF can be downloaded at <https://eifu.bbraun.com/> or <https://www.tech-service-portal.bbraun.com/p/PRID00009622>.

2 Preparation for the function inspection

2.1 Language installation

Connect the mains cord to the machine.

If language installation is required:

1. Ensure that the required language file is stored on the FSU stick (folder *LANGUAGES*) in the correct version compatible with the installed software. The language file can be downloaded from the service portal: <https://www.tech-service-portal.bbraun.com/p/PRID00009622>. Do not manipulate or unzip the language file.
2. Remove the protective cover from the USB port.
3. Insert the FSU stick into the USB port.
4. Press the standby switch (ON/OFF button) to start the machine.

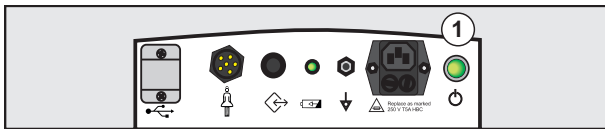


Fig. 1-4 Connector panel: standby switch

5. Once the selector screen appears, press the *FSU* button and wait until the machine has fully booted.
6. Enter the *Manage Languages* menu.
7. Click on *Add new language*.
8. Select the required language from the FSU stick.
9. Press *Install*.
 - ↳ The language is installed on the machine.
10. After the language installation is complete, switch off the machine by pressing and holding the standby switch for approximately 5 seconds.

2.2 Start the machine in TSM mode

1. Insert the FSU stick into the USB port.
2. Press the standby switch (ON/OFF button) to start the machine.
3. Once the selector screen appears, press the *TSM* button and wait until the machine has fully booted.

2.3 Check the machine's date and time

1. Navigate to the tab *User Configuration* and open the menu *Localization*.
2. Check the *Date* and *Time*. Update, if required.
3. If you needed to update the *Date* and *Time*, reboot the machine afterwards.



If the date and time reset to 2016, replace the 3 V battery (Panasonic CR2032, Art. No. 34519327) on the single board computer (SBC) and try again.



Rebooting the machine after setting the date and time is essential. Otherwise, the calibration date will be incorrect and the automatic load cell tare function (introduced in SW V1.77.10) will not work.

3 Function inspection: Pressures

3.1 Pressure sensors AP, FP, VP, SP, EP: 0 mmHg

Test the pressure sensors according to the service manual. If a failure is detected, first perform troubleshooting by checking your test equipment and all connections. Then, repeat the test before initiating calibration procedures.

1. Navigate to the menu *Test: Pressures/Lev. Reg* in TSM.
2. No pressure is applied to the pressure sensors (0 mmHg).
3. Check that the values of all pressure sensors ① -⑤ (CS and PS) are within the permissible tolerance of +/- 10 mmHg.



Fig. 1-5 TSM test pressures

- 1 Arterial pressure sensor
- 2 Pre-filter pressure sensor
- 3 Venous pressure sensor
- 4 Solution pressure sensor
- 5 Effluent pressure sensor

3.2 Pressure sensors AP, FP, VP, SP, EP: +600 mmHg

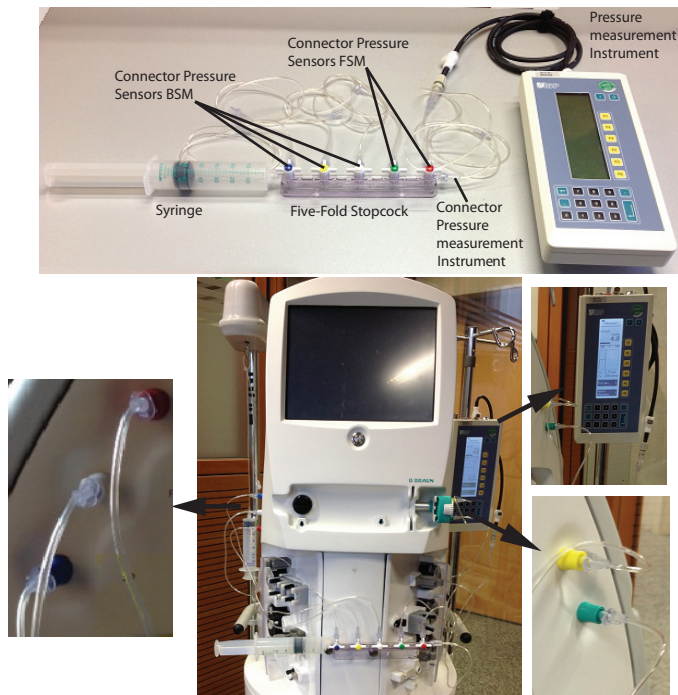


Fig. 1-6 Pressures: equipment and connections

Required tools / materials

- Five-fold stopcock incl. tubing
 - Calibrated pressure measurement device
 - Syringe 50 ml
1. Apply a reference pressure of approximately +600 mmHg to the pressure sensors. Document the set value (value displayed on the reference meter) in the check list.
 2. Check that the values of all pressure sensors (CS and PS) are within the permissible tolerance range: set value displayed on the reference meter +/- 10 mmHg.

3.3 Pressure sensors AP, FP, VP, SP, EP: -450 mmHg

1. Apply a reference pressure of approximately -450 mmHg to the pressure sensors. Document the set value (value displayed on the reference meter) in the check list.
2. Check that the values of all pressure sensors (CS and PS) are within the permissible tolerance range: set value displayed on the reference meter +/- 10 mmHg.

