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OMNI®

Acute Blood Purification System

Service Manual SW 1.50.xx EN

CE 0123

CE marking according to directive 93/42/EEC.

Technical alterations reserved.

B. Braun Avitum AG

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EN / Rev. 02.04.00 / 11/2017

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1 About this Service Manual

Read the service manual carefully before servicing the machine.

The edition of this service manual is for the maintenance and repair of the OMNI blood purification system with a software ≥ 1.xx.xx. The service manual is subject to amendments.

1.1 Copyright

1.2 Information and Documentation

1.2.1 Instructions for Use

The technical service shall consider the instructions for use during service activities. An instructions for use can be ordered at your local B. Braun Avitum AG representative or dealer.

1.2.2 Circuit Diagrams

Circuit diagrams are available on request.

1.2.3 Figures/Images

The displayed figures and images can differ slightly from the machines on site, due to different hardware configurations.

1.3 Terminology

The following terminology is used in this service manual:

Term	Definition
Service Technician	The service technician is a service personnel who is trained to service the acute machine (see Service Training; Skills and Knowledge; Prerequisites for Service).
User	The user is a person of the medical staff who actively operates and uses the OMNI.
Responsible Organization	The responsible organization is a person or organization which uses or operates a medical device for commercial purposes or provides third parties and other users with machines taking all legal responsibilities for the product and safety of the patients and users.
Machine	OMNI acute blood purification system

1.3.1 Abbreviations

The following abbreviations are used in this service manual:

Abbreviation	Definition
AP	Arterial Pressure
BLD	Blood Leak Detector
BSM	Blood Side Manifold
CS	Control System
CSS	Control System Software
CVVHDF	Continuous Veno-Venous Hemodiafiltration
DSS	Display System Software
EP	Effluent Pressure
FP	Pre-Filter Pressure
FSM	Fluid Side Manifold
GUI	Graphic User Interface
PS	Protective System
PSS	Protective System Software
RTS	Run-Time System
SADC	Safety Air Detector Calcium
SADV	Safety Air Detector Venous
SP	Solution Pressure
TMP	Transmembrane Pressure
TSI	Technical Safety Inspection
TSM	Technical Support and Maintenance
VEX	Version Exchange Mode
VP	Venous Pressure

1.4 Validity

This service manual applies to OMNI with the following article number (REF, see type plate)

- 7101505

1.4.1 Software Version

The software version SW 1.50.xx is described in this service manual. If available, higher software versions are described in the appendix as technical information.

The software can be installed in the software mode VEX: Service manual chapter 5: Software installation.

1.5 Target Group

The target group for this service manual is the service technician.

The OMNI shall only be serviced by trained service technicians.

1.6 Warnings, Notices and Symbols

1.6.1 Signal Words and Definitions

4 signal words are used in this document: DANGER, WARNING, CAUTION and NOTICE.

The signal words DANGER, WARNING and CAUTION point out particular hazardous situations for users and patients.

The signal word NOTICE points out information directly or indirectly related to prevention of damage and not to personal injury.

The signal word and the color of header indicate the degree or level of hazard:

⚠ DANGER!

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

⚠ WARNING!

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ CAUTION!

Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE!

Used to address practices not related to personal injury, i.e. information directly or indirectly related to prevention of damage.

Warning messages also suggest measures that shall be taken in order to avoid the respective hazardous situation. Thus, warning messages related to the risk of personal injury have the following structure:

Header with signal word
Here, the type of hazard is indicated!
Here, the source of hazardous situation is indicated and possible consequences if measures are not followed.
• This is the list of measures to prevent the hazard.

1.6.2 Information and Activities

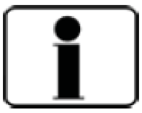
Information

This is additional useful information concerning procedures, background information and recommendations.

Activities

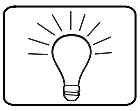
1. In this way instructions for an activity are listed.
   ↳ This symbol marks the result of an activity.

1.6.3 Symbols



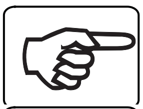
Information

This symbol is additional useful information concerning procedures, background information and recommendations.



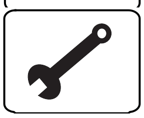
Tips

The symbol gives additional tips, which can be helpful.



Handling

The symbol indicates an activity. The activities are numbered consecutively.



Calibration Equipment/Tools

The symbol gives remarks for necessary calibration equipment/tools, e.g. calibration, disassembly or assembly.

1.7 Typographic Conventions

Key and menu designations, button inscriptions as well as messages and prompts of the control software are represented in *italic* letters. In addition, they are written in uppercase and lowercase letters, exactly as they are displayed on the software interface.

Examples:

- Press *Enter* key to confirm.
- The *SETUP* screen appears.
- The message *System restored!* is displayed.

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2 Safety

2.1 Servicing of Machine

Never service or maintain the machine or activate the TSM service program while a patient is connected.

2.2 Service Training

Service training is essential to meet the B. Braun Avitum AG standard operating procedures for qualified service and support.

- Participation in a B. Braun Avitum AG service training to accomplish qualified maintenance, repair and service support.

2.2.1 Skills and Knowledge

The service technician shall have the following skills and knowledge:

- Mechanics, digital/analog techniques, measurement and PC techniques.

2.2.2 Prerequisites for Service

The service technician:

- shall perform the service activities on the machine and taking part in regular service trainings.
- shall use the service manual to perform the service activities
- shall service the machine with the following tools only:
  – Availability of approved and calibrated test equipment and tools given in this service manual 9.2 Test and Calibration Equipment and Tools (418).

Contact your local B. Braun Avitum AG representative or dealer for detailed information concerning training courses.

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2.3 Special Hazards and Precautions

2.3.1 Mains Voltage Supply

The mains voltage supply shall correspond with the mains voltage on the machine type plate.

The machine can be isolated from mains supply by removing the detachable mains cord from mains inlet on the connector panel.

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.

Component	Description
Mains connection	IEC 60320-2-2 / C-14 with locking bracket, for connection to mains with cable provided by manufacturer.The AC power socket must be equipped with three conductors: Phase, Neutral and Protective Earth.
Nominal voltage	100 V AC ... 240 V AC
Connected load	500 VA

2.3.2 Chemical Burns and Scalding

During servicing on running machines: prevent chemical burns and scalding of the skin due to the penetration of disinfectant or hot liquid.

2.3.3 Contaminated Machines

Protective gear should be worn in case of servicing of assumed contaminated machines.

2.3.4 ESD/EMC Information

Electronic components are sensitive to electrostatic discharges.

Pay attention the ESD/EMC information (see 10.1 ESD/EMC Information (423)for additional information):

- Electrostatic discharge (ESD)
- Electromagnetic compatibility (EMC)

2.3.5 Technical Support and Maintenance TSM Service Program

Activate the TSM service program for service activities only. If the TSM service program is activated the therapy alarm system is disabled. The TSM service program is started in the service mode: Service manual chapter 6: Start TSM service program.

2.4 Responsibilities

2.4.1 Electrical Installation

The electrical installation shall correspond with national regulations for initial operation of the machine (e.g. IEC publications). The machine shall not be operated in hazardous locations or rooms. The potential equalization shall be in accordance with national requirements (e.g. IEC publications).

2.4.2 Commissioning and Service

NOTICE!

Prevent fluid residue after service activities;:

- immediately remove any fluid residue during servicing of the machine, e.g. after repair, installation or maintenance

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Only trained service technicians shall service the OMNI, i.e.commissioning, repair, maintenance, software installation and firmware update of the OMNI.

Commissioning and servicing shall only be performed with proper tools, calibration equipment and be in accordance with the most recent revision of this service manual/technical information, which shall be clearly and thoroughly understood.
Do not hand over the machine to the customer if safe operation is not guaranteed.

2.4.3 Function Check

Check the respective function of the assembly group/component after servicing.

2.4.4 Repair Matrix

A complete function check shall be performed after every service according to the repair matrix (see chapter 5 Repair Instructions) and instructions for use.

2.4.5 Technical Safety Inspection

Perform regular technical safety inspections as described in chapter 7 of this service manual. The technical safety inspections shall be executed every 24 month.

The technical safety inspection can be executed more frequently if it is required by local formalities or other reasons.

2.4.6 Preventive Maintenance

Perform regular preventive maintenance as described in chapter 7 of this service manual. The preventive maintenance shall be executed every 12 month.

2.4.7 Calibration Procedures

2.4.7.1 Calibration

Only perform a calibration after the OMNI has reached working temperature. You should save the calibration data to the FSU before you exit the TSM service program.

2.4.7.2 Ambient Temperature

Before the OMNI is switched on the machine shall have room temperature (see instructions for use).

2.4.7.3 Calibration Service

All calibration devices shall be approved and registered with an identification number. The calibration equipment is subject to the B. Braun Avitum AG calibration service and shall be checked and recalibrated in regular intervals, to meet the B. Braun Avitum AG standard operating procedures SOPs. Only approved and registered calibration equipment shall be used for servicing.

2.5 Handling of Parts

2.5.1 Spare Parts

⚠ WARNING!

Risk of patient injury due to malfunction of the machine!

- Only use original spare parts manufactured and sold by B. Braun Avitum AG. Provide part number and description respectively when ordering any spare parts. Order spare parts at the local B. Braun Avitum AG representative or dealer. The tracking of critical parts will be done in the respective system of B. Braun Avitum AG.

2.5.2 Tubing

NOTICE!

Machine will not pass the selftest due to a bad or wrong tubing connection.

- Connect the silicon tubing of each manometer connector to the level regulation block according to the labeling printed on the level regulation block.
- Connect the silicon tubing between the level regulation pump and the regulation block according to the provided description.

⚠ WARNING!

The air flow can be interrupted if tubing are kinked or twisted. Tubing can be damaged if it touches moving or rotating components

- Make sure that the tubing in the machine are not kinked or twisted after servicing (e.g. if rear housing is disassembled and assembled again or if a manifold is disassembled and assembled again).
- The tubing shall not touch moving/rotating components (e.g. motors of gear pumps).

2.5.3 Wiring

⚠ WARNING!

The voltage can be interrupted if wiring is kinked. Wiring can be damaged if it touches moving or rotating components.

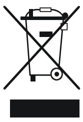
- Make sure that the wiring is not kinked after servicing.
- Wiring shall be replaced only by the same cable type/length and identical installation manner.
- The cables shall not touch moving/rotating components (e.g. motors of gear pumps).

2.5.4 O-Rings

Always check o-rings from disassembled groups/components and replace if necessary.

2.5.5 Fuses

If fuses are replaced, they shall exactly match the type and rating specified by the manufacturer in the spare parts list/technical information. Where applicable fuses shall be approved by UL/CSA.



2.5.6 Disposal and Taking Back of Spare Parts

Dispose spare parts (e.g. boards or batteries) according to local disposal guidelines or send back to B. Braun Avitum AG free of charge.
The material return form shall be used if spare parts are sent back (see chapter 9, Material Return Form).

2.6 Modifications of the Machine

⚠ WARNING!

Risk to the patient or risk to the user due to modifications of the machine!

- It is not allowed to modify the machine.

It is prohibited to change hardware in the machine unless otherwise specified/ described.

2.7 Measurement Equipment

Additional measurement equipment used to servicing the machine must demonstrably meet the relevant IEC specifications.

- IEC 60601-1, ed 3.1
- ISO 13485
- EN 62353

Service technicians connecting additional measurement equipment to the machine are responsible for ensuring that the valid version of the System Standard IEC 60601-1 is complied with.

The measurement equipment must be calibrated.

The machine is distributed in countries where it is registered and classified according to local regulations.

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3 Commissioning

3.1 Commissioning Check List

1 Standby switch
2 Mains inlet
3 Potential equalization bolt
4 Battery charge indicator light
5 Data port
6 Staff call
7 USB port

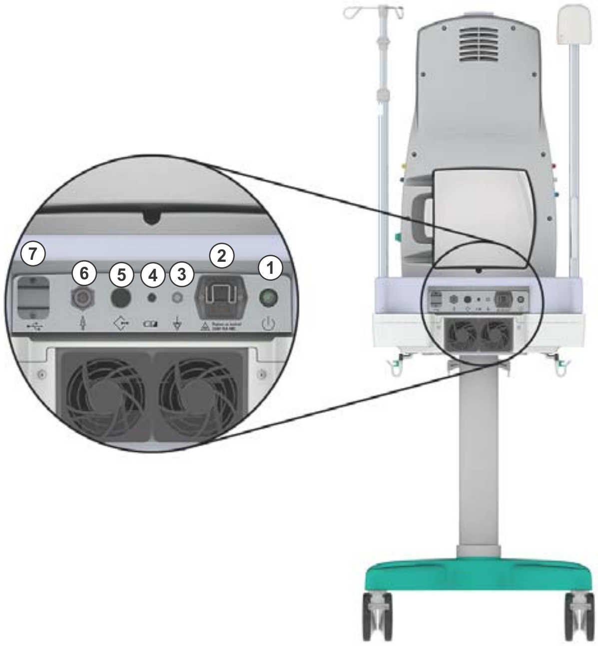


Fig. 3-1 Connector panel of the machine

The commissioning (putting into service) must be performed and documented before the machine is handed over to the responsible organization (user), according to the specified check list, with reference to the service manual and instructions for use.

REF (reference No./Nr.)	
SN (serial No./Nr.)	
Year of purchase	
Responsible organization (user)	
Operating hours [h]	
Inventory number	
SW version	
Manufacturer	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen, Germany

Commissioning Check List			OK
1.	**Unpack and initial checks**		
1.1	Unpack machine		O
1.2	Visual inspection (exterior)		O
1.3	**Visual inspection** (interior) Open machine Connect *power input* connector on the main board (J18)		 O O
1.4	**Protective earth resistance** Measurement points: Exterior: Potential equalization bolt (connector panel); Screw on the bottom of the machine body Interior: Base plate (free position) **Note highest value**		O
	Max. Value= Actual Value =	<0.1 **[Ω]** _______ **[Ω]**	O
1.5	**Staff call parameters** Staff call system is present: (select hospital system configuration) STAT (default) DYN DYN OFF		 O O O
1.6	Close machine		O
1.7	Instructions for use present (local language)		O
2	**Function inspection**		
2.1	**Preparation for the function inspection**		
2.1.1	**Preparation for the function inspection** Language installation required: Yes No		 O O
2.1.2	Start machine in TSM mode		O
2.2	**Pressure sensors AP, FP, VP, SP, EP** (0 mmHg) (permissible tolerance +/-10 mmHg) **Set value**: 0 **mmHg**		O

Commissioning Check List			OK
	Arterial pressure CS Pre-Filter pressure CS Venous pressure CS Solution pressure CS Effluent pressure CS	_______ mmHg _______mmHg _______mmHg _______mmHg _______mmHg	O O O O O
	Arterial pressure PS Pre-Filter pressure PS Venous pressure PS Solution pressure PS Effluent pressure PS	_______mmHg _______mmHg _______mmHg _______mmHg _______mmHg	O O O O O
2.3	**Pressure sensors AP, FP, VP, SP, EP** (approx.:+600 mmHg) (permissible tolerance +/-10 mmHg) **Set value**: _______ **mmHg**		O
	Arterial pressure CS Pre-Filter pressure CS Venous pressure CS Solution pressure CS Effluent pressure CS	_______mmHg _______mmHg _______ mmHg _______mmHg _______mmHg	O O O O O
	Arterial pressure PS Pre-Filter pressure PS Venous pressure PS Solution pressure PS Effluent pressure PS	_______mmHg _______mmHg _______mmHg _______mmHg _______mmHg	O O O O O
2.4	**Pressure sensors AP, FP, VP, SP, EP** (approx.: -450 mmHg) (permissible tolerance +/-10 mmHg) **Set value**: _______**mmHg**		O
	Arterial pressure CS Pre-Filter pressure CS Venous pressure CS Solution pressure CS Effluent pressure CS	_______mmHg _______mmHg _______mmHg _______mmHg _______mmHg	O O O O O
	Arterial pressure PS Pre-Filter pressure PS Venous pressure PS Solution pressure PS Effluent pressure PS	_______mmHg _______mmHg _______mmHg _______mmHg _______mmHg	O O O O O

Commissioning Check List			OK
2.5	Syringe pump Running/not running Forward/reverse direction Syringe pump stops when the lock detector is open		 O O O
2.6	Blood leak detector		O
2.7	Load cell calibration and comparison measurement		
2.7.1	Left load cell calibration (0 g) (permissible tolerance +/-5 g) Set value: 0 g		O
	Difference CS	_______ [g]	O
	Difference PS	_______[g]	O
2.7.2	Center load cell calibration (0 g) (permissible tolerance +/-5 g) Set value: 0 g		O
	Difference CS	_______[g]	O
	Difference PS	_______[g]	O
2.7.3	Right load cell calibration (0 g) (permissible tolerance +/-5 g) Set value: 0 g		O
	Difference CS	_______ [g]	O
	Difference PS	_______ [g]	O
2.7.4	Citrate load cell calibration (0 g) (permissible tolerance +/-5 g) Set value: 0 g		O
	Difference CS	_______ [g]	O
	Difference PS	_______ [g]	O
2.7.5	Left load cell calibration (2 x 5,000 g) (permissible tolerance +/-5 g) Set value: _______g		O
	Actual value CS Difference CS	_______ [g] _______[g]	 O
	Actual value PS Difference PS	_______[g] _______[g]	 O

Commissioning Check List				OK
2.7.6	**Center load cell calibration (2 x 5,000 g)** (permissible tolerance +/-5 g) **Set value: _______g**			O
	Actual value CS **Difference CS**	_______[g] _______[g]		O
	Actual value PS **Difference PS**	_______[g] _______[g]		O
2.7.7	**Right load cell calibration (2 x 5,000 g)** (permissible tolerance +/-5 g) **Set value: _______ g**			O
	Actual value CS **Difference CS**	_______[g] _______ [g]		O
	Actual value PS **Difference PS**	_______[g] _______[g]		O
2.7.8	**Citrate load cell calibration (2,000 g)** (permissible tolerance +/-5 g) **Set value: _______g**			O
	Actual value CS **Difference CS**	_______[g] _______[g]		O
	Actual value PS **Difference PS**	_______[g] _______ [g]		O
2.7.9	Perform pressure leak test			O
2.8	Check door detector sensitivity			O
2.9	Check SADC function			O
2.10	**Set and confirm user configuration parameters** (according to user configuration protocol p.(30))			O
2.11	Option Handling The following option is activated: ___________________________________			O
3	**Start preparation**			
3.1	No weight present on load cell			O
3.2	Select treatment mode and parameters			O
3.3	Prepare and set up disposable kit			O
3.4	Machine passed self test successfully			O

Commissioning Check List		OK
3.5	**Enter parameters for therapy** Net fluid removal: 2000 ml/h Substitution: 7000 ml/h Dialysate: 1000 ml/h Heparin: 1ml/h	 O O O O
3.6	**Start Therapy** Set blood pump to 500 ml/min and press *Therapy* button. Wait until parameters are reached.	 O O
3.7	Check battery function Check charge indicator function	O O
3.8	Check alarm function of blood side door and fluid side door	O
4	**Electrical safety check according to EN 62353/EN 60601-1**	
4.1	**Equipment leakage current**	O
	Max. Value = ≤ 0.5 [mA] Actual Value = _______[mA]	 O
4.2	**Patient leakage current**	O
	Max. Value = <10 [µA] AC Actual Value = _______ [µA] AC	 O
4.3	Stop key function	O
4.4	Test staff call	O
4.5	Stop therapy	O
4.6	Remove disposables and test equipment	O
5	**Setting into service**	
5.1	**Machine released for patient use**	O
5.2	**Applied accessories/disposables** Applied disposable kit:	
5.3	Clean outer surface	O

Applied Measurement Equipment	Description	ID/Serial No.
Electrical safety		
Reference weight 5,000 g		
Reference weight 5,000 g		
Reference weight 2,000 g		
Other measurement device		
Other measurement device		
Other measurement device		
Other measurement device		
Other measurement device		

Comments:		
The commissioning was performed and the machine was handed over to the responsible organization (user).		O
Next inspection date:		
Name service technician		
Date	Signature	

3.1.1 Default Parameters User Configuration

The responsible organization is responsible for the user configuration. The technician will only release and set the parameters according to the instructions of the responsible organization.

Blood Side Parameters	Default	Changed Value
Temporary access problem suppression Arterial	ON	
Temporary access problem suppression Venous	ON	

Fluid Side Parameters	Default	Changed Value
Warmer outlet temperature [°C] CRRT	37	
Warmer outlet temperature [°C] TPE	37	
Automatic substitution reduction Based on effluent pressure	ON	
Filtration ratio alarm limit [%] CRRT alarm	40	
Filtration ratio alarm limit [%] CRRT info	25	
TPE Filtration ratio alarm limit [%] TPE alarm	40	
TPE Filtration ratio alarm limit [%] TPE info	30	
Alarm Override Additional blood side stop in case of BLD alarm	OFF	
Plasma flow setting mode Ratio setting	ON	

Anticoagulation Parameters	Default	Changed Value
Heparin rate maximum [l/h]	20	
Stop Before Therapy End (TPE)	ON	
Time Before Therapy End (TPE)	0:30	
Calcium Concentration [mmol/l]	230	
Citrate Concentration [mmol/l	113	
Select syringe types used in the hospital/center	All	O

Pressure Alarm Limits	Default	Changed Value
SCUF pressure alarm limit		
Arterial pressure [mmHg] Limit max Limit min	 100 -200	
Pre-filter pressure [mmHg] Window high Window low	 80 40	
Venous pressure [mmHg] Window high Window low	 60 20	
Transmembrane pressure [mmHg] Limit max	400	
Pressure drop [mmHg] Limit max	250	
Effluent pressure [mmHg] Limit min	-100	
CVVHD pressure alarm limit		
Arterial pressure [mmHg] Limit max Limit min	 100 -200	
Pre-filter pressure [mmHg] Window high Window low	 80 40	

Pressure Alarm Limits	Default	Changed Value
Venous pressure [mmHg] **Window high** Window low	 60 20	
Transmembrane pressure [mmHg] **Limit max**	400	
Pressure drop [mmHg] **Limit max**	250	
Effluent pressure [mmHg] Limit min	-100	
CVVHDF (Post) pressure alarm limit		
Arterial pressure [mmHg] **Limit max** Limit min	 100 -200	
Pre-filter pressure [mmHg] **Window high** Window low	 80 40	
Venous pressure [mmHg] **Window high** Window low	 60 20	
Transmembrane pressure [mmHg] **Limit max**	400	
Pressure drop [mmHg] **Limit max**	250	
Effluent pressure [mmHg] Limit min	-40	
CVVH (Pre) pressure alarm limit		
Arterial pressure [mmHg] **Limit max** Limit min	 100 -200	
Pre-filter pressure [mmHg] **Window high** Window low	 80 40	

Pressure Alarm Limits	Default	Changed Value
Venous pressure [mmHg] **Window high** Window low	 60 20	
Transmembrane pressure [mmHg] **Limit max**	400	
Pressure drop [mmHg] **Limit max**	250	
Effluent pressure [mmHg] Limit min	-40	
CVVH (Post) pressure alarm limit		
Arterial pressure [mmHg] **Limit max** Limit min	 100 -200	
Pre-filter pressure [mmHg] **Window high** Window low	 80 40	
Venous pressure [mmHg] **Window high** Window low	 60 20	
Transmembrane pressure [mmHg] **Limit max**	400	
Pressure drop [mmHg] **Limit max**	250	
Effluent pressure [mmHg] Limit min	-40	
CVVH (Pre-Post) pressure alarm limit		
Arterial pressure [mmHg] **Limit max** Limit min	 100 -200	
Pre-filter pressure [mmHg] **Window high** Window low	 80 40	

Pressure Alarm Limits	Default	Changed Value
Venous pressure [mmHg] **Window high** Window low	 60 20	
Transmembrane pressure [mmHg] **Limit max**	400	
Pressure drop [mmHg] **Limit max**	250	
Effluent pressure [mmHg] Limit min	-40	
CVVH (Post-Post) pressure alarm limit		
Arterial pressure [mmHg] **Limit max** Limit min	 100 -200	
Pre-filter pressure [mmHg] **Window high** Window low	 80 40	
Venous pressure [mmHg] **Window high** Window low	 60 20	
Transmembrane pressure [mmHg] **Limit max**	400	
Pressure drop [mmHg] **Limit max**	250	
Effluent pressure [mmHg] Limit min	-40	
TPE pressure alarm limit		
Arterial pressure [mmHg] **Limit max** Limit min	 100 -100	
Pre-filter pressure [mmHg] **Window high** Window low	 80 40	

Pressure Alarm Limits	Default	Changed Value
Venous pressure [mmHg] **Window high** Window low	 60 20	
Transmembrane pressure [mmHg] **Limit max**	80	
Pressure drop [mmHg] **Limit max**	150	
Effluent pressure [mmHg] Limit min	-10	

Display Options	Default	Changed Value
Screensaver defaults **Status** **Time** [s]	 ON 300	
Screensaver display **Left top** **Left middle** **Left bottom** **Right top** **Right middle** **Right bottom**	 Arterial pres. Pre-filter pres. TMP Venous pres. Blood flow Next intervention	

Rinsing and Recirculation	Default	Changed Value
Rinsing parameters **Rinsing volume** [ml] **Fluid side rinsing** CRRT **Fluid side rinsing** TPE **Rinsing blood flow rate** [ml/min]	 200 OFF OFF 50	
Recirculation parameters **Recirculation blood flow rate** [ml/min]	50	

Localization	Default	Changed Value
Localization settings Language Date Time	English	

Other	Default	Changed Value
Therapy type	CVVH	
Dilution type	Post	
Anticoagulation type	Heparin	
Patient data management interface	Trend Viewer	

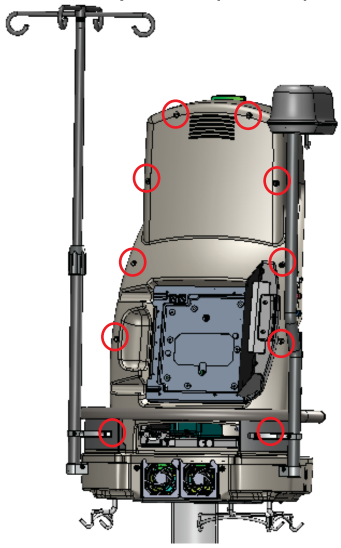
Signatures	Default	Changed Value
Technician:	Date	Signature
Responsible organization/User	Date	Signature

3.2 Execution Protocol Commissioning Check List

Executive Protocol Commissioning Check List	
1.	**Unpack and initial checks**
1.1	**Unpack the machine** • Remove packaging from the machine. • Check the packaging for damages. In case of any damages please note on the service report.
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. • Check housing gap between front housing and rear housing. • Check housing gap between lower housing and base plate housing. • Labels to check: – Device max. weight – Pressure labels are legible (AP,FP,VP,EP,SP) – Load cells symbols are present (each load cell (4) 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 – Symbols on the connector panel are legible

Executive Protocol Commissioning Check List

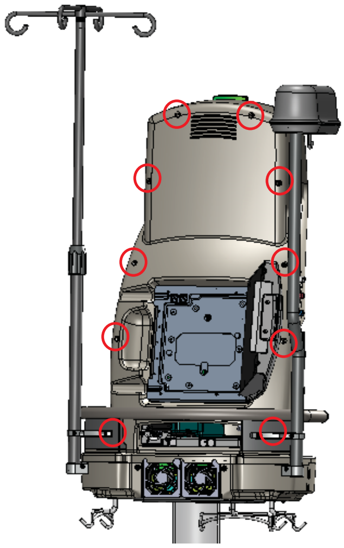
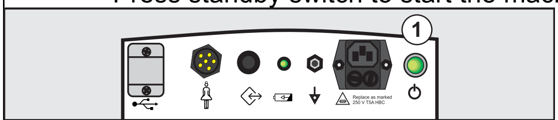
1.3 **Visual inspection (interior)**



- Remove rear housing
  - Remove ten screws from the rear housing.
- Connect power supply connector on 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 fixed position of connectors and tubing.
- Check fixed position of potential equalization cable and staff call
- Check gasket between touch screen and front housing for damages.
- Check gasket between front and rear housing for damages.

1.4 **Protective earth resistance**

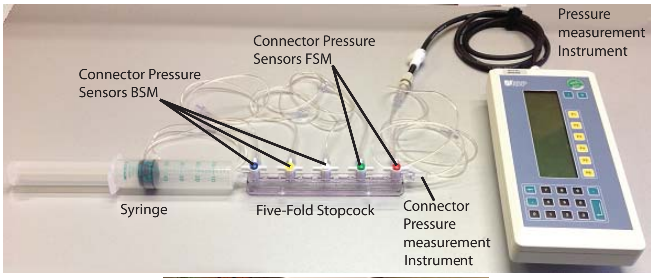
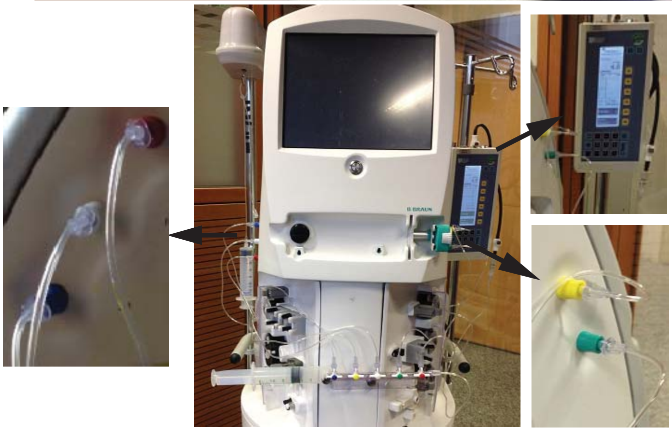
- Connect and secure the mains cord to the machine.
- Move the mains cord during the check, so that possible loose connections can be detected. The potential equalization cable must not be connected during the check of the protective earth resistance.
- Measurement points:
  - Exterior: Potential equalization (connector panel); Screw below the machine body
  - Interior: Base plate (free position)
  - note the highest value

Executive Protocol Commissioning Check List	
1.5	Set staff call parameters according to the hospital system. The dip switch is based on the staff call board behind the connector panel. Only one operation mode can be selected. Dip switch positions: On 1 = STAT (default), 2 and 3 = OFF On 2 = DYN, 1 and 3 = OFF On 3 = DYN OFF, 1 and 2 = OFF
1.6	• Close machine – Fix warmer on the machine. – Reassemble the screws on the rear housing. 
1.7	Instructions for use is delivered with the machine.
2	**Functional inspection**
2.1	Preparation for functional inspection
2.1.1	Language installation is required • Yes – Insert FSU to the USB port. – Press standby switch to start the machine.  • Once the selector screen appears, press FSU button. – Machine starts running in FSU mode. • Enter the *Manage Language* menu. • Install the required language on the machine. If it is not required to install a new language on the machine, start machine in TSM mode.

3

<table>
<tr><th colspan="2">Executive Protocol Commissioning Check List</th></tr>
<tr><td>2.1.2</td><td>• Plug in mains cord to mains.
• Insert FSU to the USB port.
• Press standby switch to start the machine.
• Once the selector screen appears, press TSM button.
– Machine starts running in TSM mode.</td></tr>
<tr><td>2.2</td><td>Arterial, pre-filter, venous, solution and effluent pressure sensors
Test pressure sensors according to the service manual. If there is any failure, first troubleshoot and test again before start any calibration action.
No pressure on the pressure sensors (approx. 0 mmHg) (permissible tolerance +/-10 mmHg).

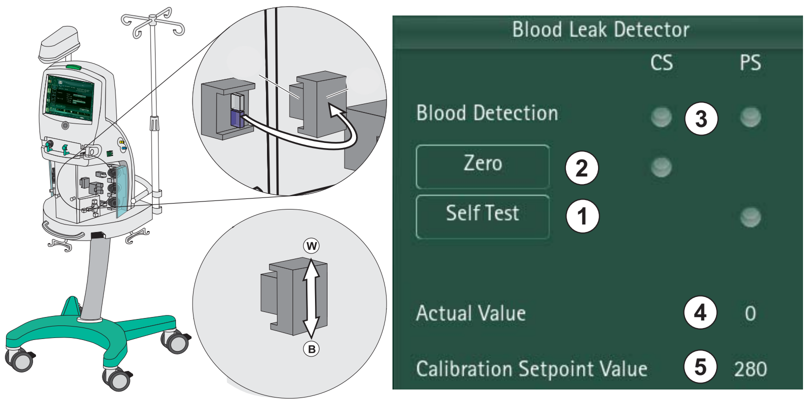
</td></tr>
</table>

Executive Protocol Commissioning Check List	
2.3 2.4	**Pressure sensors AP, FP, VP, SP, EP** • Set a pressure on the pressure sensors (approx. +600 mmHg and -400 mmHg); (permissible tolerance +/-10 mmHg)  
2.5	**Syringe Pump and SADC/SADV** • Check lock detector and syringe detector with a 30 ml syringe,e.g B|Braun Omnifix. • Check syringe pump operation – Running/not running – Forward/reverse direction – Syringe pumps stops when the lock detector is open

<table>
<tr><th colspan="2">Executive Protocol Commissioning Check List</th></tr>
<tr><td>2.6</td><td>

Blood leak detector

- Insert the white glass of the test tool into the blood leak detector and press *Zero* button ② . Wait until CS LED is activated.
- Release *Zero* button ② .
  - Actual value ④ is 0 (permissible tolerance +/- 3).
  - Actual value ④ is lower than calibration setpoint value ⑤ .
  - Blood detection control system CS and protective system PS LEDs ③ are not activated.
- Insert the blue glass of the test tool into the blood leak detector.
  - Value ④ increase.
  - Actual value ④ is higher than calibration setpoint value ⑤ (between 490-540).
  - Blood detection CS and PS LEDs ③ are activated.



</td></tr>
</table>

<table>
<tr><th colspan="2">Executive Protocol Commissioning Check List</th></tr>
<tr><td>2.7</td><td>

Load cell calibration and comparison measurement

If the measurement fails, start calibration and measure again before start trouble shooting.
</td></tr>
<tr><td>2.7.1</td><td>Left load cell
• Without reference weight approx. 0 g (permissible tolerance +/-5 g)</td></tr>
<tr><td>2.7.2</td><td>Center load cell
• Without reference weight approx. 0 g (permissible tolerance +/-5 g)</td></tr>
<tr><td>2.7.3</td><td>Right load cell
• Without reference weight approx. 0 g (permissible tolerance +/-5 g)</td></tr>
<tr><td>2.7.4</td><td>Citrate load cell
• Without reference weight approx. 0 g (permissible tolerance +/-5 g)</td></tr>
<tr><td>2.7.5</td><td>Left load cell
• With reference weight approx. 2 x 5,000 g (permissible tolerance +/-5 g)
• One weight per one hook</td></tr>
<tr><td>2.7.6</td><td>Center load cell
• With reference weight approx. 2 x 5,000 g (permissible tolerance +/-5 g)
• One weight per one hook</td></tr>
</table>

Executive Protocol Commissioning Check List	
2.7.7	Right load cell • With reference weight approx. 2 x 5,000 g (permissible tolerance +/-5 g) • One weight per one hook
2.7.8	Citrate load cell • With reference weight approx. 2,000 g (permissible tolerance +/-5 g)
2.7.9	Pressure leak test • Apply a pressure of 530 mmHg • Turn the valve closest to the syringe port to block the syringe • Wait 1 minute • Pressure must be above 500 mmHg for each pressure sensor
2.8	Check door detector sensitivity • Insert test and calibration tool for the door detector and close blood side door. – Machine displays a closed door • Open the blood side door – Machine displays immediately an opened door • Insert test and calibration tool for the door detector and close fluid side door. – Machine displays a closed door • Open the fluid side door – Machine displays immediately an opened door
2.9	Check self test function of the SADC. • Insert fluid filled tube in the SADC • Press *Selftest* button in TSM test menu
2.10	Check/set user configuration parameters according to the protocol
2.11	Option handling • Enter the *Options* menu • Scan the delivered barcode or enter the barcode manually. • Wait 10 seconds – Machine checks the CRC, the article number and the serial number • Check that the option is activated

Executive Protocol Commissioning Check List	
3	**Start preparation** • Exit TSM mode – Remove the FSU stick from the USB port. – Press the standby switch (5 sec) to switch off the machine. • Press the standby switch to start the machine in therapy mode.
3.1	**No weight present on load cells**
3.2	**Select treatment mode and parameters** • Check load cells: No weight present • Select CVVHDF therapy • Dilution type: Post dilution • Anticoagulation type: Heparin • Press *Next* • Confirm therapy parameters • Enter 12345 as *Patient ID* • Enter 80 kg as *Patient Weight* • Press *Next* • Select *Syringe Type* B.Braun OMNIFIX 30 • Press *Next*
3.3	**Prepare and set up Disposable Kit** • Open the disposable kit • Open both doors (blood side and fluid side) • Fix the disposable kit on the machine • Close both doors (blood side and fluid side) • Connect all pressure lines to the manometer connection • Close all unused clamps • Load the disposable kit • Press *Next* • Follow the instructions on the screen to start the automatic priming of the machine
3.4	**Machine passed self test successfully** • All test passed successfully

Executive Protocol Commissioning Check List	
3.5	**Enter parameters for therapy** • Net fluid removal: 2000 ml/h • Substitution: 7000 ml/h • Dialysate: 1000 ml/h • Heparin: 1ml/h • Press *Next* • Select *White Connection* and follow the instructions on the screen
3.6	**Start therapy** Start blood side and therapy side
3.7	**Check battery function of the machine** • Disconnect machine from mains • Check visual and audio alarm • Machine runs without mains connection • Connect machine to mains **Check charge indicator on the connector panel** • Charge indicator is on after connection machine to mains
3.8	**Check alarm function of blood side door and fluid side door** 1. Open blood side door – Machine gives alarm 2. Open fluid side door – Machine gives alarm
4	**Electrical safety check according to EN 62353/EN 60601-1**
4.1	**Equipment leakage current** • All data lines (e.g. staff call) must be connected during the check of the equipment leakage current • During therapy when all pumps are running change mains polarity and note highest value
4.2	**Patient leakage current** • All data lines (e.g. staff call) must be connected during the check of the patient leakage current

3

<table>
<tr><th colspan="2">Executive Protocol Commissioning Check List</th></tr>
<tr><td>4.3</td><td>

Stop key function

- Press Stop key below the display (red light around the Stop key is activated)
  - All pumps stop running
  - Voltage ① and ② decrease < 0.5 V.

- Press Stop key below the display (red light around the Stop key is deactivated)
  - All pumps start running
  - Voltage ① and ② increase to 24 V

</td></tr>
<tr><td>4.4</td><td>

- Open blood side door
  - Machine gives alarm
  - Measure at the staff call connector with a multimeter if the machine generates an alarm to the hospital system.

</td></tr>
<tr><td>4.5</td><td>Stop therapy</td></tr>
<tr><td>4.6</td><td>

Remove disposables and test equipment

- Disconnect test equipment from the machine
- Open blood side door
- Open fluid side door
- Unlock and remove disposable kit
- Close blood side door and fluid side door

</td></tr>
<tr><td>5</td><td>

Setting into service

- Remove disposables from the machine
- Clean outer surface

</td></tr>
</table>

Executive Protocol Commissioning Check List	
5.1	**Machine released for patient use** • All checks passed • No damages are visible
5.2	Note serial number and article number of the disposable kit
5.3	Clean outer surface according to the instructions for use

4

Table of Contents

4 Technical System Description

4.1 General Information

The OMNI is intended to perform continuous acute blood purification treatments for patients with acute renal failure and/or intoxication and therapeutic plasma exchange for patients where removal of plasma components is indicated. The system can be used in intensive care units or renal wards environment. t.

The machine has an instructions for use for detailed information.

The OMNI is powered by an internal power supply. This power supply is connected to the local mains supply through a double insulated detachable power cord. The power cord can be connected and fixed to the machine at the connector panel. The internal power supply isolates the machine from the mains supply and provides the necessary power for the machine.

The main user interface to control and monitor the machine is the 12.1 inch capacitive touch screen. The machine has two independent microprocessors, one for the control system, and one for the protective system.

The control system is responsible for controlling fluid flow rates based on weight, pressure, temperature and other physical parameters to provide the prescribed therapy to the patient. The control system software runs in a single board computer (SBC) and has interfaces to the sensors and actuators of the machine through the main board, blood side board, fluid side board and the warmer board.

The protective system is responsible for continuously monitoring (independently where necessary) the above parameters and for ensuring the safe operation at all times. The protective system software runs in a microcontroller on the main board and has interfaces to the sensors and actuators of the machine through the main board, blood side board, fluid side board and the warmer board. A level regulation block is used to control fluid levels in the disposable kit chambers through the pressure monitoring lines.

The machine has an intelligent alarm system initiating audible alarms via the loudspeaker and visual alarms via the visual indicator lights on the light board if necessary. The machine has a syringe pump and an air detector to administer anticoagulant solutions. It has a blood side that contains three pressure ports, two pumps (citrate pump and blood pump), a venous safety air detector, a tubing clamp, two level detectors, two kit locking mechanisms that are used for fixing and detecting the disposable kit and a door detector to detect if the blood side door is closed.

It has a fluid side that contains two pressure ports, three pumps, a 3 way clamp, a blood leak detector, a level sensor, two kit locking mechanisms that are used for fixing and detecting the disposable kit and a door detector to detect if the fluid side door is closed.

It has a fluid warmer to control the temperature of dialysate or substitution fluid that contacts the patient blood in the tubing or filter. The OMNI has four load cells to measure the weight of disposable bags containing various fluids. Interfaces to other systems include staff call, data (RS-232) and USB ports.

Component	Description
Protection class	IP21 (IEC 60529): Protection against intrusion with objects larger than 12.5 mm, protection against dripping water
Enclosure material	Aluminium, plastic
Weight without disposable kit and without bags	62 kg
Maximum weight with disposable kit and substitution bags, dialysate bags, effluent bags and citrate bag	115 kg
Packaging weight	< 55 kg
Packaging material	Corrugated paper, wood and low-density polyethelene (LDPE)

4.1.1 Machine Overview

1 Touch screen
2 Syringe pump
3 Pressure ports fluid side
4 IV pole
5 Citrate pole
6 Pressure ports blood side
7 Citrate load cell
8 Blood side manifold BSM
9 Caster with brake
10 Dialysate load cell (right), effluent load cell (center), substitution load cell (left)
11 Fluid side manifold FSM
12 Barcode scanner
13 Handles

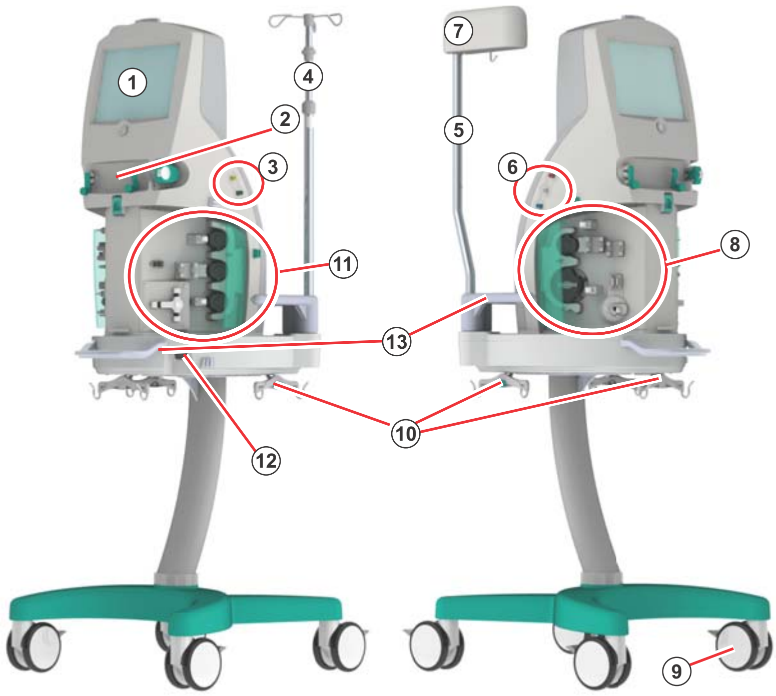


Fig. 4-1 Front view

The touch screen enables the user to control the machine (user interface).

The syringe pump delivers anticoagulant during the therapy.

The pressure ports on the fluid side are the connection for the pressure lines to the pressure sensors of the solution pressure and effluent pressure.

The IV pole gives the possibility to hang bags on the machine which should not be measured by the load cells.

The citrate pole fix the citrate load cell on the machine.

The pressure ports of the blood side are the connection for the pressure lines to the pressure sensors of arterial pressure, venous pressure and pre-filter pressure.

The citrate load cell controls the weight for the citrate bag during the therapy.

The blood side manifold includes all components for the blood circuit.

The caster with brake enables or disables the machine to move.

The load cells control the weight of effluent, dialysate and substitution bag during the therapy.

The fluid side manifold includes all components of the fluid circuit.

The barcode scanner read the information of the disposable kit for therapy.

The handle shall be used to move the machine.

1 Warmer

2 Warmer door

3 Connector panel

4 Fan including filter

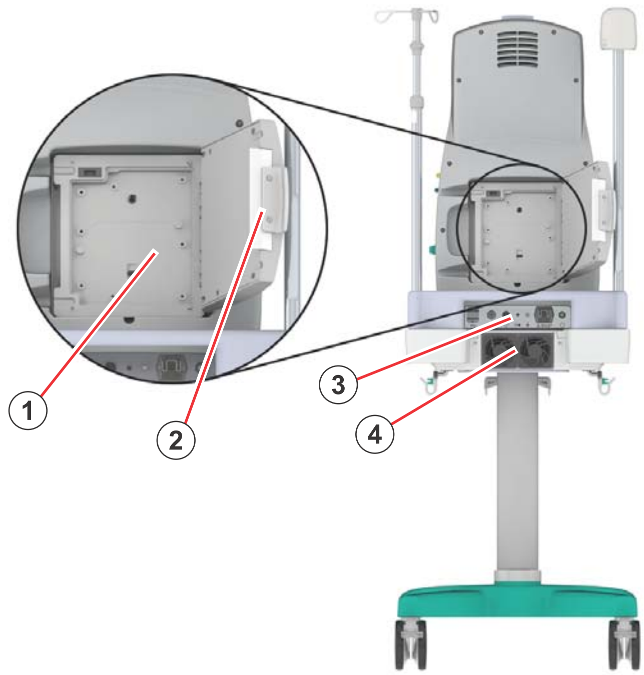


Fig. 4-2 Rear view

The warmer heats up the fluid for the therapy. Only fluid placed on the right load cell can be heated up.

The warmer door prevents the warmer bag for damages and touching during the therapy.

The connector panel includes all connectors for external equipment, the mains cord and the standby switch.

The two fans including there filters regulate the temperature inside the machine.

4.2 Front View

4.2.1 Load Cells

1 Dialysate load cell (right)

2 Effluent load cell (center)

3 Substitution load cell (left)

4 Citrate load cell

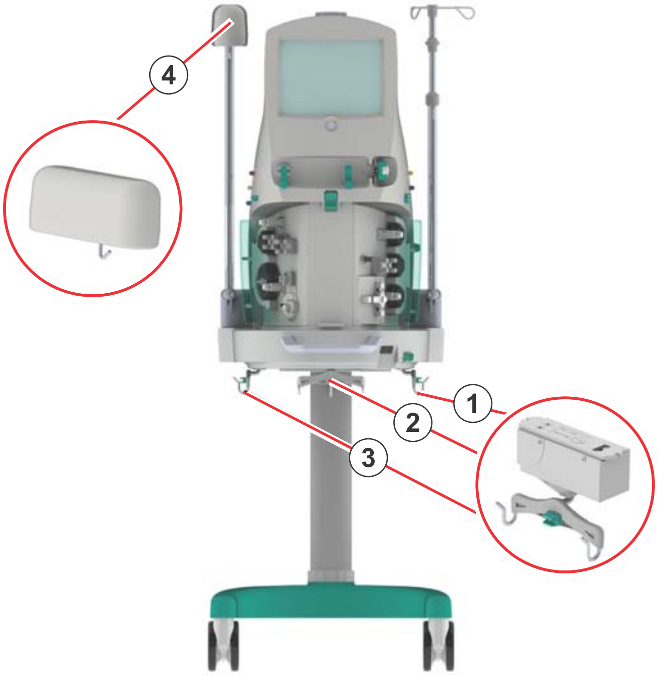


Fig. 4-3 Load cells

Dialysate load cell, effluent load cell and substitution load cell: 0 g - 15,000 g.

Citrate load cell: 0 g - 3,000 g.

4.2.2 Barcode Scanner

1 Barcode scanner

Fig. 4-4 Barcode scanner

4.2.3 Blood Side Manifold

1 Kit locking mechanism with detector
2 Pre- Filter level detector
3 Venous level detector
4 Venous safety air detector
5 Venous clamp
6 Blood pump
7 Door detector
8 Citrate pump
9 Blood side door

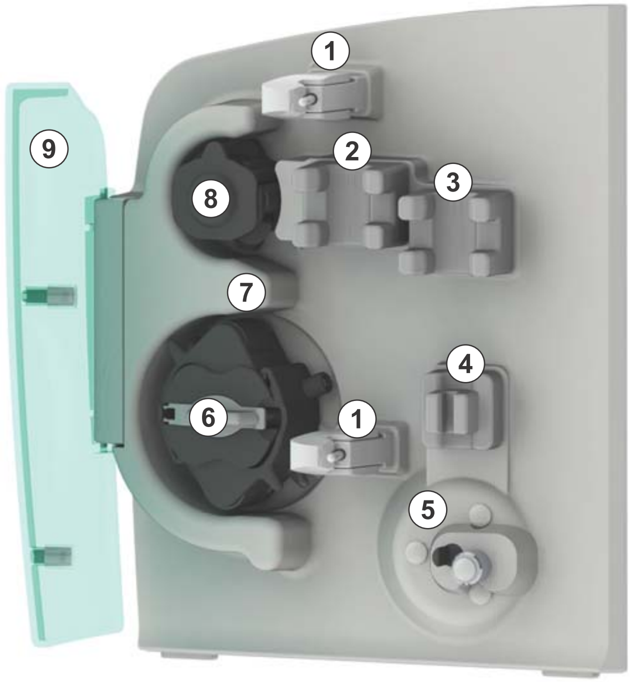


Fig. 4-5 Blood side manifold

The machine controls the pumps via an address code. The address code is set by a switch on the pump board.

Component	Adresscode
Blood pump	0
Citrate pump	4

The kit locking mechanism including kit detector fix the disposable kit and send a feedback to the machine about the status.

The pre-filter level detector traps bubbles and protects the machine from pressure shocks.

The venous level detector traps bubbles and protects the machine from pressure shocks.

The venous safety air detector: detects if air bubbles are in the tubing system at the end of the venous line. (right before patient access.)

The venous clamp closes the venous line in any case of a machine problem (alarm).

The blood pump is responsible for the blood flow.

The door detector monitors the status of the blood side door.

The citrate pump is responsible for the citrate flow.

4.2.4 Fluid Side Manifold

1 Kit locking mechanism with detector
2 Substitution pump
3 Door detector
4 Dialysate pump
5 Effluent pump
6 3-way clamp
7 Blood leak detector BLD
8 Solution level detector
9 Fluid side door

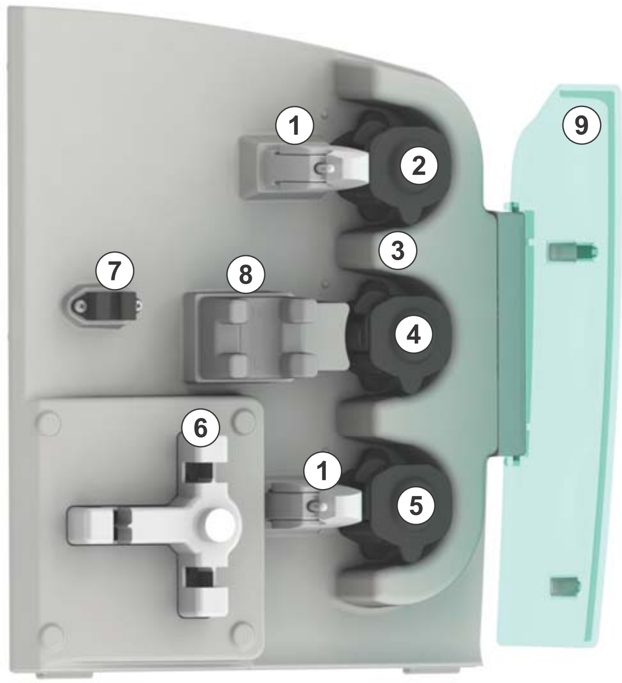


Fig. 4-6 Fluid side manifold

The machine controls the pumps via an address code. The address code is set by a switch on the pump board.

Component	Adresscode
Substitution pump	2
Dialysate pump	1
Effluent pump	3
3-way clamp	7

The kit locking mechanism including kit detector fix the disposable kit and send a feedback to the machine about the status.

The substitution pump is responsible for the substitution flow.

The door detector monitors the status of the blood side door

The dialysate pump is responsible for the dialysate flow.

The effluent pump is responsible for the effluent flow.

The 3-way clamp enables the user to change therapy types during a therapy without set up a new disposable kit.

The blood leak detector detects blood in the effluent line.

The solution level detector traps bubbles and prevents the machine for pressure shocks.

4.2.5 Syringe Pump

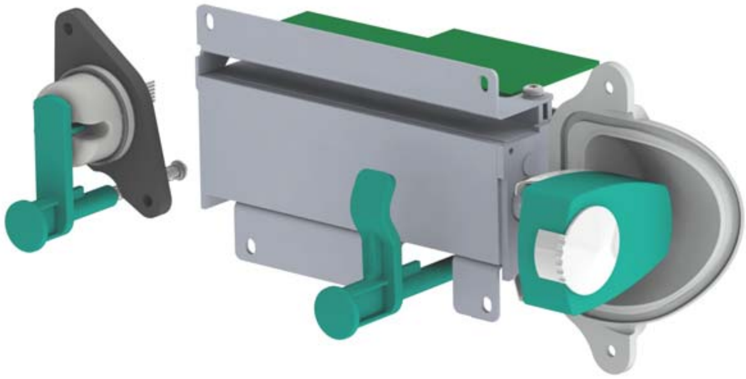


Fig. 4-7 Syringe pump

4.2.6 Touch Screen and Status Indicator Lights

1 Status indicator lights
2 Touch screen
3 Stop key

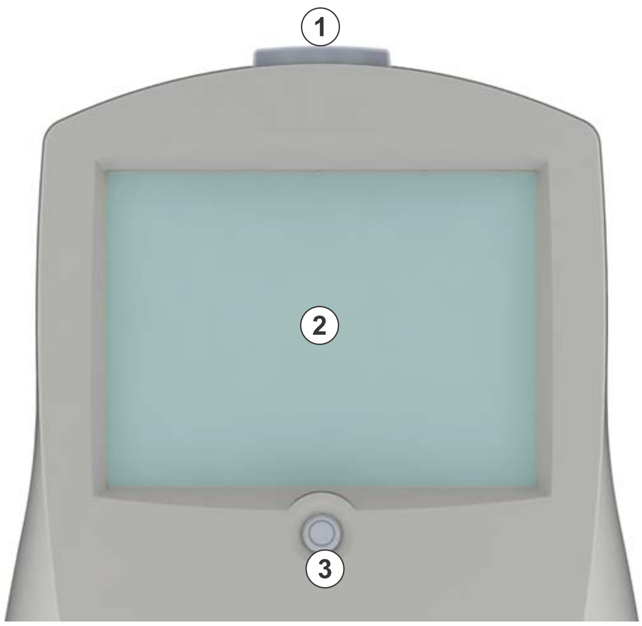


Fig. 4-8 Touch screen and status indicator lights

4.3 Rear View

4.3.1 Connector Panel

1 Standby switch

2 Mains inlet with integrated fuses

3 Potential equalization bolt

4 Battery charge indicator LED

5 Data port

6 Staff call

7 USB port

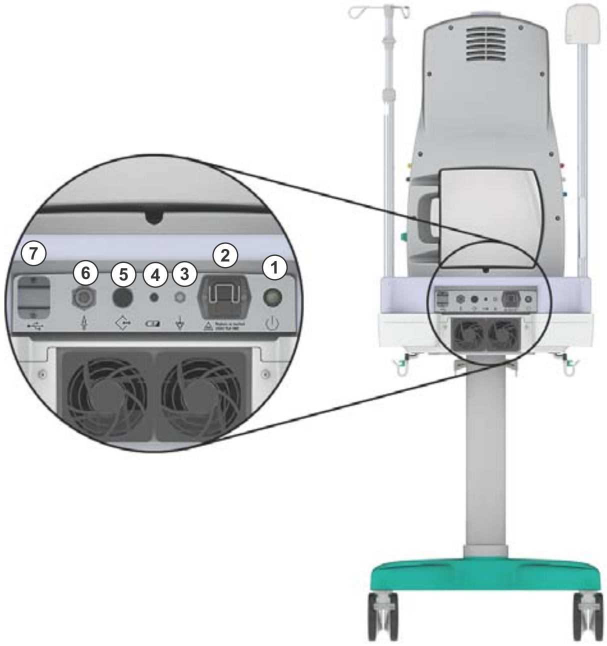


Fig. 4-9 Connector panel of the machine

The connector panel of the machine is used for all exterior connection to the machine.

The mains cord, the potential equalization cable. the data communication cable, the staff call cable and the USB stick can be connected to the machine on the connector panel. The battery indicator lights gives information about the charging status of the machine.

4

4.3.1.1 Staff Call

Fig. 4-10 Staff Call

Hardware Description

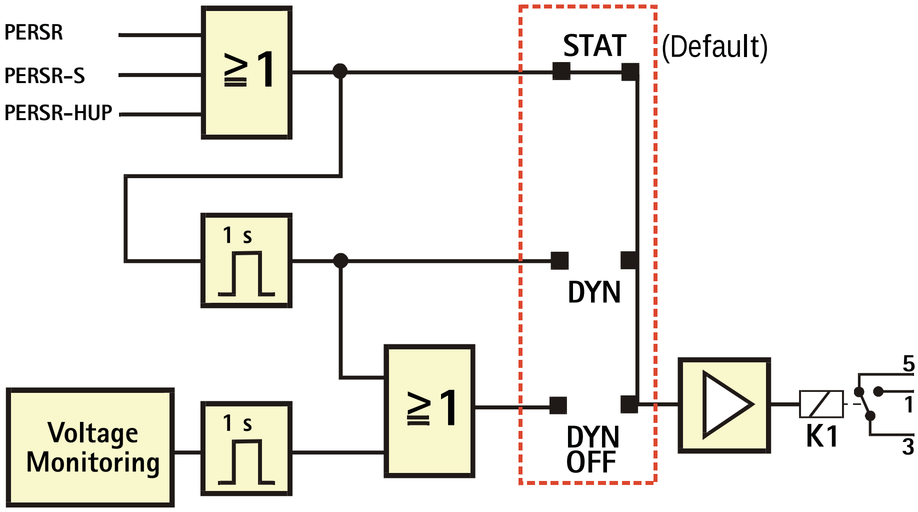


Fig. 4-11 Block diagram staff call

1 Dip switch 1

2 Dip switch 2

3 Dip switch 3

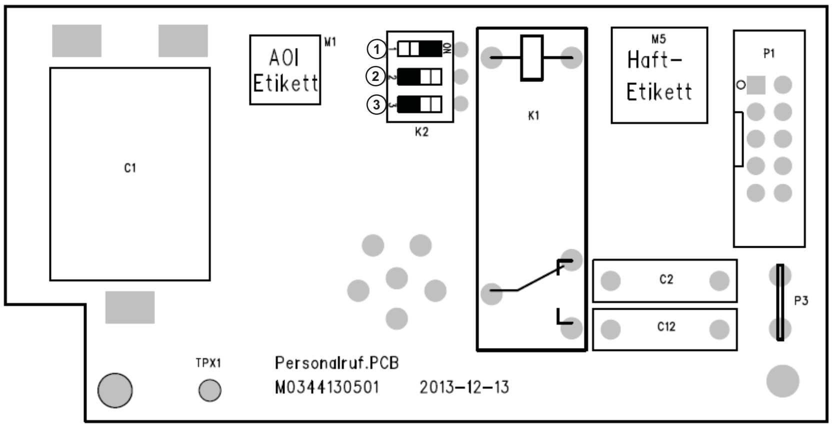


Fig. 4-12 Staff call board

Operating Mode

The operating modes static with OFF alarm, dynamic without OFF alarm or dynamic with OFF alarm are set with soldering bridges on the staff call board. The default setting ex factory is static with OFF alarm

- STAT: static with OFF alarm (default)
- DYN: dynamic without OFF alarm
- DYNOFF: dynamic with OFF alarm

Static without OFF Alarm STAT

The relay K1 switches as long as one of the three inputs PERSR-S, PERSR-HUP or PERSR are active.

Dynamic without OFF Alarm DYN

If at least one input PERSR-S, PERSR-HUP or PERSR changes from active to inactive the relay K1 is switched for one second. The monoflop U1 generates a switch time of one second.

Dynamic with OFF Alarm DYNOFF

If at least one input PERSR-S, PERSR-HUP or PERSR changes from active to inactive the relay K1 is switched for one second or if the +12 VD voltage drops more than 10 %. A monoflop U1 generates a switch time of one second. The supply voltage for the staff call circuit is decoupled by a diode from the +5 V voltage and buffered by a 1 F capacitor C1.

Staff Call Connectors

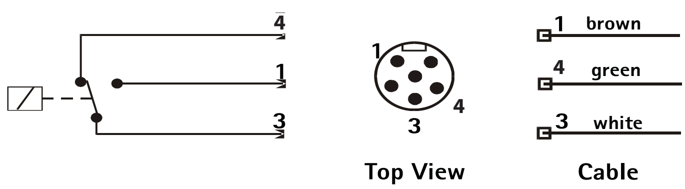


Fig. 4-13 Staff call connectors

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

4.3.2 Warmer

1 Warmer
2 Warmer door

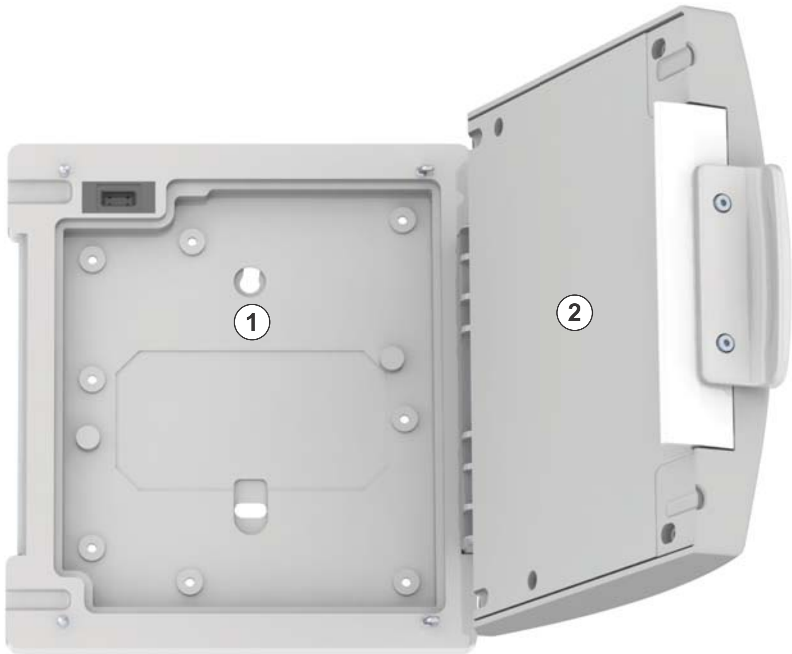


Fig. 4-14 Warmer with opened door

The warmer heats up the fluid for the therapy. Only fluid placed on the right load cell can be heated up.

The warmer door protects the warmer bag for physical influences.

4.3.3 Power Supply and Battery

1 Battery

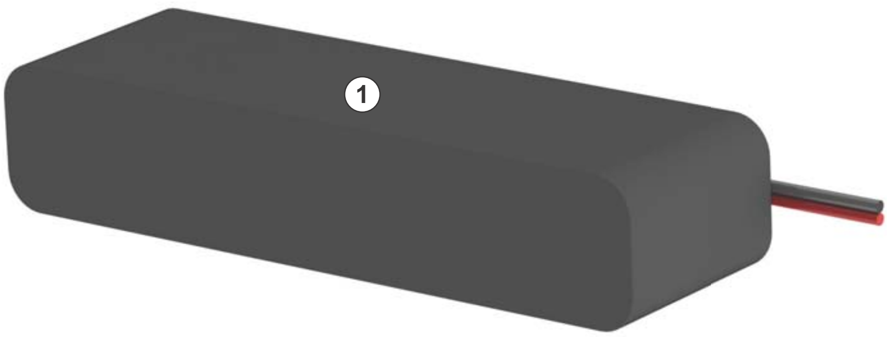


Fig. 4-15 Battery

The battery is the backup power source in case the first power source (integrated power supply) cannot supply the machine.Battery is running 30 minutes when it is fully charged.

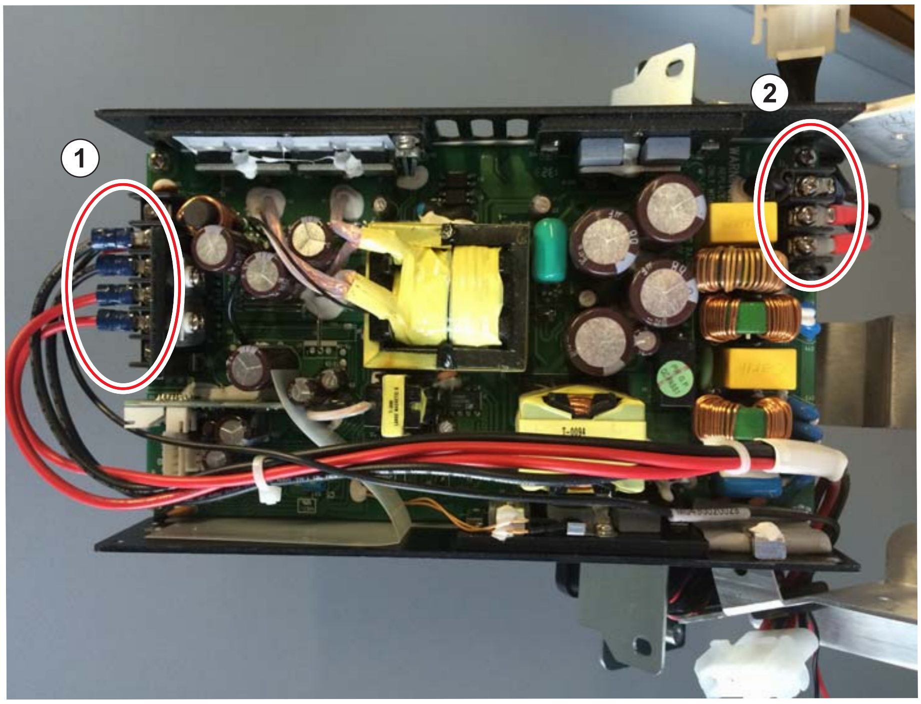


Fig. 4-16 Power supply

Specifications of the power supply: 500 W, 24 DC

The power supply is the primary power source of the machine. The power supply provides all necessary voltages to run the machine.

4.4 Interior View

4.4.1 Blood Side Board

1 Blood side board

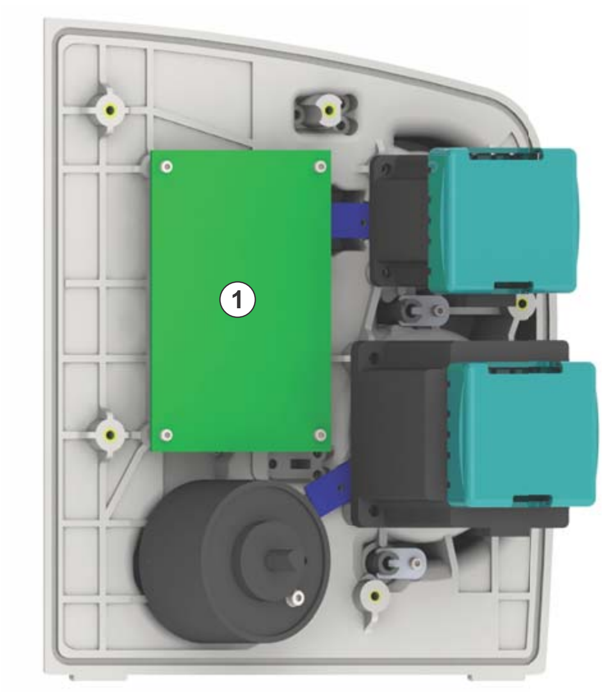


Fig. 4-17 Blood side board

4.4.2 Fluid Side Board

1 Fluid side board

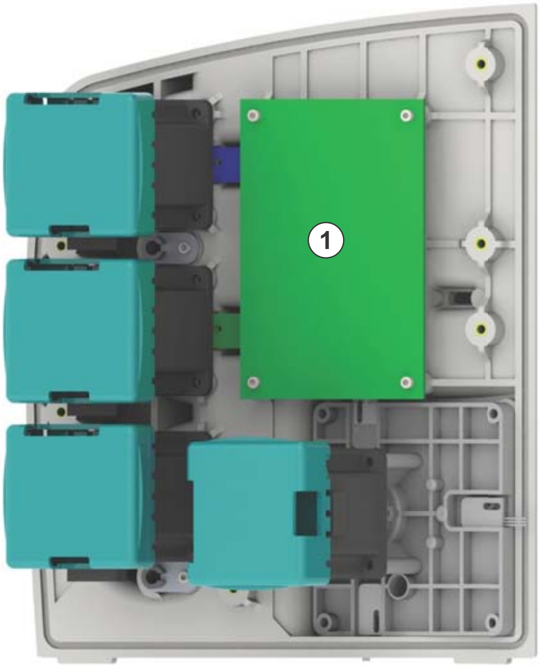


Fig. 4-18 Fluid side board

The fluid side board controls and checks the function of all components on the fluid side manifold.

4.4.3 Warmer Board

1 Warmer board

2 Warmer

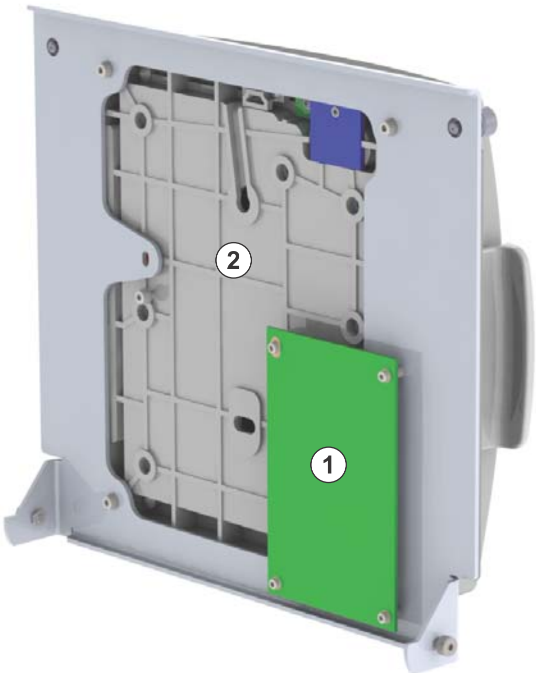


Fig. 4-19 Warmer board

The warmer board controls and checks the temperature of the fluid and the plate warmer.

4.4.4 Main Board

1 Main board

Fig. 4-20 Main board

The main board is connected to all actuators and sensors of the machine. The protective system is stored on a micro controller on the main board and it monitors all sensors and actuators continuously and sets the safety state of the machine if the primary system fails.

4.4.5 Top Level Boards

1 Light bar board
2 Single board computer
3 Audio codec board
4 Touch controller board

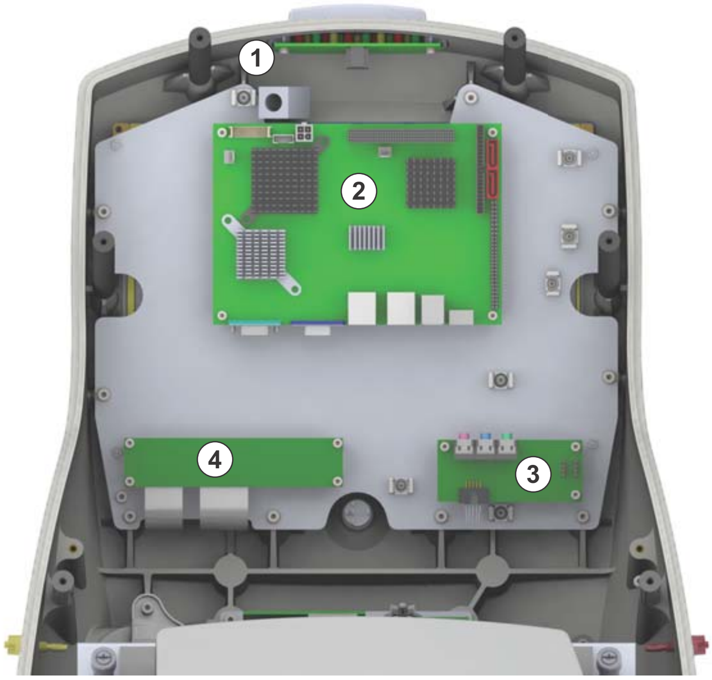


Fig. 4-21 Single board computer

The light bar board controls the status indicator lights.

The single board computer controls the fluid flows based on the weight, the pressures and the temperatures of the machine. The control system is running in the SBC.

The audio codec board is responsible for displaying, processing and generating audio signals of the machine.

The touch controller board controls the touch function of the machine.

4.4.6 Level Regulation

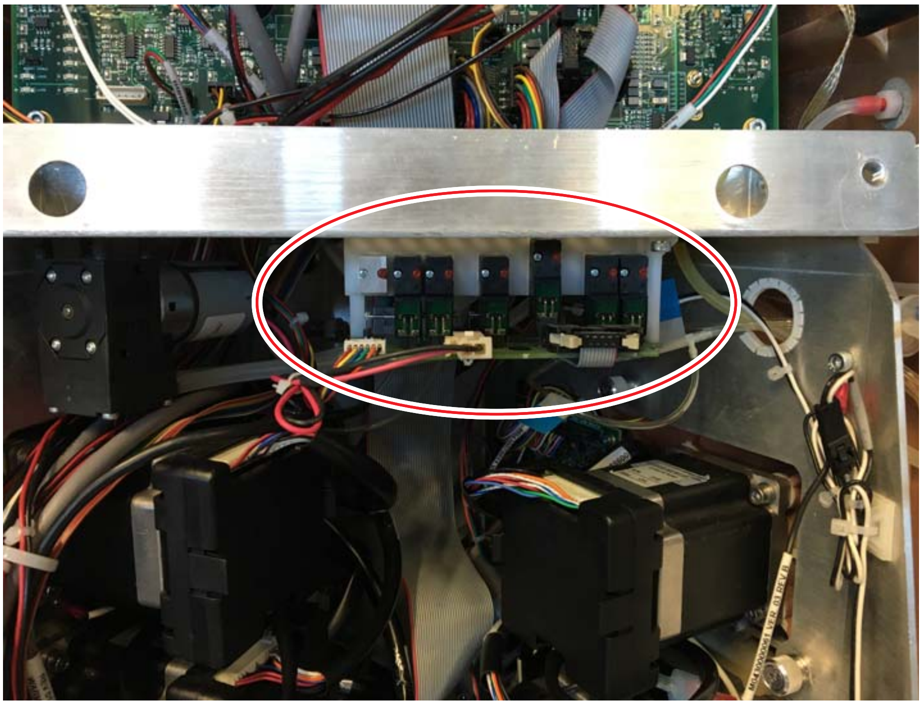


Fig. 4-22 Level regulation block

The level regulation block is used to set the fluid level inside the level detectors of the blood side manifold and the fluid side manifold.

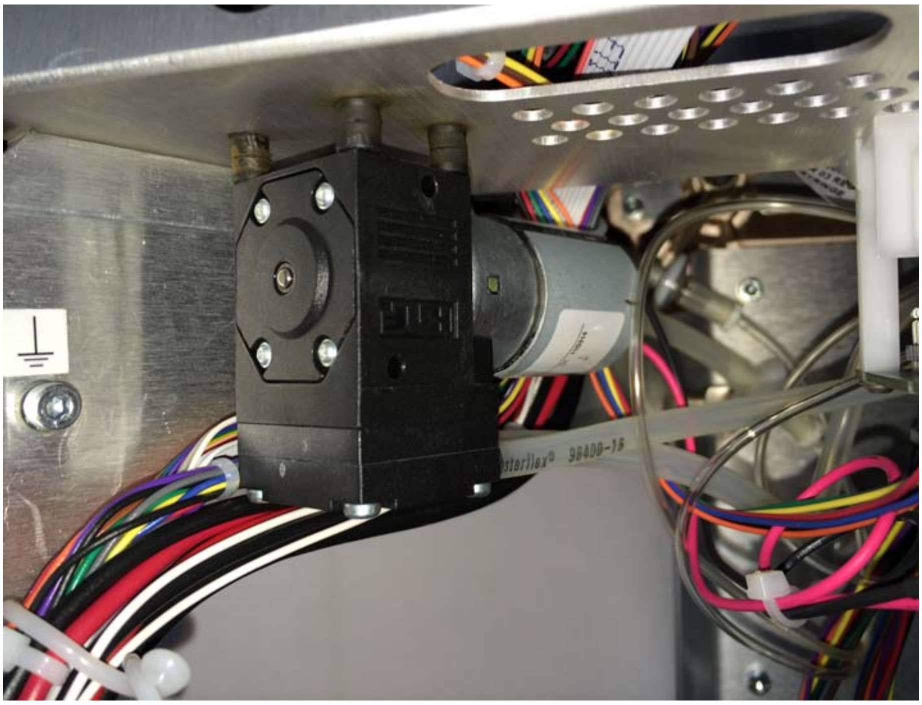


Fig. 4-23 Level regulation pump

The level regulation pump increases or decreases the pressure for the level regulation block to set the fluid level of the level detectors.

4.5 Lower Housing

1 Barcode scanner

2 Speaker

3 Microphone

4 Buzzer

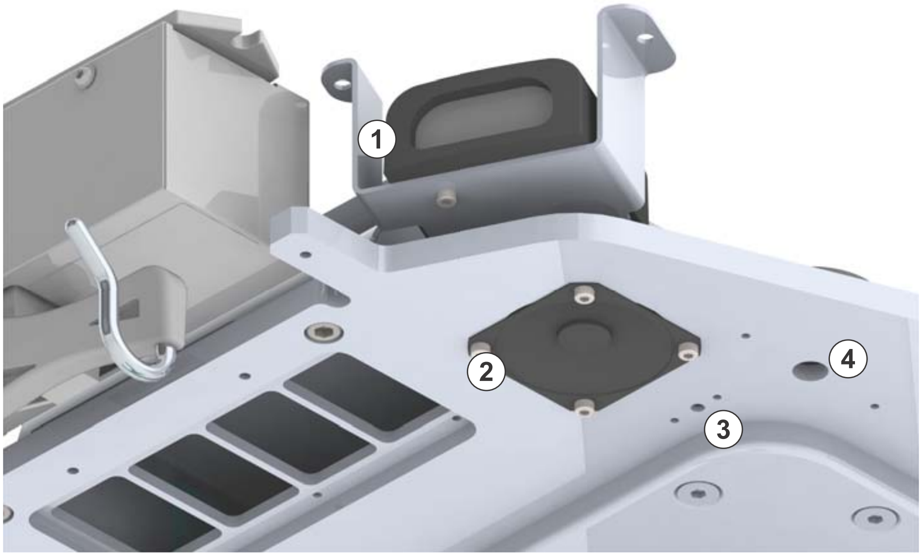


Fig. 4-24 Components lower housing

The barcode scanner reads the information of the disposable kit for the treatment.

The speaker is one part of the audio system of the machine. It creates alarm sounds and sound messages.

The microphone detects all sound messages of the machine given by the loudspeaker and the buzzer.

The buzzer is one part of the audio system of the machine. It creates alarm sounds and sound messages.

Table of Contents

5 Repair Instructions

5.1 Repair Matrix

5.1.1 Description of Repair Activities

A self test has to be performed after all repair activities.

Activity	Description of Repair Activities
TSM function check	Check function of the new component according to chapter 6.
Install software	Install new software according to chapter 5 (software installation).
Data restore and backup	System configuration and calibration data can be saved and reloaded by an USB stick.
Pressure test and calibration	Check the pressure sensors according to chapter 6 (TSM pressure test). Calibrate the new pressure sensor according to chapter 6 (TSM pressure calibration).
Load cell test and calibration	Check the load cells according to chapter 6 (TSM load cell test). Calibrate the new cell according to chapter 6 (TSM load cell calibration).
Temperature test and calibration	Check the temperature sensor according to chapter 6 (TSM pressure test). Calibrate the new temperature sensor according to chapter 6 (TSM temperature calibration).
Door detector test and calibration	Check the door detector according to chapter 6 (TSM door detector test). Calibrate the new door detector according to chapter 6 (TSM door detector calibration).
Blood leak detector test	Check the blood leak detector according to chapter 6 (TSM blood leak test).
Venous clamp gap test	Check the venous clamp according to chapter 6 (TSM venous clamp test). Check the venous gap with the 1.4 template.
Electrical safety test	Perform the electrical safety test according to the description of the electrical safety test in this service manual (p. 73).
Selftest	Follow the instructions of this service manual to perform the selftest of the machine according to the selftest description (p. 77).

Activity	Description of Repair Activities
Surface cleaning	Detailled disinfectant and cleaning procedures are described in the instructions for use. Clean surface of the machine according to the description of service cleaning in this service manual (p. 76).
Disassembly and assembly instructions	Follow the disassembly and assembly instructions of this service manual. It is described how to disassemble and assemble all available spare parts.

5.1.2 Description of Electrcial Safety Test

Protective Earth Resistance

Prerequisites

- Test current: ≥ 200mA

1. Set the measurement device to Protective Earth Measurement setup.
2. Connect the machine to the measurement device.
3. Use the probe to measure the protective earth resistance of the machine. (Measurement points: Potential equalization bolt,

↳ Protective earth resistance must be <0.1 **[Ω]**.

Equipment Leakage Current

Prerequisites

- Differential Measurement
- Test current must be measured in both directions. (N->L / L->N)
- Machine is running in treatment mode (CVVHDF with heparin) and all pumps reach the maximum speed.

1. Set the measurement device to equipment leakage current measurement setup.
2. Connect the machine to the measurement device.
3. Start the measurement.
4. Change the polarity during the measurement and note the highest value.

↳ Equipment leakage current is ≤ 0.5 **[mA]**.

Patient Leakage Current

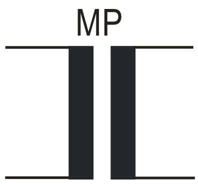
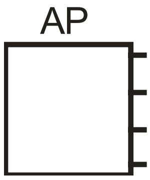
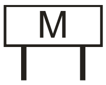
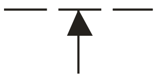
Prerequisites

- Machine is running in treatment mode (CVVHDF with heparin) and all pumps reach the maximum speed.

1. Set the measurement device to patient leakage current measurement setup.
2. Connect the machine to the measurement device.
3. Start the measurement.
4. Note the highest value (AC).

↳ Patient leakage current is <10 [µA] **AC**

Measurement Circuits for Measurement of Electrical Safety According to IEC 62353/60601-1

Abbreviations and Symbols	
	Protective earth (ground)
L, N	Supply mains terminals
PE	Protective earth terminal
	Mains part
	Applied part
	Measuring device
	Residual current meter with frequency response as MD
Ω	Resistance measurement equipment
	Part of enclosure not protectively earthed
	Connection to accessible conductive parts

Protective Earth Resistance

Test current: ≥ 200mA

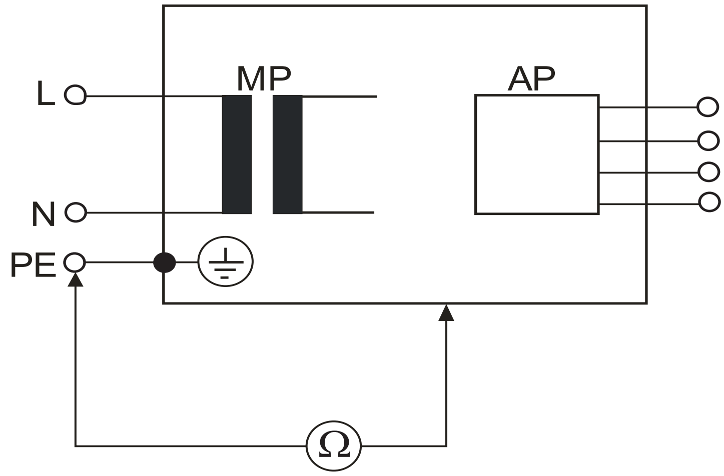


Fig. 5-1 Protective earth resistance

Equipment Leakage Current

- Differential Measurement

- Test current must be measured in both directions. (N->L / L->N)

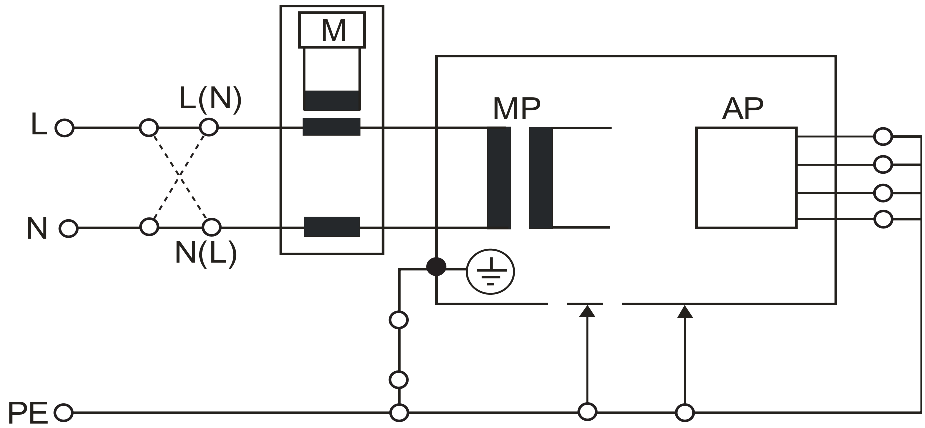


Fig. 5-2 Equipment leakage current

Patient Leakage Current

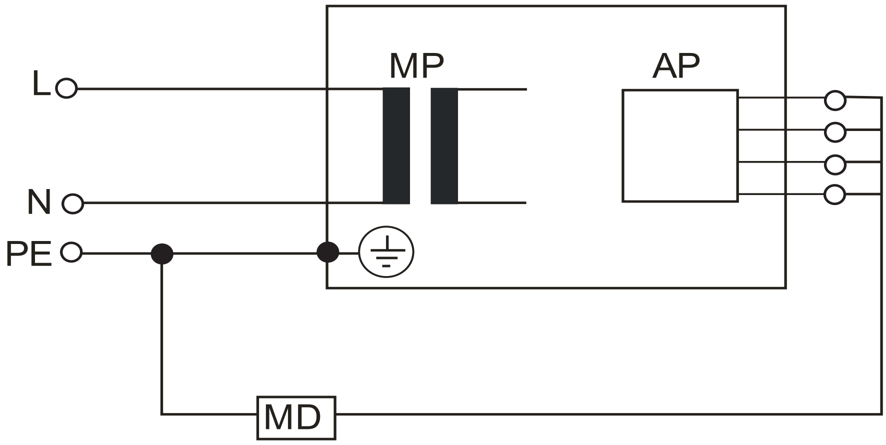


Fig. 5-3 Patient leakage current

5.1.3 Description of Surface Cleaning

Cleaning Agents for Surface Disinfection and Cleaning

For optimal cleaning and disinfection of the surface of the OMNI the following two products are best suited:

Cleaning Agent	Description
Meliseptol Wipes sensitive	Wipes for surface disinfection, active agent: propan-1-ol 17 g, didecyldimethylammoniumchlorid 0,23 g
Meliseptol Foam pure	Aerosol-free foam for surface disinfection, active agent: propan-1-ol 17 g, didecyldimethylammoniumchlorid 0,23 g

The machine is resistant against the appropriate application of the following disinfection and cleaning agents:

Cleaning Agent	Description
Melsept SF	Concentration: 2 %, active agent: didecyldimethylammonium chloride 7,5 g, glutaral 4,5 g, glyoxal 3,2 g
Isopropanol 70%	
Hexaquart plusC	Concentration: 2 %, active agent: didecyldimethylammonium chloride 6.0 g, N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 5.5 g
Virasept	Concentration: 3 %, active agent: hydrogen peroxide 3, 130 %, acetic acid 2 %

Cleaning Agent	Description
Incidin Rapid	Concentration: 3 %, active agent: glutaraldehyde 9.8 g, benzalkonium chloride 5 g, didecyldimethylammonium chloride 5 g
Medizid AF	Concentration: 3 %, active agent: didecyldimethylammonium chloride 5 g
Meliseptol	Concentration: 100 %, active agent: 1-propanol 50 g, Glyoxal 0.08 g
Meliseptol rapid	Concentration: 100 %, active agent: 1-propanol 50 g, didecyldimethylammonium chloride 0.075 g
Melsitt	Concentration: 3 %, active agent: didecyldimethylammonium chloride - 10 %, formaldehyde - 5 %, glutaraldehyde - 15 %
Ultra Clorox germicidal bleach	Concentration: 4 %, active agent: sodium hypochlorite 6.15 % - 7.35 %, sodium hydroxide 0.2 % - 1 %
Softasept N	Concentration: 100 %, active agent: ethanol 74.1 g, 2-propanol 10.0 g
Softaskin	Concentration: 100 %, active agent: sodium laureth sulfate, cocamidopropyl betaine, polyglyceryl-3-caprate, potassium cocoyl hydrolyzed, phenoxyethanol, urea, lauramine oxide, allantoin, citric acid

5.1.4 Parameters for Selftest

Prerequisites

- Exchange and test of the defective part had been performed successfully.

