Dialog^{+} SW 9.xx

Service Manual

English

Edition 1 -2010

B|BRAUN
SHARING EXPERTISE

Contact your Local
B. Braun Representative
for Service Support

B. Braun Avitum AG

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Germany

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E-Mail: guenter.nissen@bbraun.com

Valid for the following machine type:

Dialog+

For Software ≥ 9.xx

Dialog+:	from serial no. 100000
Dialog+ HDF-Online:	from serial no. 150000

Registration Number:

Service Manuals with a registration number are included in the update service!

Copyright	This document is the property of B. Braun Avitum AG with all rights reserved.
Commissioning and Service	Only trained personnel must service the Dialog+, i.e. repair, maintenance, software installation, firmware update, retrofitting and commissioning of the Dialog+. Servicing must only be performed with proper tools, calibration equipment and be in accordance with the most recent revision of this service manual/technical information, which must be clearly and thoroughly understood.
Prevent Electrical Shock Hazard	Switch off the Dialog+ and disconnect unit from mains if you have to open the machine for servicing. Do not touch any exposed wiring or conductive surfaces while the Dialog+ is opened. The voltages present when electrical power is connected to the Dialog+ can cause serious injury or death.
ESD Information	Pay attention to ESD information, because electronic components are sensitive to electrostatic discharges.
High Voltage in TFT Monitor	If a battery option is present in the machine: High voltage can be present at the backlight inverter board BIB in the TFT monitor, even if the machine has been disconnected from mains. Pull out the battery compartment in the base platform and switch off the battery voltage before opening the machine.
Protective Conductor in TFT Housing	If the TFT housing had to be opened during a service job, the tight seat of the protective conductors in the TFT housing must be checked.
TSM Service Program	Only activate the TSM service program for service activities. It is prohibited to connect a patient to the Dialog+ and to run a therapy if the TSM service program is activated in the Dialog+. If the TSM service program is activated the complete alarm system is disabled. The TSM service program is started in the service mode: digital board, service switch S1, position 2.
Software	The software is installed in the software mode: digital board, service switch S1, position 3.
Therapy Mode	After completion of all procedures switch back to the therapy mode: digital board, service switch S1, position 0.
Calibration	Only perform a calibration after the Dialog+ has reached working temperature and the machine was disinfected and decalcified. Save the calibration data (CFC) before you exit the TSM service program: *TSM Main Menu*, *File Operations*, *Save Calibration Data*.
Tubing	Tubing must be replaced only by the same tubing type/length and identical installation manner. Make sure that the tubings in the machine are not kinked or twisted after servicing (e.g. if sub-racks are pulled out and inserted again). The tubing must not touch moving/rotating components (e.g. motors of gear pumps).
Wiring	Wiring must be replaced only by the same cable type/length and identical installation manner. The cables must not touch moving/rotating components (e.g. motors of gear pumps).
Prevent 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.
Contaminated Machines	Protective gear should be worn in case of servicing of assumed contaminated machines.
Cover in Rear Door	Servicing of mechanical assembly groups (components in contact with fluid): the cover for the switch mode power supply microcontroller SMPS-MC in the rear door must be assembled during servicing because it serves as a spray protection.
O-Rings	Always check o-rings from disassembled groups/components and replace if necessary.
Figures	The displayed figures can differ slightly from the machines on site, due to different hardware statuses.
Fuses	If fuses are replaced they must exactly match the type and rating specified by the manufacturer in the spare parts list/technical information. Where applicable: fuses must be approved by UL/CSA.
Spare Parts	Only use original spare parts manufactured and sold by B. Braun Avitum AG.
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 (see chapter 7).
System Configuration	The system configuration saved on a diskette must be downloaded to an other Dialog+ machine only if: • the hardware matches and • the identical software version number is present.
Function Check	Check the respective function of the assembly group/component after servicing. A complete function check must be performed after every service, according to the operating manual.

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Conventions

Symbol	Description
⚠	**Attention** **The symbol gives information, which are safety relevant for the Dialog+ and must be observed.**
ℹ	**Information** The symbol gives additional information, which should be observed.
💡	**Tips** The symbol gives additional hints, which can be helpful.
☞	**Handling** The symbol gives information for a handling at or in the machine, i.e. during a calibration, disassembly or assembly.
↔	**Calibration** The symbol appears for necessary calibration measures.
🔧	**Calibration Equipment/Tools** The symbol gives remarks for necessary calibration equipment/tools, i.e. during a calibration, disassembly or assembly.

Service Manual

The edition of this service manual is for the maintenance and repair of the Dialog+ machine with a software ≥ 9.01. The service manual is subject to amendments.

Service Training

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

The user of this documentation should only use this documentation in combination with a participation in a B. Braun service training.

The user of this documentation should have the following qualifications and prerequisites:

1. Mechanics, digital/analogue techniques, optoelectronics, measurement and PC techniques.
2. Participation in a B. Braun service training to accomplish qualified maintenance, repair and service support.
3. Availability of approved and calibrated test equipment and tools given in this service manual.

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

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Technical Safety Inspection

Perform regular technical safety inspections as described in chapter 5 of this service manual to ensure the safety of the machine.

Instructions for Use

An instructions for use can be ordered at your local B. Braun representative or dealer.

ESD/EMC Information

Please observe the ESD/EMC information (see appendix for additional information):

- ESD: electrostatic discharge
- EMC: electromagnetic compatibility

Spare Parts

Only original spare parts manufactured and sold by B. Braun are applicable. Please provide part number and description respectively when ordering any spare parts. Please order your spare parts at your local B. Braun representative or dealer.

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The main assembly groups are defined according to the spare parts list. The main assembly groups are especially:

- All pcb's (printed circuit boards)
- Pumps
- DF block
- Ultrafiltration
- Blood leak detector
- Safety air detector
- Heater

Tamper or repairs in these assembly groups are not permissible (due to calibration, ESD, multi-layer pcb's and the application of SMT (SMT = surface mounted technology).

Calibration Service

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

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Commissioning and Service	Only trained personnel must service the Dialog+, i.e. repair, maintenance, software installation, firmware update, retrofitting and commissioning of the Dialog+. Servicing must only be performed with proper tools, calibration equipment and be in accordance with the most recent revision of this service manual/technical information, which must be clearly and thoroughly understood.
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High Voltage in TFT Monitor	If a battery option is present in the machine: High voltage can be present at the backlight inverter board BIB in the TFT monitor, even if the machine has been disconnected from mains. Pull out the battery compartment in the base platform and switch off the battery voltage (remove fuse) before opening the machine.
Protective Conductor in TFT Housing	If the TFT housing had to be opened during a service job, the tight seat of the protective conductors in the TFT housing must be checked.
TSM Service Program	Only activate the TSM service program for service activities. It is prohibited to connect a patient to the Dialog+ and to run a therapy if the TSM service program is activated in the Dialog+. If the TSM service program is activated the complete alarm system is disabled. The TSM service program is started in the service mode: digital board, service switch S1, position 2.
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Therapy Mode	After completion of all procedures switch back to the therapy mode: digital board, service switch S1, position 0.
Calibration	Only perform a calibration after the Dialog+ has reached working temperature, and the machine was disinfected and decalcified. You should save the calibration data to the hard disk drive before you exit the TSM service program: *TSM Main Menu*, *File Operations*, *Save Calibration Data*.
Prevent 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.
Contaminated Machines	Protective gear should be worn in case of servicing of assumed contaminated machines.
Cover in Rear Door	Servicing of mechanical assembly groups (components in contact with fluid): the cover in the rear door must be assembled during servicing because it serves as a spray protection for the SMPS-MC.
Tubing	Tubing must be replaced only by the same tubing type/length and identical installation manner. Make sure that the tubings in the machine are not kinked or twisted after servicing (e.g. if sub-racks are pulled out and inserted again). The tubing must not touch moving/rotating components (e.g. motors of gear pumps).
Wiring	Wiring must be replaced only by the same cable type/length and identical installation manner. The cables must not touch moving/rotating components (e.g. motors of gear pumps).
Fuses	If fuses are replaced they must exactly match the type and rating specified by the manufacturer in the spare parts list/technical information. Where applicable: fuses must be approved by UL/CSA.
Spare Parts	Only use original spare parts manufactured and sold by B. Braun Avitum AG.
Instructions for Use	Please pay attention to the information in the instructions for use
Check Machine	Check completeness of machine and transport damages after unpacking.
Commissioning	Do not start machine if a safe operation is not guaranteed.
Electrical Installation	The electrical installation must correspond with national regulations for initial operation of the unit (e.g. IEC publications). The machine must not be operated in hazardous locations or rooms. The potential equalisation must be in accordance with national requirements (e.g. IEC publications)
Mains Voltage Supply	The mains voltage supply must correspond with the mains voltage on the unit type plate!
Ambient Temperature	Before the Dialog+ is switched on the machine must have room temperature (see instructions for use, chapter 15).
Water Installation	The installation must be in accordance with national regulations e.g. DVGW work sheet W503 for haemodialysis equipment and VDE 0753 (rules of application for haemodialysis equipment). A pipe disconnector is not necessary if a water softener or water softener with built-in reverse osmosis system is installed. A nonreturn valve and a bleed pipe are adequate. Please see DVGW work sheet W 503, section 4.4 and VDE 0753 part 4 (Rules of application for haemodialysis equipment).
Water Quality	Only water of the highest quality should be applied. Please consider the following, especially for bicarbonate dialysis: • Inlet water shall be free of Mg^{++} and Ca^{++}.
Central Hot Cleaning System	If the machine is connected to a central hot cleaning system a high temperature tubing must be used for the water inlet.

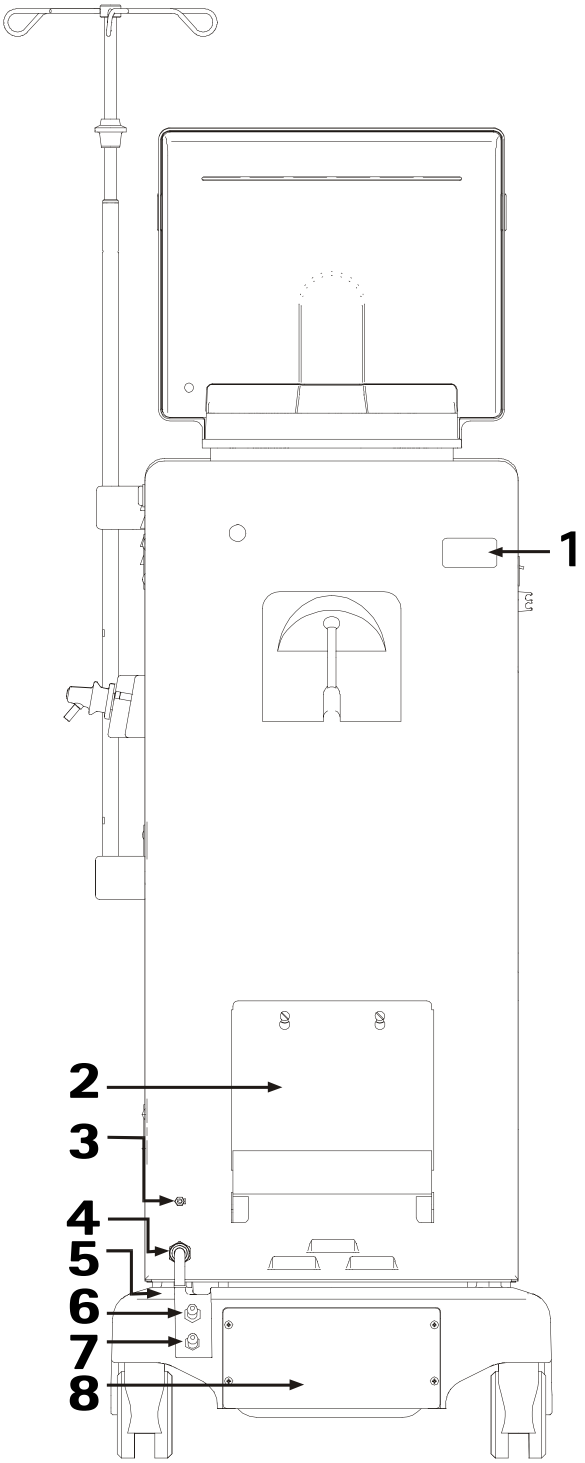

Fig.: Dialog+ Rear View

Legend

1. **Type Plate**
2. **Canister Holder**
3. **Potential Equalisation Bolt**
4. **Main Cord**
5. **Central Concentrate Supply Option**
6. **Tubing Connection Water Inlet**
   - PVC tubing 10 x 3 mm (red) (fasten with two single ear clamps 19.5)
   - Tubing length: approx. 3 m

6.1 Tubing Connection Water Inlet for Osmosis Device with Hot Disinfection of the Loop Line

- Silicone tubing 8 x 3.2 mm (high temperature tubing, red) (fasten with two single ear clamps 19.5)

7. **Tubing Connection Dialysate Outlet**
   - PVC tubing 10 x 3 mm (black) (fasten with a single ear clamp 19.5 and a tubing clamp 12-20 mm)
   - Tubing length: approx. 3 m
   - Drain height: max. 80 cm
8. **Emergency Power Supply/Battery Option**

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1.1 Commissioning Check List

For **Dialog+ SW 9.xx**

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

REF {Type/Typ}:.. **SN {Serien-No./Nr.}:** ....

Year of Purchase: .... **Responsible Organisation (User):** ....

....

Operating Hours: .... **h** **Inventory No.:** ....

SW Version: ....

Manufacturer:

B. Braun Avitum AG
34209 Melsungen, Germany

Check List

Note: Text in { } brackets is information for the execution of the check list!

			OK
1.	**Visual Inspection**		☐
1.1	{Machine: clean/complete; no damages/moisture influences or loose assemblies; no moveable parts touching tubings or wires; casters are moveable; type plate legible}		
1.2	{Check tight seat and damages of mains supply (power supply cord, strain relief), potential equalisation cable, staff call/data lines (if present) and connectors}		
2.	**Protective Earth Resistance According to EN 62353**		
2.1	**Protective Earth Resistance:** < 0.3 [Ω] {note highest value}: .... **[Ω]** {(Machine incl. power supply cord. Move the power supply cord during the check. Thus possible loose connections can be detected. Data lines and potential equalisation cable must not be connected during the check of the of the protective earth resistance (see figure 1)} {Measurement points:} {Exterior: Potential equalisation bolt, rinsing bridge (dialyser inlet and outlet)} {Interior: Heater body (top), rear door (top left corner), frame (rear), housing cover (top left), front door (top left)} {Monitor: Monitor (one of the screws in the front panel/housing}		☐
3.	**Install Machine**		☐
3.1	{Connect water inlet to the metal tubing connector and fasten with single ear clamp. Connect dialysate outlet to plastic tubing connector and fasten with tubing clamp.}		
3.2	{Connect central supply for concentrate (central supply option) and deaerate tubings}		
3.3	{Assemble holder for disinfectant (if option present)}		
3.4	{Assemble dialyser holder}		
3.5	{Assemble filter holder. Insert DF filter (option)}		
3.6	{Assemble DF filter/HDF filter (if option present)}		
4.	**Function Inspection**		
{Pay attention to the filling procedure of the machine to prevent dry run of the heater!}			
4.1	**Switch on machine, fill and rinse:**	- {Switch machine in *Test 1.10 Degassing and Heating* menu and fill with water until water flows out of the dialysate outlet. Then rinse in disinfection (approx. 5 minutes).}	☐
4.2	**Automatic Blood Pressure Measurement ABPM**	Option present no ☐ yes ☐	☐
4.2.1	**ABPM Option:**	- Measurement on a test person is plausible	☐
4.3	**Customer Specific System Setting:**	- {Switch machine in TSM Service Program: Execute *Treatment Support* (calibrate PE offset for altitudes > 1000 m}	☐

Check List

Note: Text in { } brackets is information for the execution of the check list!

SN **{Serien-No./Nr.}** .... **OK**

5. Setting into Service According to Instructions for Use with Electrical Safety Check According to EN 62353/EN 60601-1

5.1	**Applied Accessories/Disposables:**	- Applied line system: Name:		
5.2	**Switch on machine:**	- Self-test passed {and 15 minutes therapy with UF safety check}		☐
		- Ultrafiltration comparison measurement 15 minutes with UF rate 500 ml/h: (125 ml UF volume ±15 ml)	.... **[ml]**	☐
5.3	**Temperature:**	- Comparison measurement {at dialyser coupling}, at 37 °C (-1.5; +0.5):	.... **[°C]**	☐
5.4	**Conductivity:**	- Comparison measurement {at dialyser coupling}, e.g. 14.3 mS/cm (±0.2):	.... **[mS/cm]**	☐
5.5	**Equipment Leakage Current:** {All water connections and data lines must be connected during the check of the equipment leakage current (see figure 2)}			
	≤ 0.5 [mA]	- During heat-up phase {change mains polarity and note highest value}:	.... **[mA]**	☐
5.6	**Patient Leakage Current:** {All water connections and data lines must be connected during the check of the patient leakage current (see figure 3)}			
	< 10 [µA] AC	- Under normal conditions {at dialyser coupling}, conductivity at 13 – 15 mS/cm:	.... **[µA]**	☐
5.7	**Safety Air Detector (SAD):**	- Test alarm function (visual/audible) passed		☐
5.8	**Disinfection:**	- Start		☐

Applied Measurement Equipment:

Electrical Safety: .... * ID/Serial No.: ....

Conductivity: .... * ID/Serial No.: ....

Temperature: .... * ID/Serial No.: ....

Pressure: .... * ID/Serial No.: ....

Balance: .... * ID/Serial No.: ....

Pressure Manometer: .... * ID/Serial No.: ....

Other Measurement Device: .... * ID/Serial No.: ....

.... * ID/Serial No.: ....

* If applicable, please enter the type and identification number of the equipment used.

Comments:

....

....

....

Next Inspection Date: ....

The commissioning was performed and the machine was hand over to the responsible organisation (user).

Name Service Technician:

....

....
Date/Signature

Name of Company:

....