3.4 Pressure leak test

1. Apply a reference pressure of 530 mmHg to the pressure sensors.
2. Close all valves on the five-fold stopcock (set to a 45° angle).
3. Wait for 1 minute.
 - ↳ Pressures displayed on the machine screen must be > 500 mmHg for all pressure sensors (CS and PS).

4 Function inspection: Syringe Pump and SAD

4.1 Syringe Pump

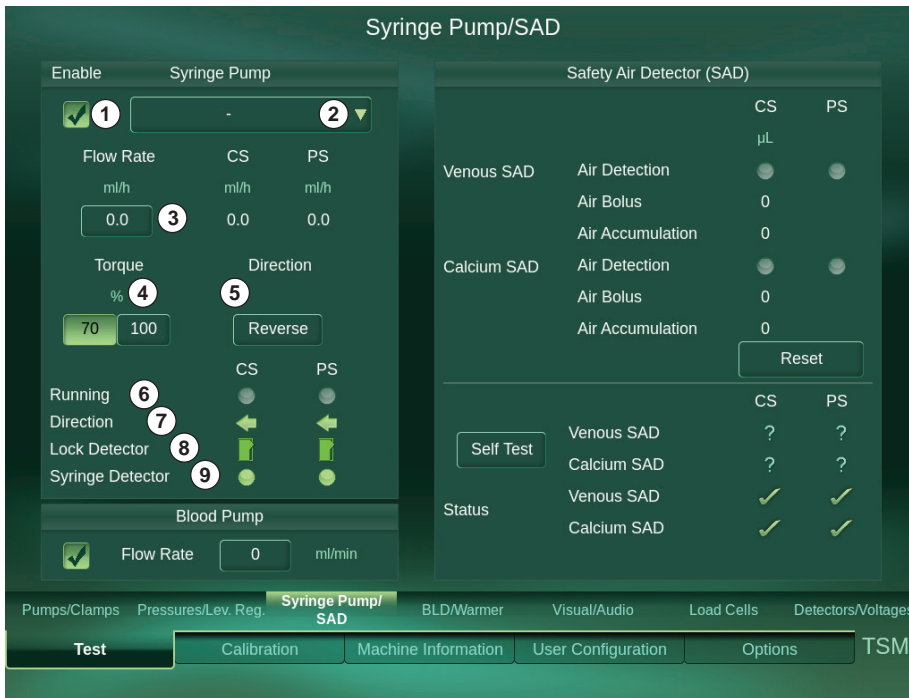


Fig. 1-7 TSM Test syringe pump

- 1 Enable check box
- 2 Select syringe
- 3 Flow rate
- 4 Torque
- 5 Direction
- 6 Running
- 7 Direction
- 8 Lock detector
- 9 Syringe detector

Prerequisites

- No syringe is inserted in the syringe pump.
- Lock detector of the syringe pump is closed. Lock detector ⑧ indicates a closed state.
- Syringe detector ⑨ CS and PS visual indicators are deactivated.

Required tools / materials

- Syringe (e.g.:B|Braun Omnifix 50ml).
1. Open lock detector.
 - ↳ Lock detector ⑧ indicates open state.
 2. Insert a syringe and press button ②.
 - ↳ Syringe type shall be selected.
 - ↳ Syringe detector ⑨ CS and PS visual indicators are activated.

3. Deactivate syringe pump *Enable* check box ①.
4. Reverse button ⑤ is deactivated.
5. Press button ③ and set flow rate to 50 ml/h.
 - ↵ Syringe pump is standing still.
 - ↵ *Running* ⑥ CS and PS visual indicators are deactivated.
6. Select syringe pump *Enable* check box ①.
 - ↵ Syringe pump moves slowly to the lower end stop.
 - ↵ *Running* ⑥ CS and PS visual indicators are activated.
 - ↵ *Direction* ⑦ arrows point in the left direction.
 - ↵ Flow rate CS and PS display 50 ml/h +/- 1 ml/h.
7. Press button ③ and set flow rate to 500 ml/h.
 - ↵ Syringe pump moves faster to the lower end stop.
 - ↵ Flow rate CS and PS display 500 ml/h +/- 1 ml/h.
8. Press *Reverse* button ⑤.
 - ↵ Syringe pump moves to the upper end stop.
 - ↵ *Running* ⑥ CS and PS visual indicators are still activated.
 - ↵ *Direction* ⑦ arrows point in the right direction.
 - ↵ Values of flow rate CS and PS are inverted.
9. Release *Reverse* button ⑤.
10. Deactivate syringe pump *Enable* check box ①.
11. Set torque ④ of the syringe pump to 70%.
12. If necessary open lock detector and press the plunger into the syringe, so that the plunger is nearly in empty position.
13. Select syringe pump *Enable* check box ①.
 - ↵ Check if the syringe pump runs although the syringe empty position is reached.
 - ↵ Lock detector ⑧ is closed.
14. Deactivate syringe pump *Enable* check box ①.
15. Set torque ④ of the syringe pump to 100%.
16. Open lock detector and set the plunger of the syringe, so that the plunger is nearly in empty position.
17. Select syringe pump *Enable* check box ①.
 - ↵ Check if the syringe pump stops when the syringe empty position is reached.
 - ↵ Lock detector ⑧ is open.