1. Start machine in treatment mode.
2. Select CVVHDF therapy with heparin anticoagulation and post dilution.
3. Follow the instructions on the graphical user interface to perform the priming procedure.
4. Enter the therapy mode when the priming procedure has been performed successfully.

5.1.5 Components of Blood Side Manifold

Art. No.	Blood Side Manifold
34710029	Blood pump
34710066	Blood pump cable
34710027	Blood side board
34710026	Blood side door, complete
34710030	Citrate pump
34710065	Citrate pump cable
34710025	Door detector, complete
34710060	Encoder board CP
34710036	Kit locking mechanism
34710035	Level detector
34710056	Roller Pumphead for blood pump
34710061	Roller pumphead for fluid pumps (citrate)
34710032	Safety air detector, venous
34710034	Venous clamp, complete

Activities	Components of Blood Side Manifold			
	Level Detector	Safety Air Detector Venous	Venous Clamp	Blood Pump, Citrate Pump
TSM function check	X (p.333)	X (p. 340)	X (p. 328)	X (p. 319)
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				

Activities	Components of Blood Side Manifold			
	Level Detector	Safety Air Detector Venous	Venous Clamp	Blood Pump, Citrate Pump
Temperature test and calibration				
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test			X (p. 328)	
Electrical safety test	X (p. 73)	X (p. 73)	X (p. 73)	X (p. 73)
Selftest	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 77)
Disassembly and assembly instructions	X (p. 206)	X (p. 208)	X (p. 209)	X (p. 192)

Activities	Components of Blood Side Manifold			
	Door complete	Door Detector	Roller Head for CP	Kit Locking Mechanism
TSM function check			X (p. 322)	
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration	X (p. 354)/ (p. 366)	X (p. 354)/ (p. 366)		
Blood leak detector test				
Venous clamp gap test				
Electrical safety test				X (p. 73)
Selftest	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 190)	X (p. 205)	X (p. 203)	X (p. 204)

Activities	Components of Blood Side Manifold			
	Blood Pump Cable	Citrate Pump Cable	Encoder Board CP	Roller Head for BP
TSM function check	X (p. 320)	X (p. 322)	X (p. 322)	X (p. 320)
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test				
Electrical safety test	X (p. 73)	X (p. 73)	X (p. 73)	
Selftest	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 195)	X (p. 201)	X (p. 202)	X (p. 197)

Activities	Components of Blood Side Manifold			
	Blood Side Board			
TSM function check	X (p. 319) / (p. 328) / (p. 333) / (p. 354) / (p. 340)			
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test				
Electrical safety test	X (p. 73)			
Selftest	X (p. 77)			
Surface cleaning	X (p. 76)			
Disassembly and assembly instructions	X (p. 191)			

5.1.6 Components of Fluid Side Manifold

Art. No.	Fluid Side Manifold
34710042	3-way clamp
34710068	3-Way clamp cable
34710044	Blood leak detector
34710064	Dialysate pump cable
34710025	Door detector, complete
34710069	Effluent pump cable
34710059	Encoder board DP
34710058	Encoder board EP
34710057	Encoder board SP
34710041	Fluid pump (effluent, dialysate, substitution)
34710039	Fluid side board
34710038	Fluid side door, complete
34710036	Kit locking mechanism
34710035	Level detector
34710061	Roller Pumphead for fluid pumps
34710067	Substitution pump cable

Activities	Components of Fluid Side Manifold			
	Substitution, Dialysate, Effluent Pump	3-Way Clamp	Blood Leak Detector	Level Detector
TSM function check	X (p. 323)		X (p. 342)	X (p. 333)
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				

Activities	Components of Fluid Side Manifold			
	Substitution, Dialysate, Effluent Pump	3-Way Clamp	Blood Leak Detector	Level Detector
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration				
Blood leak detector test			X (p. 342)	
Venous clamp gap test				
Electrical safety test	X (p. 73)	X (p. 73)	X (p. 73)	X (p. 73)
Self test	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 215) / (p. 220) / (p. 225)	X (p. 235)	X (p. 234)	X (p. 232)

Activities	Components of Fluid Side Manifold			
	Door complete	Door Detector	Kit Locking Mechanism	
TSM function check				
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration	X (p. 354) / (p. 366)	X (p. 354) / (p. 366)		
Blood leak detector test				
Venous clamp gap test				
Electrical safety test		(p. 73)	X (p. 73)	
Self test	X (p. 77)	X (p. 77)	X (p. 77)	
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	
Disassembly and assembly instructions	X (p. 213)	X (p. 231)	X (p. 230)	

Activities	Components of Fluid Side Manifold			
	Substitution, Dialysate, Effluent Pump Cable	3-Way Clamp Cable	Encocer Board DP, EP, SP	Roller Head for DP
TSM function check	X (p. 323)	X (p. 327)	X (p. 323)	
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test				
Electrical safety test	X (p. 73)	X (p. 73)	X (p. 73)	
Self test	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 222) / (p. 227) / (p. 217)	X (p. 237)	X (p. 223) / (p. 228) / (p. 218)	X (p. 224)

Activities	Components of Fluid Side Manifold			
	Roller Head for EP	Roller Head for SP	Fluid Side Board	
TSM function check			X (p. 323)/ (p. 327)/ (p. 333)/ (p. 342)/ (p. 354)	
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration			X (p. 354) / (p. 366)	
Blood leak detector test				
Venous clamp gap test				
Electrical safety test	X (p. 73)	X (p. 73)	X (p. 73)	
Self test	X (p. 77)	X (p. 77)	X (p. 77)	
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	
Disassembly and assembly instructions	X (p. 229)	X (p. 219)	X (p. 214)	

5.1.7 Components Lower Housing

Art. No.	Interior Lower Section
34710003	Barcode scanner
34710072	Buzzer
34710053	Fuse, 250 V T5A HBC for mains inlet
7103330	Power cord type G
34710002	Dust filter
34710001	Fan
34710062	Fan filter cover
34710000	Load cell (effluent, dialysate, substitution)
34710071	Microphone
7103331	Power cord type B
7103332	Power cord type E & F
7103340	Power cord type I - AR
7103339	Power cord type I - AU & NZ
7103337	Power cord type I - CN
7103333	Power cord type J
7103338	Power cord type K
7103334	Power cord type L
7103335	Power cord type M
7103336	Power cord type N
34710004	Power supply, 500 W, 24 DC
34710017	Battery pack, 24.0V,2.7 Ah, 65Wh Sealed rechargeable Ni-MH
34710016	Speaker
34710055	Staff call board

Activities	Components of Interior Lower Section	
	Power Supply	Barcode Scanner
TSM function check		
Install Software		
Data restore and backup		
Set system configuration		
Pressure test and calibration		
Load cell test and calibration		X[1] (p. 352) / (p. 362)
Temperature test and calibration		
Door detector test and calibration		
Blood leak detector test		
Venous clamp gap test		
Electrical safety test	X (p. 73)	X (p. 73)
Self test	X (p. 77)	X[2] (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 280)	X (p. 276)

X[1]Check the function of the load cells because of the disassembling of the lower housing

X[2] Barcode has to be read by the barcode scanner

Activities	Components of Interior Lower Section		
	Effluent, Dialysate, Substitution Load Cell	Fan and Dust Filter	Speaker
TSM function check		X (p. 358)	
Install Software			
Data restore and backup			
Set system configuration			
Pressure test and calibration			
Load cell test and calibration	X (p. 352) / (p. 362)		
Temperature test and calibration			
Door detector test and calibration			
Blood leak detector test			
Venous clamp gap test			
Electrical safety test	X (p. 73)		
Self test	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 286)	X (p. 278) / (p. 278)	X (p. 285)

X[1] Check function of the staff call during self test of the machine.

5.1.8 Components Upper Housing

Art. No.	Interior Upper Section
34710014	Audio codec board
34710047	Citrate load cell, complete
34710052	Citrate pole
34710007	Compact flash card 4 GB
34710009	Data acquisition board
34710010	Digital counter board
34710011	Digital input/output board
34710054	Gasket for all housing parts
34516409	Hydrophobic filter
34710048	IV pole
34710019	LCD, incl. Touch Screen
34710008	Level regulation block (For machines ≤ SN 165000133 the mounting bracket for level regulation block need to be exchanged first before the new level regulation block can be installed.)
34710012	Level regulation pump
34710024	Light bar board
34710006	Main board
3451884A	Manometer connection blue
3451576A	Manometer connection green
3451833A	Manometer connection red
3457058A	Manometer connection white
3451577A	Manometer connection yellow
34710073	Mounting bracket for level regulation block
34710023	Safety air detector, calcium
34565299	Silicon tubing 2x8
34710013	Single Board Computer
34710021	Syringe holder incl. spring and clip

Art. No.	Interior Upper Section
34710020	Syringe pump
34710015	Touch controller board
34710022	Tube holder, safety air detector calcium
34710049	Warmer
34710050	Warmer board

Activities	Components of Interior Upper Section			
	Main Board	CF Card		
TSM function check				
Install Software	X (p. 292)	X (p. 292)		
Data restore and backup	X[1] (p. 306)	X[1] (p. 306)		
Set system configuration	X (p. 368)	X (p. 368)		
Pressure test and calibration	X (p. 331)/ (p. 359)	X (p. 331)/ (p. 359)		
Load cell test and calibration	X (p. 352)/ (p. 362)	X (p. 352)/ (p. 362)		
Temperature test and calibration	X (p. 345)/ (p. 364)	X (p. 345)/ (p. 364)		
Door detector test and calibration	X (p. 354)/ (p. 366)	X (p. 354)/ (p. 366)		
Blood leak detector test	X (p. 342)	X (p. 342)		
Venous clamp gap test				
Electrical safety test	X (p. 73)			
Self test	X (p. 77)	X (p. 77)		

Activities	Components of Interior Upper Section			
	Main Board	CF Card		
Surface cleaning	X (p. 76)	X (p. 76)		
Disassembly and assembly instructions	X (p. 254)	X (p. 261)		

In case the CF card and the main board have to be changed t the same time, a preprogrammed CF card should be ordered by the manufacturer.

X[1] Additionally required language has to be reinstalled.

Activities	Components of Interior Upper Section			
	Level Reg. Block	Level Reg. Pump	Single Board Computer	Mounting Bracket for Level Reg. Block
TSM function check				
Install Software				
Data restore and backup				
Set system configuration				
Pressure test and calibration	X (p. 331)/ (p. 359)	X (p. 331)/ (p. 359)		X (p. 331)/ (p. 359)
Load cell test and calibration				X (p. 352)/ (p. 362)
Temperature test and calibration				X (p. 345)/ (p. 364)
Door detector test and calibration				X (p. 354)/ (p. 366)
Blood leak detector test				X (p. 342)
Venous clamp gap test				
Electrical safety test		X (p. 73)	X (p. 73)	X (p. 73)
Self test	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 250)	X (p. 252)	X (p. 259)	X (p. 246)

Activities	Components of Interior Upper Section		
	Data Acquisition Board	Digital Counter Board	Digital Input/ Output Board
TSM function check			
Install Software			
Data restore and backup			
Set system configuration			
Pressure test and calibration	X (p. 331)/ (p. 359)		
Load cell test and calibration			X (p. 352)/ (p. 362)
Temperature test and calibration	X (p. 345)/ (p. 364)		
Door detector test and calibration			X (p. 354)/ (p. 366)
Blood leak detector test			X (p. 342)
Venous clamp gap test			
Electrical safety test	X (p. 73)	X (p. 73)	X (p. 73)
Self test	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)
Disasselmbly and assembly instructions	X (p. 256)	X (p. 258)	X (p. 256)

Activities	Components of Interior Upper Section			
	Touch Controller Board	Software Update	Audio Codec Board	Gasket for housing
TSM function check	X		X (p. 350)	X[1]
Install Software		X (p. 292)		
Data restore and backup				
Set system configuration		X (p. 368)		
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test				
Electrical safety test			X (p. 73)	X[1] (p. 73)
Self test	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 267)	X (p. 292)	X (p. 240)	X

X[1]: Perform the test according to the repair matrix for the component where the gasket has to be changed.

Activities	Components of Interior Upper Section			
	Safety Air Detector Calcium	Syringe Pump Complete	LCD Display	Light Bar Board
TSM function check	X (p. 340)	X (p. 340)		
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration				
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test				
Electrical safety test				
Self test	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 265)	X (p. 262)	X (p. 272)	X (p. 245)

5

Activities	Components of Interior Upper Section			
	Syringe Holder incl. Spring and Clip	Tubing Holder, Safety Air Detector Calcium	Warmer	
TSM function check	X[1]	X[2]		
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration				
Load cell test and calibration				
Temperature test and calibration			X (p. 345)/ (p. 364)	
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test				
Electrical safety test			X (p. 73)	
Self test	X (p. 77)	X (p. 77)	X (p. 77)	
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	
Disassembly and assembly instructions	X (p. 264)	X (p. 266)	X (p. 186)	

X [1,2] Check mechanical function of the components.

Activities	Components of Interior Upper Section			
	Manometer connection AP, FP, VP, SP, EP	Citrate Load Cell	Citrate Pole	IV Pole
TSM function check				X[1]
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration	X (p. 331)/ (p. 359)			
Load cell test and calibration		X (p. 352)/ (p. 362)	X (p. 352)/ (p. 362)	
Temperature test and calibration				
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test				
Electrical safety test	X (p. 73)	X (p. 73)	X (p. 73)	
Self test	X (p. 77)	X (p. 77)	X (p. 77)	X (p. 77)
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	X (p. 76)
Disassembly and assembly instructions	X (p. 242)	X (p. 239)	X (p. 240)	X (p. 275)

Activities	Components of Interior Upper Section			
	Hydrophobic Filter	Battery Pack	Staff Call	Warmer Board
TSM function check		X (p. 356)	X[1] (p. 357)	
Install software				
Data restore and backup				
Set system configuration				
Pressure test and calibration	X (p. 331)/ (p. 359)			
Load cell test and calibration				
Temperature test and calibration				X (p. 345)/ (p. 364)
Door detector test and calibration				
Blood leak detector test				
Venous clamp gap test				
Electrical safety test		X (p. 73)		
Self test	X (p. 77)	X (p. 77)	X (p. 77)	
Surface cleaning	X (p. 76)	X (p. 76)	X (p. 76)	
Disassembly and assembly instructions	X (p. 244)	X (p. 238)	X (p. 271)	

X[1] Check functionality of the IV pole. Check tide seat of the new IV pole in the housing.

Activities	Components of Interior Upper Section		
	Connector Panel: Mains Cord, Fuses,		
TSM function check	X		
Install Software			
Data restore and backup			
Set system configuration			
Pressure test and calibration			
Load cell test and calibration			
Temperature test and calibration			
Door detector test and calibration			
Blood leak detector test			
Venous clamp gap test			
Electrical safety test	X (p. 73)		
Self test	X (p. 77)		
Surface cleaning	X (p. 76)		
Disassembly and assembly instructions	X (p. 269) / (p. 270)		

5.1.9 Execution Protocol for Repair Matrix

REF (reference No./Nr.)	
SN (serial No./Nr.)	
Year of purchase	
Responsible organization (user)	
Operating hours [h]	
Inventory number	
SW version	
Manufacturer	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen, Germany

Execution Protocol for Repair Matrix			
Measures According Repair Matrix	Measurement Values/ Executed Measures	N/A	OK
Install software	executed correctly	O	O
Check system configuration and set if necessary	executed correctly	O	O
Self test	executed correctly	O	O
Electrical safety check Protective earth resistance: <0.1 [Ω] Equipment leakage current: ≤ 0.5 [mA] Patient leakage current: <10 [μA] AC	 [Ω] [mA] [μA]	O	O
Perform surface disinfection	executed correctly	O	O
Test and calibration according to the service manual	executed correctly	O	O
The respective measures were executed correctly after servicing according to the repair matrix.			
Name Service Technician	____________________ Date / Signature		

5.2 Start-Up Test Description

Title	Description
System Start-Up	-
Start-Up checks	-
Calibration	The Display system communicates the Calibration data, reference data and tolerance limit files from the CF card to the Control and Protective systems (if custom reference and tolerance files are present these files are used, in other case the default ones are used). The Control and Protective system checks the CRC of the files and generates alarm, in case of corrupted files.
Load cell calibration (during power-up)	CSS: The calibration data stored in CSS Load Cells is compared with the corresponding data stored in calibration file during power-up: - get the Load Cell calibration data, - compare with the calibration data stored in calibration file, - in case of inconsistency send data to LC and give logmessage, - read and check data again, - set alarm in case of error. Note: during LC calibration the stored values are also compared. PSS: The calibration data stored in Load Cells is compared with the corresponding data stored in calibration file during power-up: - get the Load Cell calibration data, - compare with the calibration data received from dss, - in case of inconsistency send data to LC, - read and check data again, - set alarm in case of error. Note: during LC calibration the stored values are also compared.
Protective System	-

Title	Description
Microcontroller self test	The design of operation is based on the related official document released by Microchip: Class B safety software library for PIC MCUs and dsPIC DSCs. The tests have been supplemented with the instruction test, and revised in order to be more manageable in the software‘s source code. The tests are the following.
Register test	The registers of the controller are mapped into the general purpose data memory, but they can be reached with other instructions as well. There are special function registers that require special handling; the bits of these registers are not general purpose bits, a few of these bits cannot be set or cleared. For this reason the examination of these registers is separated from the data memory test. Method:1. 0xAA... and the 0x55... bit patterns are written into the registers (where it is allowed) 2. Results are checked
Data memory test	The general purpose data memory is tested with March C minus and March B algorithms in two steps. Method:1. Upper part of the memory is checked (heap area) 2. Stack is moved to this upper section 3. Same tests are carried out on the first part of the memory 4. Stack is moved back to its original position
Program counter test	The purpose of this test is to prove that the microcontroller can call the routine it wants to. Method:1. Two functions are called that return their own addresses 2. Results are checked
Program memory test	The program memory is separated into two parts and both of them are protected with a 16 bit CRC code.
Clock and interrupt handling tests	These tests are recommended by Microchip, but their implementation would be complicated in the system. Indirectly, clock behavior and interrupt handling are tested through the proper starting of the subsystem communication.

Title	Description
Instruction test	This test is not recommended by Microchip, but necessary for safe operation. The goal of this test is to execute all the instructions of the controller, and check the operation with certain coverage. For this purpose Microchip's self-test library is used, detailed information can be found in the related official document released by Microchip: 16-bit CPU Self-Test Library User ´s Guide
CRC checking	During Start-up, the Display System checks the CRC of the binaries of the SRI, Display and Control System tasks, and the CRC of the language data (including the reference images used for the SRI process). If the there is an error, the Display System stops the communication and generates an alarm. The Control and Protective System monitors the communication and in case of missing communication the safety state is set by either or both components.
Start screen	After starting the machine in treatment mode, the first screen is the Start screen. The Operator may select to proceed to perform therapy or to check the history of the last 10 treatments. If the Protective System cannot start due to one of its selftest fails the PS sends error code to the DS. The DS atempts to communicate with the PS five times and if communication cannot be established than the DSS checks the input buffer. If the input buffer contains the error code, then generate alarm. Possible error codes from PS: 0xA1 0xA1 0xA1 - uC ERROR 0xA2 0xA2 0xA2 - BL CRC error 0xA3 0xA3 0xA3 - FW CRC error The System does not allow to continue in case an alarm is present in Start screen. History: The Operator may check the trends of previous therapies (See FDS-905).

Title	Description
	Treatment: After selecting treatment mode the machine provides the Operator the possibility start Preparation, the Operator has to enter disposable kit barcode information in order to proceed (See FDS-328). After entering disposable kit barcode information the system (GUI and Display system) provides the Operator the possibility to select therapy, dilution and anticoagulation types (See FDS-605). After confirming Therapy selection the system starts dry tests (See FDS-149). Daylight saving time setting: The User has the possibility to modify the time and date settings. On the treatment Start screen the User can open a popup window to adjust the current date and time. The window can be canceled or confirmed. When entering a time or a date value a difference is calculated between the entered value and the system time. This difference value is saved in a database table. Then the values on the pop-up window are updated. They are calculated based on the addition of the system time and the difference value from the database which is the desired value. By Cancelling (e.g. pressing a Back button) the database table is updated with zero values, so none of date or time adjustment is desired. By Confirming (e.g. pressing a Confirm and reboot button) another pop-up window is opened. After confirmation a reboot has to be made. From the confirmation window no GUI action is accepted, only reboot can be performed. The date and time modifications will apply at the next boot of the machine. It will set the time, date and the hardware time compensated with the offset values in the database.

Tbl. 5-1 OMNI:Start-up test description

5.3 Selftest Description

Title	Description
Preparation	-
Machine and disposable set up	Select therapy and load disposables
System self tests	Dry tests
Device tests	Running device tests are displayed on the GUI.
Power relay	This test checks the safety power relay, which is used by PSS in case of any alarm detection. At the beginning of test the PSS switches OFF the power relay for 2 s, after that it switches ON again. The PSS and CSS check their own supply voltage continuously. The test is finished successfully when PSS and CSS detect the supply voltage switching OFF/ON after each other. The overall timeout in CSS is 5 s. (CS input signal: PAUSE_STAT_CS) (PS output signal: SHUTDOWN) 1.PSS turns it off (OFF for 2 s). 2.PSS and CSS checks the voltage level (24VSW), PSS timeout is 4 s, CSS timeout is 3 s. 3.PSS turns it on. 4.PSS and CSS checks the voltage level (24VSW), PSS timeout is 6 s, CSS timeout is 5 s.

Title	Description
Warmer relay	This test checks the Warmer relay, which will be used by PSS in case of any warmer alarm detection. At the beginning of test PSS switches ON the warmer relay for 1 s, then turns OFF the warmer relay for 2 s, and finally switches the relay ON again. CSS checks its own supply voltage continuously. The test is finished successfully when CSS detects the supply voltage switching ON/OFF/ON after each other. (CS input signal: WRM_ENABLED_PS) (PS output signal: WRM_HTR_PS) 1.PSS turns it on (ON for 1 s). 2.CSS checks the voltage level (Warmer 24V), timeout is 2 s. 3.PSS turns it off (OFF for 2 s) 4.CSS checks the voltage level (Warmer 24V), timeout is 2 s. 5.PSS turns it on 5.CSS checks the voltage level (Warmer 24V) , timeout is 2 s. Test is not performed if the Warmer switched off for the therapy
Safety Air Detector SAD(Venous Safety Air Detector SADV, Calcium Safety Air Detector SADC)	1.Air (not fluid) detection AND, 2.Successful self test (initiated by CSS, checked by PSS). 3.If self test failed or self test is time out (PSS: 4 s, CSS: 3 s) -> Low Priority Alarm signal to DSS
Load cells(Citrate LC, Substitution LC, Dialysate LC / Plasma Substitution LC, Effluent LC)	1.Load cell shall detect weight value between -20 g and 20 g for 5 s 2.CSS and PSS check the measured values 3.if measured values are beyond limit -> Low Priority Alarm Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the operation of the machine for Safety reasons (CS weight values - PS weight values). During Kit exchange CSS disables Load cell dry tests.
-	-

Title	Description
Pressure sensors(Arterial Pressure, Pre-Filter Pressure, Venous Pressure, Effluent Pressure, Solution Pressure)	1.Pressure sensors shall detect pressure value between -20 and 20 mmHg for 5 s 2.CSS and PSS check the measured values. 3.if measured values are beyond limit -> Low Priority Alarm Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the operation of the machine for Safety reasons (CS pressure values - PS pressure values).
Temperature sensors(Output Temperature Sensor (to CS and PS), Plate temperature Sensor (to CS and PS))	1.Plate temperature is measured by CSS and PSS. 2.Same temperature shall be measured for 1 s (tolerance: 0.5 °C). 3.Output temperature is measured by CSS and PSS. 4.Same temperature shall be measured for 1 s (tolerance: 0.5 °C). 5.if measured values are beyond limit -> Low Priority Alarm Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the operation of the machine for safety reasons (CS temperature values - PS temperature values).

Title	Description
Audio tests	1.Two 0.5 s beeps generated by PSS on buzzer. 2.detected by the microphone (PS). 3.Two 0.5 s beeps generated by DSS on speaker requested by CSS. 4.detected by the microphone (PS). 5.if any of the sounds is not detected by PS -> Low Priority Alarm Audio test in noisy environment: Environmental noise is calculated with an fc=0.05Hz lowpass filter, and adaptive treshold is calculated with the following formula: treshold = noise + ((3000 - noise) / 2) At the start of the device and the periodic audio test, a treshold value is set for the audio test. The maximum accepted environmental noise is 2000. If noise is bigger than 2000, the audio test is immediately terminated. A PSS alarm informs the user in case of the environmental noise is bigger than 2000 at the start of the selftest.
Traffic light	1.CSS turns on the RED LEDs for 1 s - checked by PSS. 2.CSS turns on the YELLOW LEDs for 1 s - checked by PSS. 3.CSS turns on the GREEN LEDs for 1 s - checked by PSS. 4.PSS turns on the RED LEDs for 1 s - checked by PSS. 5.if any of the checked values returns OFF state or self test lasts beyond time out (10 s) by PSS -> Low Priority Alarm
Level detectors	1.Air shall be detected at both (upper and lower) levels. 2.results are checked by CSS for 2 s and by PSS for 2.5 s. 3.if any of the values returns 'fluid' -> Low Priority Alarm

Title	Description
Voltage levels	1.PSS shall switch off battery charging. 2.CSS waits 4 s from the battery charging switch off and measures the battery voltage. 3.PSS waits 6 s from the battery charging switch off and measures the battery voltage. 4.The battery voltage level shall be checked if it is between 15 V and 29 V both by CSS and PSS. 2.If the checked value is beyond limit -> Low Priority Alarm
Level regulation - Level Regulation Pump	1.CSS starts, then stops the pump (ON time: 0.5 s). 2.Pump status (started then stopped) is checked by PSS. 3.if the checked states are incorrect (ON timeout is 1.5 s, OFF timeout is 3.5 s) -> Low Priority Alarm
3-Way Clamp(3-Way Clamp, 3-Way Clamp Hall sensor)	1.CSS switches the clamps one-by-one (All closed-Dia-Pre-Post). 2.Switching is checked by PSS (both states for each clamp - Hall sensor). 3.Switching is checked by CSS (RS422 comm.), time out is 2 s. 4.if any of the checked values returns incorrect state -> Low Priority Alarm
Venous Clamp	1.CSS and PSS open the clamp. 2.Open state is checked by PSS and CSS (time out by CSS is 1 s). 3.CSS closes the clamp. 4.Closed state is checked by PSS and CSS (time out by CSS is 1 s). 5.CSS and PSS open the clamp. 6.After 1 s. PSS closes the clamp . 7.Closed state is checked by PSS and CSS. 8.if any of the checked values returns incorrect state or self test is beyond time out (PSS: 10 s, CSS: 3 s) -> Low Priority Alarm

Title	Description
Kit installation tests	Running kit tests are displayed on the GUI. (An icon for each selftest separately shows the state of the selftest. Hourglass icons signs that the specific selftest is running. Green tick icon signs that the specific selftest was successfully executed. Red cross icon signs that the specific selftest failed.)
Kit detector tests(Blood Side Kit Detector, Fluid Side Kit Detector)	1.No kit shall be detected by either Kit Detectors. 2.During kit mounting Kit Detector status shall change from 'not present' to 'present' (kit shall be detected by both Kit Detectors). 3.If kit is detected at beginning of self test-> Low Priority Alarm
Door detector tests(Blood Side Door Detector, Fluid Side Door Detector)	1.Wait for 'open' state. 2.During kit mounting Door Detector status shall change from 'open' to 'closed' Opened and closed states shall be detected for at least continuous 1 second.

Title	Description
Pump tests - rotation detection(Citrate Pump, Blood Pump, Substitution Pump, Dialysate Pump / Plasma Substitution Pump, Effluent Pump)	The mechanical construction of the pumps does not prevent rotation in the reverse direction. Therefore, the direction of the blood pump is detected by the protective system with two magnets in the pump rotor and two Hall sensors. In case reverse rotation is detected, the protective system safety state is set and an alarm will be issued. (Cl. 201.12.4.4.109) 1.During the loading of the tubes, CSS rotates 4 pumps in reverse direction at -30.0 rpm: - Blood Pump - Substitution Pump - Dialysate Pump / Plasma Substitution Pump - Effluent Pump and rotates the Citrate pump in forward direction. 2.Reverse direction is checked by PSS (Hall sensors) for the 4 pumps (Blood, Substitution, Dialysate / Plasma Substitution, Effluent). 3. After the tube loading procedure CSS rotates the Citrate pump in reverse direction for two complete turns and additional 1 s at -30.0 rpm. 4.Reverse direction is checked by PSS (Hall sensors) for the Citrate pump. 5.Test is successful if reverse direction is detected for all pumps. 6.In case no reverse direction is detected for all pumps -> Low Priority Alarm
-	-
Syringe test	1.Syringe Piston Detector Status - no syringe shall be detected. 2.Syringe Piston Detector Status shall detect that syringe is present. 3.During kit mounting Clasp Nut shall see both open and closed states. 4.If syringe is detected at beginning of self test-> Low Priority Alarm During Kit exchange the Control System should disable the Syringe dry tests.

Title	Description
Warmer(Warmer Door)	1.Wait for 'open' state. 2.During kit mounting Door Detector status shall change from 'open' to 'closed'. Opened and closed states shall be detected for at least 2 seconds.
Disposable kit identification	During Preparation the disposable kit (and the filter) can be identified by the barcode scanner. Alternatively, the information - carried by the barcode except Version number - can be entered manually. Barcode format: GS1 Data Matrix Barcode contents: - GTIN number, - Expiration date, - Lot number, - Version number (optional). The operator has to enter this information (except Version number) either manually or automatically in order to proceed. If the disposable kit has expired a Low priority alarm is issued and the operator cannot continue the preparation procedure. The list of the selectable disposable kits can be customized in user configuration. If the scanned disposable kit is out of the list the Operator cannot continue the preparation procedure.
Therapy selection	The system (GUI and Display system) provides the operator a screen, where the therapy type (also the dilution type) and anticoagulation type can be selected. The system restricts the selection to valid therapy modes based on the identified disposable kit. If the disposable kit is not compatible with the selected therapy mode the Operator cannot continue the preparation procedure.
Kit installation	-

Title	Description
Central kit fixation	The disposable kit is designed that it can mechanically only be inserted in one way. The Kit is fixed first on the front, with a latch and then the blood and fluid side has to be closed, and fixed with 2-2 kit fixation mechanism. The filter is fixed to the disposable. In case the pressure sensors are connected wrongly, this error is detected during the Kit Installation tests / Loading process.
'Open Venous clamp' and 'Open 3-way clamp' buttons	In Preparation, until the end of Priming, the Venous clamp and the 3-way clamp the can be opened manually at any point of the process. (since these functions are safety related additional features, these options should be available on the Service screen and the state of this buttons should define the state of the venous clamp / 3-way clamp as long as Automatic Priming is stopped).
Syringe	The Display system shall provide a Syringe type selector. The selectable syringes are stored in a database along with the following data (no default value should be set): - Syringe name - Syringe diameter - Syringe Nominal volume - Syringe Maximum filled volume The operator has to select the syringe type and the amount of Heparin or Calcium in it. The Control System and Protective system calculates the Syringe pump flow based on the selected Syringe diameter. The Control System calculates the remaining volume in the syringe based on the set filled volume. In TSM User Configuration / Anticoagulation Parameters menu the followings shall be configurable: Heparin Maximum Flow Rate (default: 20 ml/h, range: 5 - 20 ml/h), Heparin Stop Before Therapy End (TPE) function status (ON / OFF), Heparin Stop Time Before Therapy End (TPE) (default: 0:30 h:min, range: 00:05 - 02:00 h:min), Calcium Concentration (default: 230 mmol/l, range: 100 - 500 mmol/l), Citrate Concentration (default: 113 mmol/l, range: 100 - 200 mmol/l), Syringe type selector (default: full syringe list, syringe list can be limited to B.Braun syringe types).

Title	Description
Additional filter	The hemofilter arterial connection can be opened. Here an additional filter can be connected. Additional filter may be fixed to one of the pole/handle with a separate holder (not scope of the OMNI system). Related values: - Nominal filling volume - CSS/PSS Blood-side Kit Volume (measured) - sum volume of blood lines and blood filling volume of filter(s), - CSS/PSS Patient Connection Volume (calculated) - the volume of blood that will start to paint the priming waste bag red in case of "red connection". The Disposable Kit Table contains the Nominal filling volumes (BB_NominalVolume) and Patient filling volumes (BB_BloodFillingVolume) WITHOUT the additional filter for the Plus kit type. In Preparation (during Arterial line filling, see FDS: FDS-360 for details) the System measures the CSS/PSS Blood-side Kit Volume from priming bag to the Safety Air Detector on Venous line (SADV) based on the change on the Effluent load cell. The volume of the venous line (20 ml) is added as a fix volume. See FDS: FDS-1166 for details. At the beginning of Connect Patient and Temporarily Disconnect Patient - Connect Patient phase, if: - CSS Blood-side Kit Volume > 10 ml/kg * patient weight, or - CSS Blood-side Kit Volume has been reset from above 500 ml, CSS generates a low priority, Blood side stop alarm, that the extracorporeal volume is too high. The alarm can be reset. CSS/PSS Patient Connection Volume is calculated based on the CSS/PSS Blood-side Kit Volume with the proportion of the filling and nominal volumes (connection_volume_rate): CSS/PSS Patient Connection Volume = CSS/PSS Blood-side Kit Volume * connection_volume_rate, where: connection_volume_rate = BB_BloodFillingVolume / BB_NominalVolume from the Barcode Table (different values for each kit type). This calculation method is applied for all kits (CRRT (bellcos, pros, open). For TPE always the nominal volume is used (the measurement is biased as the priming fluid gets to the fluid size). The CSS/PSS Patient Connection Volume is used during: - Connect patient, see FDS: FDS-1173 for details, - Return Blood, see FDS: FDS-1177 for details.

Title	Description
Priming	CRRT and SCUF therapies: The system fills the disposable kit tubing and the filter with saline. If substitution and dialysate lines are used, they are filled with substitution and dialysate fluids accordingly. The extracorporeal blood circuit is filled from the Arterial access through the filter. The priming waste is collected in the priming waste bag that is attached to the venous line. TPE therapy: The system fills the disposable kit tubing and the plasmafilter with saline. Plasma substitution line is filled with plasma fluid. The extracorporeal blood circuit is filled from the Arterial access through the plasmafilter. The priming waste is collected in the priming waste bag that is attached to the venous line.
Blood Side Filling	-

Title	Description
Arterial line filling	CRRT therapies: 1.CSS drives the Blood pump at 200 ml/min. 2.CSS starts Blood-side Kit Volume Measuring test (See FDS: FDS-1166) 3. CSS starts Fluid Side Warmer test (see FDS: FDS-198). Warmer test runs parallel with the Blood Side Filling, because it takes several minutes to heat up to the required temperature - Warmer is expected to be appr. at the required temperature by the time the Fluid Side Filling starts 4.Blood Pump shall deliver 50 ml fluid. 5.Start Blood Pump Filling Test and Tube Calibration (see FDS: FDS-182). if Heparin anticoagulation is set 6.CSS drives the Syringe pump at 600 ml/h (bolus). 7.Syringe Pump Filling Test (see FDS: FDS-187), 16 ml heparin shall be delivered to proceed. 8.Proceed to Venous line filling when Blood-side Kit Volume Measuring test has been finished succesfully but at least the kit-dependent nominal filling volume has been delivered and 'Blood Pump Filling Test and Tube Calibration' is finished successfully if Citrate Calcium anticoagulation is set 6.CSS drives the Citrate pump at 3000 ml/h. 7.CSS drives the Syringe pump at 600 ml/h. 8.Citrate Pump Filling Test (see FDS: FDS-185), 25 ml citrate shall be delivered to proceed. 9.Syringe Pump Filling Test (see FDS: FDS-187), 16 ml calcium shall be delivered to proceed. 10.Proceed to Venous line filling when Blood-side Kit Volume Measuring test has been finished succesfully but at least the kit-dependent nominal filling volume has been delivered and 'Blood Pump Filling Test and Tube Calibration' is finished successfully

Title	Description
	SCUF therapy: 1.CSS drives the Blood pump at 200 ml/min. 2.CSS starts Blood-side Kit Volume Measuring test (See FDS: FDS-1166) 3.Blood Pump shall deliver 50 ml fluid. 4.Start Blood Pump Filling Test and Tube Calibration (see FDS: FDS-182). if Heparin anticoagulation is set 5.CSS drives the Syringe pump at 600 ml/h (bolus). 6.Syringe Pump Filling Test (see FDS: FDS-187), 16 ml heparin shall be delivered to proceed. 7.Proceed to Venous line filling when Blood-side Kit Volume Measuring test has been finished succesfully but at least the kit-dependent nominal filling volume has been delivered and 'Blood Pump Filling Test and Tube Calibration' is finished successfully TPE therapy: 1.CSS drives the Blood pump at 200 ml/min. 2.CSS starts Blood-side Kit Volume Measuring test (See FDS: FDS-1166) 3. CSS starts Fluid Side Warmer test (see FDS: FDS-198). Warmer test runs parallel with the Blood Side Filling, because it takes several minutes to heat up to the required temperature - Warmer is expected to be appr. at the required temperature by the time the Fluid Side Filling starts 4.Blood Pump shall deliver 50 ml fluid. 5.Start Blood Pump Filling Test and Tube Calibration (see FDS: FDS-182). if Heparin anticoagulation is set 6.CSS drives the Syringe pump at 600 ml/h (bolus). 7.Syringe Pump Filling Test (see FDS: FDS-187), 16 ml heparin shall be delivered to proceed. 8.Proceed to Venous line filling when Blood-side Kit Volume Measuring test has been finished succesfully but at least the kit-dependent nominal filling volume and additional 70 % volume has been delivered and 'Blood Pump Filling Test and Tube Calibration' is finished successfully

Title	Description
Venous line filling	1.CSS drives the Blood pump at 200 ml/min 2.Start Air bubble removal at Filling - parallel process (see FDS: FDS-387) 3.Proceed to 'Filter pressure chamber level adjustment' when 50 ml fluid has been delivered
Filter pressure chamber level adjustment	1.CSS drives the Blood pump at 350 ml/min while Venous clamp is open 2.Set fluid level in the middle of the chamber (above the lower level detector and below the upper level detector) 3.Automatic Level Regulation for FPC is activated (see FDS: FDS-408) 4. Proceed to Venous Pressure Chamber level adjustment when test is finished successfully
Venous pressure chamber level adjustment	1.CSS drives the Blood pump at 350 ml/min while Venous clamp is open 2.Set fluid level above the upper level detector 3.Automatic Level Regulation for VPC is activated (see FDS: FDS-408) 4. Proceed to Fluid-Side Filling when test is finished successfully
-	-
Air bubble removal during Blood Side Filling (Pressure wave generation)	1.Venous Clamp (VC) closed until VP < 150 mmHg 2.Venous Clamp opens above VP 150 mmHg and remains open as long as VP > 150 mmHg but at least for 2 s

Title	Description
Fluid Side Filling	CRRT therapies: All available Fluid Side lines of the installed kit are filled (Pre-dilution, Post-dilution, Dialysate lines) no matter what therapy has been selected. (Blood Pump is stopped for the duration of the Fluid Side filling - in order to have a valid Effluent Load Cell measurement, this way the Effluent Load Cell will measure only the volume delivered by the Effluent Pump) SCUF therapy: CSS starts the Fluid Side Filling with Effluent line filling. TPE therapy: All available Fluid Side lines of the installed kit are filled (Post-dilution line, Plasma Bypass line). (Blood Pump is stopped for the duration of the Plasma filling - in order to have a valid Plasma Substitution Load Cell measurement, this way the Plasma Substitution Load Cell will measure only the volume delivered by the Plasma Substitution Pump)
Dialysate line filling	Dialysate and Effluent line fillings are combined, the synchronized operation of the Dialysate and Effluent pumps are required. 1.3-Way clamp shall be set to Dialysate line open state (bottom open) 2.CSS continues Warmer test (see FDS: FDS-198) Warmer test runs parallel with the Blood Side Filling, because it takes several minutes to heat up to the required temperature - Warmer is expected to be appr. at the required temperature by the time the Fluid Side Filling starts 3.CSS drives the Dialysate pump and the Effluent pump at 8000 ml/h 4.30 ml fluid shall be delivered (during Warmer Test - Cool down phase) 5.Dialysate pump is regulated to stabilize the Solution Pressure to the predefined value (-15...-5 mmHg) in order to keep the Warmer bag collapsed during its filling 6.When Warmer test is finished CSS starts 'Dialysate Pump Filling Test' and '3-Way Clamp Filling Test: Dialysate line open (bottom-open)' , (see FDS: FDS-184 and FDS-397) 7.Proceed to Effluent line filling when 'Dialysate Pump Filling Test' and '3-Way Clamp Filling Test: Dialysate line open (bottom-open)' are finished successfully

Title	Description
Effluent line filling	CRRT therapies: Dialysate and Effluent line fillings are combined, the synchronized operation of the Dialysate and Effluent pumps are required (Blood Pump is stopped for the duration of the Fluid Side filling). 1. CSS drives the Dialysate Pump and the Effluent pump: - Dialysate pump is regulated to stabilize the Solution Pressure to the predefined value (-15...-5 mmHg) - Effluent pump is driven at 8000 ml/h 2.Effluent line is filled when weight change is detected by the Effluent Load Cell (20 ml fluid shall be present in the Effluent bag) 3.Start Effluent Pump Filling Test (see FDS: FDS-186) 4.After Effluent Pump Filling Test is finished successfully proceed to Substitution line filling SCUF therapy: 1.CSS starts the Effluent pump and the Blood pump in order to fill the Effluent line. 2. CSS drives the Effluent pump and the Blood pump: - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 300 mmHg - Blood pump is driven at Effluent pump speed + 10 % ml/h 3.Effluent line is filled when weight change is not detected by the Effluent Load Cell 4.Start Effluent Pump Filling Test (see FDS: FDS-186) 5.After Effluent Pump Filling Test is finished successfully proceed to Effluent Pressure Chamber level adjustment TPE therapy: 1.CSS starts the Effluent pump and the Effluent pump in order to fill the Effluent line. 2. CSS drives the Effluent pump and the Blood pump: - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 150 mmHg - Blood pump is driven at Effluent pump speed + 10 % ml/h 3.Effluent line is filled when weight change is not detected by the Effluent Load Cell 4.Start Effluent Pump Filling Test (see FDS: FDS-186) 5.After Effluent Pump Filling Test is finished successfully proceed to Effluent Pressure Chamber level adjustment

Title	Description
Substitution line filling	During Substitution line filling the CSS disables the air bubble removal processes. air bubble removal processes: When the levels of the chambers with level detectors (FPC, VPC, SPC) are regulated in order to automatically remove the air bubbles from the wall of chambers.
Pre-dilution substitution line filling by Dialysate Pump	1.3-way clamp is set to Pre-dilution line open position (left-open) 2.CSS drives the Dialysate pump at 8000 ml/h (Effluent pump is stopped) 3.Dialysate Pump shall deliver 20 ml fluid to match the pressure on Blood Side (Pre-Filter pressure - FP) 4.Start '3-way clamp Filling Test: Pre-Substitution line open (left-open)'(see FDS-398) 5.Additional 20 ml fluid shall be delivered to fill the pre-dilution line 6.After successful '3-way clamp Filling Test: Pre-Substitution line open' and 40 (20+20) ml fluid is delivered proceed to Post-dilution substitution line filling
Post-dilution substitution line filling by Dialysate Pump	1.3-way clamp is set to Post-dilution line open position (top-open) 2.CSS drives the Dialysate pump at 8000 ml/h (Effluent pump is stopped) 3.Dialysate Pump shall deliver 10 ml fluid to match the pressure on Blood Side (Venous pressure - VP) 4.Start '3-way clamp Filling Test: Post-Substitution line open (top-open)' (see FDS-399) 5.After '3-way clamp Filling Test: Post-Substitution line open' test is finished successfully, start '3-way clamp Filling Test: All closed state' (see FDS-395) 6.After '3-way clamp Filling Test: All closed state' test is finished successfully and 10 ml fluid is delivered, proceed to Main substitution line filling.
Main substitution line filling by Substitution Pump	1.CSS drives the Substitution pump at 8000 ml/h (3-way clamp in all closed state) 2.30 ml fluid shall be delivered 3.Start Substitution Pump Filling Test (see FDS: FDS-183) 4.After Substitution Pump Filling Test is finished successfully and 30+30 ml fluid has been delivered proceed to Solution Pressure Chamber level adjustment

Title	Description
Post-dilution substitution line filling by Plasma Substitution Pump	1.3-way clamp is set to Post-dilution line open position (top-open) 2.CSS drives the Plasma Substitution pump at 6000 ml/h (Effluent pump is stopped) 3.Plasma Substitution Pump shall deliver 110 ml fluid to match the pressure on Blood Side (Venous pressure - VP) 4.Start '3-way clamp Filling Test: Post-Substitution line open (top-open)' (see FDS-399) 5.After '3-way clamp Filling Test: Post-Substitution line open' test is finished successfully, start '3-way clamp Filling Test: All closed state' (see FDS-395) 6.After '3-way clamp Filling Test: All closed state' test is finished successfully and 110 ml fluid is delivered, proceed to Solution Pressure Chamber level adjustment.
Solution Pressure Chamber level adjustment	CRRT therapies: 1.CSS drives the Dialysate Pump: - Dialysate pump is regulated to stabilize the Solution Pressure to the predefined value (-15...-5 mmHg) 2.Set fluid level above the upper level detector 3.Start Solution Pressure Chamber Level detector test (see FDS: FDS-193) (inactive) 4.Automatic Level Regulation for SPC is activated (see FDS: FDS-408) 5. Proceed to Effluent Pressure Chamber level adjustment when test is finished successfully TPE therapy: 1.CSS drives the Plasma Substitution Pump 2.Set fluid level above the upper level detector 3.Automatic Level Regulation for SPC is activated (see FDS: FDS-408) 4. Proceed to Plasma line filling when test is finished successfully

Title	Description
Plasma Bypass line filling	During Plasma Bypass line filling the CSS disables the air bubble removal processes. air bubble removal processes: When the levels of the chambers with level detectors (FPC, VPC, SPC) are regulated in order to automatically remove the air bubbles from the wall of chambers. 1.3-Way clamp shall be set to bypass line open state (bottom open) 2.CSS drives the Plasma Substitution pump at (- 6000 ml/h) 3.10 ml fluid shall be delivered in order to fill the Bypass Line 4.When 10 ml fluid is delivered by the Plasma Substitution pump, CSS drives the Plasma Substitution pump at 6000 ml/h and starts '3-Way Clamp Filling Test: Bypass line open (bottom-open)' , (see FDS: FDS-1005 and FDS-397) 5.Proceed to Effluent line filling when 10 ml fluid is delivered by the Plasma Substitution pump and '3-Way Clamp Filling Test: Bypass line open (bottom-open)' are finished successfully

Title	Description
Effluent Pressure Chamber level adjustment	CRRT therapies: 1.CSS drives the Dialysate Pump and the Effluent pump: - Dialysate pump is regulated to stabilize the Solution Pressure to the predefined value (-15...-5 mmHg) - Effluent pump is driven at 8000 ml/h 2.Set fluid level by driving the Level regulation pump for max. 8 s in order to set EP (effluent pressure): - Calculation: add EP + 780 at every 250 ms; cumulated value shall reach 3320 (e.g. if EP=50 mmHg the process takes 1 s (4*250 ms)) 3. Proceed to Dialyser degassing process if the Blood Side and Fluid Side have been filled SCUF therapy: 1. CSS drives the Effluent pump and the Blood pump: - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 300 mmHg - Blood pump is driven at Effluent pump speed + 10 % ml/h 2.Set fluid level by driving the Level regulation pump for max. 8 s in order to set EP (effluent pressure): - Calculation: add EP + 780 at every 250 ms; cumulated value shall reach 3320 (e.g. if EP=50 mmHg the process takes 1 s (4*250 ms)) 3. Proceed to Dialyser degassing process if the Blood Side and Fluid Side have been filled TPE therapy: 1. CSS drives the Effluent pump and the Blood pump: - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 150 mmHg - Blood pump is driven at Effluent pump speed + 10 % ml/h 2.Set fluid level by driving the Level regulation pump for max. 8 s in order to set EP (effluent pressure): - Calculation: add EP + 780 at every 250 ms; cumulated value shall reach 3320 (e.g. if EP=50 mmHg the process takes 1 s (4*250 ms)) 3. Proceed to Dialyser degassing process if the Blood Side and Fluid Side have been filled

Title	Description
Filter degassing	The remaining air at the top of the Filter will be removed in the Filter pressure chamber air trap (due to the reverse rotation of the blood pump). Filter degassing means the followings according to the different therapy types: - CVVHD, CVVHDF:degassing the Dialyser, - CVVH, SCUF: degassing the Hemofilter, - TPE: degassing the Plasma filter. During Priming Filter degassing the CSS shall disable the air bubble removal processes. air bubble removal processes: When the levels of the chambers with level detectors (FPC, VPC, SPC) are regulated in order to automatically remove the air bubbles from the wall of chambers. 1.If fluid-side is filled the CSS shall start the Filter Degassing by increasing the VP chamber level until fluid reaches high level and for additional 2 seconds while the VENOUS CLAMP is opened. 2.The CSS starts to suck air bubbles from Filter to FP chamber until CSS detects Air by Venous Air Detector but max. 20 seconds. 3.The CSS drives the Blood pump at -300 ml/min while Venous clamp is open if the PRE-FILTER CHAMBER is not empty. 4.The CSS operates the Blood pump with 40 ml/min if the PRE-FILTER CHAMBER is empty. 5.After the air removal the CSS shall increase the Filter pressure for 4 s or until the pressure is below 0 mmHg. 6.At the end of the Filter Degassing the CSS shall decrease the VP chamber level for 2 seconds. 7.Proceed to Rinsing.

Title	Description
Automatic Level Regulation	During Priming (Filling and Rinsing) the levels of the chambers with level detectors (FPC, VPC, SPC) are regulated in order to automatically remove the accumulated air from the chambers 1.Each Automatic Level Regulation is activated after the specific Chamber level has been adjusted (during Filling) 2.Check chamber level continuously (Fluid shall be detected at both lower and upper detector) 3.If fluid level drops below the upper detector, CSS increases the fluid level back to the upper detector level using the level regulation pump During Priming (Filling and Rinsing) the levels of the chambers with level detectors (FPC, VPC, SPC) are regulated in order to automatically remove the air bubbles from the wall of chambers. 1.Check chamber level continuously (fluid shall be detected at lower detector if the upper detector shows fluid). 2.If air is detected at lower detector and fluid is detected at upper detector the CSS decreases the fluid level below the lower detector to remove air bubbles. 3.After emptying the chamber the CSS increases the level above the upper detector.
System self tests: Priming tests	Running priming tests are displayed on the GUI.

Title	Description
Blood Leak Detector	Blood leak detector selftest is performed when the Kit is already installed (to have the shielding in place), but before fluid-side filling to be able to detect tube in the detector). 1.Set 'Set point' to 700. (checked by CSS and PSS on serial interface) - CSS timeout is 10 s for 1. step, PSS timeout is 12 s for 1. step 2.Read 'Set point'. (checked by CSS on serial interface) - CSS timeout is 10 s for 2. step 3.Send 'Zero' command to make sure the self test drive acquiring is valid (using the serial interface). 4.Confirm 'Zero point' set (response to serial Zeroing) using the serial interface to check zeroing process (Rx is tested). 5.Send 'Get self test drive' command using the serial interface to make sure the self test is valid. 6.Confirm 'Get self test drive' set using the serial interface. 7.Send 'Zero' command again to make sure the self test is valid (using the serial interface). 8.Confirm 'Zero point' set (response to serial Zeroing) using the serial interface to check zeroing process. - CSS timeout is 40 s for 3.-8. steps, PSS timeout is 52 s for 2.-8. steps 9.Self test I (initiated by CSS using the RS232 interface, checked by CSS on serial interface) (self test drive acquiring, zeroing and Tx line is tested). - CSS timeout is 10 s for 9. step 10.Self test II (initiated by CSS using the BLDTST digital line, checked by CSS and PSS on digital interfaces) - if blood is detected after self test -> Low priority alarm - CSS timeout is 10 s for 10. step, PSS timeout is 25 s for 9.-10. steps 11.Set 'Set point' to proper value (from system config, checked by CSS and PSS on serial interface). - CSS timeout is 10 s for 11. step, PSS timeout is 12 s for 11. step 12.Read 'Set point'. (checked by CSS on serial interface) - CSS timeout is 10 s for 12. step 13.Send 'Zero' command to make sure the self test drive acquiring is valid (using the serial interface). 14.Confirm 'Zero point' set (response to serial Zeroing) using the serial interface to check zeroing process (Rx is tested). 15.Send 'Get self test drive' command using the serial interface to make sure the self test is valid. 16.Confirm 'Get self test drive' set using the serial interface. 17.Send 'Zero' command again to make sure the Blood Leak Detector Tube Test is valid (FDS: FDS-856).

Title	Description
	18.Confirm 'Zero point' set (response to serial Zeroing) using the serial interface to check zeroing process. - CSS timeout is 20 s for 13.-18. steps, PSS timeout is 32 s for 12.-. steps If self test is failed or self test is time out: - CSS gives Low Priority alarm signal. If CSS gives alarm signal, DSS pops up a help window. The help window: - is opened if the alarm signal occurs, - can be closed by Close button, - is reopened with a 15-sec timeout, if the alarm signal is present, - is closed if the alarm is not present anymore. GUI displays the current self test status on the help window. - CSS checks continuously in self test failed state whether the self test can be restarted or not and indicates it to GUI. CSS prohibits self test restarting until CSS receives character(s) on serial communication line from Blood Leak Detector and indicates to GUI that the self-test cannot be restarted. GUI displays the current self test status on the help window as failed (red cross icon). CSS enables self test restarting if serial communication is free and indicates to GUI that the self-test can be restarted. GUI displays the current self test status on the help window as passed (green tick icon). - CSS prohibits Blood Pump Filling test restarting until the BLD self test is passed.

Title	Description
Blood-side Kit Volume Measuring Test	1.CSS initiates Blood-side Kit Volume Measuring Test during Priming Arterial line filling (see FDS: FDS-360 for details). 2.CSS and PSS start Blood-side Kit Volume Measuring from the volume of Venous line (20 ml). 3.CSS and PSS measure Blood-side Kit Volume based on Effluent loadcell weight change if SADV detects air. 4.Test is passed if both CSS and PSS detect fluid by SADV. During the Blood-side Kit Volume Measuring Test the PSS monitors and verifies the CS Blood-side Kit Volume till both CSS and PSS detect fluid by SADV. PS Blood-side Kit Volume is assigned to the validated CS Blood-side Kit Volume when the Blood-side Kit Volume Measuring Test succeeded. Low priority alarm is issued by CSS if the measured Blood-side Kit Volume is equal to or over 500 ml. Blood side is stopped, alarm can be reset. On alarm reset, CSS restarts the Blood pump from 250 ml (94 ml Hemofilter in worst case + 125 ml CO2 filter) and the alarm limit is increased by 250 ml (new alarm limit = 750 ml). Low priority alarm is issued by PSS if the difference between CS and PS Blood-side Kit Volume is higher than 10 ml for 2 seconds. Blood side is stopped, alarm cannot be reset. In CRRT (including SCUF) therapies CSS and PSS set the Blood-side Kit Volume to the Nominal filling volume (BB_NominalVolume from Disposable Kit Table) when CS and PS detect fluid by SADV, if the calculated volume is less than the nominal volume (BB_NominalVolume) or more than 500 ml. Low priority alarm is issued by PSS if (CS Blood-side Kit Volume > 500 ml or CS Blood-side Kit Volume < BB_NominalVolume) when CS and PS detect fluid by SADV and CS does not set CS Blood-side Kit Volume to the BB_NominalVolume. Blood side is stopped, alarm cannot be reset. In TPE therapy CSS and PSS set the Blood-side Kit Volume to the Nominal filling volume (BB_NominalVolume from Disposable Kit Table) when CS and PS detect fluid by SADV. Low priority alarm is issued by PSS if (CS or PS Blood-side Kit Volume) is not equal to BB_NominalVolume when CS and PS detect fluid by SADV. Blood side is stopped, alarm cannot be reset. The CS/PS Blood-side Kit Volume is used to calculate Patient Connection Volume, see FDS: FDS-1185 for details.

Title	Description
Blood Pump Filling Test and Tube Calibration(Blood Pump Hall sensor, Effluent Load Cell, Tube calibration)	1.CSS drives the pump at 200 ml/min 2.100 ml fluid shall be delivered 3.CSS checks if the volume is delivered based on CSS load cell measurement - tolerance: 20% 4.PSS checks if the calculated volume based on PSS measured rpm and PSS load cell measurement - tolerance: 22% 5.PSS communicates the test result to CSS 6.If both PSS and CSS measurements are successful tube constant shall be calculated based on rotation of the pump and weight of the fluid delivered 7.Test is passed if both PSS and CSS measurements are successful Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS rpm - PS rpm; CS weight - PS weight).
Syringe Pump Filling Test	-
Heparin Pump Filling Test	1.PSS stops the syringe pump 2.CSS drives the pump at 600 ml/h (bolus) 3.CSS and PSS checks if no rotation is detected 4.CSS drives the pump at 600 ml/h (bolus) 5.Syringe pump shall deliver 3 ml fluid (depends on tube volume) 6.CSS rotates the pump forward mode at 15 rpm for (1 + 1/3) rotation 7.CSS rotates the pump reverse mode at 15 rpm for (1 + 1/3) rotation 8.PSS and CSS checks if pump rotation is detected 9.PSS checks if the reverse rotation is detected and measured flow is within +/- 4 % and measured volume is between 25 and 35 ml

Title	Description
Calcium Pump Filling Test	1.PSS stops the syringe pump 2.CSS drives the pump at 600 ml/h 3.CSS and PSS checks if no rotation is detected 4.CSS drives the pump at 600 ml/h until 0.5 ml is delivered - Low Priority Alarm is issued by PSS if measured flow is not within +/- 4 % 5.PSS and CSS checks if pump rotation is detected 6.CSS rotates the pump reverse mode for (1 + 1/3) whole rotation - Low Priority Alarm is issued by PSS if measured flow is not within +/- 4 % 7.CSS drives the pump at 600 ml/h until 1 ml fluid is delivered - Low Priority Alarm is issued by PSS if measured flow is not within +/- 4 % 8.CSS and PSS checks that fluid reaches the tube (by Calcium SAD) - Low Priority Alarm is issued by CSS and PSS if fluid does not reach the SADC or air bubble is detected 9.Syringe pump shall deliver additional 11 ml fluid (depends on tube volume) - Low Priority Alarm is issued by CSS and PSS if air bubble is detected by SADC - Low Priority Alarm is issued by PSS if measured flow is not within +/- 4 % - Low Priority Alarm is issued by PSS if delivered volume is less than 1 ml at the end of test

Title	Description
Substitution Pump Filling Test(Substitution Pump Hall sensor, Substitution Load Cell)	1.CSS drives the Substitution pump at 8000 ml/h 2.30 ml fluid shall be delivered 3.CSS checks if the volume is delivered based on CSS load cell measurement - tolerance: 40% 4.PSS checks if the calculated volume based on PSS measured rpm and PSS load cell measurement - tolerance: 50% 5.PSS communicates the test result to CSS 6.Test is passed if both PSS and CSS measurements are successful Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS rpm - PS rpm; CS weight - PS weight).
Dialysate Pump Filling Test(Dialysate Pump Hall Sensor, Dialysate Load Cell)	1.CSS drives the Dialysate pump at 8000 ml/h 2.30 ml fluid shall be delivered 3.CSS checks if the volume is delivered based on CSS load cell measurement - tolerance: 40% 4.PSS checks if the calculated volume based on PSS measured rpm and PSS load cell measurement - tolerance: 50% 5.PSS communicates the test result to CSS 6.Test is passed if both PSS and CSS measurements are successful Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS rpm - PS rpm; CS weight - PS weight).

Title	Description
Plasma Substitution Pump Filling Test (Plasma Substitution Pump Hall Sensor, Plasma Substitution Load Cell)	1.CSS drives the Plasma Substitution pump at 6000 ml/h 2.30 ml fluid shall be delivered 3.CSS checks if the volume is delivered based on CSS load cell measurement - tolerance: 12 ml 4.PSS checks if the calculated volume based on PSS measured rpm and PSS load cell measurement - tolerance: 15 ml 5.PSS communicates the test result to CSS 6.Test is passed if both PSS and CSS measurements are successful Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS rpm - PS rpm; CS weight - PS weight).
Citrate Pump Filling Test(Citrate Pump Hall Sensor, Citrate Load Cell)	1.CSS drives the pump at 3000 ml/h 2.20 ml fluid shall be delivered 3.CSS checks if the volume is delivered based on CSS load cell measurement - tolerance: 40% 4.PSS checks if the calculated volume based on PSS measured rpm and PSS load cell measurement - tolerance: 50% 5.PSS communicates the test result to CSS 6.Test is passed if both PSS and CSS measurements are successful Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS rpm - PS rpm; CS weight - PS weight).

Title	Description
Effluent Pump Filling Test(Effluent Pump Hall Sensor, Effluent Load Cell)	CRRT therapies: 1.CSS drives the Effluent pump at 8000 ml/h 2.30 ml fluid shall be delivered 3.CSS checks if the volume is delivered based on CSS load cell measurement - tolerance: 40% 4.PSS checks if the calculated volume based on PSS measured rpm and PSS load cell measurement - tolerance: 50% 5.PSS communicates the test result to CSS 6.Test is passed if both PSS and CSS measurements are successful Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS rpm - PS rpm; CS weight - PS weight). SCUF therapy: 1.CSS drives the Effluent pump depending on Transmembrane pressure 2.30 ml fluid shall be delivered 3.CSS checks if the volume is delivered based on CSS load cell measurement - tolerance: on the load cell max. 12 ml measured weight difference is allowed during the test 4.PSS checks if the calculated volume based on PSS measured rpm and PSS load cell measurement - tolerance: on the load cell max. 15 ml measured weight difference is allowed during the test 5.PSS communicates the test result to CSS 6.Test is passed if both PSS and CSS measurements are successful Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS rpm - PS rpm; CS weight - PS weight).

Title	Description
	TPE therapy: 1.CSS drives the Effluent pump depending on Transmembrane pressure 2.30 ml fluid shall be delivered 3.CSS checks if the volume is delivered based on CSS load cell measurement - tolerance: on the load cell max. 12 ml measured weight difference is allowed during the test 4.PSS checks if the calculated volume based on PSS measured rpm and PSS load cell measurement - tolerance: on the load cell max. 15 ml measured weight difference is allowed during the test 5.PSS communicates the test result to CSS 6.Test is passed if both PSS and CSS measurements are successful Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS rpm - PS rpm; CS weight - PS weight).
3-way clamp Filling Test	The 3-way clamp Filling Test is divided into 4 subtests that can be performed at different stages of the Filling procedure.
3-way clamp Filling Test: All closed state	CRRT therapies: 1.All valves shall be closed 2.CSS drives the Dialysate pump at 8000 ml/h 3.Solution pressure shall increase by 150 mmHg or reach 300 mmHg (checked by both CSS and PSS) 4.Test is successful if the predefined solution pressure is reached in 15 s (by both CSS and PSS) TPE therapy: 1.All valves shall be closed 2.CSS drives the Plasma Substitution pump at 6000 ml/h 3.Solution pressure shall increase by 150 mmHg or reach 300 mmHg (checked by both CSS and PSS) 4.Test is successful if the predefined solution pressure is reached in 20 s (by both CSS and PSS)

Title	Description
3-way clamp Filling Test: Bottom line open	CRRT therapies: 1.3-way clamp shall be set to Dialysate line open state (bottom open) 2.CSS drives the Dialysate pump at 8000 ml/h 3.Solution pressure shall keep its actual value, i.e. Solution pressure shall not increase more than 40 mmHg (checked by CSS) and 60 mmHg (checked by PSS) 4.Test is successful if Solution pressure does not exceed the predefined limit for 10 s (by both CSS and PSS) TPE therapy: 1.3-way clamp shall be set to Bypass line open state (bottom open) 2.CSS drives the Plasma Substitution pump at -6000 ml/h for 10 ml then at 6000 ml/h 3.Solution pressure shall keep its actual value, i.e. Solution pressure shall not increase more than 40 mmHg (checked by CSS) and 60 mmHg (checked by PSS) 4.Test is successful if Solution pressure does not exceed the predefined limit for 10 s (by both CSS and PSS)
-	-
3-way clamp Filling Test: Left line open	CRRT therapies: 1.3-way clamp shall be set to Pre-Substitution line open (left-open) 2.CSS drives the Dialysate pump at 8000 ml/h 3.Solution pressure shall keep its actual value, i.e. Solution pressure shall not increase more than 60 mmHg (checked by CSS) and 70 mmHg (checked by PSS) 4.Test is successful if Solution pressure does not exceed the predefined limit for 10 s (by both CSS and PSS) TPE therapy: There is no test due to Pre-Substitution line is not used.
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Title	Description
3-way clamp Filling Test: Top line open	CRRT therapies: 1.3-way clamp shall be set to Post-Substitution line open (top-open) 2.CSS drives the Dialysate pump at 8000 ml/h 3.Solution pressure shall keep its actual value, i.e. Solution pressure shall not increase more than 60 mmHg (checked by CSS) and 70 mmHg (checked by PSS) 4.Test is successful if Solution pressure does not exceed the predefined limit for 10 s (by both CSS and PSS) TPE therapy: 1.3-way clamp shall be set to Post-Substitution line open (top-open) 2.CSS drives the Plasma Substitution pump at 6000 ml/h 3.Solution pressure shall keep its actual value, i.e. Solution pressure shall not increase more than 60 mmHg (checked by CSS) and 70 mmHg (checked by PSS) 4.Test is successful if Solution pressure does not exceed the predefined limit for 10 s (by both CSS and PSS)
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Title	Description
Warmer Test	CRRT therapies: This is a combined Temperature sensor, Warmer 24V Relay and Warmer functional test Warmer test runs parallel with the Blood Side Filling, because it takes several minutes to heat up to the required temperature - Warmer is expected to be appr. at the required temperature by the time the Fluid Side Filling starts Heat up phase - during Blood Side Filling 1.Dialysate and Effluent pumps are stopped (disabled) 2. Warmer is ON (PWM=100%) 3. When the Plate temperature measured by PS exceeds 49.5 Celsius (for 3 s) the PSS switches OFF the Warmer 24V Relay. - CSS sets PWM to 0% and Low Priority Alarm is issued: - if PSS fails to switch off the Warmer 24V Relay and Plate Temperature exceeds 49.5+2.0 (tolerance) Celsius, - if Heat up phase should take more than 250 seconds (timeout) 4.Wait for the Blood Side Filling to end Cool down phase - during Fluid Side Filling 5.CSS sets the PWM to 0% 6.The specific Pumps are restarted (enabled) according to the selected therapy to cool the warmer, and the CS waits for the PS to switch the Warmer relay back ON (if Plate temperature drops below Tmax) - Low Priority Alarm is issued if Cool down phase (steps 5-6) should take more than 250 seconds (timeout) 7.The test finished successfully when the Plate temperature is decreased to the max. Output temperature (tolerance: 0.5 C) - Low Priority Alarm is issued if the complete Cool down phase should take more than 250 seconds (timeout) Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS Plate Temp. - PS Plate Temp.; CS Output Temp. - PS Output Temp. with 2 C tolerance) Test is not performed if the Warmer switched off for the therapy.

Title	Description
	TPE Therapy: This is a combined Temperature sensor, Warmer 24V Relay and Warmer functional test Warmer test runs parallel with the Blood Side Filling, because it takes several minutes to heat up to the required temperature - Warmer is expected to be appr. at the required temperature by the time the Fluid Side Filling starts Heat up phase - during Blood Side Filling 1.Plasma Substitution and Effluent pumps are stopped (disabled) 2. Warmer is ON (PWM=100%) 3. When the Plate temperature measured by PS exceeds 41.5 Celsius (for 3 s) the PSS switches OFF the Warmer 24V Relay. - CSS sets PWM to 0% and Low Priority Alarm is issued: - if PSS fails to switch off the Warmer 24V Relay and Plate Temperature exceeds 41.5+2.0 (tolerance) Celsius, - if Heat up phase should take more than 200 seconds (timeout) 4.Wait for the Blood Side Filling to end Cool down phase - during Fluid Side Filling 5.CSS sets the PWM to 0% 6.The specific Pumps are restarted (enabled) according to the selected therapy to cool the warmer, and the CS waits for the PS to switch the Warmer relay back ON (if Plate temperature drops below Tmax) - Low Priority Alarm is issued if Cool down phase (steps 5-6) should take more than 200 seconds (timeout) 7.The test finished successfully when the Plate temperature is decreased to the max. Output temperature (tolerance: 0.5 C) - Low Priority Alarm is issued if the complete Cool down phase should take more than 200 seconds (timeout) Note: Measured values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS Plate Temp. - PS Plate Temp.; CS Output Temp. - PS Output Temp. with 2 C tolerance) Test is not performed if the Warmer switched off for the therapy.

Title	Description
Rinsing	Flush the extracorporeal blood circuit with a given volume from the arterial access through the filter into the Rinsing waste bag attached to the venous line. Furthermore, flush the fluid side lines.
Air bubble removal at Rinsing (Pressure wave generation)	Air bubble removal is a parallel process that runs continuously during Rinsing except for the optional procedures CRRT therapies: 1.Venous Clamp (VC) closed until VP < 315 mmHg 2.Venous Clamp opens above VP 315 mmHg and remains open as long as VP > 315 mmHg but at least for 2 s TPE therapy: 1.Venous Clamp (VC) closed until VP < 125 mmHg 2.Venous Clamp opens above VP 125 mmHg and remains open as long as VP > 125 mmHg but at least for 2 s

Title	Description
Required rinsing	CRRT therapies: 1.CSS drives: - the Blood Pump at 200 ml/min - Dialysate pump is regulated to stabilize the Solution Pressure to the predefined value (-15...-5 mmHg) - the Effluent Pump at 8000 ml/h - the Substitution Pump at 6000 ml/h 2.Start Air bubble removal at Rinsing - parallel process (FDS: FDS-405) 3. Proceed to Final Test when 200 ml fluid has been delivered by the Blood Pump (60 s) SCUF therapy: 1.CSS drives: - the Blood Pump at 200 ml/min - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 300 mmHg 2.Start Air bubble removal at Rinsing - parallel process (FDS: FDS-405) 3. Proceed to Final Test when 200 ml fluid has been delivered by the Blood Pump (60 s) TPE therapy: 1.CSS drives: - the Blood Pump at 200 ml/min - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 150 mmHg 2.Start Air bubble removal at Rinsing - parallel process (FDS: FDS-405) 3. Proceed to Final Test when 200 ml fluid has been delivered by the Blood Pump (60 s) During TPE Priming Required Rinsing the CSS shall stop the Plasma Substitution Pump in order to avoid the wastage of Fresh Frozen Plasma.

Title	Description
Final tests	1.CSS sets the Venous Clamp into open state to reduce the Blood side pressures after the pressure waves. 2.Start Blood Leak Detector Tube Test (FDS: FDS-856) and CSS stops the fluid side pumps and adjusts the VP and FP chamber levels in order to prepare the Disposable Leakage Test, then stops all pumps 3.Start Blood Leak Detector Test when Blood Leak Detector Tube Test finished successfully (FDS: FDS-196) and CSS stops the fluid side pumps and adjusts the VP and FP chamber levels in order to prepare the Disposable Leakage Test, then stops all pumps 4.Start Disposable Leakage Test after successful Blood Leak Detector Test (FDS: FDS-412) 5. Start Level Regulation Test when Disposable Leakage Test is finished successfully (FDS: FDS-195) 6. Start Air Detector Test when Level Regulation Test is finished successfully (FDS: FDS-188) 7.If the Air Detector Test is passed the CSS starts the Level Regulation Pump in order to set the fluid level in the Pre-Filter, Venous and Solution(omitted in SCUF) chambers above the upper Level Detectors. 8.Proceed to Final Rinsing when the tests are finished successfully

Title	Description
Final rinsing	CRRT therapies: 1.CSS drives: - the Blood Pump at 200 ml/min - Dialysate pump is regulated to stabilize the Solution Pressure to the predefined value (-15...-5 mmHg) - the Effluent Pump at 8000 ml/h - the Substitution Pump at 6000 ml/h 2.Start Air bubble removal at Rinsing - parallel process (see FDS: FDS-405) 3.If 100 ml fluid is delivered by the Blood pump: - and the upper level detector of the Pre-Filter chamber detects fluid the CSS starts the Level Regulation Pump in order to set the fluid level in the Pre-Filter and the Venous chambers between the upper and lower Level Detectors. - the CSS starts the Level Regulation Pump in order to set the fluid level in the Solution chamber between the upper and lower Level Detectors. 4. CSS stops the pumps and the machine is Ready for Therapy after 200 ml volume has been delivered by the Blood pump (60 s) SCUF therapy: 1.CSS drives: - the Blood Pump at 200 ml/min - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 300 mmHg 2.Start Air bubble removal at Rinsing - parallel process (see FDS: FDS-405) 3.If 100 ml fluid is delivered by the Blood pump and the upper level detector of the Pre-Filter chamber detects fluid the CSS starts the Level Regulation Pump in order to set the fluid level in the Pre-Filter and the Venous chambers between the upper and lower Level Detectors. 4. CSS stops the pumps and the machine is Ready for Therapy after 200 ml volume has been delivered by the Blood pump (60 s)

Title	Description
	TPE therapy: 1.CSS drives: - the Blood Pump at 200 ml/min - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 150 mmHg 2.Start Air bubble removal at Rinsing - parallel process (see FDS: FDS-405) 3.If 100 ml fluid is delivered by the Blood pump: - and the upper level detector of the Pre-Filter chamber detects fluid the CSS starts the Level Regulation Pump in order to set the fluid level in the Pre-Filter and the Venous chambers between the upper and lower Level Detectors. - the CSS starts the Level Regulation Pump in order to set the fluid level in the Solution chamber between the upper and lower Level Detectors. 4. CSS stops the pumps and the machine is Ready for Therapy after 200 ml volume has been delivered by the Blood pump (60 s) During TPE Priming Final Rinsing the CSS shall stop the Plasma Substitution Pump in order to avoid the wastage of Fresh Frozen Plasma.
System self tests: Rinsing	-

Title	Description
Blood Leak Detector Tube	Self test is initiated by CSS on digital line, checked by CSS and PSS on digital interfaces. If blood is detected during self test or time is out by PSS (6 s) and no self test is initiated by CSS: - CSS gives Low Priority alarm signal. If CSS gives alarm signal, DSS pops up a help window. The help window: - is opened if the alarm signal occurs, - can be closed by Close button, - is reopened with a 15-sec timeout, if the alarm signal is present, - is closed if the alarm is not present anymore. GUI displays the current self test status on the help window. - CSS checks continuously in self test failed state whether the self test can be restarted or not and indicates it to GUI. CSS prohibits self test restarting until CSS receives character(s) on serial communication line from Blood Leak Detector or CSS detects blood on digital line and after that for 6 seconds. GUI displays the current self test status on the help window as failed (red cross icon). CSS enables self test restarting if serial communication and blood leakage digital line are free or blood is not detected for 6 seconds and indicates to GUI that the self-test can be restarted. GUI displays the current self test status on the help window as passed (green tick icon).

Title	Description
Blood Leak Detector	1.Send 'Zero' command to make sure the self test drive acquiring is valid (using the serial interface). 2.Confirm 'Zero point' set (response to serial Zeroing) using the serial interface to check zeroing process (Rx is tested). 3.Send 'Get self test drive' command using the serial interface to make sure the self test is valid. 4.Confirm 'Get self test drive' set using the serial interface to check serial communication. 5.Send 'Zero' command again to make sure the right Zero level has been set for the BLD (on serial interface). 6.Confirm 'Zero point' set (response to serial Zeroing) using the serial interface to check zeroing process. 7. Request BLD value; BLD must be lower than 20 - if BLD level is greater than 20 -> Low priority alarm 8.Self test (initiated by CSS on digital line, checked by CSS and PSS on digital interfaces) - if blood is detected after self test -> Low priority alarm 9.If time is out by CSS (30 s) or PSS (32 s): low priority alarm signal to DSS. 10.After successful self test check detection level: BLD must detect 'No Blood' (digital line). If self test is failed or self test is time out: - CSS gives Low Priority alarm signal. If CSS gives alarm signal, DSS pops up a help window. The help window: - is opened if the alarm signal occurs, - can be closed by Close button, - is reopened with a 15-sec timeout, if the alarm signal is present, - is closed if the alarm is not present anymore. GUI displays the current self test status on the help window. - CSS checks continuously in self test failed state whether the self test can be restarted or not and indicates it to GUI. CSS prohibits self test restarting until CSS receives character(s) on serial communication line from Blood Leak Detector and indicates to GUI that the self-test cannot be restarted. GUI displays the current self test status on the help window as failed (red cross icon). CSS enables self test restarting if serial communication is free and indicates to GUI that the self-test can be restarted. GUI displays the current self test status on the help window as passed (green tick icon).

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Title	Description
Disposable Leakage Test	(Pressure sensor, Venous Clamp and connection tests) The Disposable leakage test checks: - the whole disposable with the blood and fluid sides, - the damaged pump segment between the rollers (Human error: damaged segment due to wrong insertion), - the connections of the pressure sensors on blood and fluid sides CRRT therapies: 1.Venous Clamp is closed by PSS only (CSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected) 2.Prepare Test pressure CSS drives the pumps: Note: Low Priority Alarm is issued by CSS if: - difference between VP and FP is greater than 60 mmHg 10 seconds after test start and VP > 365 or - difference between SP and EP is greater than 60 mmHg 10 seconds after test start and SP > 365 or - pressures measured at VP and SP do not reach 395 mmHg in 40 seconds (timeout) Low Priority Alarm is issued by PSS if pressures measured at VP and SP do not reach 365 mmHg in 41 seconds (timeout) 3.Venous Clamp is closed by CSS only (PSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected) 4.CSS shall set the 3-Way Clamp position to Pre-dilution 5.Pressure stabilization I - wait for 5 s

<table>
<tr><th>Title</th><th>Description</th></tr>
<tr><td></td><td>6.Leakage Test I

Low Priority Alarm is issued by CSS and PSS if the monitored values are beyond the predefined limits for the duration of the test (10 s)

CSS limits:
- (delta AP > 5 [mmHg])
- (delta VP > 30 [mmHg])
- (|FP-VP| > 30 [mmHg])
- (|SP-VP| > 30 [mmHg])
- (|EP-VP| > 30 [mmHg])
PSS limits:
- (delta VP > 40 [mmHg])
- (|FP-VP| > 40 [mmHg])
- (|SP-VP| > 40 [mmHg])
- (|EP-VP| > 40 [mmHg])

The CSS and PSS starts checking the pressures from 5 seconds after the beginning/restart of the test. (In case of reset, the Venous clamp is opened for a short time. The Venous and Pre-Filter pressure escapes rapidly to the Venous line. Therefore the difference between Venous and Pre-Filter pressure can be high temporarily.)

7.Pump segment Test

CSS sets the 3-Way Clamp position to Dialysate

CSS drives the pumps with a slow rotation for 22 s to check the leakage of pump segments (less than a half rotation):
- Blood Pump = 10 [ml/min],
- Dialysate Pump = 180 [ml/h],
- Substitution Pump = 180 [ml/h],
- Effluent Pump = 780 [ml/h].

If the 22 seconds is exceeded CSS sets the 3-Way Clamp position to Post-dilution.

Slight pressure differences between the Blood Side and the Fluid Side build up during the Pump Segment Test due to the different pump flows on the two sides. In the settling down period (after 22 seconds) the pressures will equalize through the high-flux filter. The equalized pressure value shall be the same as the pressure value before the test if the pump segments are not damaged.

8.Pressure Stabilization II

- wait for 5 s</td></tr>
</table>

Title	Description
	9.Leakage Test II Low Priority Alarm is issued by CSS if the monitored values are beyond the predefined limits for the duration of the test (10 s) CSS limits: - (delta AP > 10 [mmHg]) - (delta VP > 40 [mmHg]) - (|FP-VP| > 40 [mmHg]) - (|SP-VP| > 40 [mmHg]) - (|EP-VP| > 40 [mmHg]) PSS limits: - (delta VP > 50 [mmHg]) - (|FP-VP| > 50 [mmHg]) - (|SP-VP| > 50 [mmHg]) - (|EP-VP| > 50 [mmHg]) The CS starts checking the pressures from 5 seconds after the beginning/restart of the test. Note: Measured pressure values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS pressure values - PS pressure values with 20 mmHg tolerance) SCUF therapy: 1.Venous Clamp is closed by PSS only (CSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected) 2.Prepare Test pressure CSS drives the pumps: Note: Low Priority Alarm is issued by CSS if difference between VP and FP is greater than 60 mmHg 10 seconds after test start and VP > 365 or pressure measured at VP does not reach 395 mmHg and at EP does not reach 390 mmHg in 40 seconds (timeout) Low Priority Alarm is issued by PSS if pressure measured at VP does not reach 365 mmHg in 41 seconds (timeout) 3.Venous Clamp is closed by CSS only (PSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected)

Title	Description
	4.Pressure stabilization I - wait for 5 s 5.Leakage Test I Low Priority Alarm is issued by CSS and PSS if the monitored values are beyond the predefined limits for the duration of the test (10 s) CSS limits: - (delta AP > 5 [mmHg]) - (delta VP > 30 [mmHg]) - (|FP-VP| > 30 [mmHg]) - (|EP-VP| > 30 [mmHg]) PSS limits: - (delta VP > 40 [mmHg]) - (|FP-VP| > 40 [mmHg]) - (|EP-VP| > 40 [mmHg]) The CSS and PSS starts checking the pressures from 5 seconds after the beginning/restart of the test. (In case of reset, the Venous clamp is opened for a short time. The Venous and Pre-Filter pressure escapes rapidly to the Venous line. Therefore the difference between Venous and Pre-Filter pressure can be high temporarily.) 6.Pump segment Test CSS drives the pumps with a slow rotation for 22 s to check the leakage of pump segments (less than a half rotation): - Blood Pump = 10 [ml/min], - Effluent Pump = 600 [ml/h]. Slight pressure differences between the Blood Side and the Fluid Side build up during the Pump Segment Test due to the different pump flows on the two sides. In the settling down period (after 22 seconds) the pressures will equalize through the high-flux filter. The equalized pressure value shall be the same as the pressure value before the test if the pump segments are not damaged. 7.Pressure Stabilization II - wait for 5 s

Title	Description
	8.Leakage Test II Low Priority Alarm is issued by CSS if the monitored values are beyond the predefined limits for the duration of the test (10 s) CSS limits: - (delta AP > 10 [mmHg]) - (delta VP > 40 [mmHg]) - (|FP-VP| > 40 [mmHg]) - (|EP-VP| > 40 [mmHg]) PSS limits: - (delta VP > 50 [mmHg]) - (|FP-VP| > 50 [mmHg]) - (|EP-VP| > 50 [mmHg]) The CS starts checking the pressures from 5 seconds after the beginning/restart of the test. Note: Measured pressure values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS pressure values - PS pressure values with 20 mmHg tolerance) TPE therapy: 1.Venous Clamp is closed by PSS only (CSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected) 2.Prepare Test pressure CSS drives the pumps: Note: Low Priority Alarm is issued by CSS if: - difference between VP and FP is greater than 60 mmHg 10 seconds after test start and VP > 175 or - pressures measured at VP and SP do not reach 205 mmHg in 40 seconds (timeout) Low Priority Alarm is issued by PSS if pressures measured at VP and SP do not reach 175 mmHg in 41 seconds (timeout) 3.Venous Clamp is closed by CSS only (PSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected)

Title	Description
	4.CSS sets the 3-Way Clamp position to Bypass 5.Pressure stabilization I - wait for 5 s 6.Leakage Test I Low Priority Alarm is issued by CSS and PSS if the monitored values are beyond the predefined limits for the duration of the test (10 s) CSS limits: - (delta AP > 5 [mmHg]) - (delta VP > 30 [mmHg]) - (|FP-VP| > 30 [mmHg]) - (|SP-VP| > 30 [mmHg]) - (|EP-VP| > 30 [mmHg]) PSS limits: - (delta VP > 40 [mmHg]) - (|FP-VP| > 40 [mmHg]) - (|SP-VP| > 40 [mmHg]) - (|EP-VP| > 40 [mmHg]) The CSS and PSS starts checking the pressures from 5 seconds after the beginning/restart of the test. (In case of reset, the Venous clamp is opened for a short time. The Venous and Pre-Filter pressure escapes rapidly to the Venous line. Therefore the difference between Venous and Pre-Filter pressure can be high temporarily.) 7.Pump segment Test CSS shall sets the 3-Way Clamp position to Post-dilution CSS drives the pumps with a slow rotation for 22 s to check the leakage of pump segments (less than a half rotation): - Blood Pump = 10 [ml/min], - Plasma Substitution Pump = 180 [ml/h], - Effluent Pump = 780 [ml/h]. Slight pressure differences between the Blood Side and the Fluid Side build up during the Pump Segment Test due to the different pump flows on the two sides. In the settling down period (after 22 seconds) the pressures will equalize through the high-flux filter. The equalized pressure value shall be the same as the pressure value before the test if the pump segments are not damaged. 8.Pressure Stabilization II - wait for 5 s

<table>
<tr><th>Title</th><th>Description</th></tr>
<tr><td></td><td>9.Leakage Test II

Low Priority Alarm is issued by CSS if the monitored values are beyond the predefined limits for the duration of the test (10 s)

CSS limits:
- (delta AP > 10 [mmHg])
- (delta VP > 40 [mmHg])
- (|FP-VP| > 40 [mmHg])
- (|SP-VP| > 40 [mmHg])
- (|EP-VP| > 40 [mmHg])
PSS limits:
- (delta VP > 50 [mmHg])
- (|FP-VP| > 50 [mmHg])
- (|SP-VP| > 50 [mmHg])
- (|EP-VP| > 50 [mmHg])

The CS starts checking the pressures from 5 seconds after the beginning/restart of the test.