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

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

Table 1: Legend of Abbreviations and Symbols

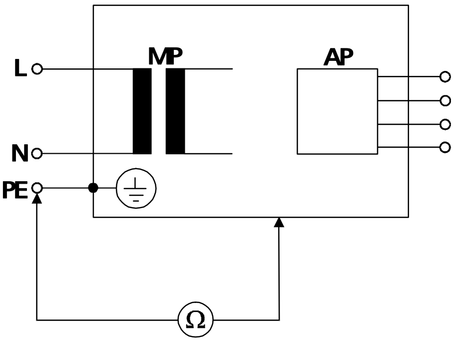

Fig. 1: Protective Earth Resistance

Protective Earth Resistance

Test current: ≥ 200 mA

The test current must be measured in both directions.

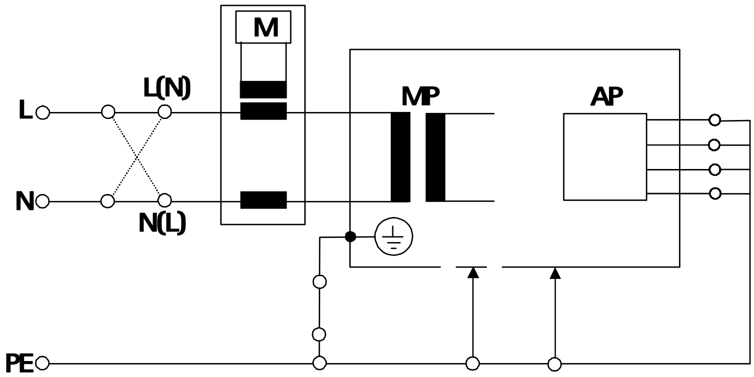

Fig. 2: Equipment Leakage Current

Equipment Leakage Current:

- Differential Measurement

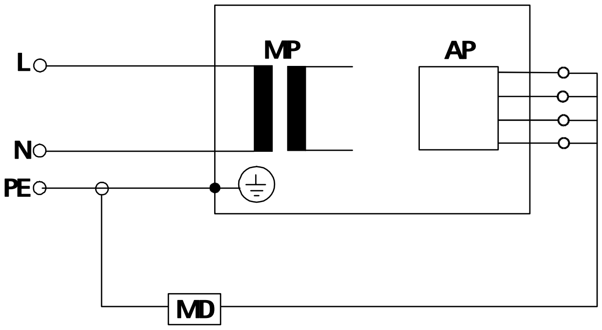

Fig. 3: Patient Leakage Current

Patient Leakage Current

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General Information

Operation is accomplished via a touch screen (TFT monitor). Two microprocessor systems control and monitor the machine.

The hardware concept consists of the following systems:
- Top Level System
- Low Level System

Top Level System

The top level system consists of the following components:
- Communication module
- Top level controller TLC (motherboard)
- Compact flash card CFC
- Options

The communication between the user and the machine is performed via the top level.

Example data exchange to communication module:
- Entry via input mask of the touch screen or keyboard
- Output via the output mask of the TFT monitor

Example data exchange to low level:
- Transmitting and receiving data from/to low level controller and supervisor on the digital board DB (LLD)

Low Level System

The low level system consists of the following components:
- Digital board DB (LLD)
- Analog board AB (LLA)
- Power board motors PBM
- Power board valves PBV

The low level controls and monitors all functions.

Data exchange to top level controller (motherboard):
- Transmitting and receiving data from/to low level supervisor
- Transmitting and receiving data from/to low level controller

Data exchange between low level controller to supervisor:
- Transmitting and receiving messages, data and commands

All sensor data are sent separately, via two serial bus systems, to the supervisor and controller via the analog board to the digital board. The actuators, motors and valves are driven via the power board valves PBV and power board motors PBM.

Dialog+

For Software ≥ 9.xx

2.1 Overview Sub-Racks

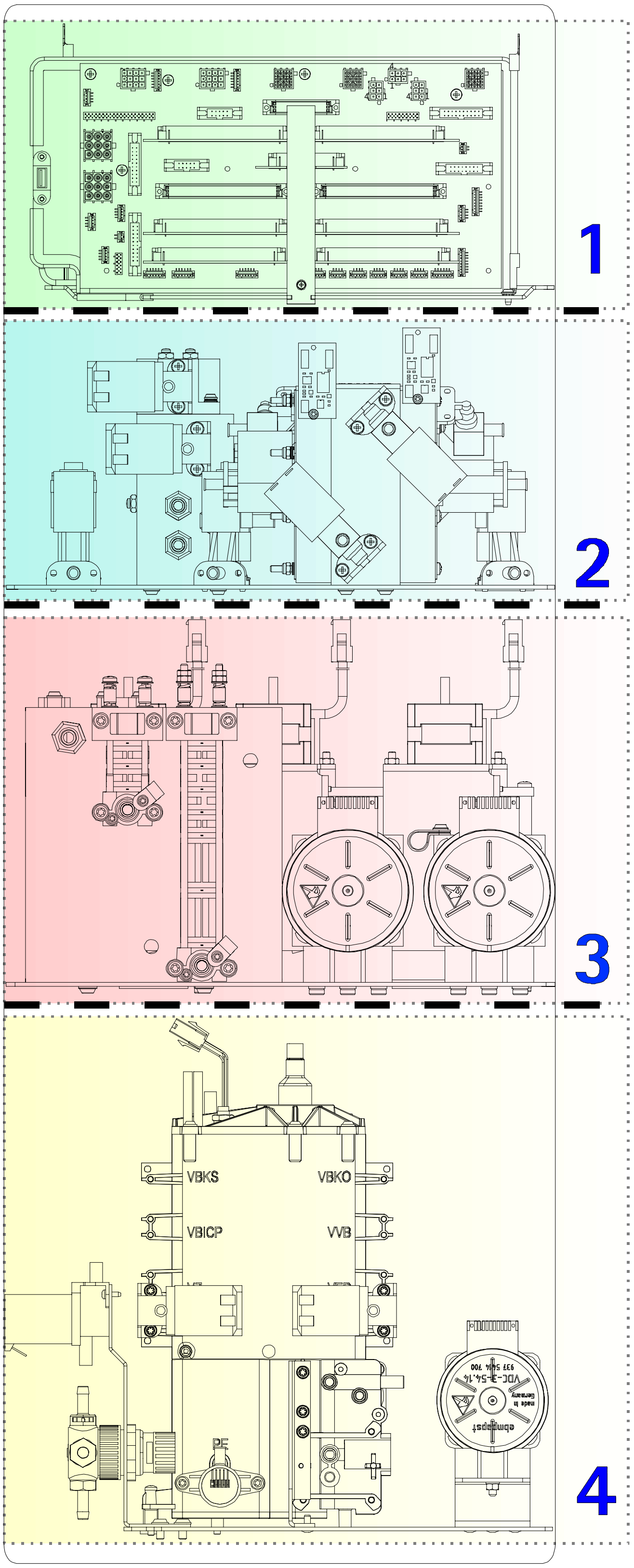


Fig. : Overview Sub-Racks Rear View Dialog+

2.1.1 Legend Overview Sub-Racks

1	Top Level Sub-Rack	**3**	DF Sub-Rack
2	UF Sub-Rack	**4**	Water Sub-Rack

2.2 Top Level Sub-Rack

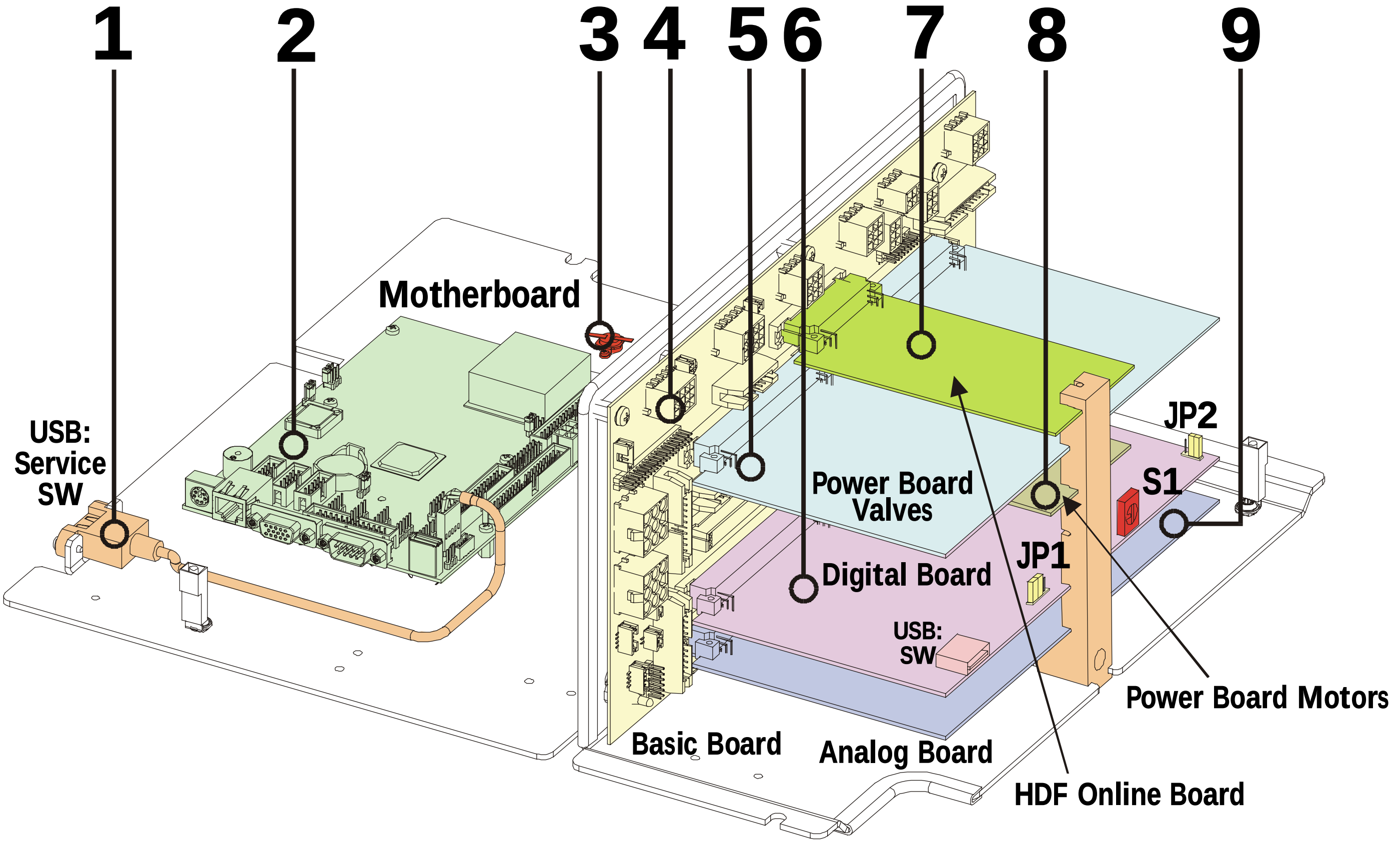


Fig. : Top Level Sub-Rack

2.2.1 Legend Top Level Sub-Rack

1 USB Port:
Service (FSU)/Software Installation TLC
2 LX800 Motherboard
3 Temperature Switch TS (closes at 50 ± 3 °C, opens at 35 ± 6 °C)
4 Basis Board BB
5 Power Board Valves PBV
6 Digital Board DB (LLD):
USB Port: Software Installation LLC/LLS; Service-Switch S1; Jumper JP1/JP2
7 HDF Online Board HOB
8 Power Board Motor PBM
9 Analog Board AB (LLA)

2.3 Basic Board BB

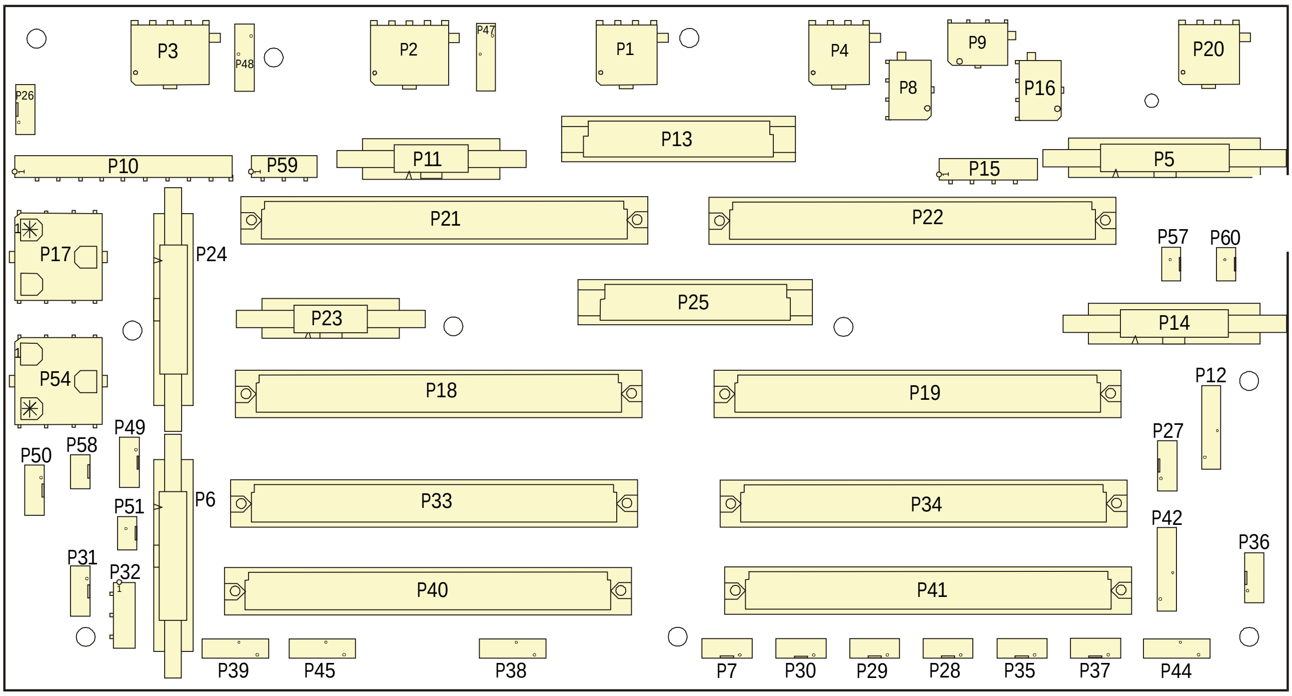


Fig. : Basic Board

2.3.1 Legend Basic Board

P1	Degassing Pump **EP**
P2	Venous Blood Pump **BPV**
P3	Arterial Blood Pump **BPA**
P4	Outlet Flow Pump **FPA**
P5	Safety Air Detector **SAD**
P6	Heparin Pump **HP (HEP)**
P7	Air Separator Level Sensor **LAFS**
P8	BIC Pump **BICP**
P9	Concentrate Pump **KP**
P10	All Valves (+ Option BIC) **VALVES**
P11	Level Regulation **LR**
P12	**DIABUS**
P13	HDF Online Board **HOB**
P14	Front Panel Board **FPB**
P15	Valves Balance Chamber **VCH**
P16	UF Pump **UFP**
P17	Power Supply 1 **PS1**
P18	Not Applicable
P19	Not Applicable
P20	Inlet Flow Pump **FPE**
P21/P22	Power Board Valves **PBV**
P23	Staff Call **PERS-R**
P24	Control **SMPS-MS (NT)**
P25	Power Board Motors **PBM**
P26	Disinfection Valve **VD**
P27	Membrane Position Sensors Balance Chamber **MSBK**
P28	Temperature Sensor Dialysate **TSD**
P29	Temperature Sensor Heater Inlet **TSHE**
P30	Degassing Temperature Sensor **TSE**
P31	Level Sensor Upline Tank **NSVB**
P32	Blood Leak Detector **BL**
P33/P34	Digital Board **DB**
P35	Temperature Sensor BIC **TSBIC**
P36	Temperature Sensor Dialyser Inlet **TSDE**
P37	Temperature Sensor Dialysate Supervisor **TSD-S**
P38	Pressure Sensor Dialysate Outlet **PDA**
P39	Blood Side Pressure Sensor **PBLOOD**
P40/P41	Analog Board **AB (LLA)**
P42	END Conductivity Sensor (Controller/Supervisor) **ENDLF+S**
P44	BIC Conductivity Sensor **BICLF**
P45	Pressure Sensor Degassing **PE**
P47	Speed/Rotation Direction Venous Blood Pump **DZ/DR BPV**
P48	Speed/Rotation Direction Arterial Blood Pump **DZ/DR BPA**
P49	BIC and Concentrate Sensors for Suction Rods **BIC-K**
P50	Rinsing Bridge Sensors **SBS**
P51	BIC Cartridge Holder Sensor **BKUS**
P54	Power Supply 2 **PS2**
P57	Power Supply Bedside Link **BSL-PWR**
P58/P60	Power Supply Hall Sensors