4.2 Safety Air Detectors (SAD)

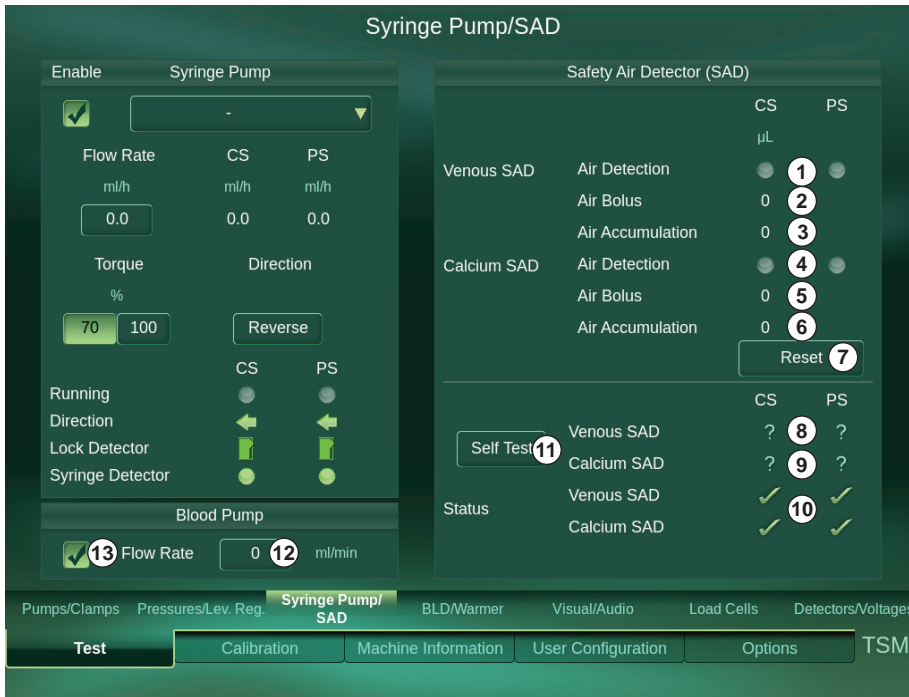


Fig. 1-8 TSM Test SADC and SADV

- 1 Air detection SADV
- 2 Air bolus SADV
- 3 Air accumulation SADV
- 4 Air detection SADC
- 5 Air bolus SADC
- 6 Air accumulation SADC
- 7 ResetSelftest SADV
- 8 Selftest SADV
- 9 Selftest SADC
- 10 Status SADV/SADC
- 11 Selftest
- 12 Blood pump flow rate
- 13 Enable check box blood pump

Prerequisites

- No tube is inserted in the venous SAD
 - No tube is inserted in the calcium SAD
1. PS and CS LED of air detection ① and ④ are activated.
 2. Insert a fluid filled tube in the venous SAD.
 - ↳ PS and CS LED of air detection ① is not activated.

3. Insert a water filled tube in the calcium SAD
4. PS and CS LED of air detection ④ is not activated.
5. Remove tube from venous and calcium SAD.
6. Set blood pump flow ② rate to 26 ml/min.
↳ CS value of air bolus ② increases.
7. Set blood pump flow ② rate to 126 ml/min.
↳ CS value of air bolus ② increases more rapidly than before.
8. Set blood pump flow ② rate to 0 ml/min.
↳ CS value of air bolus ② stop increasing.
9. Insert a fluid filled tube in the venous SAD
10. Set blood pump flow ② rate to 6 ml/min.
↳ CS Value of air accumulation ③ is not changing.
11. Remove tube out of the venous SAD.
12. Deactivate enable check box ⑬ of the blood pump.
↳ CS value of air bolus ② is still not changing.
13. Insert a syringe into the syringe pump and select syringe type.
14. Enable check box of the syringe pump is selected.
15. Set syringe pump flow to 50 ml/h.
↳ CS value of air bolus ⑤ increases.
16. Set syringe pump flow to 100 ml/h.
↳ CS value of air bolus ⑤ increases more rapidly than before.
17. Deactivate enable check box for the syringe pump.
↳ CS value of air bolus ⑤ stop increasing.
18. Insert a fluid filled tube in the calcium SAD.
19. Check if a syringe is inserted in the syringe pump.
20. Select enable check box of the syringe pump.
21. Set syringe pump flow to 50 ml/h.
↳ CS value of air accumulation ⑥ is not changing.
22. Remove and insert back the tube as quick as possible.
↳ CS value of air accumulation ⑥ increases.

Prerequisites

- Tube filled with water is inserted in the venous SAD
- Tube filled with water is inserted in the calcium SAD
- Press *Reset* button ⑦. Venous and calcium SAD values of air bolus and air accumulation are 0.
- Self test CS and PS icons ⑧ and ⑨ are blue questions marks.

Test of Venous and Calcium Safety Air Detector SADV/SADC

1. Press *Self Test* button ⑩.
 - ↪ Check if CS and PS icons for both detectors ③ and ⑨ change to a sand glass symbol.
 - ↪ During the test the visual indicators of *Air Detection* ① and ④ are activated.
 - ↪ Values of *Air Accumulation* ① and ④ are increasing.
 - ↪ Values of *Air Bolus* ② and ⑤ are increasing.
 - ↪ Test is finished successfully if CS and PS icons of both detectors ① and ④ change to green ticks.
2. Remove tubes from venous and calcium SAD.
3. Press *Self Test* button ⑩.
 - ↪ When test is finished CS and PS icons of both detectors ① and ④ change to red crosses.
4. Check if all four icons of status section ⑩ are green ticks.