Note: Measured pressure values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS pressure values - PS pressure values with 20 mmHg tolerance)</td></tr>
</table>

Title	Description
Level Regulation Test - Level Regulation Pump	CRRT therapies: 1.Prepare pressure - Venous Clamp is closed by CSS only (PSS sets it open) - CSS drives the pumps and opens the AP valve to VP for 2 seconds when VP reaches 365 mmHg: Note: Low Priority Alarm is issued by CSS if pressures measured at VP and SP does not reach 395 mmHg in 40 seconds (timeout) or Arterial Pressure is greater than 0 mmHg. Low Priority Alarm is issued by PSS if pressures measured at VP and SP does not reach 335 mmHg in 45 seconds (timeout). 2.Pressure stabilization I - open Venous Pressure Chamber Level Regulation valve - wait 2 s - Low Priority Alarm is issued by CSS if Arterial Pressure is greater than 0 mmHg 3.Level regulation pump test - increase VP by 20 mmHg (to appr. 420 mmHg) using the Level Regulation Pump - Low Priority Alarm is issued by CSS if 420 mmHg is not reached in 20 seconds (timeout) or Arterial Pressure is greater than 0 mmHg - Low Priority Alarm is issued by PSS if 350 mmHg is not reached in 20 seconds (timeout) 4.Pressure stabilization II - wait 5 s (to stabilize pressure between blood and fluid side through the high flux filter) - Low Priority Alarm is issued by PSS if the time while the Level Regulation Pump is working is greater than 5 seconds 5.Leakage test - open Venous Pressure Chamber Level Regulation valve - connect Arterial pressure sensor to Venous Pressure Chamber

Title	Description
	Low Priority Alarm is issued by CSS and PSS if the monitored values are beyond the predefined limits for the duration of the test (10 s) - CSS limits: - (delta VP > 60 [mmHg]) - (|AP-VP| > 20 [mmHg]) - PSS limits: - (delta VP > 70 [mmHg]) - (|AP-VP| > 20 [mmHg]) 6.Decrease pressure (5 seconds): - decrease VP by 20 mmHg (to appr. 395 mmHg) using the Level Regulation Pump (to set the air spring of the Venous Pressure Chamber to its previous value (prior to the test)) - Venous Clamp is opened by CSS - Low Priority Alarm is issued by PSS if Venous Clamp is not opened or Venous Pressure is not decreased by 10 mmHg for 15 seconds (timeout) Note: Measured pressure values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS pressure values - PS pressure values with 20 mmHg tolerance) SCUF therapy: 1.Prepare pressure - Venous Clamp is closed by CSS only (PSS sets it open) - CSS drives the pumps and opens the AP valve to VP for 2 seconds when VP reaches 365 mmHg: Note: Low Priority Alarm is issued by CSS if pressure measured at VP does not reach 395 mmHg and at EP does not reach 390 mmHg in 40 seconds (timeout) or Arterial Pressure is greater than 0 mmHg. Low Priority Alarm is issued by PSS if pressure measured at VP does not reach 335 mmHg in 45 seconds (timeout). 2.Pressure stabilization I - open Venous Pressure Chamber Level Regulation valve - wait 2 s - Low Priority Alarm is issued by CSS if Arterial Pressure is greater than 0 mmHg

Title	Description
	3.Level regulation pump test - increase VP by 20 mmHg (to appr. 420 mmHg) using the Level Regulation Pump - Low Priority Alarm is issued by CSS if 420 mmHg is not reached in 20 seconds (timeout) or Arterial Pressure is greater than 0 mmHg - Low Priority Alarm is issued by PSS if 350 mmHg is not reached in 20 seconds (timeout) 4.Pressure stabilization II - wait 5 s (to stabilize pressure between blood and fluid side through the high flux filter) - Low Priority Alarm is issued by PSS if the time while the Level Regulation Pump is working is greater than 5 seconds 5.Leakage test - open Venous Pressure Chamber Level Regulation valve - connect Arterial pressure sensor to Venous Pressure Chamber Low Priority Alarm is issued by CSS and PSS if the monitored values are beyond the predefined limits for the duration of the test (10 s) - CSS limits: - (delta VP > 60 [mmHg]) - (|AP-VP| > 20 [mmHg]) - PSS limits: - (delta VP > 70 [mmHg]) - (|AP-VP| > 20 [mmHg]) 6.Decrease pressure (5 seconds): - decrease VP by 20 mmHg (to appr. 395 mmHg) using the Level Regulation Pump (to set the air spring of the Venous Pressure Chamber to its previous value (prior to the test)) - Venous Clamp is opened by CSS - Low Priority Alarm is issued by PSS if Venous Clamp is not opened or Venous Pressure is not decreased by 10 mmHg for 15 seconds (timeout) Note: Measured pressure values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS pressure values - PS pressure values with 20 mmHg tolerance)

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Title	Description
	TPE therapy: 1.Prepare pressure - Venous Clamp is closed by CSS only (PSS sets it open) - CSS drives the pumps and opens the AP valve to VP for 2 seconds when VP reaches 165 mmHg: Note: Low Priority Alarm is issued by CSS if pressures measured at VP and SP does not reach 205 mmHg in 40 seconds (timeout) or Arterial Pressure is greater than 0 mmHg. Low Priority Alarm is issued by PSS if pressures measured at VP and SP does not reach 145 mmHg in 45 seconds (timeout). 2.Pressure stabilization I - open Venous Pressure Chamber Level Regulation valve - wait 2 s - Low Priority Alarm is issued by CSS if Arterial Pressure is greater than 0 mmHg 3.Level regulation pump test - increase VP by 20 mmHg (to appr. 230 mmHg) using the Level Regulation Pump - Low Priority Alarm is issued by CSS if 230 mmHg is not reached in 20 seconds (timeout) or Arterial Pressure is greater than 0 mmHg - Low Priority Alarm is issued by PSS if 160 mmHg is not reached in 20 seconds (timeout) 4.Pressure stabilization II - wait 5 s (to stabilize pressure between blood and fluid side through the high flux filter) - Low Priority Alarm is issued by PSS if the time while the Level Regulation Pump is working is greater than 5 seconds 5.Leakage test - open Venous Pressure Chamber Level Regulation valve - connect Arterial pressure sensor to Venous Pressure Chamber

<table>
<tr><th>Title</th><th>Description</th></tr>
<tr><td></td><td>Low Priority Alarm is issued by CSS and PSS if the monitored values are beyond the predefined limits for the duration of the test (10 s)
- CSS limits:
- (delta VP > 60 [mmHg])
- (|AP-VP| > 20 [mmHg])
- PSS limits:
- (delta VP > 70 [mmHg])
- (|AP-VP| > 20 [mmHg])

6.Decrease pressure (5 seconds):
- decrease VP by 20 mmHg (to appr. 205 mmHg) using the Level Regulation Pump (to set the air spring of the Venous Pressure Chamber to its previous value (prior to the test))
- Venous Clamp is opened by CSS
- Low Priority Alarm is issued by PSS if Venous Clamp is not opened or Venous Pressure is not decreased by 10 mmHg for 15 seconds (timeout)

Note: Measured pressure values are periodically and mutually compared (continuous communication between CS and PS) during the whole operation of the machine for safety reasons (CS pressure values - PS pressure values with 20 mmHg tolerance)</td></tr>
<tr><td>Safety Air Detectors(Venous Safety Air Detector SADV, Calcium Safety Air Detector SADC)</td><td>1.Fluid detection AND,
2.Successful self test (continuously running internal self test checked by CSS and PSS).
3.If self test failed: low priority alarm signal to DSS</td></tr>
</table>

Title	Description
Rinsing (optional)	CRRT therapies: 1.CSS drives: - the Blood Pump at 50 ml/min (rate can be set by user: 10 - 500 ml/min) - volume limit must be set (default: 200 ml) Optional (user can turn Fluid Side Rinsing ON/OFF): - Dialysate pump is regulated to stabilize the Solution Pressure to the predefined value (-15...-5 mmHg) - the Effluent Pump at 8000 ml/h - the Substitution Pump at 6000 ml/h 2. CSS stops the pumps and the machine is Ready for Therapy (again) after the volume set by the user has been delivered by the Blood pump Default rinsing parameters (flow and fluid side) can be selected in User configuration. SCUF therapy: 1.CSS drives: - the Blood Pump at 50 ml/min (rate can be set by user: 10 - 250 ml/min) - volume limit must be set (default: 200 ml) Optional (user can turn Fluid Side Rinsing ON/OFF): - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 300 mmHg 2. CSS stops the pumps and the machine is Ready for Therapy (again) after the volume set by the user has been delivered by the Blood pump Default rinsing parameters (flow and fluid side) can be selected in User configuration. TPE therapy: 1.CSS drives: - the Blood Pump at 50 ml/min (rate can be set by user: 10 - 200 ml/min) - volume limit must be set (default: 200 ml)

Title	Description
	Optional (user can turn Fluid Side Rinsing ON/OFF): - Effluent pump is regulated to stabilize the Transmembrane Pressure to the predefined value (TMP upper limit - 50 mmHg...- TMP upper limit - 35 mmHg) TMP upper limit = TMP max set but maximum 150 mmHg 2. CSS stops the pumps and the machine is Ready for Therapy (again) after the volume set by the user has been delivered by the Blood pump Default rinsing parameters (flow and fluid side) can be selected in User configuration.
Recirculation (optional)	The arterial and venous lines are connected to the same bag. Fluid is circulated at set rate (from the bag from arterial access through the filter to the venous access and back into the bag). CRRT and SCUF therapies: 1.CSS drives: - the Blood Pump at 50 ml/min (rate can be set by user: 10 - 500 ml/min) 2. When the user stops the recirculation process the CSS stops the pumps and the machine is Ready for Therapy (again) Default recirculation flow can be selected in User configuration. TPE therapy: 1.CSS drives: - the Blood Pump at 50 ml/min (rate can be set by user: 10 - 200 ml/min) 2. When the user stops the recirculation process the CSS stops the pumps and the machine is Ready for Therapy (again) Default recirculation flow can be selected in User configuration.

Title	Description
Patient data and therapy parameters setting	User may set parameters on the user interface. For detailed information see UID - User Interface Design (GUI design description).

Title	Description
System configuration	During startup the Display System communicates the complete system configuration data to the Protective System. The Protective System checks the CRC of the data and generates alarm in case of an error. After therapy selection (in preparation) the Display System and the Protective System loads Initial System Configuration data based on the selected therapy and dilution type (BB_InitDefault as init_value, min, max, step, visibility, selectability and pressing state values). If there is a failure in the load of data or different data is loaded by DSS and PSS, the PSS generates alarm (the _SET and _SRI data mismatches). Set parameters are defined in the Signal Attribute Database System configuration requirements are marked as 'S1, S2, etc.' The following attributes are used: - BB_TherapyType (therapy_mode_with_dilution): selects therapy type (with dilution) in which the parameter has to be set - BB_MainState (main_state_id): can be TRMT, TSM, VEX. - BB_InitDefault (init_default): Defines the value, the Display System loads, if the specified therapy is selected. If init_default = '-', BB_Confirm should be 1. - BB_Default (change_value): if 1, value is overwritten during Therapy exchange. Other attributes (min, max, step etc) are overwritten independent from this value. - BB_Min (min): sets the minimum of the settable range of CM - BB_Max (max): sets the maximum of the settable range of CM - BB_Step (step): sets the step of a CM (modifies the calculator behaviour) - BB_Confirm (confirmed): indicates whether the CM is confirmed on the 'enter therapy confirmation window'. - If it is on the confirm window, and the actual value is out of limit, the value is set to invalid (confirmation cannot be fulfilled without entering a new value). - If the CM is not confirmed (e.g.: pressure limits), the value is overwritten with the closer limit (modified to be in the settable range). - BB_Visibility_ST (visibility_st): Controls the default visibility state of a settable CM - BB_Selectability_ST (selectability_st): Controls the default selectability (enabled or disabled) state of a settable CM - BB_Pressing_ST (pressing_st): Controls the default pushing state (pushed or released) of a settable CM

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Title	Description
Ready for Therapy	The machine is ready for Therapy if: - both Blood and Fluid sides are filled, - all the self tests have been finished successfully. Proceed to Therapy when the user presses Next button and connect Patient.

Tbl. 5-2 OMNI: Selftest description

5.4 Periodically 24 h Test Description

Title	Description
Periodic tests (24 h and Syringe Change tests)	-
-	-

Title	Description
General	Every 24 hours during Therapy, the System shall perform the daily tests. First occurance is 24 hours from the beginning of therapy or 24 hours after kit change (i.e. kit exchange resets the 24h timer for the daily tests). The Protective System shall measure the time and execute alarm in case of a missed test. Green LED of lightbar is blinking during tests (except for the visual alarm source test). The Control System initiates an information signal about the selftest. The GUI displays a window (24h selftest window) which: - indicates that the 24h selftests are running, - warns the operator not to touch the machine, - informs the operator about resuming the therapy after selftests are finished, - informs the operator about restarting the selftests in case of any failure. This window covers the Function buttons to prevent the operator from pushing them. In case any test fails the 24h selftest window can be closed and the operator can reach Function buttons (e.g. initiate End of Therapy - Return Blood). During CRRT therapies the Control System shall start daily tests when the following conditions are all true: - Kit Time is reached 24 h or 48 h, - There is no any alarm reaction issued, - Self-tests are not running, - Apply Heparin is not in progress, - Heparin Bolus is not in progress, - VENOUS PRESSURE window is closed, - Change Therapy, Change Dilution and Temporary Disconnect Patient Confirm windows are closed. The daily test shall consist two main phase:

Title	Description
	1. Preparation for Pressure leakage test (there is no target time for this phase of the 24h tests, since the time required for carrying out the pressure leakage test depends on the value of the blood flow set by the user. For example, in case of a low blood flow (10 ml/min) it takes appr. 45-50 s to reach the required pressure level) - Pressure leakage - Audio Alarm - Warmer Relay (not included for SCUF therapy, or in case PS switched the warmer off permanently) - Syringe Pump (not included if 'no anticoagulation' has been selected for the therapy) - Level Regulation (initiated when the required pressure is not reached yet (pressure limit)) - Visual alarm (if there is a free self test channel) 2. Ready for Pressure leakage test - Visual Alarm (in case it has not been carried out yet) - SAD - Level Regulation (in case it has not started yet, but only after Pressure Leakage test) - Power Relay (after 24V dependant tests have been carried out)

Title	Description
Pressure test	Tests: Blood and Fluid side pressure sensors, Venous clamp 1.During Daily Pressure Test the CSS sets the 3-Way Clamp position to Dialysate 2.Venous Clamp is opened by CSS and PSS for 5 seconds then closed by PSS only (CSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected) 3.Prepare Test pressure CSS drives the pumps and opens the AP valve to VP for at least 2 seconds when VP reaches 250 mmHg: In case of CVVH, CVVHD, CVVHDF therapies: Note: Low Priority Alarm is issued by CSS if pressures measured at VP and EP do not reach 250 mmHg - in 120 seconds (timeout) - calculated blood volume is greater than 30 ml - calculated (blood + fluid) volume is greater than 60 ml - venous clamp is opened - difference between VP and FP is greater than 60 mmHg after the AP valve was opened - difference between SP and EP is greater than 60 mmHg after the AP valve was opened Low Priority Alarm is issued by PSS if pressures measured at VP and EP do not reach 230 mmHg and CSS do not indicate to the PSS that the pressures are ready - in 130 seconds (timeout) - calculated blood volume is greater than 40 ml - calculated (blood + fluid) volume is greater than 70 ml - self test is failed by CSS and calculated blood volume is greater than 20 ml - self test is failed by CSS and calculated (blood + fluid) volume is greater than 40 ml - venous clamp is opened - venous clamp is not closed within 8 seconds after start of self-test

Title	Description
	In case of SCUF therapy: Note: Low Priority Alarm is issued by CSS if pressures measured at VP do not reach 250 mmHg - in 120 seconds (timeout) - calculated blood volume is greater than 30 ml - venous clamp is opened - difference between VP and FP is greater than 60 mmHg after the AP valve was opened Low Priority Alarm is issued by PSS if pressures measured at VP do not reach 230 mmHg and CSS do not indicate to the PSS that the pressures are ready - in 130 seconds (timeout) - calculated blood volume is greater than 40 ml - self test is failed by CSS and calculated blood volume is greater than 20 ml - venous clamp is opened - venous clamp is not closed within 8 seconds after start of self-test 4.Venous Clamp is closed by CSS only (PSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected) 5.Set the 3-Way Valve into all-closed state 6.Arterial Pressure sensor test The Control System switches the Arterial Pressure sensor to the Venous Pressure sensor 7. Pressure stabilization I - wait for 5 s 8. The sets the 3-Way Valve to Post-dilution mode for 5 seconds 9. The sets the 3-Way Valve to Pre-dilution mode. The Protective System checks whether all position of the 3-Way Valve have been activated.

Title	Description
	10.Leakage Test Low Priority Alarm is issued by CSS and PSS if the monitored values are beyond the predefined limits for the duration of the test (10 s) - (delta VP > 30 [mmHg]), - (|FP-VP| > 30 [mmHg]), - (|AP-VP| > 20 [mmHg]) separate alarm in CSS (Pressure valve error instead of Pressure test (24h) failed), - (delta EP > 30 [mmHg]) only in CVVH, CVVHD, CVVHDF therapies, - (|SP-EP| > 30 [mmHg]) only in CVVH, CVVHD, CVVHDF therapies.
Power relay test	This test checks the safety power relay, which is used by PSS in case of any alarm detection. At the beginning of test the PSS switches OFF the power relay for 2 s, after that it switches ON again. The PSS and CSS check their own supply voltage continuously. The test is finished successfully when PSS and CSS detect the supply voltage switching OFF/ON after each other. The overall timeout in CSS is 5 s. (CS input signal: PAUSE_STAT_CS) (PS output signal: SHUTDOWN) 1.PSS turns it off (OFF for 2 s). 2.PSS and CSS checks the voltage level (24VSW), PSS timeout is 4 s, CSS timeout is 3 s. 3.PSS turns it on. 4.PSS and CSS checks the voltage level (24VSW), PSS timeout is 6 s, CSS timeout is 5 s.

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Title	Description
Warmer relay test	During daily test the following warmer relay test is performed This test checks the Warmer relay, which will be used by PSS in case of any warmer alarm detection. At the beginning of test PSS switches ON the warmer relay for 1 s, then turns OFF the warmer relay for 2 s, and finally switches the relay ON again. CSS checks its own supply voltage continuously. The test is finished successfully when CSS detects the supply voltage switching ON/OFF/ON after each other. (CS input signal: WRM_ENABLED_PS) (PS output signal: WRM_HTR_PS) 1.PSS turns it on (ON for 1 s). 2.CSS checks the voltage level (Warmer 24V), timeout is 2 s. 3.PSS turns it off (OFF for 2 s) 4.CSS checks the voltage level (Warmer 24V), timeout is 2 s. 5.PSS turns it on 5.CSS checks the voltage level (Warmer 24V) , timeout is 2 s. Test is not performed if the Warmer switched off for the therapy
SAD test	The CS intiates selftest on the SADV reset pin. The CS and PS checks if the SADV selftest is performed successfully The CS intiates selftest on the SADC reset pin. The CS and PS checks if the SADC selftest is performed successfully
Visual alarm source test	1.CSS turns on the RED LEDs for 1 s - checked by PSS. 2.CSS turns on the YELLOW LEDs for 1 s - checked by PSS. 3.CSS turns on the GREEN LEDs for 1 s - checked by PSS. 4.PSS turns on the RED LEDs for 1 s - checked by PSS. 5.if any of the checked values returns OFF state or self test lasts beyond time out (10 s) by PSS -> Low Priority Alarm

Title	Description
Audio source test	1.Two 0.5 s beeps generated by PSS on buzzer. 2.detected by the microphone (PS). 3.Two 0.5 s beeps generated by DSS on speaker requested by CSS. 4.detected by the microphone (PS). 5.if any of the sounds is not detected by PS -> Low Priority Alarm
Level Regulation test	Tests the Protective System ability to identify running level regulation pump (every 24 h) - The Protective System checks that the level regulation pump is stopped. - At the beginning of the leakage test - pressure preparation the Control System shall push air into the pre-filter chamber with the level regulation pump (0.5 s). - The Protective System checks that the level regulation pump is started. - The Protective System checks that the level regulation pump is stopped after the level regulation pump is started. - Automatic level regulation is switched back

Title	Description
3 Way Valve selftest	Daily Pressure Test includes the 3 Way Valve selftest. 1.During Daily Pressure Test the CSS sets the 3-Way Clamp position to Dialysate 2.Venous Clamp is opened by CSS and PSS for 5 seconds then closed by PSS only (CSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected) 3.Prepare Test pressure CSS drives the pumps and opens the AP valve to VP for at least 2 seconds when VP reaches 250 mmHg: In case of CVVH, CVVHD, CVVHDF therapies: Note: Low Priority Alarm is issued by CSS if pressures measured at VP and EP do not reach 250 mmHg - in 120 seconds (timeout) - calculated blood volume is greater than 30 ml - calculated (blood + fluid) volume is greater than 60 ml - venous clamp is opened - difference between VP and FP is greater than 60 mmHg after the AP valve was opened - difference between SP and EP is greater than 60 mmHg after the AP valve was opened Low Priority Alarm is issued by PSS if pressures measured at VP and EP do not reach 230 mmHg and CSS do not indicate to the PSS that the pressures are ready - in 130 seconds (timeout) - calculated blood volume is greater than 40 ml - calculated (blood + fluid) volume is greater than 70 ml - self test is failed by CSS and calculated blood volume is greater than 20 ml - self test is failed by CSS and calculated (blood + fluid) volume is greater than 40 ml - venous clamp is opened - venous clamp is not closed within 8 seconds after start of self-test

Title	Description
	In case of SCUF therapy: Note: Low Priority Alarm is issued by CSS if pressures measured at VP do not reach 250 mmHg - in 120 seconds (timeout) - calculated blood volume is greater than 30 ml - venous clamp is opened - difference between VP and FP is greater than 60 mmHg after the AP valve was opened Low Priority Alarm is issued by PSS if pressures measured at VP do not reach 230 mmHg and CSS do not indicate to the PSS that the pressures are ready - in 130 seconds (timeout) - calculated blood volume is greater than 40 ml - self test is failed by CSS and calculated blood volume is greater than 20 ml - venous clamp is opened - venous clamp is not closed within 8 seconds after start of self-test 4.Venous Clamp is closed by CSS only (PSS sets it open) - Venous Clamp state is checked by both CSS and PSS (closed state shall be detected) 5.Set the 3-Way Valve into all-closed state 6.Arterial Pressure sensor test The Control System switches the Arterial Pressure sensor to the Venous Pressure sensor 7. Pressure stabilization I - wait for 5 s 8. The sets the 3-Way Valve to Post-dilution mode for 5 seconds 9. The sets the 3-Way Valve to Pre-dilution mode. The Protective System checks whether all position of the 3-Way Valve have been activated.

Title	Description
	10.Leakage Test Low Priority Alarm is issued by CSS and PSS if the monitored values are beyond the predefined limits for the duration of the test (10 s) - (delta VP > 30 [mmHg]), - (|FP-VP| > 30 [mmHg]), - (|AP-VP| > 20 [mmHg]) separate alarm in CSS (Pressure valve error instead of Pressure test (24h) failed), - (delta EP > 30 [mmHg]) only in CVVH, CVVHD, CVVHDF therapies, - (|SP-EP| > 30 [mmHg]) only in CVVH, CVVHD, CVVHDF therapies.
Syringe pump selftest	Backward rotation detection is tested during 24 hour test The Control System shall rotate the Syringe pump reverse mode for (1 + 1/3) whole rotation The Protective System shall detect the reverse rotation in 12 seconds The Control System shall rotate the Syringe pump forward mode for (1 + 1/3) whole rotation

Tbl. 5-3 OMNI: 24 h test description

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5.5 Service Screens in Therapy

This menu provides an overview about all components that belong to the blood side.

1 Pumps
2 Load cell
3 Pressures
4 Total Volumes
5 Diviations
6 Chambers
7 Level regulation pump
8 Syringe pump
9 Calcium SAD
10 Venous SAD
11 Venous Clamp

Fig. 5-4 Service screen *Blood Side*

This menu provides all current values and status of the blood side components. The following values and status are displayed:

- Speed of the blood pump and the citrate pump
- Weight hanging on the citrate load cell
- Pressures of VP, AP and FP
- Air detection, air bolus and air accumulation of the venous SAD
- Venous clamp
- Level of the pre filter chamber and the corresponding valve
- Level of the venous chamber and the corresponding valve
- Status of the arterial valve
- Status and direction of the level regulation pump
- Status and direction of the syringe pump.
- Status of lock detector and syringe detector of the syringe pump
- Air detection, air bolus and air accumulation of the calcium SAD

This menu provides an overview about all components that belong to the fluid side.

1 Pumps
2 NFR
3 Load cells
4 Diviations
5 Pressures
6 Chambers
7 Level regulation pump
8 3-way clamp
9 Blood leak detector bld
10 Warmer

Fig. 5-5 Service screen *Fluid Side*

This menu provides all current values and status of the fluid side components. The following values and status are displayed:

- Speed of the dialysate pump, effluent pump and the substitution pump
- Weights hanging on the dialysate, effluent and substitution load cell
- Pressures of EP and SP
- Level of the solution chamber and the corresponding valve
- Status of the effluent valve
- Status and direction of the level regulation pump
- Status of the 3-way clamp
- Blood detection, actual value and the calibration set point of the blood leak detector
- Status of the warmer and the warmer door
- Set temperature, outlet temperature and plate temperature of the warmer

This menu provides an overview about all components which are not located on the fluid side or the blood side.

1 Therapy parameters
2 Working time counter
3 Audio
4 Detectors
5 Status indicator lights
6 Screensaver
7 Voltages
8 Battery
9 Alarm explanation code

Fig. 5-6 Service screen *Other*

This menu provides all current values and status of components which are not located on one of the two manifolds. The following values and status are displayed:

- Therapy parameters
- Working time counter
- Sound level and sound type which is activated in the machine
- Door and kit detectors of the blood side and the fluid side
- Status AIO board and DIO board: Both are able to run if the led is lit.
- Status of the indicator lights
- Status and time for the screensaver
- Power source (plug or battery) of the machine
- Output voltages of the power supply
- Voltage and charge status of the battery

This menu provides an overview about the flow scheme of the selected therapy type.

1 Menu: Flow scheme

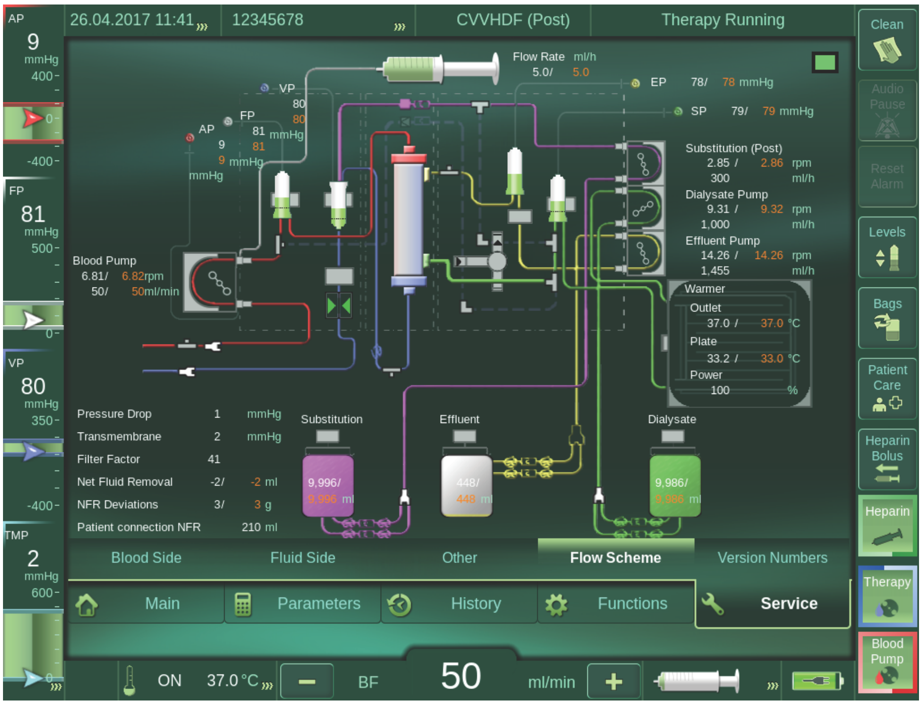

Fig. 5-7 Service screen *Flow Scheme*

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This menu provides a complete flow scheme of the selected therapy. All CS and PS values of the running pumps, load cells, warmer, pressure sensor and net fluid removal are displayed. The status of the 3-way clamp and the level detectors are visible. The filter factor, pressure drop and the transmembrane pressure is displayed.

This menu provides information about the version numbers of the software and hardware components of the machine.

1 Version numbers
2 HW Versions
3 Firmware: Blood leak detector; barcode scanner; touch screen
4 Unit info
5 Load cells
6 Pumps/clamps
7 I/O card

Fig. 5-8 Service Screen: Version numbers

This menu provides information about the version numbers of the software and hardware components of the machine. The following information are displayed:

- Version numbers of the software
- Serial number of the machine
- Version numbers of main board, blood side board, fluid side board and warmer board
- Firmware version of the blood leak detector, barcode scanner and touch
- Serial number, boot loader version and application version of all four load cells
- Serial number, firmware, pump code and pump rev of all five pumps and the 3-way clamp
- Serial number, device number and product ID of the three I/O cards

5.6 Trouble Shooting

N/A

5.7 Disassembly and Assembly of Components

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.

NOTICE!

If it is needed to cut a cable tie, check all cables which belong to this cable harness for damages. When the repair activity is finished successfully, make sure that all removed cable ties are replaced on the same position.

NOTICE!

When the repair activity is finished successfully, check the function of the machine according to the repair matrix.

Before starting any service activity remove the rear housing by loosening the 10 screws. Disconnect the 24 V of the main board (J 18) and set the jumper on J 12 to mute the machine. After finishing the service activity remove the Jumper J 12 and connect the plug J 18.

1 J 12

2 J 18

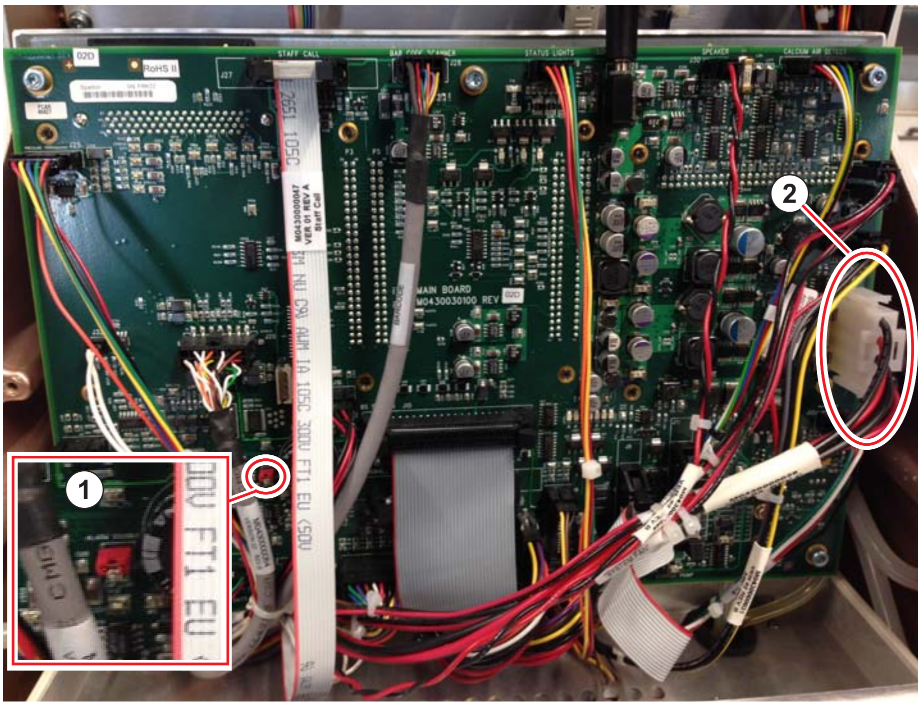

Fig. 5-9 Main board 24 V and J 12

5.7.1 Rear Housing

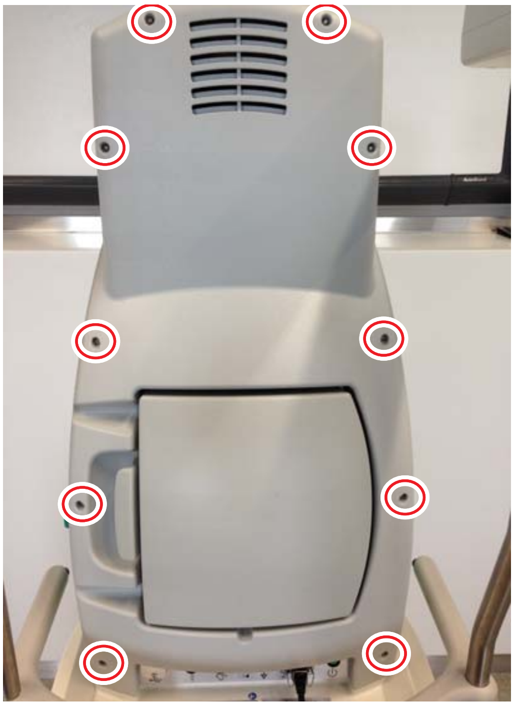

Fig. 5-10 Screws rear housing

Dissambling if Rear Housing

1. Disconnect mains plug.
2. Loosen 10 screws to disassemble the rear housing.

Assembling of Rear Housing

1. Fasten the 10 screws to assemble the rear housing.
2. Connect mains plug.

5.7.2 Lower Housing

Disassembling of the Lower Housing

1. Disconnect mains plug.

Fig. 5-11 Load cells

2. Loosen hex screws and remove hooks of the load cells ① .

NOTICE!

Do not use hole ③ because it is used for the microphone.

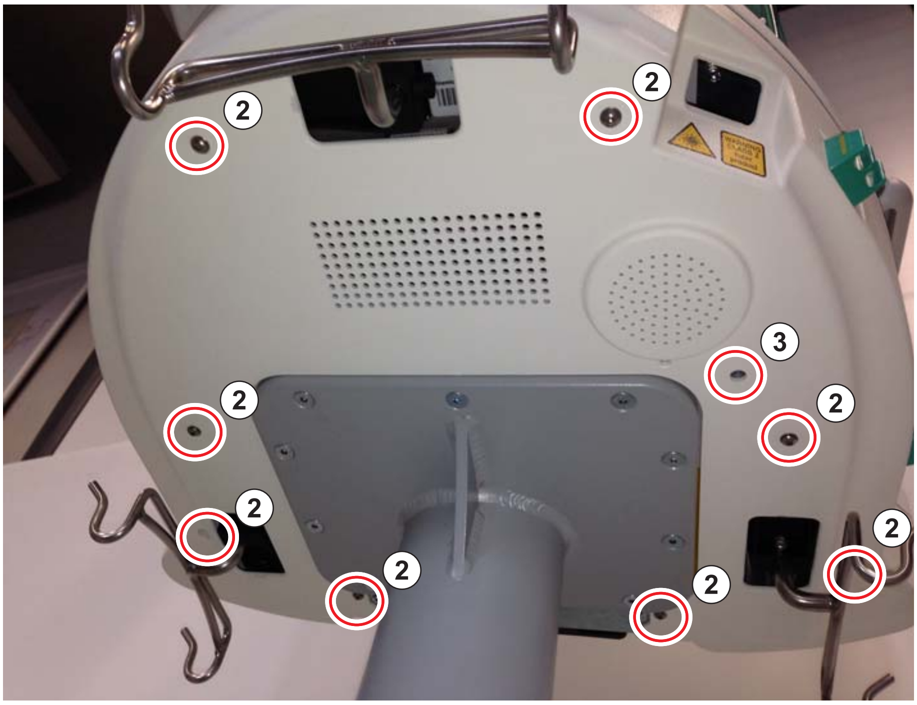

Fig. 5-12 Screws lower housing

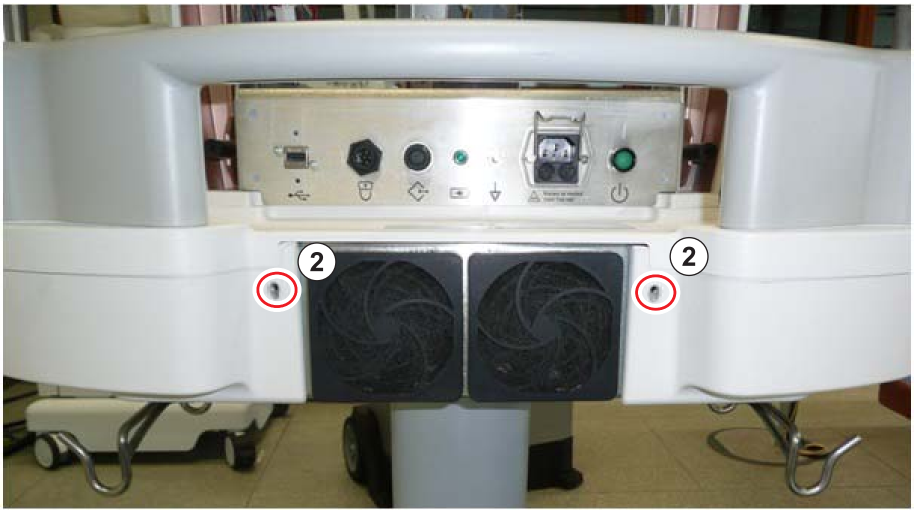

Fig. 5-13 Screws rear lower housing

3. Loosen the 10 screw ② to disassemble the lower housing.

Assembling of the Lower Housing

1. Fasten the 10 screws to assemble the lower housing.

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The hooks are identified by *D* for dialysate load cell ① (green marked tube holder), an *E* for effluent load cell ② (no tube holder) and *S* for substitution load cell ③ (purple marked tube holder). Fix the marked hook to the corresponding load cell.

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1 Middle load cell (no colour tube holder)

2 Left load cell (purple color code on tube holder)

3 Right load cell (green colour code on tube holder)

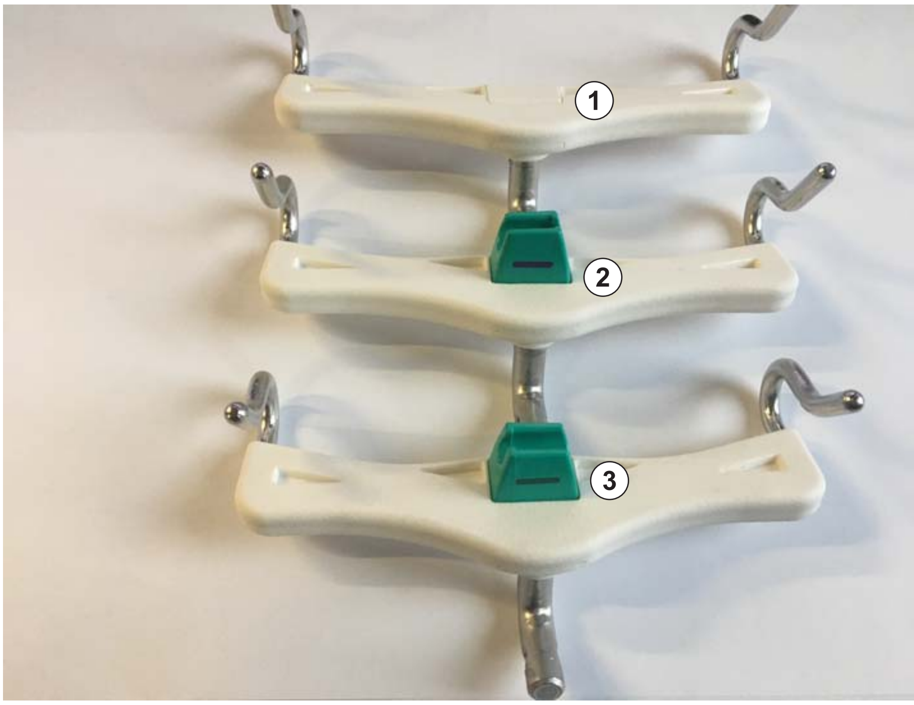

Fig. 5-14 Labeling load cell hooks

2. Fasten the hex screws to assemble the hooks on the load cells.
3. Connect mains plug.

5.7.3 Warmer

Prerequisites

- Rear housing is removed.

Disassembling of the Warmer

1. Loosen two captive knurled screws of the warmer assembly ① .

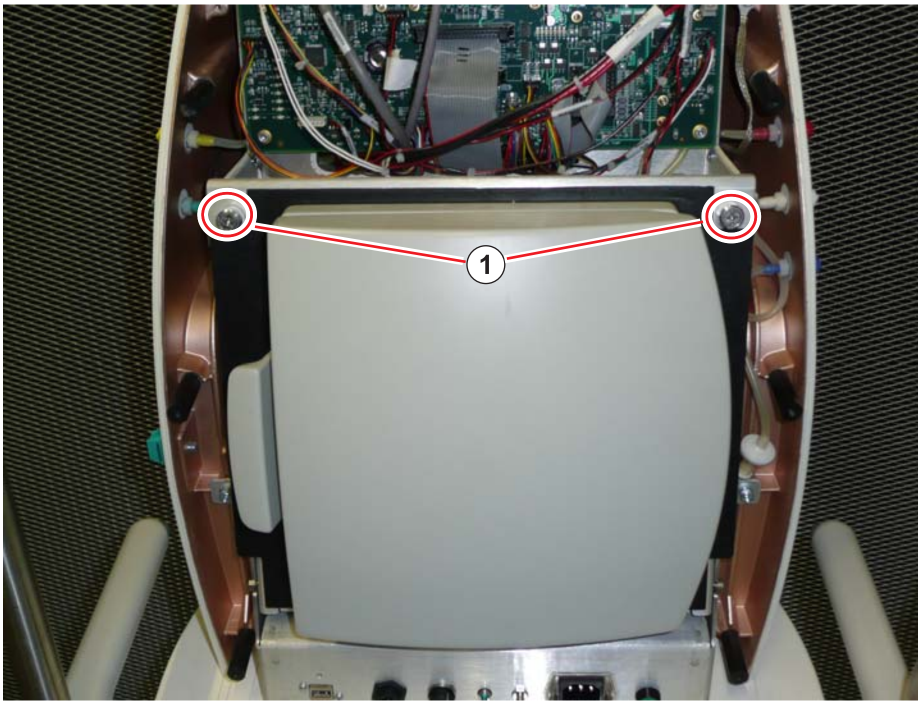

Fig. 5-15 Knurled screws warmer

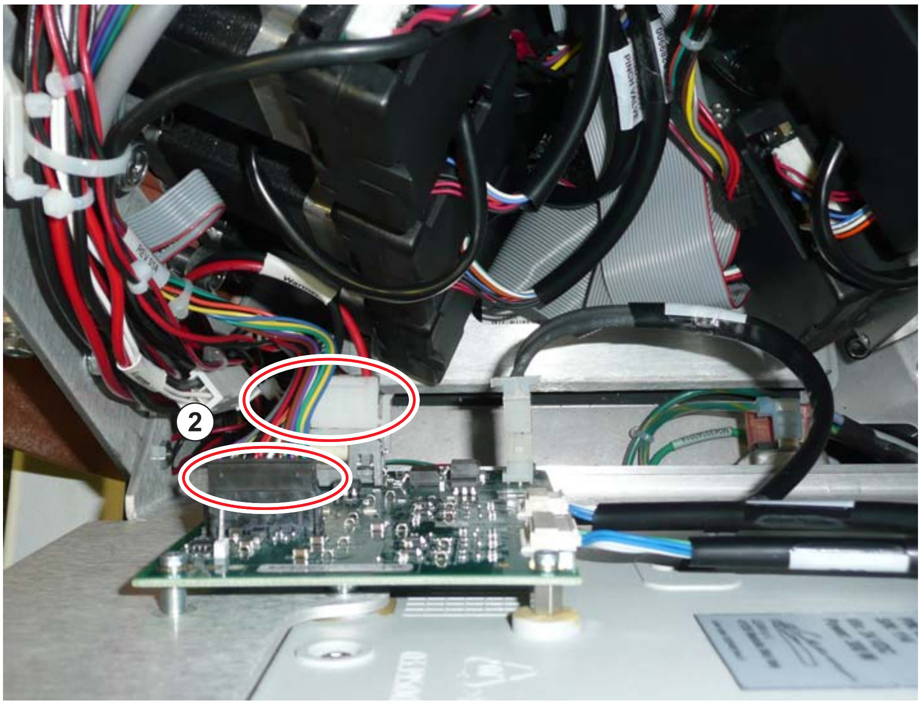

Fig. 5-16 Warmer board connectors

2. Disconnect warmer board connectors ② .
3. Take out complete warmer assembly.

Fig. 5-17 Disassembled warmer

Assembling of the Warmer

1. Insert complete warmer assembly.
2. Connect both warmer connectors.
3. Fasten the two captive knurled screws

Prerequisites

- Warmer is disassembled.

Disassembling of the Warmer Board

1. Disconnect CS sensor ①

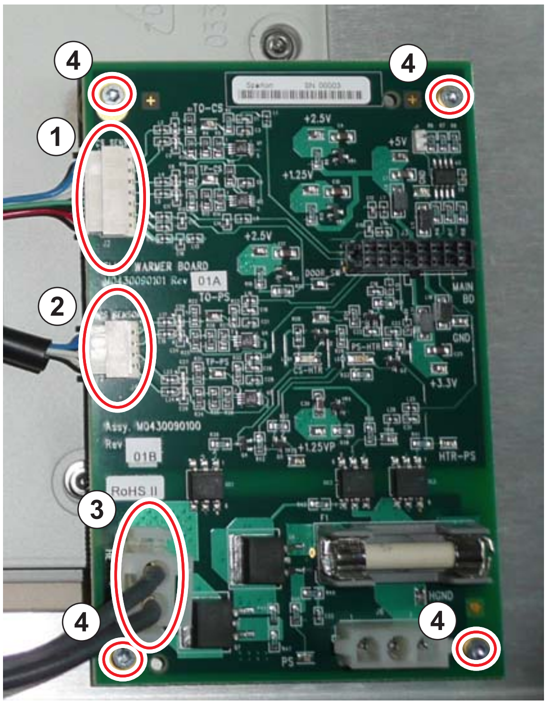

Fig. 5-18 Warmer board

2. Disconnect PS sensor ② .
3. Disconnect heater connector ③ .
4. Loosen the 4 screws ④ to disassemble the warmer board.

Assembling of the Warmer Board

1. Fasten the 4 screws ④ to assemble the warmer board.
2. Connect CS sensor cable ① , PS sensor cable ② and heater cable ③ .

5.7.4 Blood Side Manifold

Prerequisites

- Warmer is disassembled

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Disassembling of the Blood Side Manifold

1. Loosen the screw ① for grounding connection of the blood side manifold.

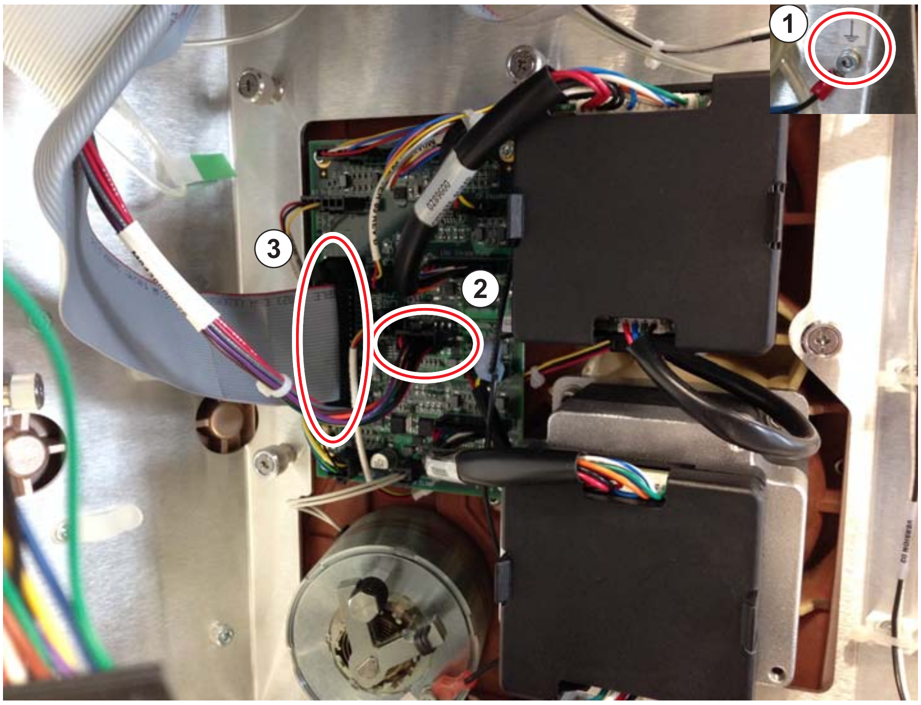

Fig. 5-19 Connectors blood side manifold

2. Disconnect pump control cable ② (blood side board J 9).
3. Disconnect the ribbon cable ③ (blood side manifold J 6 to main board).

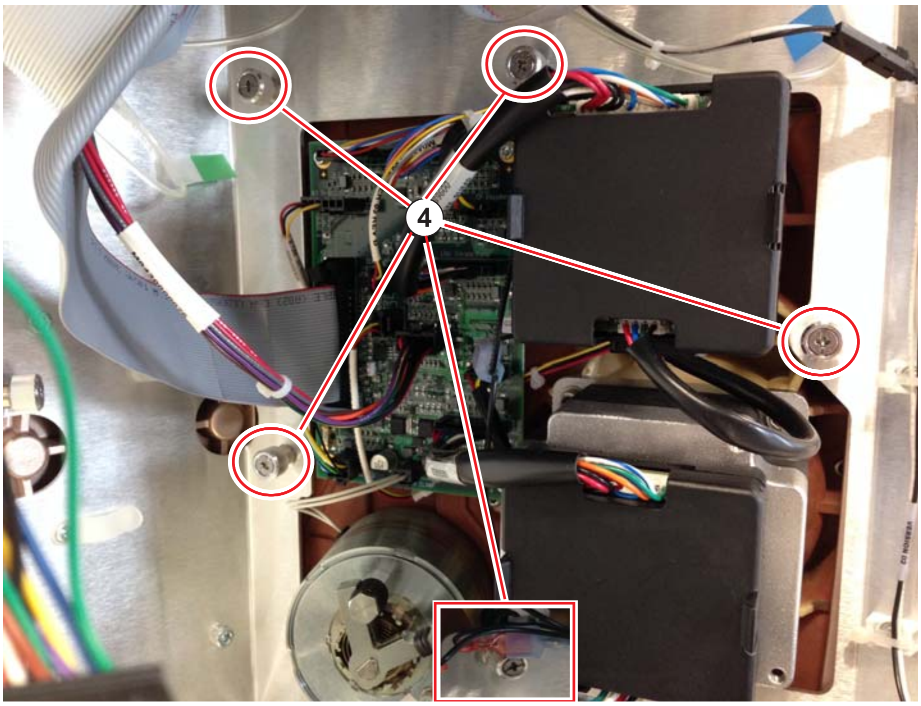

Fig. 5-20 Knurled screws blood side manifold

4. Loosen five captive knurled screws of the blood side manifold ④ .
5. Take out the blood side manifold.

Assembling of the Blood Side Manifold

1. Insert the blood side manifold into the two existing slots of the housing.

NOTICE!

Pay attention that no cable is squeezed between the manifold and the machine housing.

2. Connect pump control cable.
3. Connect ribbon cable.
4. Fasten the five captive knurled screws of the blood side manifold.
5. Assemble grounding connection to the housing.
6. Assemble warmer assembly.

5.7.4.1 Blood Side Door

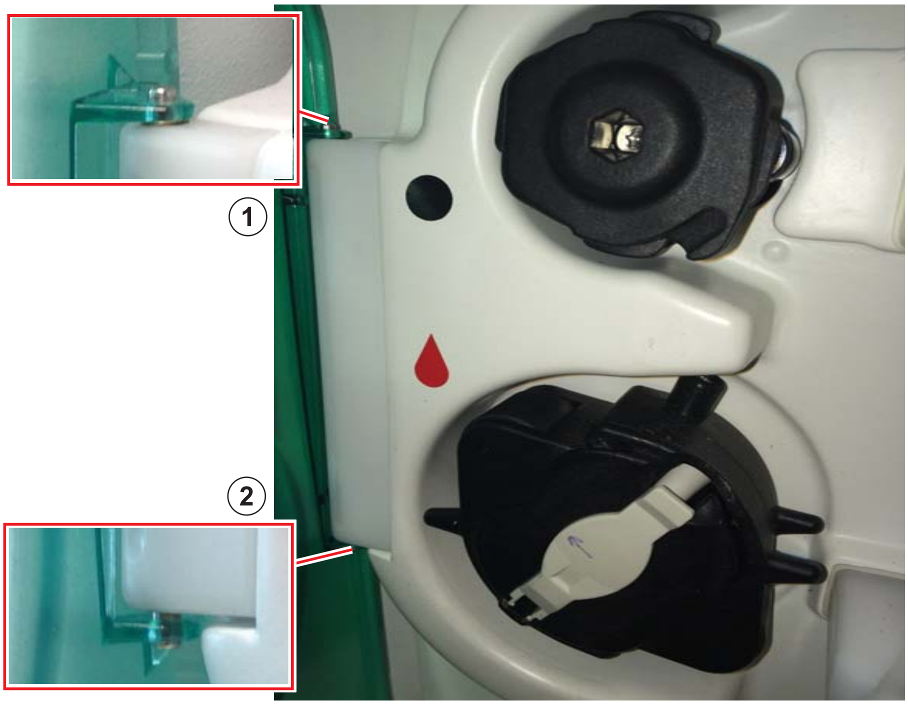

Fig. 5-21 Blood side door

Disassembling of the Blood Side Door

1. Open blood side door.
2. Push upper pin of the blood side door down ① .
3. Skip and take out blood side door.

Assembling of the Blood Side Door

1. Insert the blood side door on the lower pin of the blood side door ② .
2. Push upper pin of the blood side door down ① and assemble the blood side door.

5.7.4.2 Blood Side Board

NOTICE!

Machine will not pass the selftest due to a bad or wrong cable connection.

- Connect all cables regarding the labeling on the cable and the labeling on the board.
- All connections are described in the service manual chapter 8.

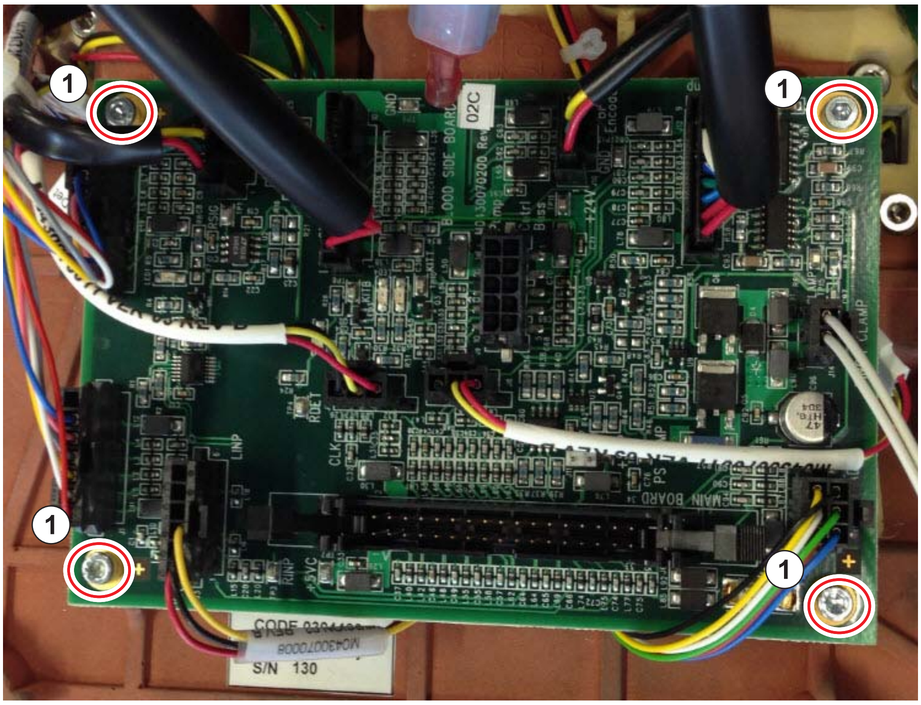

Fig. 5-22 Blood side board

Prerequisites

- Blood side manifold is disassembled

Disassembling of the Blood Side Board

1. Disconnect all connectors of the blood side board.
2. Loosen the 4 screw ① to disassemble the blood side board.

Assembling of the Blood Side Board

1. Fasten the 4 screws ① to assemble blood side board.
2. Connect all connectors of the blood side board.

5.7.4.3 Blood Pump

Prerequisites

- Blood side manifold is disassembled

Disassembling of the Blood Pump

1. Disassemble blood pump roller by opening the arm of the blood pump roller ① .

Fig. 5-23 Blood pump roller closed

Fig. 5-24 Blood pump roller opened

2. Turn the pump roller until it is possible to take out the roller ② .

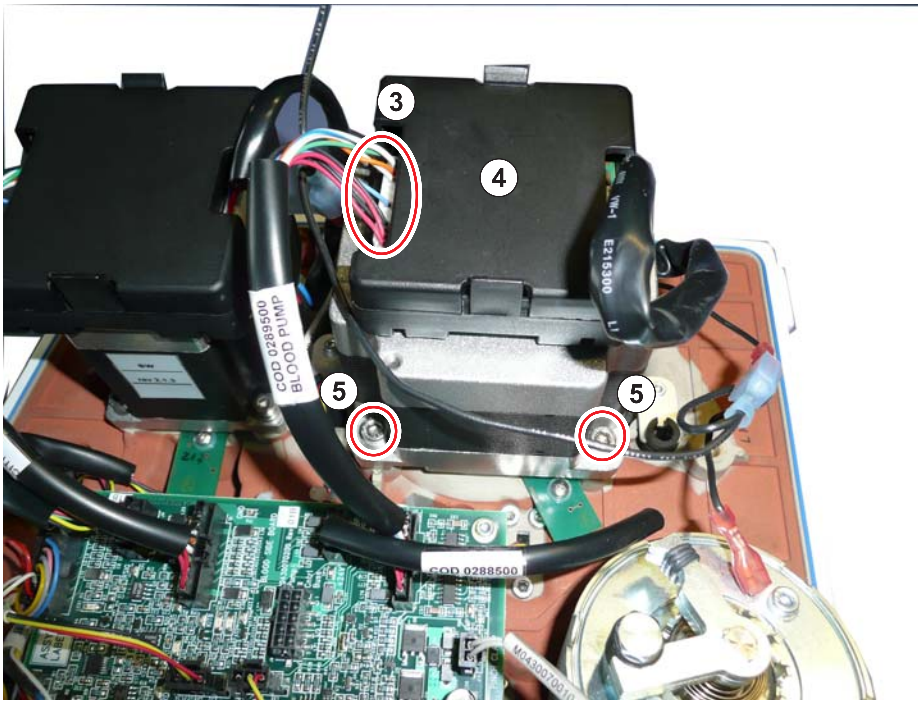

Fig. 5-25 Blood pump rear view

3. Disconnect blood pump cable from the blood pump motor ③
4. Disassemble the cover of the pump motor ④ (dip switch position 0)

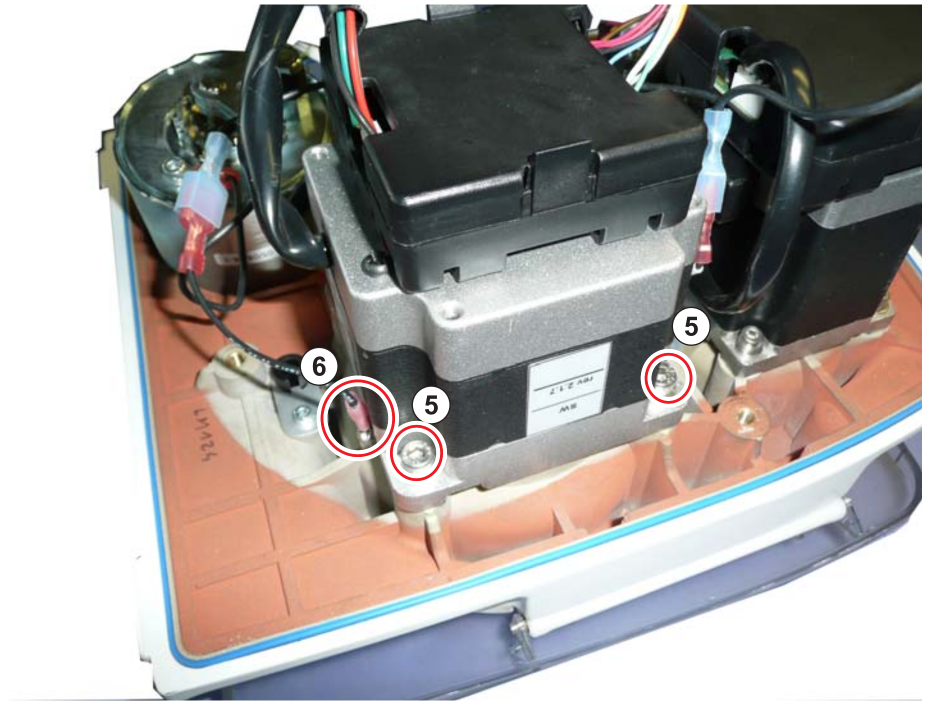

Fig. 5-26 Blood pump rear view

5. Disassemble the blood pump by loosening the screws ⑤
6. Disassemble grounding connector ⑥

Assembling of the Blood Pump

1. Check/set blood pump code ① (dip switch position 0).

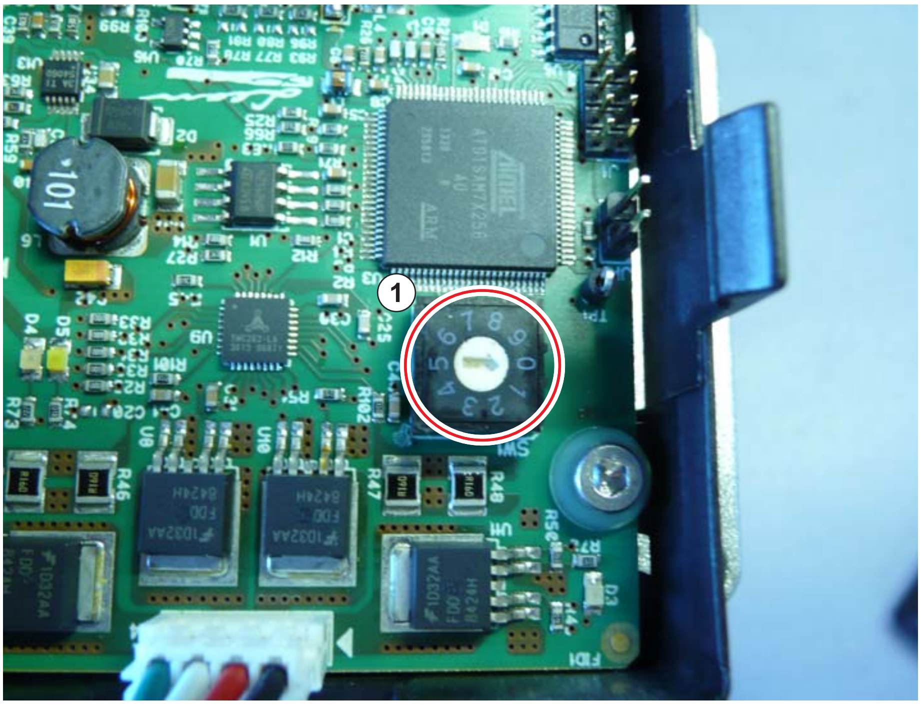

Fig. 5-27 Blood pump code

2. Close housing of the blood pump motor.
3. Fasten the screws to assemble the pump.
4. Connect grounding on the blood pump.
5. Close the roller arm to assemble the blood pump roller.

5.7.4.3.1 Blood Pump Cable

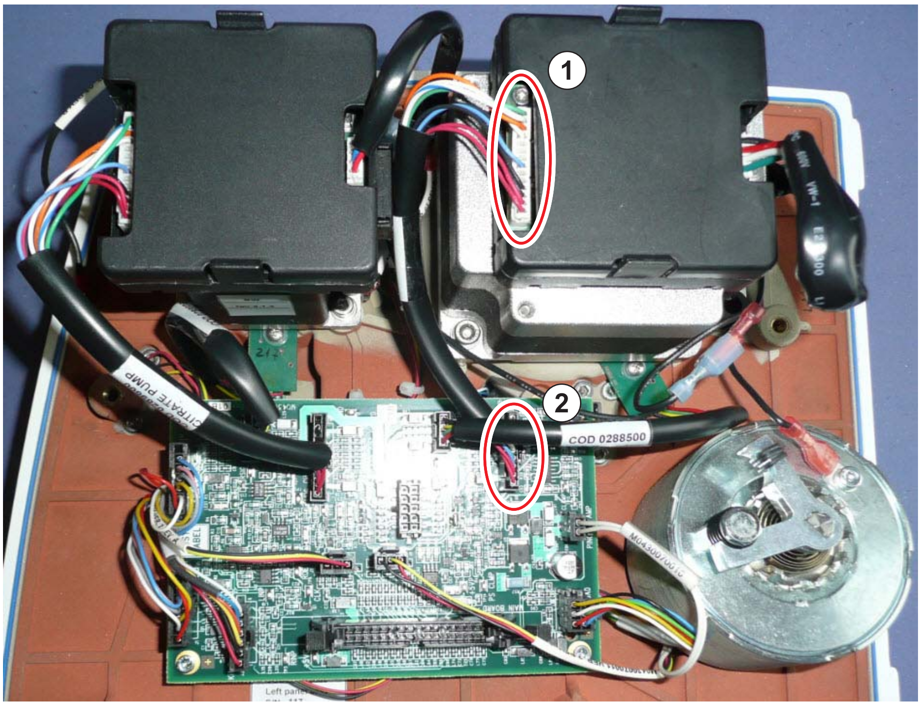

Fig. 5-28 Blood pump cable

Prerequisites

- Blood side manifold is disassembled

Disassembling of the Blood Pump Cable

1. Disconnect blood pump cable from the blood pump motor ① .
2. Disconnect blood pump cable from the blood side board ② (J12).

Assembling of the Blood Pump Cable

1. Connect blood pump cable to the blood side board ② (J12).
2. Connect blood pump cable to the blood pump motor ① .

5.7.4.3.2 Blood Pump Encoder Board

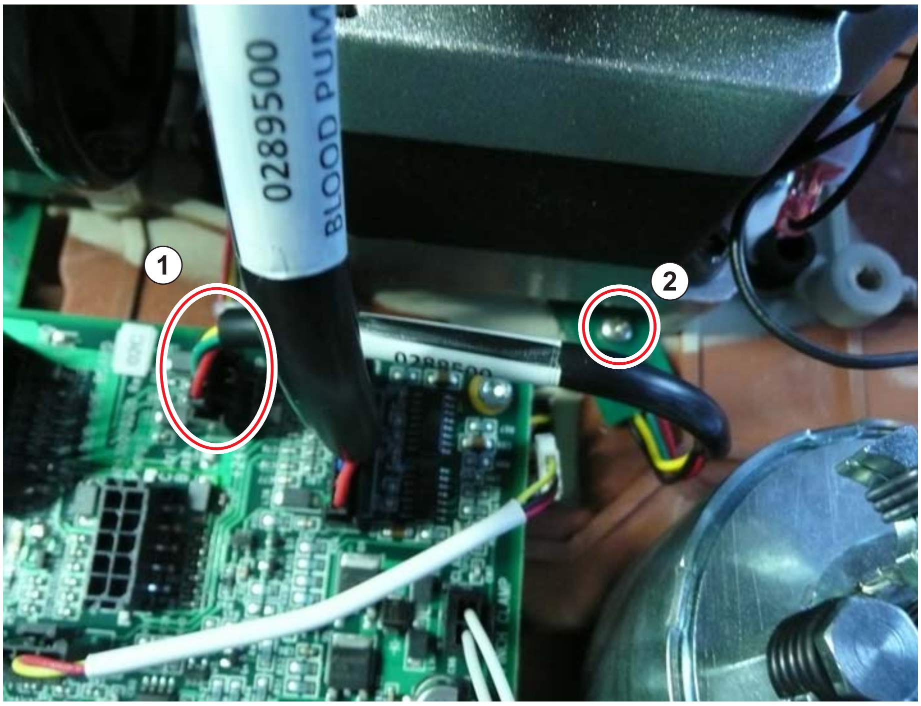

Fig. 5-29 Blood pump encoder board

Prerequisites

- Blood side manifold is disassembled

Disassembling of the Blood Pump Encoder Board

1. Disconnect cable ① from the blood side board (J10).
2. Loosen screw ② to disassemble the blood pump encoder board.

Assembling of the Blood Pump Encoder Board

1. Fasten the screw ② to assemble the blood pump encoder board.
2. Connect the cable to blood side board (J10).

5.7.4.3.3 Blood Pump Roller

Fig. 5-30 Blood pump roller closed

Fig. 5-31 Blood pump roller opened

Disassembling of the Blood Pump Roller

1. Open the blood pump roller ① .
2. Turn the pump roller 90° clockwise until it is possible to take out the roller ② .

Assembling of the Blood Pump Roller

1. Assemble the roller on the blood pump shaft.
2. Turn the pump roller 90° clockwise until it is possible to close the roller arm and fix the blood pump roller.

5.7.4.4 Citrate Pump

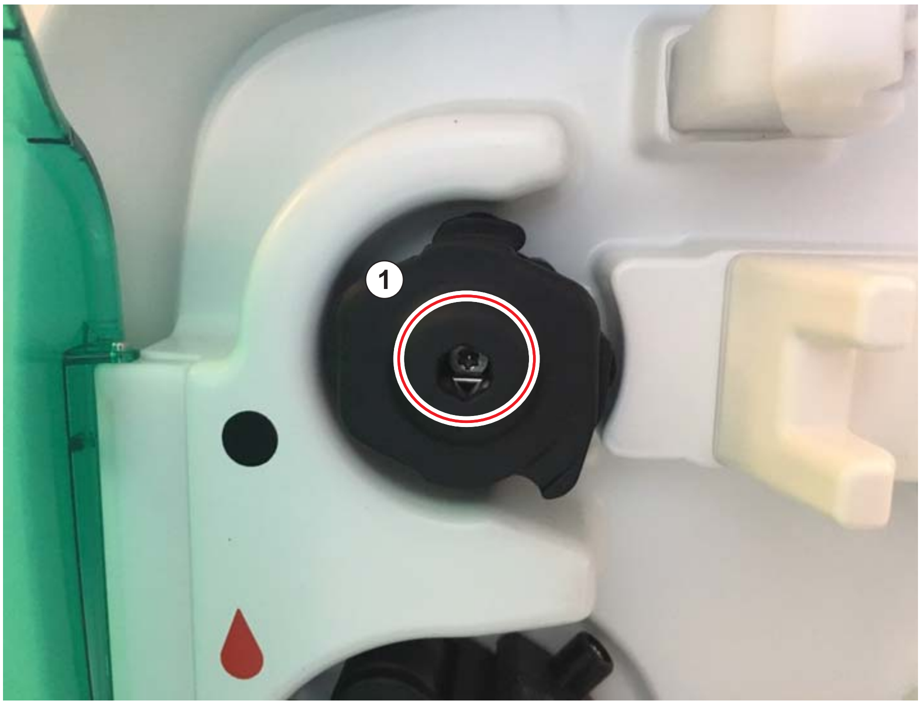

Fig. 5-32 Citrate pump roller

Prerequisites

- Blood side manifold is disassembled

Disassembling of the Citrate Pump

1. Open blood side door.
2. Remove citrate pump roller by loosing the screw ① .

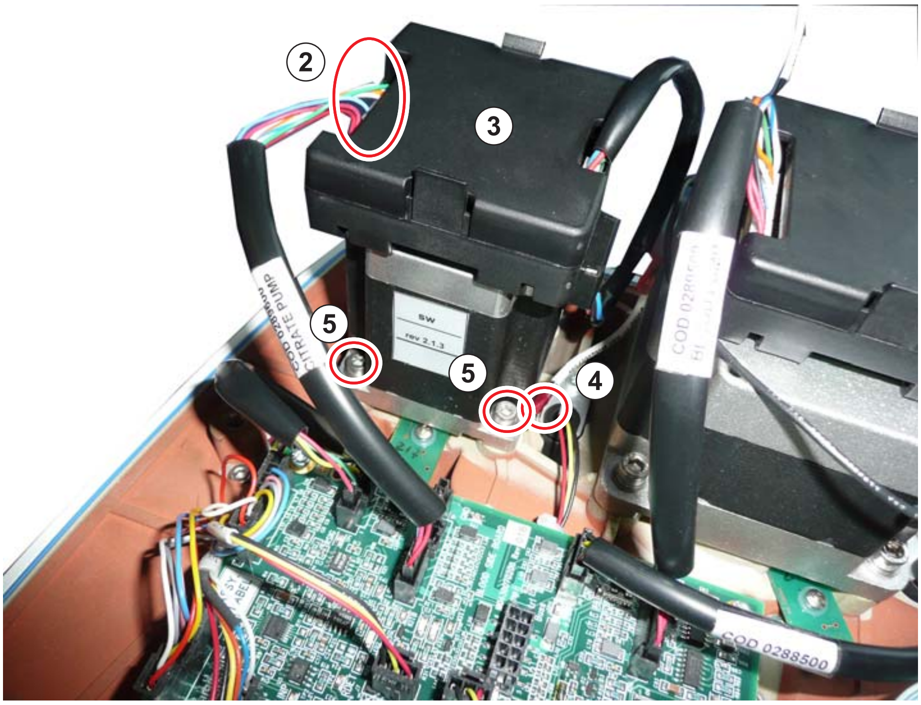

Fig. 5-33 Citrate pump front view

3. Disconnect citrate pump cable from the citrate pump motor ② .

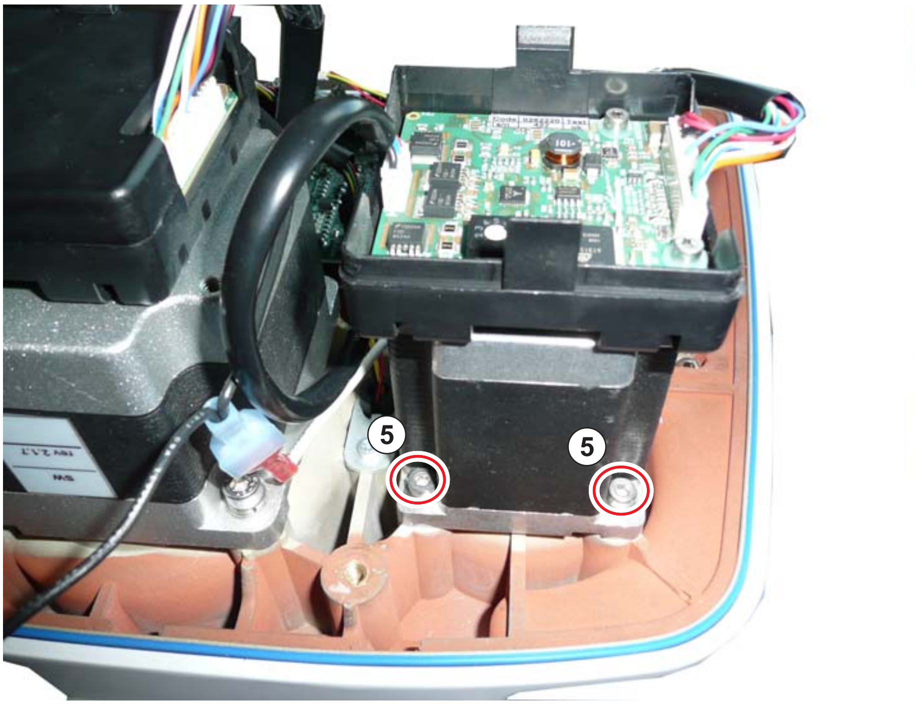

Fig. 5-34 Citrate pump rear view

4. Disassemble the cover of the pump motor ③ (dip switch position 4).
5. Disassemble grounding connector ④ .
6. Disassemble the citrate pump by loosening the screws ⑤ .

Assembling of the Citrate Pump

1. Check/set citrate pump code ① (dip switch position 4).

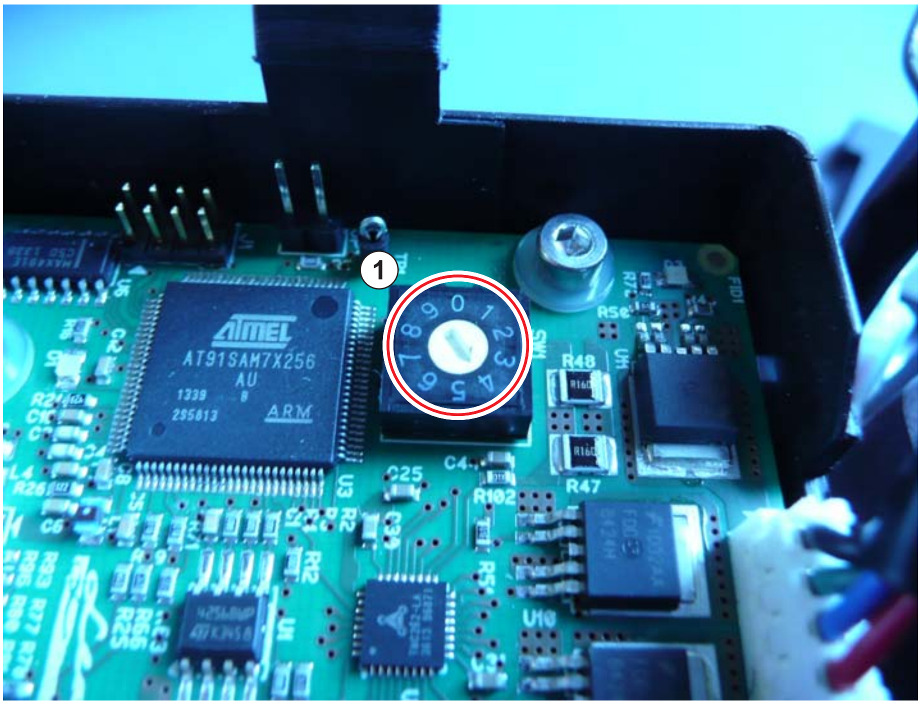

Fig. 5-35 Citrate pump code

2. Close housing of the citrate pump motor.
3. Fastening the screws on the manifold to assemble citrate pump.
4. Connect grounding on the citrate pump.
5. Fasten the screw in the middle of the roller to assemble the citrate pump roller.
6. Check the home position of the citrate pump roller in TSM.

5.7.4.4.1 Citrate Pump Cable

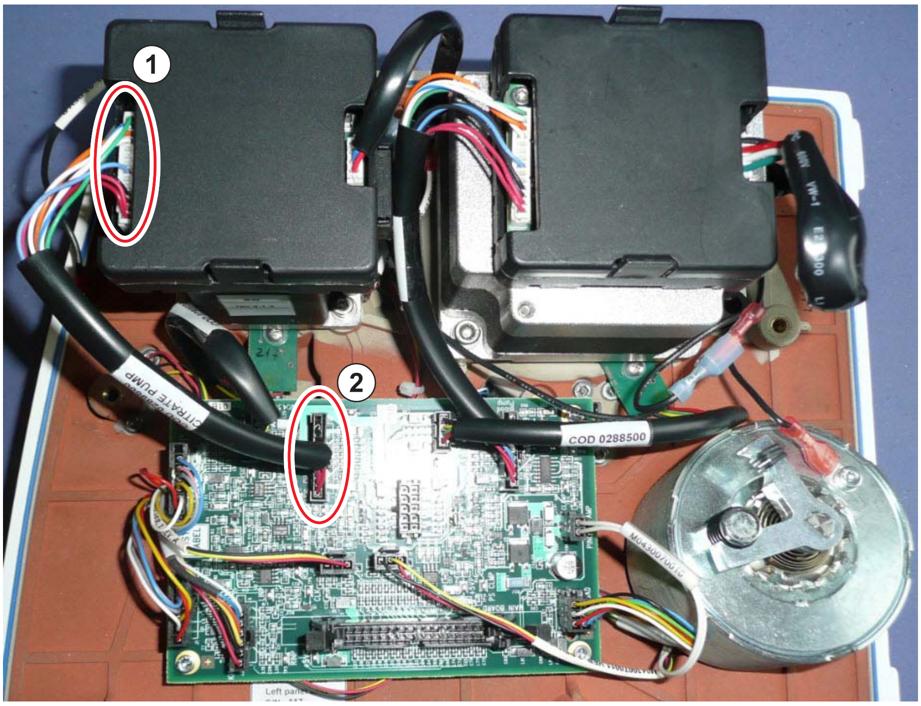

Fig. 5-36 Citrate pump cable

Prerequisites

- Blood side manifold is disassembled

Disassembling of the Citrate Pump Cable

1. Disconnect citrate pump cable from the citrate pump motor ① .
2. Disconnect citrate pump cable from the blood side board ② (J5).

Assembling of the Citrate Pump Cable

1. Connect citrate pump cable to the blood side board ② (J5).
2. Connect citrate pump cable to the citrate pump motor ① .

5.7.4.4.2 Citrate Pump Encoder Board

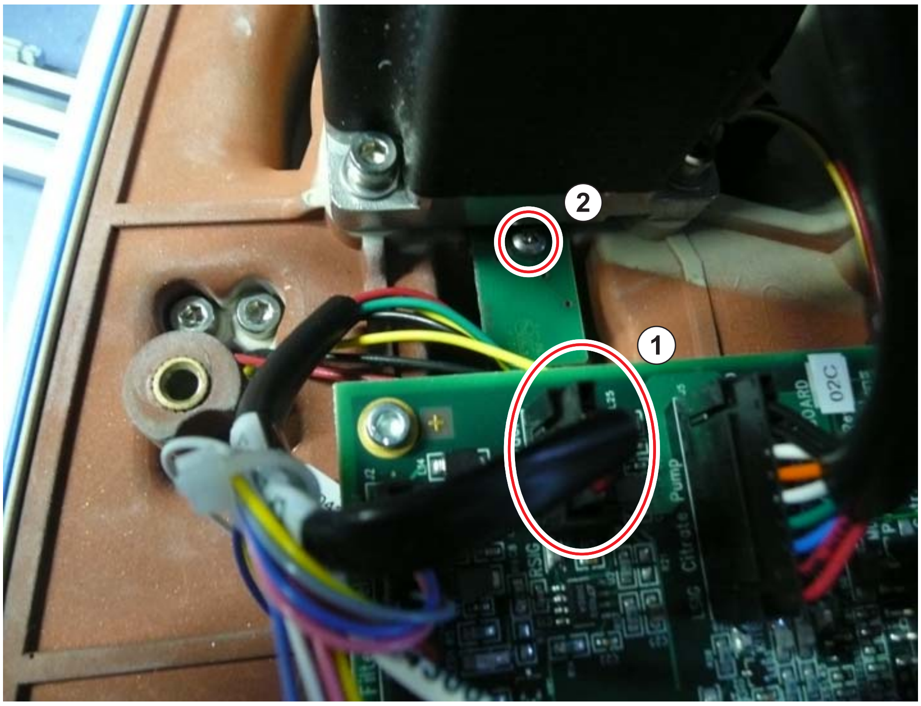

Fig. 5-37 Citrate pump encoder board

Prerequisites

- Blood side manifold is disassembled.
- Citrate pump is disassembled.

Disassembling of Citrate Pump Encoder Board

1. Disconnect cable ① from the blood side board (J4).
2. Loosen screw ② to remove the citrate pump encoder board.

Assembling of Citrate Pump Encoder Board

1. Fastening the screw to the manifold to fix the citrate pump encoder board.
2. Connect the cable to blood side board (J4).

5.7.4.4.3 Citrate Pump Roller

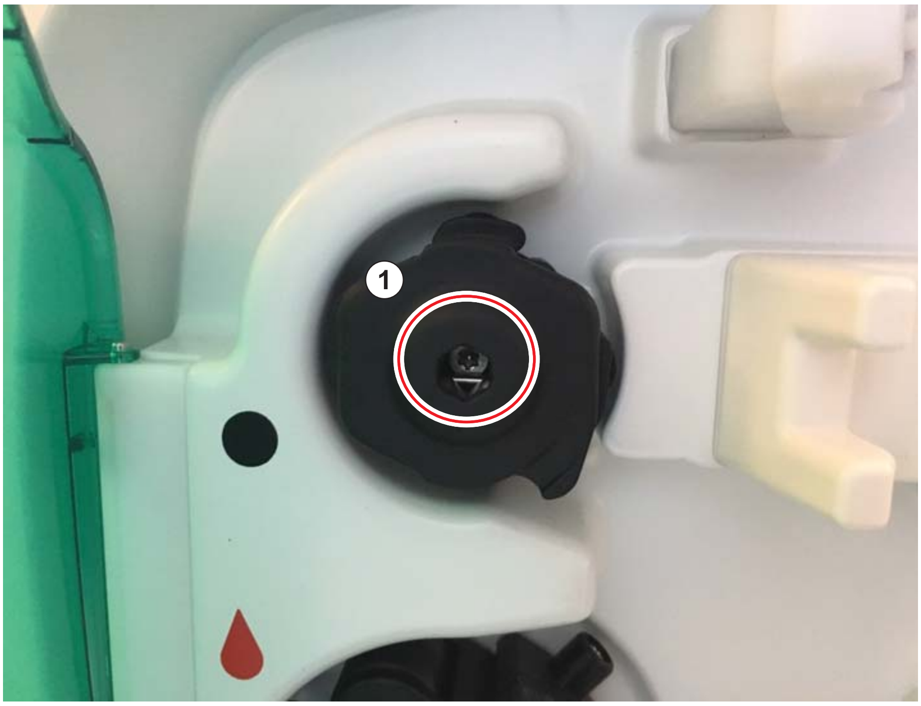

Fig. 5-38 Citrate pump roller

Disassembling of the Citrate Pump Roller

1. Remove citrate pump roller by loosing the screw ① .

Assembling of the Citrate Pump Roller

1. Fasten the screw in the middle of the roller to assemble the citrate pump roller.
2. Check the home position of the citrate pump in TSM.

5.7.4.5 Kit Locking Mechanism

Cut cable ties only if necessary. Make sure that all attached components are working properly when service activity is successfully done.

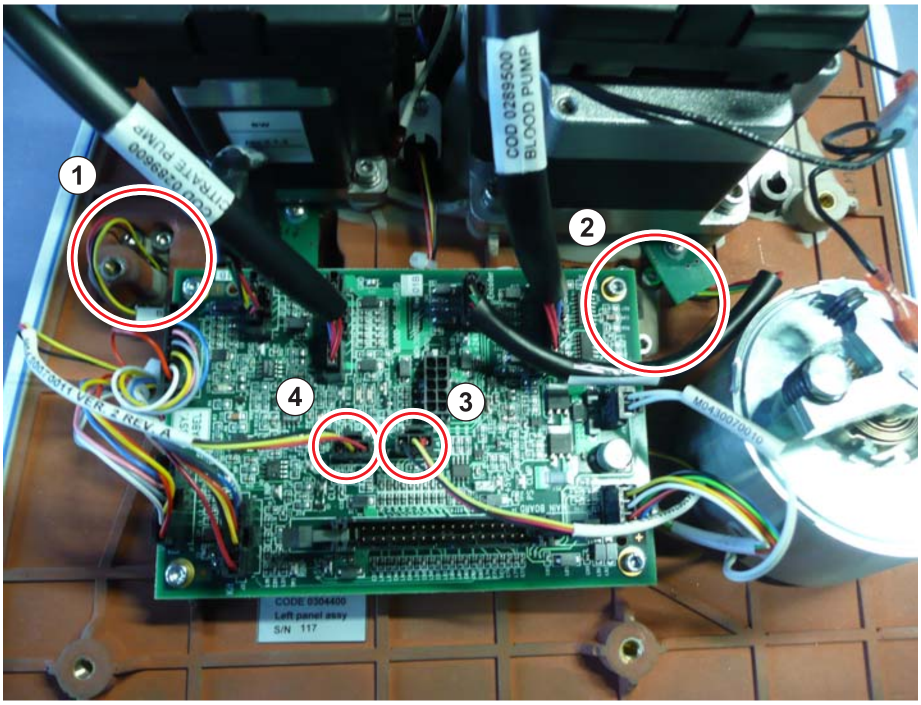

Fig. 5-39 BSM kit locking mechanism

Prerequisites

- Blood side manifold is disassembled
- Blood pump encoder board is disassembled

Disassembling of BSM Kit Locking Mechanism

1. Disconnect cable ③ (J8) for the upper kit locking mechanism ① .
2. Disassemble the screws to take out the upper kit locking mechanism ① .
3. Disconnect cable ④ (J7) for the lower kit locking mechanism ② .
4. Disassemble the screws to take out the lower kit locking mechanism ② .

Assembling of BSM Kit Locking Mechanism

1. Fasten the screws to assemble the upper kit locking mechanism ① .
2. Connect cable ③ (J8).
3. Fasten the screws to assemble the lower kit locking mechanism ② .
4. Connect cable ③ (J7).