2.4 Power Board Valves PBV

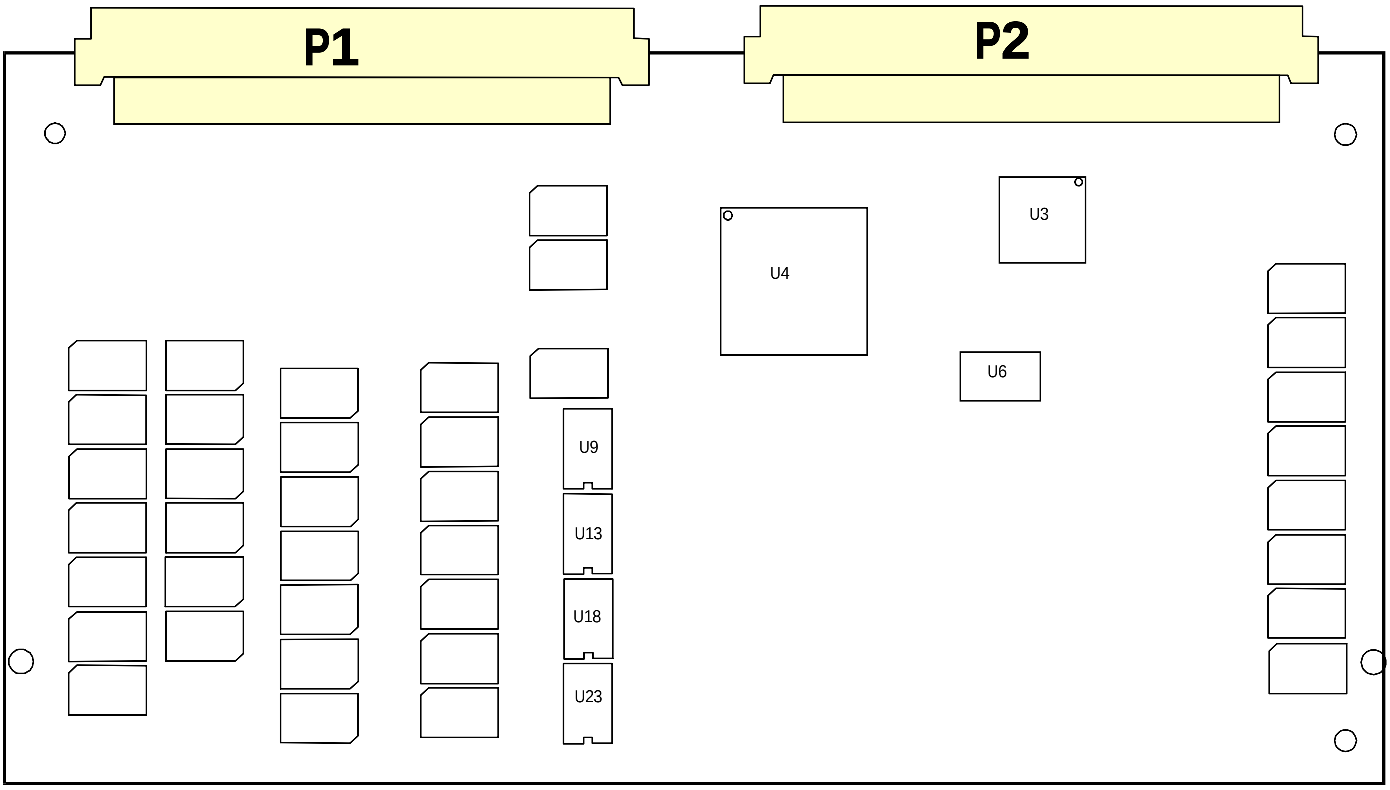


Fig. : Power Board Valves

2.4.1 Legend Power Board Valves

P1 Valves:

Inlet Upline Tank Valve **VVBE**
Degassing Inlet Valve **VEB**
Air Separator Valve Luftabscheider **VLA**
Dialyser Inlet Valve **VDE**
Dialyser Outlet Valve **VDA**
Bypass Valve **VBP**
Option BIC Cartridge Valves **VBICP, VBKS, VBKO, VVB**
Disinfection Valve **VD**
Circulation Valve **VZ**
Venous Tubing Clamp **SAKV**
Arterial Tubing Clamp **SAKA**

P2 Valves:

Valve Balance Chamber **VDEBK1/2, VDABK1/2, VEBK1/2, VABK1/2**
Valves Level Module **VBT, VPV, VPE, VPU, VPD, VPA**

2.5 Power Board Motors PBM

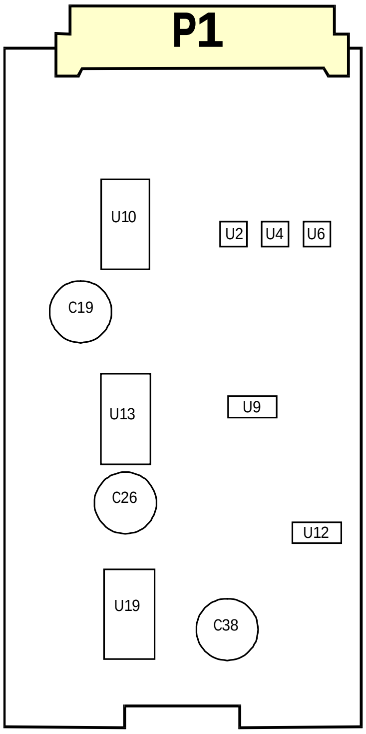


Fig. : Power Board Motors

2.5.1 Legend Power Board Motors

P1	BIC Piston Pump **BICP** Concentrate Piston Pump **KP** UF Piston Pump **UFP** Level Regulation Pump (Diaphragm Pump) **LRP (PPR)**

2.6 Digital Board DB

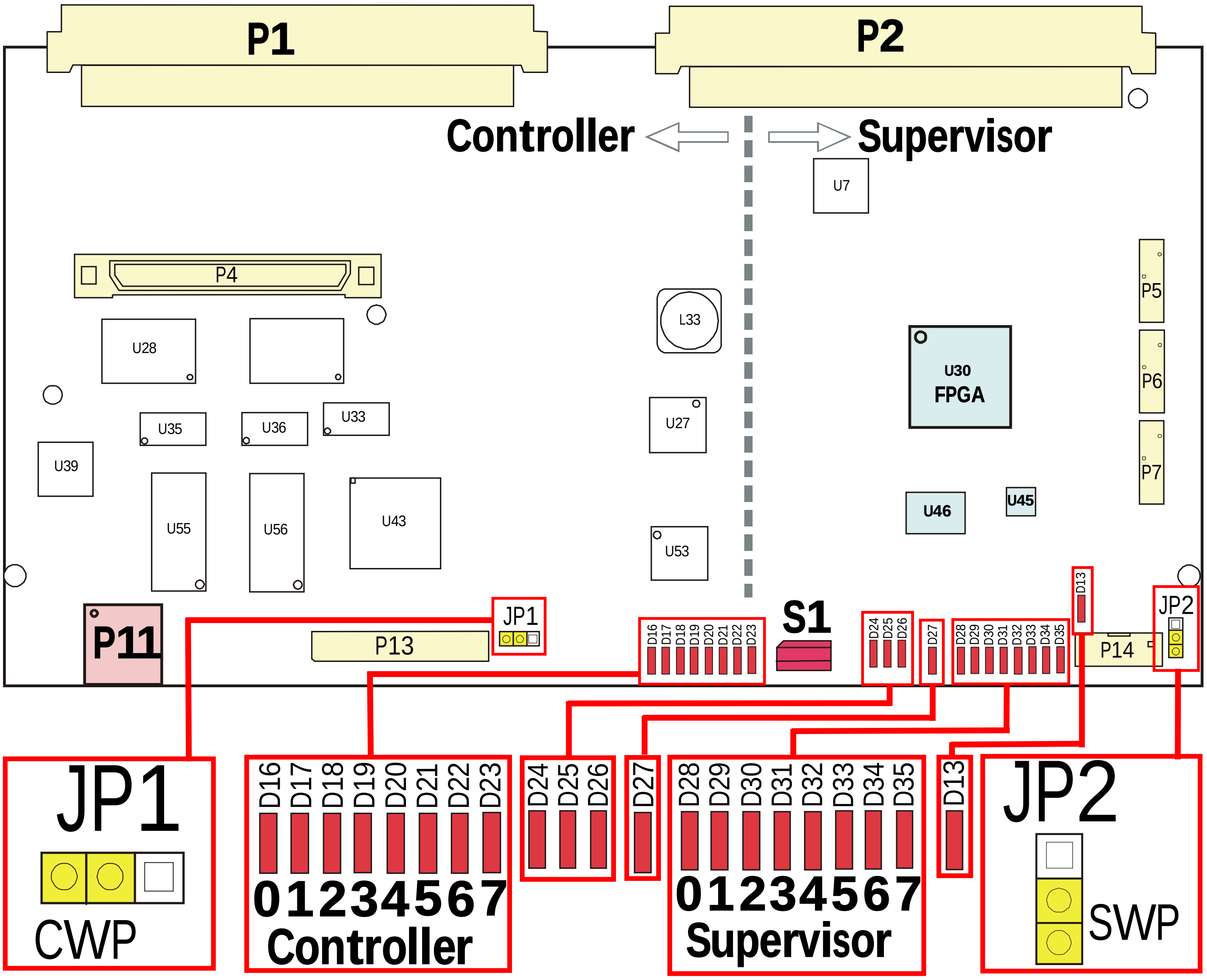


Fig. : Digital Board DB (LLD) with Controller and Supervisor

2.6.1 Legend Digital Board

Calibration Data
All calibration data are stored on the digital board. The calibration data must be stored additionally on the compact flash card CFC.

12 Bit AD Converter
Both supervisor and controller have a 12 bit AD converter with a range of 0 to 4095.

P4/P5/P6/P7/P13/P14: not applicable

P11 USB Type A for SW installation with USB stick

Supervisor Sensors:
BICPOS, KPPOS, UFPOS

Controller/Supervisor Sensors:
BKUS, SBS1, SBS2, BPS_IMP, BPA_DIR, BPV_IMP, BPV_DIR

Pumps:
BPA, BPV, EP, FPA, FPE

Controller Sensors:
NSVB, BICSS, KSS, MSBK1/2, RDV, SAD, BPADS, BPVDS,
BL (Controller/Supervisor Sensor Analog Board)

Jumper JP1:
Default: Controller Write Protect CWP (for controller firmware)

Controller LEDs D13 – D20:
Status 0 – 7 for installation of LLC software

FPGA LEDs V7 – V9: always ON
Voltages for FPGA (U30) and periphery
(FPGA: Field Programmable Gate Array – configurable logical circuit)

LED V10: flashes permanently
Cycle time, system is running

Supervisor LEDs V11 – V18:
Status 0 – 7 for installation of LLS software

LED V5: always ON after loading
The content of the memory (U45) is loaded to FPGA (U30) during switch-on. The therapy program and the service program is stored in the RAM (U45).

Jumper JP2:
Default: Supervisor Write Protect SWP (for supervisor firmware)

S1 **Service Switch:**
Position 0: Therapy Mode
Position 2: TSM Service Program Mode
Position 3: Software Installation/Update Mode

2.7 Analog Board AB

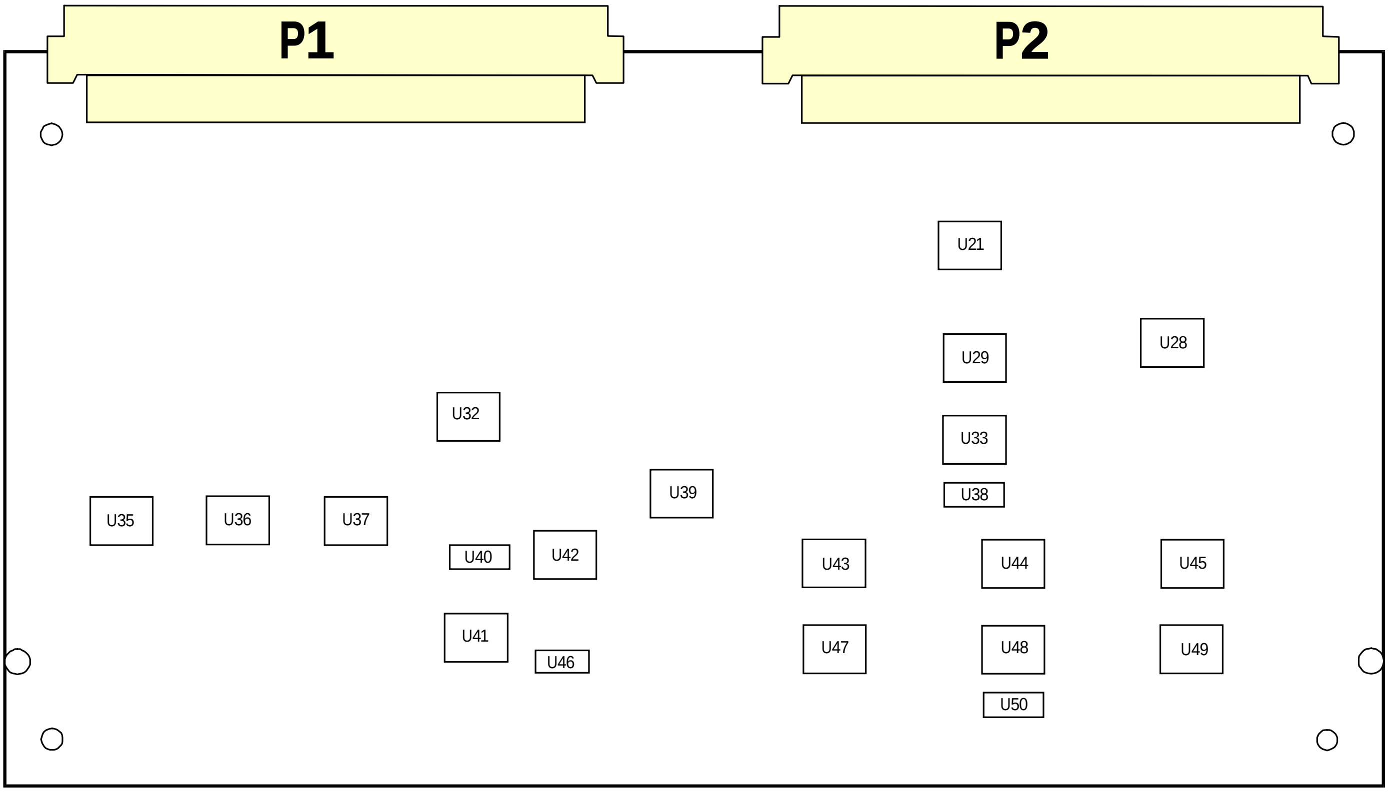


Fig. : Analog Board AB (LLA)

2.7.1 Legend Analog Board

P1/P2

Controller Sensors:
PBS, TSHE, TSE, TSBIC, TSD, TSDE, BICLF, ENDLF, PE, LAFS

Supervisor Sensors:
TSD-S, ENDLF-S

Controller/Supervisor Sensors:
BL, PBE, PA, PV, PDA

2.8 HDF Online Board HOB

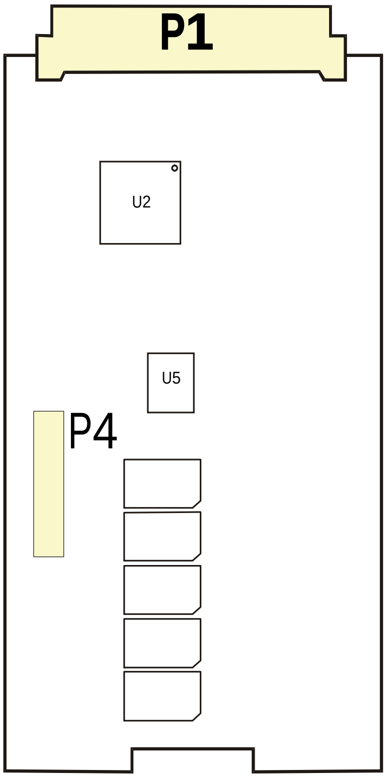


Fig. : HDF Online Board

2.8.1 Legend HDF Online Board

P1: Sensors: **PSABFS, PSAUS, PSPOSS, FEHDFS, FEDFFS**

P4: Valves **VBE, VDFF, VSAA, VSAE, VSB**

2.9 UF Sub-Rack

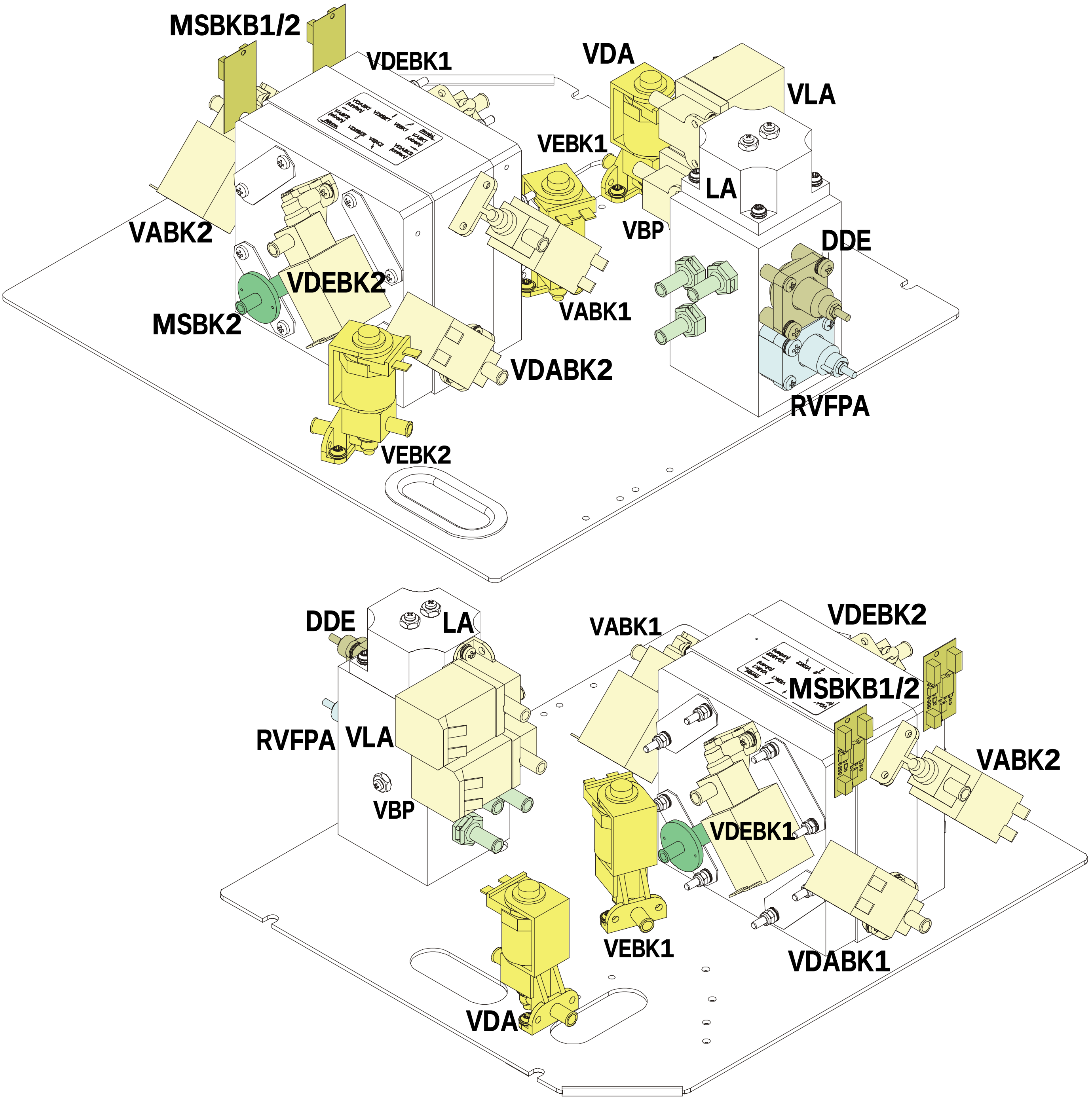


Fig. : UF Sub-Rack

2.9.1 Legend UF Sub-Rack

Balance Chamber **BK1/2**
Bypass Valve **VBP**
Throttle Dialyser Inlet **DDE**
Air Separator **LA**
Membrane Position Sensor Balance Chamber Board **MSBKB1/2**
Membrane Position Sensor Balance Chamber **MSBK1/2**
Non-Return Valve Outlet Flow Pump **RVFPA**
Outlet Balance Chamber Valve **VABK1**
Outlet Balance Chamber Valve **VABK2**
Outlet Dialyser Balance Chamber Valve **VDABK1**
Outlet Dialyser Balance Chamber Valve **VDABK2**
Inlet Dialyser Balance Chamber Valve **VDEBK1**
Inlet Dialyser Balance Chamber Valve **VDEBK2**
Inlet Balance Chamber Valve **VEBK1**
Inlet Balance Chamber Valve **VEBK2**
Air Separator Valve **VLA**