5 Function inspection: Blood Leak Detector (BLD) and Warmer

5.1 Blood Leak Detector (BLD)



Fig. 1-9 TSM Test BLD

- 1 *Blood detection indicator lights*
- 2 *Zero button*
- 3 *Self-Test button*
- 4 *Actual value*
- 5 *calibration setpoint value*
- 6 *Setpoint*
- 7 *Calibrate*

Two different blood leak detector test tools are available for the OMNI. Check the picture below (📖 "Fig. 1-10 Blood leak detector (BLD) test tool comparison" (20)) to identify which version of the blood leak detector (BLD) test tool you have.

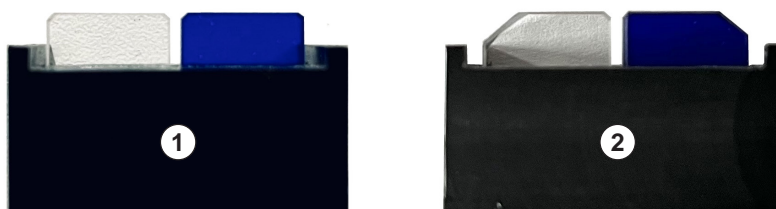



Fig. 1-10 Blood leak detector (BLD) test tool comparison

- 1 *BLD test tool 1*
- 2 *BLD test tool 2*

Required tools / materials

- Blood leak detector test tool (1 or 2)
1. Insert the transparent glass of the BLD test tool into the blood leak detector and press *Zero* button ② (see  "Fig. 1-11 TSM Test BLD test tool" (21)). Wait until the CS LED next to the *Zero* button is activated and the *Zero* button is released.
 - ↪ *Actual Value* ④ is 0 (permissible tolerance +/- 3).
 - ↪ *Actual Value* ④ is lower than the *Calibration Setpoint Value* ⑤.
 - ↪ *Blood Detection* control system CS and protective system PS LEDs ① are not activated.
 2. Insert the blue glass of the BLD test tool into the blood leak detector.
 - ↪ *Actual Value* ④ increases.
 - ↪ *Actual Value* ④ is higher than the *Calibration Setpoint Value* ⑤. For BLD test tool 1, the *Actual Value* ④ is between 490-540. For BLD test tool 2, the *Actual Value* ④ is between 630 - 700.
 - ↪ *Blood Detection* CS and PS LEDs ① are activated.

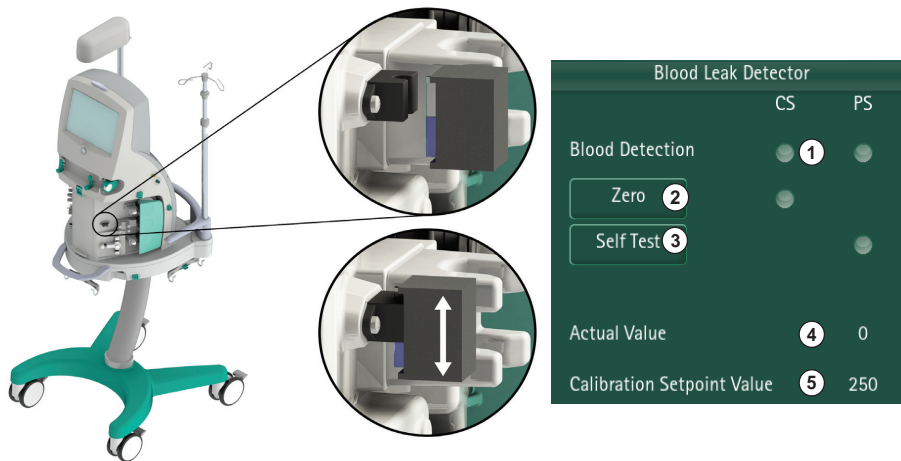


Fig. 1-11 TSM Test BLD test tool

3. Press the *Self Test* button ③.
 - ↪ LED for PS *Self Test* is lit for a short time.
 - ↪ Machine checks the functionality of the BLD.

5.2 Warmer and temperature sensors



Fig. 1-12 TSM Test warmer

- 1 Warmer enable CS *ON*
- 2 Warmer enable PS *ON*
- 3 Enter warmer power CS
- 4 Warmer Door status CS and PS
- 5 Outlet temperature CS and PS
- 6 Plate temperature CS and PS

⚠ WARNING!

Electrical shock hazard!

Mains voltage is present if machine is switched off.

- Disconnect machine from mains if the machine is opened for servicing.
- If service activities require mains, do not touch any exposed wiring or conductive surfaces while the machine is opened.



The previous warmer board has been replaced by an updated version. You can find the connections of the warmer test and calibration board to both warmer boards in the pictures below.



Fig. 1-13 Connection of the warmer test and calibration board to the previous warmer board