5.7.4.6 Door Detector

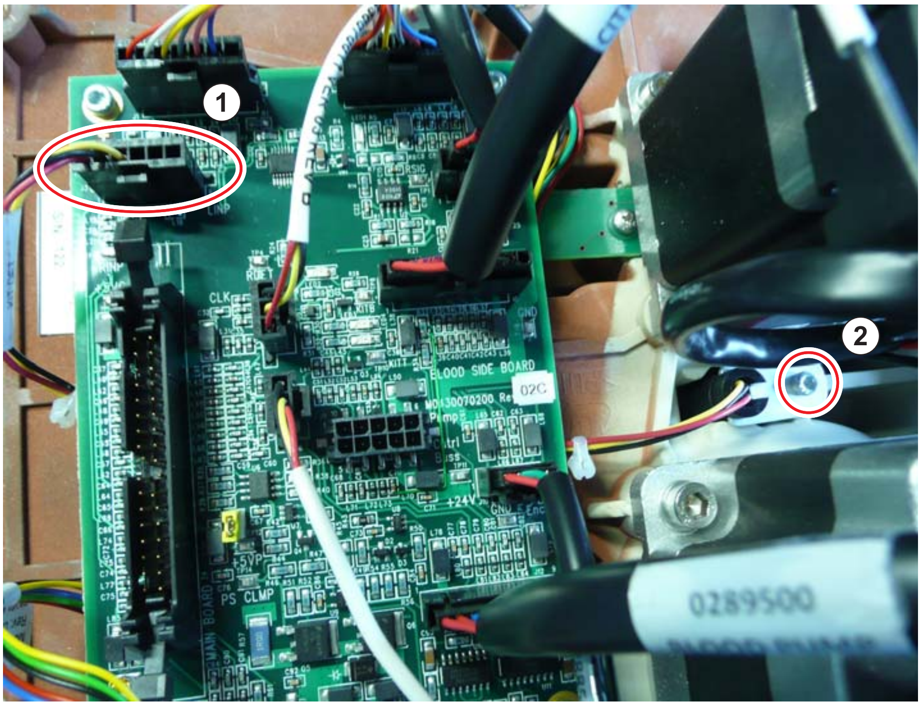

Fig. 5-40 BSM door detector

Prerequisites

- Blood side manifold is disassembled

Disassembling of the BSM Door Detector

1. Disconnect cable ① from blood side board (J3).
2. Loosen screw ② to disassemble the door detector.

Disassembling of the BSM Door Detector

1. Fasten the screw ② to assemble the door detector on the blood side manifold.
2. Connect the door detector cable to the blood side board (J3).

5.7.4.7 Level Detectors

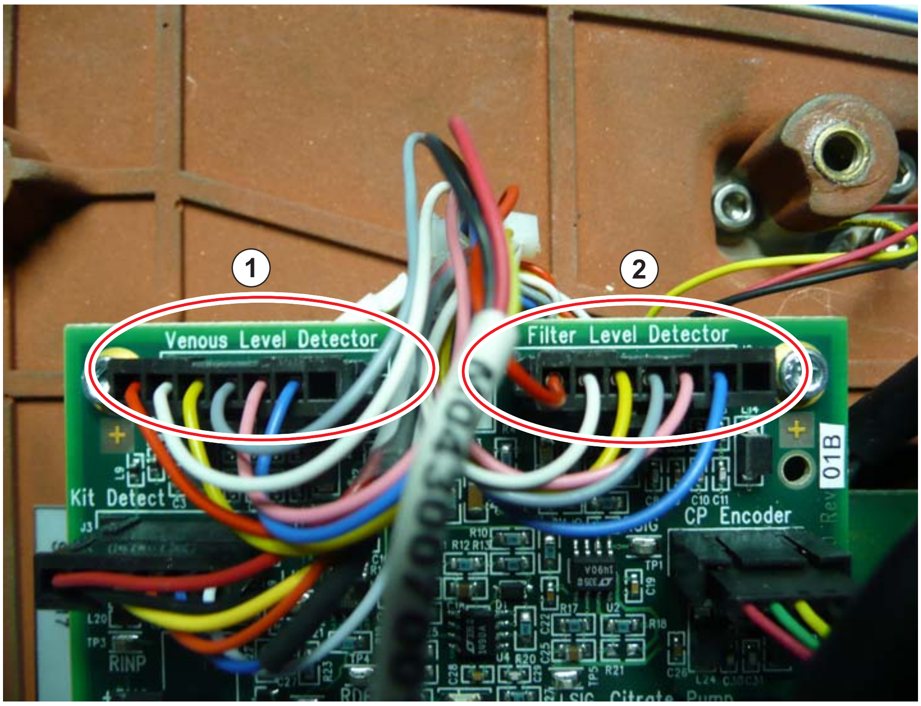

Fig. 5-41 BSM level detector connectors

Prerequisites

- Blood side manifold is disassembled

Disassembling of BSM Level Detector

1. Disconnect ① for the venous level detector (J1).
2. Disconnect ② for the filter level detector (J2).
3. Loosen screws of the blood side board.

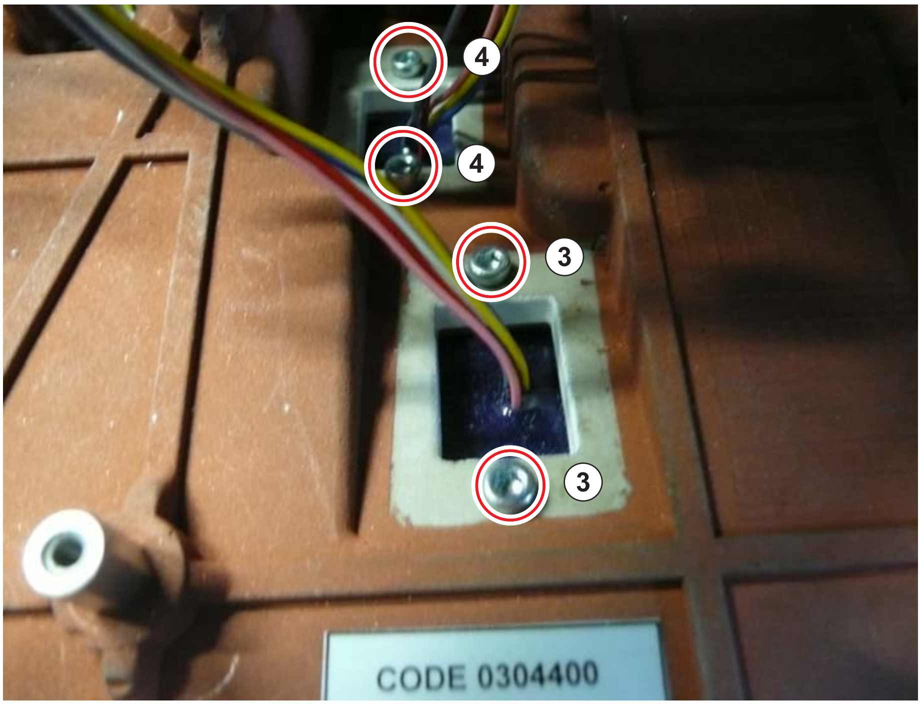

Fig. 5-42 BSM level detectors

4. Loosen screws ③ to disassemble the venous level detector.
5. Loosen screws ④ to disassemble the filter level detector.

Assembling of BSM Level Detector

1. Fasten screws to fix the level detector to the manifold.
2. Fasten the blood side board on the blood side manifold.
3. Connect the cable to the blood side board.

5.7.4.8 Venous Safety Air Detector

Prerequisites

- Blood side manifold is disassembled

Disassembling of Venous Safety Air Detector

1. Loosen the 4 screws of the blood side board.

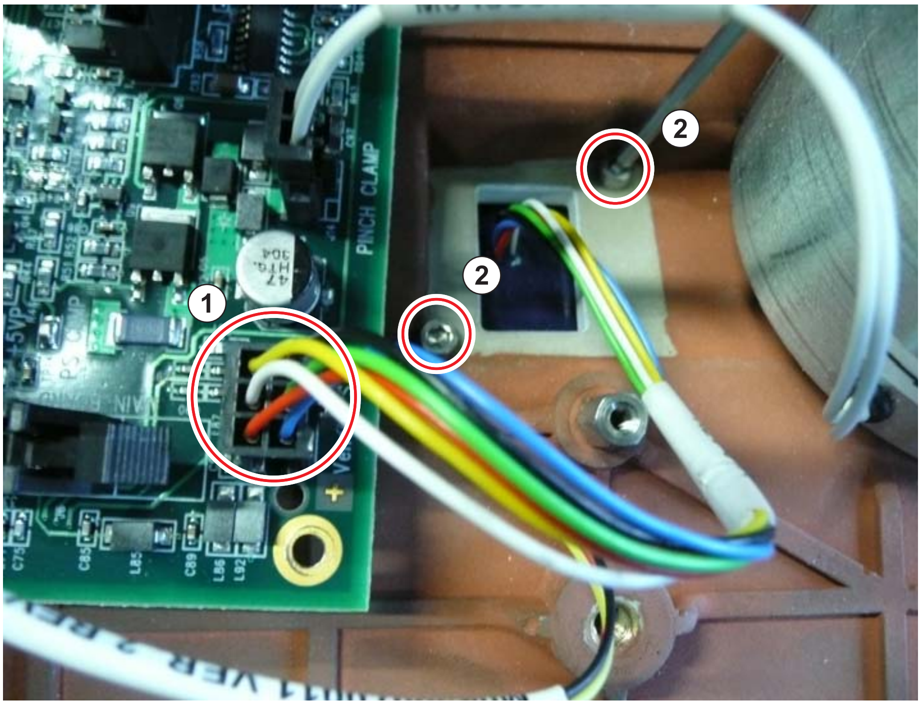

Fig. 5-43 Venous safety air detector

2. Disconnect the VSAD cable from the blood side board ① .
3. Loosen screws ② to remove the VSAD.

Assembling of Venous Safety Air Detector

1. Fasten screws to assemble the VSAD on the blood side manifold.
2. Connect VSAD cable to the blood side board (J13).
3. Fasten the 4 screws to assemble the blood side board.

5.7.4.9 Venous Clamp

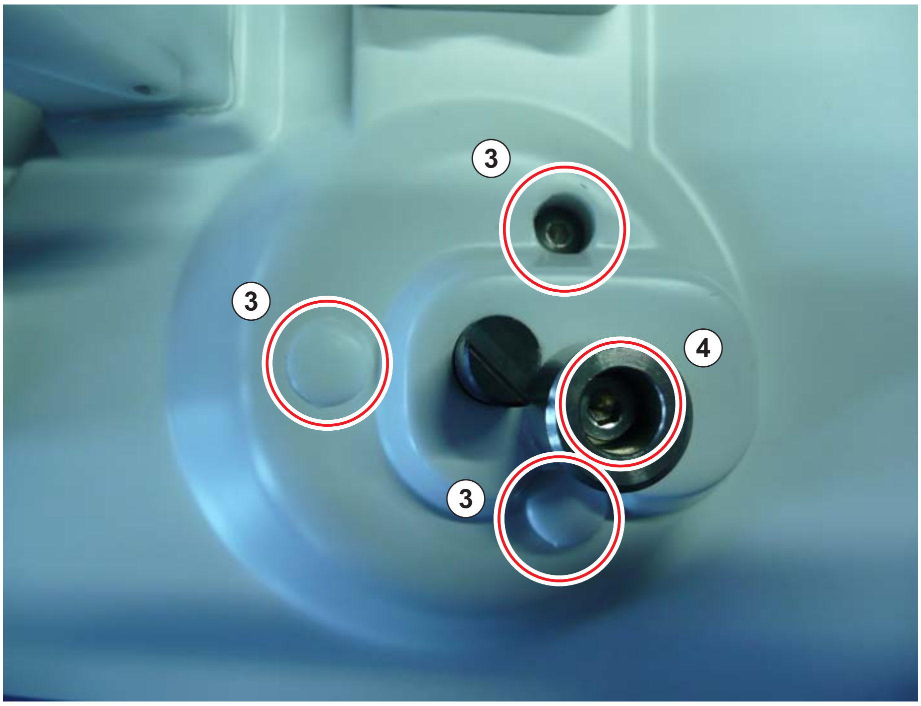

Fig. 5-44 Venous clamp eccentric

Prerequisites

- Blood side manifold is disassembled

Disassemlbing of the Venous Clamp

1. Remove white plugs on the front housing.
2. Loosen the screws ③ and ④ .

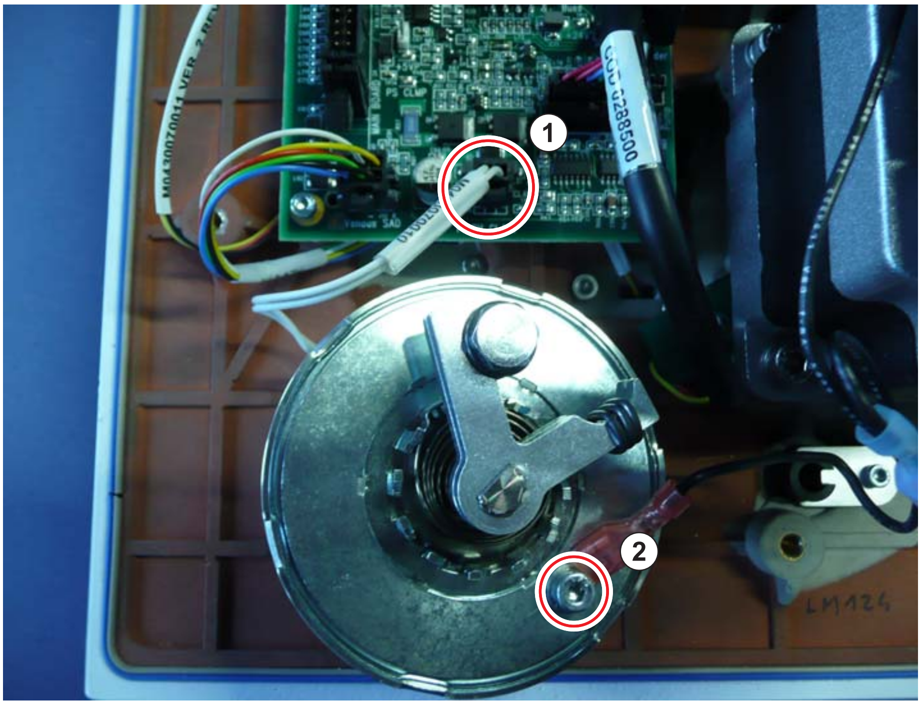

Fig. 5-45 Venous clamp

3. Disconnect venous clamp cable ① (J14).
4. Disconnect grounding cable ② .

Remove venous clamp carefully. A small pin is fixed on the backside of the venous clamp to ensure the correct position of the venous clamp.

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5. Loosen the screw inside the eccentric shaft ④ to remove the venous clamp.

Assemlbing of the Venous Clamp

1. Fasten screws to the blood side manifold to fix the venous clamp on the blood side manifold.
2. Fasten screw of the eccentric and set the gap according to the venous clamp test (6.4.1.4 Test of Venous Clamp (328).
3. Close the holes for the screws and the eccentric with white plugs.
4. Assemble grounding cable to the venous clamp.
5. Connect venous clamp cable to the blood side board (J14).

5.7.5 Fluid Side Manifold

Prerequisites

- Blood side manifold is disassembled

Disassembling of the Fluid Side Manifold

1. Flip down and disconnect warmer assembly.

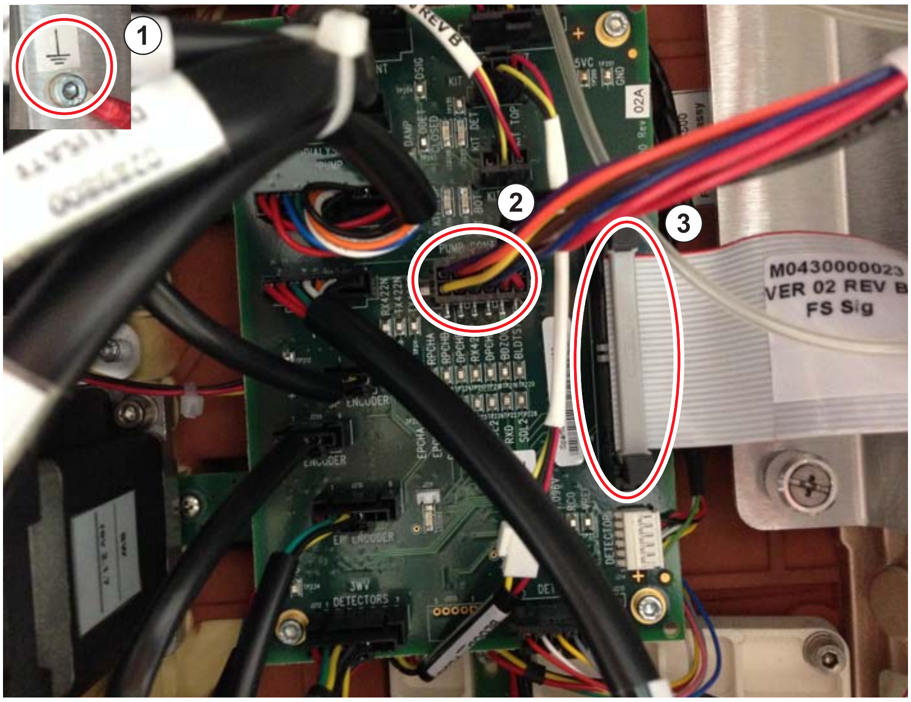

Fig. 5-46 Connectors fluid side manifold

2. Loosen screw for grounding connection of the fluid side manifold ① .
3. Disconnect pump control cable (fluid side board J 207) ② .
4. Disconnect the ribbon cable (fluid side manifold J 206 to main board) ③ .

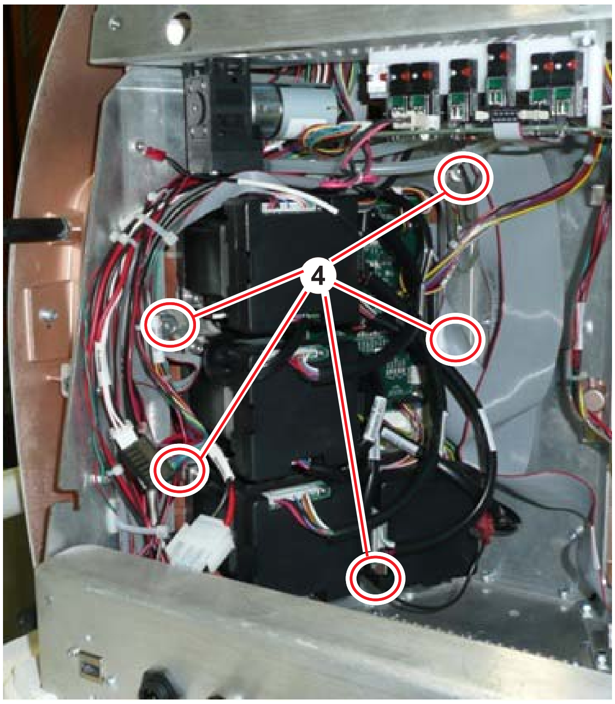

Fig. 5-47 Knurled screws fluid side manifold

5. Loosen five captive knurled screws of the fluid side manifold ④ .
6. Take out the fluid side manifold.

Fig. 5-48 Fluid side manifold

Assembling of the Fluid Side Manifold

1. Insert the fluid side manifold into the two existing slots of the housing.

NOTICE!

Pay attention that no cable is squeezed between the manifold and the machine housing.

2. Assemble grounding connection to the machine housing.
3. Connect pump control cable to fluid side board J 207.
4. Connect ribbon cable to fluid side board J 206.
5. Fasten the five captive knurled screws of the fluid side manifold.

5.7.5.1 Fluid Side Door

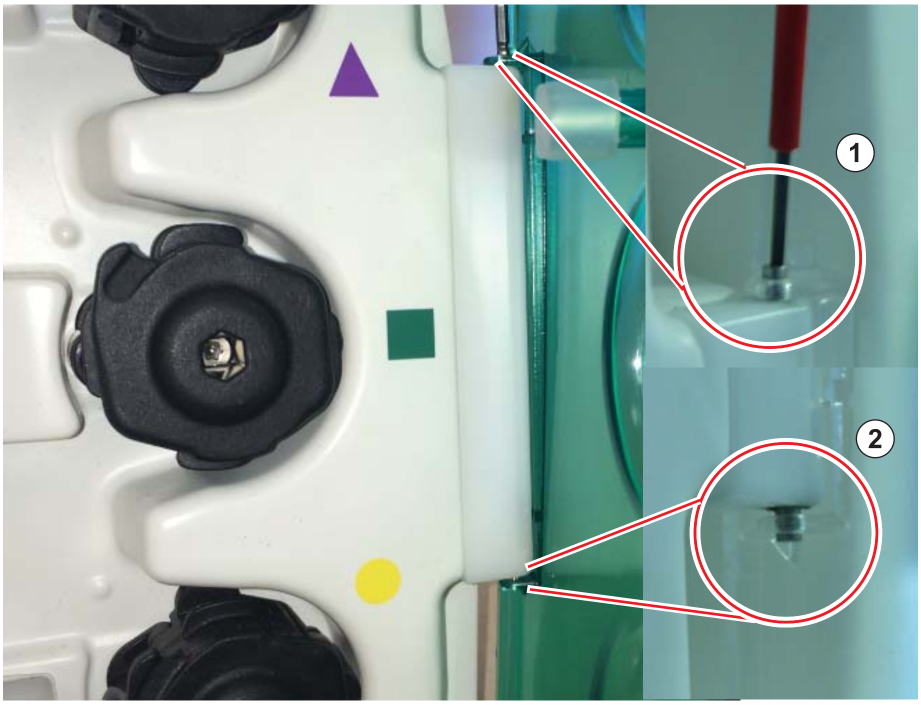

Fig. 5-49 Fluid side door

Disassembling of the Fluid Side Door

1. Open fluid side door
2. Push upper pin of the fluid side door down ① .
3. Skip and take out fluid side door.

Assembling of the Fluid Side Door

1. Insert the cover on the lower pin of the fluid side door ② .
2. Push upper pin of the fluid side door down ① and assemble the fluid side door.

5.7.5.2 Fluid Side Board

NOTICE!

Machine will not pass the selftest due to a bad or wrong cable connection.

- Connect all cables regarding the labeling on the cable and the labeling on the board.
- All connections are described in the service manual chapter 8.

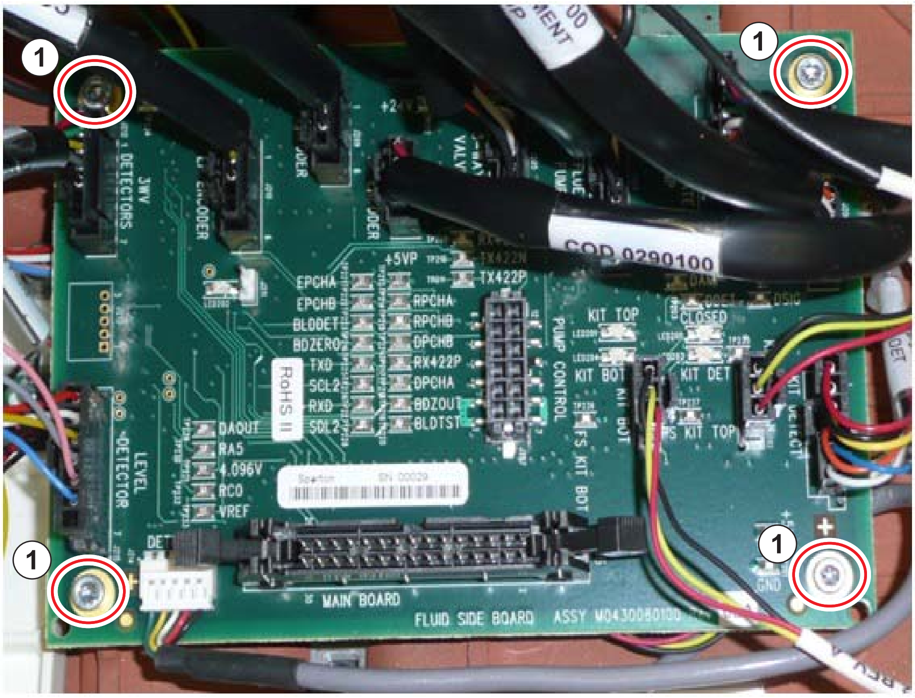

Fig. 5-50 Fluid side board

Prerequisites

- Fluid side manifold is disassembled

Disassembling of the Fluid Side Board

1. Disconnect all connectors of the fluid side board.
2. Loosen the screws ① to disassemble the fluid side board.

Disassembling of the Fluid Side Board

1. Fasten the 4 screws ① to assemble the fluid side board.
2. Connect all connectors of the fluid side manifold.

5.7.5.3 Substitution Pump

Prerequisites

- Fluid side manifold is disassembled.

Disassembling of the Substitution Pump

1. Fix substitution pump roller and loose the screw ① to remove the roller head.

Fig. 5-51 Substitution pump roller

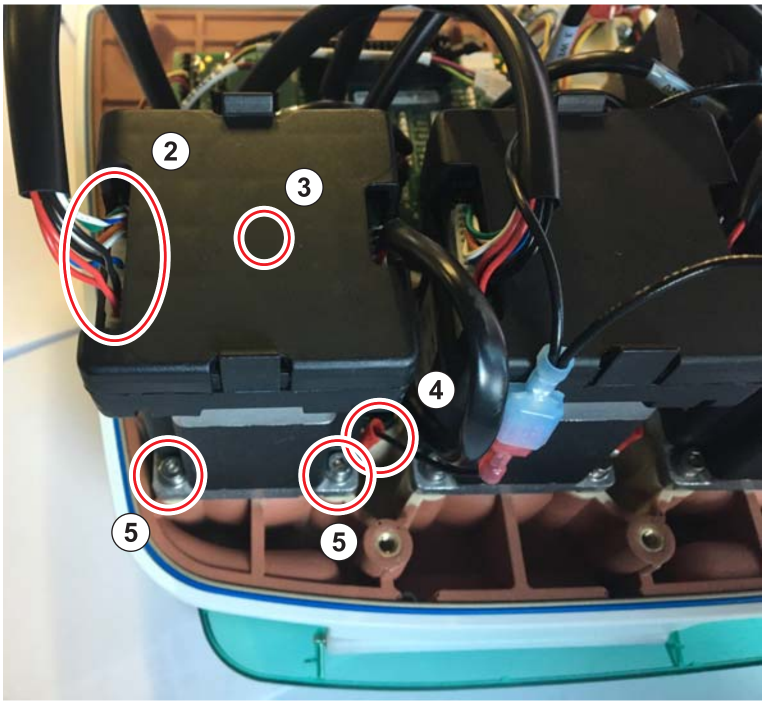

Fig. 5-52 Substitution pump front view

2. Disconnect substitution pump cable from the substitution pump motor ② .
3. Remove the cover of the pump motor ③ (dip switch position 2).
4. Remove grounding connector ④ .

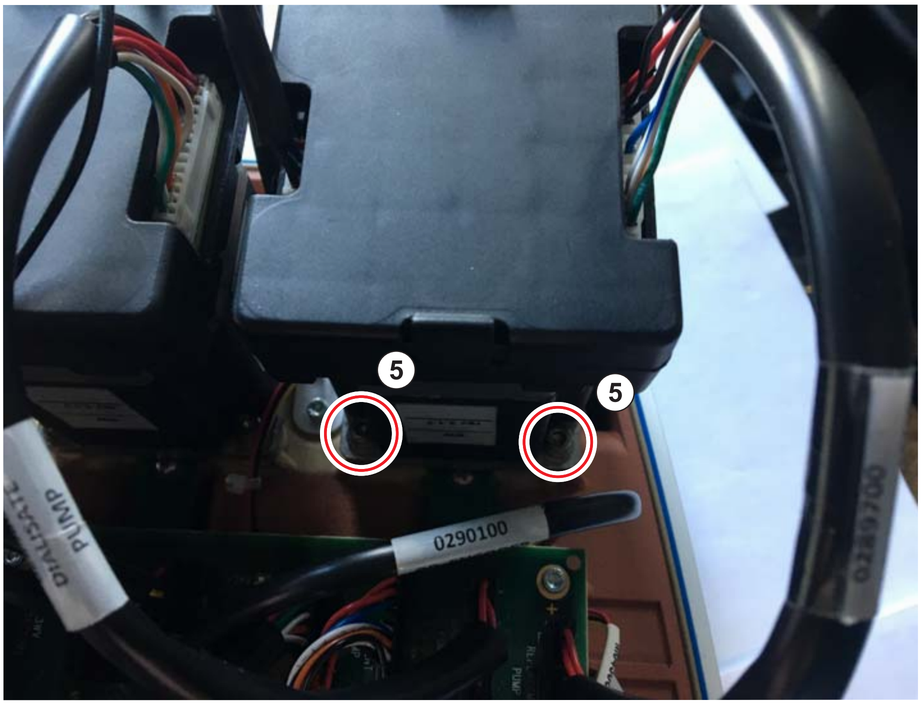

Fig. 5-53 Substitution pump rear view

5. Loosening screws ⑤ to remove the substitution pump.

Assembling of the Substitution Pump

1. Check/set substitution pump code ① (dip switch position 2).

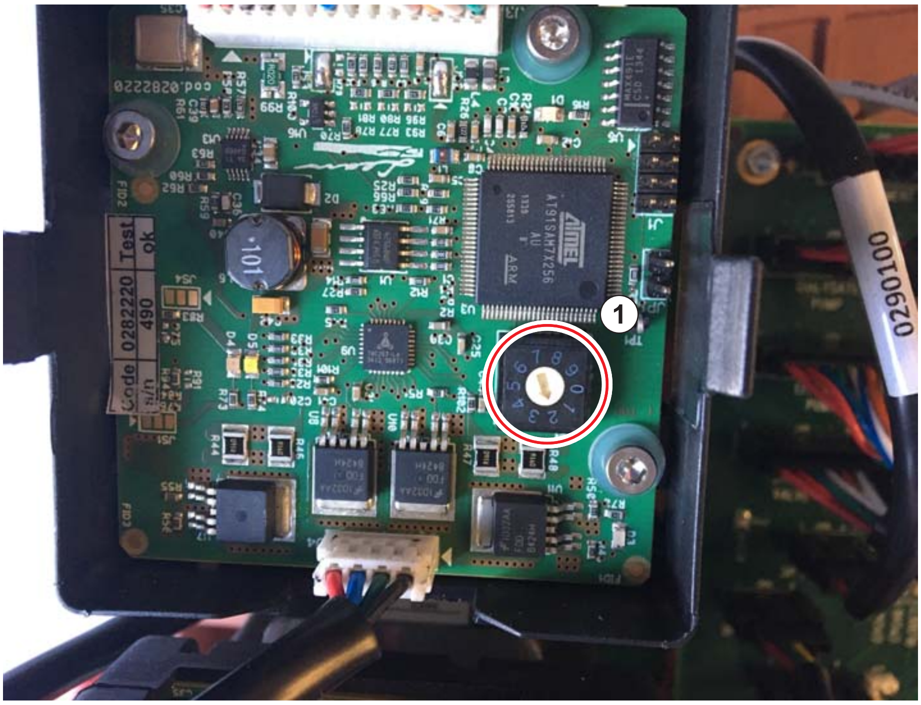

Fig. 5-54 Substitution pump code

2. Close housing of the substitution pump motor.
3. Fastening the screws on the manifold to fix the substitution pump.
4. Connect grounding on the substitution pump.
5. Fastening the screw in the middle of the roller to fix the substitution pump roller.

5.7.5.3.1 Substitution Pump Cable

Cut cable ties only if necessary. Make sure that all attached components are working properly when service activity is successfully done.

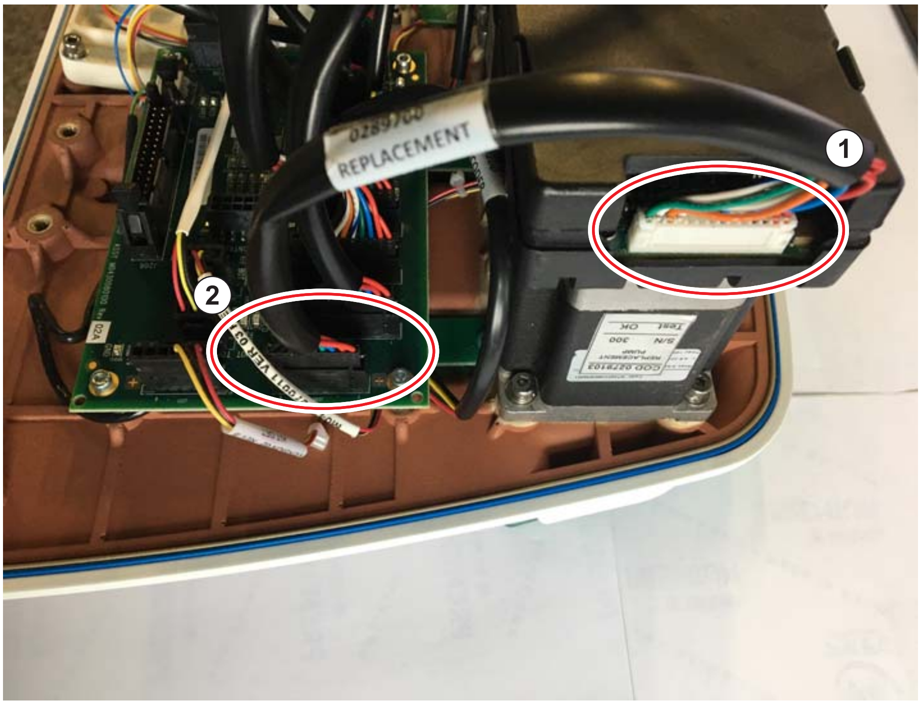

Fig. 5-55 Substitution pump cable

Prerequisites

- Fluid side manifold is disassembled.

Disassembling of the Substitution Pump Cable

1. Disconnect substitution pump cable from the substitution pump motor ① .
2. Disconnect substitution pump cable from the fluid side board ② (J200).

Assembling of the Substitution Pump Cable

1. Connect substitution pump cable to the substitution pump motor ① .
2. Connect substitution pump cable to the fluid side board ② (J200).

5.7.5.3.2 Substitution Pump Encoder Board

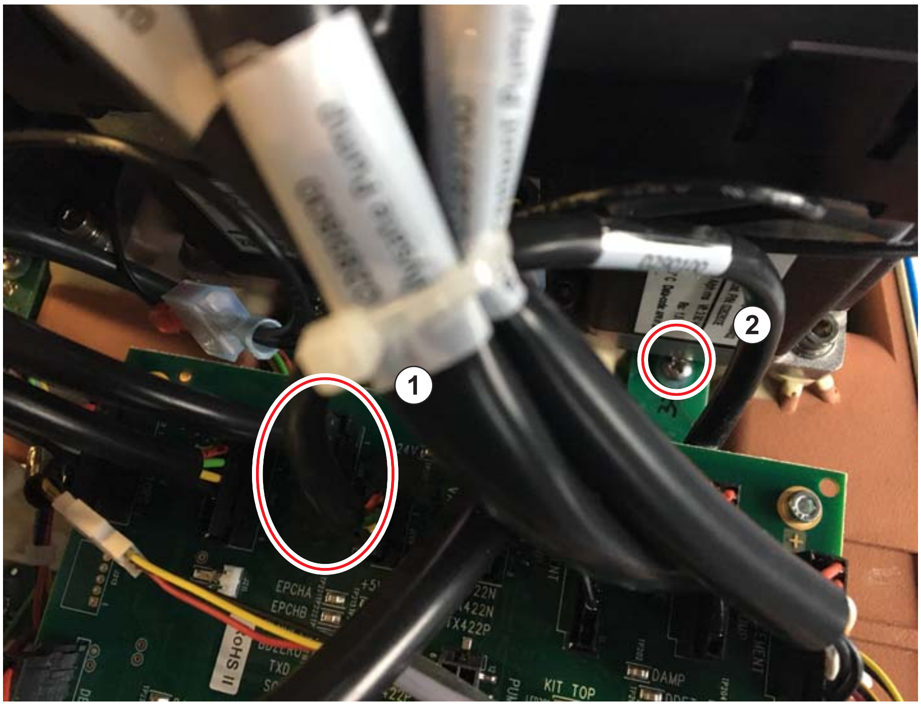

Fig. 5-56 Substitution pump encoder board

Prerequisites

- Fluid side manifold is disassembled
- Substitution pump is disassembled

Disassembling of the Substitution Pump Encoder Board

1. Disconnect cable ① from the fluid side board (J4).
2. Loosen screw ② to remove the substitution pump encoder board.

Assembling of the Substitution Pump Encoder Board

1. Fastening the screw to the manifold to fix the substitution pump encoder board.
2. Connect the cable to fluid side board (J4).

5.7.5.3.3 Substitution Pump Roller

Fig. 5-57 Substitution pump roller

Disassembling of the Substitution Pump Roller

1. Fix substitution pump roller and loose the screw ① to remove the roller head.

Assembling of the Substitution Pump Roller

1. Fix the substitution pump roller and fasten the screw in the middle of the roller to assemble the substitution pump roller.

5.7.5.4 Dialysate Pump

Prerequisites

- Fluid side manifold is disassembled.

Disassembling of the Dialysate Pump

1. Remove dialysate pump roller by loosing the screw ① .

Fig. 5-58 Dialysate pump roller

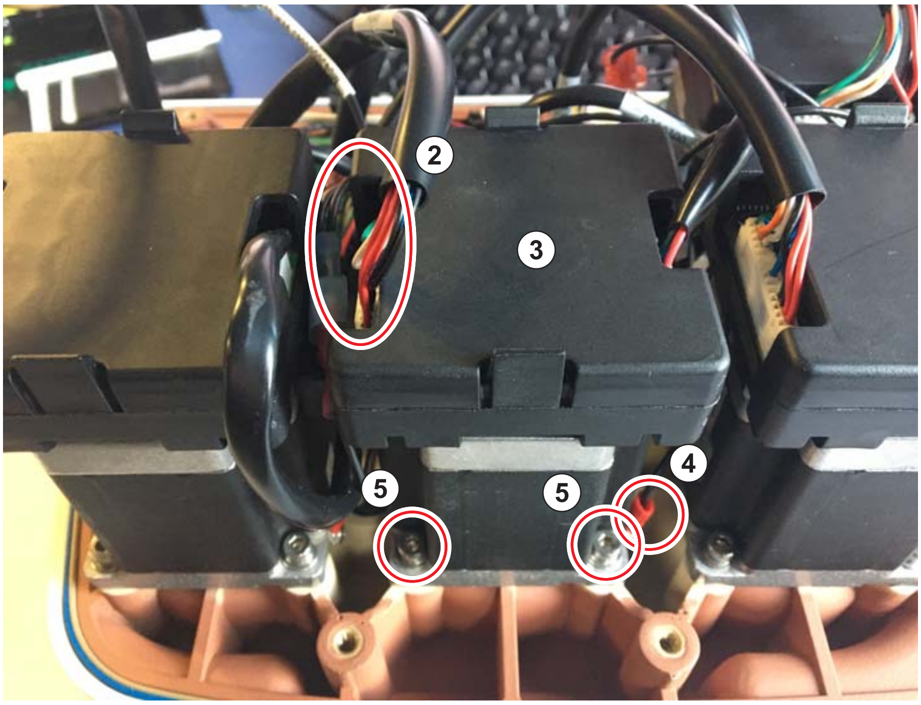

Fig. 5-59 Dialysate pump front view

2. Disconnect dialysate pump cable from the dialysate pump motor ② .
3. Remove the cover of the pump motor ③ (dip switch position 3).
4. Remove grounding connector ④ .

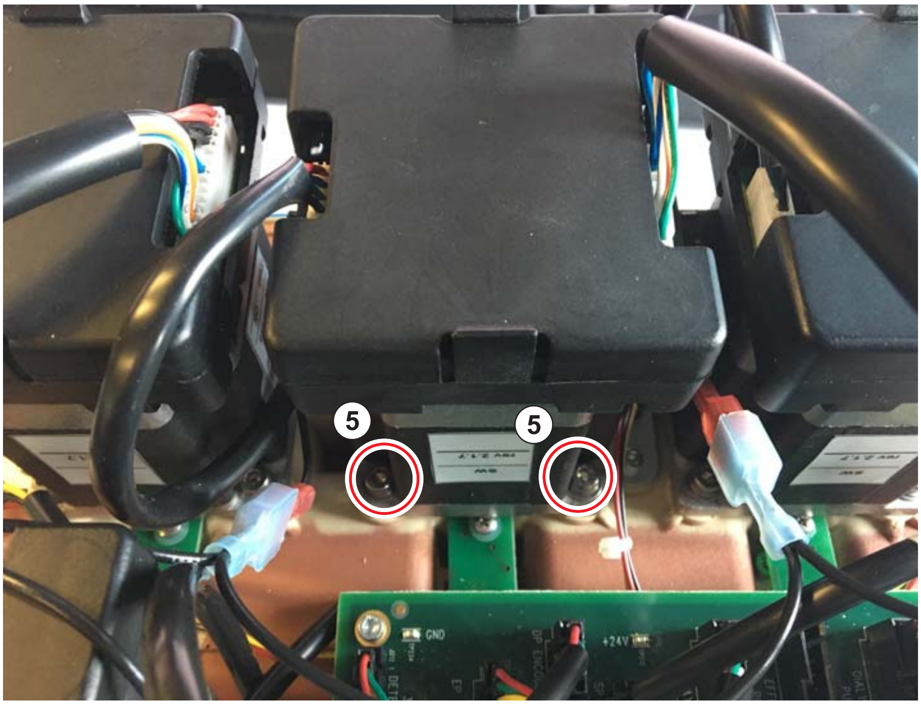

Fig. 5-60 Dialysate pump rear view

5. Loosening screws ⑤ to remove the dialysate pump.

Assembling of the Dialysate Pump

1. Check/set dialysate pump code ① (dip switch position 3).

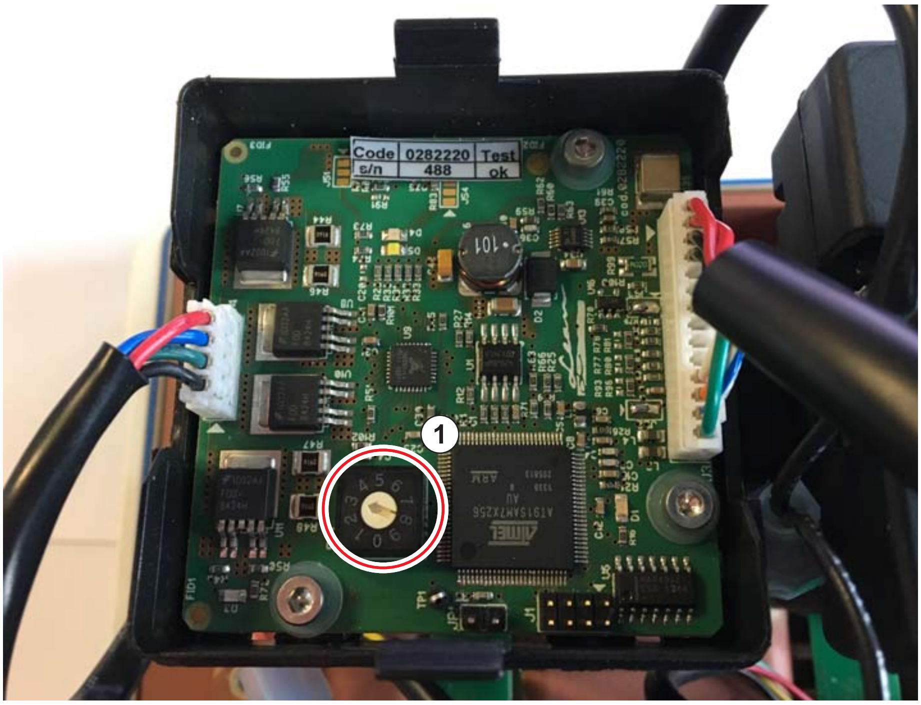

Fig. 5-61 Dialysate pump code

2. Close housing of the dialysate pump motor.
3. Fastening the screws on the manifold to fix the dialysate pump.
4. Connect grounding on the dialysate pump.
5. Fastening the screw in the middle of the roller to fix the dialysate pump roller.

5.7.5.4.1 Dialysate Pump Cable

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Cut cable ties only if necessary. Make sure that all attached components are working properly when service activity is successfully done.

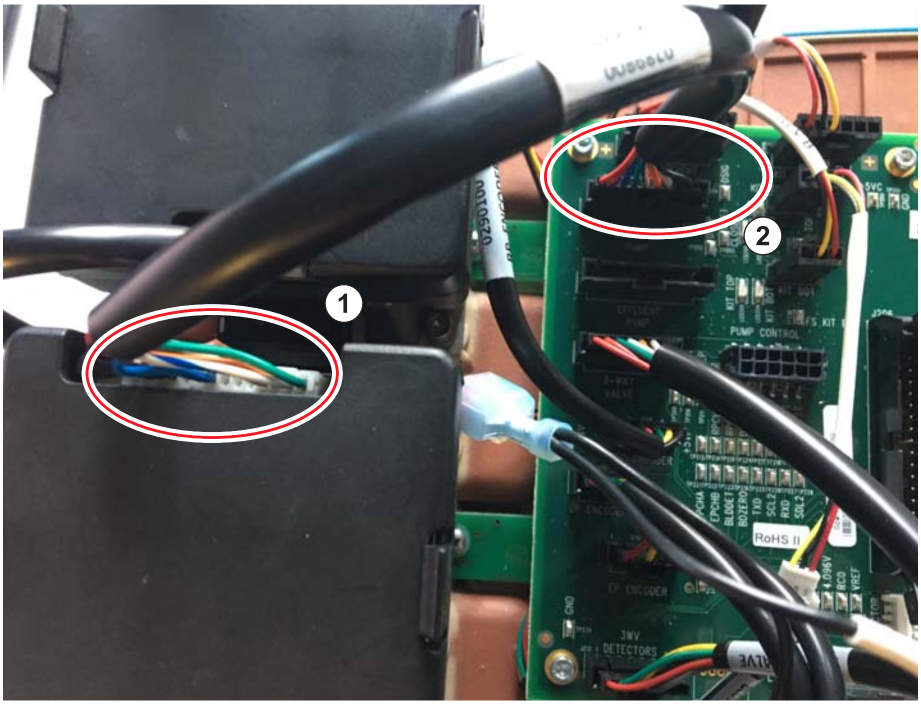


Fig. 5-62 Dialysate pump cable

Prerequisites

- Fluid side manifold is disassembled.

Disassembling of the Dialysate Pump Cable

1. Disconnect dialysate pump cable from the dialysate pump motor ① .
2. Disconnect dialysate pump cable from the fluid side board ② (J203).

Assembling of the Dialysate Pump Cable

1. Connect dialysate pump cable to the dialysate pump motor ① .
2. Connect dialysate pump cable to the fluid side board ② (J203).

5.7.5.4.2 Dialysate Pump Encoder Board

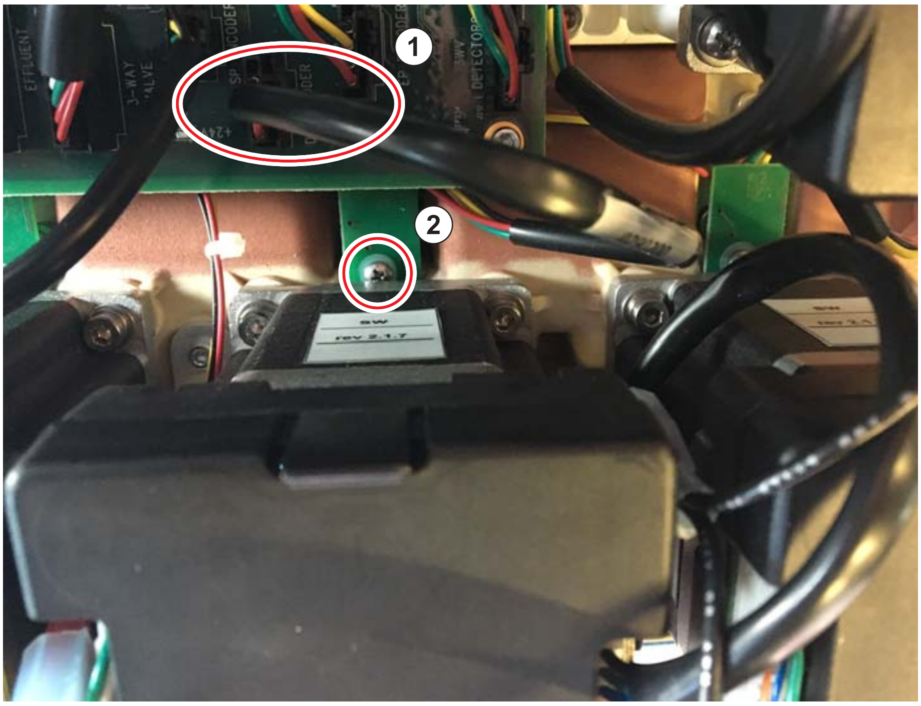


Fig. 5-63 Dialysate pump encoder board

Prerequisites

- Fluid side manifold is disassembled
- Dialysate pump is disassembled

Disassembling of the Dialysate Pump Encoder Board

1. Disconnect cable ① from the fluid side board (J4).
2. Loosen screw ② to remove the dialysate pump encoder board.

Assembling of the Dialysate Pump Encoder Board

1. Fastening the screw to the manifold to fix the dialysate pump encoder board.
2. Connect the cable to fluid side board (J4).

5.7.5.4.3 Dialysate Pump Roller

Fig. 5-64 Dialysate pump roller

Disassembling of the Dialysate Pump Roller

1. Loose the screw ① to disassemble the dialysate pump roller.

Assembling of the Dialysate Pump Roller

1. Fasten the screw in the middle of the roller to assemble the dialysate pump roller.

5.7.5.5 Effluent Pump

Fig. 5-65 Effluent pump roller

Prerequisites

- Fluid side manifold is disassembled.

Disassembling of the Effluent Pump

1. Remove effluent pump roller by loosing the screw ① .

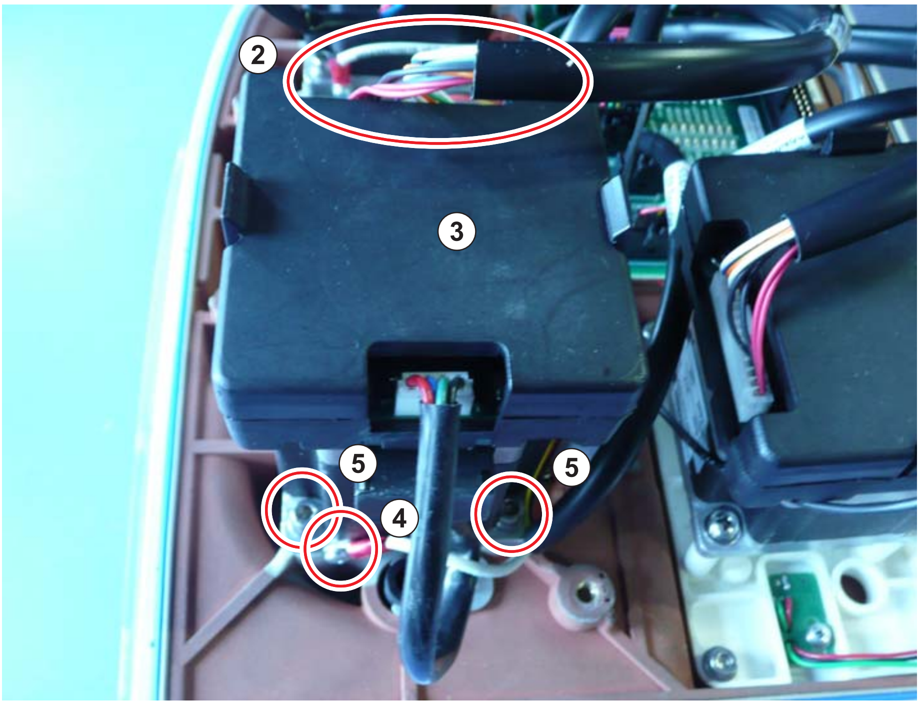


Fig. 5-66 Effluent pump front view

2. Disconnect effluent pump cable from the effluent pump motor ② .
3. Remove the cover of the pump motor ③ (dip switch position 3).
4. Remove grounding connector ④ .

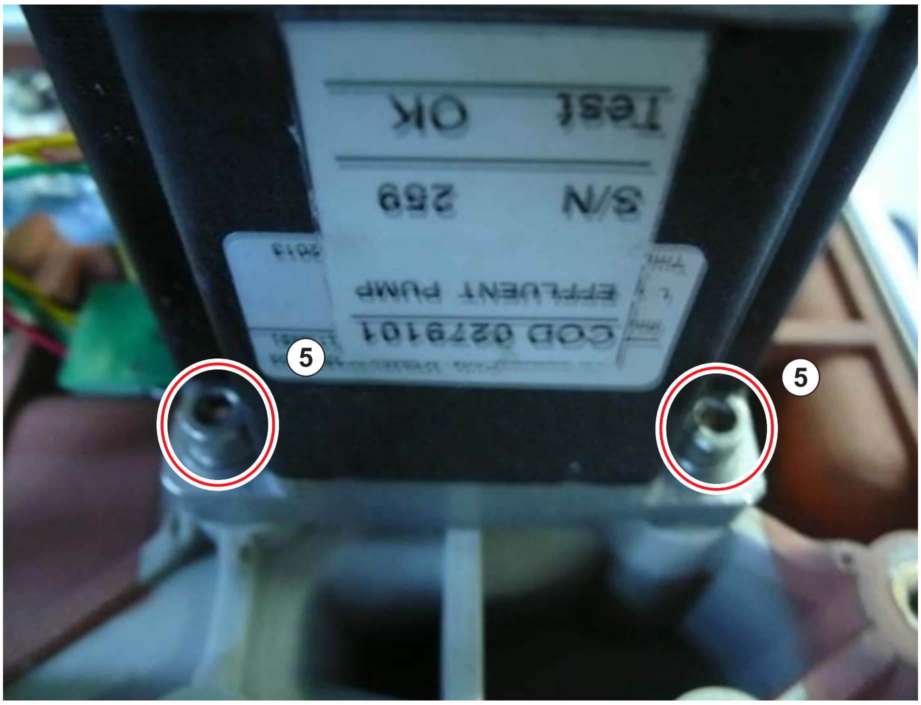


Fig. 5-67 Effluent pump rear view

5. Loosening screws ⑤ to remove the effluent pump.

Assembling of the Effluent Pump

1. Check/set effluent pump code ① (dip switch position 3).

Fig. 5-68 Effluent pump code

2. Close housing of the effluent pump motor.
3. Fastening the screws on the manifold to fix the effluent pump.
4. Connect grounding on the effluent pump.
5. Fastening the screw in the middle of the roller to fix the effluent pump roller.

5.7.5.5.1 Effluent Pump Cable

Cut cable ties only if necessary. Make sure that all attached components are working properly when service activity is successfully done.

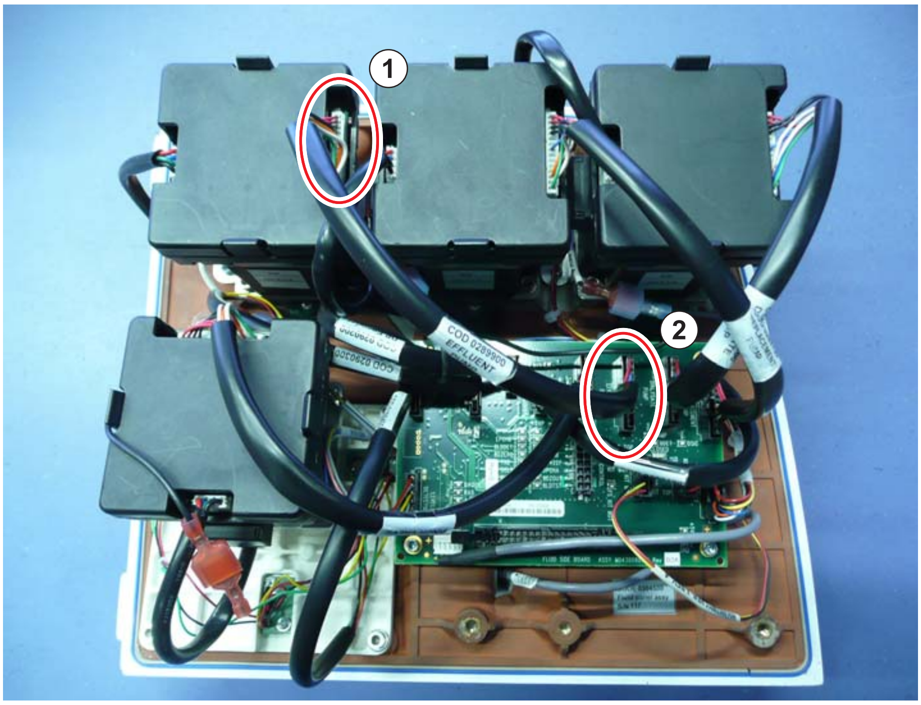


Fig. 5-69 Effluent pump cable

Prerequisites

- Fluid side manifold is disassembled.

Disassembling of the Effluent Pump Cable

1. Disconnect effluent pump cable from the effluent pump motor ① .
2. Disconnect effluent pump cable from the fluid side board ② (J204).

Assembling of the Effluent Pump Cable

1. Connect effluent pump cable to the fluid side board ② (J204).
2. Connect effluent pump cable to the effluent pump motor ① .

5.7.5.5.2 Effluent Pump Encoder Board

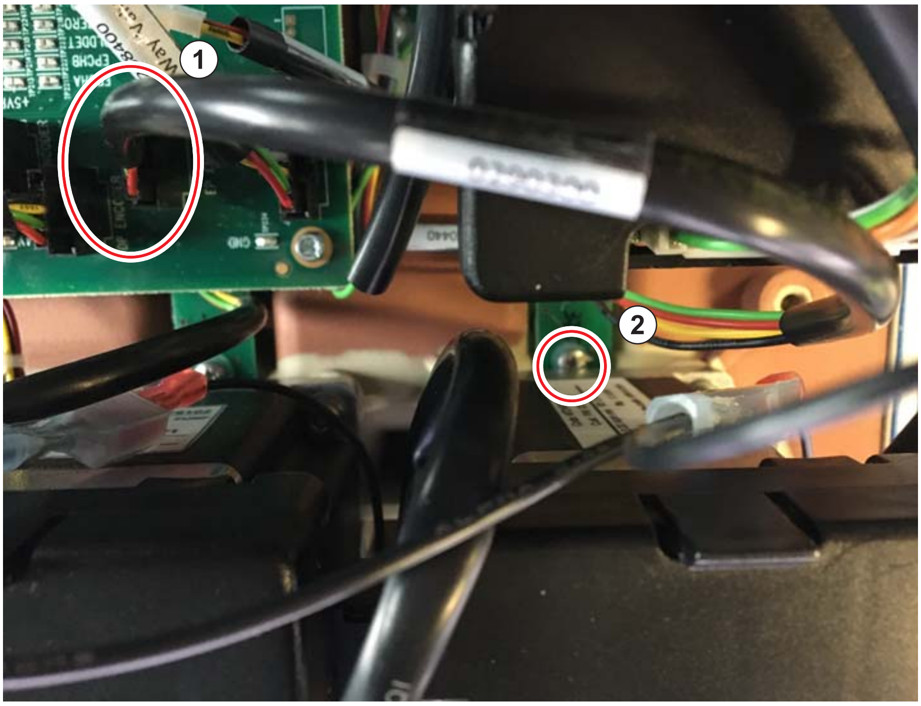


Fig. 5-70 Effluent pump encoder board

Prerequisites

- Fluid side manifold is disassembled
- Effluent pump is disassembled

Disassembling of the Effluent Pump Encoder Board

1. Disconnect cable ① from the fluid side board (J4).
2. Loosen screw ② to remove the effluent pump encoder board.

Assembling of the Effluent Pump Encoder Board

1. Fastening the screw to the manifold to fix the effluent pump encoder board.
2. Connect the cable to fluid side board (J4).

5.7.5.5.3 Effluent Pump Roller

Fig. 5-71 Effluent pump roller

Disassembling of the Effluent Pump Roller

1. Loose the screw ① to disassemble the effluent pump roller.

Assembling of the Effluent Pump Roller

1. Fasten the screw in the middle of the roller to assemble the effluent pump roller.

5.7.5.6 Kit Locking Mechanism

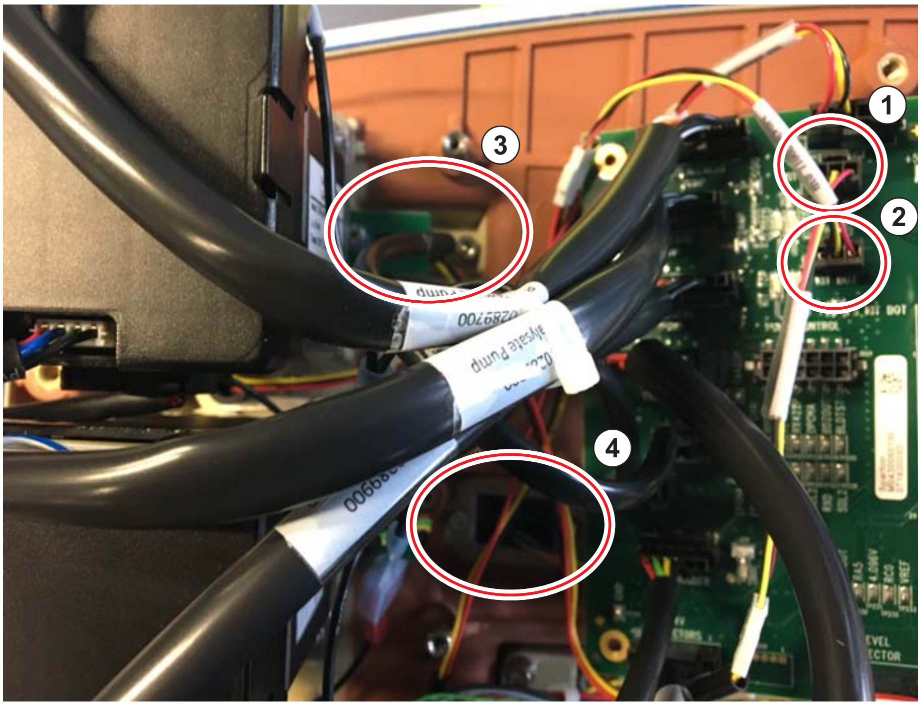


Fig. 5-72 FSM kit locking mechanism

Prerequisites

- Fluid side manifold is disassembled
- Substitution pump encoder board is disassembled
- Fluid side board is loose

Disassembling of FSM Kit Locking Mechanism

1. Disconnect cable ① (J202) for the upper kit locking mechanism ③ .
2. Disassemble the screws to take out the upper kit locking mechanism.
3. Disconnect cable ② (J216) for the lower kit locking mechanism ④ .
4. Disassemble the screws to take out the lower kit locking mechanism.

Assembling of FSM Kit Locking Mechanism

1. Fasten the screws to assemble the upper kit locking mechanism
2. Connect cable ③ (J202).
3. Fasten the screws to assemble the lower kit locking mechanism
4. Connect cable ③ (J216).

5.7.5.7 Door Detector

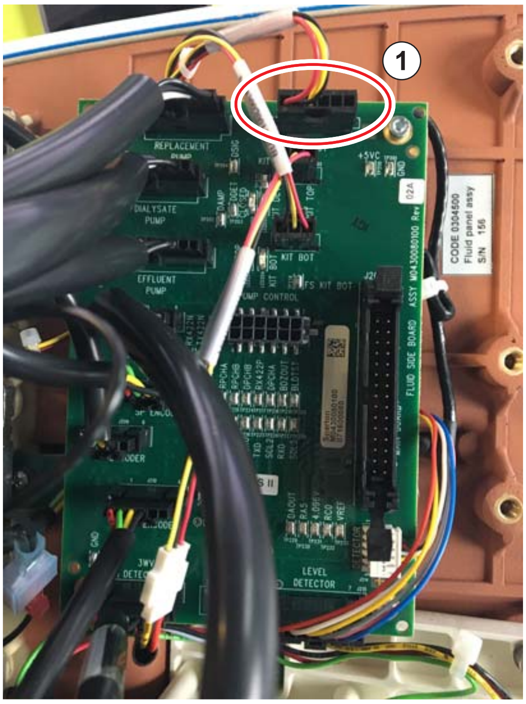


Fig. 5-73 FSM door detector

Prerequisites

- Fluid side manifold is disassembled

Disassembling of FSM Door Detector

1. Disconnect cable ① from fluid side board (J201).
2. Loosen screw ② to disassemble the door detector (located behind the fluid side board).

Assembling of FSM Door Detector

1. Fasten the screw ② to assemble the door detector on the fluid side manifold.
2. Connect the door detector cable to the fluid side board (J201).

5.7.5.8 Level Detectors

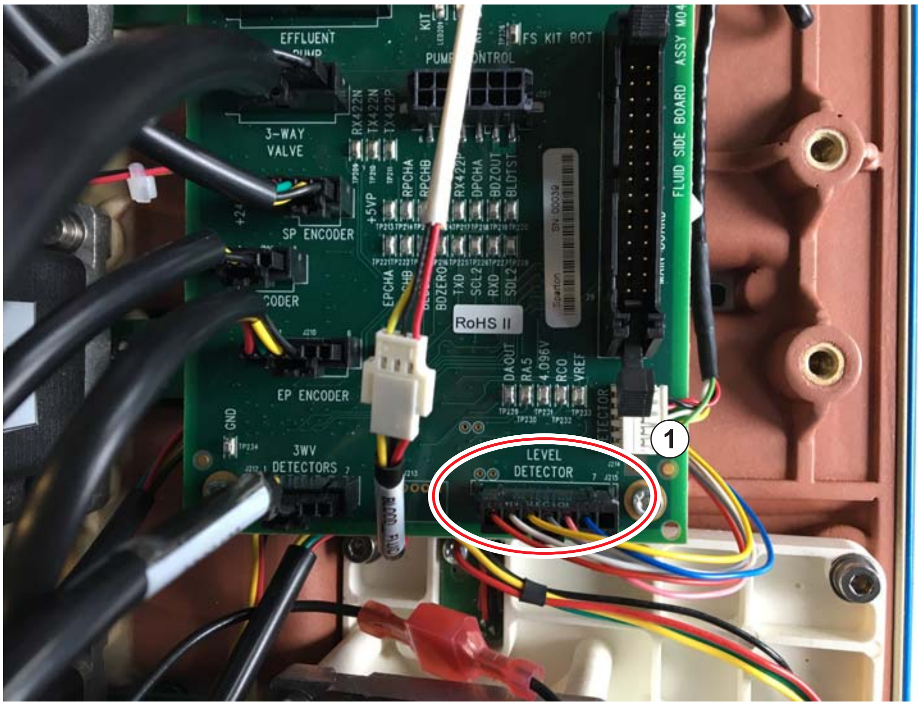


Fig. 5-74 FSM level detector connector

Prerequisites

- Fluid side manifold is disassembled

Disassembling of FSM Level Detector

1. Disconnect the solution level detector cable ① from the fluid side board (J215).
2. Loosen 4 screws of the fluid side board.

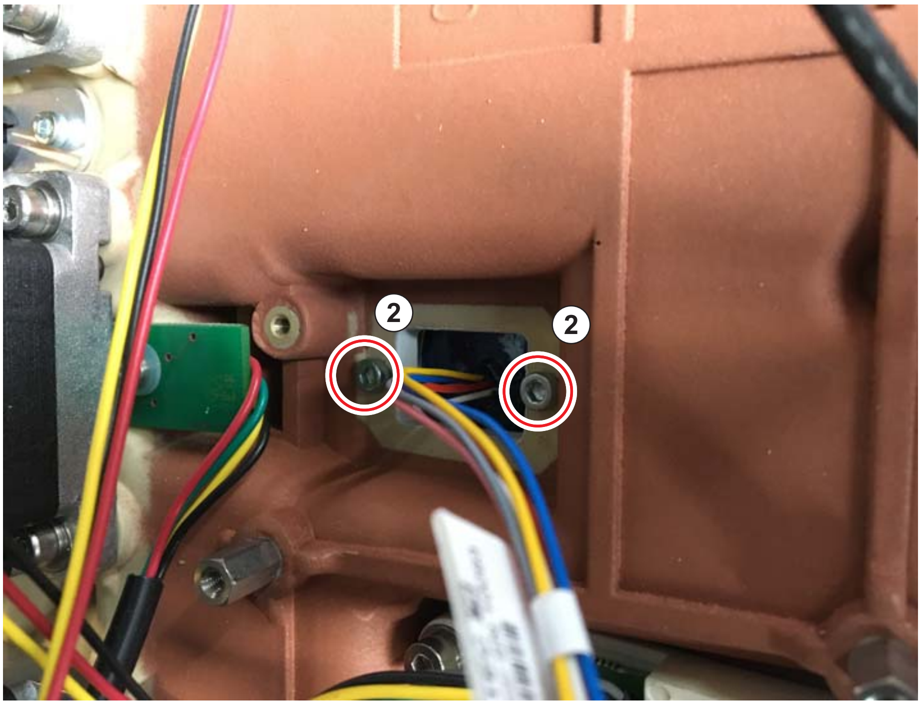


Fig. 5-75 FSM level detector

3. Loosen the 2 screws ② to disassemble the solution level detector.

Assembling of FSM Level Detector

1. Fasten the 2 screws to assemble the solution level detector.
2. Fasten the 4 screws of the fluid side board.
3. Connect the solution level detector cable ① to the fluid side board (J215).

5.7.5.9 Blood Leak Detector

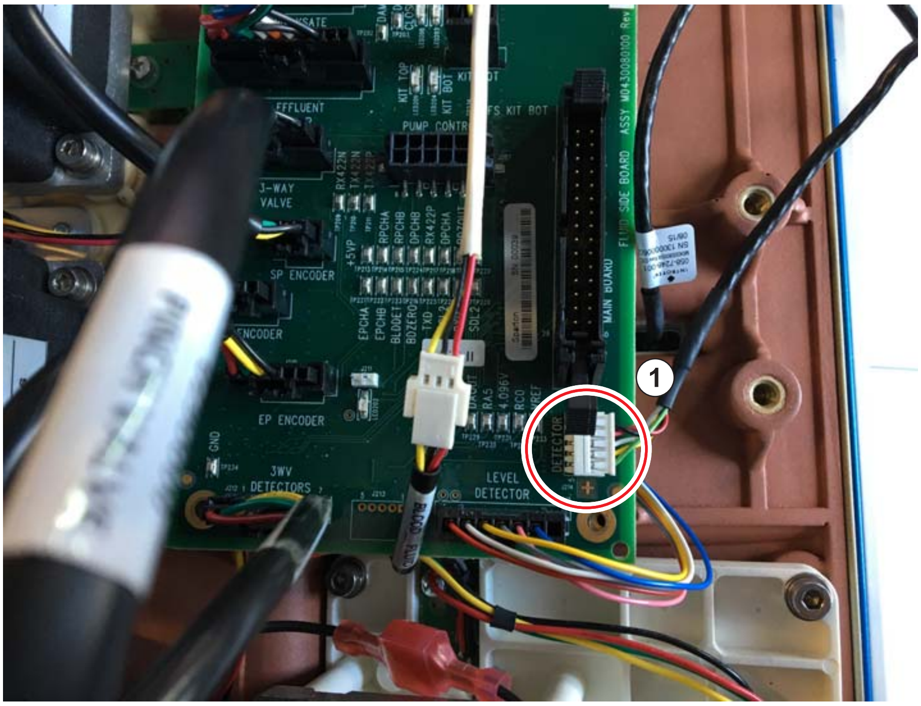


Fig. 5-76 Blood leak detector connector

Prerequisites

- Fluid side manifold is disassembled

Disassembling of the Blood Leak Detector

1. Disconnect blood leak detector cable ① from the fluid side manifold (J214).

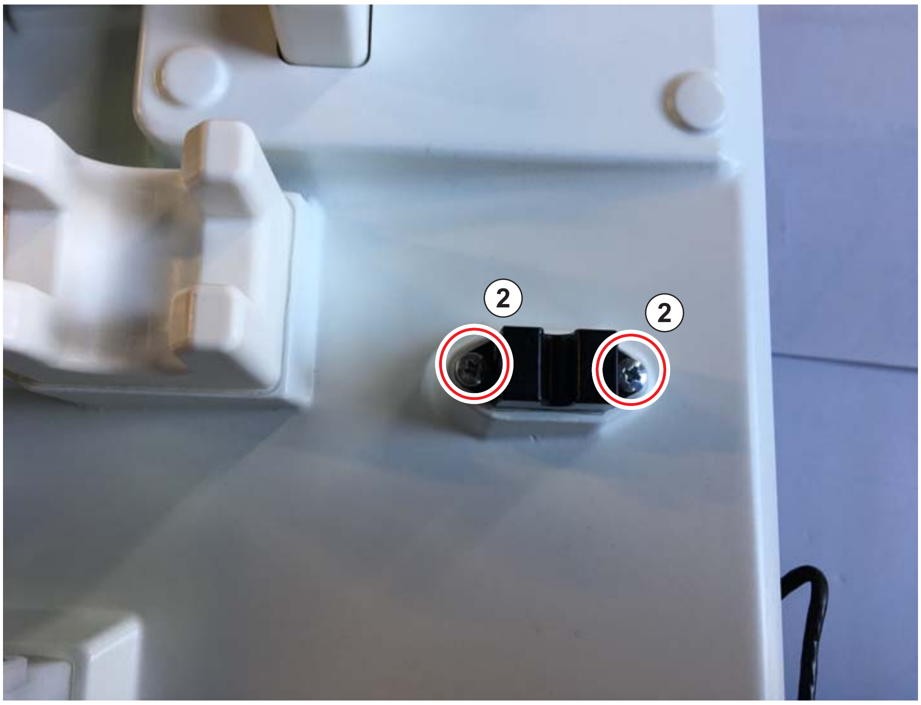


Fig. 5-77 Blood leak detector

2. Loosen two screws ② of the blood leak detector.
3. Remove the sealing of the blood leak detector.

Assembling of the Blood Leak Detector

1. Assemble sealing on the blood leak detector.
2. Fasten the two screws to assemble the blood leak detector on the manifold.
3. Connect blood leak detector cable on the fluid side manifold (J214).

5.7.5.10 3-way clamp

i

- Do not squeeze any cable during the assembling of the 3-way clamp

Prerequisites

- Rear housing is removed.
- Fluid side manifold is disassembled.

Disassembling of the 3-Way Clamp

1. Disconnect power cable from the clamp motor ①

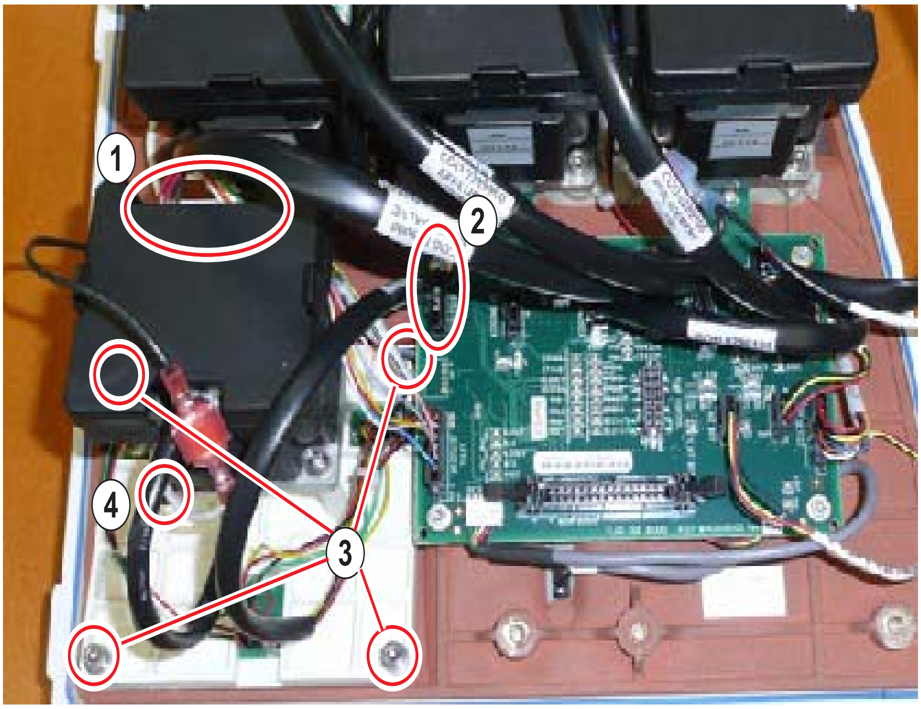


Fig. 5-78 Fluid side manifold

2. Disconnect 3-way clamp cable from the fluid side board (J212) ② .
3. Disconnect grounding connection of the 3-way clamp head ④ .
4. Disassemble 3-way clamp by loosening the 4 screws ③ .

Assembling of the 3-Way Clamp

1. Insert 3-way clamp into the fluid side manifold.
2. Fix 3-way clamp.

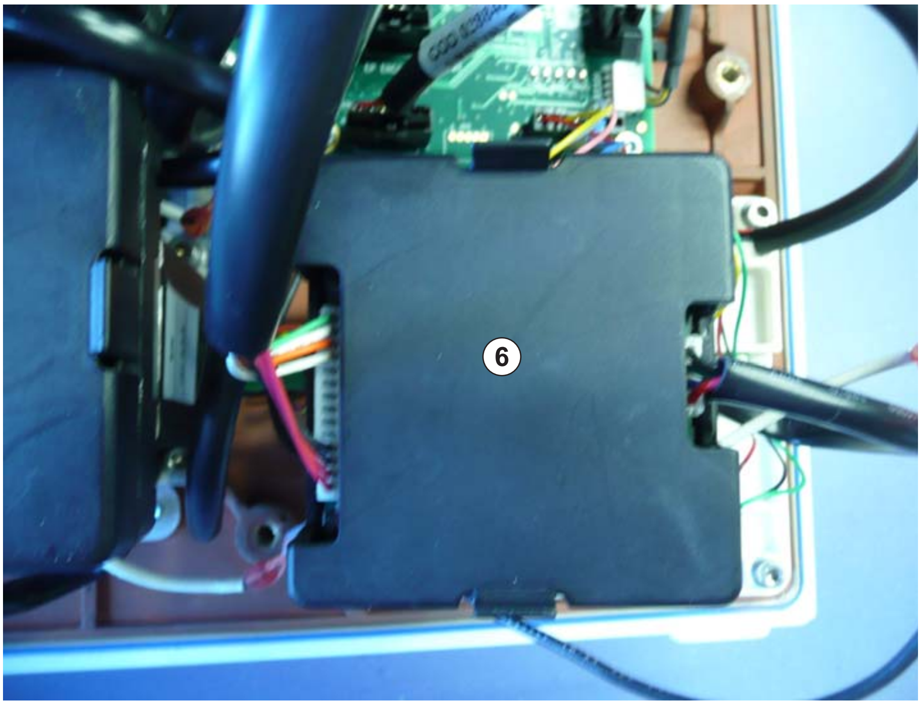


Fig. 5-79 3-way clamp cover

3. Remove 3-way clamp cover ⑤ .

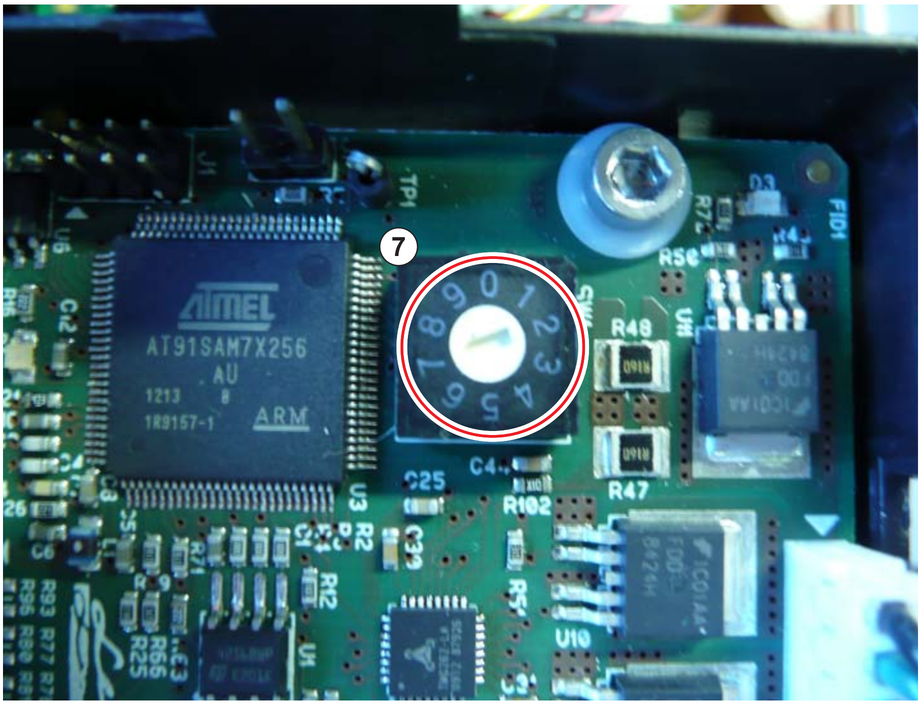


Fig. 5-80 3-way clamp code

4. Check/set dip switch ⑦ to 7.
5. Fix 3-way clamp cover.
6. Connect the power cable to the clamp motor.
7. Connect 3-way clamp cable to the fluid side board (J212).
8. Connect grounding to the 3-way clamp head.

5.7.5.10.1 3-Way-Clamp Cable

Cut cable ties only if necessary. Make sure that all attached components are working properly when service activity is successfully done.

Prerequisites

- Fluid side manifold is disassembled.

Disassembling of the 3-Way Clamp Cable

1. Disconnect 3-way clamp cable from the 3-way clamp ① (J3).

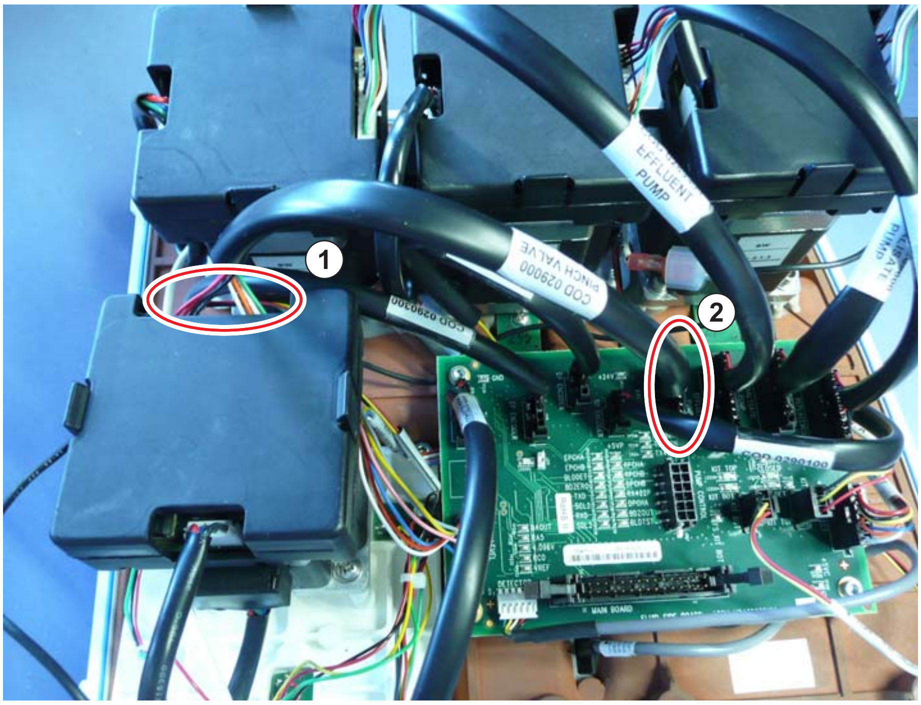


Fig. 5-81 3-way clamp cable

2. Disconnect 3-way clamp cable from fluid side board ② (J205).

Assembling of the 3-Way Clamp Cable

1. Connect 3-way clamp cable from fluid side board ② (J205).
2. Connect 3-way clamp cable from the 3-way clamp ① (J3).

5.7.6 Components Upper Housing

5.7.6.1 Battery

Prerequisites

- Rear housing is disassembled.
- Blood side manifold is disassembled.
- Fluid side manifold is disassembled..

Disassembling of the Battery

1. Loosen the 2 screws ① to disassemble the battery bracket.

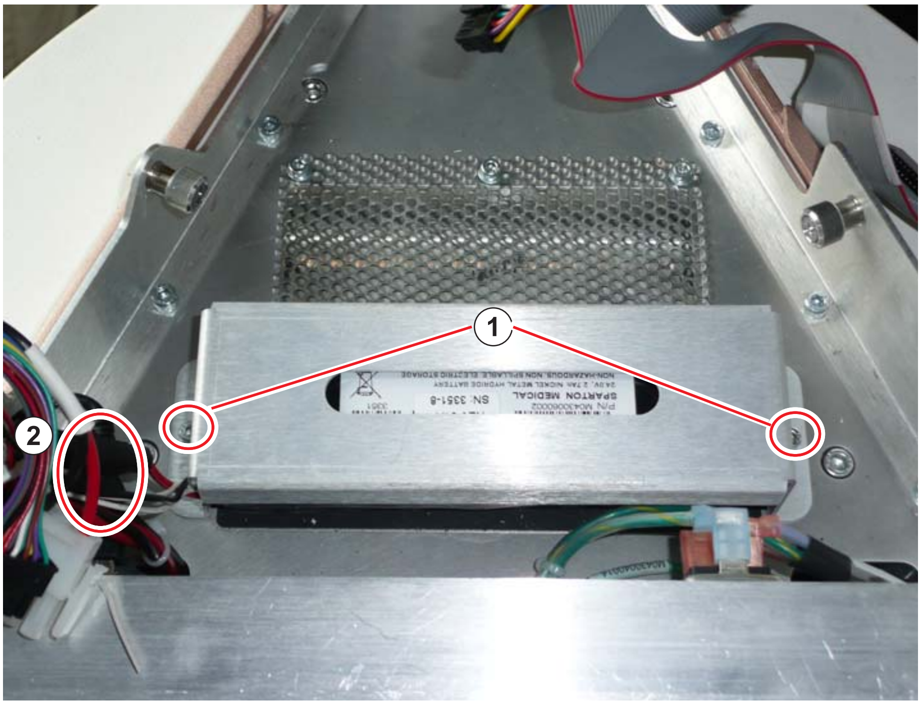


Fig. 5-82 Battery

2. Disconnect the battery ② .
3. Disassemble the battery.

Assembling of the Battery

1. Assemble battery.
2. Connect the battery ② .
3. Fasten the 2 screws ① to assemble the battery bracket.

5.7.6.2 Citrate Load Cell

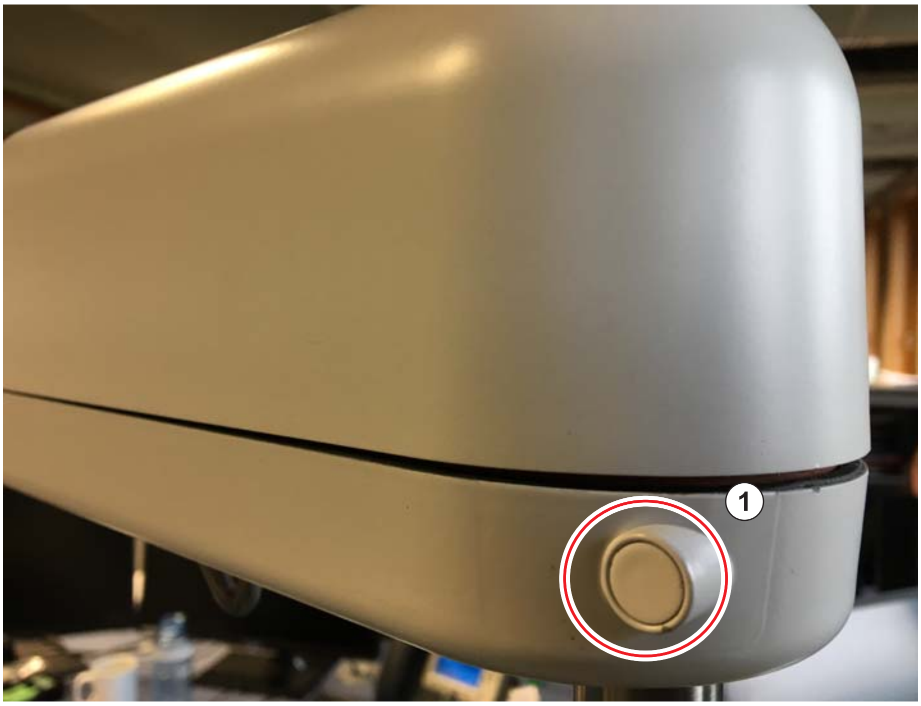


Fig. 5-83 Citrate load cell

Do not damage the painting while removing the plug of the citrate load cell cover.

Diassembling of the Citrate Load Cell

1. Remove the plug from the citrate load cell cover.
2. Loosen the 3 screws of the citrate load cell cover to open the load cell.
3. Loosen the screw to remove the citrate load cell.
4. Disconnect the citrate load cell cable.

Assembling of the Citrate Load Cell

1. Open new citrate load cell.
2. Connect the citrate load cell cable.
3. Fasten the screw to fix the citrate load cell on the citrate pole.
4. Close citrate load cell.
5. Fasten the screw of the citrate load cell on the citrate pole.

5.7.6.2.1 Citrate Pole

Prerequisites

- Citrate load cell is disassembled.
- Lower housing is disassembled.