2.10 UF Sub-Rack HDF Online

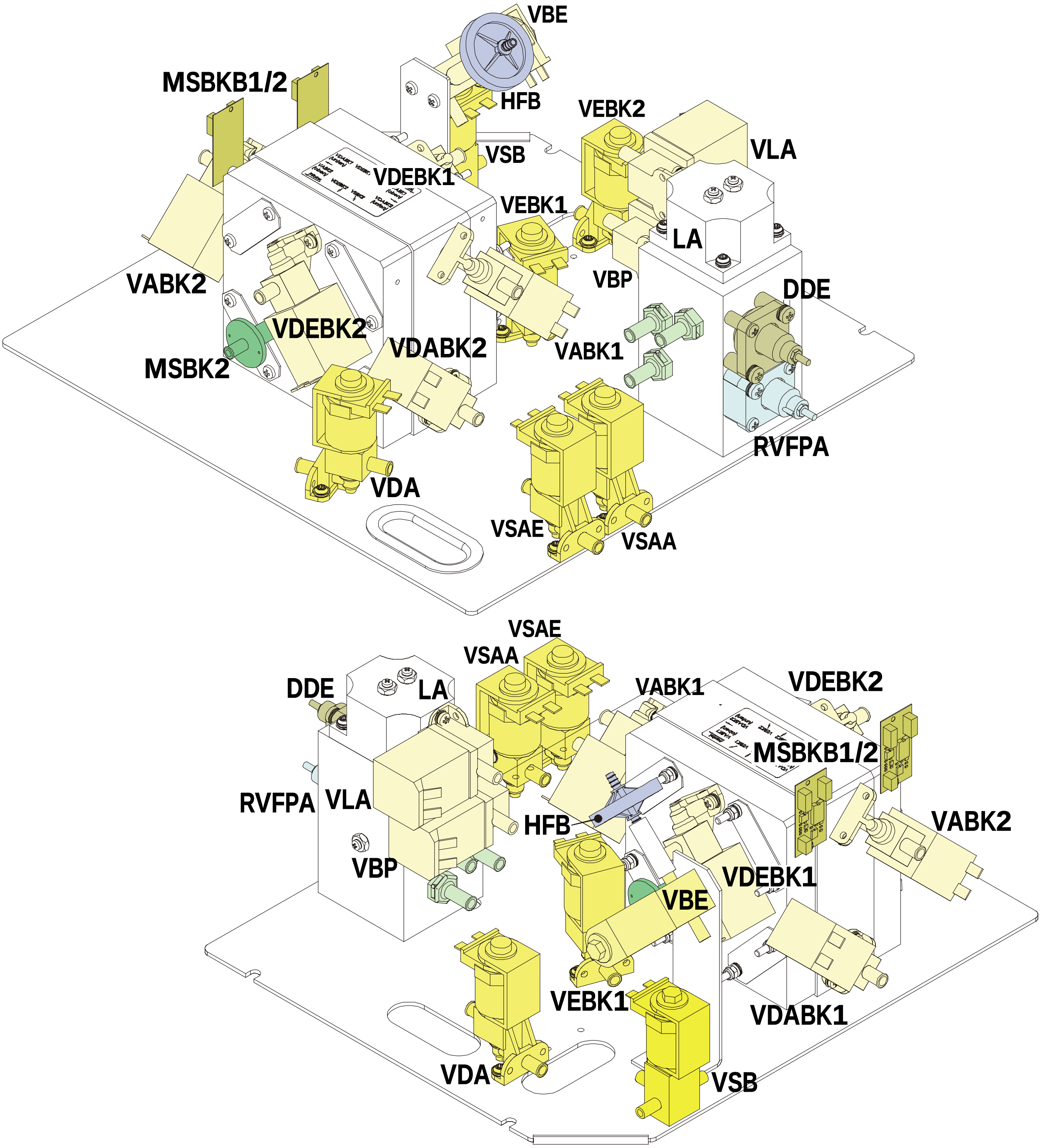


Fig. : UF Sub-Rack HDF Online

2.10.1 Legend UF Sub-Rack HDF Online

Balance Chamber **BK1/2**
Bypass Valve **VBP**
Throttle Dialyser Inlet **DDE**
Hydrophobic Vent Filter **HFB**
Air Separator **LA**
Membrane Position Sensor Balance Chamber Board **MSBKB1/2**
Membrane Position Sensor Balance Chamber **MSBK1/2**
Non-Return Valve Outlet Flow Pump **RVFPA**
Outlet Balance Chamber Valve **VABK1/2**

Outlet Dialyser Balance Chamber Valve **VDABK1/2**
Inlet Dialyser Balance Chamber Valve **VDEBK1/2**
Inlet Balance Chamber Valve **VEBK1/2**
Air Separator Valve **VLA**
Additional Components for HDF Online:
Substitute Bypass Valve **VSB**
Substitute Connection Outlet Valve **VSAA**
Substitute Connection Inlet Valve **VSAE**
Filter Vent Valve **VBE**

2.11 DF Sub-Rack

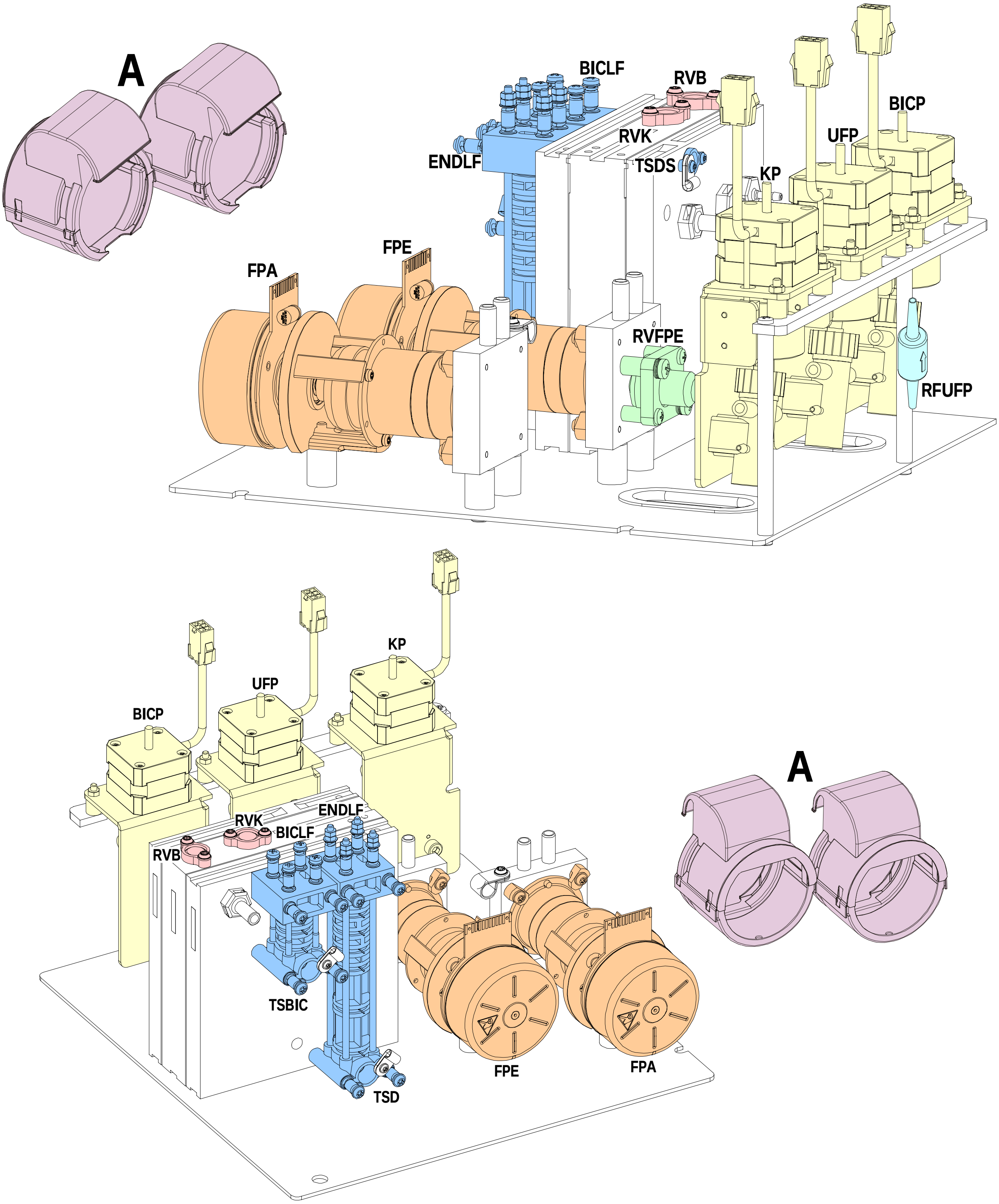


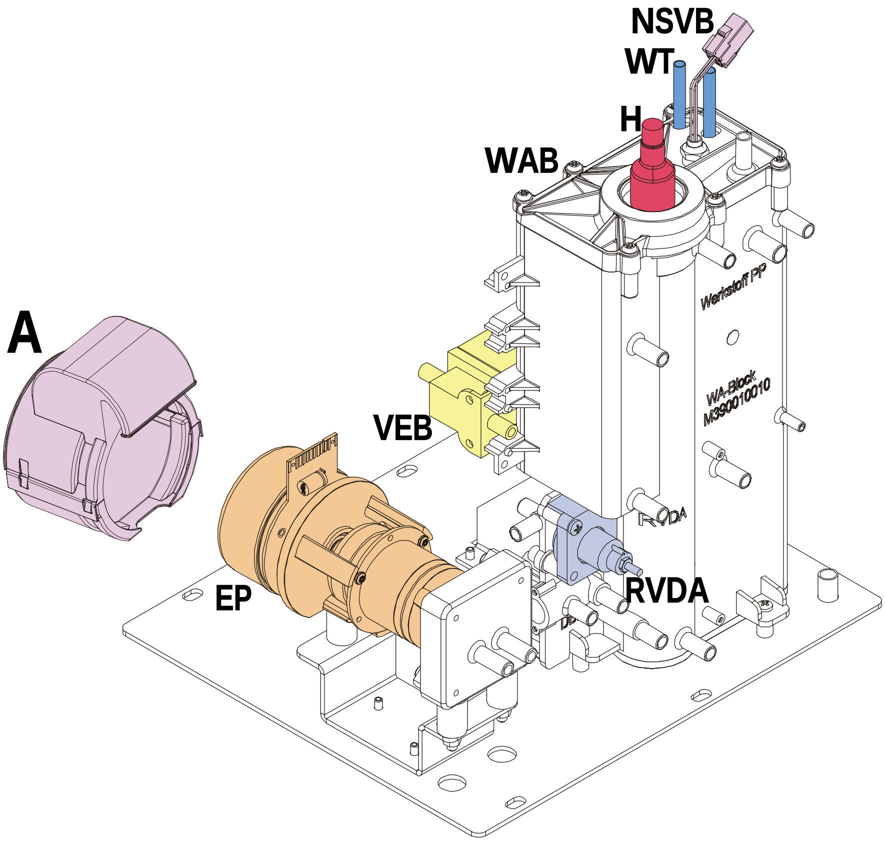
Fig. : DF Sub-Rack

2.11.1 Legend DF Sub-Rack

BIC Pump **BICP**
Degassing Pressure Sensor **PE**
END Conductivity/Supervisor **ENDLF/ENDLF-S**
Outlet Flow Pump **FPA** (Motor Cover **A**)
Inlet Flow Pump **FPE** (Motor Cover **A**)
Concentrate Pump **KP**
Bicarbonate Conductivity Sensor **BICLF**
Bicarbonate Non-Return Valve **RVB**

Non-Return Valve Flow Pump Inlet **RVFPE**
Non-Return Valve Concentrate **RVK**
Non-Return Valve UF Pump **RFUFP**
Bicarbonate Temperature Sensor **TSBIC**
Dialysate Temperature Sensor **TSD**
Dialysate Supervisor Temperature Sensor **TSD-S**
UF Pump **UFP**

2.12 Water Sub-Rack



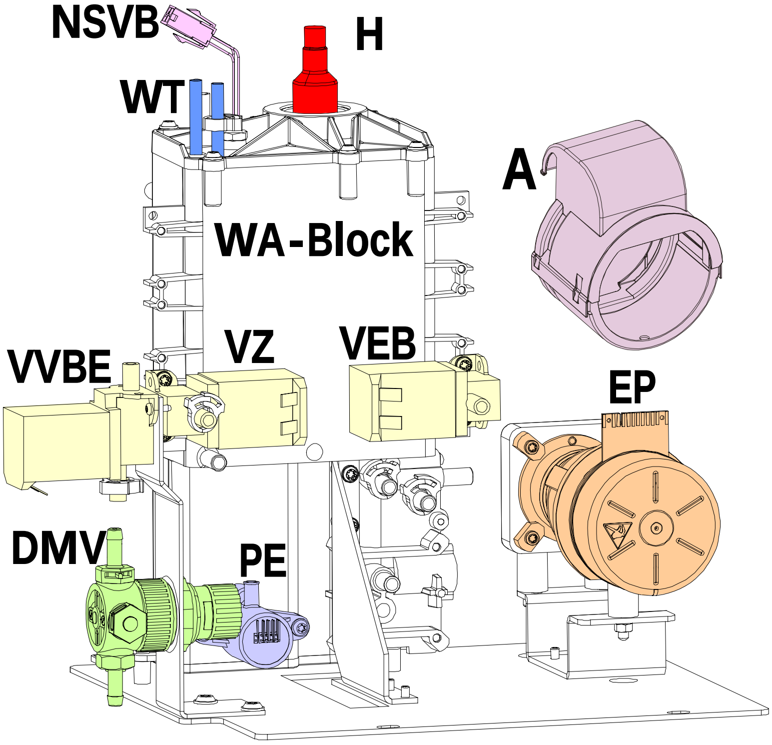


Fig. : Water Sub-Rack

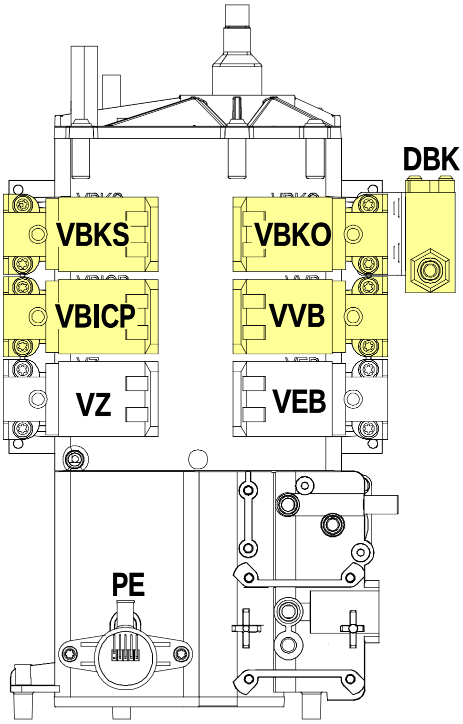


Fig. : Water Block with Valves for BIC Option

2.12.1 Legend Water Sub-Rack

Water Block **WAB** (with integrated Degassing Chamber **EK**, Upline Tank **VB** and Heat Exchanger **WT**)
Pressure Reducer **DMV**
Degassing Pressure Sensor **PE**
Degassing Chamber **EK**
Degassing Pump **EP** (Motor Cover **A**)
Heater **H**
Degassing Temperature Sensor **TSE**
Heater Temperature Sensor **TSH**
Heater Inlet Temperature Sensor **TSHE**

Upline Tank Inlet Valve **VVBE**
Upline Tank **VB**

Additional Components for Option BIC Cartridge:
Throttle BIC Cartridge Holder **DBK**
BIC Concentrate Suction Rod Valve **VBKS**
Top BIC Cartridge Valve **VBKS**
BIC Pump Valve **VBICP**
Upline Tank Valve **VVB**