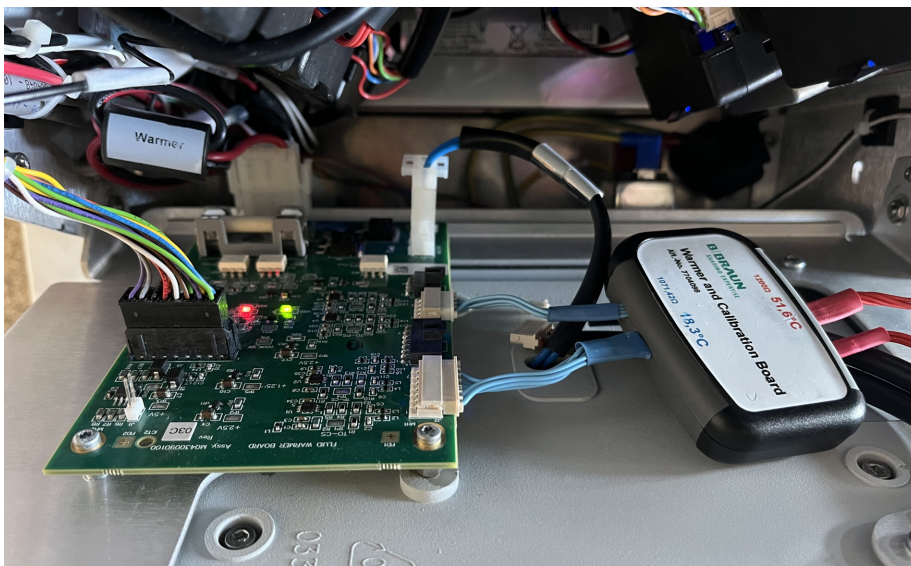
























Fig. 1-14 Connection of the warmer test and calibration board to the updated warmer board

Required tools / materials

- Warmer test and calibration board

Test with Warmer Test and Calibration Board

1. Take off the rear housing.
2. Fold the warmer back by loosening the connection between the warmer bracket and the main board bracket.
3. Disconnect the temperature sensors from the warmer board.
4. Connect the warmer test and calibration board to the warmer board (blue wires, see  "Fig. 1-13 Connection of the warmer test and calibration board to the previous warmer board" (23) /  "Fig. 1-14 Connection of the warmer test and calibration board to the updated warmer board" (23)).
5. Wait until the values are stable and compare *Outlet Temperature* CS and PS  and *Plate Temperature* CS and PS  (see  "Fig. 1-12 TSM Test warmer" (22)) with the printed value on the warmer test and calibration board (permissible tolerance: +/- 0.1 °C).
6. Disconnect the warmer test and calibration board from the warmer board and connect the other side (red wires) to the board.
7. Wait until the values are stable and compare *Outlet Temperature* CS and PS  and *Plate Temperature* CS and PS  with the printed value on the warmer test and calibration board (permissible tolerance: +/- 0.1 °C).
8. Disconnect the warmer test and calibration board and reconnect the temperature sensor connectors to the warmer board.
9. Fix the warmer assembly to the main board bracket.
10. Wait until the values are stable and compare the CS and PS values of the *Outlet Temperature*  (permissible tolerance: +/- 0.3 °C).
11. Compare the CS and PS values of the *Plate Temperature*  (permissible tolerance: +/- 0.3 °C).
12. Reassemble the rear housing.
13. Press *Warmer Enabled ON* for CS  and *ON* for PS . Set *Warmer Power*  to 50%.
 -  *Warmer Power* PS led is activated.
 -  *Plate Temperature* CS and PS values  increase.
14. Deactivate *Warmer Enabled* buttons for CS  and PS  and set *Warmer Power*  to 0%.
15. Open the warmer door.
 -  *Warmer Door* symbols  (CS and PS) display open doors.
16. Close the warmer door, but push it against the latch to achieve the maximum distance with the warmer door closed.
 -  *Warmer Door* symbols  (CS and PS) display closed doors.

6 Function inspection: Load Cell Calibration

Calibrate all load cells according to the following descriptions.



Manual calibration of the load cells during all service activities is a prerequisite for the automatic load cell tare function (introduced in SW V1.77.10) to operate as intended.



Fig. 1-15 TSM calibration load cells

- 1 Citrate load cell
- 2 Substitution load cell
- 3 Effluent load cell
- 4 Dialysate load cell
- 5 Numbers of points
- 6 Actual point
- 7 Reference
- 8 *Calibrate*
- 9 *Save*
- 10 *Cancel*



The first reference value is performed with a weight of [0 g] for all load cells. The following weights are required for the second reference value.

- 1 x 2,000 g weight for the citrate load cell.
- 2 x 5,000 g weights for the substitution load cell, effluent load cell and dialysate load cell. One weight per one hook.

Each load cell has to be calibrated separately. Each load cell is calibrated by a two point calibration.

The calibration shall be done with a closed machine.

Required tools / materials

- 1 x 2,000 g reference weight (calibrated)
 - 2 x 5,000 g reference weight (calibrated)
1. Make sure that no weight is applied to the load cells and select one of the load cells ① - ④.
 - ↳ First *Reference* value ⑦ is displayed (0 [g]).
 2. Wait until the displayed *g* values are stable and no longer decreasing.
 - ↳ Button *Calibrate* ⑧ is activated.
 3. Press the *Calibrate* button ⑧.
 - ↳ First reference value is calibrated.
 - ↳ Second *Reference* value ⑦ is displayed.
 4. Hang the defined reference weight(s) on the corresponding load cell.
 5. Wait until the weight(s), the *AD* values, and the *g* values are stable (at least 20 seconds).
 - ↳ Button *Calibrate* ⑧ is activated.
 6. Press the *Calibrate* button ⑧.
 - ↳ Second reference value is calibrated.
 7. Press the *Save* button ⑨.
 - ↳ Calibration process has finished and calibration data has been saved for the respective load cell.
 8. Remove calibration weight from the load cell.
- If there is an error during the calibration process, press the *Cancel*/button ⑩ to cancel.