Disassembling of the Citrate Load Cell Cable

1. Disconnect citrate load cell cable.

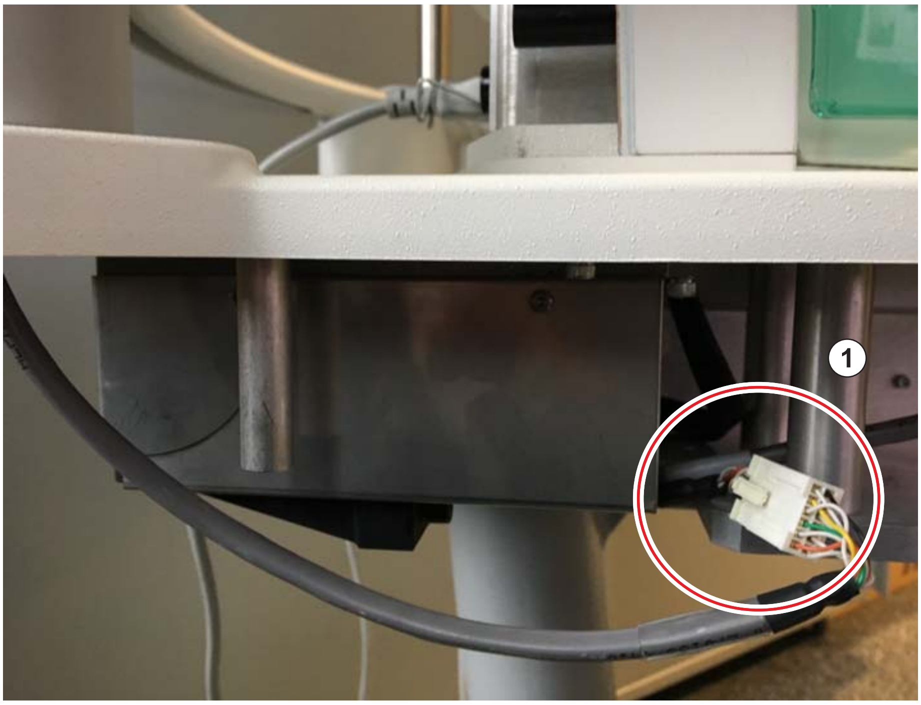


Fig. 5-84 Citrate load cell connection (lower housing)

2. Remove citrate load cell cable from the citrate pole.

Assembling of the Citrate Load Cell Cable

1. Insert the citrate load cell cable into the citrate pole.
2. Assemble citrate pole.
3. Connect the citrate load cell cable to the citrate load cell and the connector in the lower housing.
4. Assemble citrate load cell on the top of the citrate pole.

5.7.6.3 Audio Codec Board

NOTICE!

Machine will not pass the selftest due to a bad or wrong cable connection.

- Connect all cables regarding the labeling on the cable and the labeling on the board.
- All connections are described in the service manual chapter 8.

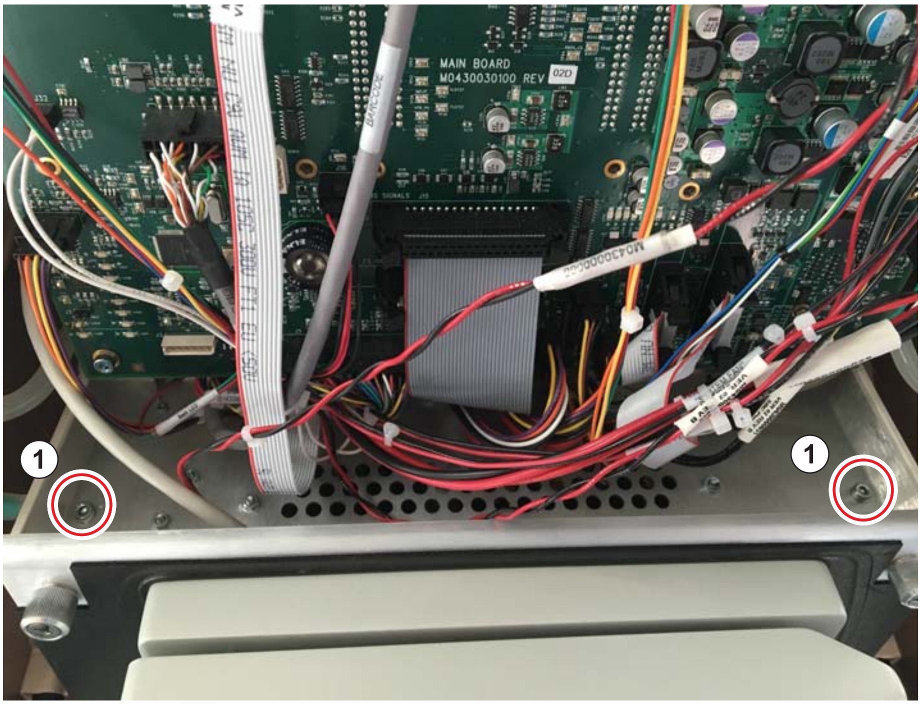


Fig. 5-85 Main board bracket

Prerequisites

- Remove rear housing.Warmer assembly has to be fixed on the main board bracket.
- Loosen the two screws for the main board bracket ① .
- Disconnect J16 (Microphone/Buzzer cable) and J 18 (Mains power).

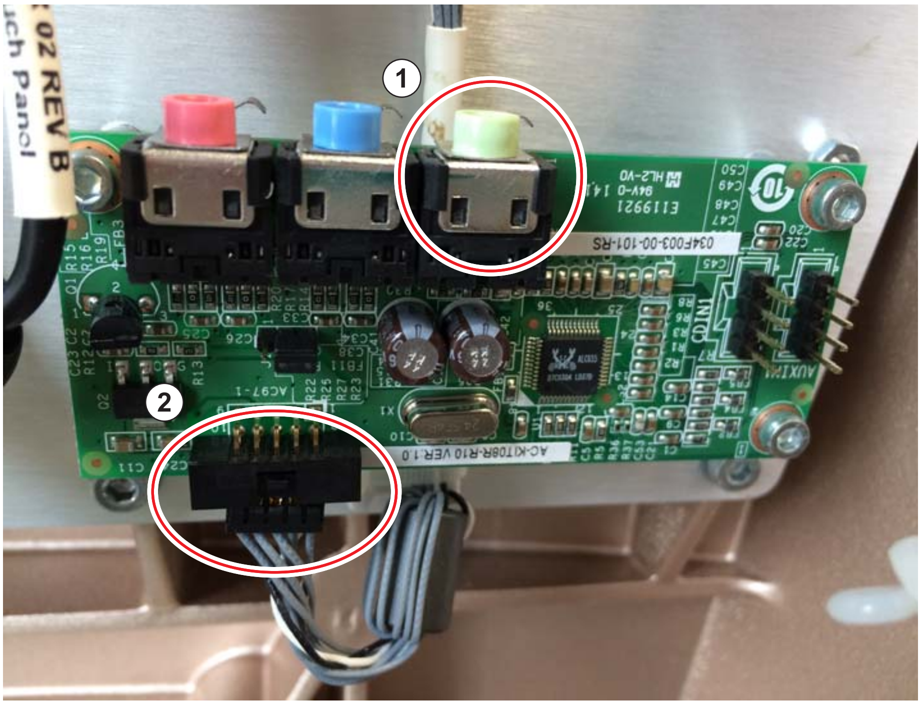


Fig. 5-86 Audio codec board

Disassembling of the Audio Codec Board

1. Disconnect the STAT LED cable and the audio jack (sound input) from the main board.
2. Flap down the main board bracket.
3. Disconnect the audio jack ① and the connection to the single board computer ② from the audio codec board.
4. Loosen the three screws of the Audio codec board.

Assembling of the Audio Codec Board

1. Fasten the 3 screws to assemble the audio codec board.
2. Connect the audio jack and the connection to the single board computer to the audio codec board.
3. Fix main board bracket.
4. Connect the STAT LED cable and the audio jack (sound input) to the main board.
5. Connect J16 and J18 to the main board.

5.7.6.4 Manometer Connectors

This instruction is valid and has to be used for all five manometer connectors of the machine.

Prerequisites

- Rear housing is disassembled..

Disassembling of the Manometer Connectors

1. Remove silicone tube from the manometer connector.

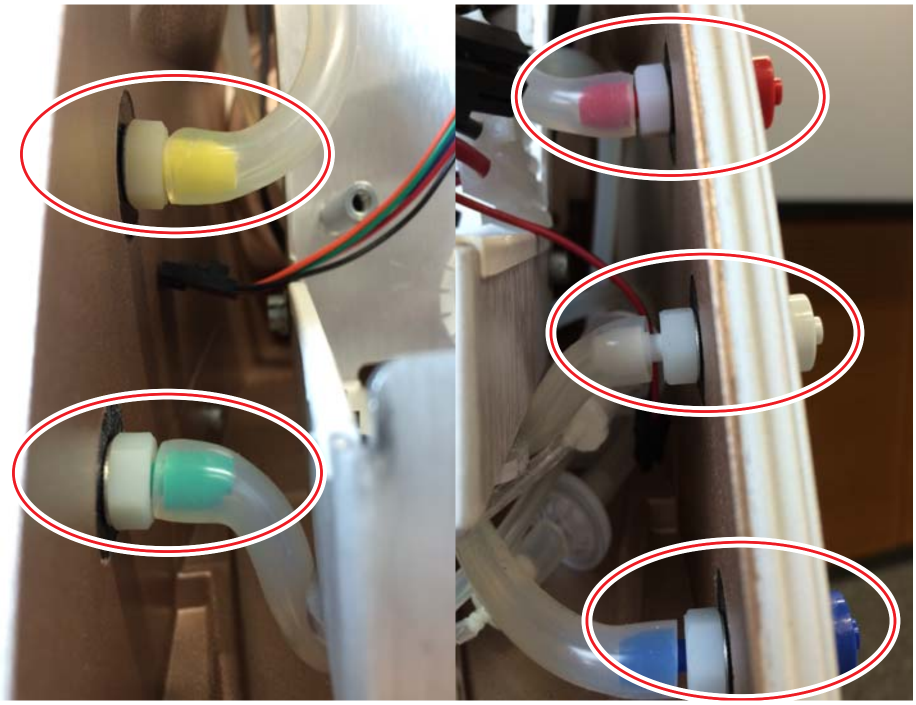


Fig. 5-87 Manometer connectors)

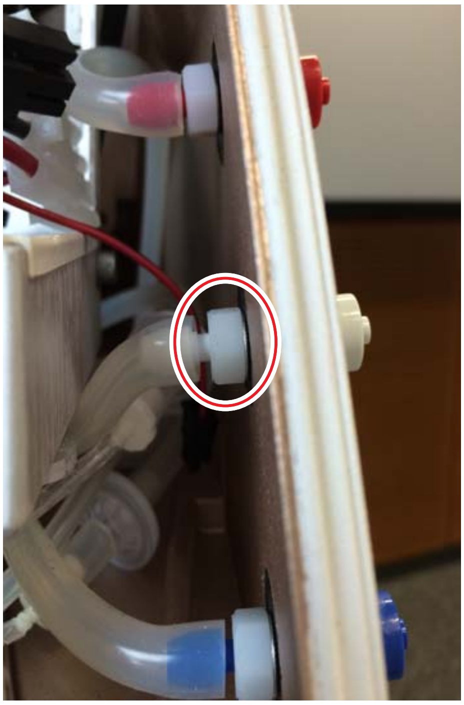


Fig. 5-88 Nut screw manometer connector

2. Loosen nut screw from the manometer connector and disassemble the manometer connector.

Assembling of the Manometer Connectors

1. Assemble manometer connector and fasten the nut screw.
2. Connect the silicon tube to the manometer connector.

5

5.7.6.5 Hydrophobic Filter

This instruction is valid and has to be used for all hydrophobic filters of the machine.

Prerequisites

- Rear housing is disassembled.

Disassembling of the Hydrophobic Filters

1. Take out the hydrophobic filter.
2. Remove the silicon tube on both sides of the filter to disassemble the filter.

Fig. 5-89 Hydrophobic filters

Assembling of the Hydrophobic Filters

1. Connect the white side of the hydrophobic filter to the silicon tube of the manometer connector.
2. Connect the transparent side of the filter to the silicon tube of the level regulation block.
3. Place the filter behind the main bracket.

5.7.6.6 Light Bar Board

Prerequisites

- Rear housing is disassembled.

Disassembling of the Light Bar Board

1. Disconnect the light bar board cable.
2. Loosen the two screws to disassemble the light bar board.

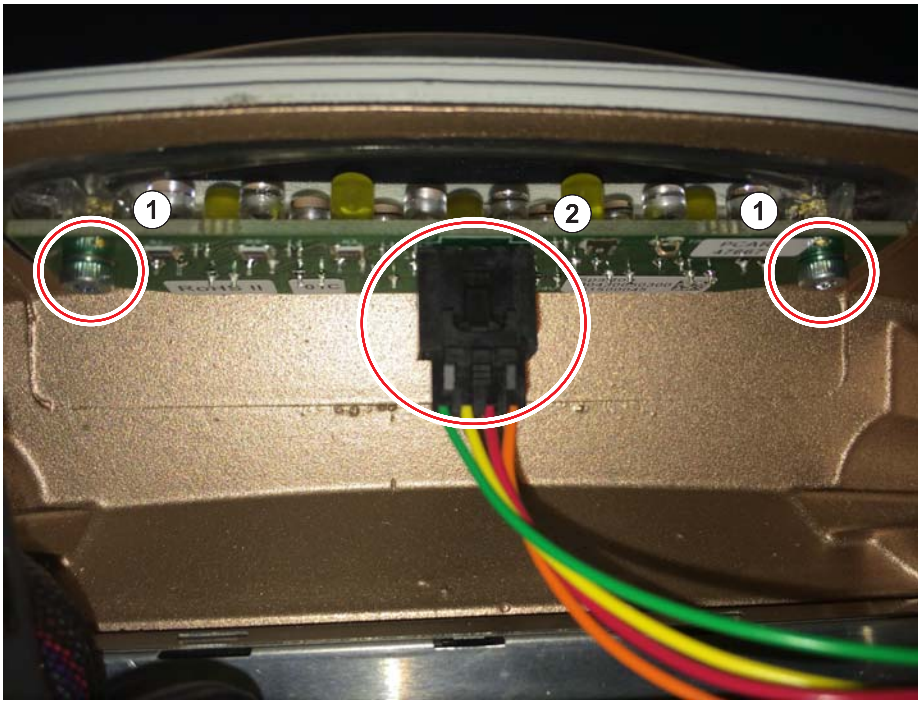


Fig. 5-90 Light bar board

Assembling of the Light Bar Board

1. Fasten the two screws to assemble the light bar board.
2. Connect the light bar board cable.

5.7.6.7 Mounting Bracket Level Regulation Block

Prerequisites

- Main board is disassembled.

Disassembling of the Mounting Bracket for Level Regulation

1. Loosen the 2 screws ① of the mounting bracket

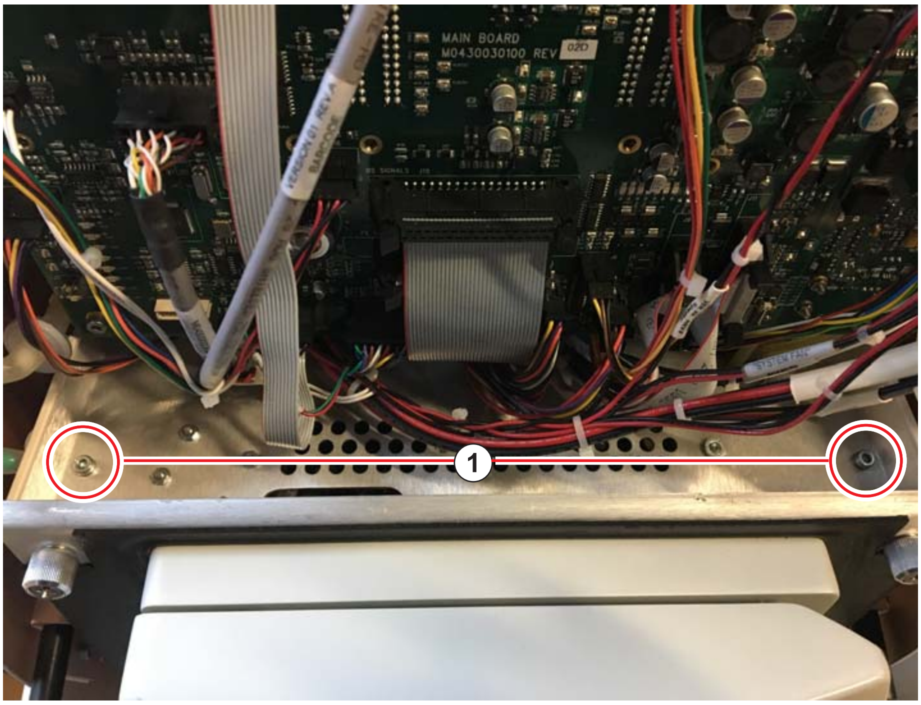


Fig. 5-91 Screws of the mounting bracket

2. Loosen the 2 screws ① to disassemble the level regulation block.

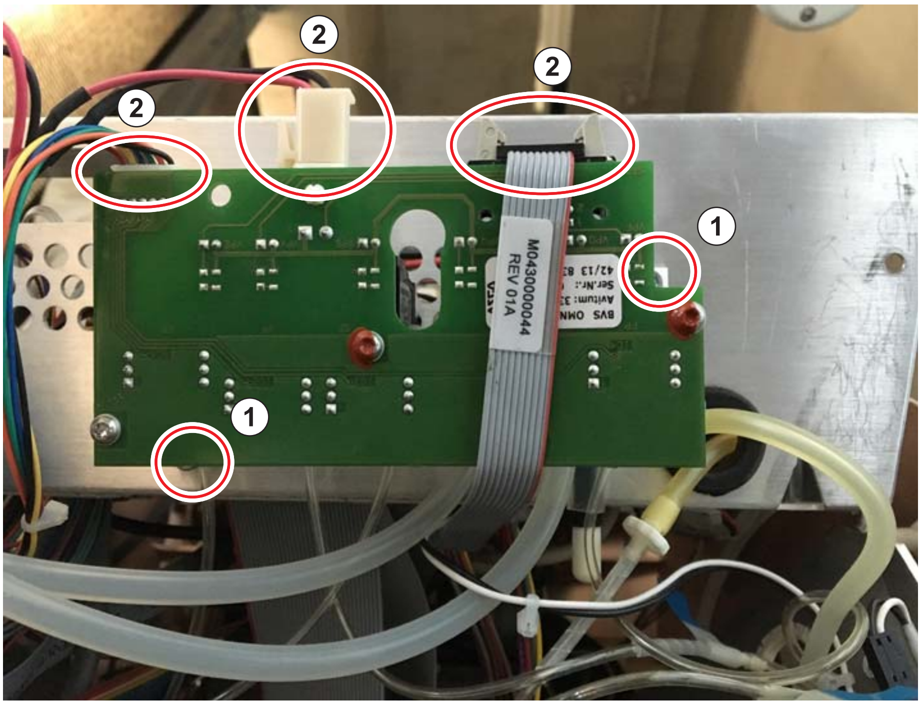


Fig. 5-92 Screws of the level regulation block

3. Loosen the 4 hex nuts to disassemble the level regulation pump.

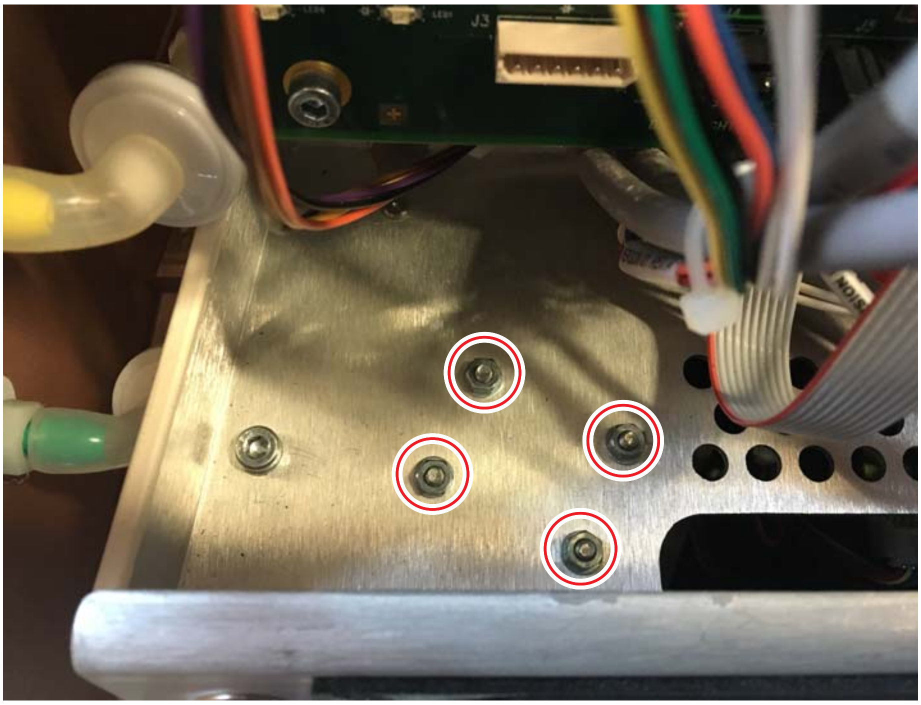
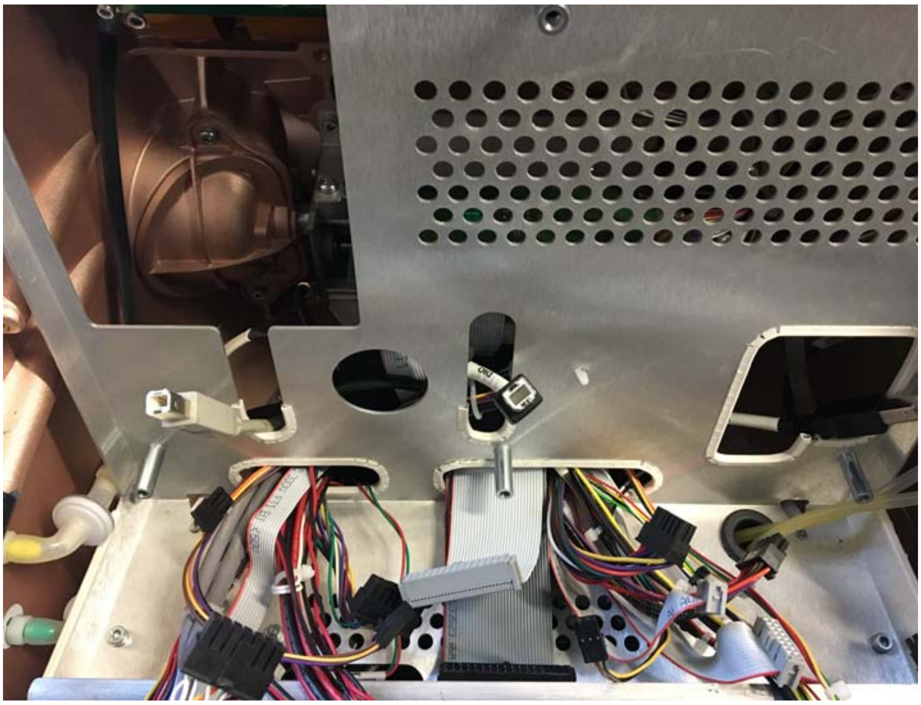


Fig. 5-93 Screws of the level regulation pump

4. Remove all cables from the mounting bracket.

Assembling of the Mounting Bracket for Level Regulation

1. Insert all cables into the holes of the new mounting bracket.



2. Fasten the 4 hex nuts to assemble the level regulation pump.

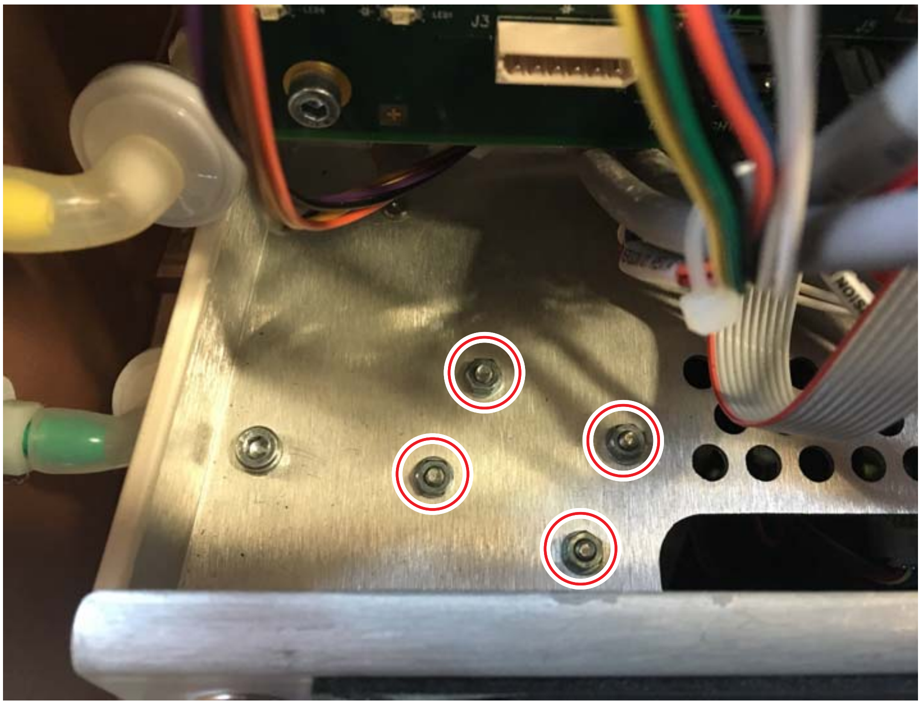


Fig. 5-94 Screws of the level regulation pump

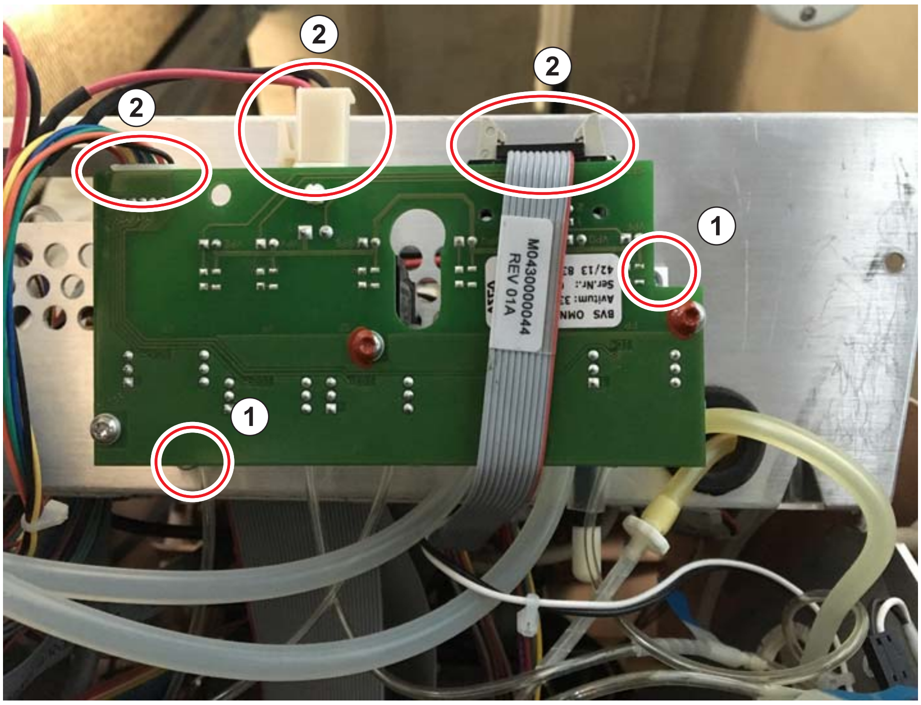


Fig. 5-95 Screws of the level regulation block

3. Fasten the 2 screws to assemble the level regulation block ① .
4. Fasten the 2 screws of the mounting bracket

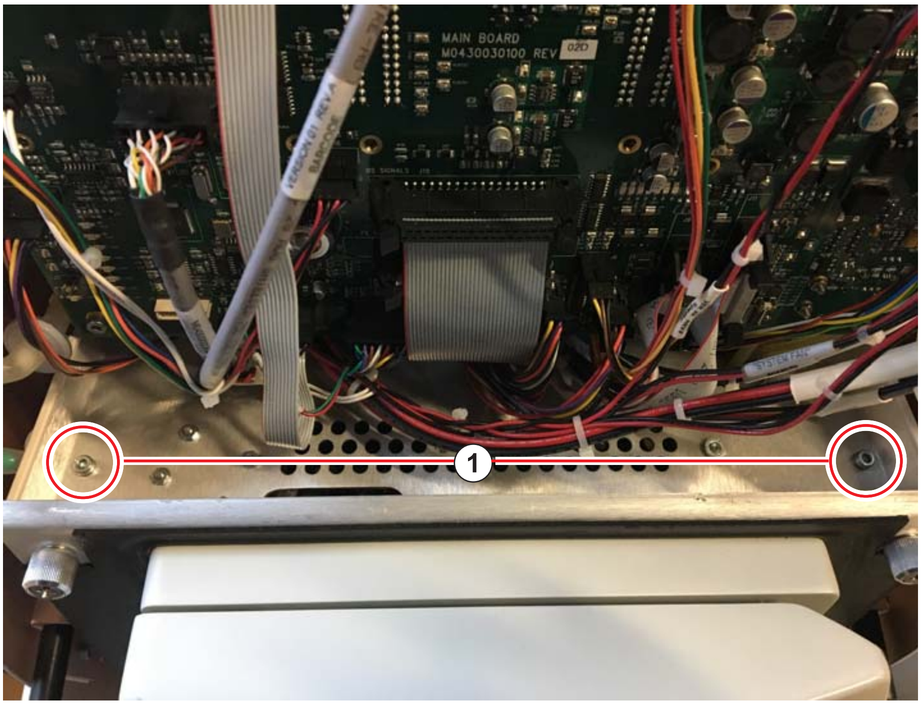


Fig. 5-96 Screws of the mounting bracket

5

5.7.6.8 Level Regulation Block

NOTICE!

Machine will not pass the selftest due to a bad or wrong tubing connection.

- Connect the silicon tubing of each manometer connector to the level regulation block according to the labeling printed on the level regulation block.
- Connect the silicon tubing between the level regulation pump and the regulation block according to the provided description.

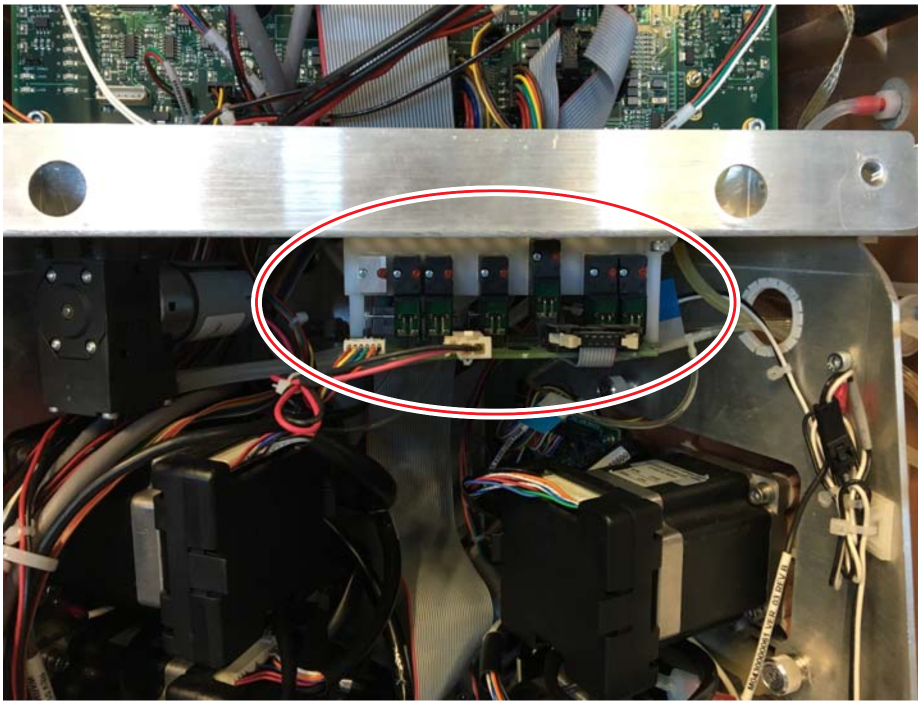


Fig. 5-97 Level regulation block

Prerequisites

- Warmer assembly is removed

Disassembling of the Level Regulation Block

1. Loosen the 2 screws of the level regulation block.
2. Disconnect all cables ② from the level regulation block.
3. Disconnect the silicon tubing from the hydrophobic filters/manometer connectors.

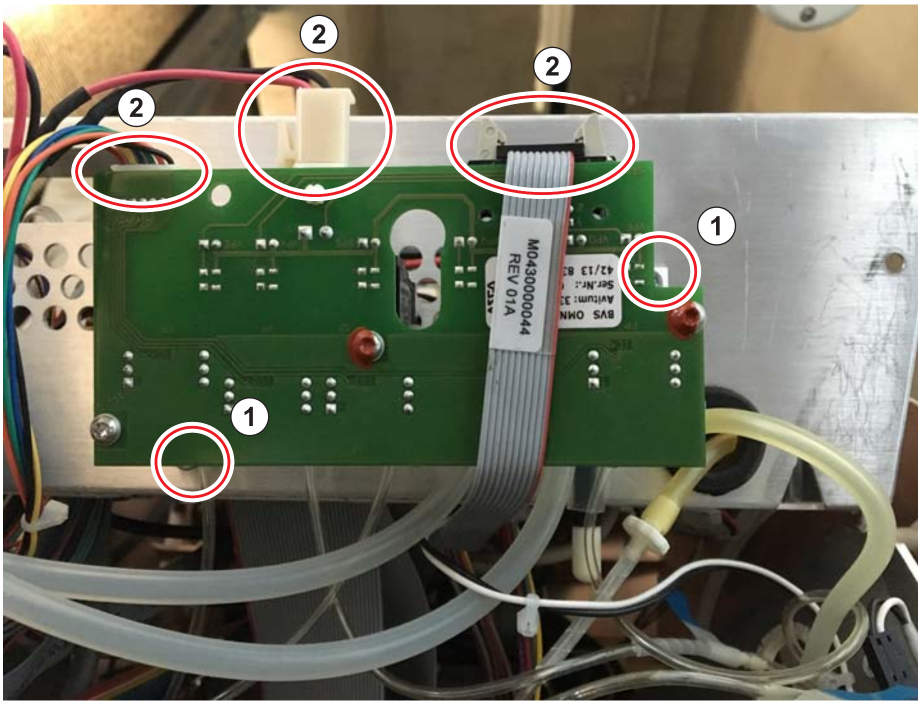


Fig. 5-98 Level regulation block Connections

4. Loosen the two screws ① to disassemble the level regulation block.

Assembling of the Level Regulation Block

1 EP
2 VP
3 SP
4 P out
5 P in
6 FP

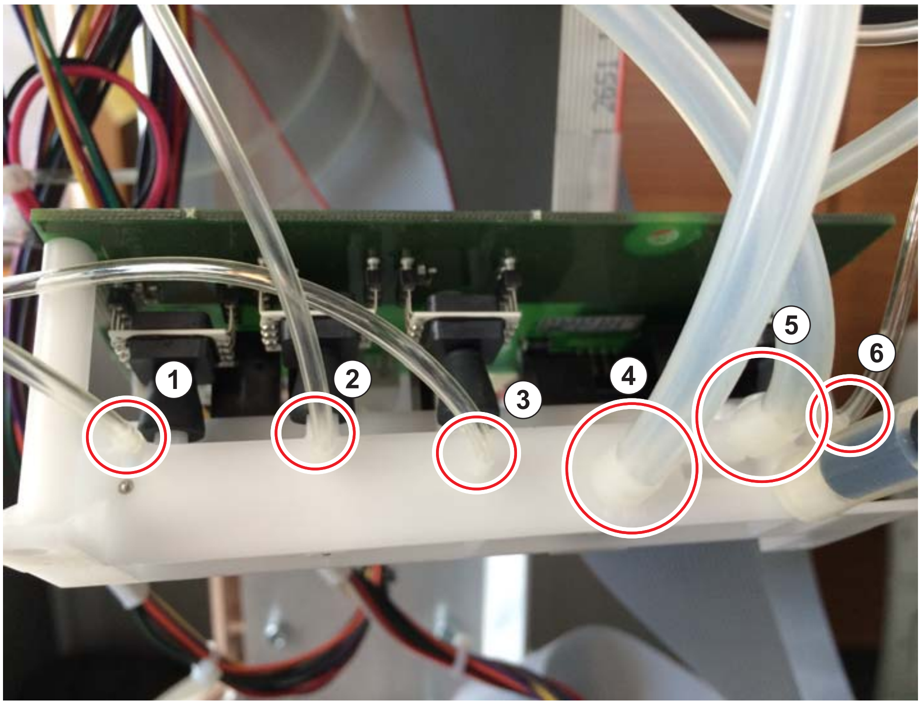


Fig. 5-99 Level regulation block tubings

5. Connect the silicon tubing of the hydrophobic filters/manometer connectors to the level regulation block according to the labeling printed on the level regulation block.
6. Connect all cables to the level regulation block.
7. Fasten the two screws to assemble the level regulation block.

5

5.7.6.9 Level Regulation Pump

NOTICE!

Machine will not pass the selftest due to a bad or wrong tubing connection.

- Connect the silicon tubing of each manometer connector to the level regulation block according to the labeling printed on the level regulation block.
- Connect the silicon tubing between the level regulation pump and the regulation block according to the provided description.

The connector *P in* of the level regulation pump is connected to the connector *P out* of the level regulation block.

The connector *P out* of the level regulation pump is connected to the connector *P in* of the level regulation block.

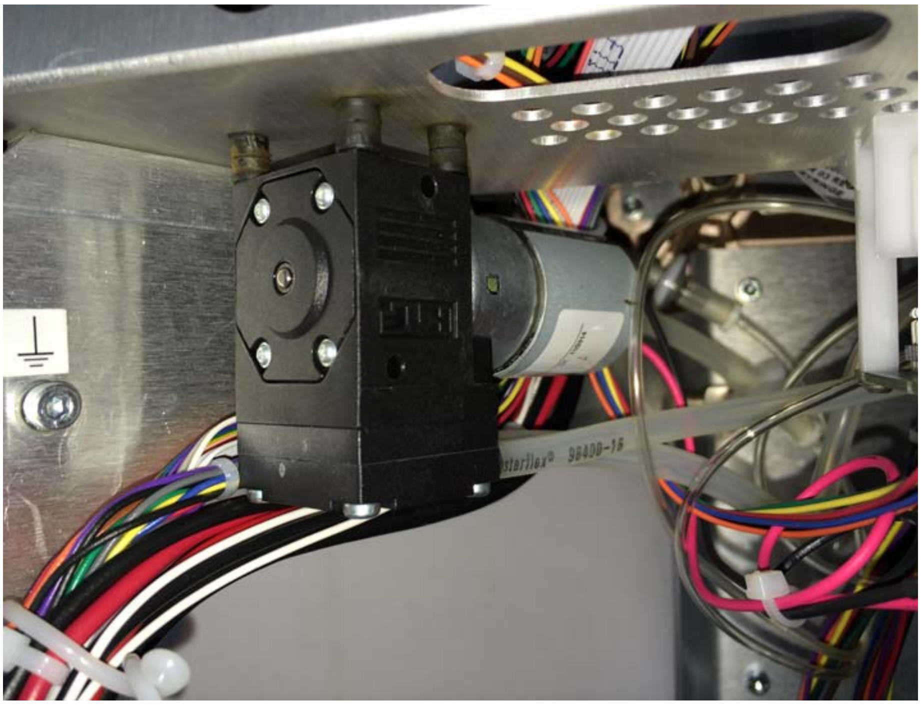


Fig. 5-100 Level regulation pump

Prerequisites

- Rear housing is disassembled.

Disassembling of the Level Regulation Pump

1. Loosen the 4 nuts of the level regulation pump.

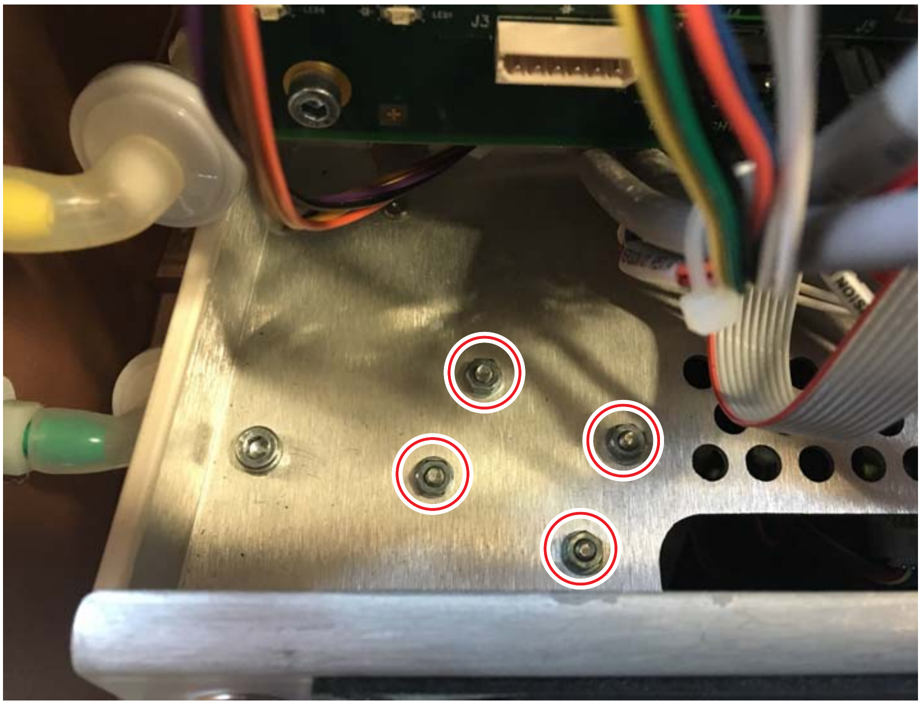


Fig. 5-101 Screws level regulation pump

2. Disconnect the cable from the level regulation block.
3. Disconnect the two silicon tubes from the level regulation pump.

1 P out

2 P in

Fig. 5-102 Level regulation pump tubings

5

Assembling of the Level Regulation Pump

1. Connect silicon tubing to the level regulation pump.
2. Connect the level regulation pump cable to the level regulation block.
3. Fasten the four nuts to assemble the level regulation pump.

5.7.6.10 Main Board

NOTICE!

Machine will not pass the selftest due to a bad or wrong cable connection.

- Connect all cables regarding the labeling on the cable and the labeling on the board.
- All connections are described in the service manual chapter 8.

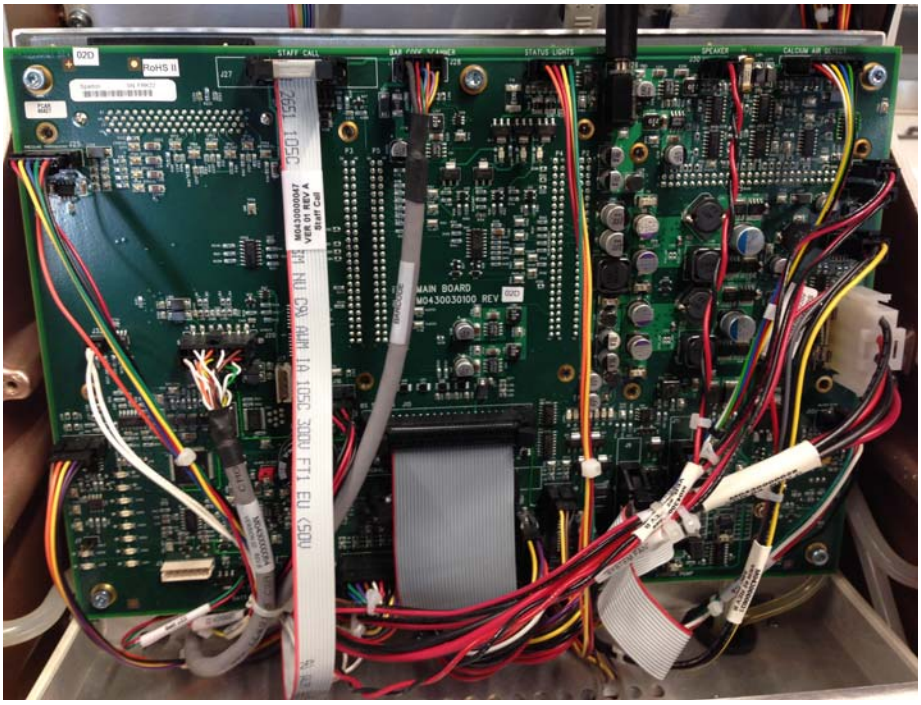


Fig. 5-103 Main board

Prerequisites

- Rear housing is disassembled.

Disassembling of the Main Board

1. Disconnect all cables from the main board.
2. Loosen the 6 screws from the main board.

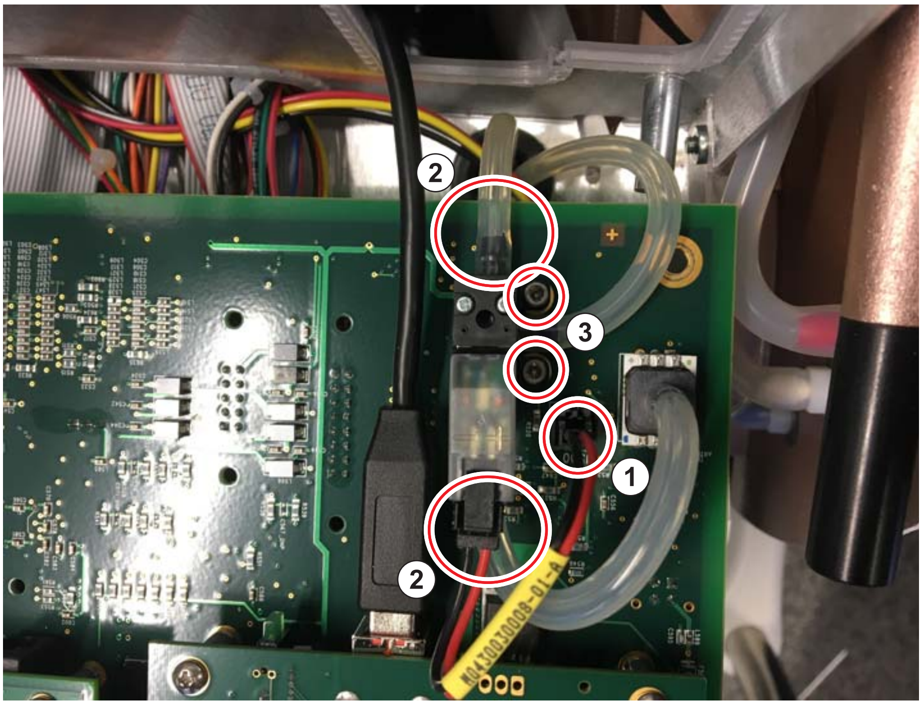


Fig. 5-104 Arterial valve connection

3. Disconnect the 2 tubes from the arterial valve ② .
4. Disconnect the 3 boards from the main board.

Assembling of the Main Board

1. Connect the 3 boards to the main board including the USB cable.
2. Connect the 2 tubes to the arterial valve ② .
3. Fasten the 6 screws to assemble the main board.
4. Connect all cables regarding their labeling on the main board.

5.7.6.11 Data Acquisition Board

Disassembling of the Data Acquisition Board

Prerequisites

- Main board is disassembled.

1. Loosen the 4 screws of the data acquisition board.

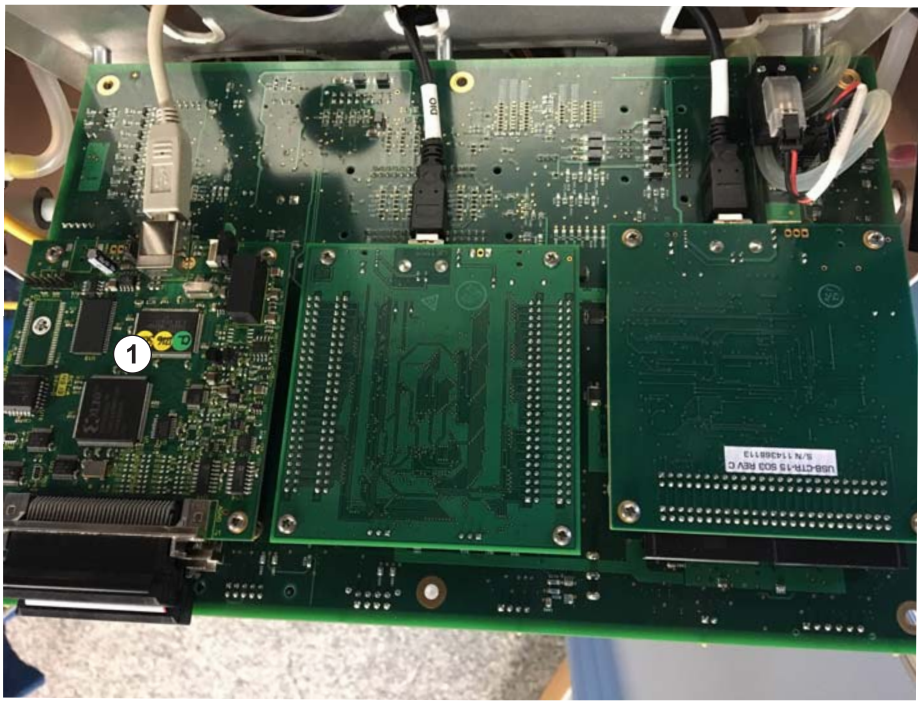


Fig. 5-105 Data acquisition board

2. Disconnect the ribbon cable.
3. Disconnect the USB connector.
4. Remove the data acquisition board from the main board.

Assembling of the Data Acquisition Board

1. Connect the ribbon cable.
2. Fasten the 4 screws to fix the data acquisition board.
3. Connect the USB connector.

5.7.6.12 Digital Input/Output Board

Prerequisites

- Main board is disassembled.

Disassembling of the Digital I/O Board

1. Disconnect the USB connector.

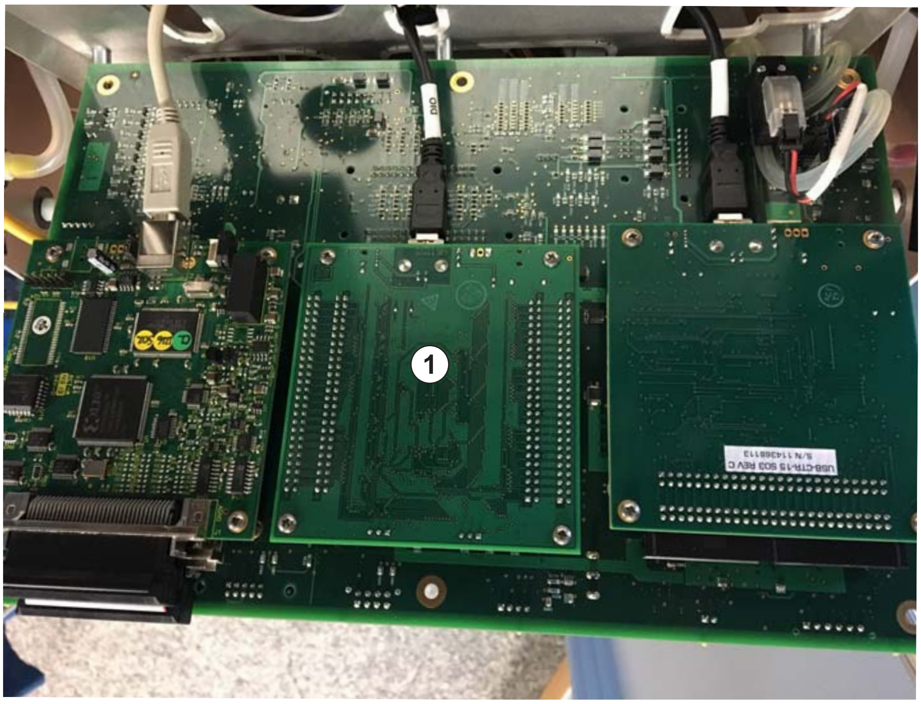


Fig. 5-106 Digital input/output board

2. Loosen the 4 screws of the digital input/output board.
3. Remove the digital input/output board.

Assembling of the Digital I/O Board

1. Assemble th digital input/out board on the main board.
2. Fasten the 4 screws to fix the digital input/output board.
3. Connect the USB connector.

5.7.6.13 Digtital Counter Board

Prerequisites

- Main board is disassembled.

Disassembling of the Digital Counter Board

1. Disconnect the USB connector.

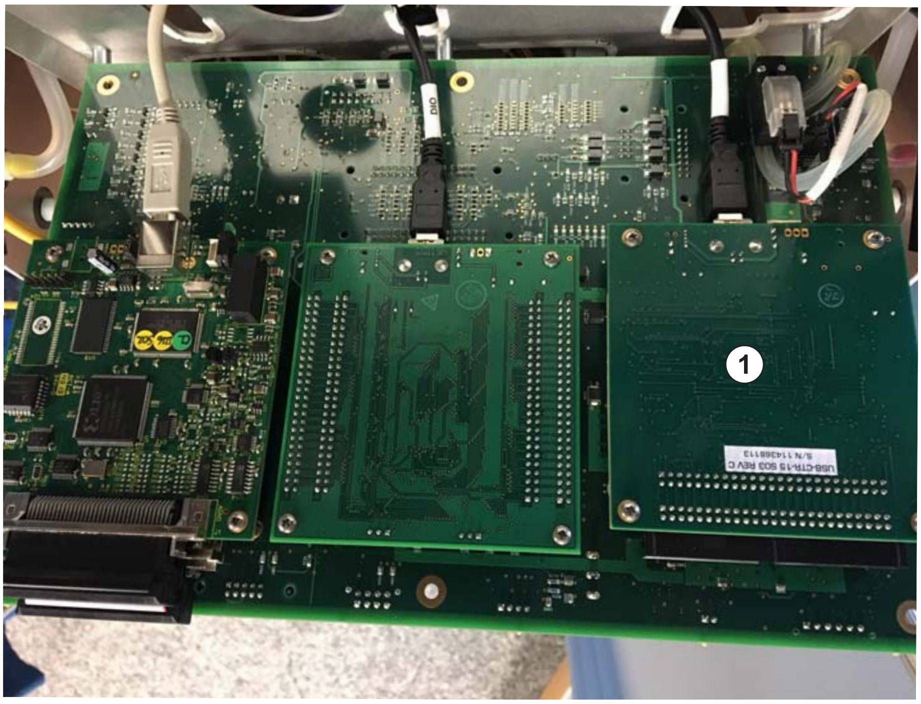


Fig. 5-107 Digital counter board

2. Loosen the 4 screws of the digital counter board.
3. Remove the digital counter board from the main board.

Assembling of the Digital Counter Board

1. Assemble the digital counter board on the main board.
2. Fasten the 4 screws to fix the digital counter board.
3. Connect the USB connector.

5.7.6.14 Single Board Computer

NOTICE!

Machine will not pass the selftest due to a bad or wrong cable connection.

- Connect all cables regarding the labeling on the cable and the labeling on the board.
- All connections are described in the service manual chapter 8.

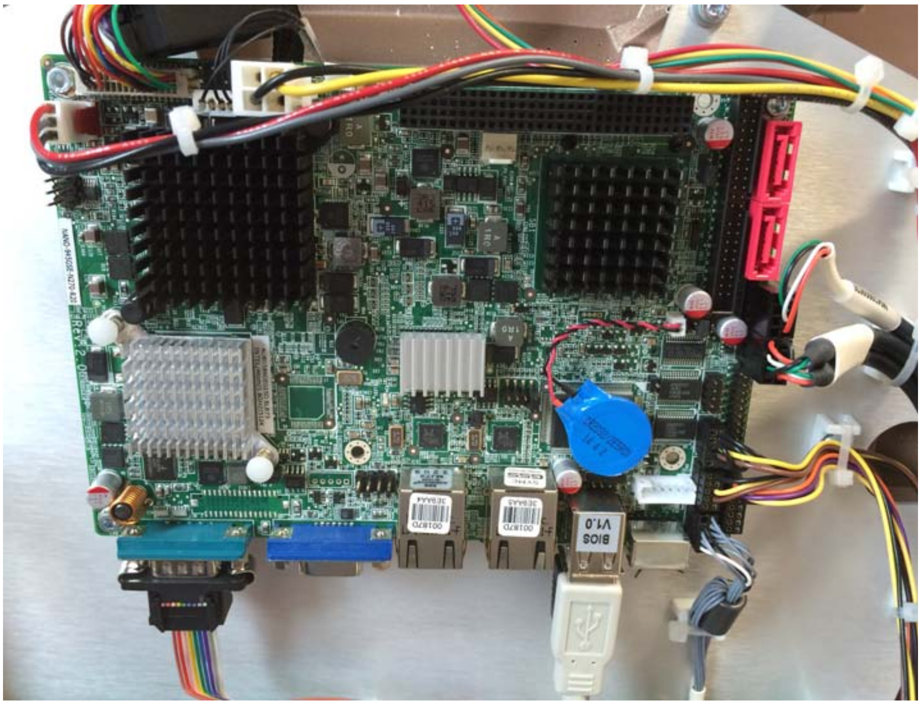


Fig. 5-108 Single board computer

Prerequisites

- Rear housing ins disassembled.

Disassembling of the Single Board Computer

1. Disconnect all cables from the single board computer.
2. Loosen the 4 screws to disassemble the single board computer.

Fig. 5-109 CF card

3. Remove CF card from the single board computer.

Assembling of the Single Board Computer

1. Insert CF card into the single board computer.
2. Fasten 4 screws to assemble the single board computer.
3. Connect all cables to the single board computer.

5.7.6.15 Compact Flash Card

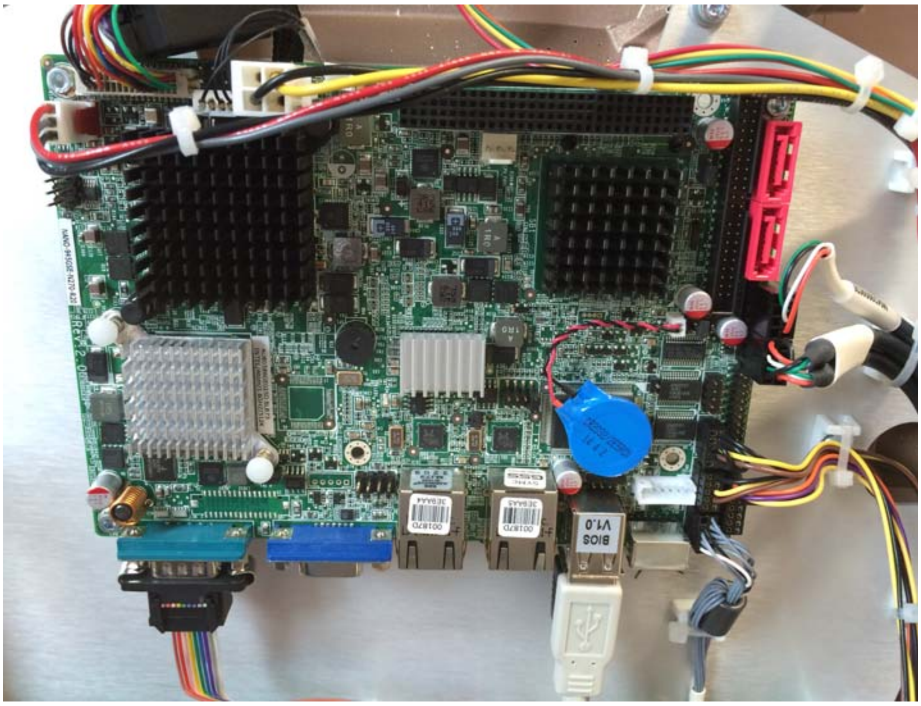


Fig. 5-110 Single board computer

Prerequisites

- Single board computer is disassembled.

Disassembling of the CF Card

1. Remove compact flash card from the single board computer.

Fig. 5-111 CF card

Assembling of the CF Card

1. Insert compact flash card into the slot on the single board computer.

5.7.6.16 Syringe Pump

Cut cable ties only if necessary. Make sure that all attached components are working properly when service activity is successfully done.

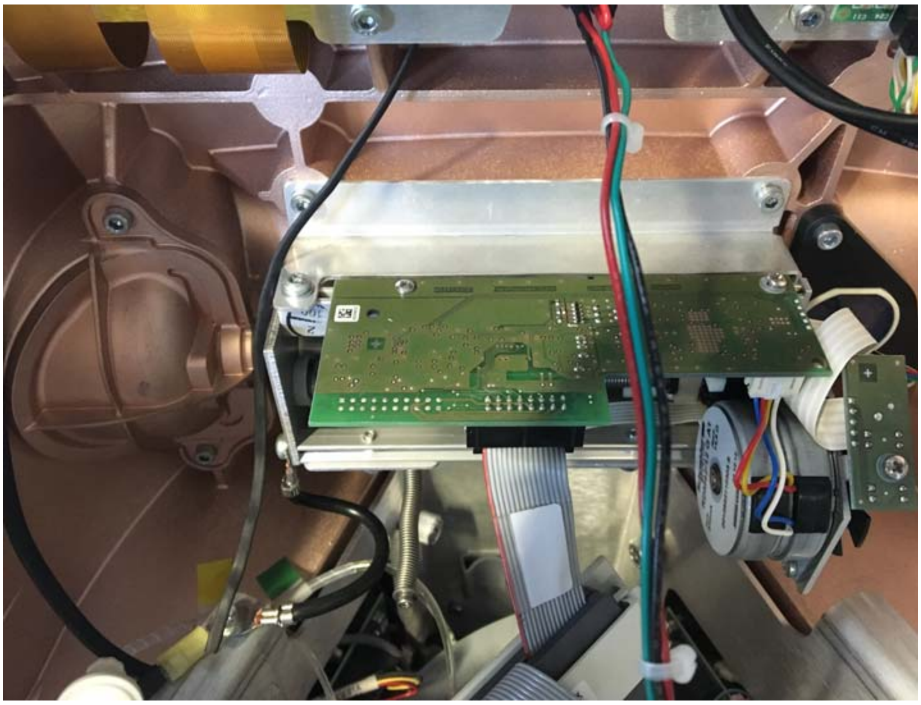


Fig. 5-112 Syringe pump

Prerequisites

- Rear housing is disassembled.
- Loosen the two screws for the main board bracket.

Disassembling of the Syringe Pump

1. Disconnect the STAT LED cable and the audio jack (sound input) from the main board.
2. Flap down the main board bracket.

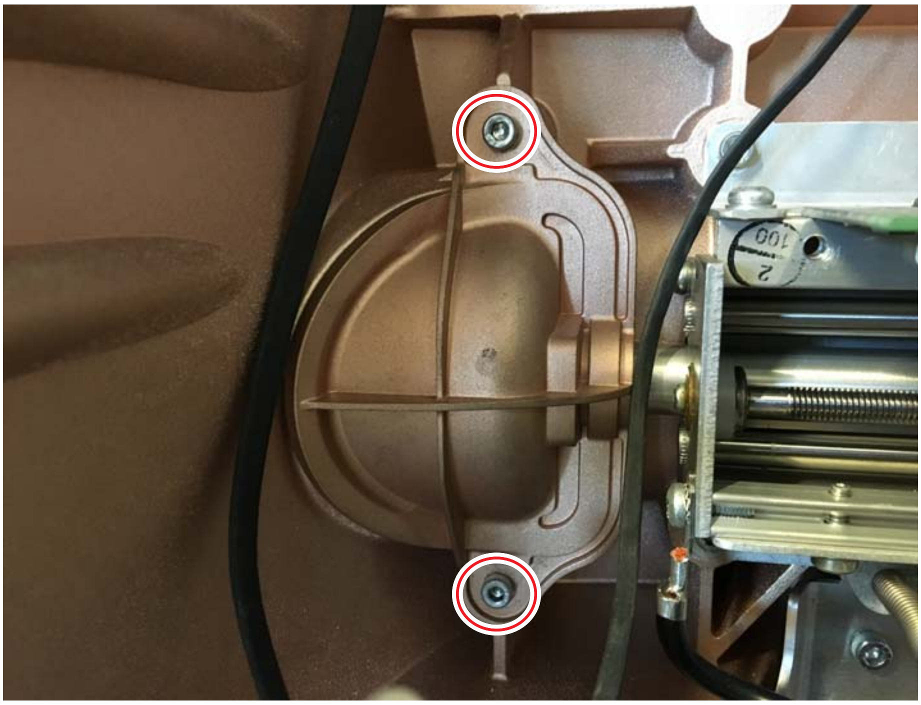


Fig. 5-113 Syringe pump cover

3. Loosen the 2 screws to disassemble the syringe pump cover.

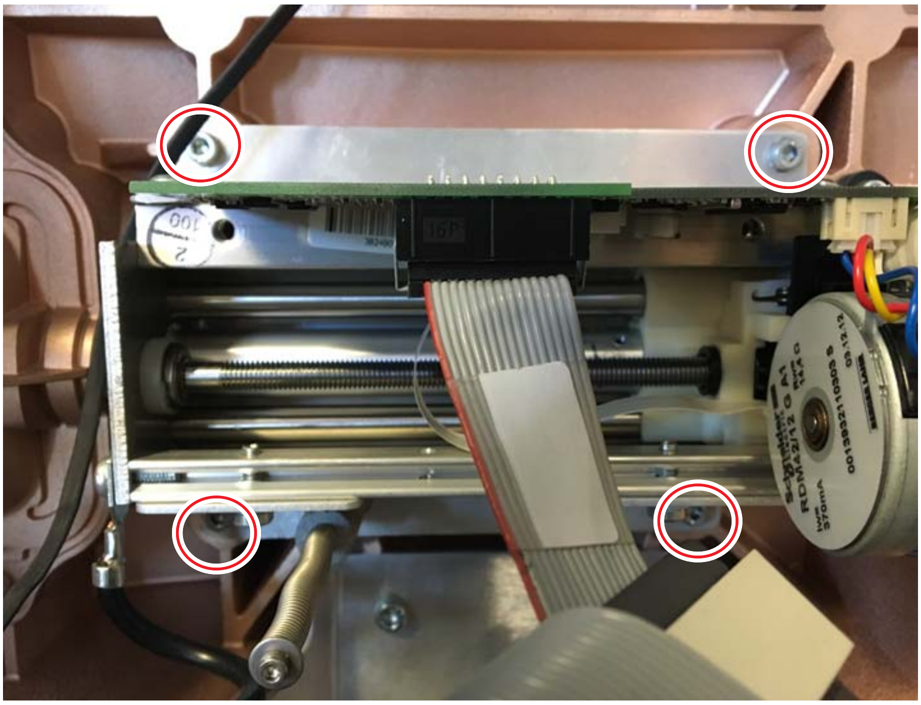


Fig. 5-114 Syringe pump fixation

4. Disconnect the ribbon cable from the syringe pump board.
5. Loosen the screw for the grounding cable.
6. Loosen the 4 screws to disassemble the syringe pump.

Assembling of the Syringe Pump

1. Insert the syringe pump into the machine housing.
2. Fasten the 4 screws to assemble the syringe pump.
3. Fasten the grounding cable.
4. Connect the ribbon cable.
5. Fasten the 2 screws to assemble the syringe pump cover.
6. Fix main board bracket.
7. Connect the STAT LED cable and the audio jack (sound input) to the main board.

5.7.6.16.1 Syringe Holder incl. Spring and Clip

Prerequisites

- Rear housing is disassembled.
- Loosen the two screws for the main board bracket.

Disassembling of the Syringe Holder

1. Disconnect the STAT LED cable and the audio jack (sound input) from the main board.
2. Flap down the main board bracket.

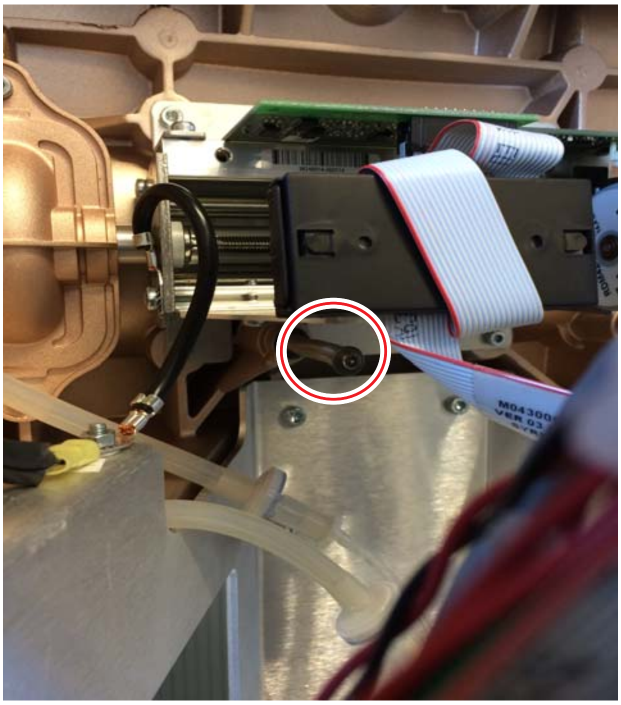


Fig. 5-115 Syringe holder

3. Loosen the screw of the syringe holder and remove the washer and the spring.
4. Disassemble the syringe holder.

Assembling of the Syringe Holder

1. Insert syringe holder into the machine housing.
2. Assemble the spring and the washer of the syringe holder.
3. Fasten the screw of the syringe holder to assemble the syringe holder on the syringe pump.
4. Fix main board bracket.
5. Connect the STAT LED cable and the audio jack (sound input) to the main board.

5.7.6.17 Calcium Safety Air Detector

Cut cable ties only if necessary. Make sure that all attached components are working properly when service activity is successfully done.

Prerequisites

- Rear housing is disassembled.
- Loosen the two screws for the main board bracket.

Disassembling of the Calcium Safety Air Detector

1. Disconnect the STAT LED cable and the audio jack (sound input) from the main board.
2. Flap down main board bracket.
3. Disconnect calcium air detector cable form the main board (J31).

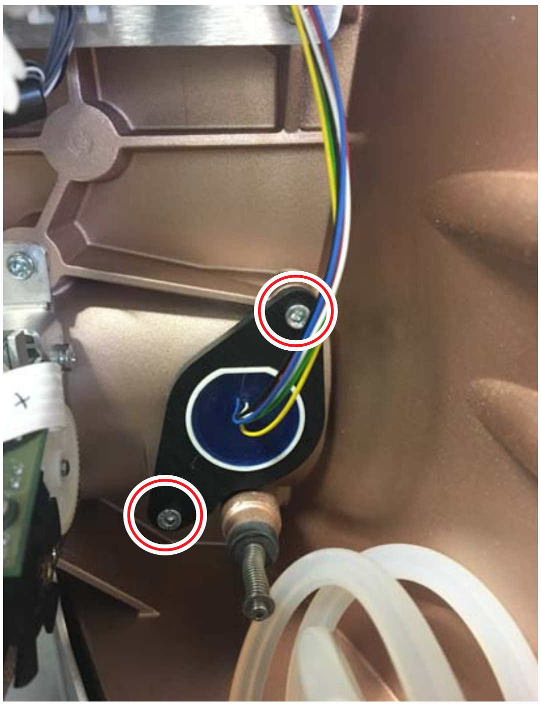


Fig. 5-116 Calcium safety air detector

4. Loosen the 2 screws to disassemble the calcium safety air detector.

Assembling of the Calcium Safety Air Detector

1. Insert the calcium safety air detector into the machine housing.
2. Fasten the 2 screws to assemble the calcium safety air detector.
3. Connect the calcium safety air detector cable to the main board (J31).
4. Fix main board bracket.
5. Connect the STAT LED cable and the audio jack (sound input) to the main board.

5.7.6.17.1 Tubing Holder incl. Spring and Clip

Prerequisites

- Rear housing is disassembled.
- Loosen the two screws for the main board bracket.

Disassembling of the Tubing Holder for SADC

1. Disconnect the STAT LED cable and the audio jack (sound input) from the main board.
2. Flap down the main board bracket.

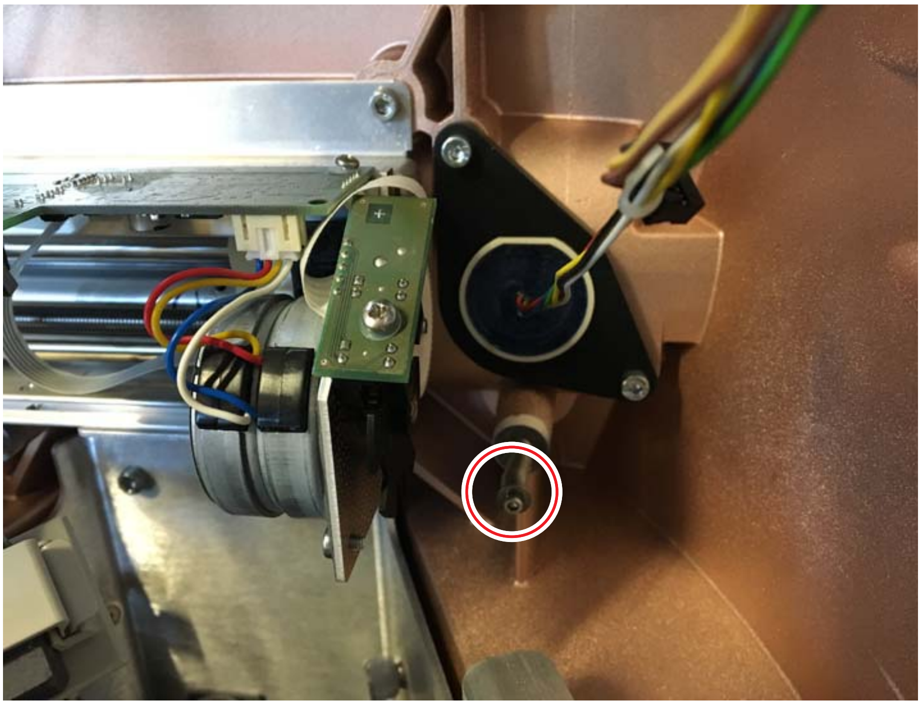


Fig. 5-117 Tubing holder fixation

3. Loosen the screw of the tubing holder and remove the washer an the spring.
4. Disassemble the tubing holder.

Assembling of the Tubing Holder for SADC

1. Insert tubing holder into the machine housing.
2. Assemble the spring and the washer in the tubing holder.
3. Fasten the screw of the tubing holder to assemble the tubing holder on the machine housing.
4. Fix main board bracket.
5. Connect the STAT LED cable and the audio jack (sound input) to the main board.

5.7.6.18 Touch Controller Board

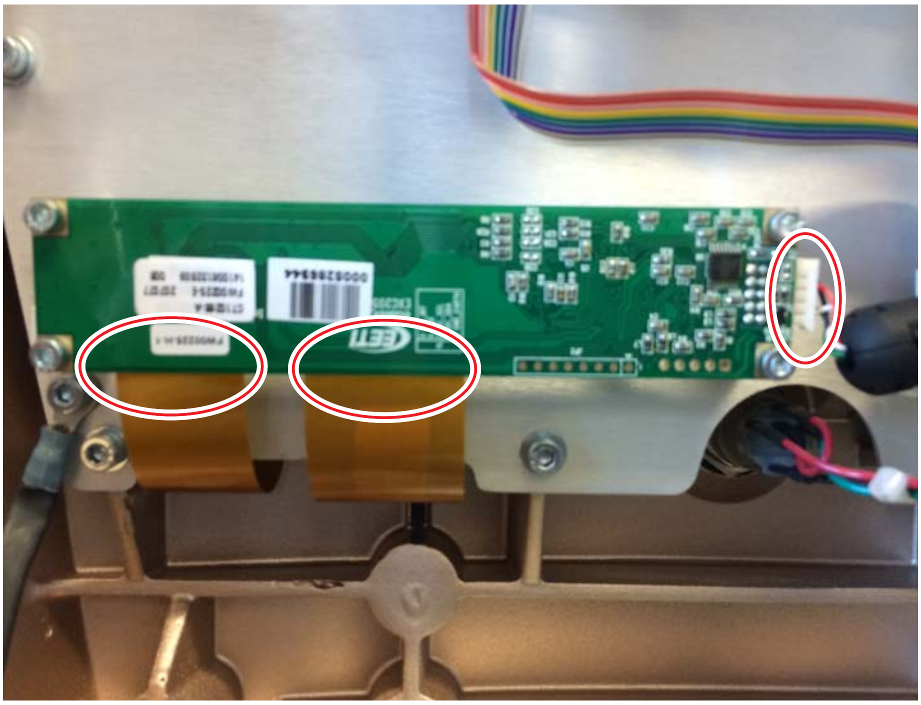


Fig. 5-118 Touch controller board

Prerequisites

- Rear housing is disassembled.
- Loosen the two screws for the main board bracket.

Disassembling of the Touch Controller Board

1. Disconnect the STAT LED cable and the audio jack (sound input) from the main board.
2. Flap down the main board bracket.

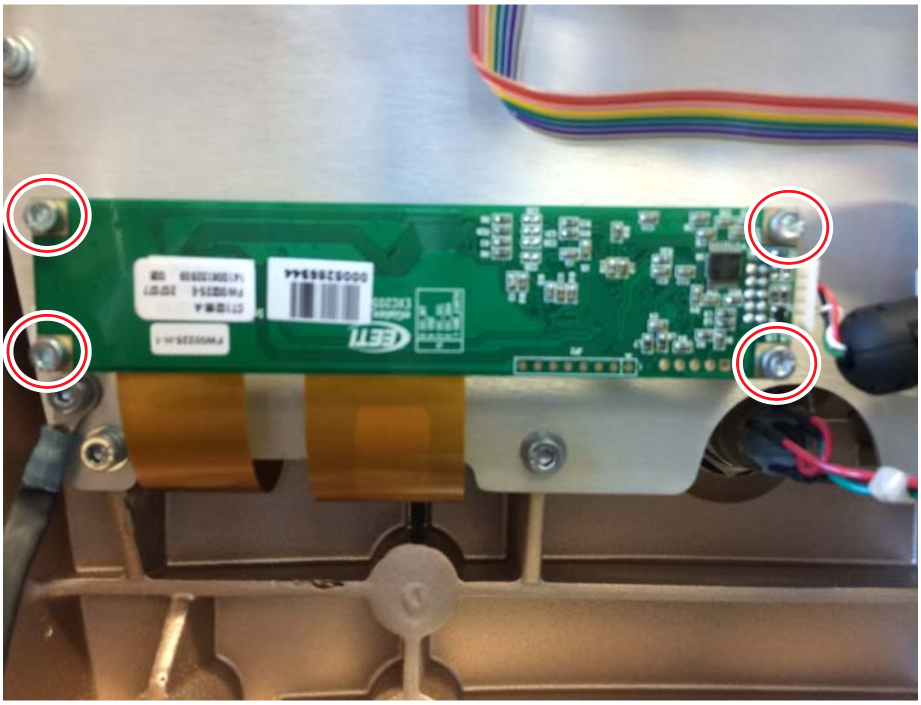


Fig. 5-119 Touch controller board fixation

3. Loosen the 4 screws to disassemble the touch controller board.
4. Disconnect the 3 cables from the touch controller board.

Assembling of the Touch Controller Board

1. Connect the 3 cables to the touch controller board.
2. Fasten the four screws to assemble the touch controller board.
3. Fix main board bracket.
4. Connect the STAT LED cable and the audio jack (sound input) to the main board.

5.7.6.19 Connector Panel

5.7.6.19.1 Mains Cord

Disassembling of the Mains Cord

1. Unlock the clip ① for the mains cord on the mains inlet.

Fig. 5-120 Mains cord

2. Disconnect mains cord from the machine ② .

Assembling of the Mains Cord

1. Connect new mains cord.
2. Lock the clip for the mains cord on the mains inlet.

5.7.6.19.2 Fuses

Prerequisites

- Mains cord is disassembled..

Disassembling of the Fuses

1. Loosen the fuse holder to take out the fuse.

Fig. 5-121 Mains fuses

Assembling of the Fuses

1. Insert new fuse.
2. Assemble fuse holder with the fuse in the mains inlet connector.

5.7.6.19.3 Staff Call

Prerequisites

- Rear housing is disassembled

Disassembling of the Staff Call

1. Disconnect the staff call cable ① .

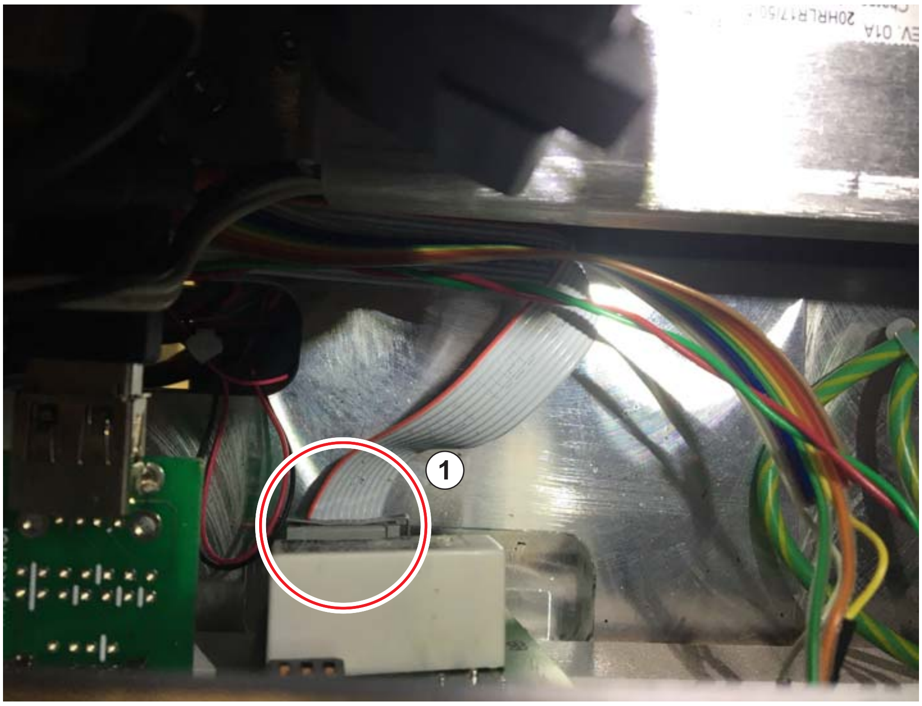


Fig. 5-122 Staff call connector

2. Loosen screw ① and remove staff call from the connector panel.

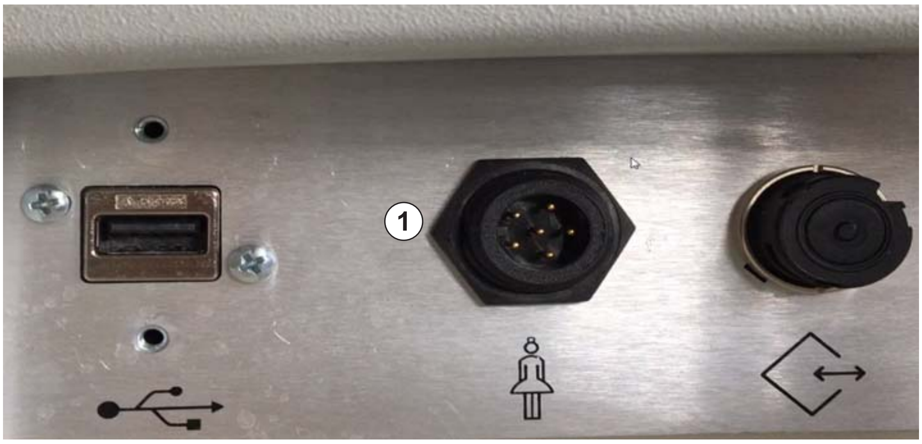


Fig. 5-123 Staff call screw

Assembling of the Staff Call

1. Insert new staff call into the connector panel.
2. Fasten the screw to fix the staff call on the connector panel.
3. Connect the staff call cable.

5

5.7.6.20 LCD incl. Touch Screen

Prerequisites

- Rear housing is disassembled.
- Loosen the two screws for the main board bracket.

Disassembling of the LCD incl. Touch Controller

1. Disconnect the STAT LED cable and the audio jack (sound input) from the main board.
2. Flap down the main board bracket.
3. Remove touch controller board ② .

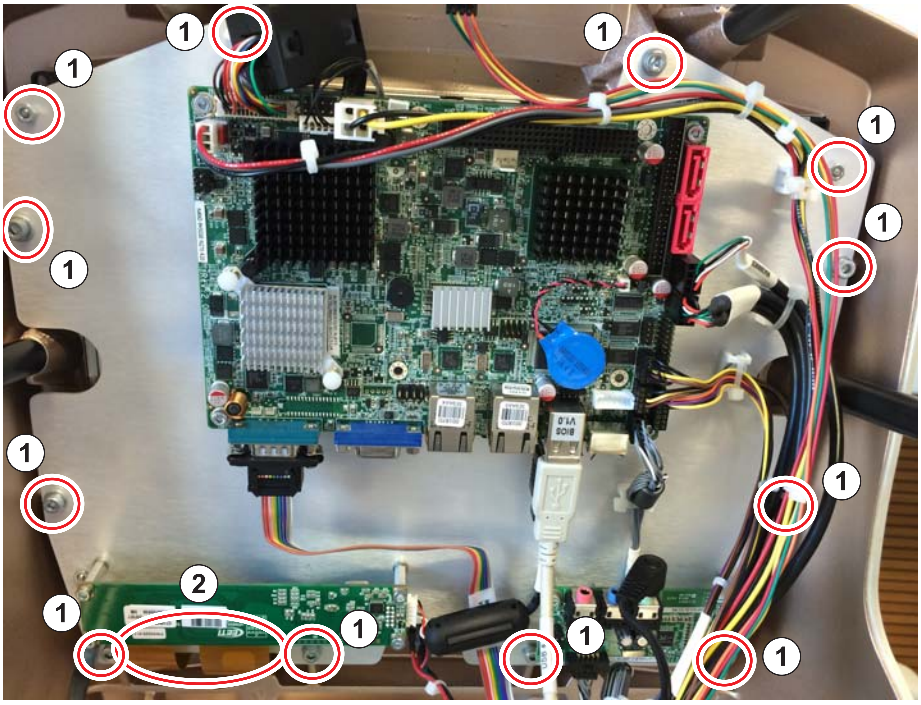


Fig. 5-124 LCD incl touchscreen

4. Loosen the 10 screws of the monitor ① .

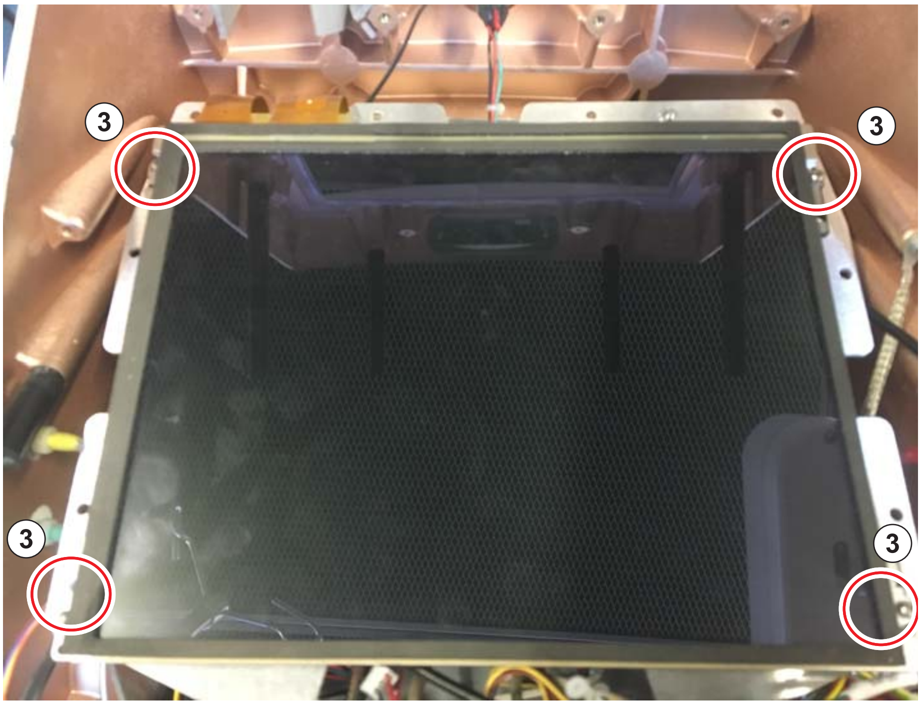
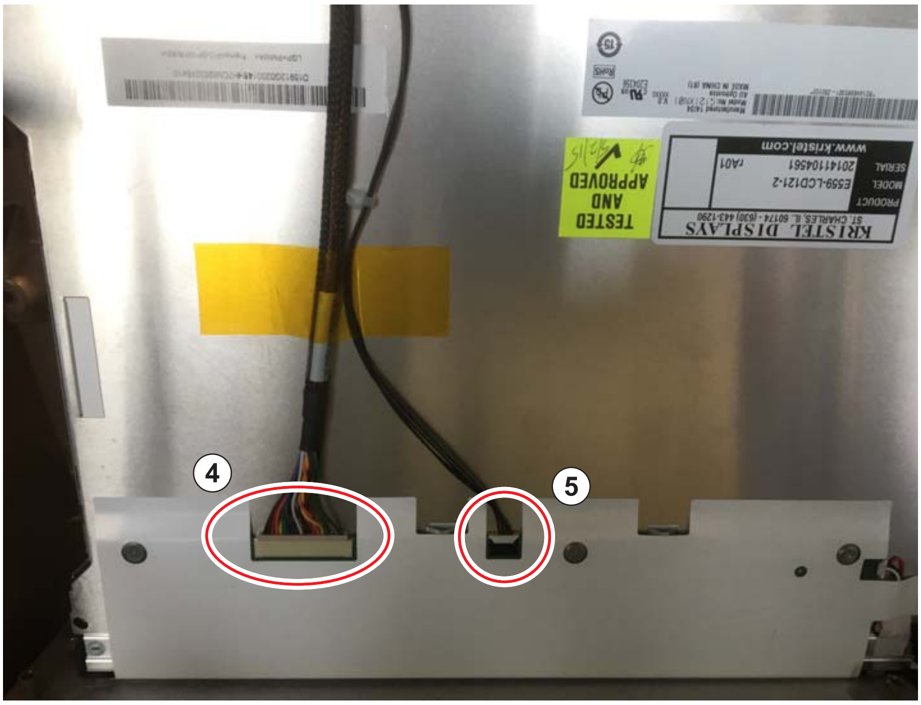


Fig. 5-125 Monitor fixation

5. Loosen the 4 screws ③ of the LCD.



6. Disconnect the LCDS1 connector ④ and the inverter connector ⑤ from the LCD.
7. Remove the LCD.

Assembling of the LCD incl. Touch Controller

1. Insert the LCD.
2. Connect the LCDS1 connector ④ and the inverter connector ⑤ from the LCD.
3. Fasten the 4 screws to assemble the LCD on the monitor bracket.
4. Fasten the 10 screws to assemble the monitor on the housing.
5. Fix main board bracket.
6. Connect the STAT LED cable and the audio jack (sound input) to the main board.