2.13 Rinsing Bridge

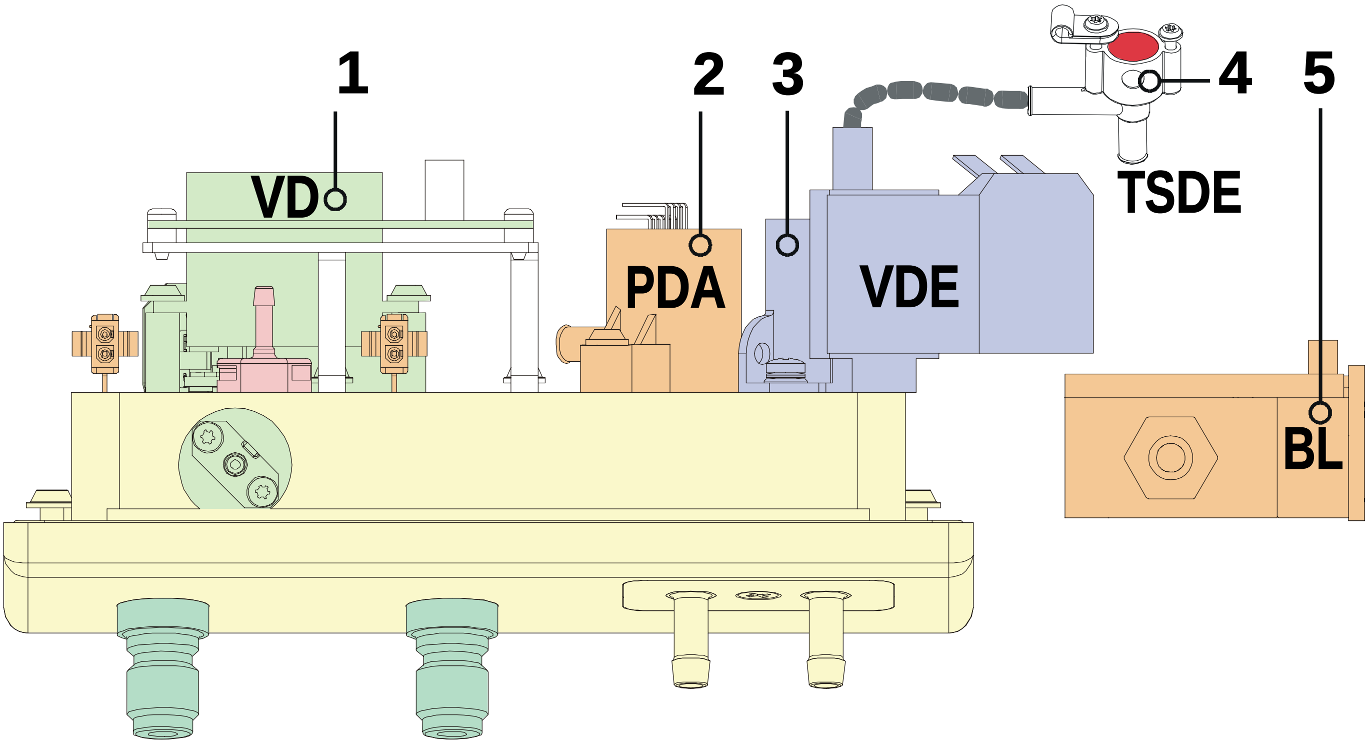


Fig. : Rinsing Bridge

2.13.1 Legend Rinsing Bridge

1 Disinfection Valve **VD**
2 Pressure Sensor Dialysate Outlet **PDA**
3 Dialyser Inlet Valve **VDE**
4 Temperature Sensor Dialyser Inlet **TSDE**
5 Blood Leak Detector **BL**

2.14 Rear Door

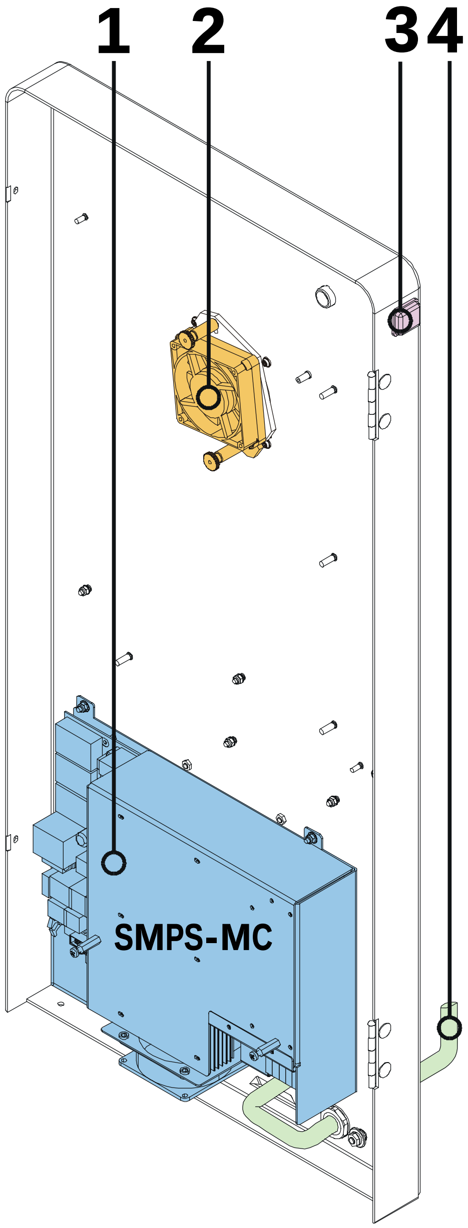


Fig. : Rear Door

2.14.1 Legend Rear Door

1. Switch Mode Power Supply Microcontroller **SMPS-MC**
2. Fan
3. Mains Switch
4. Mains Cord

2.15 Switch Mode Power Supply Microcontroller SMPS-MC

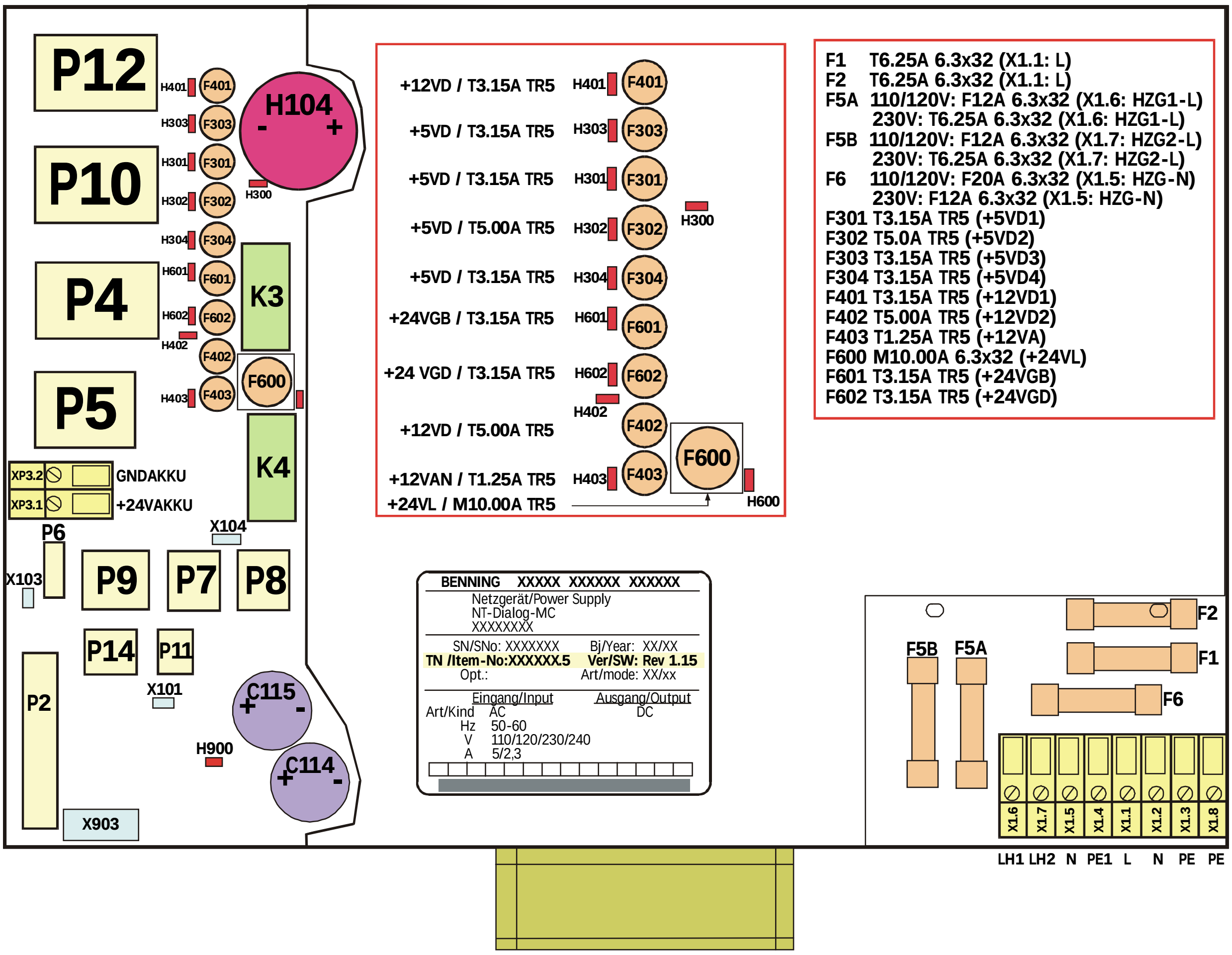


Fig. : Switch Mode Power Supply Microcontroller SMPS-MC

2.15.1 Legend Switch Mode Power Supply Microcontroller

X1.1	Mains Input L
X1.2	Mains Input N
X1.3	Mains Input PE
X1.4	Heater PE1
X1.5	Heater N
X1.6	Heater LH1
X1.7	Heater LH2
X1.8	PE
P2	Power Supply Control from Low Level Digital Board/Basic Board
XP3	Battery Connection (Screw Terminal)
P4	24 V Voltages

P5	12 V Voltages
P7	ABPM Option
P8	DSI Option
P9	Fan, Mains Switch
P10	Motherboard, Front Panel Board
P12	Options
P13	-
P14	EXT EIN
P101	Service Watchdog
X100	Fan

F1/F2	6.25 AT (6.3x32), Mains Input
F5A/F5B	12 AF (6.3x32), Heater 1800 W (110/120 V) 6.25 AT (6.3x32), Heater 1800 W (230/240 V)
F6	20 AF (6.3x32), Heater 1800 W (110/120 V) 12 AF (6.3x32), Heater 1800 W (230/240 V)
F301	3.15 AT (TR5), +5 VD
F302	5.00 AT (TR5), +5 VD

F303/F304	3.15 AT (TR5), +5 VD
F401	3.15 AT (TR5), +12 VD
F402	5.00 AT (TR5), +12 VD
F403	1.25 AT (TR5), +12 VAN
F600	10 AM (6.3x32), +24 VL
F601/F602	3.15 AT (TR5), +24 VGB

Type Plate SMPS-MC

TN/Item-No (Version Number SMPS-MC): e.g. XXXXXX.5

Ver/SW (SW Version): e.g. Rev. 1.15

2.16 TFT Monitor

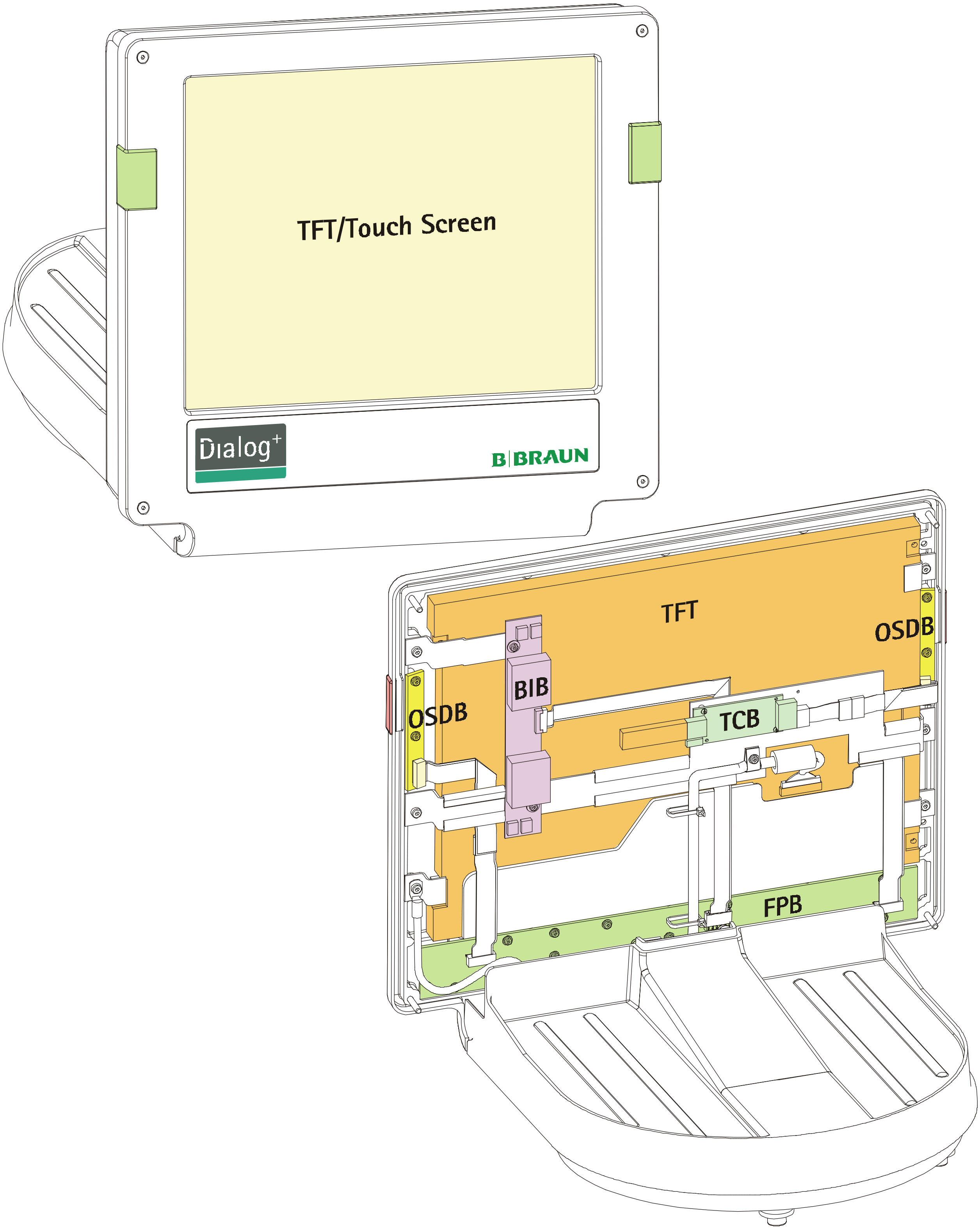


Fig. : TFT Monitor

2.16.1 Legend TFT Monitor

Backlight Inverter Board **BIB**	Optical Status Display Board **OSDB**
Front Panel Board **FPB**	Touch Controller Board **TCB**
TFT Monitor **TFT**	Touch Screen

2.17 Front Door

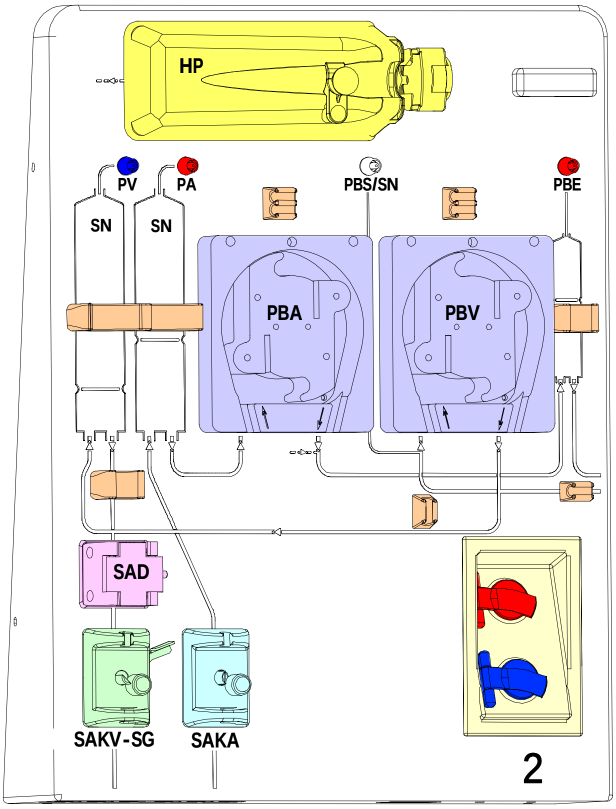


Fig. : Front Door with Double Pump

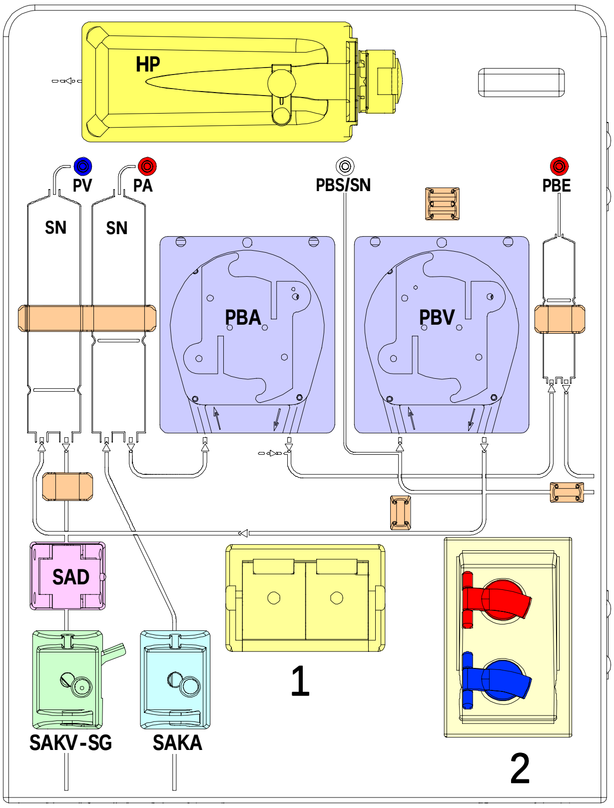


Fig. : Front Door for HDF Online

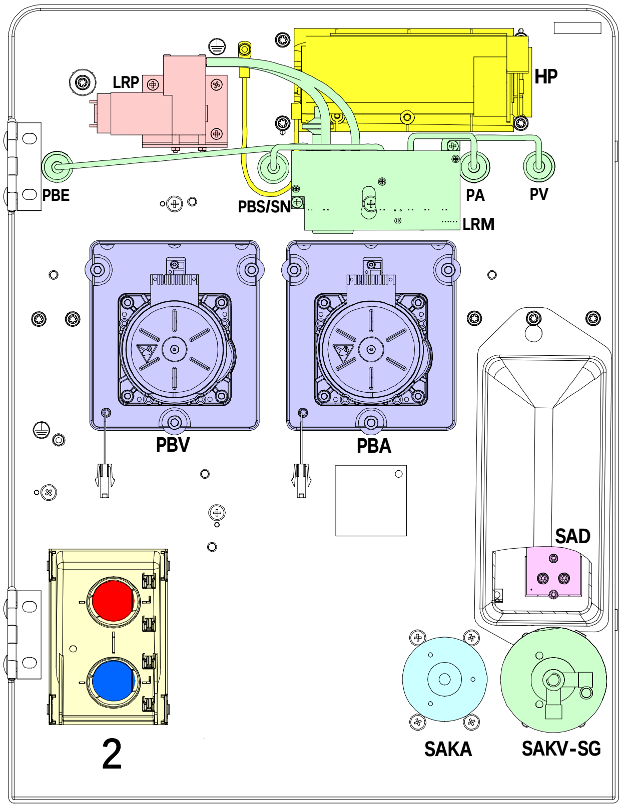


Fig. : Front Door (Inside) with Double Pump

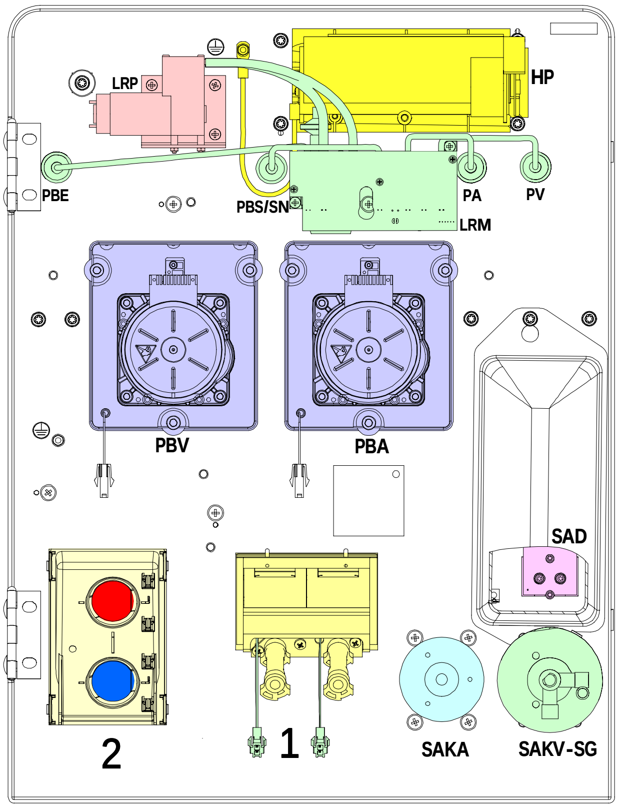


Fig. : Front Door (Inside) for HDF Online

2.17.1 Legend Front Door

Cover for Suction Rods **2**
Arterial Blood Pump **BPA**
Venous Blood Pump **BPV**
Pressure Sensor **PBE**
Pressure Sensor **PBS/SN**
Arterial Pressure Sensor **PA**
Venous Pressure Sensor **PV**