7 Function inspection: Detectors and Voltages

7.1 Check door detector sensitivity



Fig. 1-16 TSM - Test Detectors

Required tools / materials

- Door detector calibration tool (Spacer 5 mm)

Check door detectors

1. Close blood side door.
 - ↳ Symbols ③ display a closed door.
2. Place the test and calibration tool for the door detector on the upper pin of the blood side door and close the blood side door. Gently push the door shut.
 - ↳ Symbols ③ display still a closed door.
3. Open blood side door.
 - ↳ Symbols ③ display an open door.
4. Close fluid side door.
 - ↳ Symbols ⑤ display a closed door.
5. Place the test and calibration tool for the door detector on the upper pin of the fluid side door and close the fluid side door. Gently push the door shut.
 - ↳ Symbols ⑤ display still a closed door
6. Open fluid side door.
 - ↳ Symbols ⑤ display an open door.

7.2 Staff Call

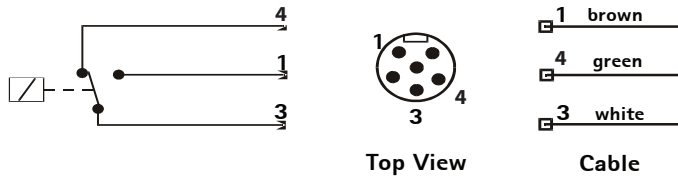


Fig. 1-17 TSM Test staff call connectors



Fig. 1-18 TSM Test staff call

1 *Staff Call* button

Staff call

1. Ensure that *Staff call* button ① is not pressed.
2. Measure the electrical resistance between pin 1 and 3.
 - ↳ Electrical resistance value is > 1.5 MΩ.
3. Measure the electrical resistance between pin 4 and 3.
 - ↳ Electrical resistance value is < 1 Ω.
4. Press *Staff call* button ①.
 - ↳ *Staff call* button is activated.
5. Measure the electrical resistance between pin 1 and 3.
 - ↳ Electrical resistance value is < 1 Ω.

6. Measure the electrical resistance between pin 4 and 3.

↳ Electrical resistance value is > 1.5 MΩ.



If *DYN* or *DYNOFF* is set for the staff call (dip switches on the staff call board), the relay is activated for one second only when the *Staff Call* button is pressed.

8 Option Handling and User Configuration

8.1 Option handling

If option(s) shall be activated:

1. Enter the *Options* menu of the TSM.
2. Scan the delivered option activation code (OAC) or enter the code manually.
 - ↳ Machine checks the CRC, the article number and the serial number.
3. Wait until the machine displays the *OAC* and check results.
4. Set the required option(s) to *ON*.
5. Document the enabled option(s) on the check list.

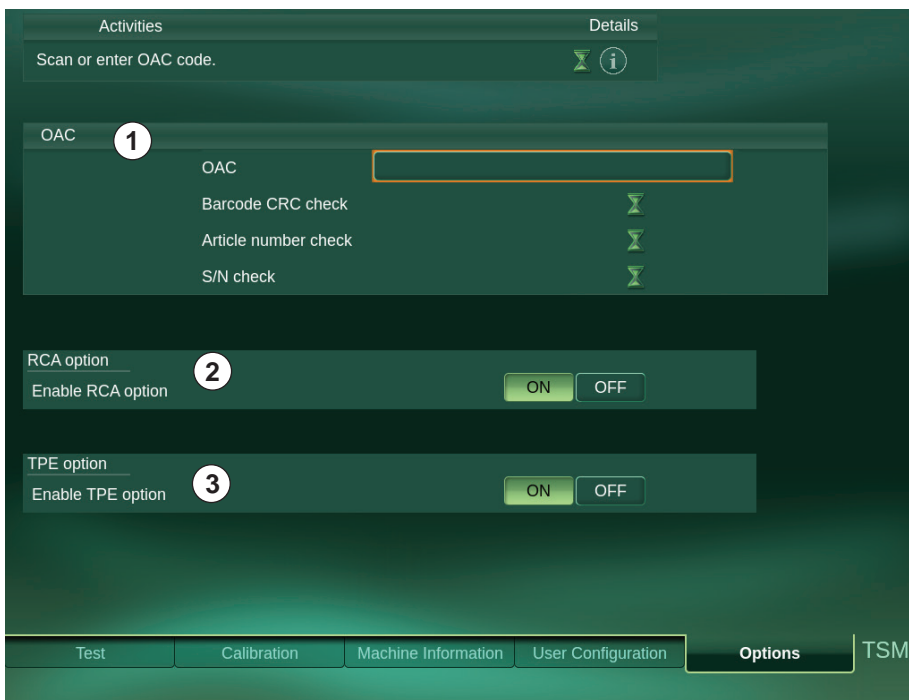


Fig. 1-19 TSM - Options

8.2 User configuration

1. Enter the menu *User Configuration* of the TSM.
2. Check/set the user configuration parameters according to the customer's requirements.
3. Ensure that all settings are documented in the latest valid *Service Protocol Parameters User Configuration* for the installed software version and that the protocol is fully signed (the protocol is available in the service portal: <https://www.tech-service-portal.bbraun.com/p/PRID00009622>).

9 Preparation and Test Therapy

9.1 Start the preparation

1. Exit the TSM mode: Press and hold the standby switch for approximately 5 seconds to turn off the machine.
2. Remove the FSU stick from the USB port at the connector panel.
3. Press the standby switch to start the machine in therapy mode.
4. Press the *Treatment* button once the machine has fully booted.

9.2 No weights are present on the load cells

Ensure that all load cells are free from any weights.

9.3 Scan disposable kit and select therapy

1. Scan the disposable kit for CVVHDF therapies and press *Next*.
2. Select therapy type: *CVVHDF*, dilution type: *Post Dilution*, Anticoagulation Type: *Heparin*.
3. Press *Next* and *Confirm*.
 - ↳ The machine performs initial self tests.
4. Ensure that the machine successfully completed the self tests.