5.7.7 Components Lower Housing

5.7.7.1 IV Pole

Disassembling of the IV Pole

1. Loose the 2 screws on the back of the machine.
2. Disassemble the IV Pole.

Fig. 5-126 IV Pole screws

Assembling of the IV Pole

1. Assemble new IV Pole (pay attention that it only fits in one direction).
2. Fasten the 2 screws on the back of the machine.

5.7.7.2 Barcode Scanner

Prerequisites

- Lower housing is disassembled.

Disassembling of the Barcode Scanner

1. Disconnect barcode scanner cable in the lower housing.
2. Loosen the 2 screws of the barcode scanner bracket ① .
3. Loosen the 2 screws ② to remove the barcode scanner from the bracket.

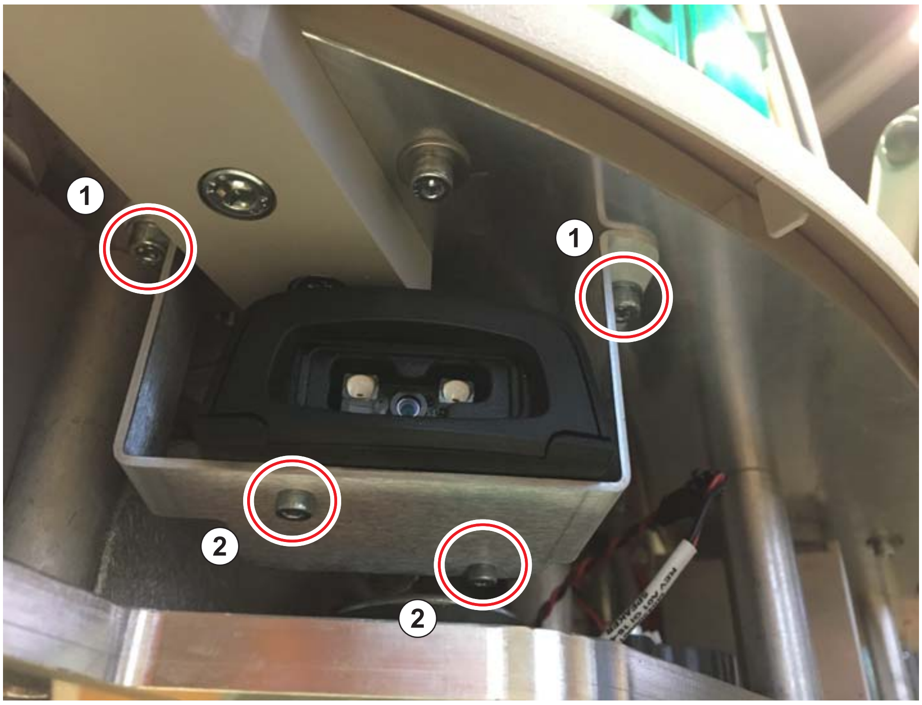


Fig. 5-127 Barcode scanner)

Assembling of the Barcode Scanner

1. Fasten the 2 screws to assemble the barcode scanner on the bracket ② .
2. Fix the 2 screws ① to assemble bracket on the machine housing.
3. Connect barcode scanner cable.

5.7.7.3 Fan Filter Cover

Disassembling of the Fan Filter Cover

1. Open the holder to disassemble fan filter cover.

Fig. 5-128 Fan filter cover

Assembling of the Fan Filter Cover

1. Assemble fan filter cover.

5.7.7.4 Dust Filter

Disassembling of the Dust Filter

1. Open the holder to disassemble fan filter cover.

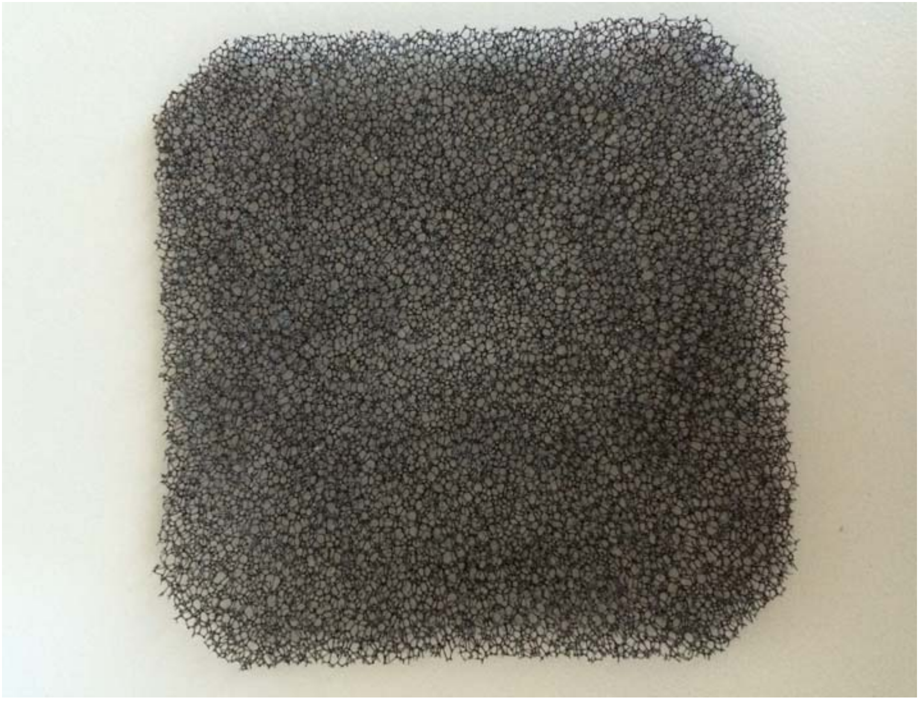


Fig. 5-129 Dust filter

Assembling of the Dust Filter

1. Exchange the dust filter.
2. Assemble fan filter cover.

5.7.7.5 Fan

Prerequisites

- Lower housing of the machine is disassembled.

Disassembling of the Fan

1. Loosen the 2 screws for the power supply bracket.
2. Pull out the power supply from the lower housing.

NOTICE!

Before it is possible to disassemble the power supply completely, it is necessary to disconnect the main board cable, the grounding connection and the fan.

Fig. 5-130 Power supply assembly

3. Disconnect the fan.
4. Loosen the 4 screws to disassemble the fan.

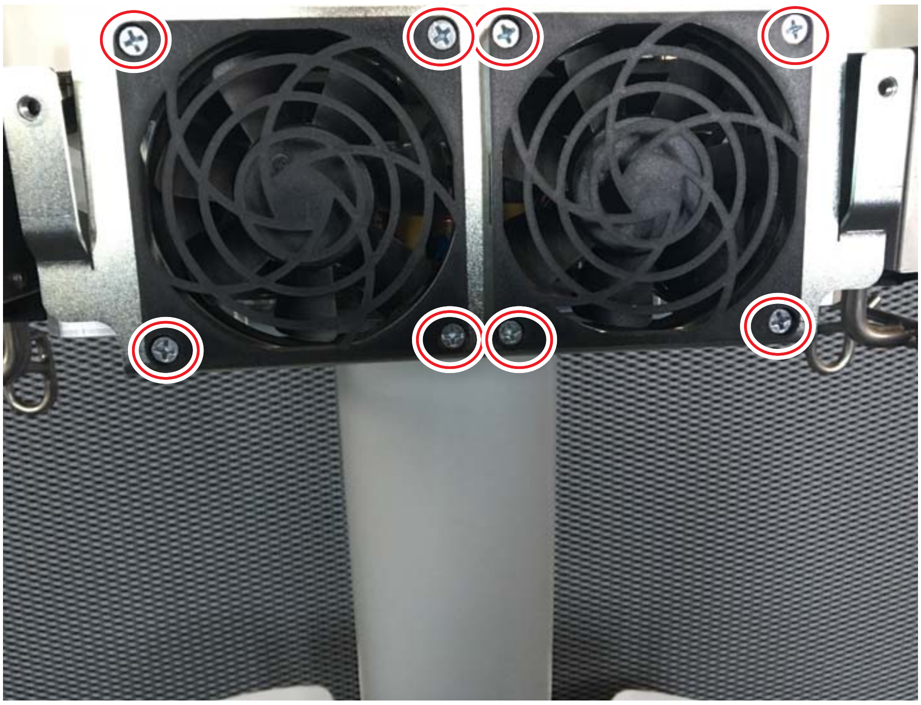


Fig. 5-131 Fan connectors

Assembling of the Fan

1. Fasten 4 screws to assemble the fans.
2. Connect the fan.
3. Insert the power supply to the lower housing.
4. Fasten the screws power supply bracket.

5.7.7.6 Power Supply

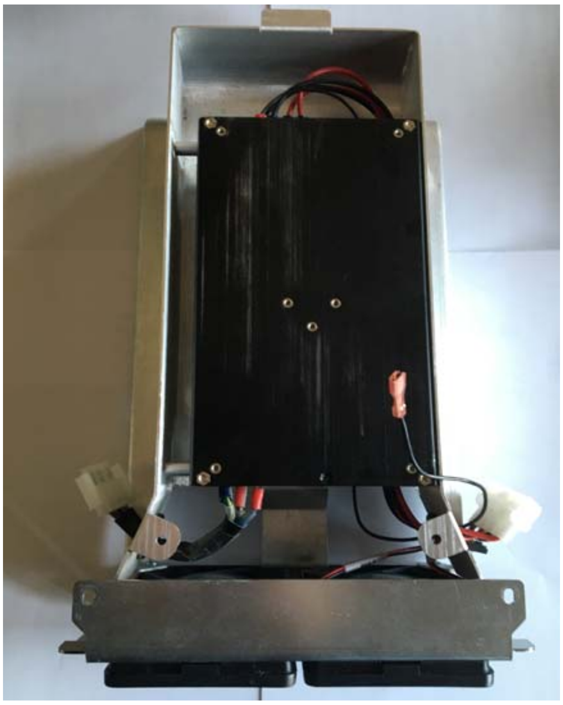


Fig. 5-132 Power supply

Prerequisites

- Lower housing of the machine is disassembled.

Disassembling of the Power Supply

1. Pull out the power supply from the lower housing.

NOTICE!

Before it is possible to disassemble the power supply completely, it is necessary to disconnect the main board cable and the fan.

Fig. 5-133 Connections of the power supply bracket

2. Disconnect the main board cable and the fan.
3. Disconnect the grounding cable.

1 Main board connector
2 Mains power

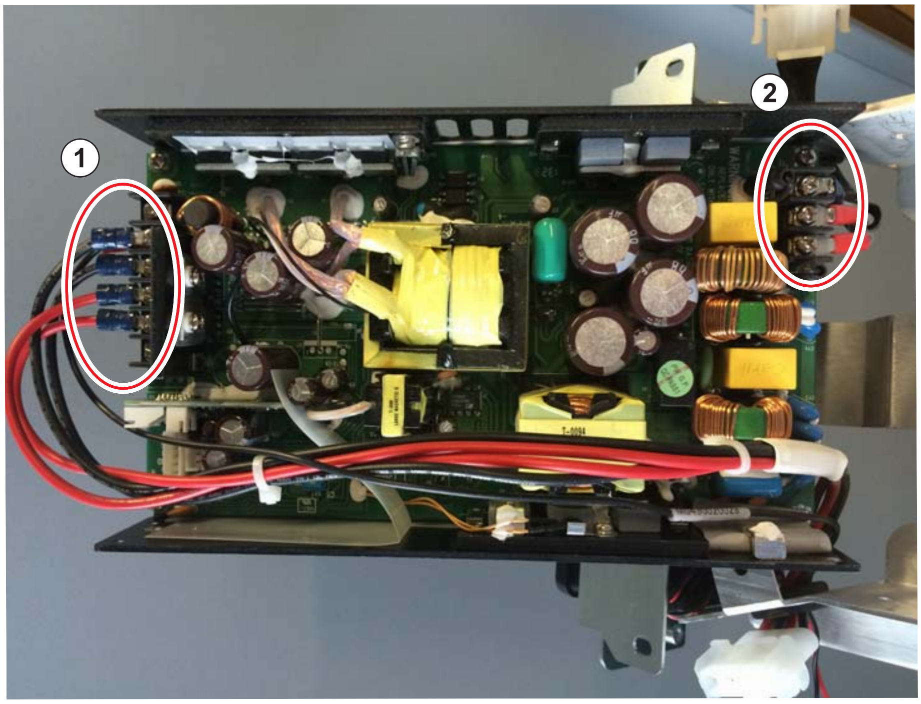


Fig. 5-134 Connectors of the power supply

4. Disconnect all cables which are connected to the power supply.

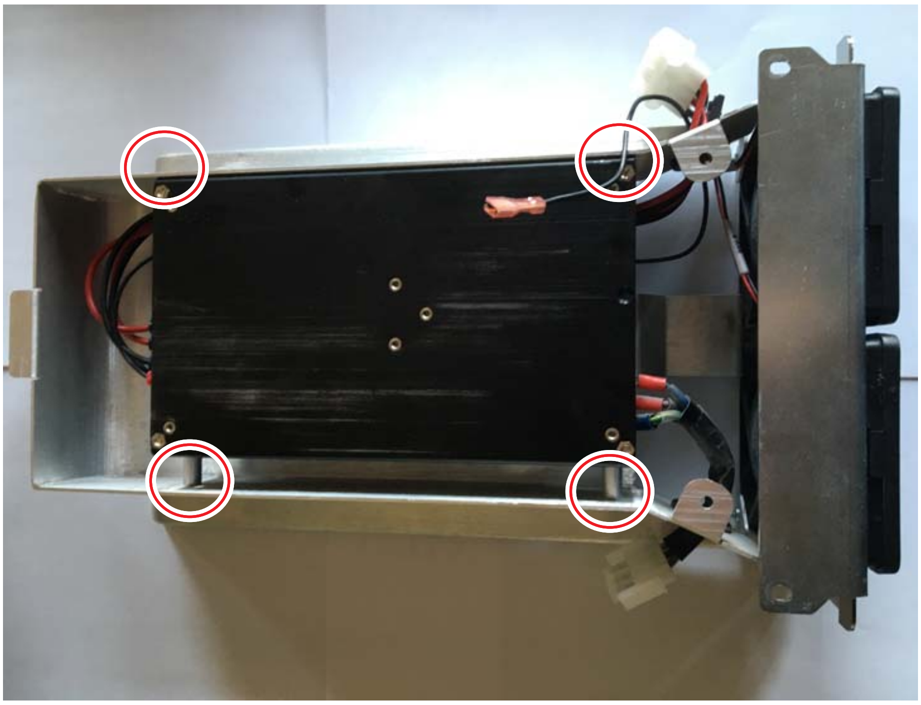


Fig. 5-135 Power supply screws

5. Loosen 4 screws to disassemble the power supply.

Assembling of the Power Supply

1. Connect all cables to the power supply.
2. Fasten 4 screws to assemble the power supply.
3. Insert the power supply to the lower housing.
4. Connect the main board cable and the fan.
5. Connect the grounding connector to the lower base plate.
6. Assemble lower housing.

5.7.7.7 Buzzer

Prerequisites

- Lower housing is disassembled.

Disassembling of the Buzzer

1. Disconnect buzzer cable ① .
2. Loosen the 2 screws to disassemble the buzzer ② .

Fig. 5-136 Buzzer

Assembling of the Buzzer

1. Fasten the 2 screws to assemble the buzzer.
2. Connect the buzzer cable.

5.7.7.8 Microphone

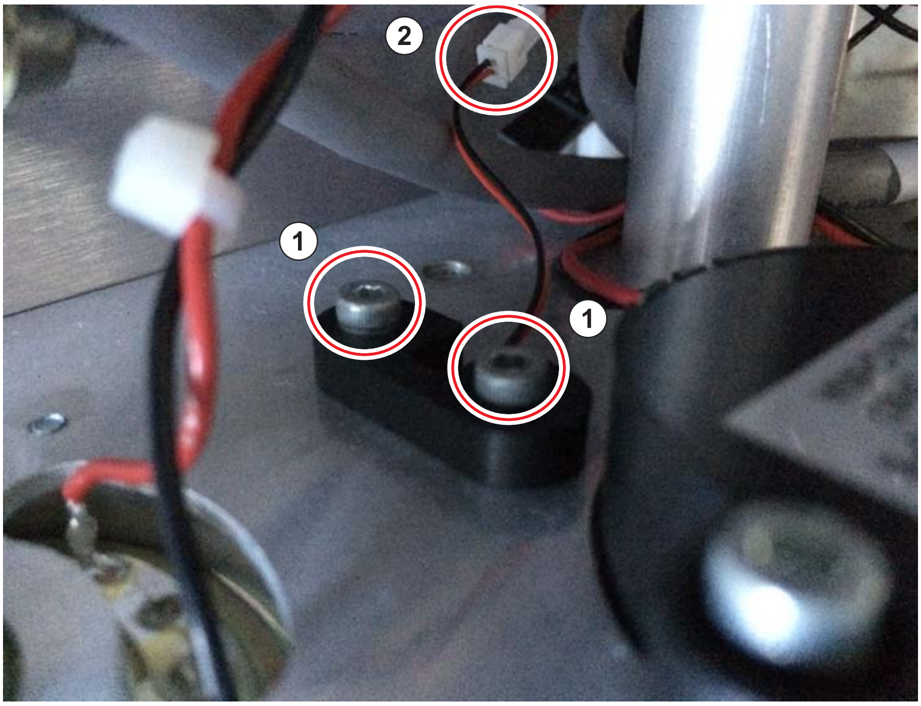


Fig. 5-137 Microphone

Prerequisites

- Lower housing is disassembled.

Disassembling of the Microphone

1. Disconnect microphone cable ② .
2. Loosen the 2 screws ① to disassemble the microphone.

Assembling of the Microphone

1. Fasten the 2 screws ① to assemble the microphone.
2. Connect the microphone cable ② .

5.7.7.9 Speaker

Prerequisites

- Lower housing is disassembled.

Disassembling of the Speaker

1. Disconnect the speaker cable.

Fig. 5-138 Speaker cable

2. Loosen the 4 screws to disassemble the speaker.

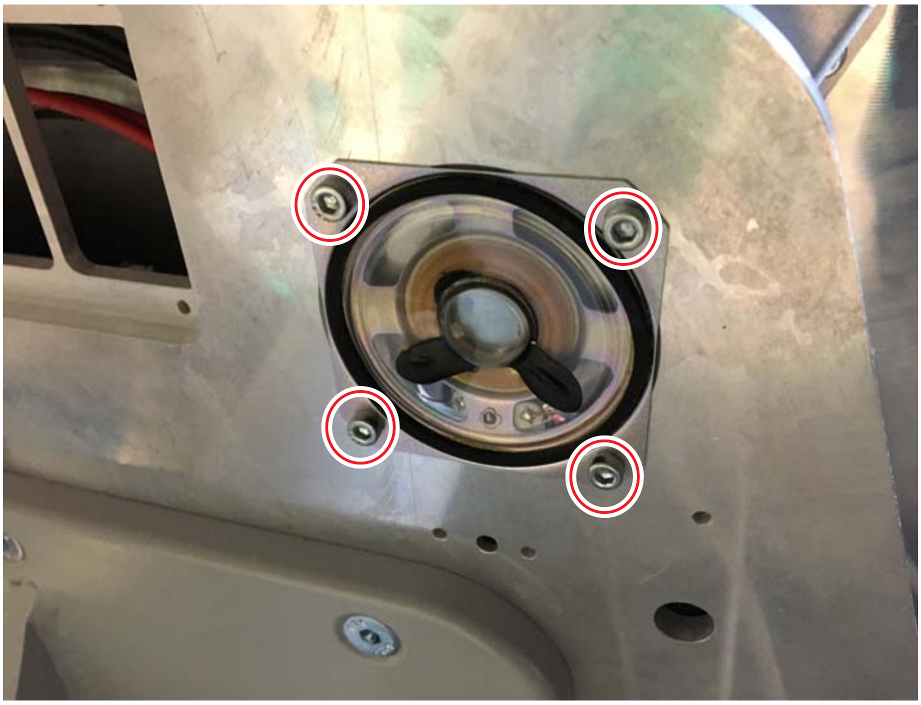


Fig. 5-139 Speaker screws

Assembling of the Speaker

1. Insert the speaker and fastening the 4 screws to assemble the speaker.
2. Connect the speaker cable.

5.7.7.10 Load Cells

5.7.7.10.1 Left Load Cell

The load cell can be fixed on the housing in two different positions. For the correct position of the load cell the connector has be close (inner side) to the lower base plate.

Prerequisites

- Lower housing is disassembled.

Disassembling of the left Load Cell

1. Loosen both screws ① of the left load cell.

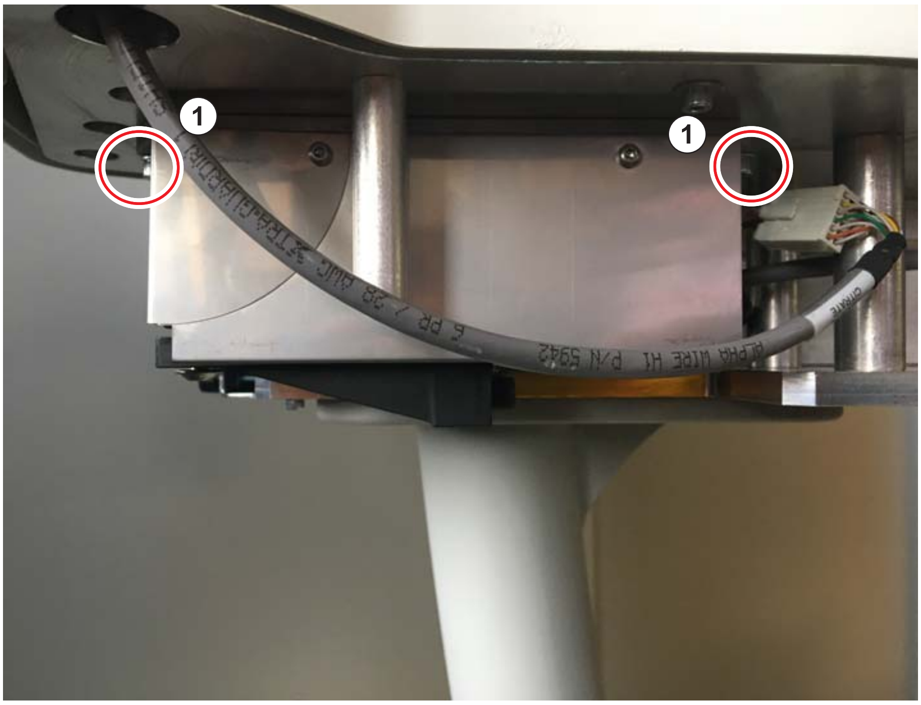


Fig. 5-140 Left load cell

2. Disconnect the left load cell cable ② .

Fig. 5-141 Cable left load cell

Assembling of the left Load Cell

1. Set the dip switch code to the new load cell.

Fig. 5-142 Address code left load cell

2. Connect the left load cell cable.
3. Fasten the two screws to fix the load cell.

5.7.7.10.2 Center Load Cell

The load cell can be fixed on the housing in two different positions. For the correct position of the load cell the connector has be close (inner side) to the lower base plate.

Prerequisites

- Lower housing is disassembled.

Disassembling of the center Load Cell

1. Loosen both screws ① of the center load cell.

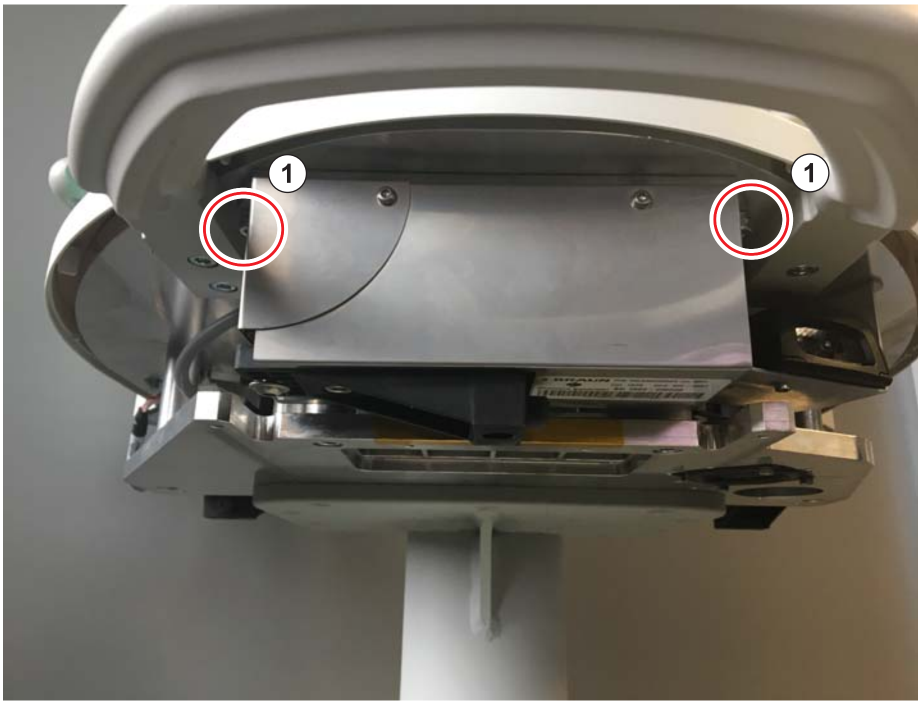


Fig. 5-143 Center load cell

2. Disconnect the center load cell cable ② .

Fig. 5-144 Cable center load cell

Assembling of the center Load Cell

1. Set the dip switch code to the new load cell.

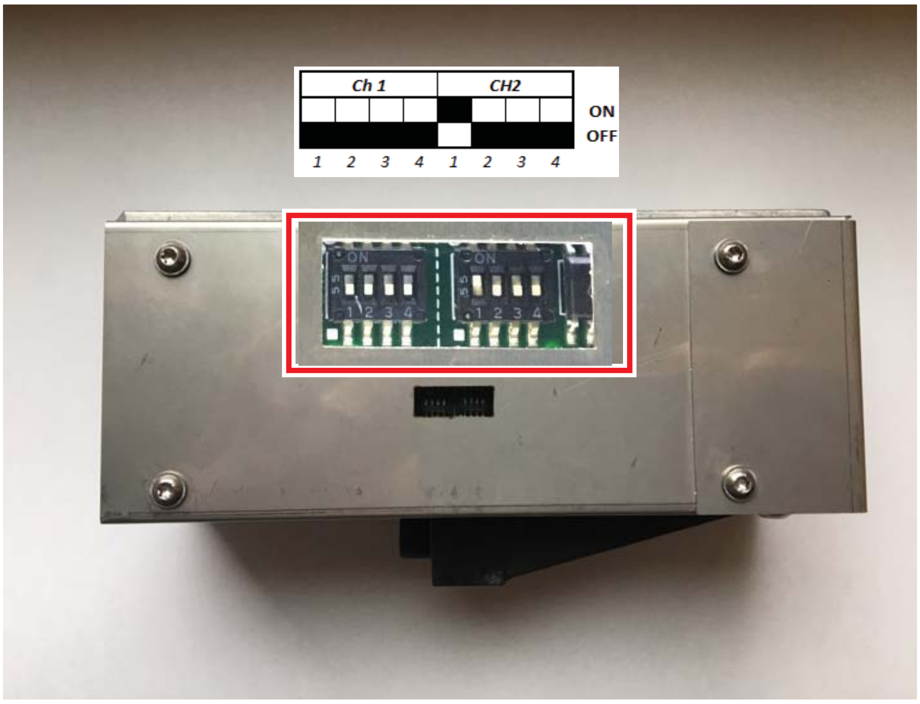


Fig. 5-145 Address code center load cell

2. Connect the center load cell cable.
3. Fasten the two screws to fix the load cell.

5.7.7.10.3 Right Load Cell

The load cell can be fixed on the housing in two different positions. For the correct position of the load cell the connector has be close (inner side) to the lower base plate.

Prerequisites

- Lower housing is disassembled.

Disassembling of the right Load Cell

1. Loosen both screws ① of the right load cell.

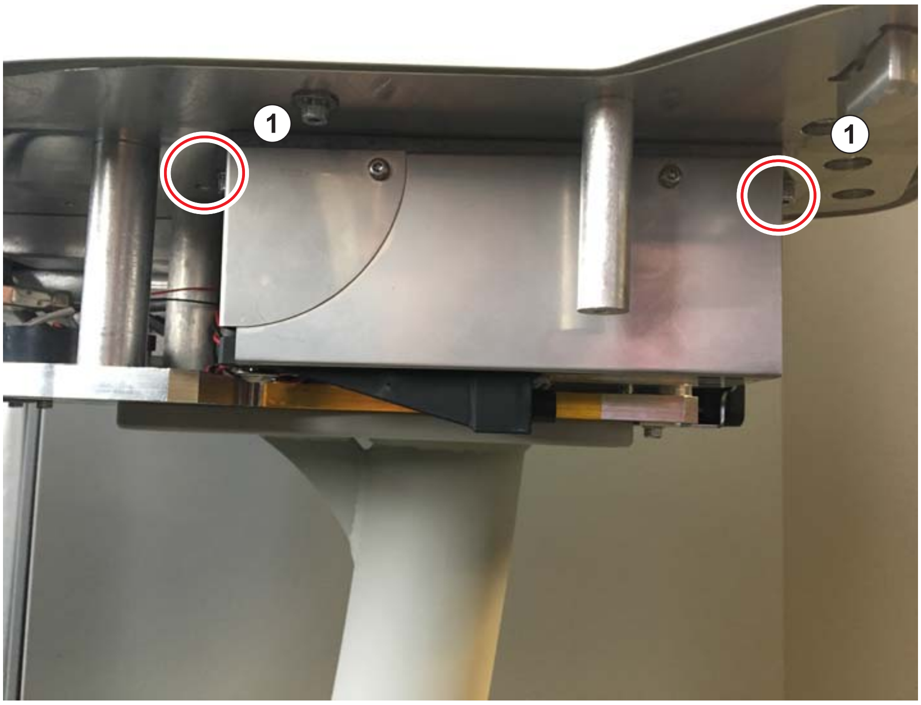


Fig. 5-146 Right load cell

2. Disconnect the right load cell cable ② .

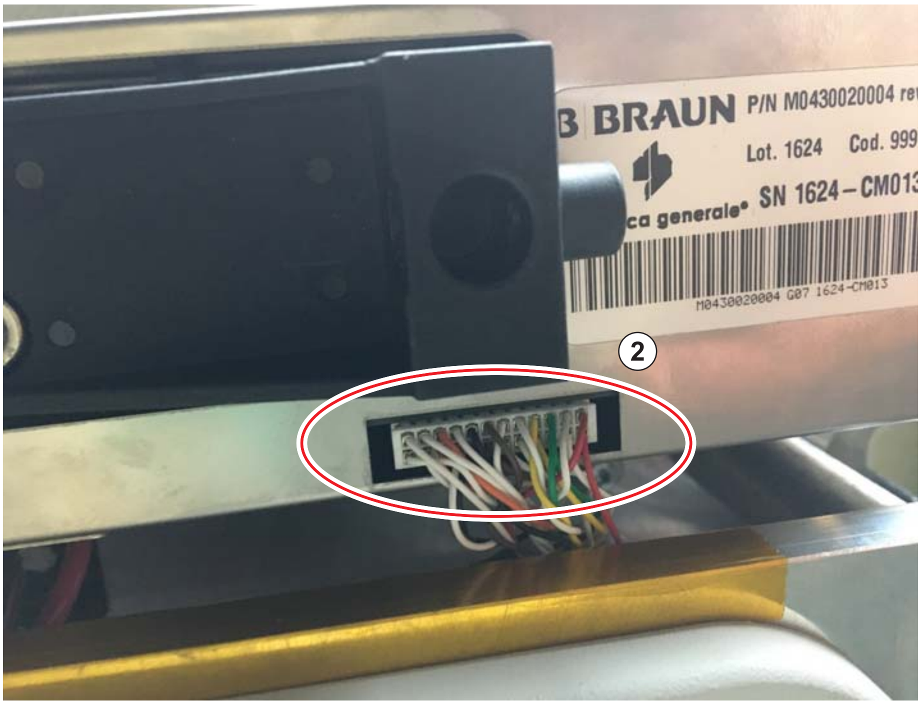


Fig. 5-147 Cable right load cell

Assembling of the right Load Cell

1. Set the dip switch code to the new load cell.

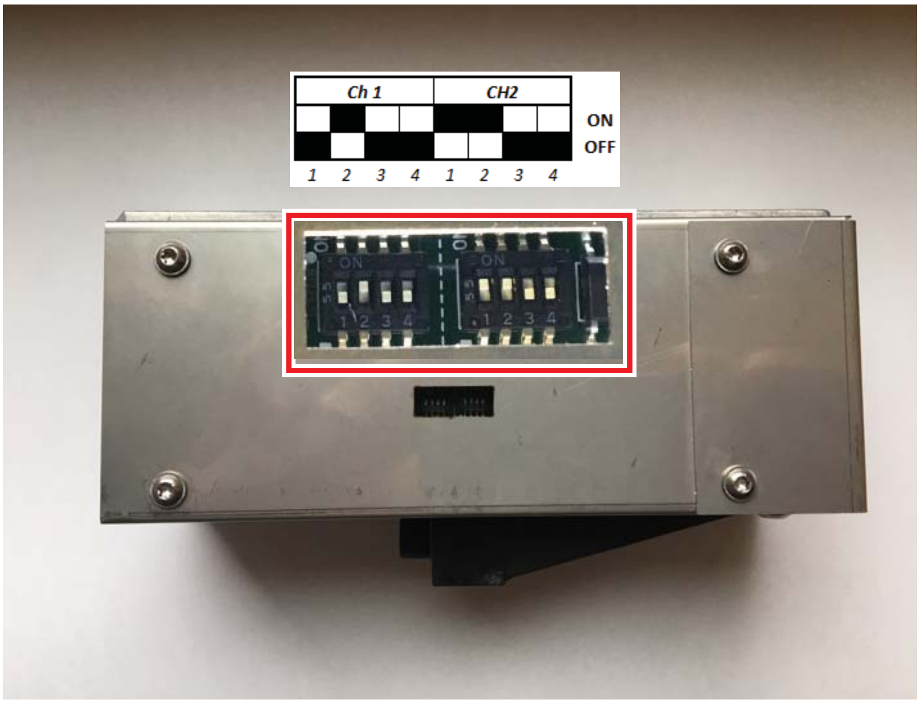


Fig. 5-148 Address code right load cell

2. Connect the right load cell cable.
3. Fasten the two screws to fix the load cell.

5.8 Software Installation

WARNING!

User configuration parameters are set to default by doing a software installation or a software update.

Machine is running with a default user configuration setup.

- When a software installation is done, the user configuration parameters has to be checked, set (if necessary) and confirmed by the responsible organization.
- When a software update is done, the user configuration parameters has to be checked, set (if necessary) and confirmed by the responsible organization.

Prerequisites

- Machine is switched off.

1. Insert the USB stick into the USB port.
2. Switch on the machine.

   ↳ Mode selection screen appear *Treatment/Version Exchange*.

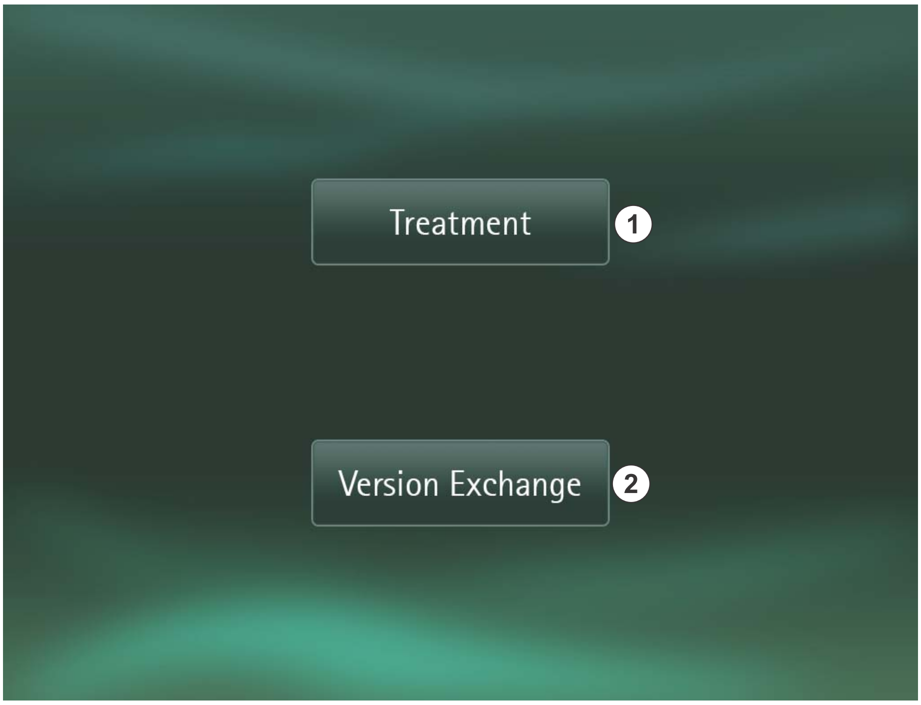


Fig. 5-149 Version Exchange

3. Press *Version Exchange* button ② .
   - ↳ The machine reboots automatically and start the installation procedure.
   - ↳ After several minutes the message *One-Shot Installation done* appears.
4. Switch off the machine and remove the USB stick.
5. Connect FSU stick and check new software version in TSM service program.
6. Check user configuration parameters and set it if necessary.
7. Confirm the user configuration parameters with the responsible organization.

5

5.9 FSU Field Service Utility

5.9.1 FSU V.1.10

Perform the following steps to run the field service utility application:

Prerequisites

- Machine is switched off.

1. Insert the FSU into the USB port.
2. Switch on the machine.
   ↳ Mode selection screen appear Treatment/TSM/FSU.
3. Press *FSU* button.
   ↳ The machine reboots automatically and start the FSU application.
4. Select desired function from the main menu.
   - *Save trends and logs* ①
   - *Manage languages* ②
   - *Manage calibration data* ③
   - *Manage calibration tolerance* ④
   - *Manage pump FW* ⑤
   - *Manage load cell FW* ⑥

1 Trends and logs menu
2 Manage Languages
3 Manage Calibration Data
4 Manage Calibration Tolernace
5 Manage Pump FW
6 Manage Load Cell FW

Fig. 5-150 FSU Main menu

5.9.1.1 Trends and Logs Menu

1 Save trends and logs

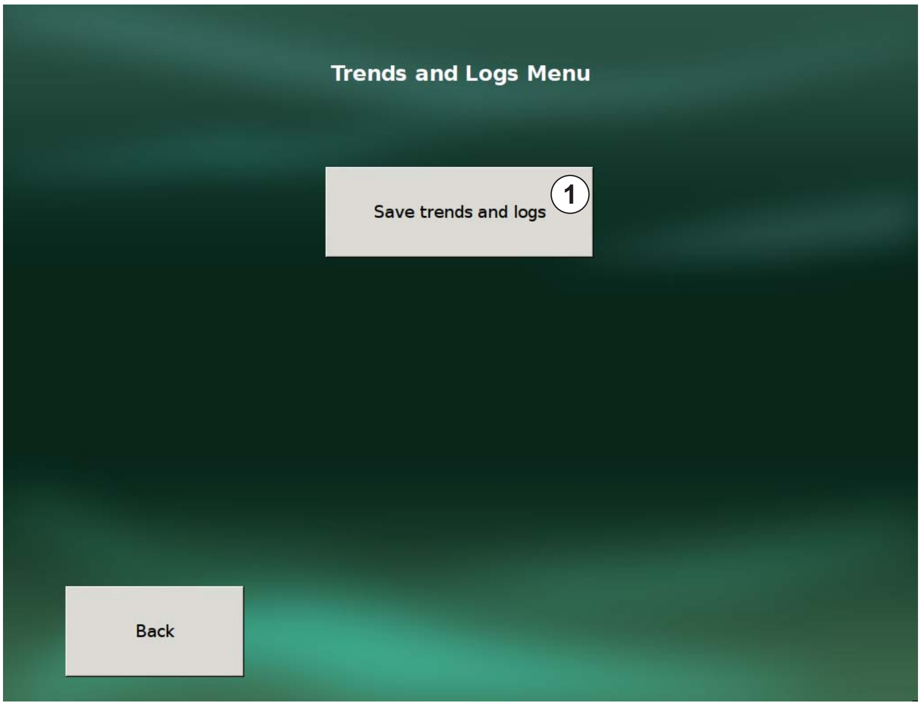


Fig. 5-151 FSU Trends and logs menu

1. Press Save *trends and logs* ① .
   - ↳ Trends and logs are saved on the FSU.

It is possible to save the trend and log files to the FSU stick.

The last 10 treatment files are saved.

5.9.1.2 Manage Languages

1 Install language

2 Select language

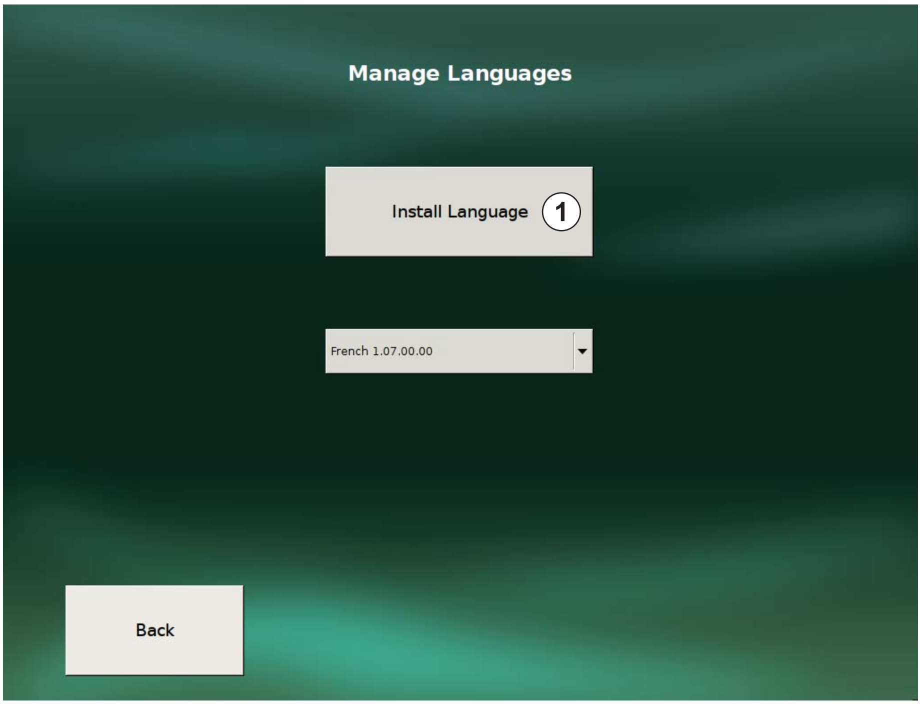


Fig. 5-152 FSU Manage languages

Do not install more than 6 languages on the machine.

Do not install more than 6 languages on the machine.

Installation of the Language Pack to the FSU

1. Download the language pack from the service portal.
2. Copy the *zip. file* to the FSU directory: *Languages*.

Prerequisites

- Required language has to be available on the FSU.

1. Select the required language from the drop down menu ② .
2. Press *Install languages* ① .

   ↳ The language is installed on the machine.

5.9.1.3 Manage Calibration Data

1 Save calibration data

2 Restore calibration data

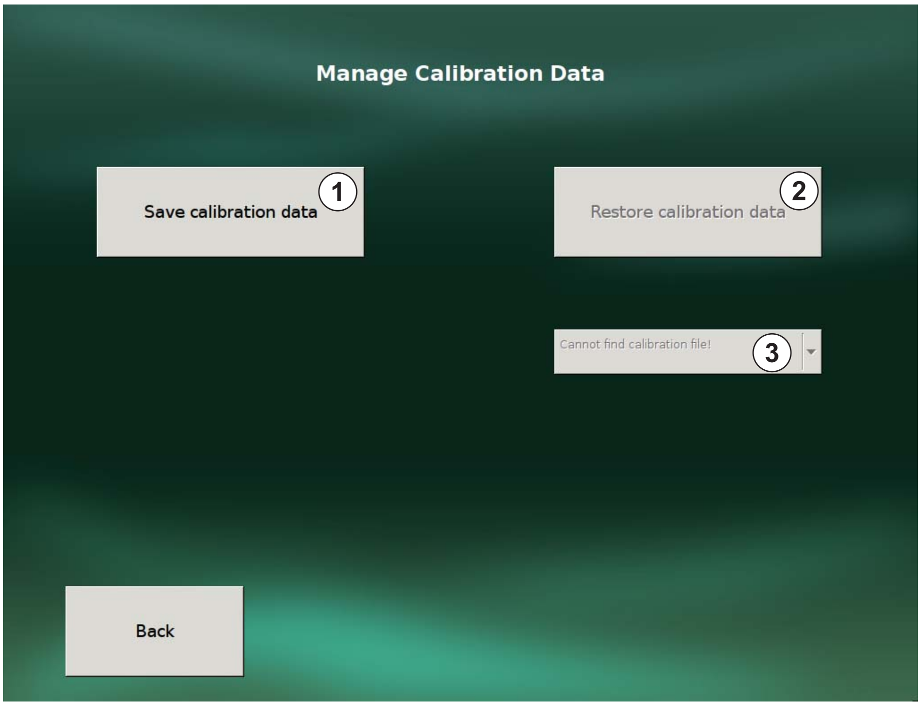


Fig. 5-153 FSU Manage calibration data

Save Calibration Data

1. Press *Save calibration data ①*.

    ↳ Calibration data of the machine is copied from the machine to the FSU.

Prerequisites

- Calibration data must be available on the FSU.

1. Select the required calibration data ③ .
2. Press Restore calibration data ② .

    ↳ Calibration data is copied from the FSU to the machine.

5

5.9.1.4 Manage Calibration Tolerance

1 Restore default tolerance
2 Load custom tolerance
3 Select custom tolerance

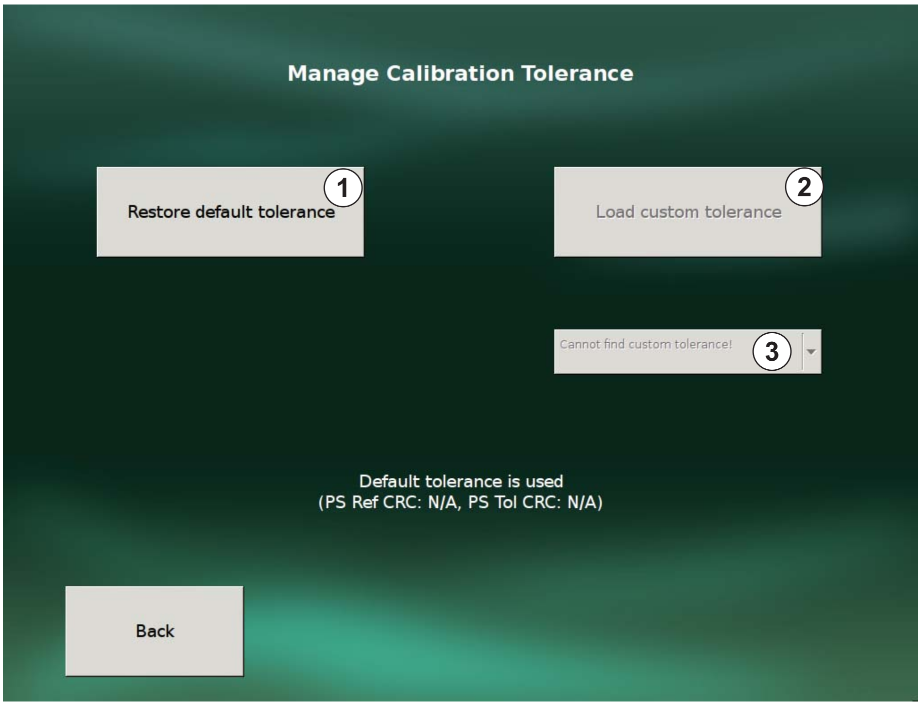


Fig. 5-154 FSU Manage calibration tolerance

Restore default tolerance

1. Press *Restore default tolerance ①* .
   ↳ Default tolerance are saved on the machine.

Prerequisites

- Calibration data must be available on the FSU.

1. Select the required custom tolerance ③ .
2. Press *Load custom tolerance ②* .
   ↳ Custom tolerance is installed on the machine.

5.9.1.5 Manage Pump FW

1 Select firmware file
2 Select required pump
3 Start FW upgrade
4 Read FW numbers

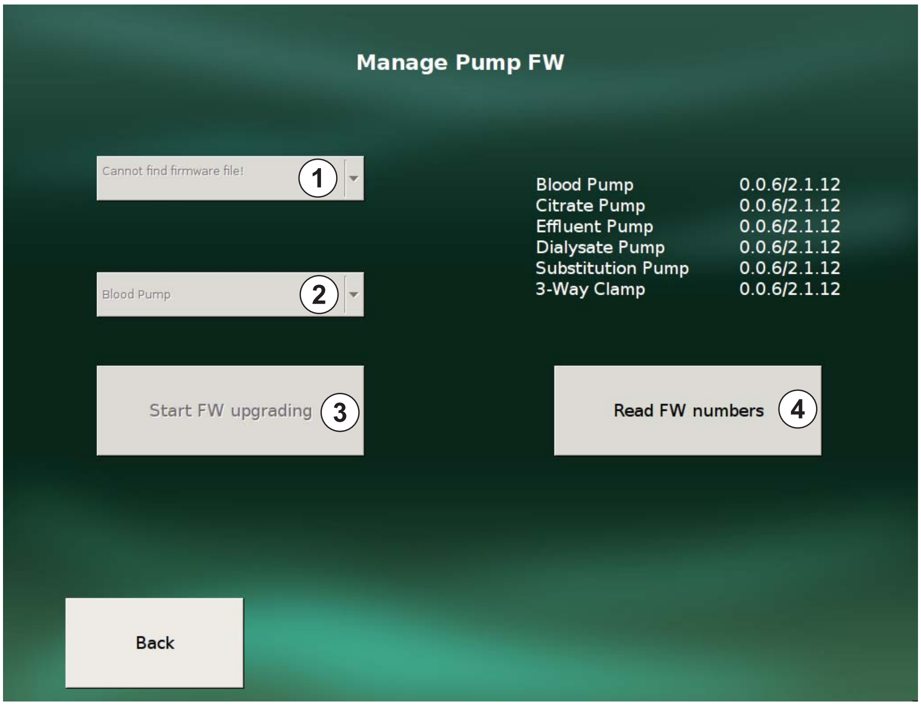


Fig. 5-155 FSU Manage pump FW

Read FW numbers

1. Press *Read FW numbers* ④ .
   ↳ Pump FW numbers are displayed.

Prerequisites

- Firmware file must be available on the FSU.

1. Select the required firmware file ① .
2. Select the required pump ② .
3. Press *Start FW upgrading* ③ .
   ↳ Firmware file is installed on the machine.

5.9.1.6 Manage Load Cell FW

1 Select firmware file
2 Select required load cell
3 Start FW upgrade
4 Read FW numbers

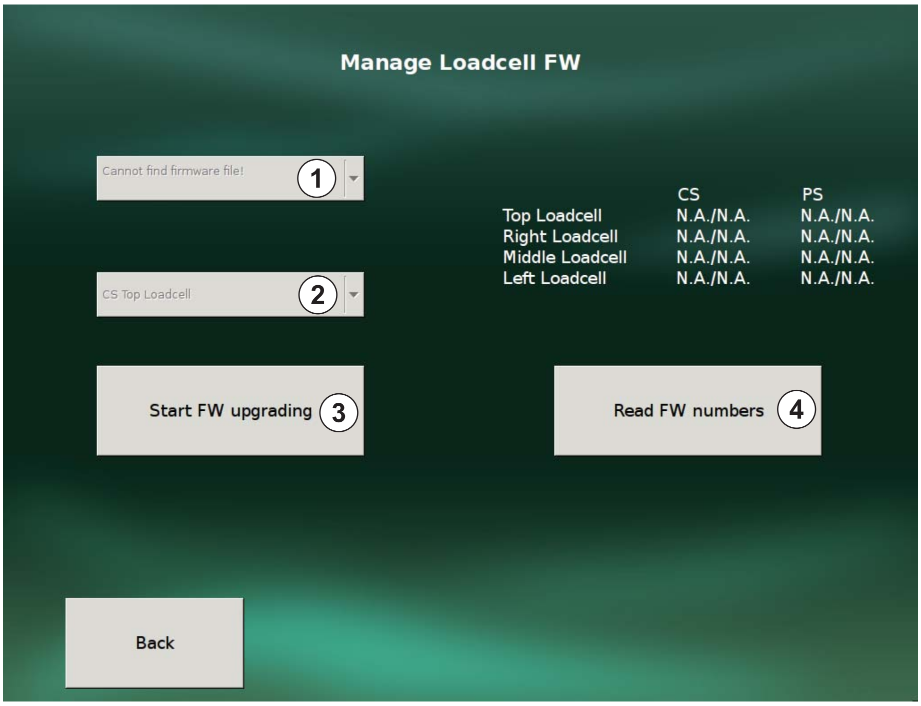


Fig. 5-156 FSU Manage load cell FW

Read FW numbers

1. Press *Read FW numbers ④ .*
   ↳ Load cell FW numbers are displayed.

Prerequisites

• Firmware file must be available on the FSU.

1. Select the required firmware file ① .
2. Select the required load cell ② .
3. Press *Start FW upgrading* ③ .
   ↳ Firmware file is installed on the machine.

5.9.2 FSU V 1.20

Perform the following steps to run the field service utility application:

Prerequisites

• Machine is switched off.

1. Insert the FSU into the USB port.
2. Switch on the machine.
   ↳ Mode selection screen appear Treatment/TSM/FSU.
3. Press *FSU* button.
   ↳ The machine reboots automatically and start the FSU application.

1 Trends and logs menu
2 Manage Languages
3 Manage Calibration Data
4 Manage Calibration Tolernace
5 Manage Pump FW
6 Manage Load Cell FW
7 Screen test
8 Manage User Configuration

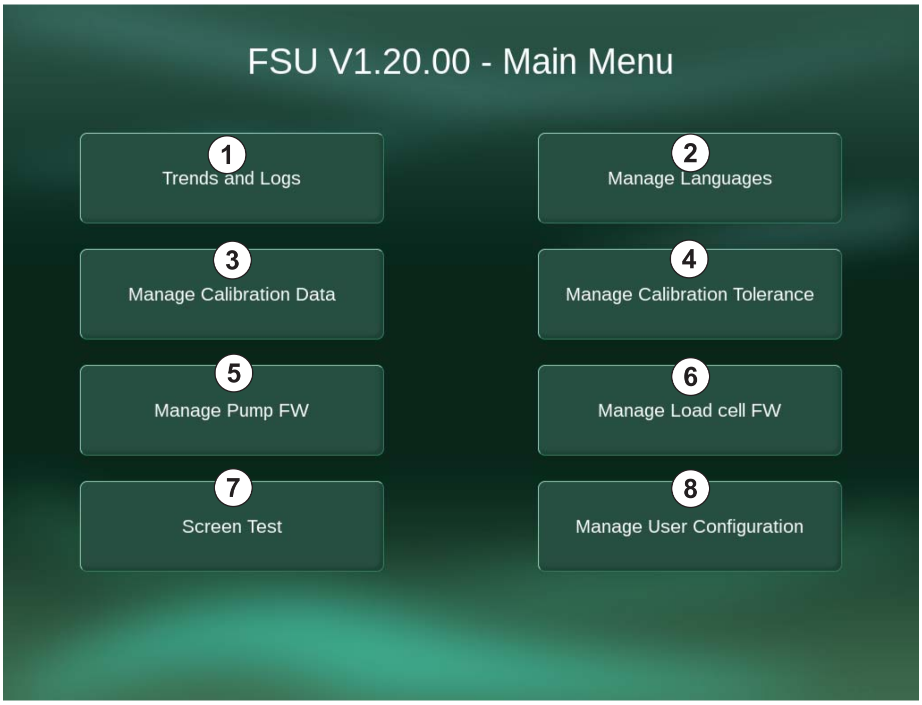


Fig. 5-157 FSU Main menu

4. Select desired function from the main menu.
   - *Save trends and logs* ①
   - *Manage languages* ②
   - *Manage calibration data* ③
   - *Manage calibration tolerance* ④
   - *Manage pump FW* ⑤
   - *Manage load cell FW* ⑥
   - *Screen test* ⑦
   - *Manague user configuration* ⑧

5.9.2.1 Trends and Logs Menu

1 Save trends and logs

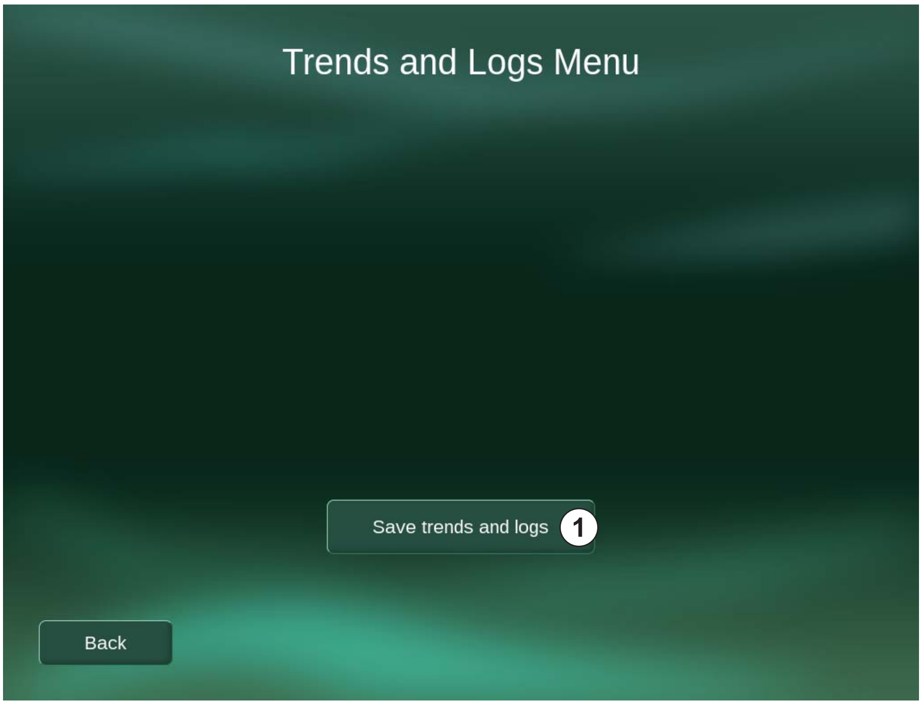


Fig. 5-158 FSU Trends and logs menu

1. Press Save *trends and logs* ① .

   ↳ Trends and logs are saved on the FSU.

1. Press Save *trends and logs* ① .

   ↳ Trends and logs are saved on the FSU.

It is possible to save the trend and log files to the FSU stick.

The last 10 treatment files are saved.

5.9.2.2 Manage Languages

1 Add new language
2 Remove language
3 Change language version

Fig. 5-159 FSU Manage languages

5

Do not install more than 6 languages on the machine.

Installation of the Language Pack to the FSU

1. Download the language pack from the service portal.
2. Copy the *zip. file* to the FSU directory: *Languages*.

Prerequisites

- Required language has to be available on the FSU.

Add a new Language

1. Press *Add new language* ② .
   ↳ New screen is visible.

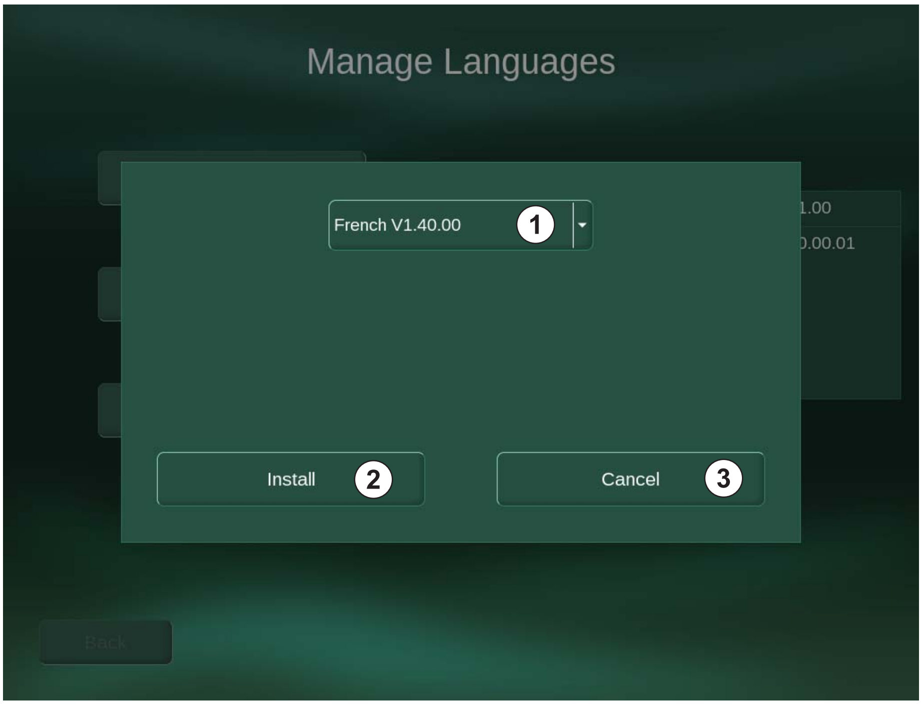


Fig. 5-160 Add new language

2. Select the new language ② .
3. Press *Install* ① .
   ↳ The language is installed on the machine.
4. Press ③ to cancel language installation.

Remove Language

1. Press *Remove languages* ②
   ↳ New screen is visible.

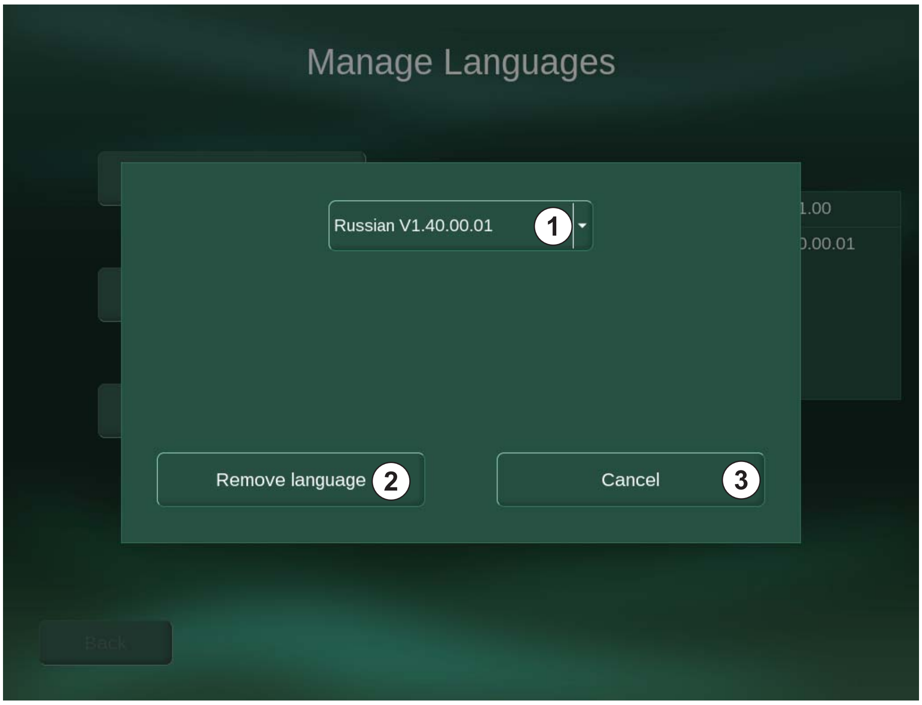


Fig. 5-161 Remove language

2. Select language ② .
3. Press *Remove language* ① .
   ↳ The language is installed on the machine.
4. Press ③ to cancel language deinstallation.

Remove Language

1. Press *Change language version* ③
   ↳ New screen is visible.

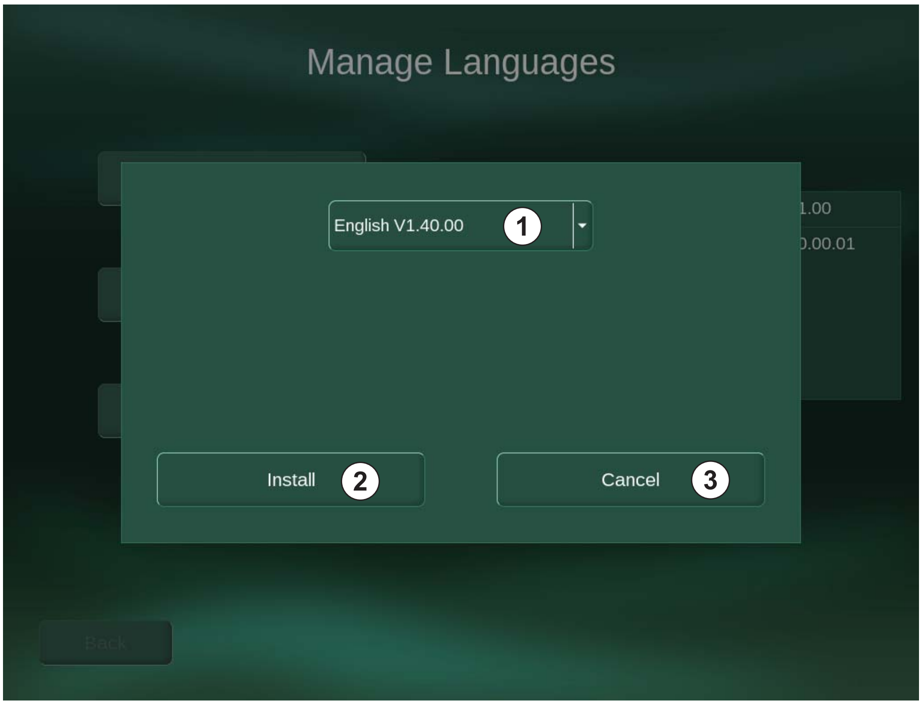


Fig. 5-162 Change language version

2. Select language ② .
3. Press *Install* ① .
   ↳ The new language version is installed on the machine.
4. Press ③ to cancel language update.

5.9.2.3 Manage Calibration Data

1 Save calibration data
2 File selection
3 Restore calibration data

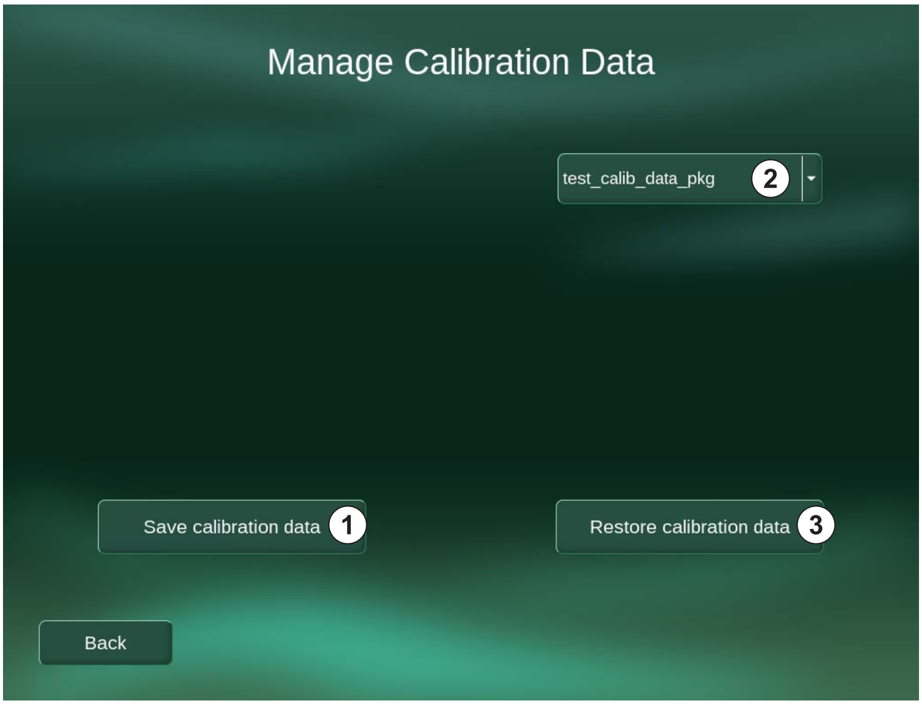


Fig. 5-163 FSU Manage calibration data

Save Calibration Data

1. Press *Save calibration data ① .*

   ↳ Calibration data of the machine is copied from the machine to the FSU.

Prerequisites

- Calibration data must be available on the FSU.

1. Select the required calibration data ③ .
2. Press Restore calibration data ② .

   ↳ Calibration data is copied from the FSU to the machine.

1 Restore default tolerance
2 Load custom tolerance
3 Select custom tolerance

5.9.2.4 Manage Calibration Tolerance

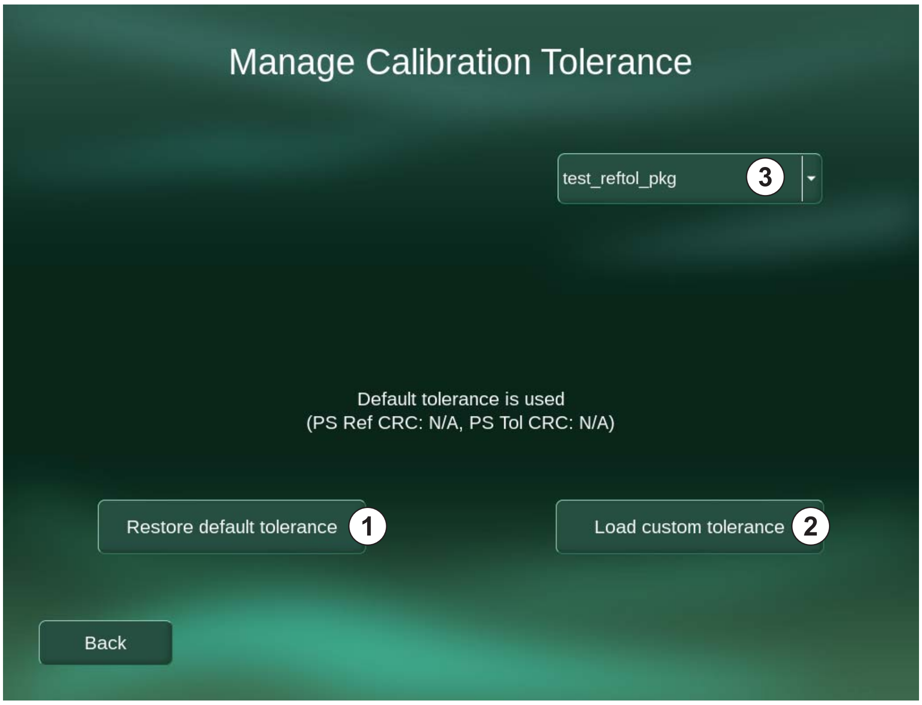


Fig. 5-164 FSU Manage calibration tolerance

5

Restore default tolerance

1. Press *Restore default tolerance* ① .
   ↳ Default tolerance are saved on the machine.

Prerequisites

- Calibration data must be available on the FSU.

1. Select the required custom tolerance ③ .
2. Press *Load custom tolerance* ② .
   ↳ Custom tolerance is installed on the machine.

5.9.2.5 Manage Pump FW

1 Select firmware file
2 Select required pump
3 Start FW upgrade
4 Rfresh FW numbers

Fig. 5-165 FSU Manage pump FW

Read FW numbers

1. Press *Refresh* ④ to read the current version of pump FW.

Prerequisites

- Firmware file must be available on the FSU.

1. Select the required firmware file ① .
2. Select the required pump ② .
3. Press *Start FW upgrading* ③ .
   ↳ Firmware file is installed on the machine.

5.9.2.6 Manage Load Cell FW

1 Select firmware file
2 Select required load cell
3 Start FW upgrade
4 Refresh FW numbers

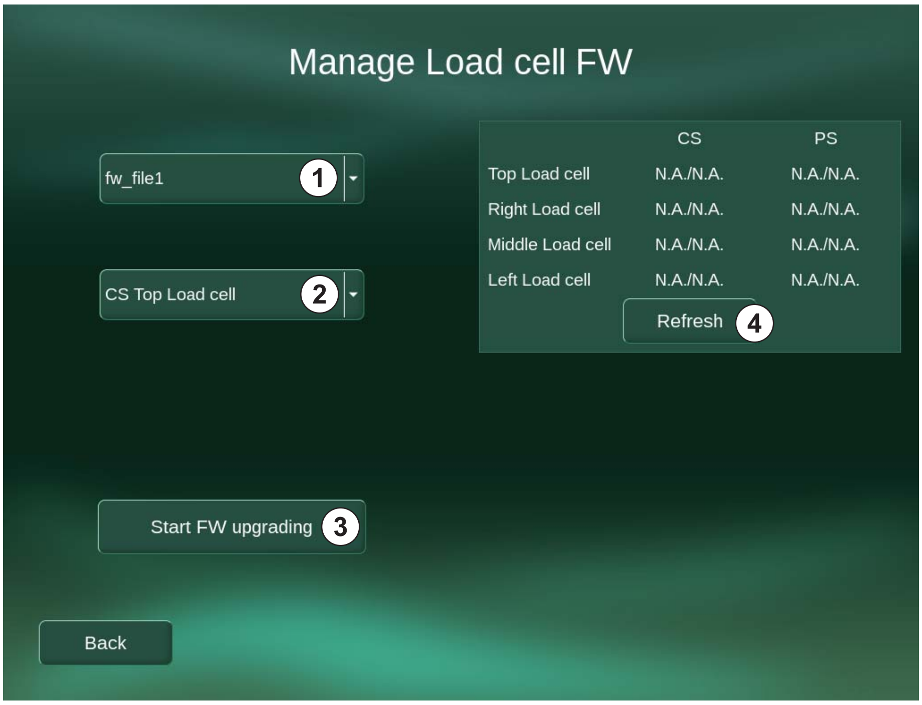


Fig. 5-166 FSU Manage load cell FW

Read FW numbers

1. Press *Read FW numbers* ④ .
   ↳ Load cell FW numbers are displayed.

Prerequisites

- Firmware file must be available on the FSU.

1. Select the required firmware file ① .
2. Select the required load cell ② .
3. Press *Start FW upgrading* ③ .
   ↳ Firmware file is installed on the machine.

5.9.2.7 Screen Test

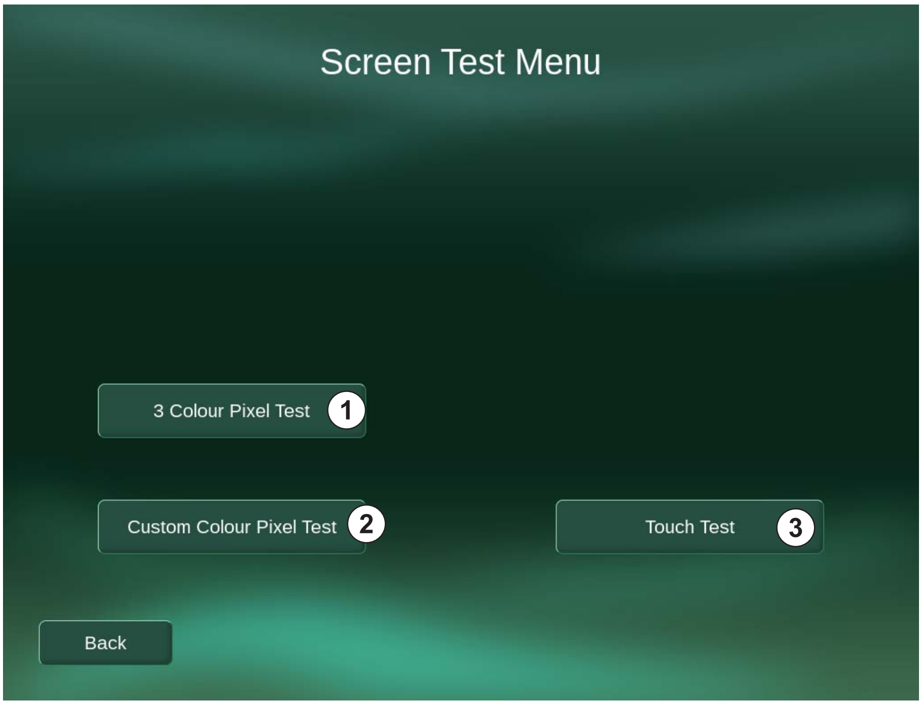


Fig. 5-167 Screen test menu

3 Colour Pixel Test

1. P*ress 3 Colour Pixel Test* ①
   - Test screen starts
2. Touch the screen.
   - Colour of the screen changes to red.
3. Touch the screen.
   - Colour of the screen changes from red to green.
4. Touch the screen.
   - Colour of the screen changes from green to blue.
5. Touch the screen.
   - Colour Test is done.

Touch Test

1. Press *Touch Test* ③ .
   - Touch test screen is displayed.
2. Draw (by your hand) a line in all available sections of the screen.
   - If the line is completely yellow the touch is working properly.
   - If the line is partially red, the touch is not working properly.

Custom Colour Pixel Test

1. Press *Custom Colour Test* ②
2. Touch and move your finger over the complete LCD.
   - ⇘ Colours are changing.
3. Double click the screen two times to remove to the menu.

5.9.2.8 Manage User Configuration

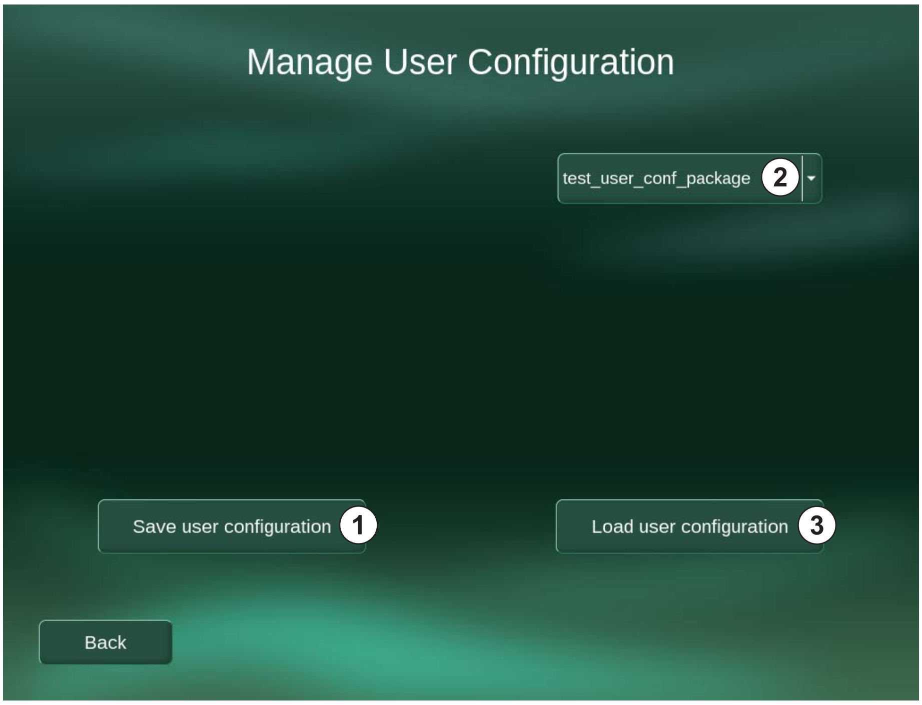


Fig. 5-168 Manage user configuration

Save User Configuration on FSU

1. Press *Save user configuration* ① .
   - ⇘ User configuration is saved on the FSU stick.

Load User Configuration from FSU

1. Press ② to select the user configuration package.
2. Press *Load user configuration* ③
   - ⇘ Selected user configuration package is saved on the machine.

Table of Contents

6 Technical Support and Maintenance TSM Service Program

6.1 Start TSM Technical Support and Maintenance Menu

The TSM main menu (TSM = Technical Support and Maintenance) is used for servicing the machine. The TSM service program is started as follows.

1. Insert FSU to the USB port.
2. Press the standby switch to start the machine.
3. Once the selector screen appears, press *TSM* button
   ↳ Machine starts running in TSM mode.

6.2 Quit TSM Technical Support and Maintenance Menu

To quit the service program the following steps must be taken.

1. Press standby switch on the connector panel for at least 5 seconds.

6.3 Overview TSM Service Program

The TSM service program consists of the *Test* menu, the *Calibration* menu and the *Machine Information* menu.

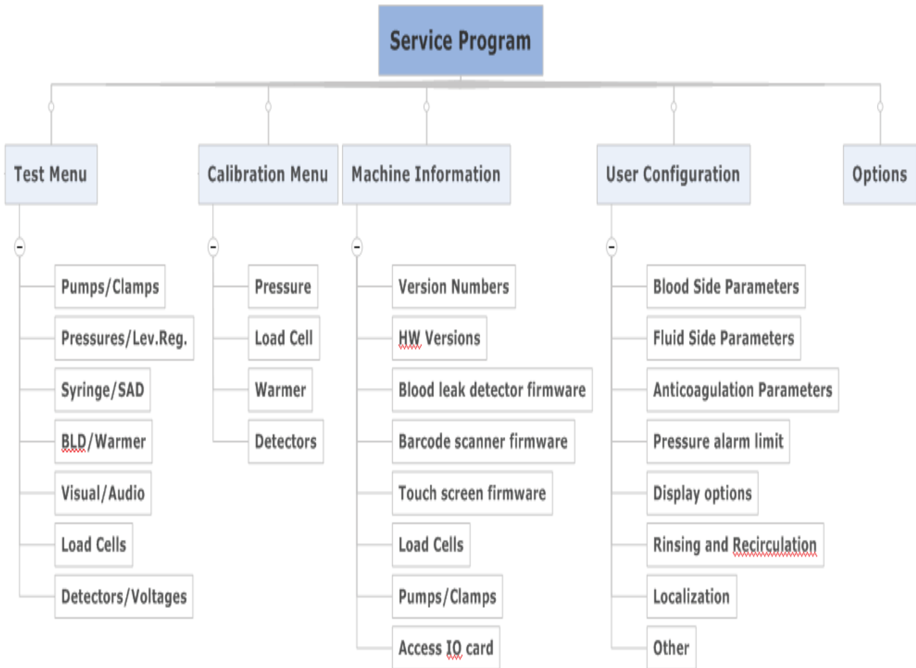


Fig. 6-1 Service program structure

6

Test Menu

1 Pumps/clamps
2 Pressures/level regulation
3 Syringe/SAD
4 Blood leak detector BLD/warmer
5 Visual/audio
6 Load cells
7 Detectors/voltages
8 Test menu

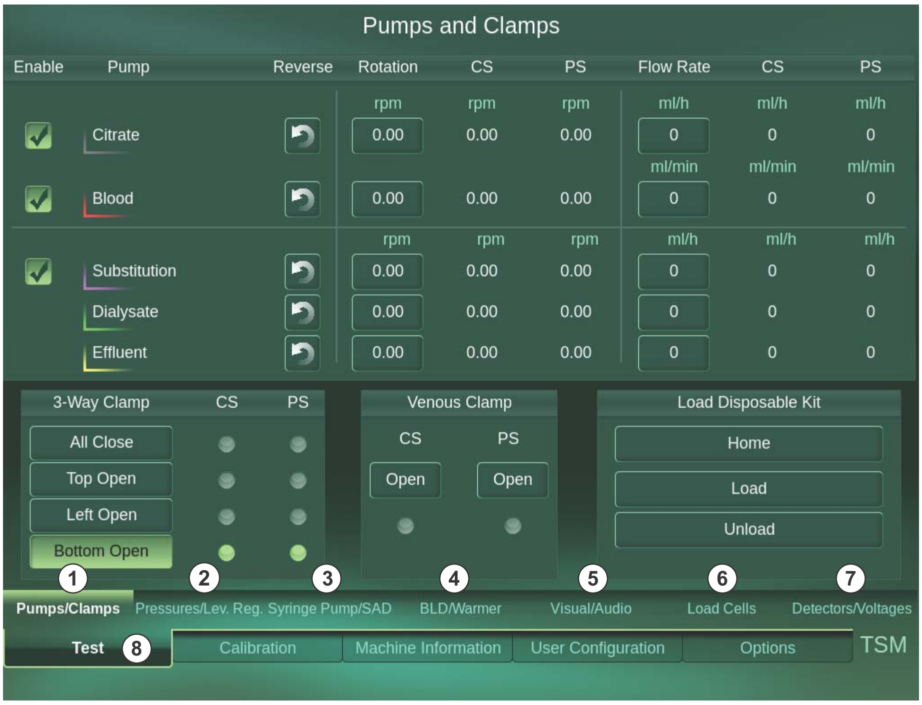


Fig. 6-2 *TSM Test* menu

The *Test* menu ⑧ *Pumps/Valves* ① is automatically displayed after the machine is switched on in the TSM mode.

The submenus ① - ⑦ can be selected in the *Test* menu ⑧ .

Calibration Menu

1 Pressure sensors
2 Load cell
3 Warmer
4 Detectors
5 Calibration menu

Fig. 6-3 *TSM Calibration* menu

The submenus ① - ④ can be selected in the *Calibration* menu ⑤ .

1 Version numbers
2 Unit Info
3 Load cells
4 Pumps/clamps
5 I/O Card
6 Working time counter
7 Blood leak detector/ barcode/touch screen firmware
8 HW versions

Machine Information **Menu**

Fig. 6-4 *TSM Machine information*

User Configuration **Menu**

The submenus ① - ⑧ can be selected in the user configuration menu.