Heparin Pump Compact **HP**
Arterial Tubing Clamp **SAKA**
Venous Tubing Clamp Current Closed **SAKV-SG**
Safety Air Detector **SAD**/Venous Red Detector **RDV**
Substitution Port **1**
Connection for concentrate Suction Rods **2**

2.18 Level Regulation Module

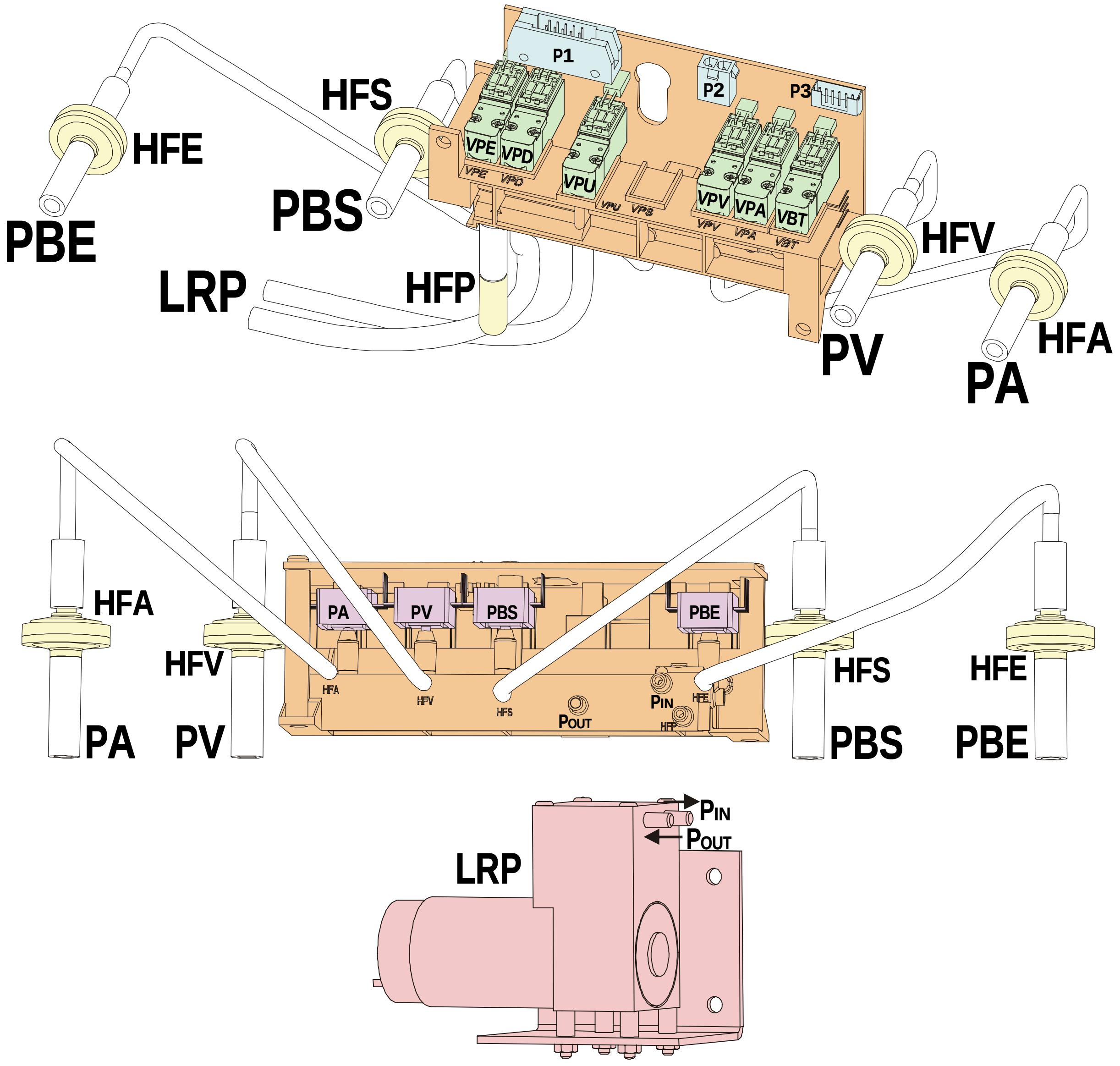


Fig. : Level Regulation Module and Level Regulation Pump

2.18.1 Legend Level Regulation Module

There are two level regulation modules with different assemblies, i.e. for machines with a single blood pump and with a double blood pump.

Inlet Pressure Sensor Valve **VPE**
Down Pressure Sensor Valve **VPD**
Up Pressure Sensor Valve **VPU**
Blood Control Pressure Sensor Valve **VPS** (Double Pump)
Venous Pressure Sensor Valve **VPV**
Arterial Pressure Sensor Valve **VPA**
Blood Side Test Pressure Sensor Valve **VBT**

Level Regulation Pump **LRP**

Arterial Hydrophobic Filter **HFA**
Venous Hydrophobic Filter **HFV**
Blood Control Pressure Hydrophobic Filter **HFS** (Double Pump)
Inlet Hydrophobic Filter **HFE**
Pump Hydrophobic Filter (Ceramic Filter) **HFP**

2.18.2 Flow Diagram Level Regulation Module

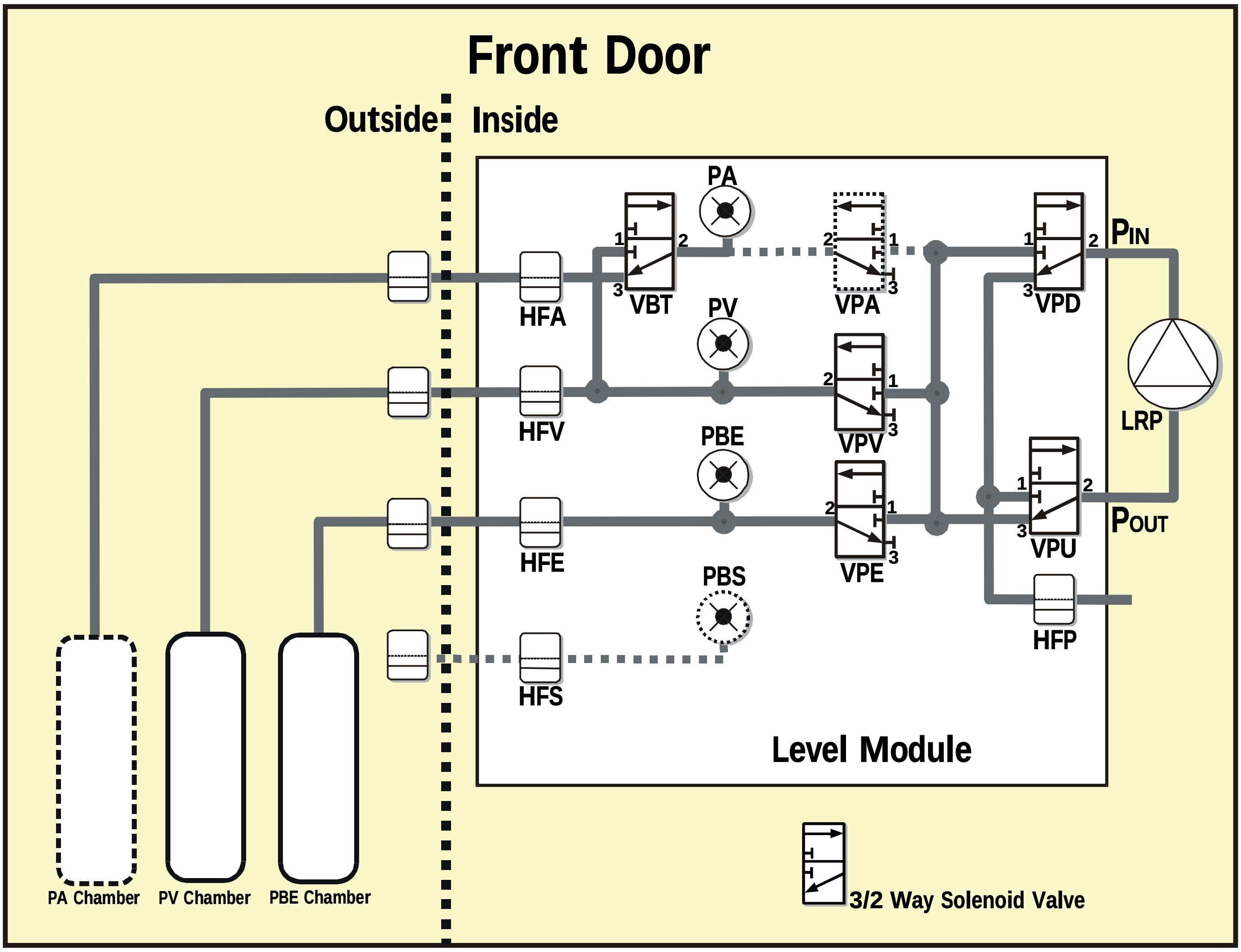


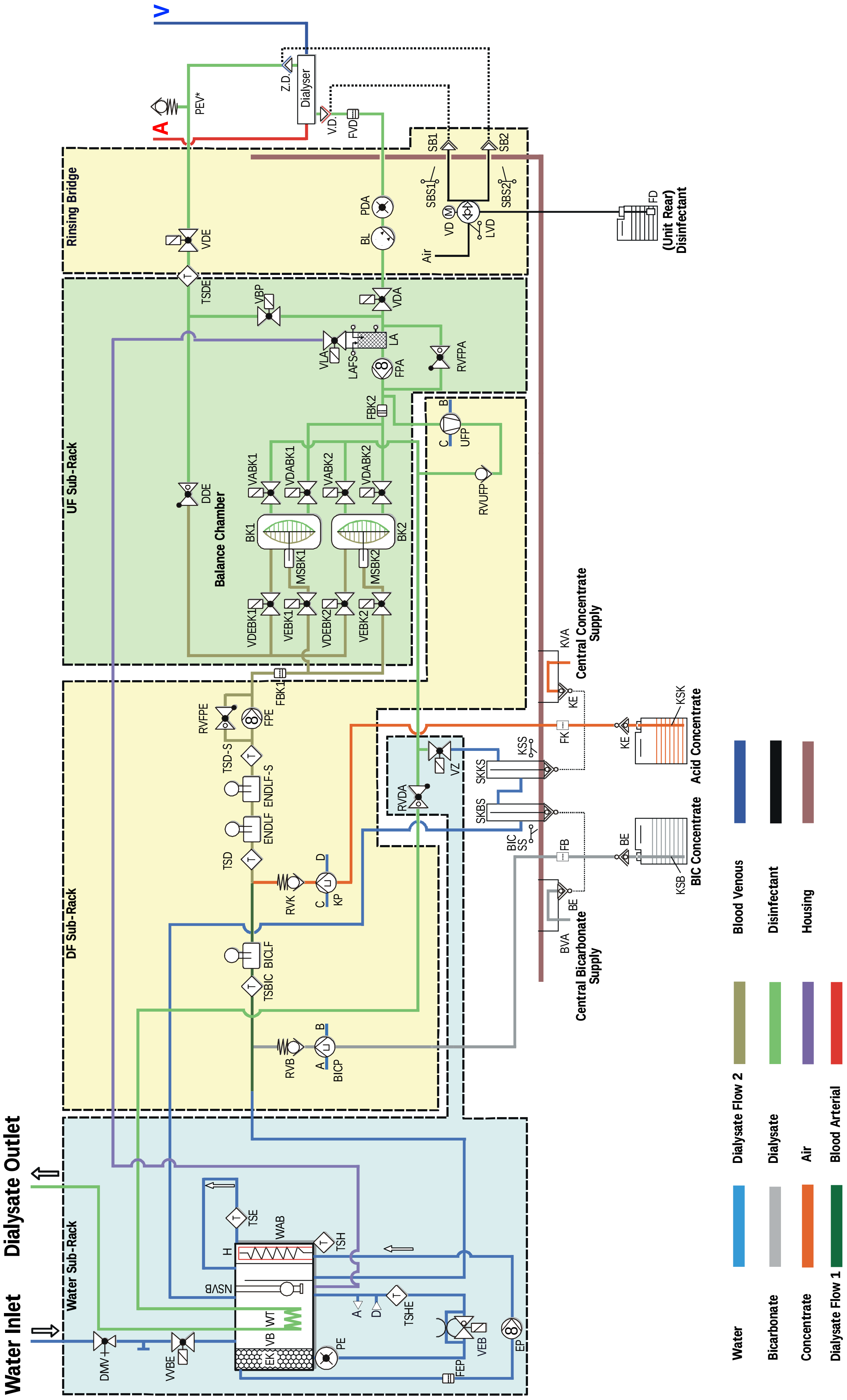
Fig. : Flow Diagram Level Regulation Module

There are two level regulation modules with different assemblies, i.e. for machines with a single blood pump and with a double blood pump. The level regulation module and the level regulation pump **LRP** are assembled on the inside of the rear door. The level regulation module and **LRP** have the following functions;

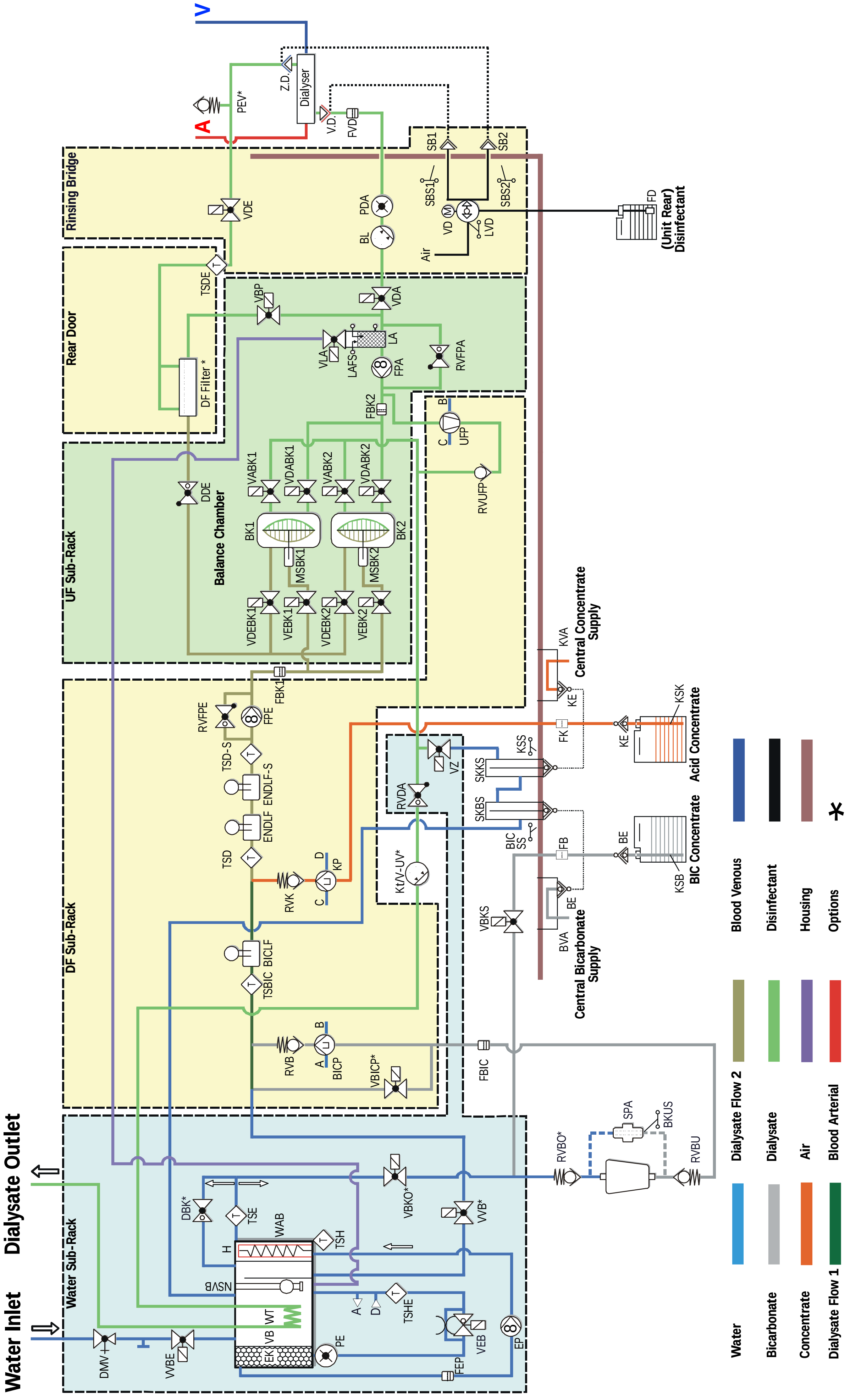
- Setting of the level in all blood side chambers (3/2 way solenoid valves **VPA**, **VPV**, **VPE**, **VPU**, **VPD** and diaphragm pump **LRP**)
- Monitoring of the blood side pressures (pressure sensors **PA**, **PV**, **PBE** and **PBS**)
- Test of the blood side pressure sensors in preparation (3/2 way solenoid valve **VBT**)