9.4 Prepare and set up disposables

1. Install the disposable kit and the syringe according to the instructions displayed on the screen.
2. Press *Load*.
 - ↳ The machine loads the disposable kit tubing into the pumps and clamps.
3. Press *Next* once the loading procedure has completed successfully.
4. Install the bags as instructed on the screen.
5. Select the number of applied effluent bags.
6. Press *Next*.
7. Start the priming process by pressing *Automatic Priming*.

9.5 Machine passed self tests successfully and is ready for therapy

The machine passed all self tests successfully and is ready for therapy.

1. Press *Next*.
 - ↳ The machine provides the options to choose *Optional Rinsing* or *Optional Recirculation*.
2. Press *Next*.

9.6 Enter the parameters for the test therapy

- *Patient ID:* 12345
- *Patient Weight:* 80 kg
- *Net Fluid Removal:* 2000 ml/h
- *Substitution (Post):* 5000 ml/h
- *Dialysate:* 1000 ml/h
- *Heparin Flow Rate:* 1 ml/h

Press *Confirm*.

9.7 Start the therapy

1. Select *White Connection*.
2. Connect the arterial line to the waste bag at the IV-pole.
3. Remove the priming bag from the center load cell.
4. Press *Enter Therapy*.
5. Set the blood flow to 500 mL/min and start the blood pump.
6. Press the *Therapy* button.
7. Wait until all parameters are reached.

9.8 Check the alarm function of the blood side door and the fluid side door

1. Open the fluid side door.
 - ↵ Check the visual and audio alarms.
 - ↵ Check that the pumps on the fluid side have stopped.
2. Close the fluid side door and reset the alarm.
3. Open the blood side door.
 - ↵ Check the visual and audio alarms.
 - ↵ Check that the pumps on the blood side have stopped.
4. Close the blood side door and reset the alarm.

9.9 Check the battery function and the function of the charge indicator light

1. Disconnect the machine from the mains.
 - ↵ Check the visual and audio alarms.
 - ↵ The machine does not switch off. It is being powered by the battery.
2. Reconnect the machine to the mains.
3. Check the battery charge indicator LED on the connector panel.
 - ↵ Charge indicator is illuminated.

9.10 Stop key function



Fig. 1-20 Service menu: Other

1. Navigate to the menu *Service: Other*
2. Press the Stop key below the monitor to activate it.
 - ↖ Red light around the stop key is activated.
 - ↖ All pumps stop running.
 - ↖ Voltages *VCC (24V)* and *24 Vsw* (section ⑦ in "Fig. 1-20 Service menu: Other" (33)) decrease to < 0.7 V.
3. Press the Stop key below the monitor to deactivate it.
 - ↖ Red light around the stop key is deactivated.
 - ↖ All pumps start running.
 - ↖ Voltages *VCC (24V)* and *24 Vsw* (section ⑦ in "Fig. 1-20 Service menu: Other" (33)) increase to appr. 24 V.

10 Electrical safety check according to EN 62353 / EN 60601-1

10.1 Wait until all set parameters are reached

Ensure that all pumps are operating at the specified speed before proceeding.

10.2 Equipment Leakage Current

1. Connect the adapter for electrical safety measurement to the tubing system (venous line).
2. Set the measurement device to equipment leakage current measurement setup (differential measurement).
3. Connect the machine to the measurement device according to the schema below. All data lines (e.g. staff call) must be connected during the measurement of the equipment leakage current.
4. Perform the measurement during therapy when all pumps are running and change the polarity during the measurement (N->L / L->N).
5. Note the highest measured value.

↪ Equipment leakage current is ≤ 0.5 mA.

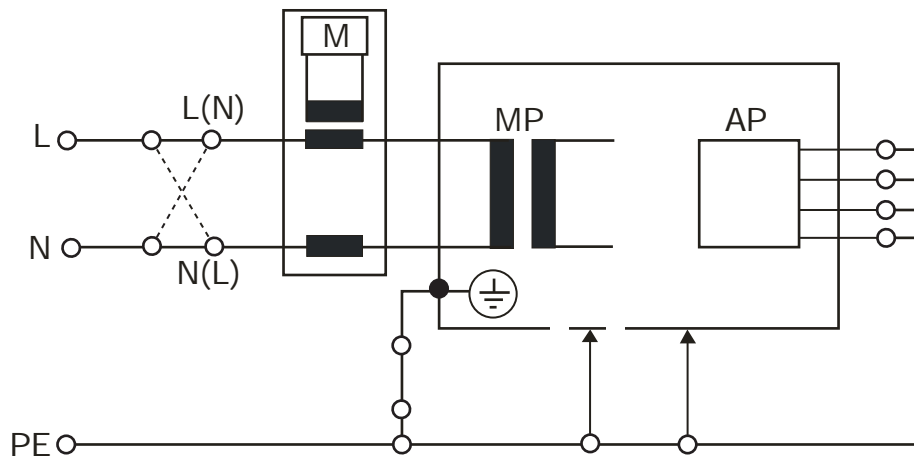


Fig. 1-21 Equipment leakage current measurement

10.3 Patient Leakage Current

1. Set the measurement device to patient leakage current measurement setup.
2. Connect the machine to the measurement device according to the schema below. All data lines (e.g. staff call) must be connected during the measurement of the equipment leakage current. The adapter for electrical safety measurement, connected to the tubing system, must be connected to the measurement device (AP).
3. Perform the measurement during therapy when all pumps are running.
4. Note the highest value (AC).
 - ↳ Patient leakage current is $< 10 \mu\text{A AC}$.