1 Blood side
2 Fluid side
3 Anticoagulation
4 Pressure alarm limit
5 Display options
6 Rinsing and recirculation
7 Localization
8 Other
9 User configuration

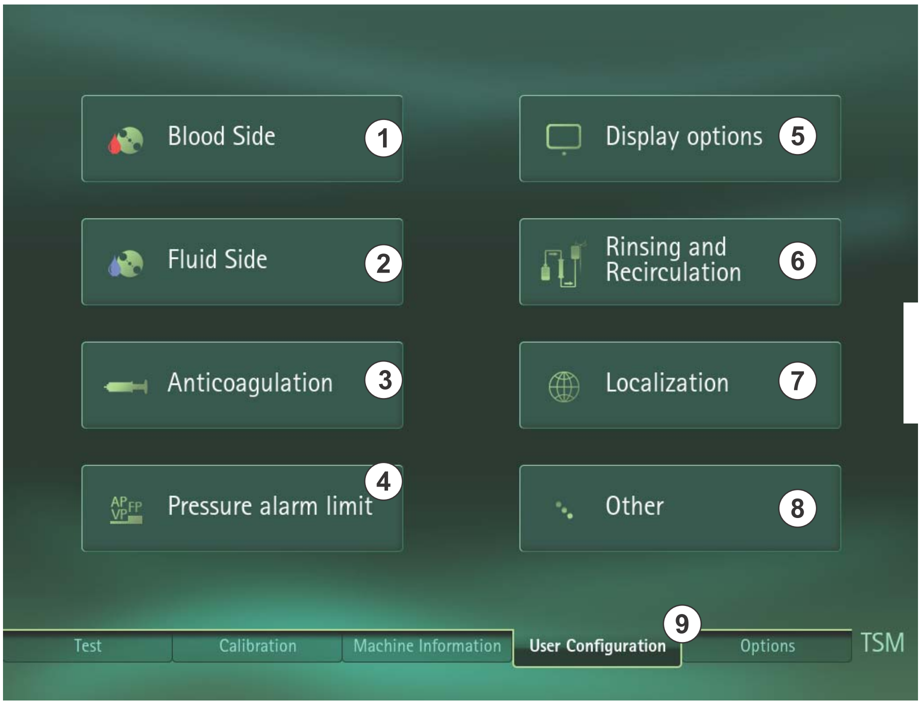


Fig. 6-5 *TSM User configuration*

6

1 QA code information
2 RCA option
3 TPE Option

Options

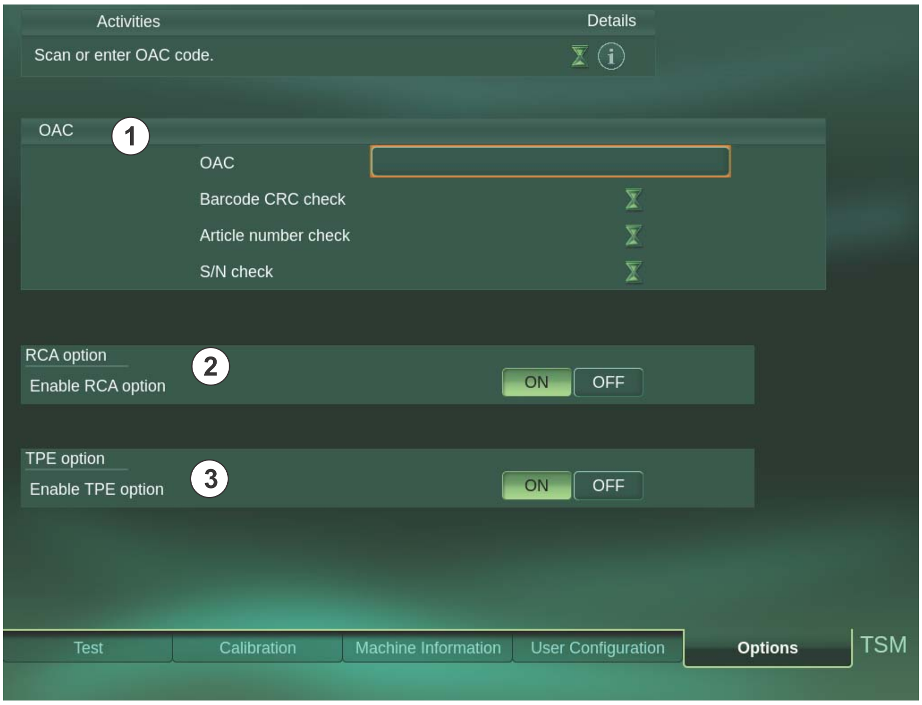


Fig. 6-6 TSM Options

6.4 Test Menu

6.4.1 Test of Pumps and Clamps

The pumps and clamps can be checked in the *Test* menu.
The five different pumps (blood/citrate/substitution/dialysate and effluent pump) of the machine, the 3-way clamp, the venous clamp and the automatic loading of the disposable kit can be checked.

1 Blood side manifold BSM
2 Fluid side manifold FSM
3 3-way clamp
4 Venous clamp
5 Loading/unloading disposable kit

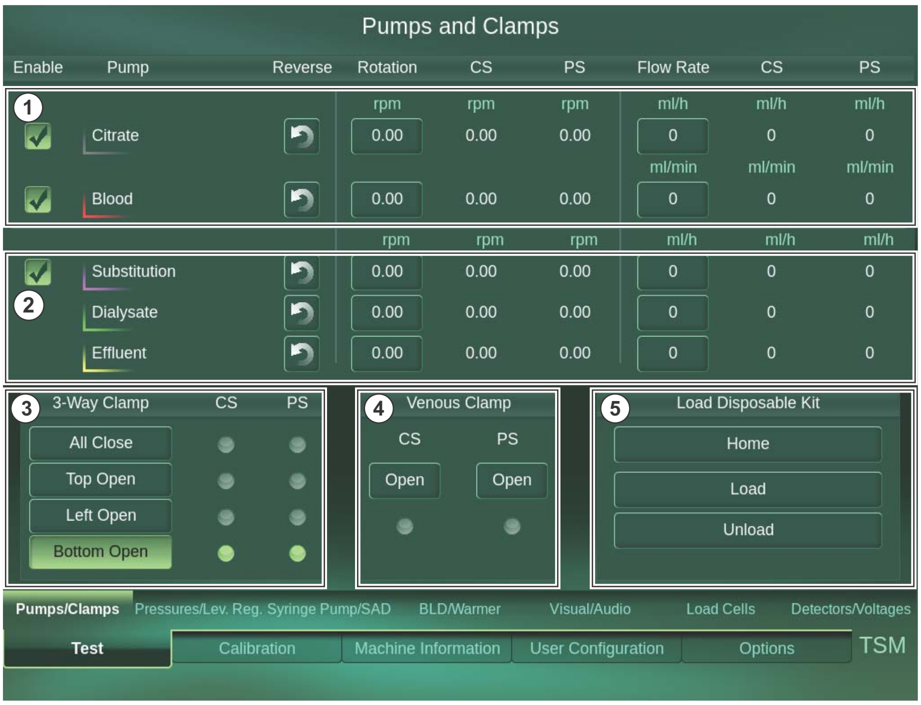


Fig. 6-7 TSM test pumps and clamps

6.4.1.1 Test of the Blood Side Manifold Components

The input box is opened by pressing the desired button to enter a new value. For example button ③ - ④ and ⑥ - ⑦ of Fig. 6-8 Inbut box (319).

1 Identification
2 Range
3 Unit
4 Done

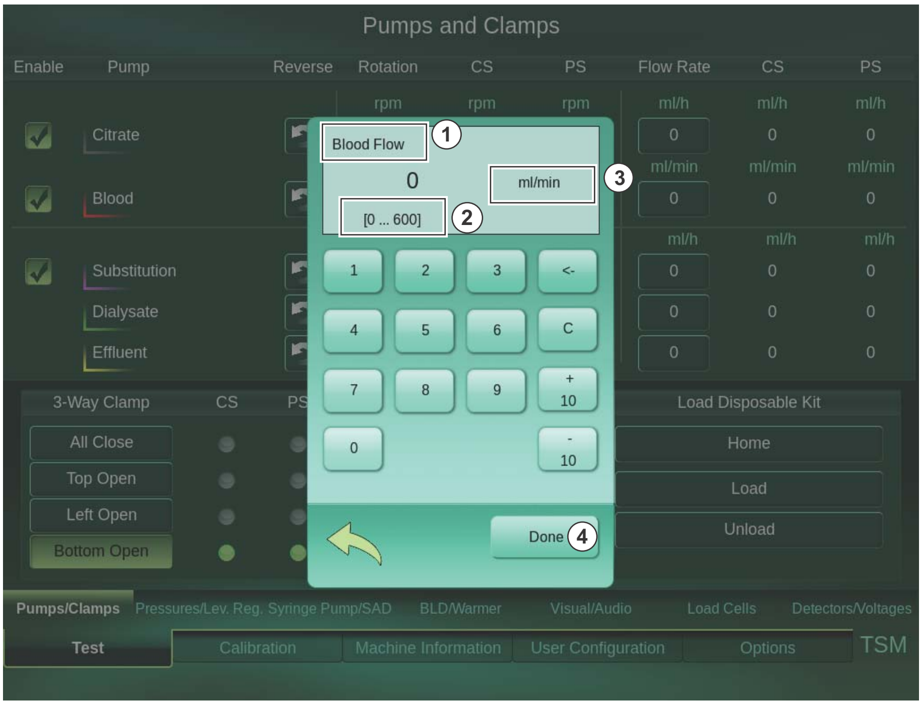


Fig. 6-8 Inbut box

The function of the blood pump and the citrate pump can be checked in two different ways (pump rate or flow). The blood side *Enable* check box ① has to be selected to enable the pumps to run.

6.4.1.1.1 Blood Pump

A visual inspection is necessary to check if the blood pump is running properly.

1 Enable check box
2 Reverse button citrate pump
3 Enter citrate pump rate
4 Enter citrate flow
5 Reverse button blood pump
6 Enter blood pump rate
7 Enter blood flow

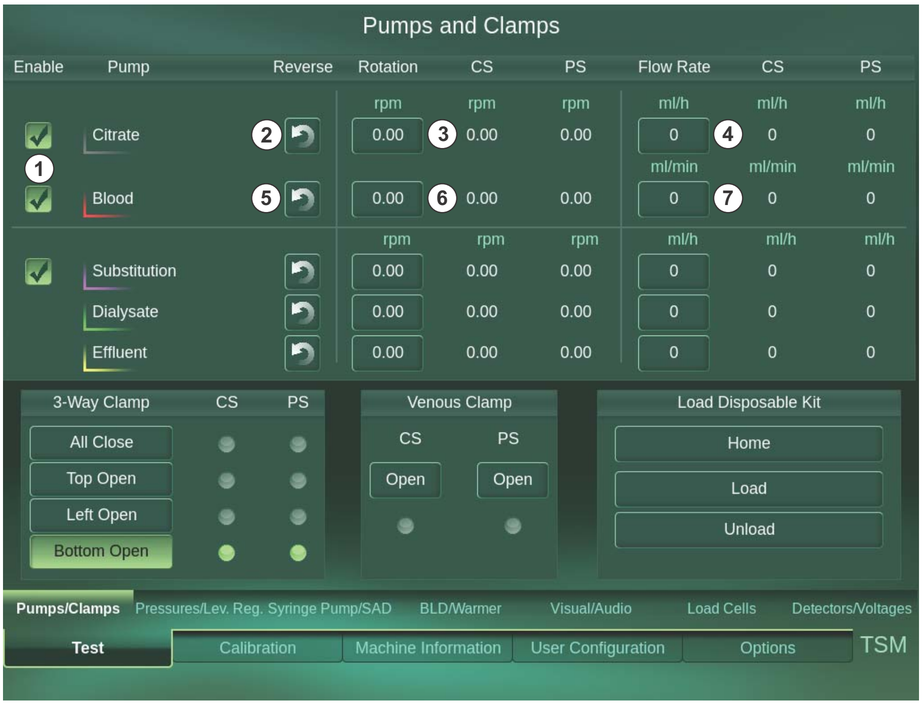


Fig. 6-9 TSM Test blood/citrate pump

Prerequisites

- *Enable* check box ① is selected.
- Blood pump rate can be entered by pressing button ⑥ .

1. Set the blood pump to 10 rpm.
   - ↳ Control system CS and protective system PS display the entered blood pump rate 10 rpm +/-5 %.
   - ↳ According to the blood pump rate, the CS and PS show the corresponding blood flow.
2. Set the blood pump rate to 80 rpm.
   - ↳ Control system CS and protective system PS display the entered blood pump rate 80 rpm +/-5 %.
   - ↳ According to the blood pump rate, the CS and PS show the corresponding blood flow.
3. Press button ⑤ .
   - ↳ The blood pump rate and the corresponding blood flow are displayed with reversed prefixes.
4. Deactivate *Enable* check box ① .
   - ↳ Blood pump is not running.
5. Select *Enable* check box ① .
6. Set blood pump rate to 0 rpm.

6.4.1.1.2 Citrate Pump

A visual inspection is necessary to check if the citrate pump is running properly.

1 Enable check box
2 Reverse button citrate pump
3 Enter citrate pump rate
4 Enter citrate flow
5 Reverse button blood pump
6 Enter blood pump rate
7 Enter blood flow

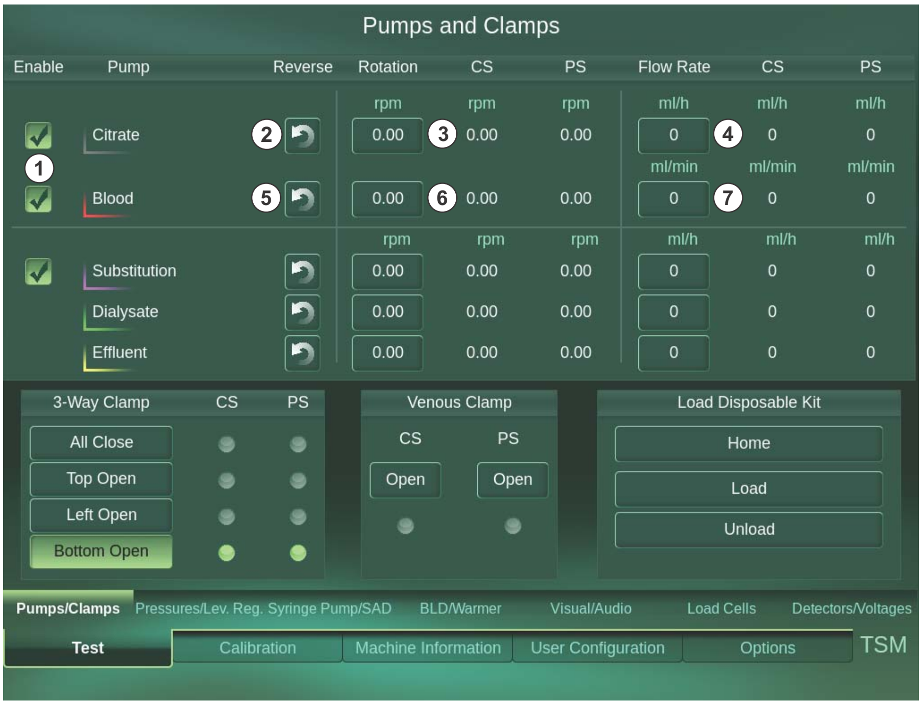


Fig. 6-10 TSM Test blood/citrate pump

Prerequisites

- *Enable* check box ① is selected
- Citrate pump rate can be entered by pressing button ③ .

1. Set the citrate pump rate to 10 rpm.
   ↳ Control system CS and protective system PS display the entered citrate pump rate 10 rpm +/-5 %.
   ↳ According to the citrate pump rate, the CS and PS show the corresponding citrate flow.
2. Set the citrate pump rate to 80 rpm.
   ↳ Control system CS and protective system PS display the entered citrate pump rate 80 rpm +/-5 %.
   ↳ According to the citrate pump rate, the CS and PS show the corresponding citrate flow.
3. Press button ② .
   ↳ The citrate pump rate and the corresponding citrate flow are displayed with reversed prefixes.
4. Deselect *Enable* check box ① .
   ↳ Citrate pump is not running.
5. Select *Enable* check box ① .
6. Set citrate pump rate to 0 rpm.

6.4.1.2 Test of the Fluid Side Manifold Components

The function of the substitution pump, dialysate pump and effluent pump can be checked in two different ways (pump rate or flow). The fluid side *Enable* check box ① has to be selected to enable the pumps to run.

6.4.1.2.1 Substitution Pump

A visual inspection is necessary to check if the substitution pump is running properly.

1 Enable check box
2 Reverse button substitution pump
3 Enter substitution pump rate
4 Enter substitution flow
5 Reverse button dialysate pump
6 Enter dialysate pump rate
7 Enter dialysate flow
8 Reverse button effluent pump
9 Enter effluent pump rate
10 Enter effluent flow

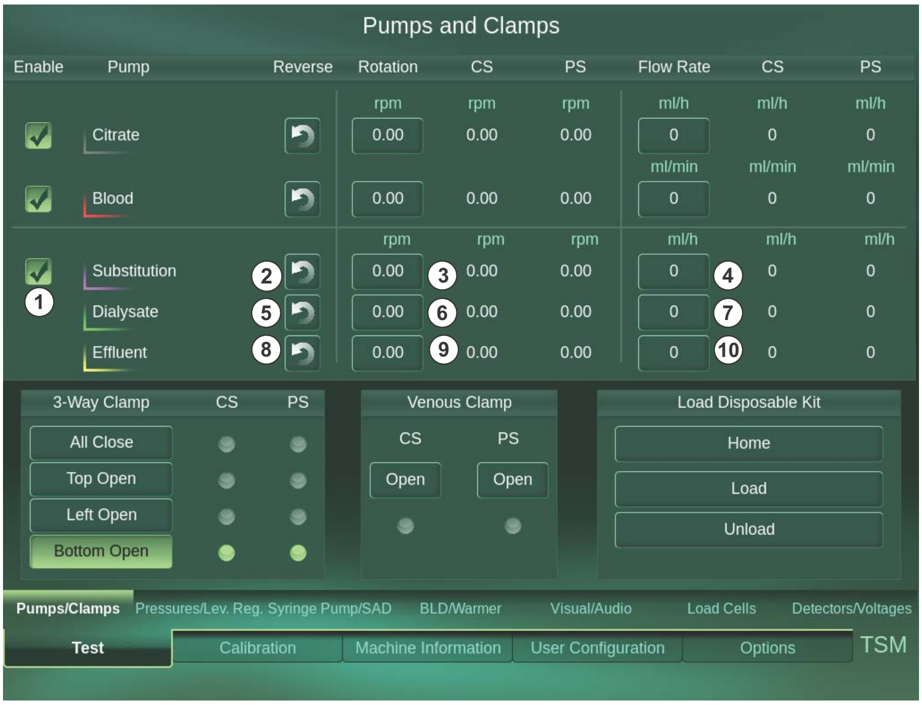


Fig. 6-11 TSM Test substitution/dialysate/effluent pump

Prerequisites

- *Enable* check box ① is selected.
- Substitution pump rate can be entered by pressing button ③ .

1. Set the substitution pump to 10 rpm.
   - ↳ Control system CS and protective system PS display the entered substitution pump rate 10 rpm +/-5 %.
   - ↳ According to the substitution pump rate, the CS and PS show the corresponding substitution flow.
2. Set the substitution pump rate to 80 rpm.
   - ↳ Control system CS and protective system PS display the entered substitution pump rate 80 rpm +/-5 %.
   - ↳ According to the substitution pump rate, the CS and PS show the corresponding substitution flow.
3. Press button ② .
   - ↳ The substitution pump rate and the corresponding substitution flow are displayed with reversed prefixes.
4. Deselect *Enable* check box ① .
   - ↳ Substitution pump is not running.
5. Select *Enable* check box ① .
6. Set substitution pump rate to 0 rpm.

6.4.1.2.2 Dialysate Pump

A visual inspection is necessary to check if the dialysate pump is running properly.

1 Enable check box
2 Reverse button substitution pump
3 Enter substitution pump rate
4 Enter substitution flow
5 Reverse button dialysate pump
6 Enter dialysate pump rate
7 Enter dialysate flow
8 Reverse button effluent pump
9 Enter effluent pump rate
10 Enter effluent flow

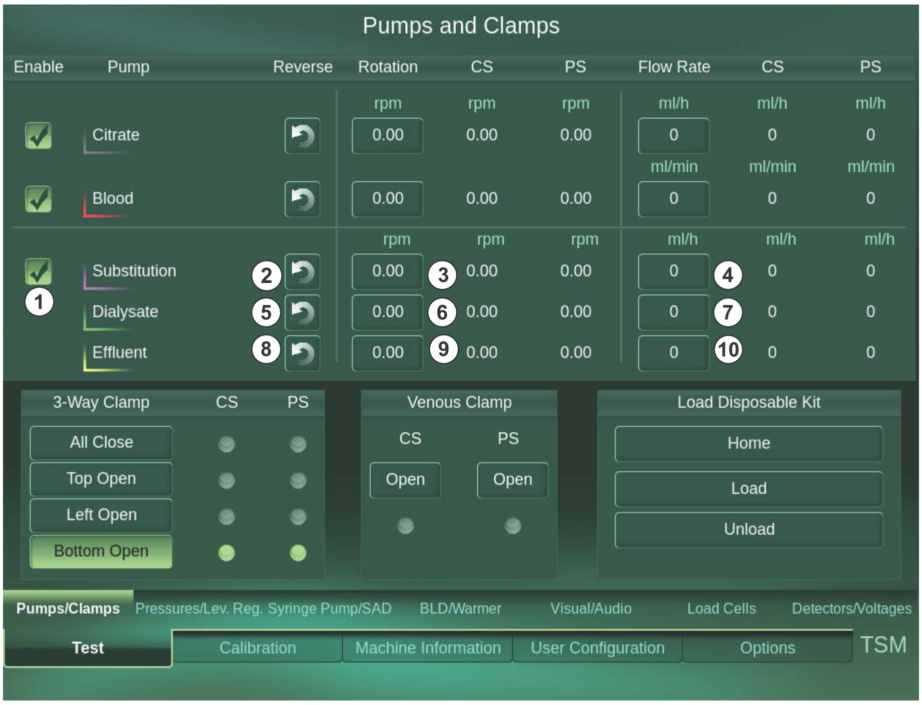


Fig. 6-12 TSM Test substitution/dialysate/effluent pump

Prerequisites

- *Enable* check box ① is selected.
- Dialysate pump rate can be entered by pressing button ⑥ .

1. Set the dialysate pump rate to 10 rpm.
   - ↳ Control system CS and protective system PS display the entered dialysate pump rate 10 rpm +/-5 %.
   - ↳ According to the dialysate pump rate, the CS and PS show the corresponding dialysate flow.
2. Set the dialysate pump rate to 80 rpm.
   - ↳ Control system CS and protective system PS display the entered dialysate pump rate 80 rpm +/-5 %.
   - ↳ According to the dialysate pump rate, the CS and PS show the corresponding dialysate flow.
3. Press button ⑤ .
   - ↳ The dialysate pump rate and the corresponding dialysate flow are displayed with reversed prefixes.
4. Deactivate *Enable* check box ① .
   - ↳ Dialysate pump is not running.
5. Select *Enable* check box ① .
6. Set dialysate pump rate to 0 rpm.

6

6.4.1.2.3 Effluent Pump

A visual inspection is necessary to check if the effluent pump is running properly.

1 Enable check box
2 Reverse button substitution pump
3 Enter substitution pump rate
4 Enter substitution flow
5 Reverse button dialysate pump
6 Enter dialysate pump rate
7 Enter dialysate flow
8 Reverse button effluent pump
9 Enter effluent pump rate
10 Enter effluent flow

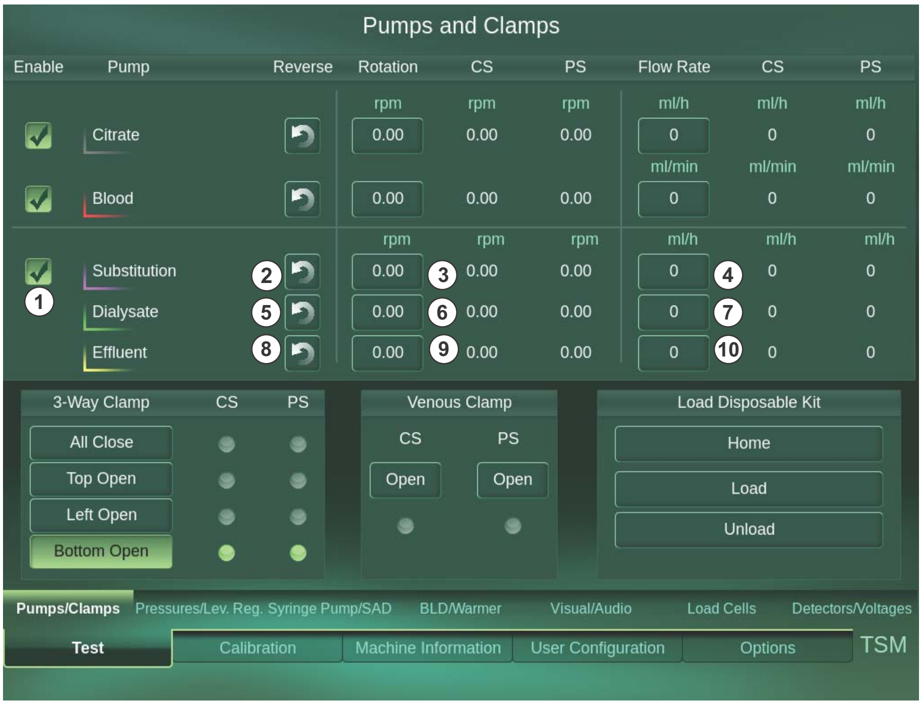


Fig. 6-13 TSM Test substitution/dialysate/effluent pump

Prerequisites

- *Enable* check box ① is selected.
- Effluent pump rate can be entered by pressing button ⑨ .

1. Set the effluent pump rate to 10 rpm.
   - ↳ Control system CS and protective system PS display the entered effluent pump rate 10 rpm +/-5 %.
   - ↳ According to the effluent pump rate, the CS and PS show the corresponding effluent flow.
2. Set the effluent pump rate to 80 rpm.
   - ↳ Control system CS and protective system PS display the entered effluent pump rate 80 rpm +/-5 %.
   - ↳ According to the effluent pump rate, the CS and PS show the corresponding effluent flow.
3. Press button ⑧ .
   - ↳ The effluent pump rate and the corresponding effluent flow are displayed with reversed prefixes.
4. Deselect *Enable* check box ① .
   - ↳ Effluent pump is not running.
5. Select *Enable* check box ① .
6. Set effluent pump rate to 0 rpm.

6.4.1.3 Test of 3-Way Clamp

The function description (top, left, bottom) of the 3-way clamp is based on the front view. Check visually if the 3-way clamp is working properly.

1 All close
2 Top open
3 Left open
4 Bottom open

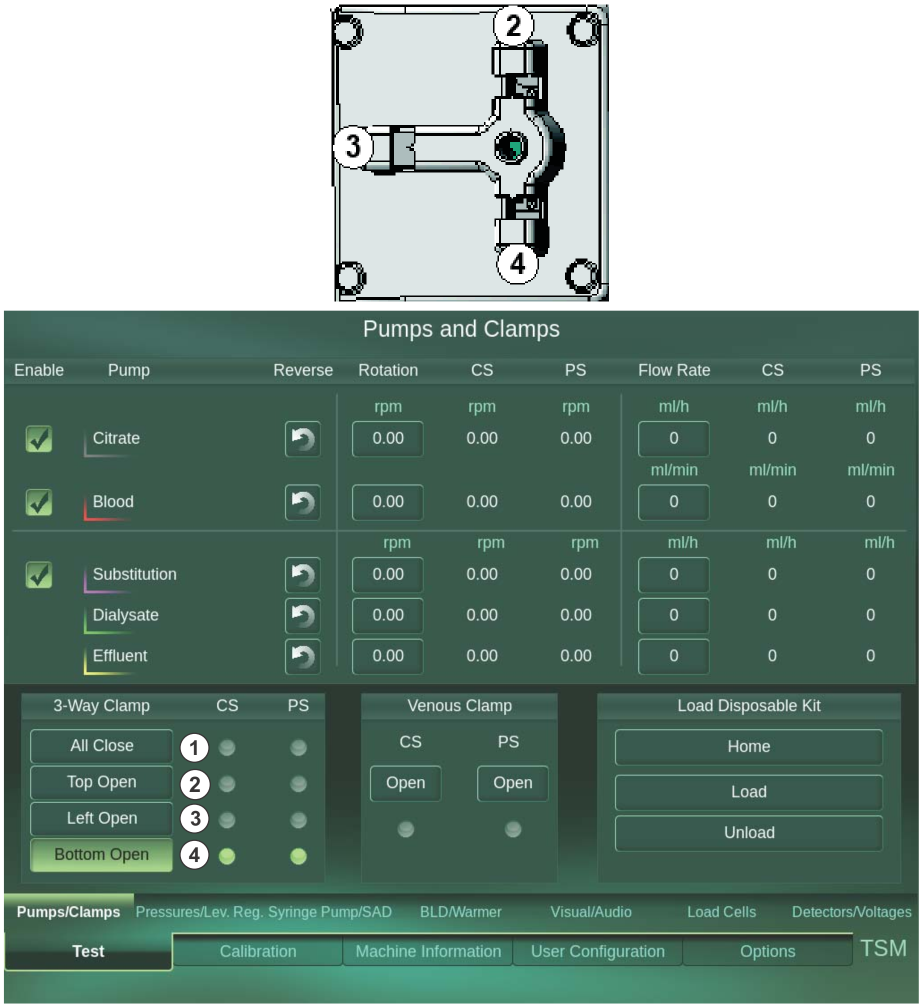


Fig. 6-14 3-way clamp

Four different positions of the 3-way clamp can be checked.

1. Press *All Close* button ① .
   - ↳ Each clamp of the 3-way clamp is closed.
   - ↳ The corresponding visual indicators of CS and PS are activated.
2. Press *Top Open* button ② .
   - ↳ Top clamp ② of the 3-way clamp is open.
   - ↳ Clamps ③ and ④ are closed.
   - ↳ The corresponding visual indicators of CS and PS are activated.
3. Press *Left Open* button ③ .
   - ↳ Left clamp ③ of the 3-way clamp is open.
   - ↳ Clamps ② and ④ are closed.
   - ↳ The corresponding visual indicators of CS and PS are activated.
4. Press *Bottom Open* button ④ .
   - ↳ Bottom clamp ④ of the 3-way clamp is open.
   - ↳ Clamps ② and ③ are closed.
   - ↳ The corresponding visual indicators of CS and PS are activated.

6.4.1.4 Test of Venous Clamp

1 CS *Open*

2 PS *Open*

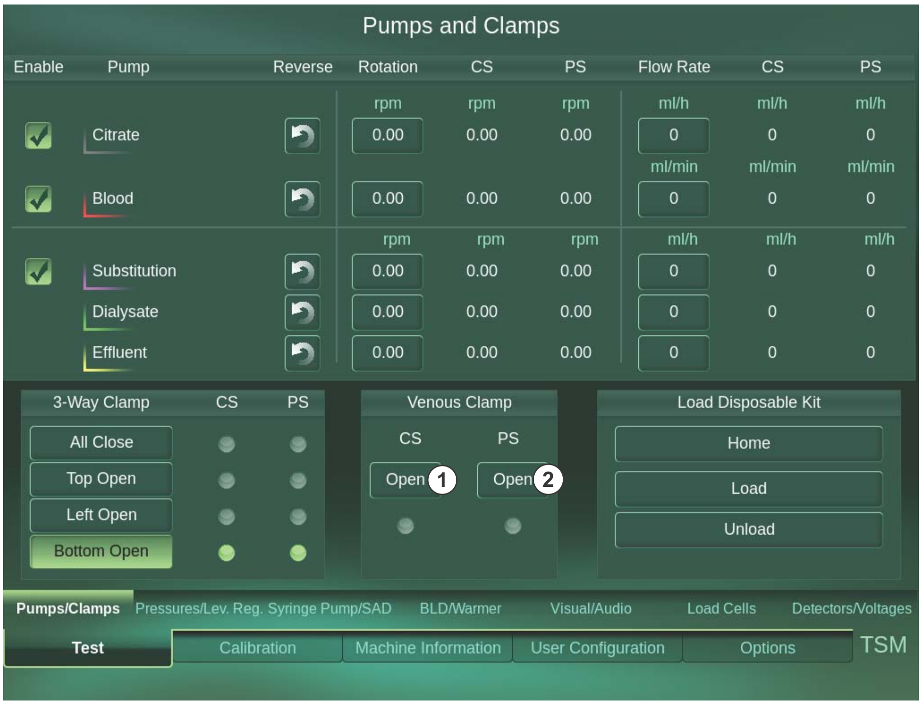


Fig. 6-15 TSM Test venous clamp

The venous clamp can be checked by the control system CS and the protective system PS.

1. No button is activated.
   - ↳ Venous clamp is closed.
   - ↳ Visual indicators of CS and PS are not activated.
2. Press button ① (button ② is not activated).
   - ↳ Venous clamp is closed.
   - ↳ Visual indicators of CS and PS are not activated.
3. Press button ② (button ① is not activated).
   - ↳ Venous clamp is closed.
   - ↳ Visual indicators of CS and PS are not activated.
4. Both buttons ① and ② are activated.
   - ↳ Venous clamp is open.
   - ↳ Visual indicators of CS and PS are activated.
5. Close venous clamp.
6. Check the gap between the axis and the eccentric with the service tool.
   - ↳ 1.4 pass the gap.
   - ↳ 1.5 does not pass the gap.

6.4.1.5 Test of Loading/Unloading Disposable Kit

1 *Home*

2 *Load*

3 *Unload*

Fig. 6-16 TSM Test load disposable

i

When the machine has finished the loading process, a visual inspection of each pump has to be performed. The disposable kit has to be loaded without any failure and inserted properly.

Automatic Loading of Disposable Kit

1. Press *Home* button ① .

   ↳ The roller of each pump and the 3-way clamp move into their home position for loading the disposable kit.

2. Open both manifold doors.
3. Fix disposable kit on the machine (both kit locking mechanism of blood side manifold and fluid side manifold are locked) and close both manifold doors.
4. Connect pressure ports on the machine.
5. Install warmer bag into the warmer with the correct position.
6. Press *Load* button ② .

   ↳ Automatic loading of the disposable kit.

7. Check all tubes if they are inserted properly.

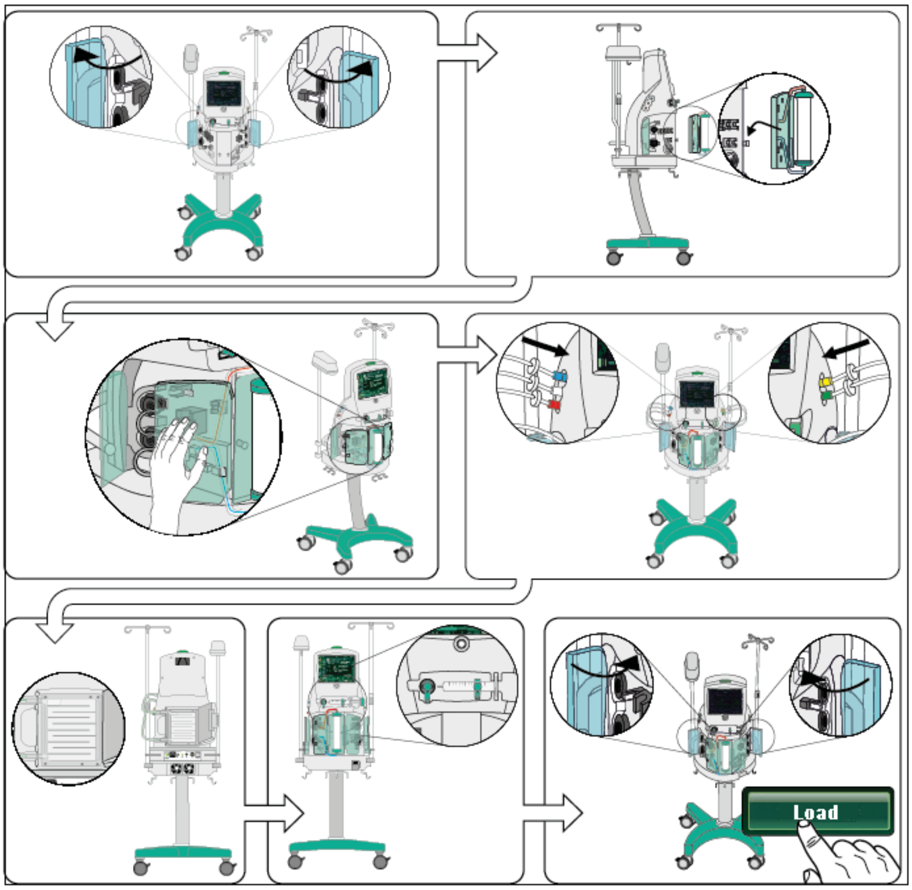


Fig. 6-17 Fix disposable kit

8. To unload the kit, unlock all four kit locking mechanism and press *Unload* button ③ .

6.4.2 Test of Pressures and Level Regulation

The pressures and level regulation can be selected in the *Test* menu.
The blood side pressure sensors, the fluid levels of the disposable kit chambers, the arterial valve and the level regulation pump can be checked.

1 Pressure sensors
2 Disposable kit chambers
3 Arterial valve
4 Level regulation pump

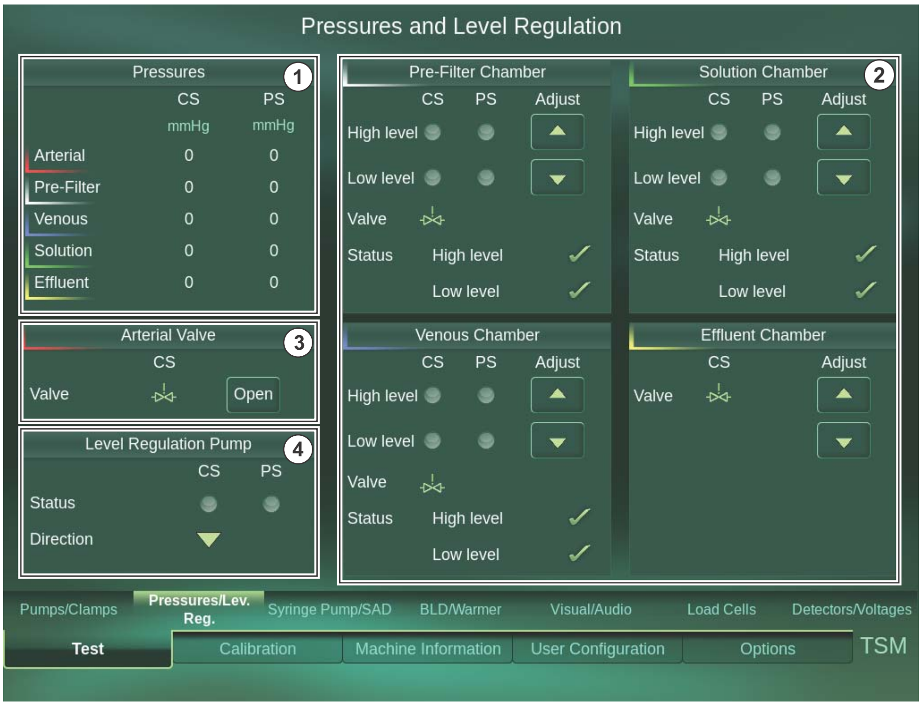


Fig. 6-18 TSM Test pressures and level regulation.

6.4.2.1 Test of Pressure Sensors

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

Fig. 6-19 TSM test pressures

The correct connection for testing the pressure sensors is described in the calibration menu. Page Fig. 6-43 Test and calibration pressure sensors (359).

Set the pressure for each pressure sensor separately to test the tightness connection between the pressure ports and the disposable kit. If the pressure increases similar for all pressure sensors, the filter of the pressure sensors inside the machine are checked too.

Required tools / materials

- Five-fold stopcock incl. tubings
- Pressure manometer
- Syringe 50 ml

1. Create a pressure manually of approx. +600 mmHg. Close all connectors of the five-fold stopcock system and wait until the values on the display are stable

   ↳ According to the selected pressure sensor, control system CS and protective system PS display the pressure in mmHg

2. Create a pressure manually of approx. -450 mmHg. Close all connectors of the five-fold stopcock system and wait until the values on the display are stable

   ↳ According to the selected pressure sensor, control system CS and protective system PS display the pressure in mmHg

Pressure Leak Test

1. Apply a pressure of 530 mmHg
2. Turn the valve closest to the syringe port to block the syringe
3. Wait for 1 minute

   ↳ All pressure sensors must be display > 500 mmHg

1 Pre-filter chamber
2 Solution chamber
3 Effluent chamber
4 Venous chamber
5 Adjust chamber levels
6 Level regulation pump

6.4.2.2 Test of Disposable Kit Chambers and Level Regulation

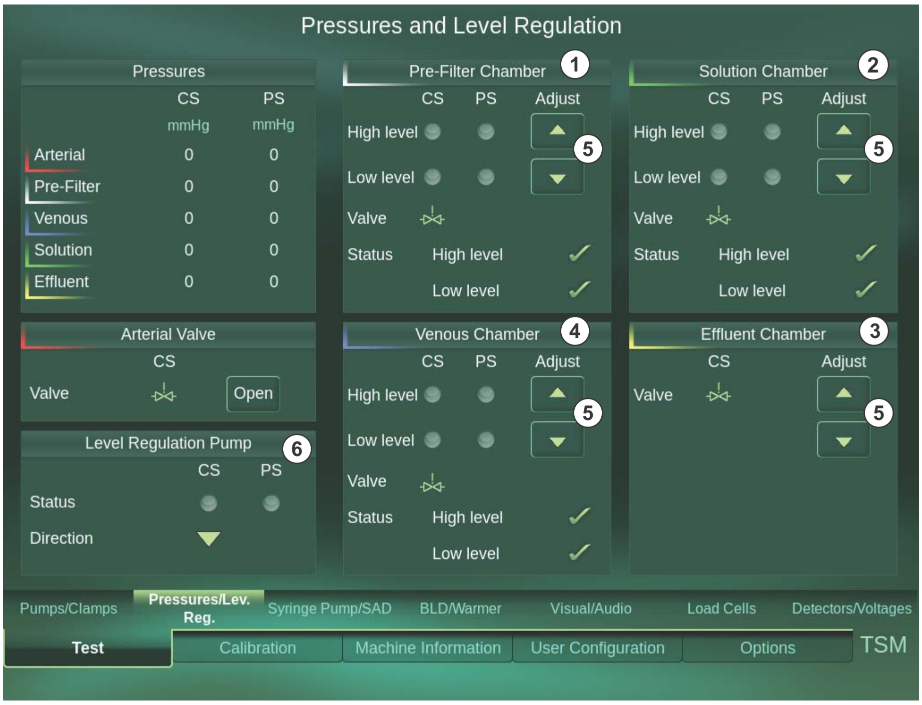


Fig. 6-20 TSM Test chambers and level regulation

The disposable kit includes four chambers to collect the air in the extracorporeal blood circuit. To set the level of the chambers ① - ③ and ④ press up and down arrow buttons ⑤ .

Required tools / materials

- Test chamber
- Syringe (e.g. B|Braun Omnifix 50 ml)

Testing Chamber ① - ② and ④

1. Connect the test chamber to the OMNI.
2. Fill test chamber with fluid. Use the syringe to set the level inside the chamber.
   ↳ As soon as the liquid inside the test chamber reaches the lower level sensor of a chamber, the control system CS and the protective system PS of the corresponding chamber are activated.
   ↳ As soon as the liquid inside the test chamber reaches the higher level sensor of a chamber, LEDs of CS and PS (low and high level) of the corresponding chamber are activated.
3. Decrease the level of the chamber.

Testing Chamber ③

1. Press one of the *Adjust* buttons ⑤
   ↳ CS Value of the valve indicates an open status.

Section ⑥
Current status and driving direction of the level regulation pump is displayed.

6.4.2.3 Test of Arterial Valve

1 Arterial pressure

2 Venous pressure

3 *Open* arterial valve button

Fig. 6-21 TSM Test arterial valve

Required tools / materials

- Five-fold stopcock incl. tubings
- Pressure manometer
- Syringe (e.g. B|Braun Omnifix 50 ml)

1. Connect arterial (red) and venous (blue) pressure port and the pressure manometer to the five-fold stopcock.
2. Close all open connections on the five-fold stopcock.
3. Close arterial pressure port connector.
4. Set a venous pressure of approx. +600 mmHg with a syringe.
5. Press button ③ .

   ↳ Arterial valve is open.

   ↳ CS symbol displays an opened valve.

   ↳ Arterial ① and venous ② pressures show the same pressure values.

6.4.3 Test of Syringe Pump and Safety Air Detector SAD

The syringe pump and safety air detector SAD can be selected in the *Test* menu.
Syringe pump and the safety air detectors SAD can be checked.

1 Syringe pump
2 Safety air detector SAD

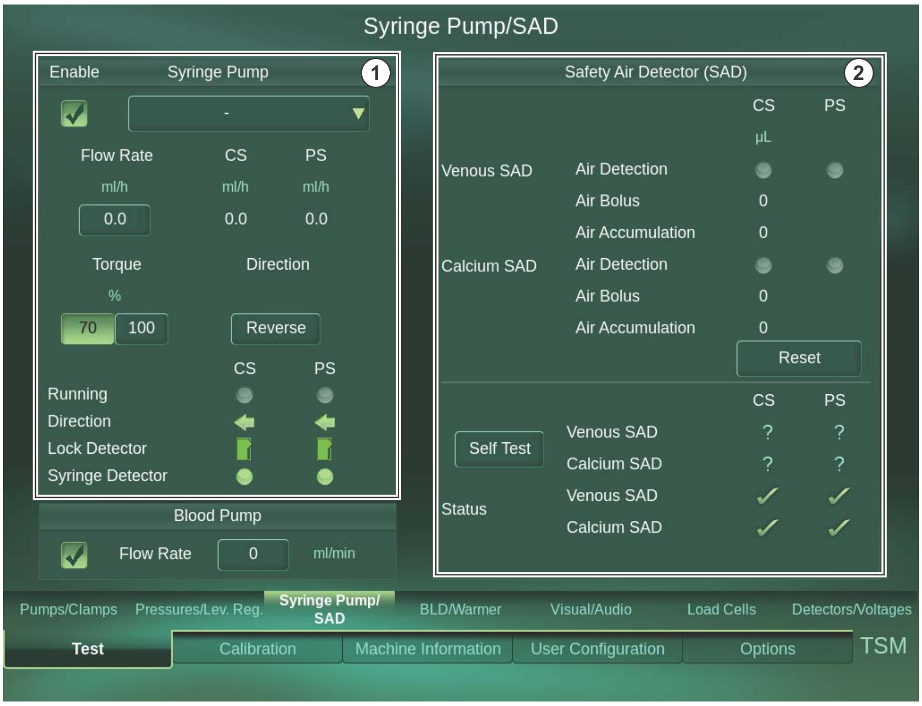


Fig. 6-22 TSM Test syringe pump and SAD

6.4.3.1 Test of 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

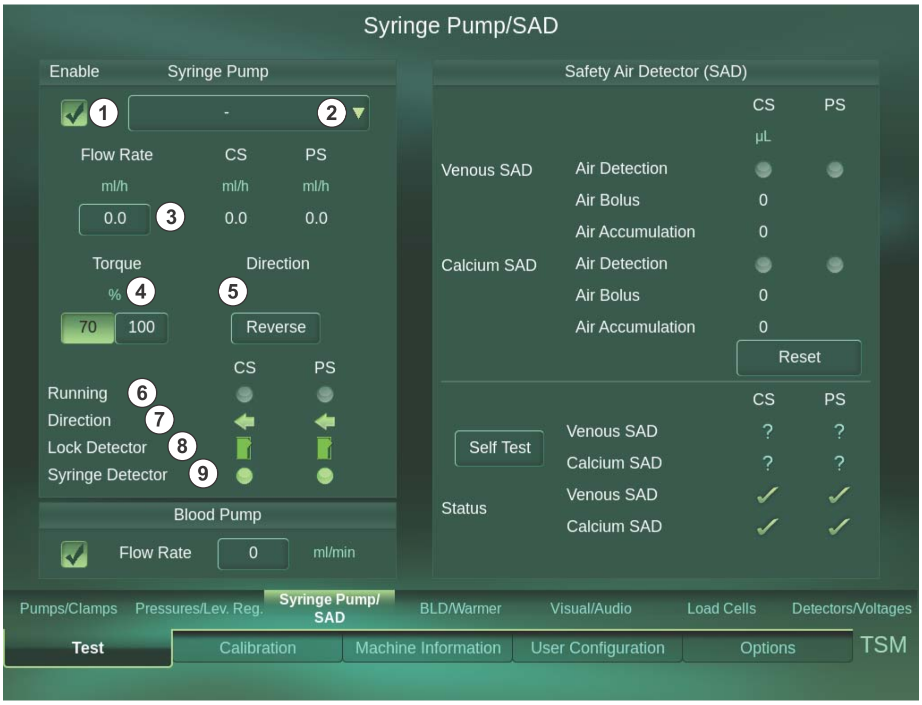


Fig. 6-23 TSM Test syringe pump

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 50%.
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.

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.

6.4.3.2 Test of Safety Air Detector SAD

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 Reset
8 Selftest SADV
9 Selftest SADC
10 Status SADV/SADC
11 Selftest
12 Blood pump flow rate
13 Enable check box blood pump

6

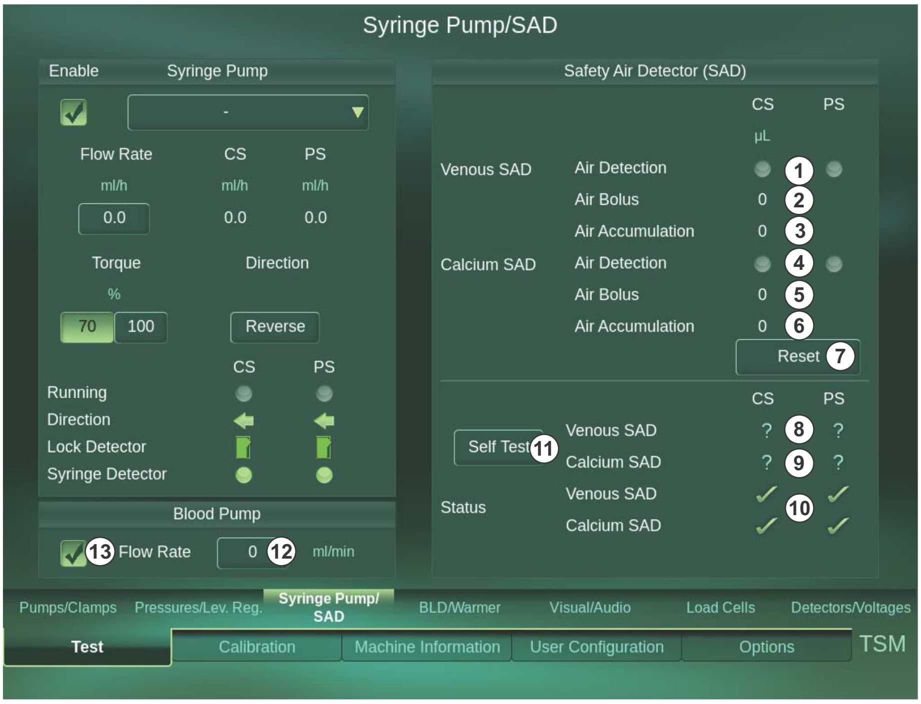


Fig. 6-24 TSM Test SADC and SADV

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 ⑫ rate to 26 ml/min.

   ↳ CS value of air bolus ② increases.
7. Set blood pump flow ⑪ rate to 126 ml/min.

   ↳ CS value of air bolus ② increases more rapidly than before.
8. Set blood pump flow ⑫ 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 ⑫ 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 ⑮ .
14. Enable check box ⑭ of the syringe pump is selected.
15. Set syringe pump flow ⑬ 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 ⑭ 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 ⑭ of the syringe pump.
21. Set syringe pump flow ⑬ 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 ⑯ .
    - ↳ Check if CS and PS icons for both detectors ⑧ 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 ⑯ .
    - ↳ 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.

6

6

6.4.4 Test of Blood Leak Detector BLD and Warmer

The blood leak detector BLD and warmer can be selected in the *Test* menu. Blood leak detector and warmer can be checked.

1 Blood leak detector BLD
2 Warmer

Fig. 6-25 TSM Test BLD and warmer

6.4.4.1 Test of Blood Leak Detector

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

Fig. 6-26 TSM Test BLD

Required tools / materials

- Blood leak detector test tool

1. Insert the white glass of the test tool into the blood leak detector and press *Zero* button. Wait until CS LED is activated.
2. Release *Zero* button ② .
   ↳ Actual value ④ is 0 (permissible tolerance ∓ 3).
   ↳ Actual value ④ is lower than calibration setpoint value ⑤ .
   ↳ Blood detection control system CS and protective system PS LEDs ① are not activated.
3. Insert the blue glass of the test tool into the blood leak detector.
   ↳ Actual value ④ increase.
   ↳ Actual value ④ is higher than calibration setpoint value ⑤ (between 490-540).
   ↳ Blood detection CS and PS LEDs ① are activated.

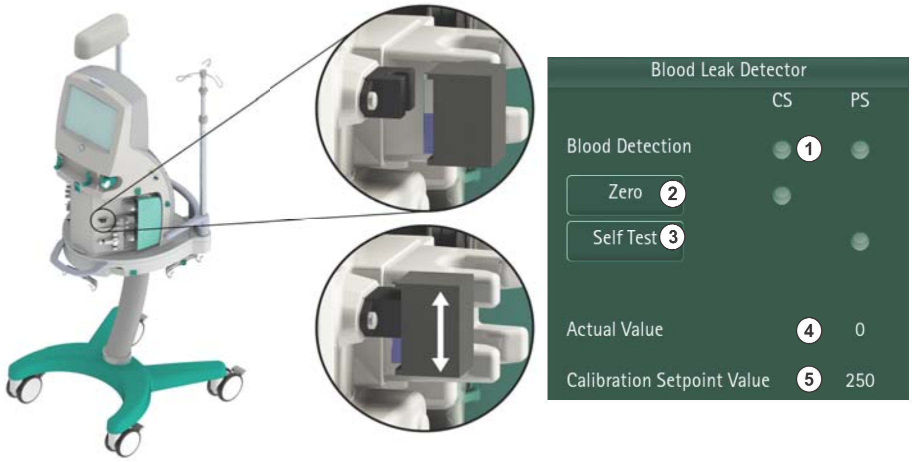


Fig. 6-27 TSM Test BLD test tool

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

Required tools / materials

- Blood leak detector test tool

1. Insert the white glass of the test tool into the blood leak detector and press *Zero* button. Wait until CS LED is activated.
2. Release *Zero* button ② .
   - ↳ Actual value ④ is 0 (permissible tolerance ∓ 3).
   - ↳ Actual value ④ is lower than calibration setpoint value ⑤ .
   - ↳ Blood detection control system CS and protective system PS LEDs ① are not activated.
3. Insert the blue glass of the test tool into the blood leak detector.
   - ↳ Actual value ④ increase.
   - ↳ Actual value ④ is higher than calibration setpoint value ⑤ (between 490-540).
   - ↳ Blood detection CS and PS LEDs ① are activated.

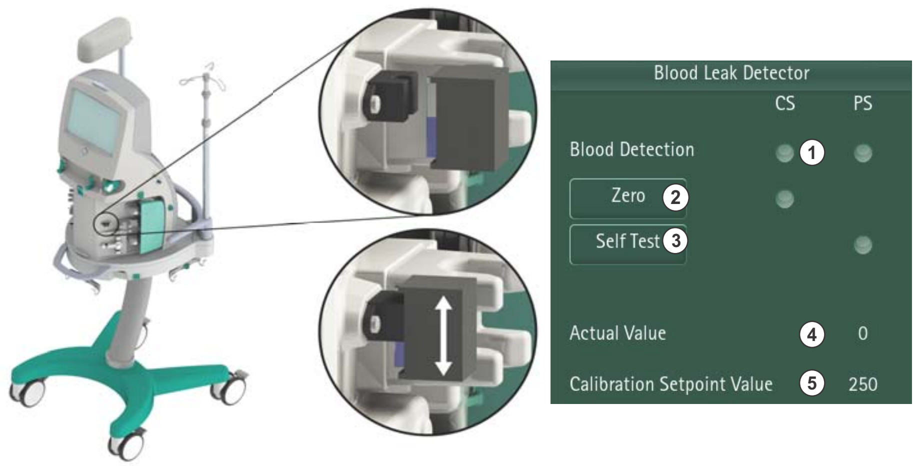


Fig. 6-28 TSM Test BLD test tool

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

1 Warmer enable CS *ON*

2 Warmer enable PS *ON*

3 Enter warmer power CS

4 Outlet temperature CS and PS

5 Plate temperature CS and PS

6.4.4.2 Test of Warmer

Fig. 6-29 TSM Test warmer

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.

6

Prerequisites

- Machine is switched off.

Fig. 6-30 Connection of the test and calibration tool

Required tools / materials

- Warmer test and calibration board

Test with Warmer Test and Calibration Board

1. Rear housing is disassembled.
2. Tilt the warmer from the machine by loosening the screws from the main bracket.
3. Disconnect the temperature sensors from the warmer board.
4. Connect the warmer test and calibration board to the warmer board.
5. Switch on the machine and enter TSM *Test* menu *BLD/Warmer*.
   ↳ Compare outlet temperature CS and PS ④ and plate temperature CS and PS ⑤ with the printed value on the warmer test and calibration board (permissible tolerance: +/- 0.1 °C).
6. Change the connectors of the warmer test and calibration board to the second value.
   ↳ Compare outlet temperature CS and PS ④ and plate temperature CS and PS ⑤ with the printed value on the warmer test and calibration board (permissible tolerance: +/- 0.1 °C).
7. Reconnect the warmer board to the temperature sensors.
8. Close warmer to the machine by fastening the screws on the bracket.
9. Reassemble rear door.
10. Switch on the machine and enter TSM *Test* menu *BLD/Warmer*.

11. Press Warmer Enable *ON* CS ① and PS ② and set Warmer Power ③ to 50%.
    - ↳ Warmer power PS led is activated
    - ↳ CS and PS plate temperature values ⑤ increase.

6.4.5 Test of Visual and Audio Signals and Barcode Scanner

The audio and visual signals and the barcode scanner can be selected in the test menu.
Status indicator lights, audio signals (speaker, buzzer and microphone) and the barcode scanner can be checked.

1 Status LEDs
2 Audio
3 Barcode scanner
4 Alarm explanation values

Fig. 6-31 TSM test visual and audio

The alarm explanation values give information for trouble shooting. The different values are indicators for several alarm scenarios.

6

6

6.4.5.1 Status Indicator Lights

The machine has three different alarm conditions. Each condition has a specific color.

Color	Alarm condition
Green	The green status light signs that the system is in normal working state. If operator intervention is required, the green status indicator light blinks. **In preparation:** The green LED is lit during automatic priming and rinsing. The green LED is blinking if the machine waits for operator action. **In therapy:** The green light is lit if the therapy is running (blood side and fluid side). The green LED is blinking, if blood side or fluid side is stopped, but no alarm situation is detected.
Yellow	The yellow light is lit in case of low priority alarm. The yellow LED is blinking in case of medium priority alarm.
Red	The red LED is blinking in case of high priority alarm.

1 Off
2 Red
3 Yellow
4 Green

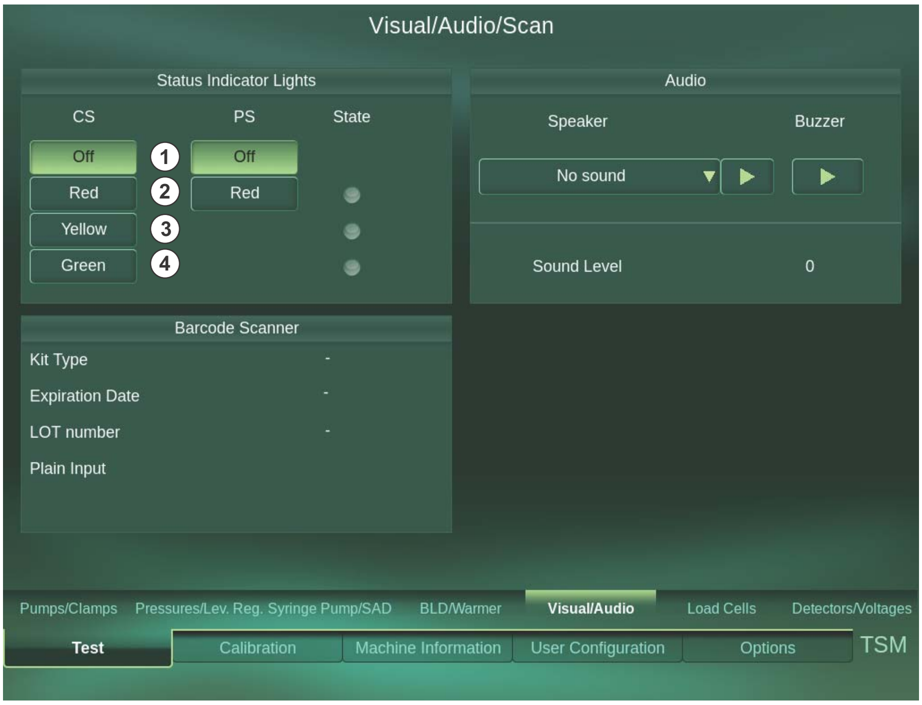


Fig. 6-32 TSM Test status indicator lights

1. Press CS or PS *Off* button ① .
   - ↳ No LED of CS state is activated.
2. Press CS and PS *Red* button ② .
   - ↳ Red LEDs are activated on the top of the monitor.
   - ↳ Corresponding LED of CS state is activated (red).
3. Press CS *Yellow* button ③ .
   - ↳ Yellow LEDs are activated on the top of the monitor.
   - ↳ Corresponding LED of CS state is activated (yellow).
4. Press CS *Green* button ④ .
5. Press PS *OFF* button ① .
   - ↳ Green LEDs are activated on the top of the monitor.
   - ↳ Corresponding LED of CS state is activated (green).

6

6.4.5.2 Audio Test

1 Speaker
2 Play
3 *Buzzer* button
4 Sound level

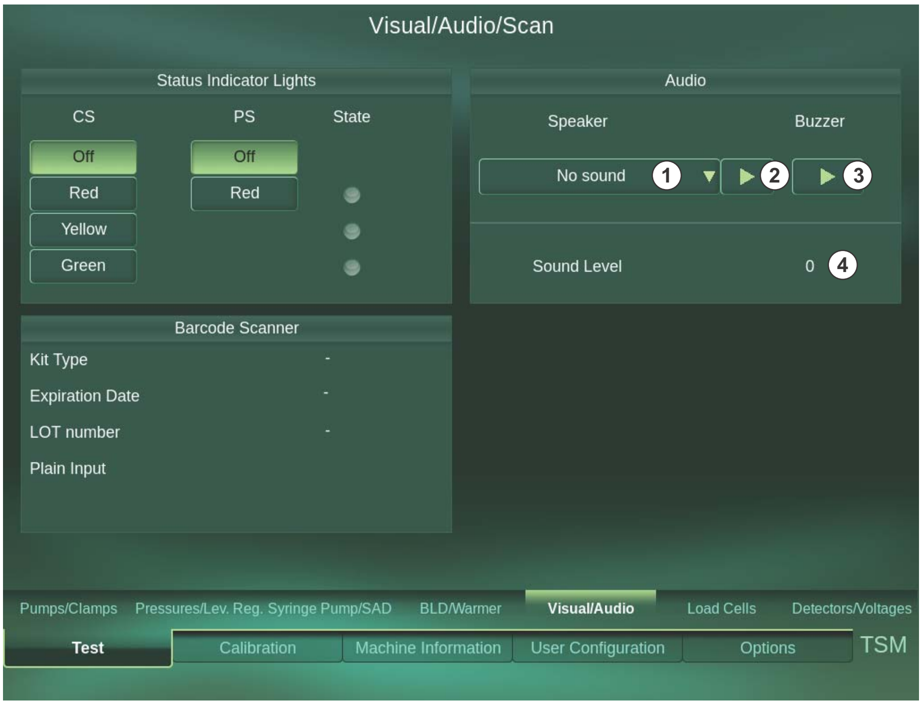


Fig. 6-33 TSM Test audio

1. Press *Buzzer* button ③ .
   - ⇘ Check if there is an audible alarm.
   - ⇘ *Sound Level* ④ value increases.
2. Release *Buzzer* button ③ .
   - ⇘ Check if there is no audible alarm.
   - ⇘ *Sound Level* ④ value decreases.
3. Press *Speaker* button ① and select *Test Medium*.
4. Press *Play* button ② .
   - ⇘ The selected audio file ① is played.
5. Press *Speaker* button ① and select *Test High*.
6. Press *Play* button ② .
   - ⇘ The selected audio file ① is played.
7. Press *Speaker* button ① and select *Test Low*.
8. Press *Play* button ② .
   - ⇘ The selected audio file ① is played.

6.4.5.3 Test of Barcode Scanner

1. Use test barcode or a disposable kit.
2. Use barcode scanner to read the test barcode or the disposable kit..

   ↳ Compare kit type ① , the expiry date ② and LOT number ③ of the test code with scanned code on the display

1 Kit type

2 Expiration date

3 LOT number

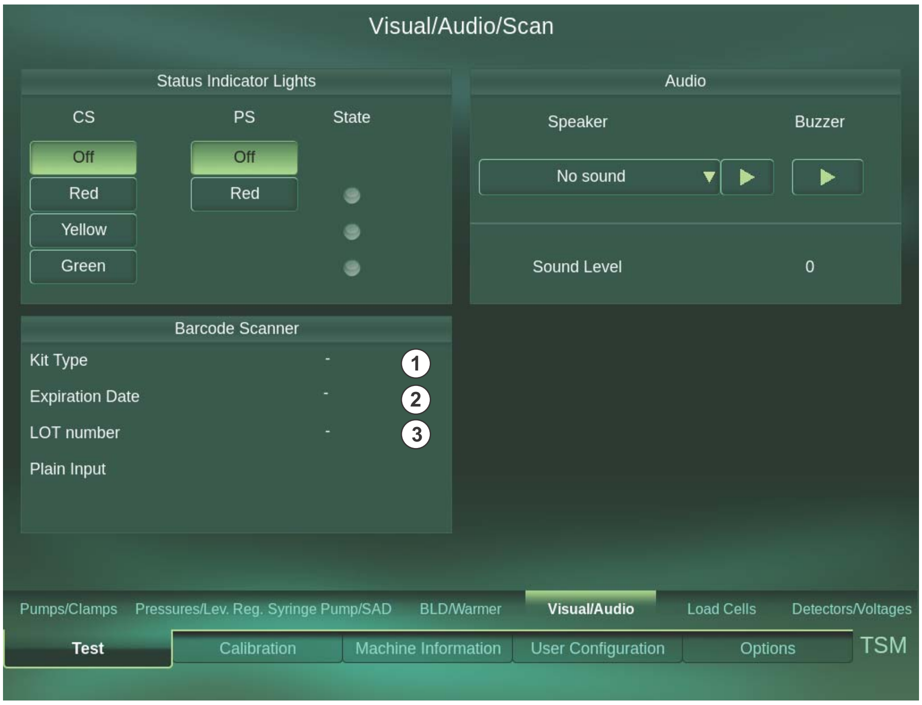


Fig. 6-34 TSM Test barcode scanner

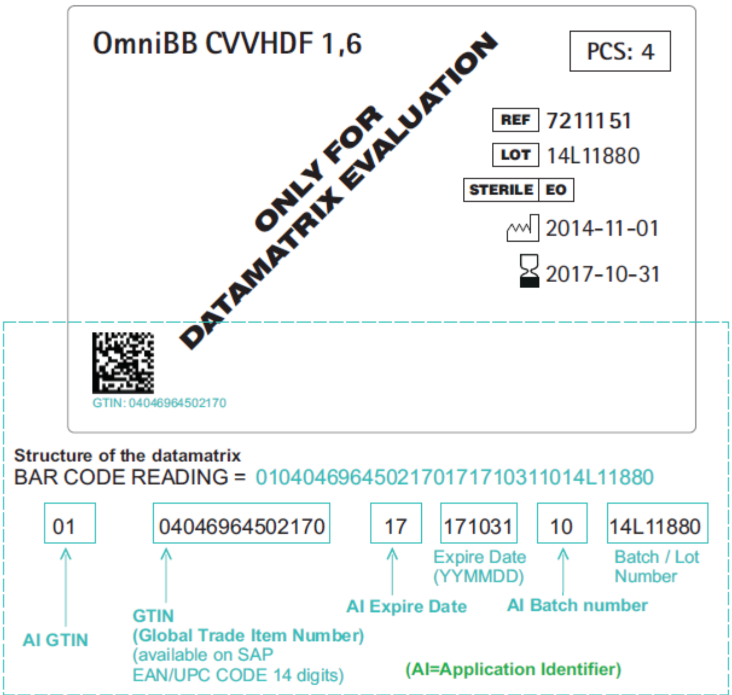


Fig. 6-35 Test barcode

6.4.6 Test of Load Cells

The load cells can be selected in the *Test* menu. All four load cells can be checked.

Defined test weights must be used for an exact test result of the load cells.

1 Citrate load cell
2 Substitution load cell
3 Dialysate load cell
4 Effluent load cell

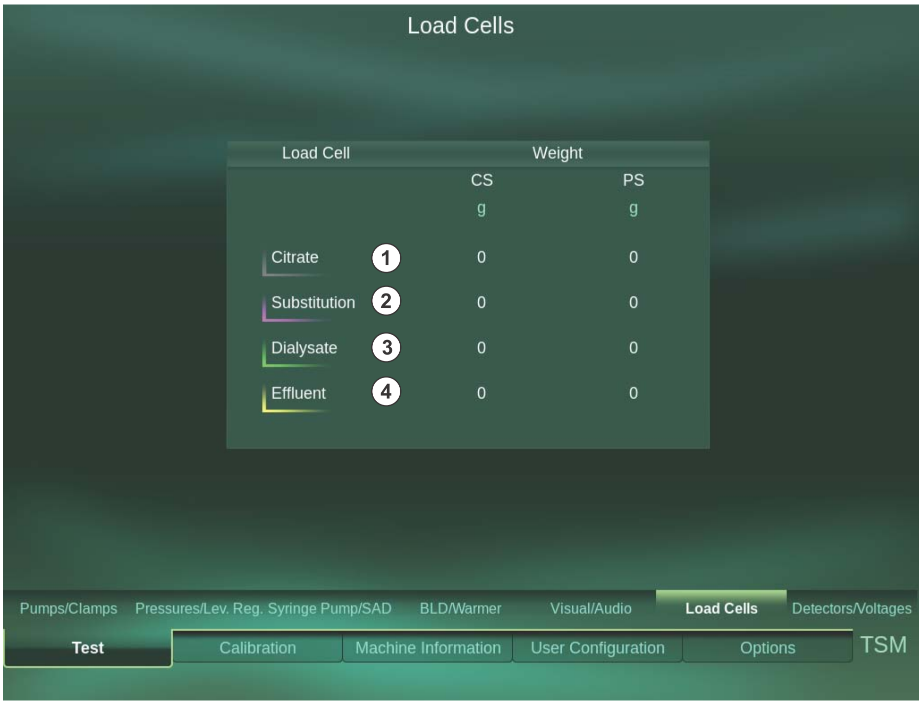


Fig. 6-36 TSM Test load cells

1. Make sure that no weight is placed on the load cells.
   ↳ Control system CS and protective system PS display *0* [g] (permissible tolerance +/-5 g).
2. Hang defined weights on the load cell. (2000g for citrate and 2 x 5000g for left/center and right load cell)
   ↳ CS and PS display the predefined weight on the corresponding load cell.
1. Make sure that no weight is placed on the load cells.
   ↳ Control system CS and protective system PS display *0* [g] (permissible tolerance +/-5 g).
2. Hang defined weights on the load cell. (2000g for citrate and 2 x 5000g for left/center and right load cell)
   ↳ CS and PS display the predefined weight on the corresponding load cell.

6.4.7 Test of Detectors and Voltages

Kit detector, door detector and voltages can be selected in the test menu.
Kit detector and door detector, voltages including the battery voltage and staff call can be checked.

1 Detectors
2 Voltages
3 Staff call
4 Fan
5 Battery

Fig. 6-37 TSM Test detectors and voltages

6

6.4.7.1 Test of Kit Detector and Door Detector

1 AIO board
2 DIO board
3 Blood side door
4 Blood side kit
5 Fluid side door
6 Fluid side kit

Fig. 6-38 TSM Test kit and door detectors

AIO board

LED ① is activated if AIO board is connected properly and communicate to the single board computer.

DIO board

LED ② is activated if DIO board is connected properly and communicate to the single board computer.

Required tools / materials

- Door detector calibration tool (Spacer 5 mm)

Check door detector

1. Close blood side door.
   - ↳ Symbols ③ displays a closed door.
2. Insert test and calibration tool for the door detector and close blood side door.
   - ↳ Symbols ③ displays still a closed door.
3. Open blood side door.
   - ↳ Symbols ③ displays an opened door.
4. Close fluid side door.
   - ↳ Symbols ⑤ displays a closed door.
5. Insert test and calibration tool for the door detector and close fluid side door.
   - ↳ Symbols ⑤ displays still a closed door
6. Open fluid side door
   - ↳ Symbols ⑤ displays an open door.

Check kit detection

1. Fix kit on the machine.
2. Both kit locking mechanisms on the blood side door has to be fixed.
   - ↳ Symbol ④ displays a closed door.
3. Both kit locking mechanisms on the fluid side door has to be fixed.
   - ↳ Symbol ⑥ displays a closed door.

6.4.7.2 Test of Voltages

1 Power source
2 PS 24V off
3 24Vsw status
4 12 VC
5 5 VSYS
6 5 VC
7 5 VP
8 3.3 VP
9 10 VP
10 VCC (24V)
11 24 Vsw
12 Voltage
13 Charge
14 Charge status

Fig. 6-39 TSM Test voltages

1. Check if the machine is connected to mains.
   ↳ *Power source* ① displays a connector plug icon.
2. Pull out mains plug.
   ↳ *Power source* ① displays a battery icon.
3. Wait 5 minutes.
   ↳ Voltage value ⑫ and charge value ⑬ decrease.
   ↳ Charge status ⑭ is deactivated.
4. Connect the mains plug to mains.
   ↳ *Power source* ① displays a plug icon.
   ↳ *Charge status* ⑭ is activated.
5. Wait 5 minutes.
   ↳ *Charge value* ⑫ increased.

Description	Current Value	Tolerance (+/- 5%)
PS Value 12 VC ④	12 V	11.4..... 12.6 V
PS Value 5 SYS ⑤	5 V	4.75..... 5.25 V
PS Value 5 VC ⑥	5 V	4.75..... 5.25 V
CS Value 5 VP ⑦	5 V	4.75..... 5.25 V
CS Value 3.3 VP ⑧	3.3 V	3.135..... 3.465 V
CS Value 9.4 VP ⑨	9.4 V	8.93..... 9.87 V

Description	Current Value	Tolerance (+/- 5%)
CS Value VCC ⑩	24 V	22.8..... 25.2 V
CS Value 24 V ⑪	24	22.8..... 25.2 V

6.4.7.3 Test of Staff Call

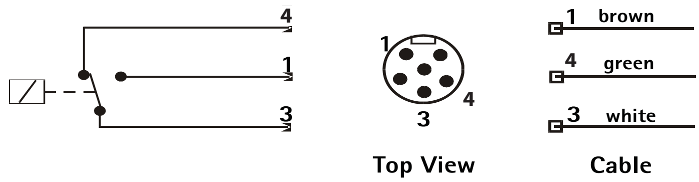


Fig. 6-40 TSM Test staff call connectors

1 *Staff Call* button

Fig. 6-41 TSM Test staff call

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 ② .
   ↳ LED is activated on the test tool.
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.

6.4.7.4 Test of Fan

1 *ON* button
2 *OFF* button

Fig. 6-42 Fan

Fan

1. *On* button ① is pressed.
   ↳ Both system fans are spinning.
2. *OFF* button ② is pressed.
   ↳ Both system fans stop spinning.

6.5 Calibration Menu

6.5.1 Calibration of Pressure Sensors

It is possible to calibrate all sensors combined. The following steps must be performed for this calibration.

The calibration shall be done with a closed machine.

Connect the test system to the machine

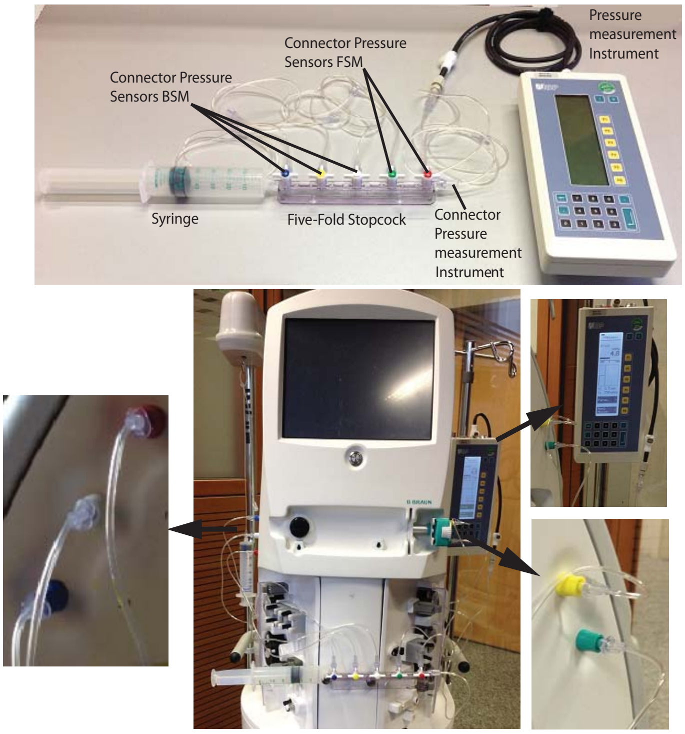


Fig. 6-43 Test and calibration pressure sensors

1 Select all
2 Arterial pressure sensor
3 Pre-filter pressure sensor
4 Venous pressure sensor
5 Solution pressure sensor
6 Effluent pressure sensor
7 Number of calibration points
8 Actual calibration point
9 Reference Value
10 *Calibrate*
11 *Save*
12 *Cancel*

Fig. 6-44 TSM Calibration pressure

Each pressure sensor is calibrated by a three point calibration.

1. Press button ① or activate all sensors separately ② - ⑥ .

Required tools / materials

- Pressure measurement instrument (e.g. HDM 99 or equivalent)
- Five-fold stopcock incl. tubings
- Syringe 50 ml

1. Select one or more pressure sensors.
   - ↳ Calibration is activated. The first of three calibration points is displayed.
   - ↳ First reference value is displayed ⑨ [0 mmHg].
2. Open the free connector of the five-fold stopcock. The first reference value is displayed at the pressure measurement instrument.
   - ↳ The AD value and mmHg value of control system CS and protective system PS change.
3. Wait until the AD value and mmHg value of CS and PS are stable.
4. Press *Calibrate* button ⑩ .
   - ↳ First reference value is calibrated.
   - ↳ Second reference value is displayed [-450 mmHg].
5. Pull out the plunger of the syringe until the second reference value is reached at pressure measurement instrument.
   - ↳ The AD value and mmHg value of control system CS and protective system PS change.

6. Wait until the AD value and mmHg value of CS and PS are stable.
7. Press *Calibrate* button ⑩ .
   ↳ Second reference value is calibrated.
   ↳ Third reference value is displayed [600 mmHg].
8. Press the plunger into the syringe until the third reference value has reached the pressure measurement instrument.
   ↳ The AD value and mmHg value of control system CS and protective system PS change.
9. Wait until the AD value and mmHg value of CS and PS are stable.
10. Press *Calibrate* button ⑩ .
    ↳ Third reference value is calibrated.
11. Press *Save* button ⑪ .
    ↳ Calibration process has finished and calibration data has been saved.

If there is an error during the calibration process, press *Cancel* button ⑩ to stop the procedure.

Function Control

Prerequisites

- Test system is connected to the machine according to Fig. 6-43 Test and calibration pressure sensors (359).

Function Control

1. Set a pressure of 500 mmHg for the pressure sensors.
   ↳ *CS mmHg* and *PS mmHg* display the preset pressure.
2. Wait for 1 minute
   ↳ External pressure measurement instrument displays a value ≥ 470 mmHg.

6.5.2 Calibration of 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*

Fig. 6-45 TSM calibration load cells

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 calibration weight
- 2 x 5,000 g calibration weight

1. Select one of the load cells ① - ④ .
   - ↳ Button *Calibrate* ⑧ is activated.
2. First reference value is displayed 0 [g].
3. Press *calibrate* button ⑧ .
   - ↳ First reference value is calibrated.
   - ↳ Second reference value is displayed.
4. Hang on one of the defined test weights to the corresponding load cell.
5. Press *Reference* button ⑦ and enter the exact value of the reference weight.
   - ↳ Wait until the *AD* value and *g* value are stable.
6. Press *Calibrate* button ⑧ .
   - ↳ Second reference value is calibrated.
7. Press *Save* button ⑨ .
   - ↳ Calibration process has finished and calibration data has been saved.
8. Remove calibration weight from the load cell.

If there is an error during the calibration process, press *Cancel* button ⑩ to cancel.

6

6

6.5.3 Calibration of the Warmer

Fig. 6-46 Connection of warmer calibration board

Outlet temperature sensor and warmer temperature sensor are calibrated at the same time.

The calibration shall be done with a closed machine.

1 Outlet sensor
2 Plate sensor
3 Numbers of points
4 Actual point
5 Reference
6 *Calibrate*
7 *Save*
8 *Cancel*

Fig. 6-47 TSM Calibration warmer

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.

Prerequisites

- Rear housing is disassembled.

1. Tilt the warmer from the machine by loosening the screws from the main bracket.
2. Connect the calibration board with the lower printed value to the warmer board.
3. Set the reference value ⑤ according to the printed value on the board.
4. Press *Calibrate* ⑧ .
5. Connect the calibration board with the higher printed value to the warmer board.
6. Set the reference value ⑤ according to the printed value on the board.
7. Press *Calibrate* ⑧
8. Press *Save* ⑦

6.5.4 Calibration of Detectors

The calibration shall be done with a closed machine.

1 *Calibrate* blood side door
2 Calibrate fluid side door
3 *Save*
4 *Cancel*

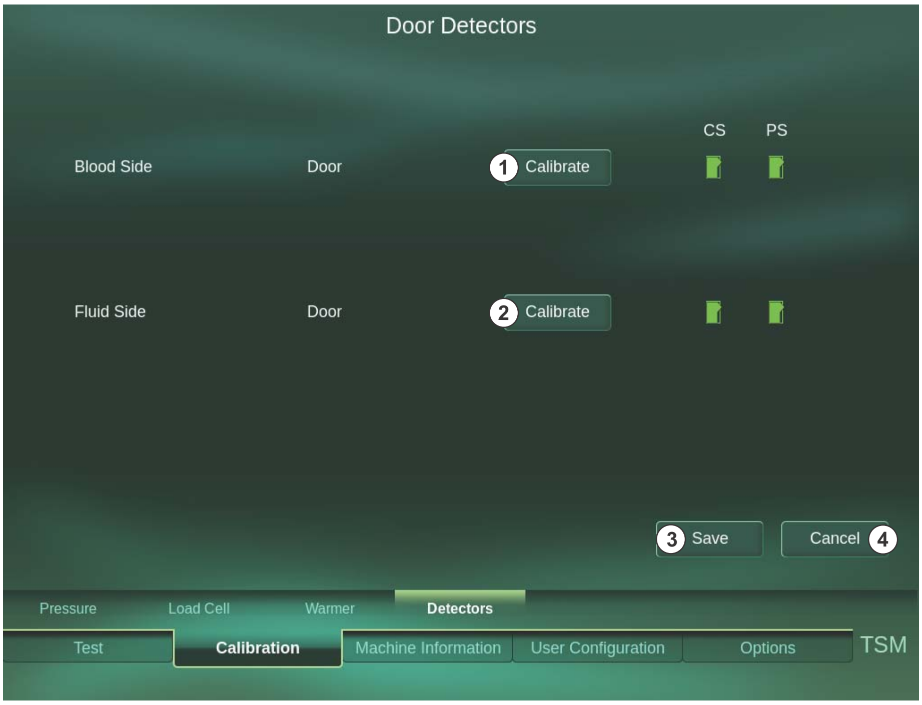


Fig. 6-48 TSM Calibration detectors

Required tools / materials

- Door detector test and calibration tool.

Blood Side Door

1. Insert door detector test and calibration tool and close blood side door.
2. Press *Calibrate* button ② .
   - ↳ Blood side door detector is calibrated.
   - ↳ Door symbols CS and PS ③ display a closed door.
3. Open blood side door.
   - ↳ Door symbols CS and PS ③ display an open door.
4. Press *Save* button ⑦ .
   - ↳ Calibration is finished and saved.

If there are any errors during the calibration process, press *Cancel* button ⑧ to cancel.

Fluid Side Door

1. Insert door detector test and calibration tool and close fluid side door.
2. Press *Calibrate* button ⑤ .
   ↳ Fluid side door detector is calibrated.
   ↳ Door symbols CS and PS ⑥ display a closed door.
3. Open fluid side door.
   ↳ Door symbols CS and PS ③ display an open door.
4. Press *Save* button ⑦ .
   ↳ Calibration has finished and calibration data has been saved.

If there are any errors during the calibration process, press *Cancel* button ⑧ to stop the procedure.

6.6 Machine Information

1 Version numbers
2 Unit Info
3 Load cells
4 Pumps/clamps
5 I/O Card
6 Working time counter
7 Blood leak detector/ barcode/touch screen firmware
8 HW versions

Fig. 6-49 TSM Machine information

The menu *Machine Information* provides information about the version numbers of software and hardware components of the machine. The machine language can be changed.

6.7 User Configuration

1 Blood side
2 Fluid side
3 Anticoagulation
4 Pressure alarm limit
5 Display options
6 Rinsing and recirculation
7 Localization
8 Other

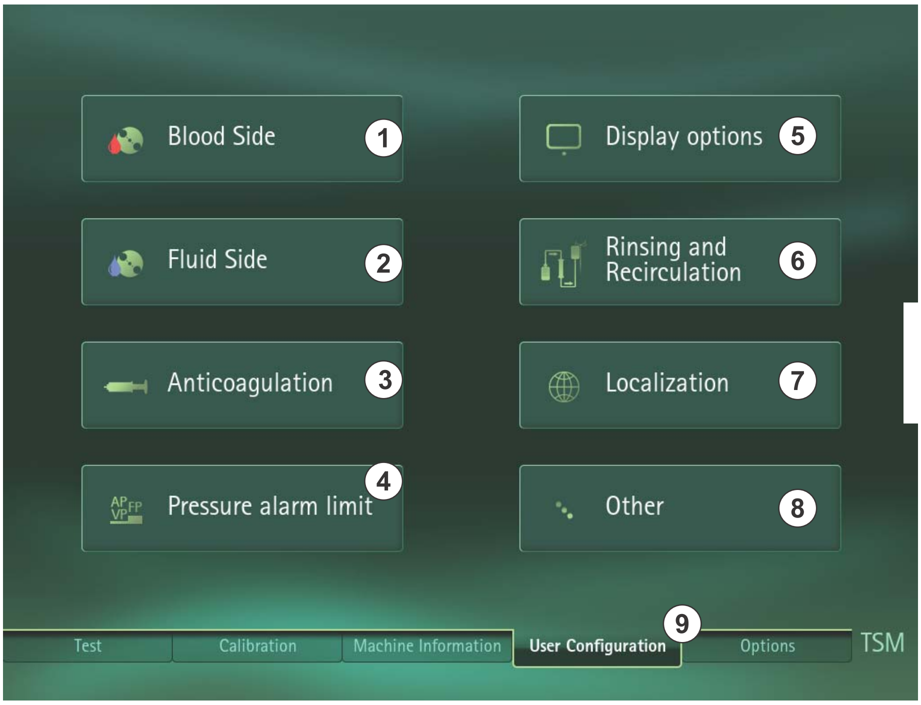


Fig. 6-50 TSM user configuration

The submenus ① - ⑧ can be selected in the User Configuration Menu ⑨ .

6.7.1 Blood Side

The temporary access problem suppression for the arterial access and the venous access can be activated and deactivated in the blood side parameters menu.