2.19 Flow Diagrams

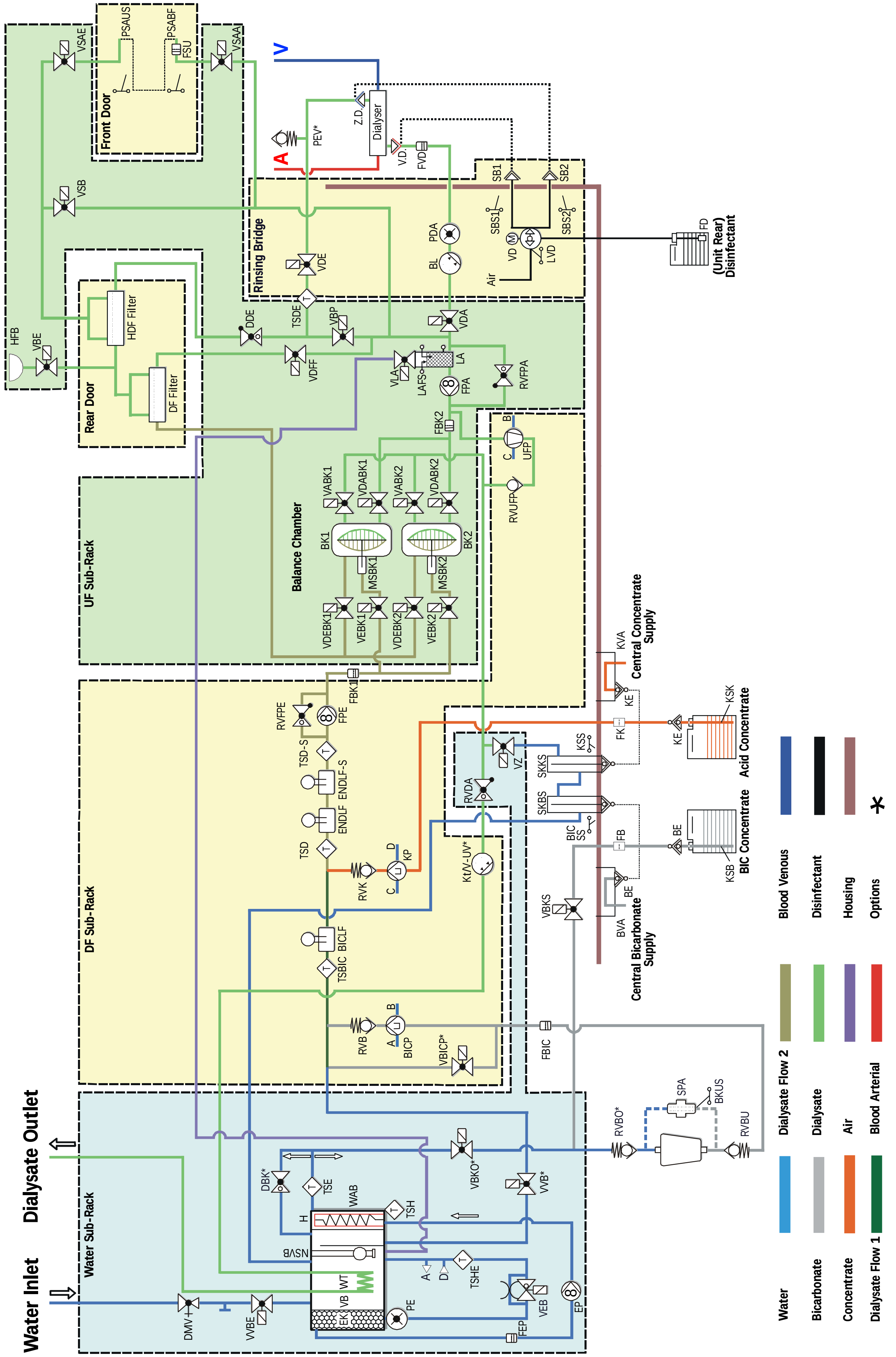
2.19.1 Dialog+



2.19.2 Dialog+ with BIC Option and DF Filter Option



2.19.3 Dialog+ HDF Online



2.19.4 Legend Flow Diagram

Abbreviation	Description
BE	Bicarbonate Withdrawal
BICLF	Bicarbonate Conductivity
BICP	Bicarbonate Pump
BICSS	Bicarbonate Rinsing Connection Sensor
BK1	Balance Chamber 1
BK2	Balance Chamber 2
BL	Blood Leak Detector
BPA	Arterial Blood Pump
BPV	Venous Blood Pump
BVA	Bicarbonate Supply Connection (Central Supply)
DBK	Throttle Bicarbonate Cartridge Holder
DDE	Throttle Dialyser Inlet
DMV	Pressure Reducer Valve
EK	Degassing Chamber
ENDLF	END Conductivity
ENDLF-S	END Conductivity Supervisor
EP	Degassing Pump
FB	Filter Bicarbonate
FBIC	Filter Bicarbonate Cartridge
FBK1	Filter Balance Chamber 1
FBK2	Filter Balance Chamber 2
FEP	Filter Degassing Pump
FK	Filter Concentrate
FM	Flowmeter
FPA	Outlet Flow Pump
FPE	Inlet Flow Pump
FVD	Filter from Dialysate
H	Heater
HP	Heparin Syringe Pump
KE	Concentrate Withdrawal
KP	Concentrate Pump
KSB	Bicarbonate Rod
KSK	Concentrate Rod
KSS	Concentrate Rinsing Connector Sensor
KVA	Concentrate Supply Connector (Central Supply)
LA	Air Separator
LAFS	Air Separator Level Sensors
LVD	Light Barrier Disinfection Valve
MSBK1	Membrane Position Sensor Balance Chamber 1
MSBK2	Membrane Position Sensor Balance Chamber 2
NSVB	Level Sensor Upline Tank
PA	Arterial Pressure Sensor
PBE	Pressure Sensor Blood Inlet
PBS	Blood Pressure Control Sensor
PDA	Pressure Sensor Dialysate Outlet
PE	Degassing Pressure Sensor

PV	Venous Pressure Sensor
RDV	Venous Red Detector
RVB	Throttle Bicarbonate
RVDA	Throttle Dialysate Valve
RVFPA	Throttle Flow Pump Outlet
RVFPE	Throttle Flow Pump Inlet
RVK	Throttle Concentrate
RFUFP	Throttle Ultrafiltration Pump
SAD	Safety Air Detector
SAKA	Arterial Tubing Clamp
SAKV-SD	Venous Tubing Clamp Currentless Closed
SBS1	Rinsing Bridge Connector Sensor 1
SBS2	Rinsing Bridge Connector Sensor 2
TSBIC	Bicarbonate Temperature Sensor
TSD	Dialysate Temperature Sensor
TSDE	Dialyser Inlet Temperature Sensor
TSD-S	Dialysate Temperature Sensor Supervisor
TSE	Degassing Temperature Sensor
TSH	Thermal Fuse Heater Element
TSHE	Heater Inlet Temperature Sensor
UFP	Ultrafiltration Pump
VABK1	Outlet Valve Balance Chamber 1
VABK2	Outlet Valve Balance Chamber 2
VB	Upline Tank
VBICP	Bicarbonate Pump Valve
VBKO	Bicarbonate Cartridge Holder Top Valve
VBKS	Bicarbonate Cartridge Holder Concentrate Rod Valve
VBP	Bypass Valve
V.D.	Dialyser Coupling (from Dialysate)
VD	Disinfection Valve
VDA	Dialyser Outlet Valve
VDABK1	Dialyser Outlet Valve Balance Chamber 1
VDABK2	Dialyser Outlet Valve Balance Chamber 2
VDE	Dialyser Inlet Valve
VDEBK1	Dialyser Inlet Valve Balance Chamber 1
VDEBK2	Dialyser Inlet Valve Balance Chamber 2
VEB	Degassing Bypass Valve
VEBK1	Inlet Valve Balance Chamber 1
VEBK2	Inlet Valve Balance Chamber 2
VLA	Air Separator Valve
VVB	Upline Tank Valve
VVBE	Upline Tank Inlet Valve
VZ	Circulation Valve
WA	Water Block
WT	Heat Exchanger
Z.D.	Dialyser Coupling (to Dialysate)

2.20 Description Flow Diagram

The flow diagram can be divided into six sections:

- Water Inlet Section with Water Block
- Degassing Circuit with Temperature System
- Dialysate Processing
- Balance Chamber
- Ultrafiltration
- Rinsing Bridge

2.20.1 Water Inlet Section with Water Block

The water inlet section has the following components

- Pressure Reducer Valve **DMV**
- Upline Tank Inlet Valve **VVBE** (2/2 way valve)
- Water Block **WAB** with integrated Upline Tank VB, Level Sensors Water Block **NSVB**, Heat Exchanger **WT**, 2 double-stage Heater **H**, Degassing Chamber **EK**

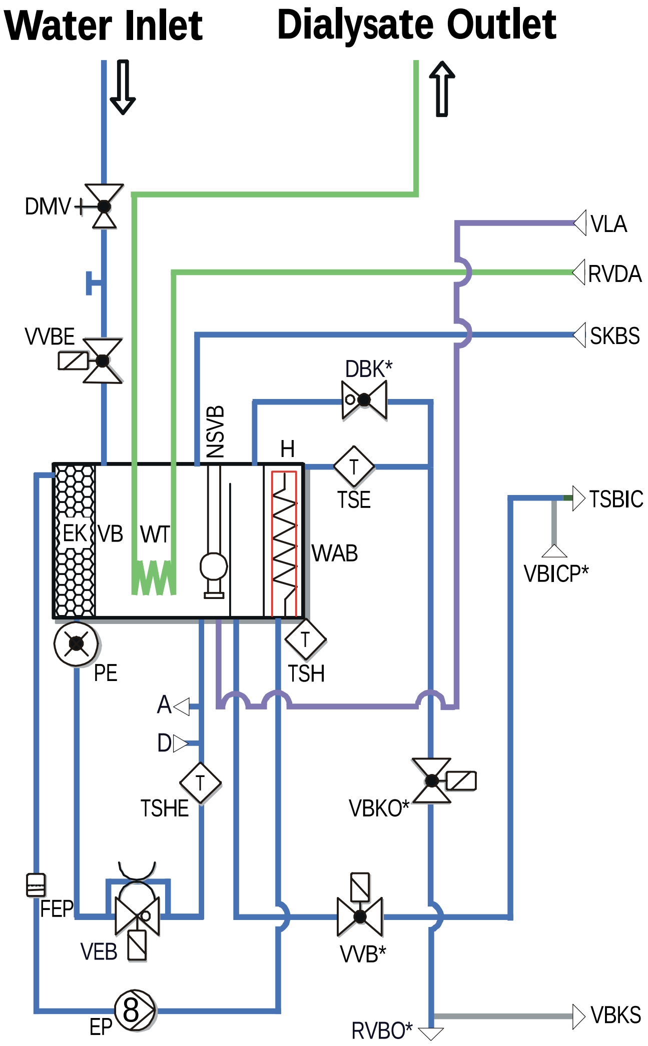


Fig. : Water Inlet with Water Block

Pressure Reducer Valve DMV

The pressure reducer valve DMV limits the pressure of the inlet water (e.g. osmosis water) to 0.9 ±0.1 bar.

Upline Tank Inlet Valve VVBE

The valve VVBE is time-delayed controlled via the level sensor **NSVB** (top) in the upline tank **VB**. The delay time depends on the dialysate flow.

Level Sensors Upline Tank NSVB

The level sensors are mounted in the upline tank VB.

NSVB top:

closed - VVBE is closed

NSVB bottom (monitoring low water level):

closed (alarm) - Water inlet is disturbed
- Heater is switched off
– Pumps are stopped

Heat Exchanger WT

The cold inlet water is warmed up via the heat exchanger WT. Thereby the heat consumption to heat up the water is reduced.

2.20.2 Degassing Circuit with Temperature System

The degassing circuit with temperature system has the following components:

- Degassing Bypass Valve **VEB**
- Degassing Pressure Sensor **PE**
- Degassing Chamber **EK**
- Degassing Pump **EP**
- Thermal Fuse Heater **TSH**
- Temperature Sensor Heater Inlet **TSHE**
- Double-Stage Heater **H**
- Degassing Temperature Sensor **TSE**

Degassing Bypass Valve VEB
Degassing Pressure Sensor PE
Degassing Pump EP

The degassing bypass valve VEB, pressure sensor PE, degassing chamber EK and degassing pump EP produce and measure a negative pressure respectively. The negative pressure is produced to separate the dissolved gas from the water.

If the degassing bypass valve VEB is closed, the flow path is reduced by means of a bypass constriction (orifice, throttle principle) in the valve. VEB is opened during disinfection to avoid this constriction. The desired negative pressure is gained by controlling the degassing pump EP. The value of the negative pressure is approx. -500 mmHg and thus always higher than the lower pressure of the dialysate behind the dialyser. The degassing pump works with constant speed, which is determined by the dialysate flow, unless the negative pressure is insufficient. Then the speed of EP is increased.

Heater H
Thermal Fuse Heater TSH
Degassing Temperature Sensor TSE

The heater H has an integrated thermal fuse TSH as a thermal cut-off. The temperature sensor TSE measures the actual temperature at the outlet of the heating.

Temperature Control

The required heat output is determined with the temperature sensors TSE and TSHE.

A detailed description for the double-stage heater control is described in the paragraph for the switch mode power supply microcontroller SMPS-MC.

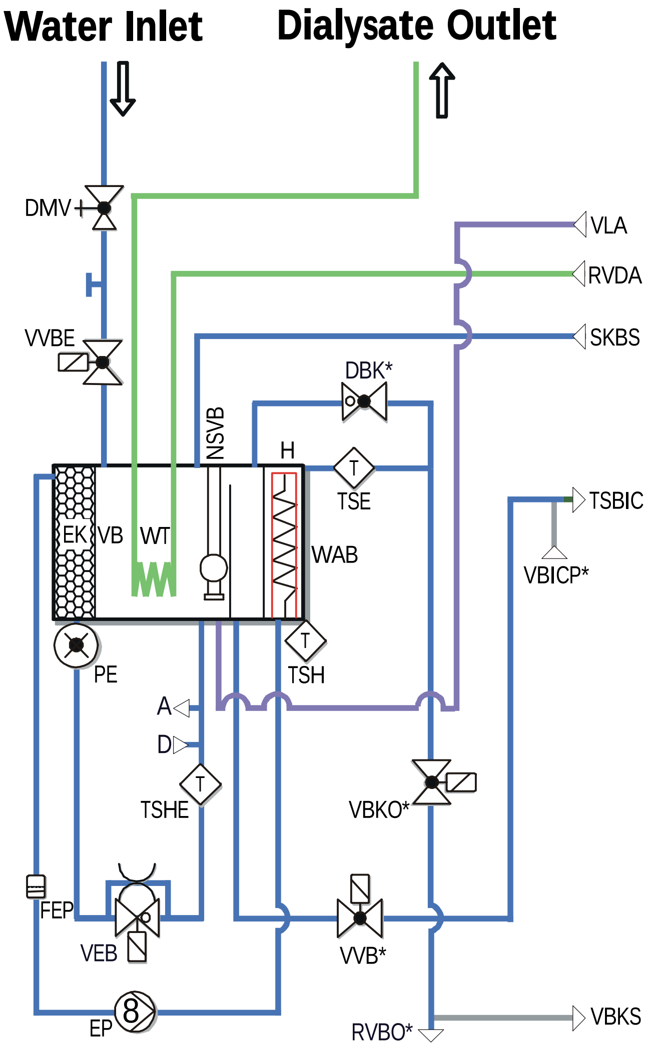


Fig. : Degassing Circuit with Temperature System

2.20.3 Dialysate Processing

The dialysate processing has the following components:

- Bicarbonate Concentrate Pump **BICP**
- Bicarbonate Throttle **RVB**
- Bicarbonate Temperature Sensor **TSBIC**
- Bicarbonate Conductivity **BICLF**
- Concentrate Pump **KP**
- Concentrate Throttle **RVK**
- END Conductivity **ENDLF**
- END Conductivity Supervisor **ENDLFS**
- Dialysate Temperature Sensor **TSD**
- Dialysate Temperature Sensor Supervisor **TSDS**
- Inlet Flow Pump **FPE**
- Inlet Flow Pump Throttle **RVFPE**
- Dialyser Inlet Temperature Sensor **TSDE**

The main components of the dialysate preparation are the bicarbonate concentrate pump BICP and the concentrate pump KP, with the conductivity cells BICLF and ENDLF and a flow pump FPE. The flow pump FPE delivers the dialysate. The bicarbonate concentrate, which is added via the bicarbonate pump BICP, is measured by the conductivity measurement cell BICLF. Thereby the pump can control the given conductivity set-point value.

The concentrate or acid concentrate addition has the same working principle. The nonreturn valves RVB and RVK stabilise the dosage of the bicarbonate and concentrate.

The temperature sensors TSBIC, TSD and TSDE are responsible for:

- the temperature compensation of the conductivity measurement and
- the temperature measurement TSD after the addition of cold concentrate (second measurement sensor for temperature system) and
- the temperature measurement TSDE directly before the dialysate leaves the machine and thus for the compensation of the temperature loss.