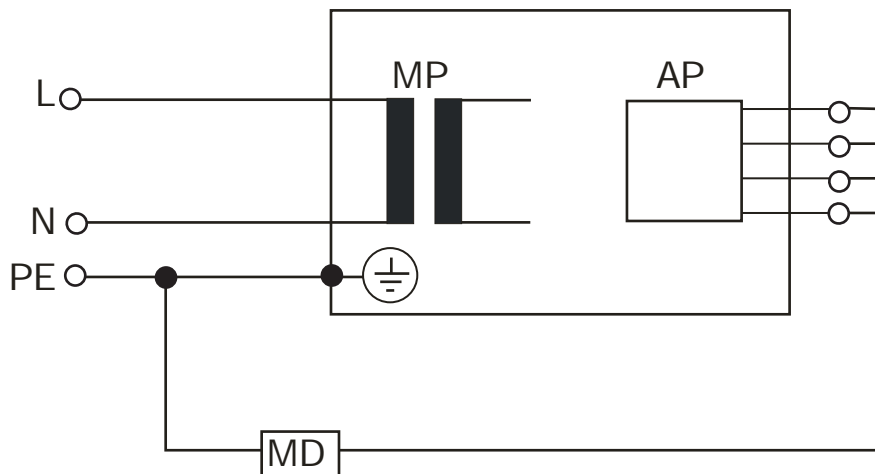


Fig. 1-22 Patient leakage current measurement

11 Setting into service

11.1 Stop the therapy

1. Navigate to the *Functions* menu, press *End Therapy* and confirm by pressing *Yes*.
2. Select *Skip blood return* and press *Next*.

11.2 Remove the disposables and the test equipment from the machine

Instructions for draining the disposable kit for reuse (only for test therapies without patient):

1. Place all bags (on IV pole and load cells) on the floor. Leave all clamps open.
2. Open all four kit locking mechanisms (blood side and fluid side).
3. Disconnect the syringe from the syringe pump.
4. Press *Unload*.
 - ↳ The machine unloads the tubing segments from the pumps and clamps.
5. Disconnect the pressure lines.
 - ↳ Fluid flows back into the bags.
6. Wait until the disposable kit is nearly empty of fluid.
7. If the hydrophobic filters of the pressure lines are wet, use a dry syringe to blow air through the filters. Ensure that no fluid has entered the manometer connectors.
8. Disconnect and remove all bags and test equipment from the machine.
9. Open the warmer door and remove the warmer bag.
10. Detach and remove the disposable kit from the machine.
11. Press *Next*.
12. Press *New Therapy* and confirm to return to the start screen.

11.3 Attach the USB port protector

Attach the protective sheet metal over the USB port.

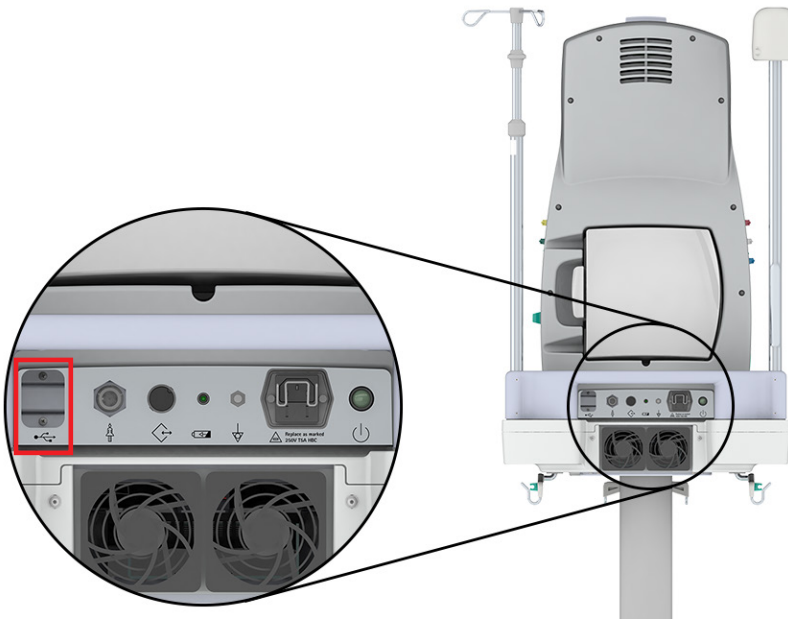


Fig. 1-23 USB port protector

11.4 Document the applied measurement equipment and the disposable kit

1. Document the article number and batch number of the applied disposable kit.
2. Record all test and measurement equipment used during the procedure in the provided table.

11.5 Clean the outer surface of the machine according to the IFU

A list of approved cleaning agents for the OMNI can be found in the OMNI instructions for use.

11.6 Machine is released for patient use

Confirm that all required steps and checks have been completed, no visible damage is present, all disposables and test tools have been removed from the machine, and the machine is ready for patient use.

Ensure that the entire protocol has been completed and signed in accordance with good documentation practices. All unused text fields must be marked with "N/A".

1.3 Document Revision Overview

Revision Number	Updates
Rev. 1.03.00 11.2025	<ul style="list-style-type: none">• Added a check for correct date and time• Replaced load cell check with mandatory load cell calibration

Tbl. 1-1 Revision overview