1 Arterial ON
2 Arterial OFF
3 Venous ON
4 Venous OFF

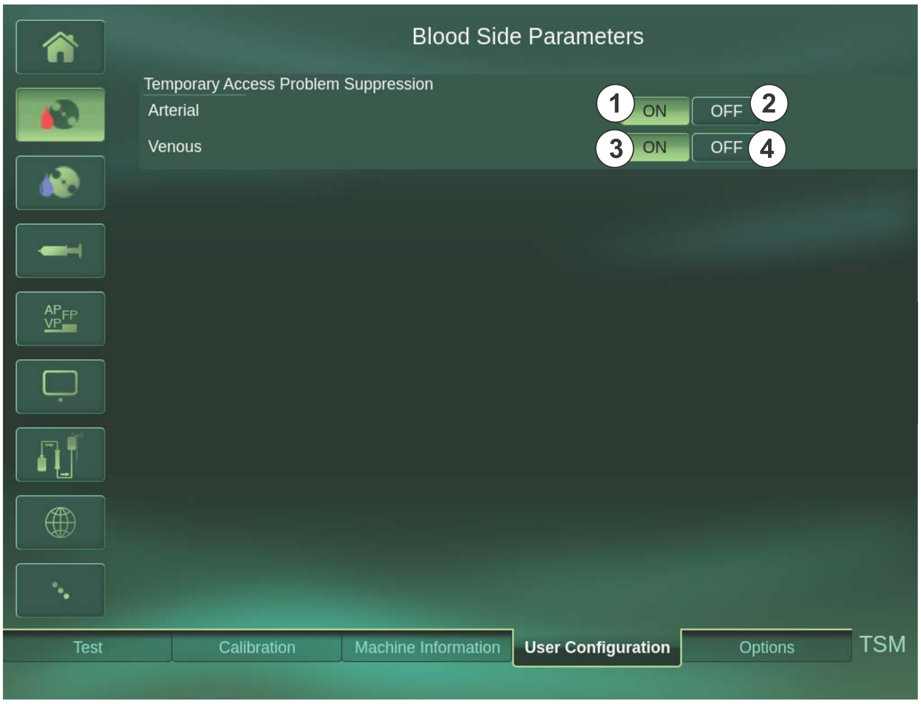


Fig. 6-51 TSM Blood side parameters

Temporary Access Problem Suppression

1. Press ① to activate the temporary access problem suppression for the arterial access
2. Press ② to deactivate the temporary access problem suppression for the arterial access
3. Press ③ to activate the temporary access problem suppression for the venous access
4. Press ④ to deactivate the temporary access problem suppression for the venous access

The detection of a low arterial pressure (AP) or high venous pressure (VP) triggers this reaction of the machine: • The blood flow is reduced to 10 ml/min for 3 seconds to avoid a blood pump stop and unnecessary alarms.• As long as the temporary alarm suppression is active therapy is paused, the VP and FP pressure windows are open and an info message informs the user about the incident. After 3 seconds have passed:• If the arterial and venous pressures have returned to the normal value range, the blood flow is ramped up to the target flow rate• If the arterial pressure remains below limits or the venous pressure above limits, the alarms Arterial pressure low and Venous pressure high are generated.This temporary suppression of arterial and venous pressure alarms can happen several times. In case the alarm suppression is continuously active for more than 5 minutes or the delivered blood volume reaches 300 ml, the alarm suppression will be disabled, and the machine issues the alarms Low arterial pressure or High venous pressure.

6

6.7.2 Fluid Side

The solution temperature for CRRT and the filtration ratio alarm limit can be set. The automatic substitution reduction can be activated and deactivated in the fluid side parameters menu .

1 Warmer outlet temperature CRRT
2 Warmer outlet temperature TPE
3 Automatic substitution reduction ON
4 Automatic substitution reduction OFF
5 Filtration CRRT alarm limit
6 Filtration CRRT info limit
7 Filtration TPE alarm limit
8 Filtration TPE info limit
9 Alarm override ON
10 Alarm override OFF
11 Plasma flow setting ON
12 Plasma flow setting OFF

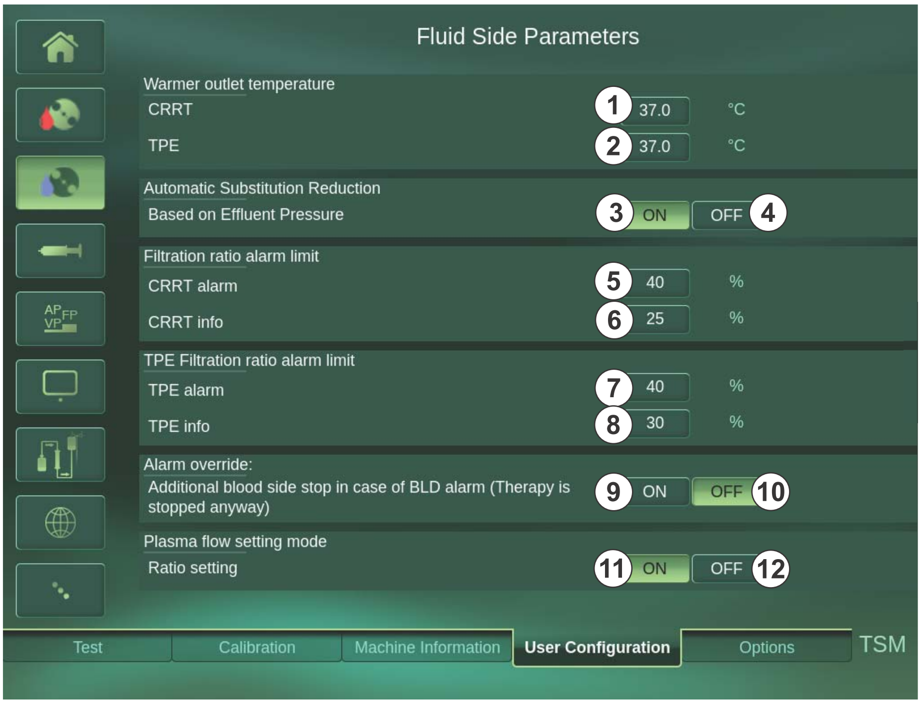


Fig. 6-52 TSM Fluid side parameters

Warmer Outlet Temperature

1. Press ① and set the required temperature for CRRT.
2. Press ② and set the required temperature for TPE.

The solution temperature for CRRT and TPE can be set in the fluid side parameters menu

Automatic Substitution Reduction

1. Press ③ to activate the automatic substitution reduction.
2. Press ④ to deactivate the automatic substitution reduction.

The automatic substitution reduction (based on the effluent pressure) can be activated or deactivated.It is used to rinse the hemofilter in case of a starting blockage inside the hemofilter.There are events occurring during treatment that contribute to the fact that the target substitution fluid volume cannot be reached: • Ramping-up of pump flow rate when starting a therapy. • Substitution fluid delivery errors, e.g. due to wrongly connected bags. • Automatic substitution fluid reduction in case of a drop in the effluent pressure. The system is designed to compensate for such backlogs over the course of the therapy in order to eventually reach the target volume.Whenever the system detects a deviation of target and delivered volume, the substitution fluid flow rate is increased temporarily by +1 % to +5 % (depending on the missing volume). When the backlog is eliminated this function is switched off.

Filtration ratio alarm limit

1. Press ⑤ to set the filtration ratio alarm limit for CRRT alarm.
2. Press ⑥ to set the filtration ratio alarm limit for CRRT info.

TPE Filtration ratio alarm limit

1. Press ⑦ to set the filtration ratio alarm limit for TPE alarm.
2. Press ⑧ to set the filtration ratio alarm limit for TPE info.

The alarm limit for CRRT and TPE and the info limit for CRRT and TPE can be set.

Filtration ratio = (PostDS+NFR)/Blood flow.

If the filtration ratio is too low it can cause an increase of the viscosity of the blood.

If the filtration ratio is to high the treatment can be ineffective.

Alarm Override

1. Press ⑨ to set additional blood side stop in case of BLD alarm to ON. (Fluid side is stopped anyway)
2. Press ⑩ to set additional blood side stop in case of BLD alarm to OFF. (Fluid side is stopped anyway)

The additional blood side stop in case of BLD alarm can be activated and deactivated.The blood leak alarm can be overridden. The alarm is overridden for a defined period of time that depends on the substitution fluid flow and the current net fluid removal. The time of the temporary override of the blood leak detection alarm is calculated as follows:500 / (P + N)• P is the flow of the post substitution fluid in ml/h. • N is the net fluid removal in ml/h. The override time is specified in hours.The machine counts the number of times blood leaks were detected.

Plasma Flow Setting

1. Press ⑪ to set ratio setting to ON.
2. Press ⑫ to set ratio setting to OFF.

There are two different plasma flow setting modes available for a TPE therapy:

- Flow mode: The plasma substitution flow can be set by the user independently of the blood flow.
- Ratio mode: The plasma filtration ratio can be set by the user. The plasma substitution flow is calculated in proportion to the set plasma filtration ratio and the blood flow.

6.7.3 Anticoagulation

The maximum heparin rate, the calcium concentration and the citrate concentration can be set in the anticoagulation parameters menu

1 Heparin maximum rate

2 Stop Before Therapy End ON

3 Stop Before Therapy End OFF

4 Time Before Therapy End

5 Calcium concentration

6 Citrate concentration

7 Syringe types

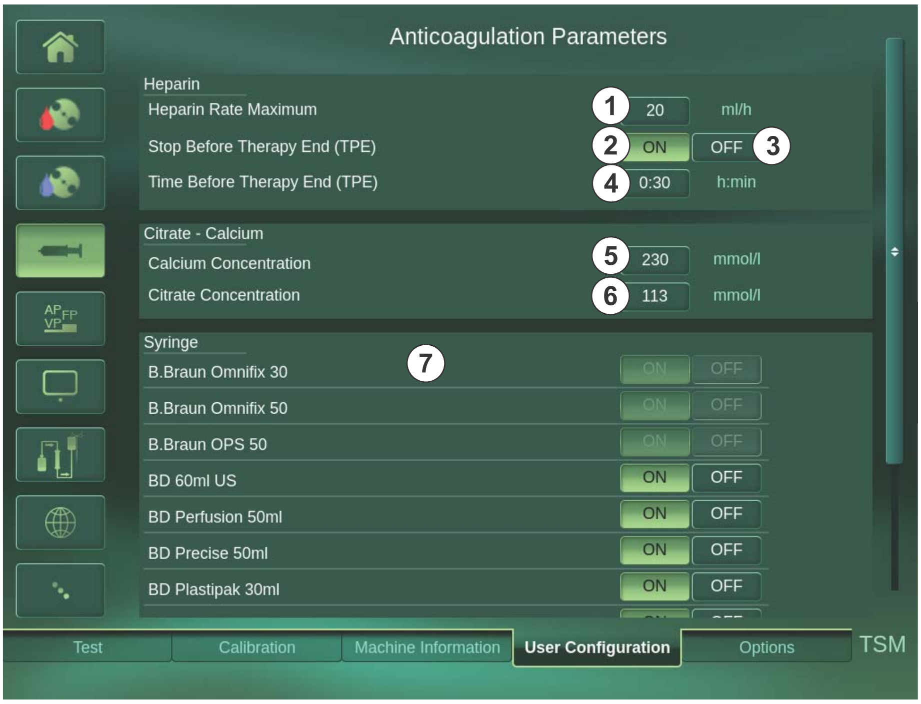


Fig. 6-53 TSM Anticoagulation parameters

Heparin

1. Press ① to set the heparin maximum rate
2. Press ② to activate the *Stop Before Therapy End (TPE)* function.
3. Press ③ to deactivate the *Stop Before Therapy End (TPE)* function.
4. Press ④ to set the time for *Time Before Therapy End (TPE)* function.

Citrate - Calcium

1. Press ⑤ to set the calcium concentration.
2. Press ⑥ to set the citrate concentration.

Syringe Selection

1. Select the preferred syringes.

6.7.4 Pressure alarm limit

The minimum and maximum limits for the arterial pressure, pre-filter pressure, venous pressure, transmembrane pressure, effluent pressure and the pressure drop can be set in the pressure alarm limit menu.

1 Therapy type
2 Max limit arterial pressure
3 Min limit arterial pressure
4 High window pre-filter pressure
5 Low window pre-filter pressure
6 High window venous pressure
7 Low window venous pressure
8 Max limit transmembrane pressure
9 Max limit pressure drop
10 Min limit effluent pressure
11 Set to all/Set to CRRT and SCUF

Fig. 6-54 TSM Pressure alarm limit

Therapy Type

1. Select the therapy type ① before setting the corresponding pressure alarm limits
2. Set all pressure alarm limits ② - ⑩ as required
3. Press ⑪ to set one parameter for all types of therapies

6.7.5 Display Options

The screensaver defaults and the screensaver display can be set in the display options menu.

1 Screensaver ON
2 Screensaver OFF
3 Screensaver time
4 Left top
5 Left middle
6 Left bottom
7 Right top
8 Right middle
9 Right bottom

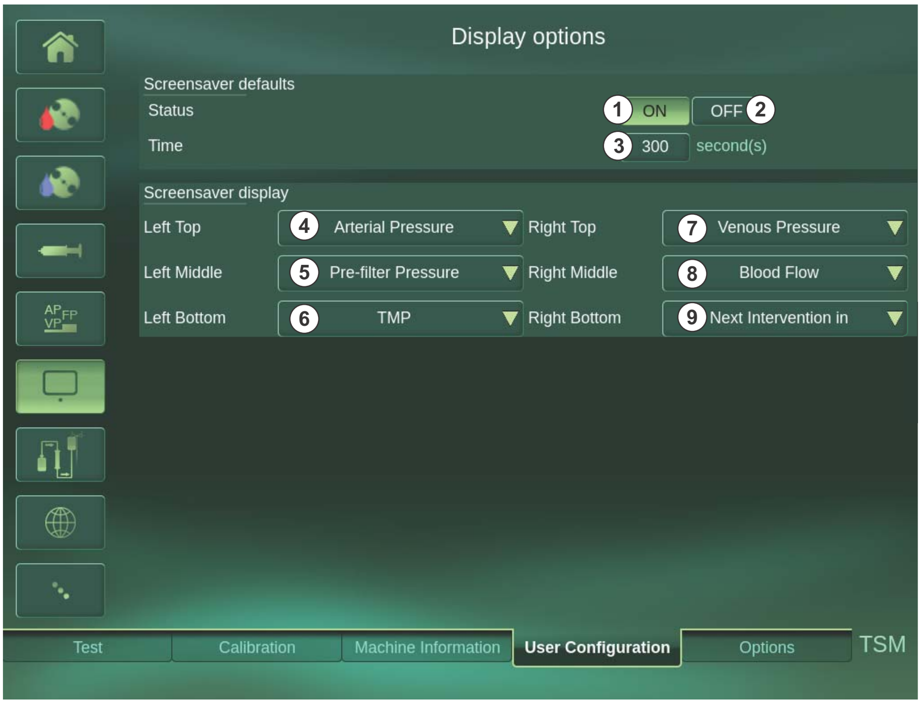


Fig. 6-55 TSM Display options

Screensaver defaults

1. Press ① to activate the screensaver
2. Press ② to deactivate the screensaver
3. Press ③ to set the time before the screensaver become active

Screensaver Display

1. Press ④ to set the desired parameter for the top left screensaver display
2. Press ⑤ to set the desired parameter for the middle left screensaver display
3. Press ⑥ to set the desired parameter for the bottom left screensaver display
4. Press ⑦ to set the desired parameter for the top right screensaver display
5. Press ⑧ to set the desired parameter for the middle right screensaver display
6. Press ⑨ to set the desired parameter for the bottom right screensaver display

6.7.6 Rinsing and Recirculation

The rinsing parameters and the recirculation parameters can be set int the rinsing and recirculation menu.

1 Rinsing volume

2 CRRT Fluid side rinsing ON

3 CRRT Fluid side rinsing OFF

4 TPE Fluid side rinsing ON

5 TPE Fluid side rinsing OFF

6 Rinsing blood flow rate

7 Recirculation blood flow rate

Fig. 6-56 TSM Rinsing and recirculation

Rinsing Parameters

1. Press ① to set the rinsing volume.
2. Press ② to activate the fluid side rinsing CRRT.
3. Press ② to deactivate the fluid side rinsing CRRT.
4. Press ④ to activate the fluid side rinsing TPE.
5. Press ⑤ to deactivate the fluid side rinsing TPE.
6. Press ⑥ to set the rinsing blood flow rate.

Recirculation Parameters

1. Press ⑦ to set the recirculation blood flow rate.

6

6.7.7 Localization

The language, date and time can be selcted/set in the localization menu.

1 Language

2 Date

3 Time

6

Fig. 6-57 TSM Localization

Localization Settings

1. Press ① to select a language
2. Press ② to set the date
3. Press ③ to set the time

6.7.8 Other

The factory defaults for the therapy type, dilution type and anticoagulation type can be set in the other menu.

1 Restore factory defaults
2 Therapy type
3 Dilution type
4 Anticoagulation type
5 Patient data management interface
6 Enable disposable kit types

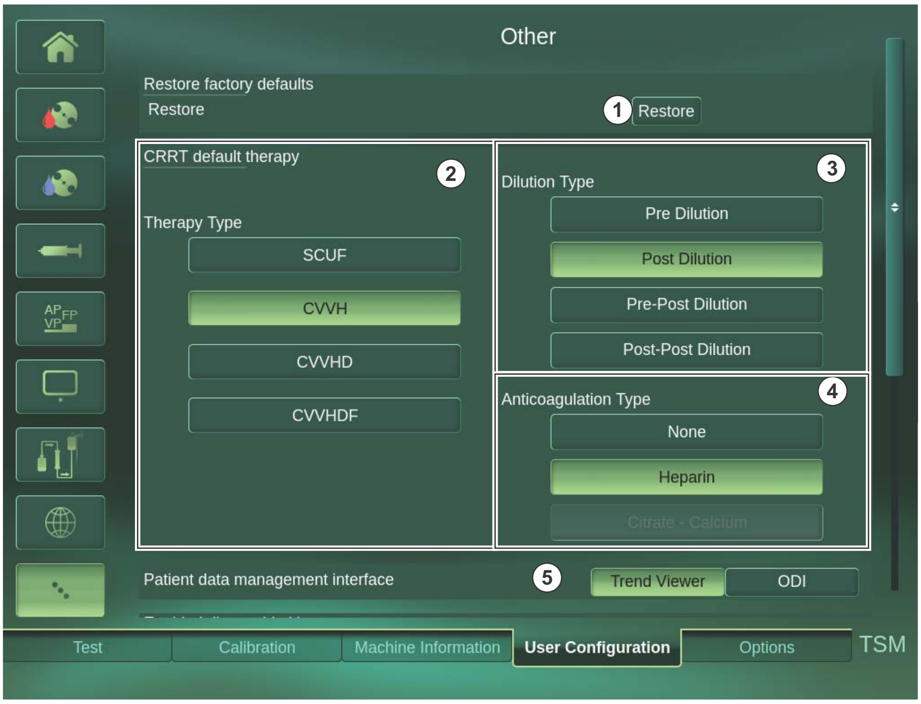


Fig. 6-58 TSM Other

Fig. 6-59 TSM Other _2

Therapy Defaults

1. Press to restore the factory defaults of the machine
2. Select the default parameters of therapy type ② , dilution type ③ and anticoagulation type ④ for the treatment
3. A specific data management interface can be selected ⑤ .
   To use the ODI function the FSU version ≥ FSU 1.20.10 has to be used for all service activities including language installation.
4. Different disposable kit types can be
5. activated or deactivated for the therapies ⑥ .

6.8 Options

All available options can be installed and enabled in the *Options* menu.

1 OA code
2 RCA option
3 TPE option

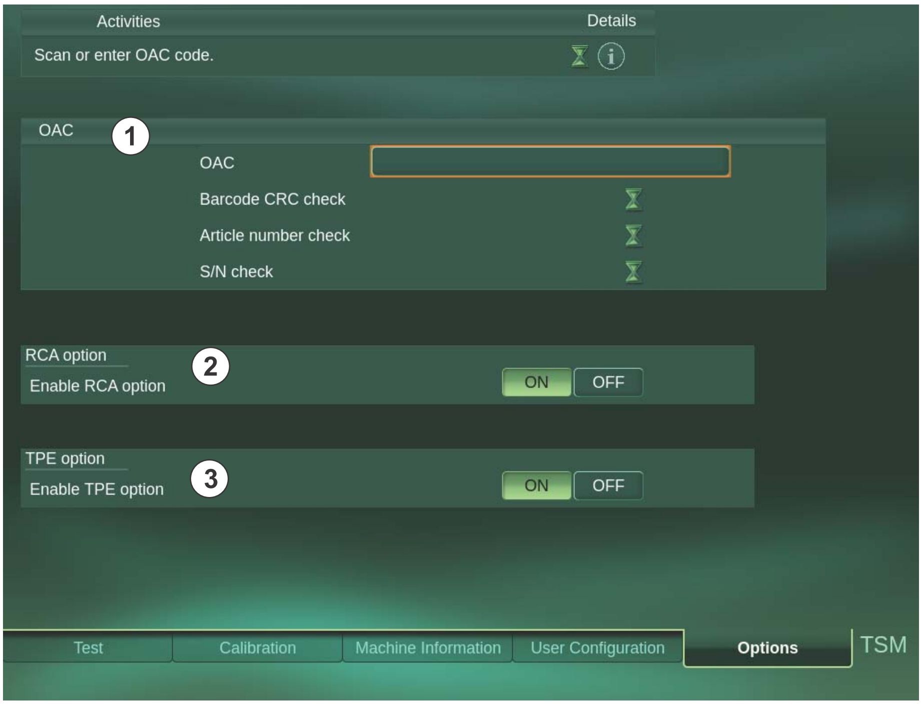


Fig. 6-60 TSM Options

All available options can be installed and enabled in the *Options* menu.

Prerequisites

- Option code must be available.

QA Code reading

1. Use the barcode scanner to read the option code.
   - ↳ The machine displays the OA code.
   - ↳ The machine checks the barcode CRC, the article number and the serial number.

RCA Option

1. Set *ON* to enable the regional citrate anticoagulation.
2. Set *OFF* to enable the regional citrate anticoagulation.

TPE Option

1. Set *ON* to enable the therapeutic plasma exchange option.
2. Set *OFF* to enable the therapeutic plasma exchange option.

Table of Contents

7 Preventive Maintenance and Technical Safety Inspection

7.1 PM and TSI Check List

Check List

The technical safety inspection TSI shall be performed and documented every 24 months, according to the specified check list and with reference to the service manual and instructions for use.

REF (reference No./Nr.)	
SN (serial No./Nr.)	
Year of purchase	
Responsible organization (user)	
Operating hours [h]	
Inventory number	
SW version	
Manufacturer	B. Braun Avitum AG Schwarzenberger Weg 73-79 34212 Melsungen, Germany

Inspection Type	
Technical safety Inspection TSI	O
Preventive Maintenance PM	O

PM	TSI	Inspection Check List		OK
X	X	**1**	**Disconnect machine from mains.**	O
X	X	**2**	**Visual inspection**	
X	X	2.1	Visual inspection (exterior)	O
X		2.1.1	Clean outer surface of the machine Remove fluid pump rollers and clean the manifolds Lubricate (SKD 4002) the axle of the pump rollers	O O O
X	X	2.2	Visual inspection (interior) Open machine Machine: clean/complete (inside the machine); no damages/ moisture influences. Check conditions and fixed position of boards, connectors mains supply parts and tubing. Check fixed position of potential equalization cable and staff call.	O
X	X	2.3	Protective earth resistance Measurement points: Exterior: Potential equalization bolt (connector panel); Screw on the bottom of the machine body Interior: Base plate (free position) **Note highest value**	O
			Max. Value= <0.1 [Ω] Actual Value = ________[Ω]	O
X		2.4	Clean interior base and housing	O
X		2.5	Replace the hydrophobic filters of the pressure sensors	O
X		2.6	Replace the dust filters	O
X	X	2.7	Close machine	O
X	X	2.8	Plug in mains cord to mains	O
X	X	**3**	**Function inspection**	
X	X	3.1	Switch on machine Enter TSM menu	O
	X	3.2	Touch screen Function check Check alarm indicator lights	O O

PM	TSI	Inspection Check List		OK
X	X	3.3	Pump functionality (Function, movability and noise rating) Blood pump Citrate pump Dialysate pump Effluent pump Substitution pump	 O O O O O
	X	3.4	Check 3-Way clamp	O
	X	3.5	Check venous clamp	O
X	X	3.6	**Pressure sensors**	
X	X	3.6.1	Pressure sensors AP, FP, VP, SP, EP (0 mmHg) (permissible tolerance +/-10 mmHg) **Set value**: 0 **mmHg**	O
X	X	3.6.2	Pressure sensors AP, FP, VP, SP, EP (approx.:+600 mmHg) (permissible tolerance +/-10 mmHg) **Set value**: _______**mmHg**	O
X	X	3.6.3	Pressure sensors AP, FP, VP, SP, EP (approx.: -400 mmHg) (permissible tolerance +/-10 mmHg) **Set value**: _______**mmHg**	O
X	X	3.6.4	Perform pressure leak test	O
	X	3.7	Check level regulation	O
	X	3.8	Syringe pump Running/not running Forward/reverse direction Syringe pumps stops when the lock detector is open	 O O O
	X	3.9	SADC/SADV Check venous safety air detector Check calcium safety air detector	 O O
	X	3.10	Check blood leak detector	O
	X	3.11	Warmer Outlet temperature sensor Plate temperature sensor	 O O
	X	3.12	Audio Speaker Buzzer	 O O
X	X	3.13	**Load cell comparison measurement**	

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PM	TSI	Inspection Check List		OK
X	X	3.13.1	Left load cell (0 g) (permissible tolerance +/-5 g) **Set value**: 0 **g**	O
X	X	3.13.2	Center load cell (0 g) (permissible tolerance +/-5 g) **Set value**: 0 **g**	O
X	X	3.13.3	Right load cell (0 g) (permissible tolerance +/-5 g) **Set value**: 0 **g**	O
X	X	3.13.4	Citrate load cell (0 g) (permissible tolerance +/-5 g) **Set value**: 0 **g**	O
X	X	3.13.5	Left load cell (2 x 5,000 g) (permissible tolerance +/-5 g) **Set value: _______g**	O
X	X	3.13.6	Center load cell (2 x 5,000 g) (permissible tolerance +/-5 g) **Set value: _______g**	O
X	X	3.13.7	Right load cell (2 x 5,000 g) (permissible tolerance +/-5 g) **Set value: _______g**	O
X	X	3.13.8	Citrate load cell (2,000 g) (permissible tolerance +/-5 g) **Set value: _______g**	O
	X	3.14	Check door detector	O
	X	3.15	Check staff call	O

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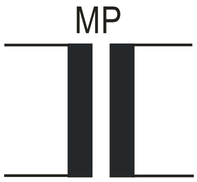
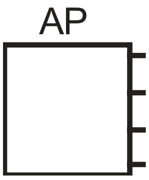
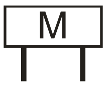
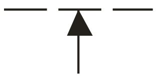
PM	TSI	Inspection Check List		OK
	X	3.16	Power fail function Switch off machine and disconnect from mains Remove rear housing Unplug battery Reassemble rear housing Connect machine to mains Start machine in TSM mode Disconnect machine from mains (Machine is not switched off) Check buzzer alarm Connect machine to mains Switch off machine Disconnect machine from mains Remove rear housing Connect battery Reassemble rear housing	O
X	X	**4**	**Start preparation**	
X	X	4.1	No weights present on the load cells	O
X	X	4.2	Check alarm function of blood side door and fluid side door. • Visual alarm • Audio alarm	O O
X	X	4.3	Prepare and set up disposables Fix disposable kit on the machine Connect pressure sensors	O O
X	X	4.4	Machine passed selftest successfully	O
X	X	4.5	Enter parameters for therapy Net fluid removal: 2000 ml/h Substitution: 7000 ml/h Dialysate: 1000 ml/h Heparin: 1ml/h	O O O O
X	X	4.6	Start therapy Set blood pump to 500 rpm and press *Therapy* button. Wait until parameters are reached.	O O
X	X	**5**	**Electrical safety check according to EN 62353/EN 60601-1**	
X	X	5.1	Equipment leakage current	O

PM	TSI	Inspection Check List			OK
			Max. Value = Actual Value =	≤ 0.5 [mA] _______[mA]	O
X	X	5.2	Patient leakage current		O
			Max. Value = Actual Value =	<10 [μA] AC _______ [μA] AC	O
	X	5.3	Stop key function		O
X	X	5.4	Stop therapy		O
X	X	5.5	Remove disposables and test equipment		O
X	X	**6**	**Setting into service**		
X		6.1	Save trends and logs of the machine		O
X	X	6.2	Machine released for patient use		O
X	X	6.3	Applied accessories/disposables Applied disposable kit: ____		
X	X	6.4	Clean outer surface		O

Description	
Comments:	
Next inspection date:	
The preventive maintenance / technical safety inspection was performed by.	
Name Service Technician/Company	
Date	Signature

Measurement Circuits for Measurement of Electrical Safety According to IEC 62353/60601-1

Abbreviations and Symbols	
	Protective earth (ground)
L, N	Supply mains terminals
PE	Protective earth terminal
	Mains part
	Applied part
	Measuring device
	Residual current meter with frequency response as MD
	Resistance measurement equipment
	Part of enclosure not protectively earthed
	Connection to accessible conductive parts

Protective Earth Resistance

Test current: ≥ 200mA

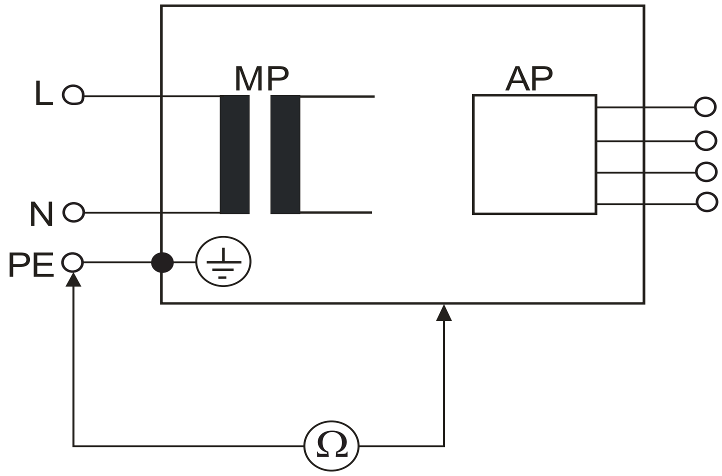


Fig. 7-1 Protective earth resistance

Equipment Leakage Current

- Differential Measurement
- Test current must be measured in both directions. (N->L / L->N)

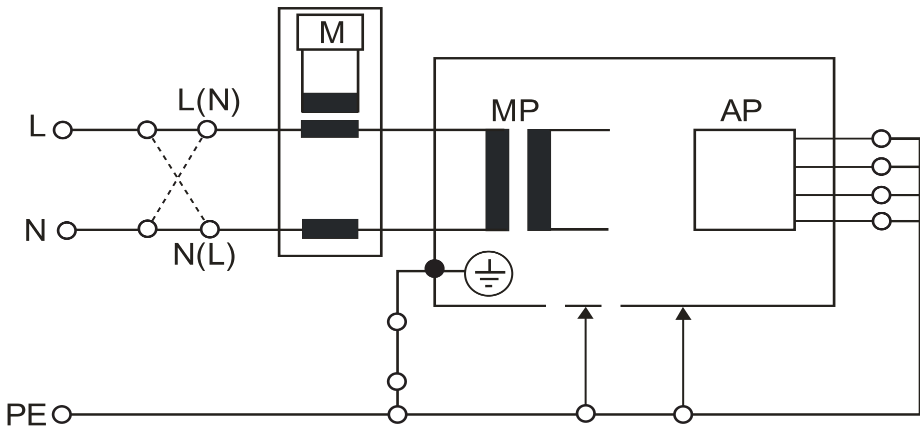


Fig. 7-2 Equipment leakage current

Patient Leakage Current

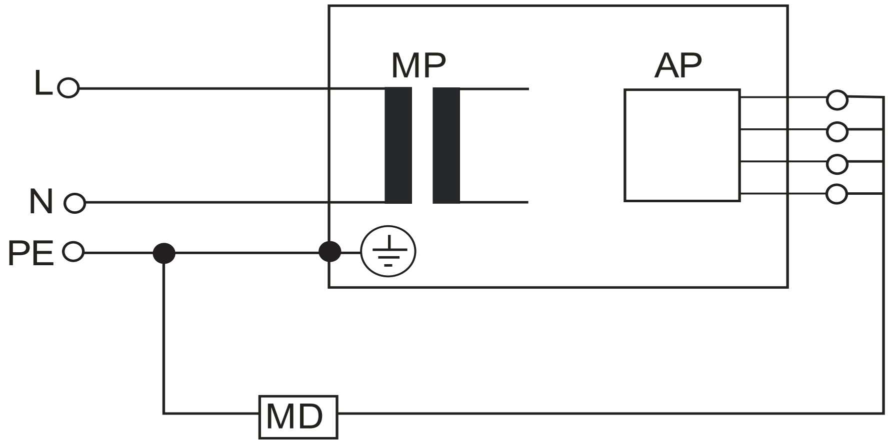


Fig. 7-3 Patient leakage current

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8 Wiring Diagram

8.1 Wiring Diagram: Power Supply and Warmer Board

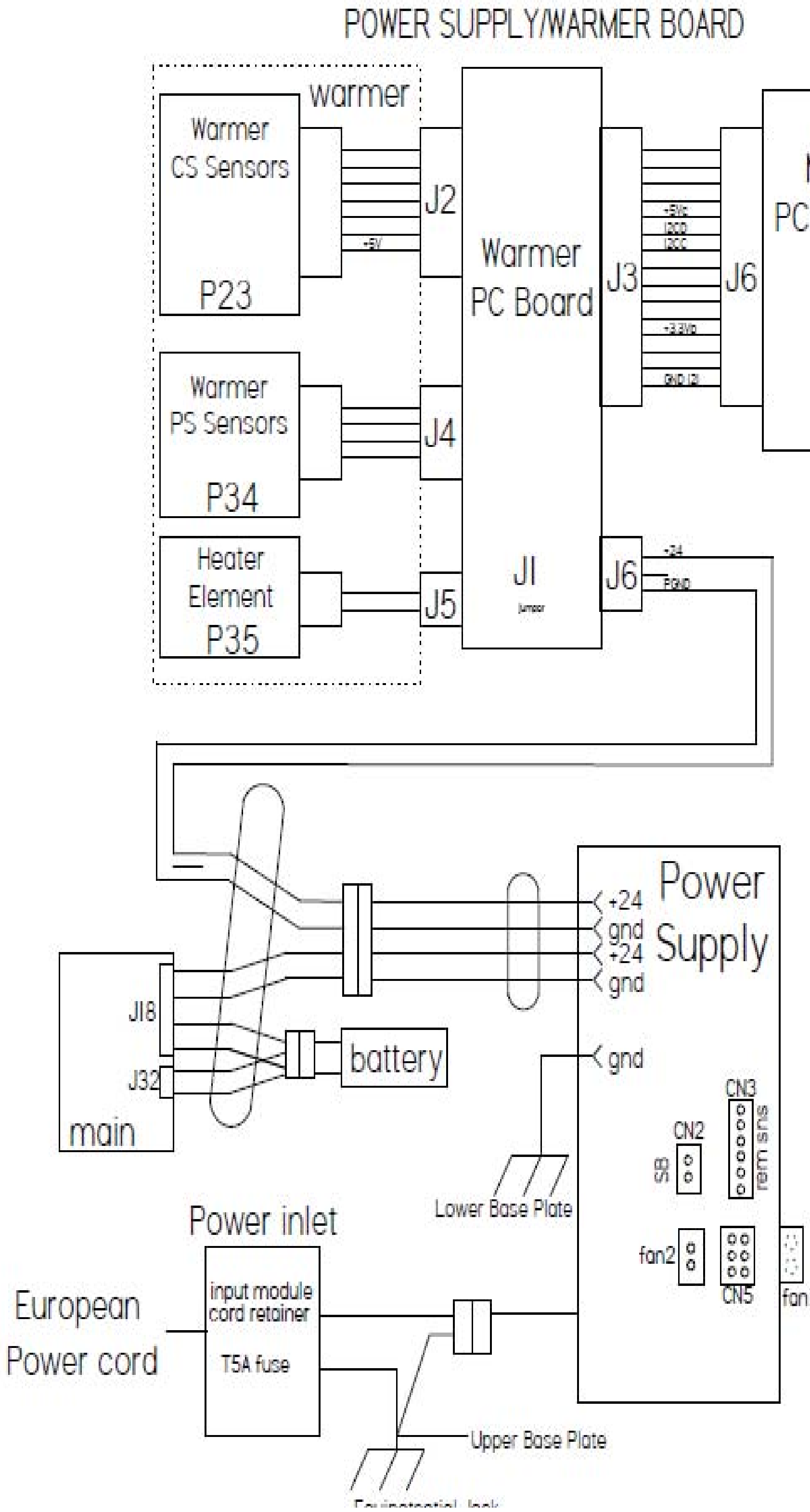


Fig. 8-1 Power supply and warmer board

8.1.1 Warmer Board Connectors

1 CS sensor
2 Main board
3 Power supply
4 Heater
5 PS sensor

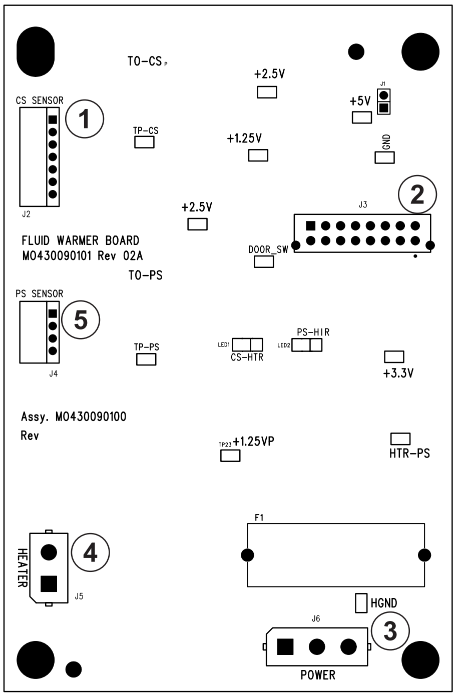


Fig. 8-2 Warmer board connectors

8.2 Wiring Diagram: Blood Side Board

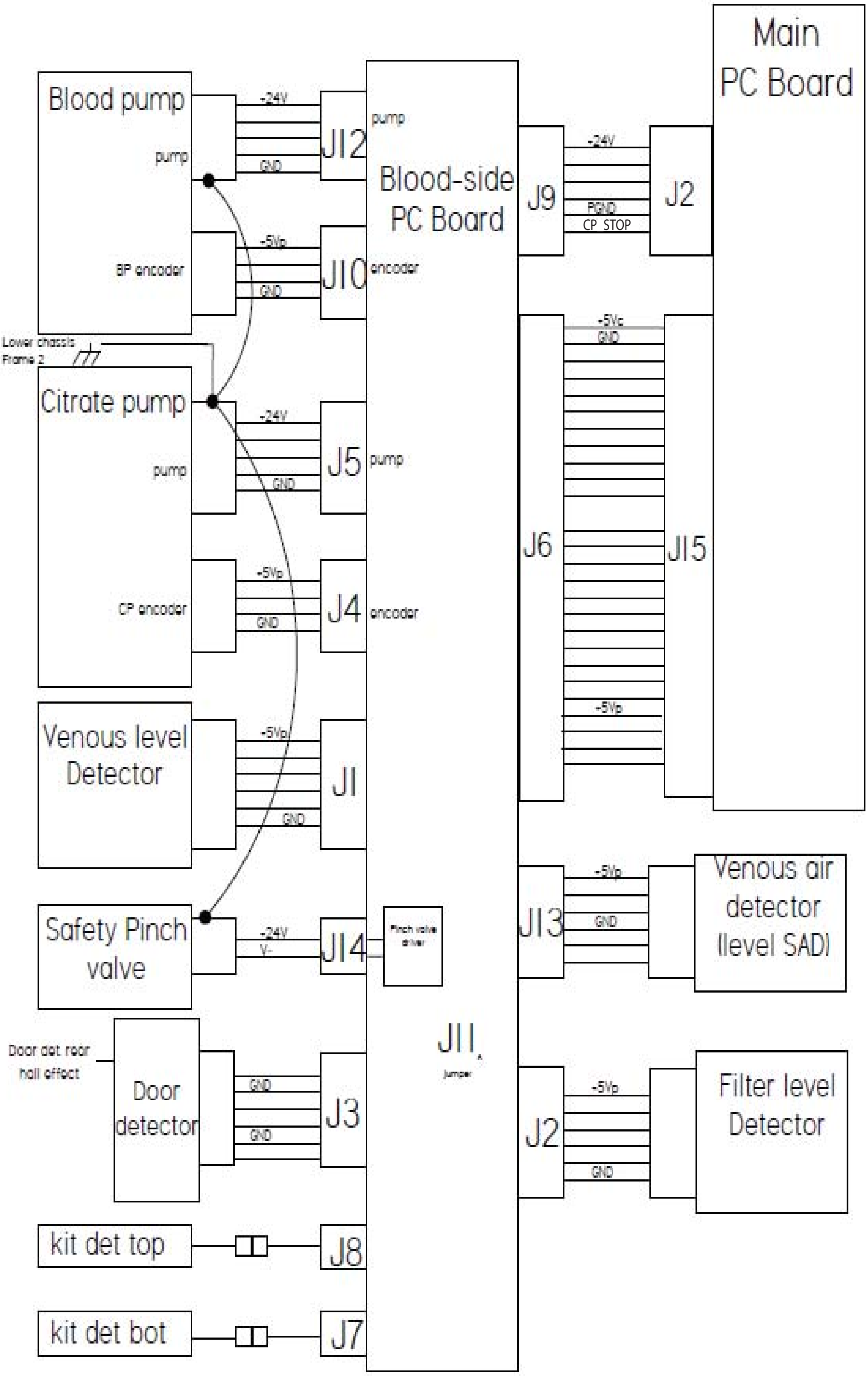


Fig. 8-3 Blood side wiring

8.2.1 Blood Side Board Connectors

1 Filter level detector
2 Citrate pump encoder
3 Citrate pump
4 Blood pump encoder
5 Blood pump
6 Main board
7 Kit detector bottom
8 Kit detector top
9 Safety pinch valve
10 Venous safety air detector
11 Main board
12 Door detector
13 Venous level detector

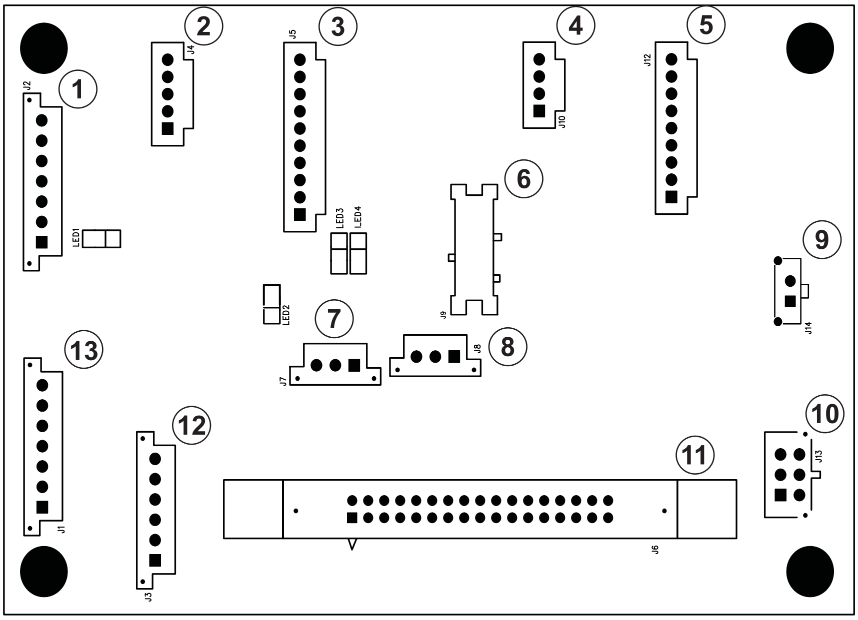


Fig. 8-4 Blood side board connectors

8.3 Wiring Diagram: Fluid Side Board

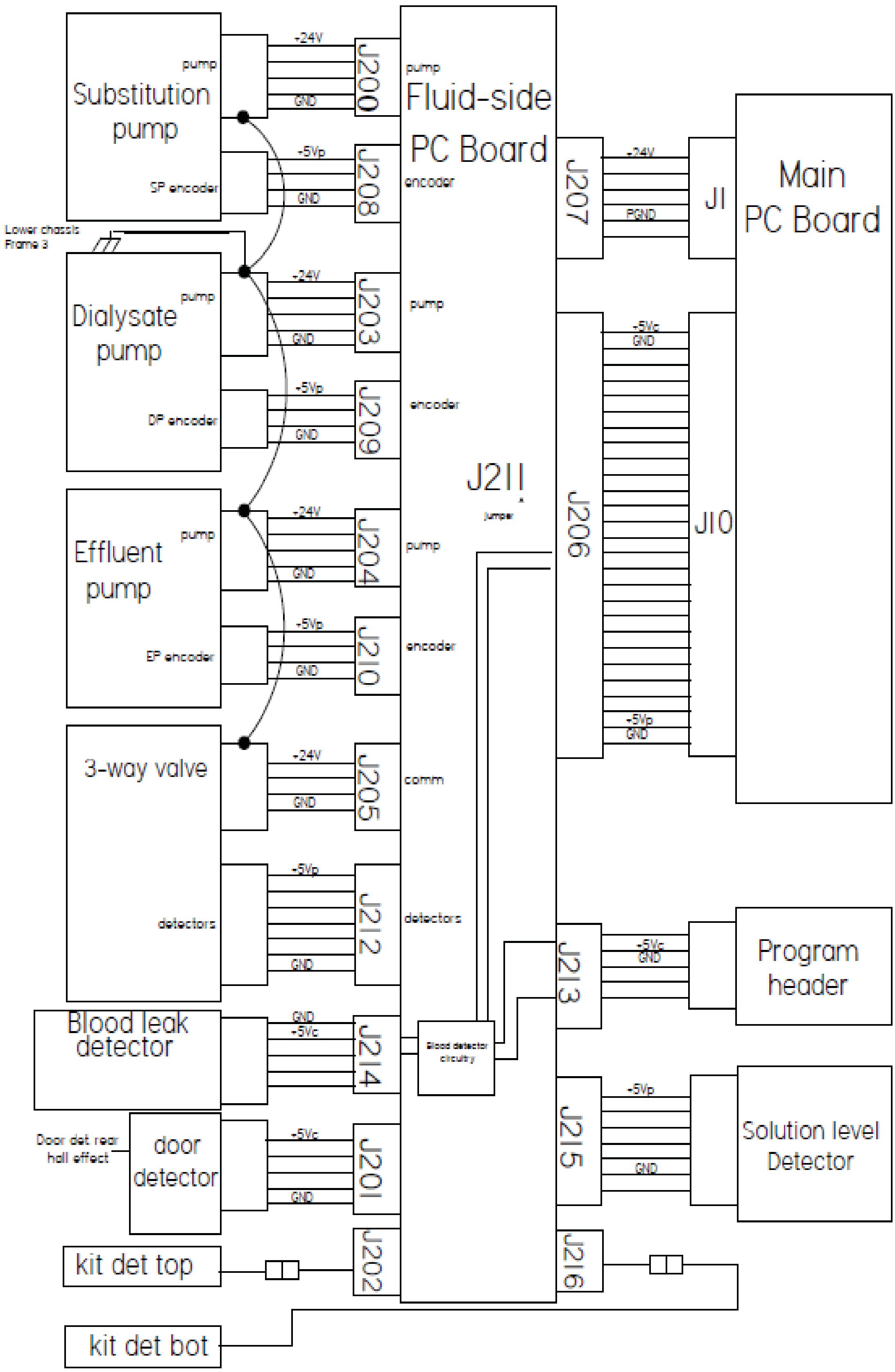


Fig. 8-5 Fluid side wiring

8.3.1 Fluid Side Board Connectors

1 Substitution pump
2 Kit detect
3 Dialysate pump
4 Kit top
5 Effluent pump
6 Kit bottom
7 3-way clamp
8 Pump control
9 Main board
10 Substitution pump encoder
11 Dialysate pump encoder
12 Effluent pump encoder
13 Blood leak detector
14 3-way clamp
15 Level detector

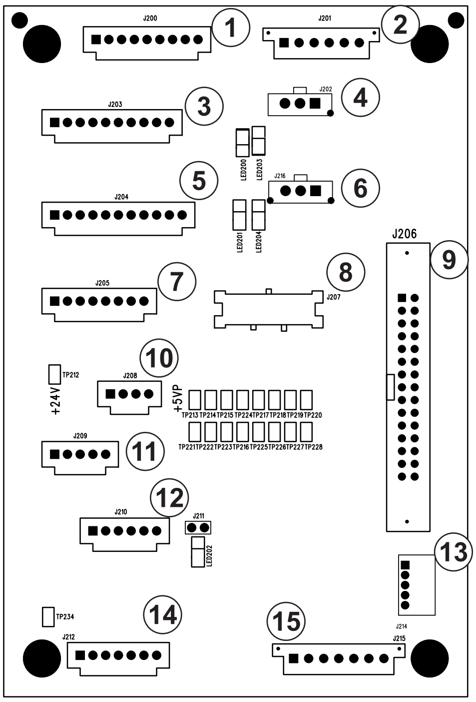


Fig. 8-6 Fluid side board connectors

8.4 Wiring Diagram: Main Board

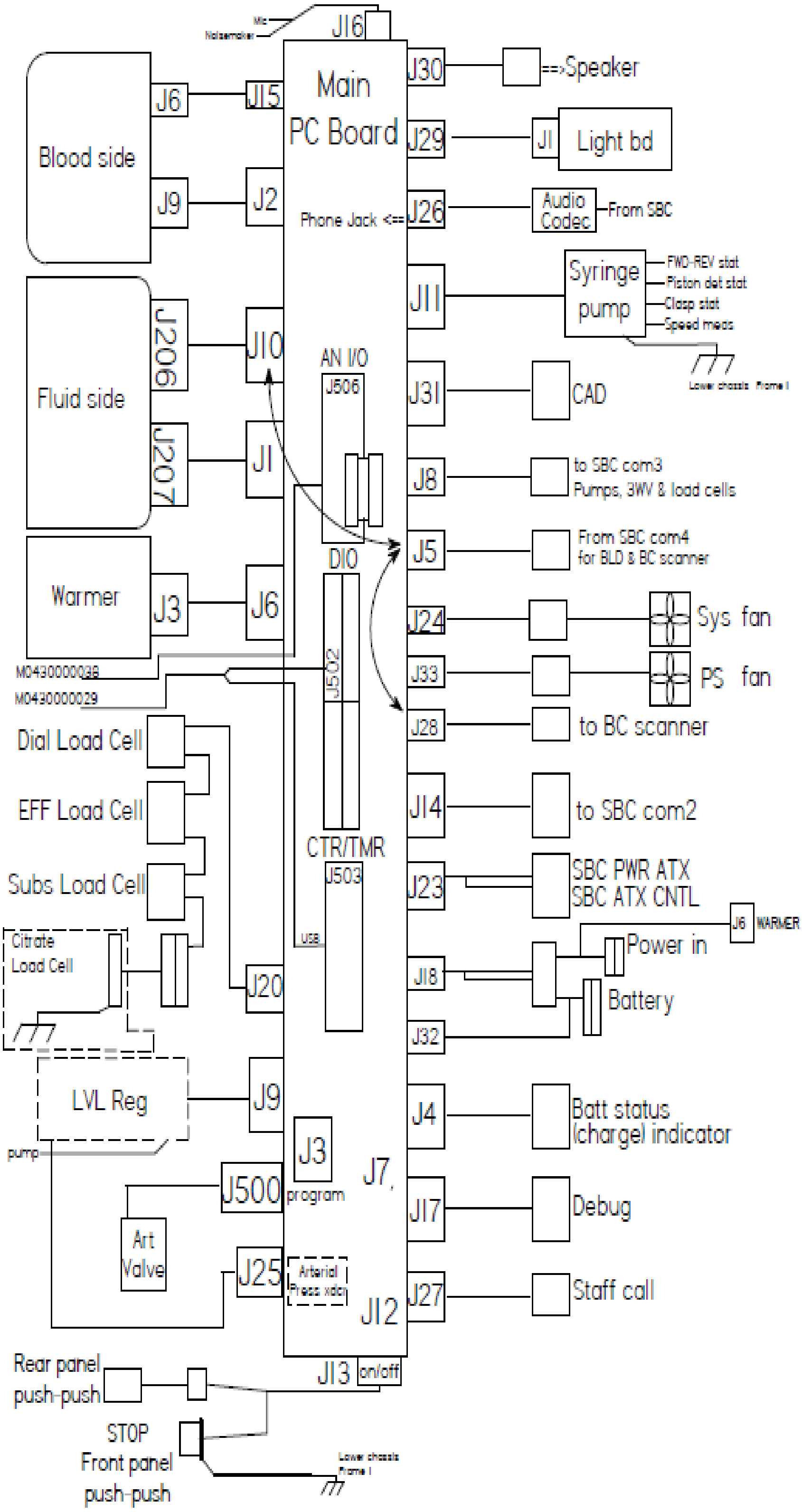


Fig. 8-7 Main board wiring

8.4.1 Main Board Connectors

1 Pressure sensors
2 Staff call
3 Barcode scanner
4 Status indicator lights
5 Sound input
6 Speaker
7 Calcium air detector
8 PS fan
9 Sys fan
10 SBC power
11 Power input
12 On/Off connector panel
13 Syringe pump
14 Level regulation
15 SBC Com 3 (pump;3WVC;LC)
16 Blood side pump counter
17 Fluid side pump counter
18 Fluid side signals
19 Blood side signals
20 Warmer board
21 Blood leak detector
22 Debug
23 Load cells
24 LED battery charging
25 PS Program
26 Memory enable
27 SBC com 2
28 Battery

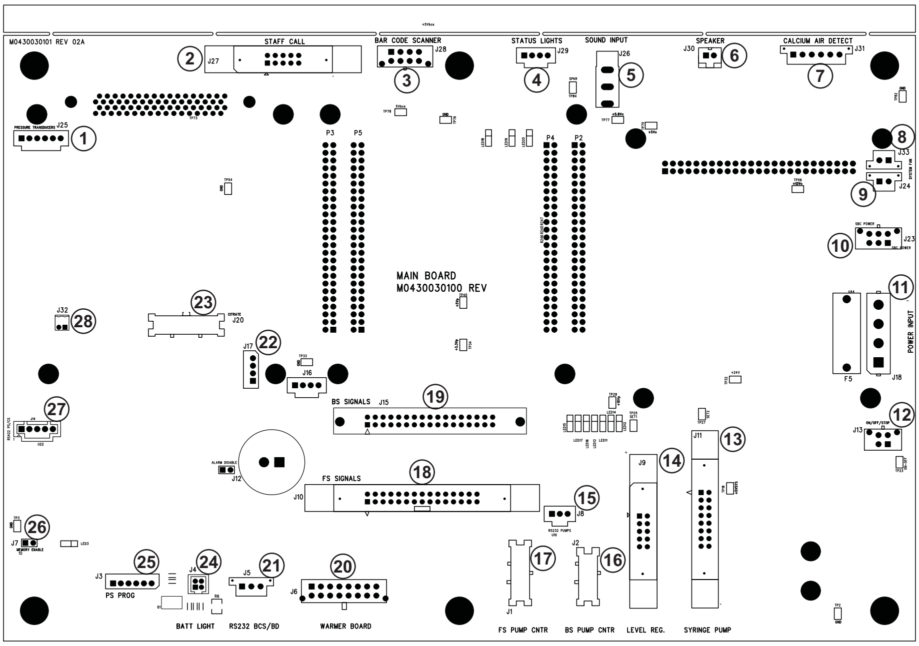
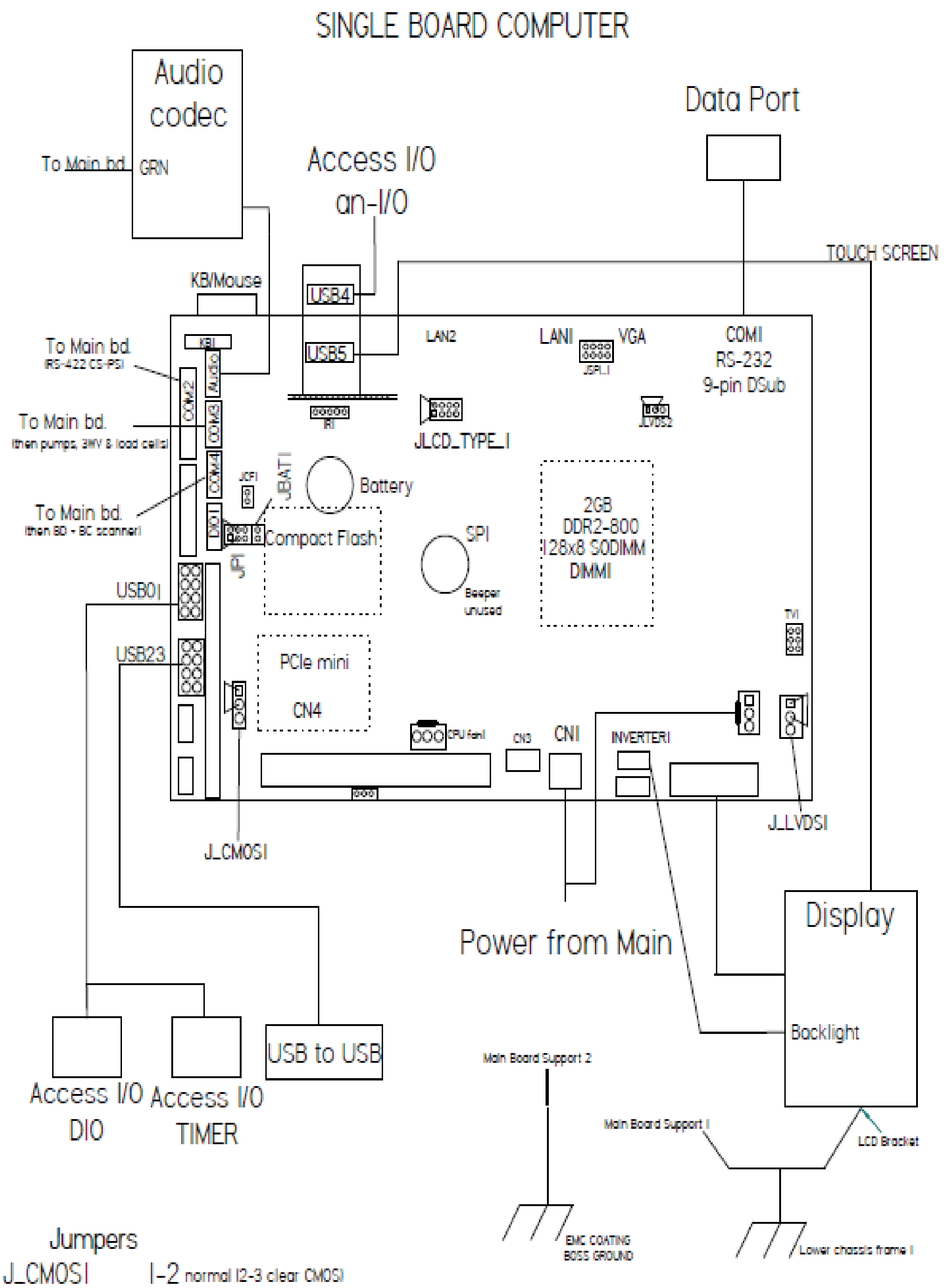


Fig. 8-8 Main board connectors

8.5 Wiring Diagram: Single Board Computer



Jumpers

J_CMOS1	1-2	normal (2-3 clear CMOS)
JP1	3-4	(COM2 config as RS-422)
J_LCD_TYPE1	1-2	(LCD, voltage, 3.3V, unused)
JLVDS1	1-2	(LVDS1, voltage, 3.3V)
JLVDS2	1-2	(LVDS2, unused)
JP2	2-3	(PC/104 voltage, unused)
ATXCTL1	open	(config ATX mode)
JCF1	open	(slave)

Fig. 8-9 Single board computer

8

1 ATX control
2 LVDS1 (36-bit)
3 Inverter
4 Front panel
5 ATX
6 5 V output
7 CPU fan
8 PC/104
9 IDE
10 2x Sata
11 Battery
12 4 x USB
13 Digital input/output
14 LPT
15 2 x COM
16 COM
17 J_Audio1
18 Keyboard
19 Keyboard & Mouse
20 IrDA
21 2 x USB
22 2 x Ethernet
23 JSPI
24 VGA
25 Inverter
26 LVDS2 (48-bit)
27 COM
28 HDTV

8.5.1 Single Board Computer Connectors

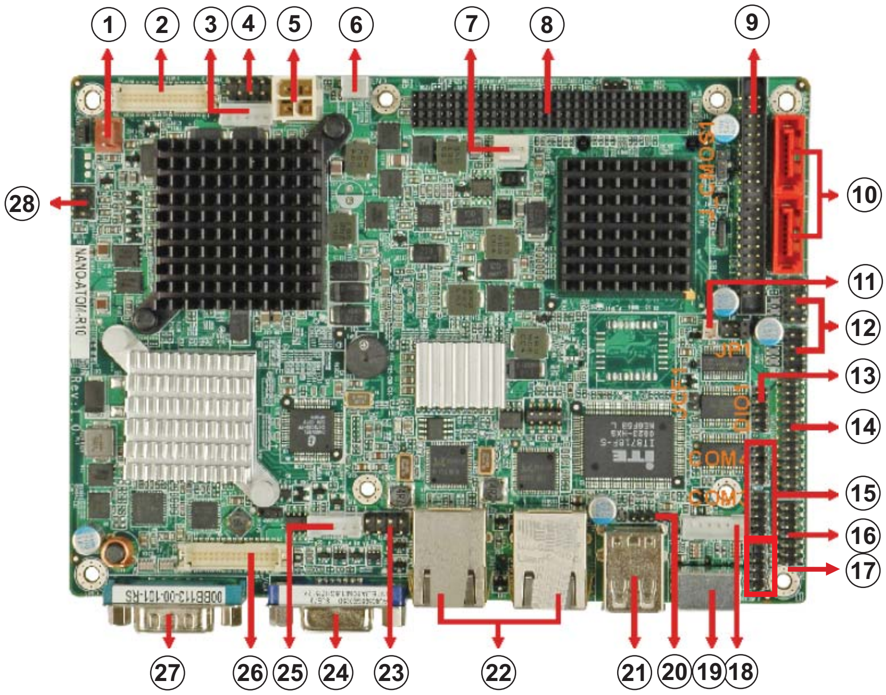


Fig. 8-10 Connections single board computer

Number	Connection insde the machine	Comments
1	Main board J 23	Power
2	LCD	
3	LCD	
4	Not connected	
5	Main board J 23	Power
6	Not connected	

Number	Connection insde the machine	Comments
7	Not connected	
8	Not connected	
9	Not connected	
10	Not connected	
11	Battery	Glued on the top of the chip
12	External USB port	Upper connector
12	USB to 2 of 3 AccessIO	Lower connector
13	Not connected	
14	Not connected	
15	Blood leak detector and Barcode scanner J 5	Upper connector: COM 4
	3-way clamp, pumps and load cells J 8	Lower connector: COM 3
16	PS-CS internal communication to J 14	Connect the cable with the wires on the upper side of the connector COM 2
17	Audio codec board	
18	Not connected	
19	Not connected	
20	Not connected	
21	1 x USB to Digital board 1 x USB to touch controller board	
22	Not connected	
23	Not connected	
24	Not connected	
25	Not connected	
26	Not connected	
27	Data port	Connector panel
28	Not connected	

Table of Contents

9 Spare Parts List

9.1 Spare Part List

9.1.1 Components of Blood Side Manifold

1 Kit locking mechanism
2 Level detector
3 Level detector
4 Safety air detector venous
5 Venous clamp
6 Blood pump / Roller pumphead for blood pump
7 Door detector
8 Citrate pump / Roller pumphead for citrate pump

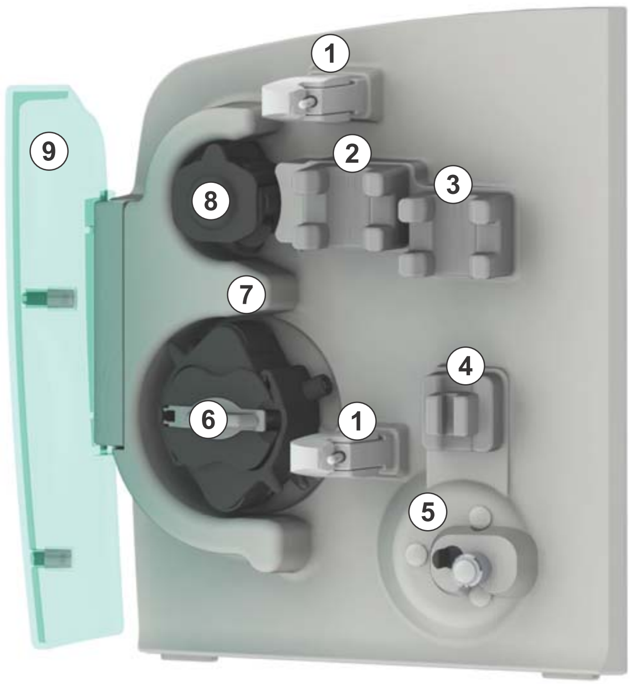


Fig. 9-1 Blood Side Manifold

Art. No.	Blood Side Manifold
34710029	Blood pump
34710066	Blood pump cable
34710027	Blood side board
34710026	Blood side door, complete
34710030	Citrate pump
34710065	Citrate pump cable
34710025	Door detector, complete
34710060	Encoder board CP
34710036	Kit locking mechanism
34710035	Level detector
34710056	Roller Pumphead for blood pump
34710061	Roller pumphead for fluid pumps (citrate)

Art. No.	Blood Side Manifold
34710032	Safety air detector, venous
34710034	Venous clamp, complete

9.1.2 Components of Fluid Side Manifold

1 Kit locking mechanism
2 Fluid pump (substitution)
3 Door detector
4 Fluid pump (dialysate)
5 Fluid pump (effluent)
6 3-way-clamp
7 Blood leak detector
8 Level detector (solution)

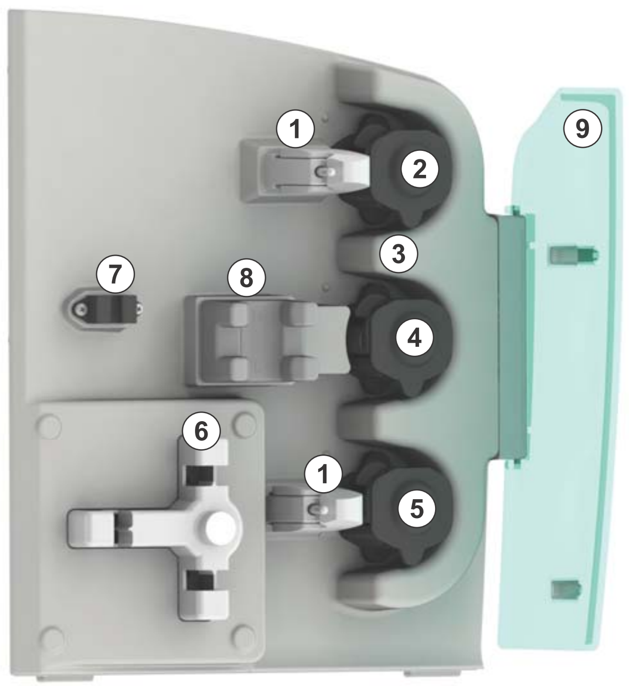


Fig. 9-2 Fluid side manifold

Art. No.	Fluid Side Manifold
34710042	3-way clamp
34710068	3-Way clamp cable
34710044	Blood leak detector
34710064	Dialysate pump cable
34710025	Door detector, complete
34710069	Effluent pump cable
34710059	Encoder board DP
34710058	Encoder board EP
34710057	Encoder board SP
34710041	Fluid pump (effluent, dialysate, substitution)
34710039	Fluid side board

Art. No.	Fluid Side Manifold
34710038	Fluid side door, complete
34710036	Kit locking mechanism
34710035	Level detector
34710061	Roller Pumphead for fluid pumps
34710067	Substitution pump cable

9.1.3 Components Lower Housing

1 Load cell (substitution/effluent/dialysate)

2 Barcode scanner

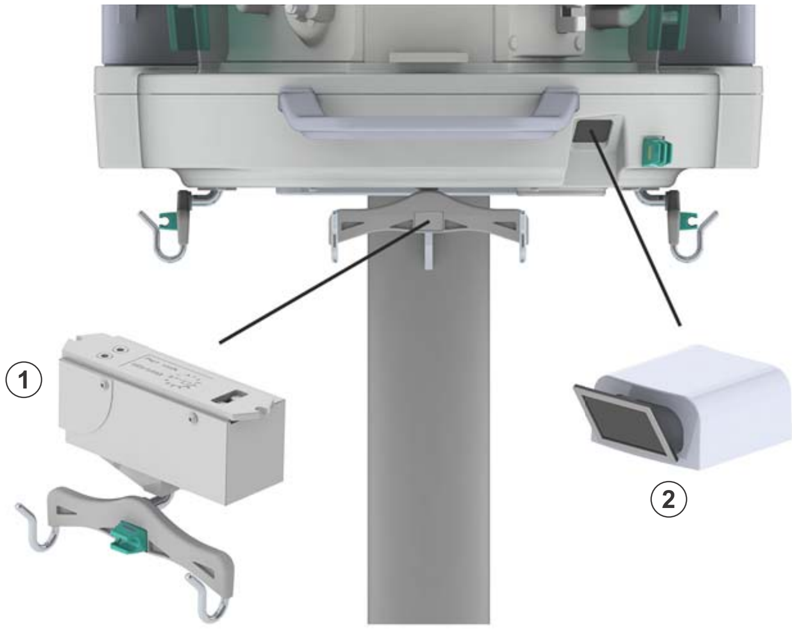


Fig. 9-3 Front Lower Section

1 Fan

2 Fan filter cover

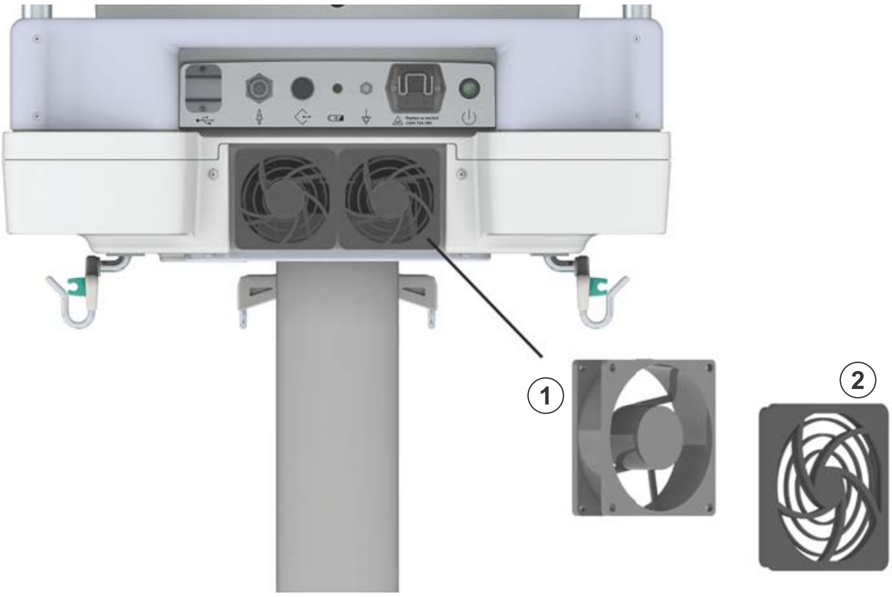


Fig. 9-4 Fan Including Filter

1 Fuse mains supply

2 Staff call

Fig. 9-5 Connector panel

Art. No.	Interior Lower Section
34710003	Barcode scanner
34710072	Buzzer
34710053	Fuse, 250 V T5A HBC for mains inlet
7103330	Power cord type G
34710002	Dust filter
34710001	Fan
34710062	Fan filter cover
34710000	Load cell (effluent, dialysate, substitution)
34710071	Microphone
7103331	Power cord type B

Art. No.	Interior Lower Section
7103332	Power cord type E & F
7103340	Power cord type I - AR
7103339	Power cord type I - AU & NZ
7103337	Power cord type I - CN
7103333	Power cord type J
7103338	Power cord type K
7103334	Power cord type L
7103335	Power cord type M
7103336	Power cord type N
34710004	Power supply, 500 W, 24 DC
34710017	Battery pack, 24.0V,2.7 Ah, 65Wh Sealed rechargeable Ni-MH
34710016	Speaker
34710055	Staff call board

9.1.4 Components Upper Housing

1 IV pole
2 Touch screen
3 Citrate pole
4 Citrate load cell

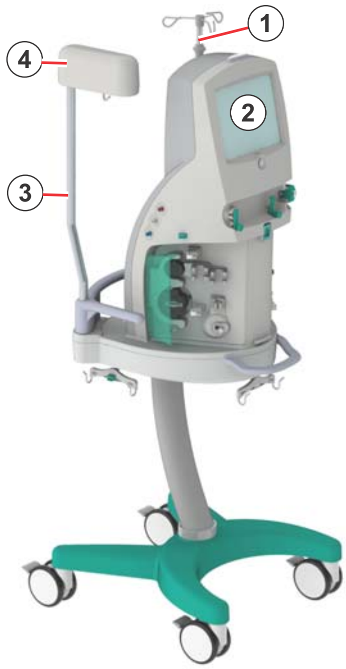


Fig. 9-6 Front view left

1 Light bar board
2 Single board computer
3 Audio codec board
4 Touch controller board

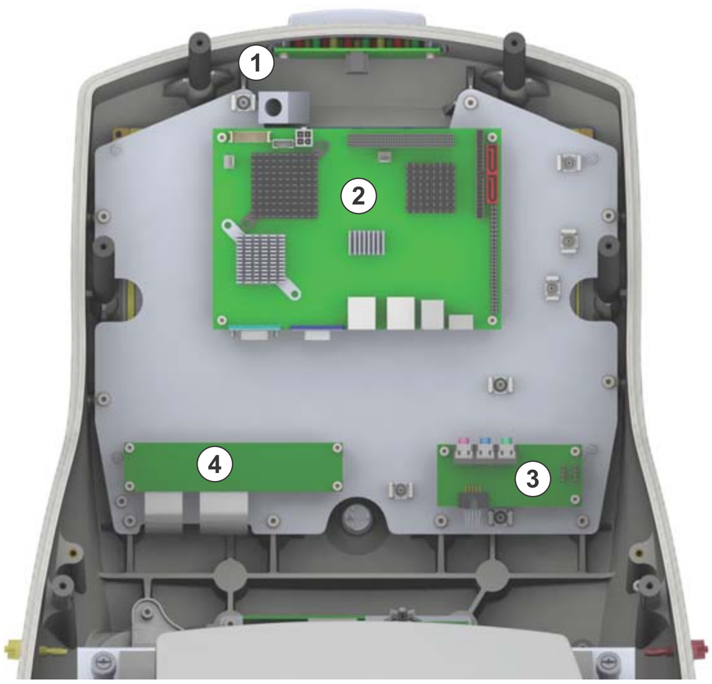


Fig. 9-7 Top level boards

1 Main board

Fig. 9-8 Main board

1 Tube holder safety air detector calcium

2 Safety air detector calcium

3 Syringe holder incl. spring and clip

4 Syringe pump

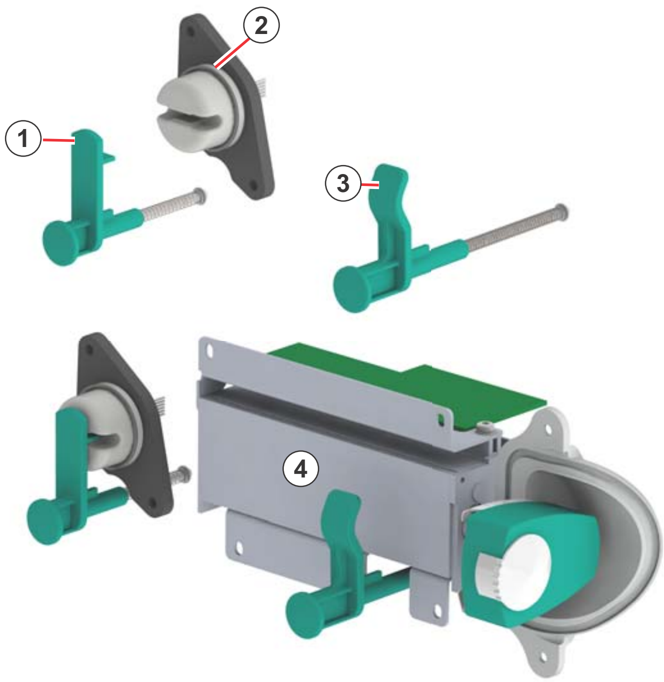


Fig. 9-9 Syringe pump

1 Warmer board

2 Warmer

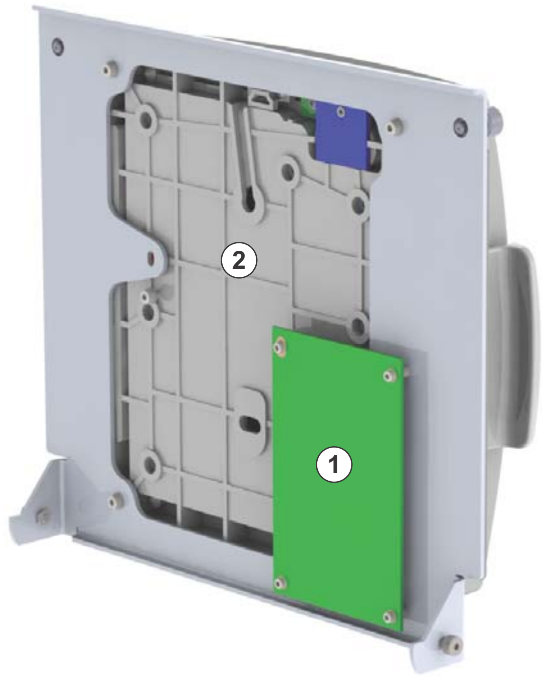


Fig. 9-10 Warmer

Art. No.	Interior Upper Section
34710014	Audio codec board
34710047	Citrate load cell, complete
34710052	Citrate pole
34710007	Compact flash card 4 GB
34710009	Data acquisition board
34710010	Digital counter board
34710011	Digital input/output board
34710054	Gasket for all housing parts
34516409	Hydrophobic filter
34710048	IV pole
34710019	LCD, incl. Touch Screen
34710008	Level regulation block (For machines ≤ SN 165000133 the mounting bracket for level regulation block need to be exchanged first before the new level regulation block can be installed.)
34710012	Level regulation pump

Art. No.	Interior Upper Section
34710024	Light bar board
34710006	Main board
3451884A	Manometer connection blue
3451576A	Manometer connection green
3451833A	Manometer connection red
3457058A	Manometer connection white
3451577A	Manometer connection yellow
34710073	Mounting bracket for level regulation block
34710023	Safety air detector, calcium
34565299	Silicon tubing 2x8
34710013	Single Board Computer
34710021	Syringe holder incl. spring and clip
34710020	Syringe pump
34710015	Touch controller board
34710022	Tube holder, safety air detector calcium
34710049	Warmer
34710050	Warmer board

Art. No.	Description
34710070	Hardware kit (including non reusable screws)

9.2 Test and Calibration Equipment and Tools

Pos.	Art. No.	Description
1	7704091	Test equipment for blood leak detector
2	7704092	Calibration weight 5,000 g (2 are required)
3	7704093	Calibration weight 2,000 g
4	770203A	Five-fold stopcock incl. tubing (for pressure sensor calibration)
5	7704095	Door detector calibration tool
6	7702493	Template 1,4/1,5 mm for venous clamp
7	7704098	Warmer test and calibration board
8	N/A	Dialysis measurement instrument for pressure measurement e.g. HDM99XP for example manufacturer IBP Medical GmbH **Contact the manufacturer or supplier for calibration service.**
9	N/A	Electrical safety analyzer for electrical safety check according to IEC 62353/EN 60601-1/IEC 601-1 e.g. Rigel 288 for example manufacturer Rigel Medical Contact the manufacturer or supplier for calibration service.

Pos.	Art. No.	Description
1	7704118	SW V1.50.20

Pos.	Art. No.	Description
1	7704115	FSU V1.20.10

9.3 Material Return Form

<table>
<tr><th colspan="4">Material Return Form</th></tr>
<tr><td colspan="4">B. Braun Avitum AG
Wareneingang - Service
Schwarzenberger Weg 73-79
D-34212 Melsungen Germany</td></tr>
<tr><td colspan="4">Reason for returning the spare part</td></tr>
<tr><td>Warranty return</td><td>O</td><td>Defective part</td><td>O</td></tr>
<tr><td>Wrong shipment</td><td>O</td><td>Spare part returned for investigation</td><td>O</td></tr>
<tr><td colspan="3">Spare part returned for disposal by B. Braun Avitum AG</td><td>O</td></tr>
<tr><td colspan="4">Sender</td></tr>
<tr><td colspan="4">Name of company:</td></tr>
<tr><td>City:</td><td></td><td>Country:</td><td></td></tr>
<tr><td>Telephone/e-mail:</td><td></td><td>Customer number:</td><td></td></tr>
<tr><td colspan="4">Name of responsible person:</td></tr>
<tr><td colspan="4">Returned part</td></tr>
<tr><td>Article number:</td><td></td><td>Part serial number:</td><td></td></tr>
<tr><td>Part description:</td><td colspan="3"></td></tr>
<tr><td>Description of the defect:</td><td colspan="3"></td></tr>
<tr><td colspan="4">Machine information</td></tr>
<tr><td>Machine type:</td><td></td><td>Serial number:</td><td></td></tr>
<tr><td>Software version:</td><td></td><td>Working hours:</td><td></td></tr>
<tr><td colspan="4">Described defect appears</td></tr>
<tr><td>Intermittent</td><td>O</td><td>Permanently</td><td>O</td></tr>
<tr><td colspan="4">Cleaned/disinfected</td></tr>
<tr><td>Cleaned</td><td>O yes</td><td>Disinfected</td><td>O yes</td></tr>
<tr><td colspan="4">Disinfectant:</td></tr>
</table>

Disposal and Taking Back of Spare Parts

Dispose spare parts (e.g. boards or batteries) according to local disposal guidelines or send back to B. Braun Avitum AG free of charge.

Cleaning and Disinfection of Spare Parts Used in OMNI

All spare parts sent by the customer to the B. Braun Avitum AG representative for repair, complaint, refurbishment, technical analysis or warranty must be cleaned and disinfected (exception: boards). Spare parts considerably contaminated, damaged or not disinfected are scrapped.

Packaging Notice

Each returned part must be properly packed to prevent any damage during transportation due to mechanical impact or due to electrostatic discharge. The safest way to prevent damage is by using the packaging material from the new spare part and by packing the returned part exactly in the same way. Returned parts containing electronic components (electrostatic sensitive devices) must be packed in special ESD packaging material. Only shielded bags or antistatic bags may be used. Unprotected electronic parts (e.g. wrapped in normal plastic bags or parts padded with Styrofoam) are assumed to be damaged by electrostatic discharge and will be scrapped.

This form must be attached to every spare part sent back to your B. Braun representative! Spare parts without this form are scraped.

Please Copy!

Table of Contents

10 Appendix

10.1 ESD/EMC Information

10.1.1 Electrostatic Discharge ESD Information

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.

ESD

Electrostatic discharge ESD is a static energy, which causes a sudden flow of electricity between two objects at different electrical potentials. ESD is the primary cause for damage or failure of integrated circuits. The following information should help service technicians to prevent static discharge during servicing.

ESD Protection

Precautions must be made when working on internal components of a system to prevent accidental static discharges to the components. At any time the human body can hold a large static voltage charge that can easily damage components in a system. If this charge suddenly flows from one device to another through logic circuits these components can be damaged.

ESD Service Workstations

Service workstations should be adequately equipped with ESD devices to establish an area which meets static charge requirements to prevent damage of electronic components on pcb's.

Each service workstation should have a work surface with a conductive/ dissipative material. The work surface and soldering iron should be connected to ground potential via protective resistors.Personnel should wear a conducting wristband connected to the work surface, via a protective resistor cable. If possible personnel should wear cotton clothing to prevent static charging. Shoes should also be antistatic. If applicable chairs, floors and mats in this area should be antistatic.

ESD Service Kit

Fig. 10-1 ESD service kit

Use ESD service kits to equalize charges between you and any of the system components. Portable service kits are designed to prevent static charge of electronic systems during field service.

In general these service kits contain a wrist band and mat, with ground bonding cable for attachment to the system frame or an earth bonding point mains plug.

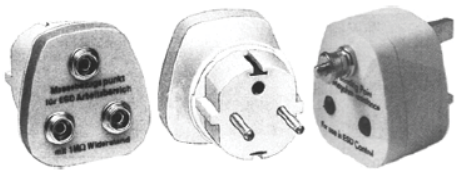


Fig. 10-2 Mains plugs with earth bonding point

Mat Material

In general the mats are made of sturdy two layer material and have reinforced edges and corners. The work surface is static dissipative (> 100 MΩ), the other side is conductive (> 100 kΩ)

Wrist Bands

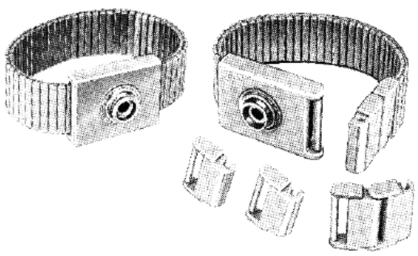


Fig. 10-3 Wrist bands

In general the wrist band is a stainless steel expandable link style band. The outer coating and edges are insulated. The wrist bands are available in different sizes. Adjustable wrist bands with clip-on links are also available. The ground bonding cable for the wrist band is coiled. The cable incorporates a high-value resistance (> 1 MΩ).

10

Earth Cable

The common point straight earth cable has a snap fastener and a crocodile clip. The cable incorporates a high-value resistor (> 1 MΩ).

Storage, Transport and Delivery of Boards

The storage, transport and delivery of pcb's and assembly groups sensitive to static charge should only be carried out in original packaging. Only use correct packaging material, e.g. conductive bags, conductive bubble bags, shielding bags, PCB cartons with low density conductive foam. The original packaging is specially designed to meet the following specifications:

- Provides physical and static protection
- prevents electrostatic charging
- prevents static induced damages
- prevents discharging of batteries equipped on PCBs.

Do not send any boards or assembly groups sensitive to static charge in packaging material unfit for shipment, e.g. normal plastic bags, bubble bags, cartons, etc.

Packaging Notice

Each returned part must be properly packed to prevent any damage during transportation due to mechanical impact or due to electrostatic discharge. The safest way to prevent damage is by using the packaging material from the new spare part and by packing the returned part exactly in the same way. Returned parts containing electronic components (electrostatic sensitive devices) must be packed in special ESD packaging material. Only shielded bags or antistatic bags may be used. Unprotected electronic parts (e.g. wrapped in normal plastic film or parts padded with foam material) are assumed to be damaged by electrostatic discharge and will be scrapped.

10.1.2 Electromagnetic Compatibility EMC

EMC

Electromagnetic compatibility EMC means that medical electrical equipment has the capability to work satisfactory in an electromagnetic environment, without causing electromagnetic emissions, which would be unacceptable for all other medical electrical equipment in this environment.

The following tables 1, 2 and 4 are guidelines from the IEC 60601-1-2 and must be observed.

<table>
<tr><th colspan="3">Guidance and manufacturer’s declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The OMNI is intended for use in the electromagnetic environment specified below. The customer or the user of the OMNI should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The OMNI uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The OMNI is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: The OMNI is intended for use by healthcare professionals only. The OMNI may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the OMNI or shielding the location.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Tbl. 10-1 Electromagnetic emissions table 1

Guidance and manufacturer's declaration – electromagnetic immunity			
The OMNI is intended for use in the electromagnetic environment specified below. The customer or the user of the OMNI should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines 1 kV for input/ output for lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment. Test not applicable for input/output lines.
Surge IEC 61000-4-5	±1 kV line(s)to line(s) ±2 kV line(s)to earth	±1 kVdifferential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 s	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle) 40 % U_T (60 % dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OMNI requires continued operation during power mains interruptions, it is recommended that the OMNI be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	10 A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Tbl. 10-2 Electromagnetic emissions table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The OMNI is intended for use in the electromagnetic environment specified below. The customer or the user of the OMNI should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the OMNI, including cables,than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.1.2 **Recommended separation distance:** NOTE: The recommended separation distances are specified in the instructions for use.
Conducted RF acc. to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	10 V_{rms}	$d = 1.2 \sqrt{P}$
Radiated RF acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz 1 V/m 2.0 Ghz to 2.7 Ghz	6 V/m	$d = 1.2 \sqrt{P}$ for 80 MHz to 800 MHz $d = 2.33 \sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter inwatts (W) according to the transmitter manufacturer and d is therecommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by anelectromagnetic site survey, [a] should be less than the compliancelevel in each frequency range. [b] Interference may occur in the vicinity of equipment marked withthe following symbol: 

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Guidance and manufacturer's declaration – electromagnetic immunity
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. [a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and landmobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the OMNI is used exceeds the applicable RF compliance level above, the OMNI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the OMNI. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Tbl. 10-3 Electromagnetic emissions table 4

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