The conductivity sensor ENDLFS is an independent monitoring unit (supervisor). The geometry of the ENDLFS sensor is different (but has the same cell constant) than the ENDLF sensor of the controller. Thereby a deposit on the sensor can be identified. The temperature compensation is carried out by the temperature sensor TSDS. The temperature sensor additionally monitors the dialysate flow temperature for the supervisor. The ENDLFS and TSDS sensors have no influence on the respective control.

The throttle RVFPE prevents a high pressure build-up and thus a bursting of tubing if the flow path is blocked behind FPE. If the set pressure is reached RVFPE is opened and the fluid can circulate.

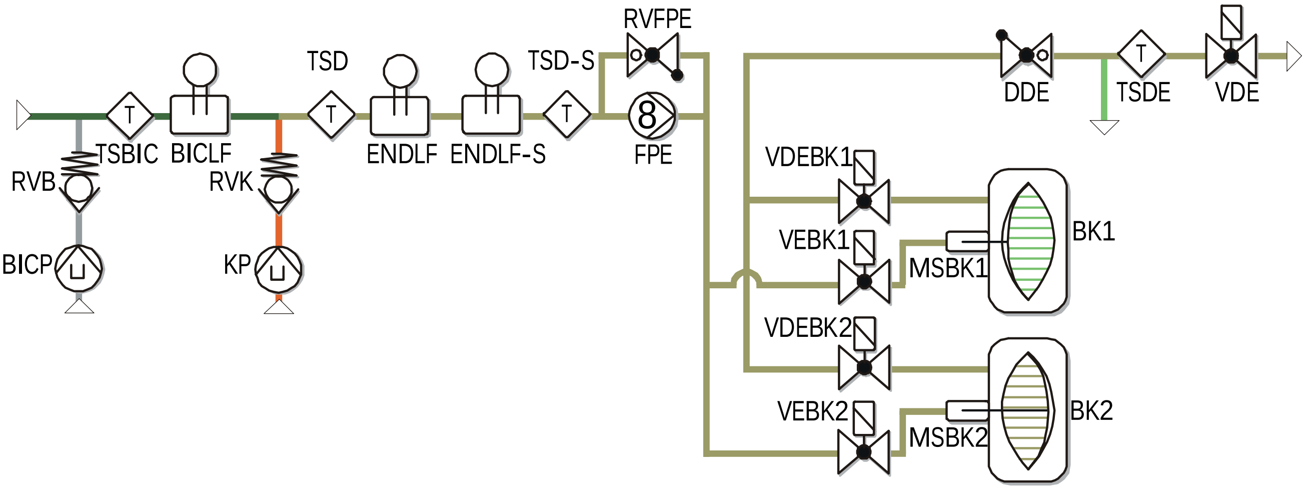


Fig. : Dialysate Processing

2.20.4 Central Bicarbonate and Concentrate Supply (Option)

A canister or central supply can be selected via the bicarbonate and concentrate supply connection BVA and KVA.

The flow pump FPE guarantees a continuous control of the desired dialysate flow into the balance chambers.

The flow rate is determined by the filling time of the balance chamber. The flow pump FPE is controlled via the predetermined volume of the chamber and a continuous detection of the position of the membrane.

2.20.5 BIC Cartridge Holder (Option)

DBK	**Throttle Bicarbonate Cartridge Holder** DBK ensures a constant pressure (approx. 300 mmHg) during the filling of the bicarbonate cartridge.
VBKO	**Bicarbonate Cartridge Holder Top Valve** The bicarbonate cartridge is filled to the limit pressure (300 mmHg) after VBKO opens.
VBKS	**Bicarbonate Cartridge Holder Concentrate Rod Valve** The bicarbonate cartridge is vented during preparation and in therapy, i.e. VBKO closes and VBKS opens for a short time. This is repeated in regular intervals during therapy. VBKS is opened after the end of the therapy to empty the bicarbonate cartridge.
VBICP	**Bicarbonate Pump Valve** VBICP opens shortly after the BIC cartridge was filled, to rinse away the initial bicarbonate. VBICP switches the BIC pump in bypass after the end of the therapy to empty the bicarbonate cartridge.
VVB	**Upline Tank Valve** VVB cuts off the main flow after the end of the therapy to empty the bicarbonate cartridge via FPE (VBICP and VBKS are opened).

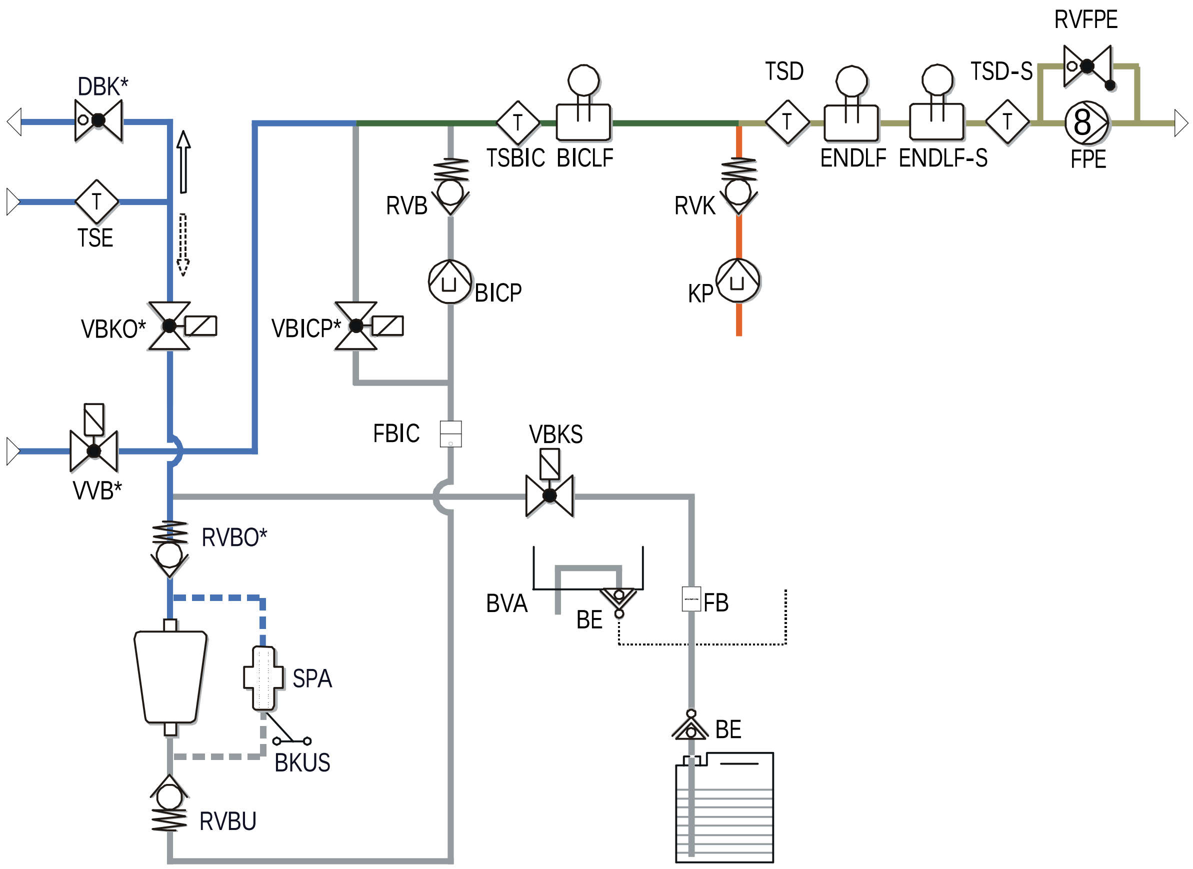


Fig. : BIC Cartridge Holder (Option)

2.20.6 Balance Chamber System

The balance chamber system has the following components:

- Balance Chamber **BK1**
- Balance Chamber **BK2**
- Balance Chamber Dialyser Inlet Valve **VDEBK1** and **VDEBK2**
- Balance Chamber Inlet Valve **VEBK1** and **VEBK2**
- Balance Chamber Membrane Position Sensor **MSBK1** and **MSBK2**
- Balance Chamber Dialyser Outlet Valve **VDABK1** and **VDABK2**
- Balance Chamber Outlet Valve **VABK1** and **VABK2**

The measurement and control of the ultrafiltration rate is accomplished by the double balance chamber system and the ultrafiltration pump UFP.

Both balance chambers BK1 and BK2 are identical. The chambers have flexible membranes, which can be moved to both sides. The membranes divide the chambers into two sub-compartments. The flow direction is defined by the membranes and the eight solenoid valves. The position of the membranes is measured by inductive membrane position sensors MSBK1 and MSBK2. The membrane position sensors (ferrites) are connected to the membranes and each move in a respective coil MSBK1 and MSBK2.

2.20.7 Working Principle Balance Chamber System

Phase 1:

The balance chamber BK1 is filled with dialysate at the beginning of phase 1. The membrane is in right position. The valves VDEBK1 and VDABK1 are opened. The balance chamber BK1 is filled by the outlet flow pump FPA with used dialysate, via valve VDABK1. Simultaneously the fresh dialysate is removed from the balance chamber BK1 via valve VDEBK1. Phase 1 is completed and the membrane is in left position (see figure).

The balance chamber BK2 is filled with fresh dialysate during this period. The used dialysate from the previous phase 2 is drained (see description phase 2).

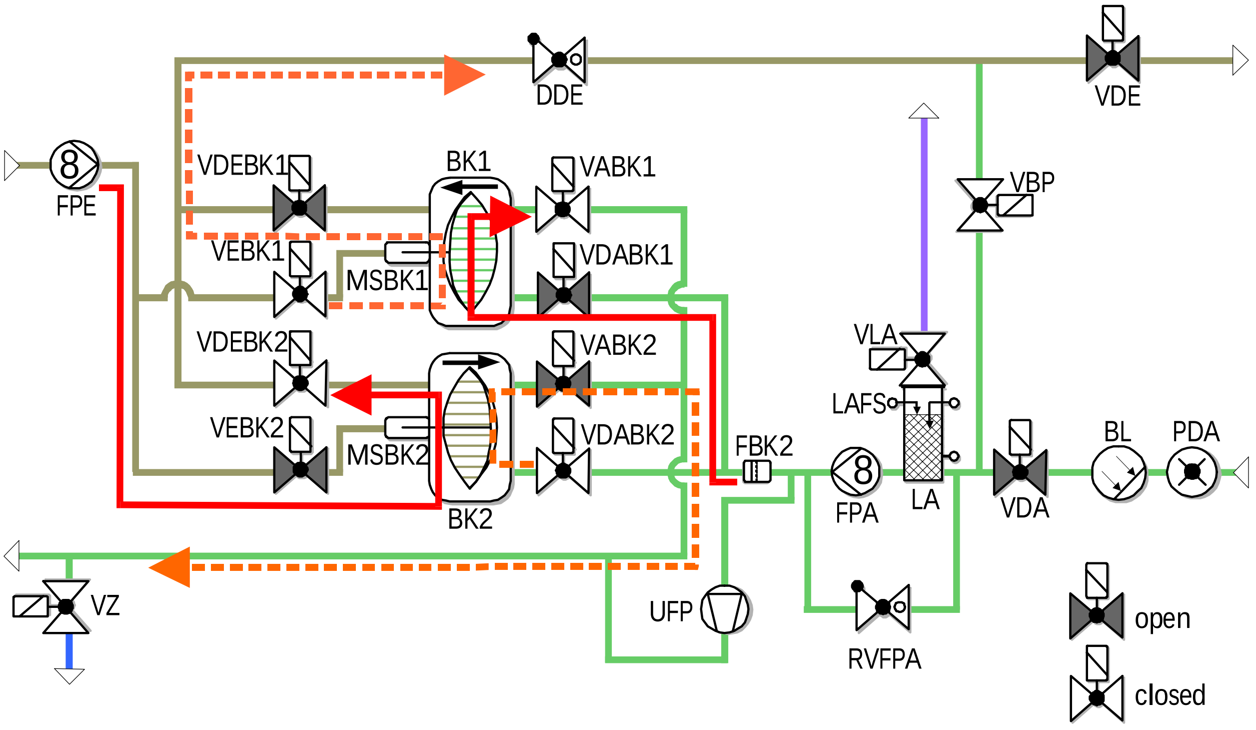


Fig. : Phase 1 Balance Chamber

Phase 2:

After phase 1 is completed there is an automatic switch to the filled balance chamber BK2 to obtain a constant flow in the dialyser. The complete cycle is repeated in phase 2, i.e. valves VDEBK2 and VDABK2 are opened. The balance chamber BK2 is filled via valve VDABK2. Simultaneously the dialysate is drained from the balance chamber BK2 via valve VDEBK2. Phase 2 is completed and the membrane is in left position (see figure).

Simultaneously the balance chamber BK1 is filled with fresh dialysate. Therefore valve VEBK1 is opened. Valve VABK1 is also opened, to initiate the flow path for the used dialysate to the drain. The membrane moves to the right position.

The outlet fluid volume is equal to the returned fluid volume, due to the closed balance chamber system

The fluid volume removed from the closed system via the ultrafiltration pump UFP is replaced from the blood in the dialyser and equals the precise ultrafiltration volume.

The system is initialised in preparation, i.e. the membrane sensors are automatically calibrated and the speed of the flow pumps FPE and FPA are determined. Thus a synchronisation of the membranes is guaranteed, and the pump speeds for the desired flow are determined.

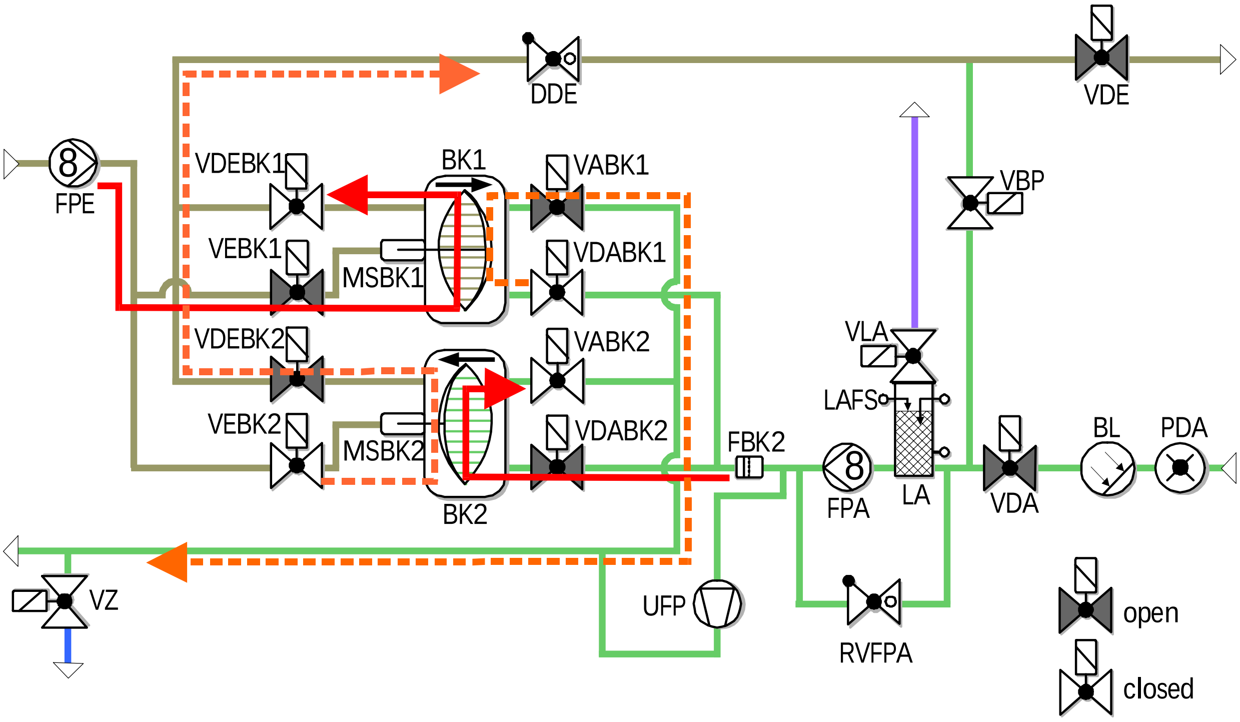


Fig. : Phase 2 Balance Chamber

2.20.8 Ultrafiltration and Rinsing Bridge

The main flow path and bypass have the following components:

- Dialyser Inlet Throttle **DDE**
- Dialyser Inlet Valve **VDE**
- Dialyser Outlet Valve **VDA**
- Bypass Valve **VBP**
- Outlet Flow Pump **FPA**

The flow path for the main flow and bypass are determined by the valves VDE, VDA and VBP. The built up flow from the flow pump FPA is stabilised by the throttle DDE. Valves VDE and VBP are closed for sequential therapy (ultrafiltration without dialysate fluid flow). The ultrafiltrate removal is carried out by the ultrafiltration pump UFP.

Further components are:

- Red sensitive blood leak detector BL
- Pressure sensor PDA which monitors the dialysate pressure (also used to calculate TMP)
- Air separator LA with built in level sensors LAFS and air separator valve VLA
- Throttle RVDA functions as a resistance to stabilise the flow of FPE

The throttle RVFPA prevents a high pressure build-up and thus a bursting of tubing if the flow path is blocked behind FPA. If the set pressure is reached RVFPA is opened and the fluid can circulate.

Detection of Air in Air Separator LA

If air is detected in the air separator LA by the air separator level sensors LAFS, the balance chamber switches to free flow:

VEBK1 and VDEBK2	opened
VABK1/2 and VDABK1/2	closed

VLA is opened and air is removed with positive pressure from LA. VLA is closed once air is not detected anymore by LAFS. The balance chamber is switched to normal operation.

2.20.9 Chemical Thermal Disinfection Program

Phase 1 The position of the couplings is checked by the sensors BICSS, KSS, SBS1 and SBS2. The machine starts to rinse as soon as the disinfection menu is entered. After the disinfection type is selected the machine will rinse for 3 minutes and preheat the system to 45 °C. During this phase all pumps (EP, FPE, FPA, BICP, KP, UFP) run and the valves are switched so that any residual concentrate is rinsed from the complete hydraulic circuit.

Phase 2 The air separator LA is filled with water via VLA. The upline tank VB is emptied, until the bottom NSVB is on, which switches off the heater H (VVBE is closed).

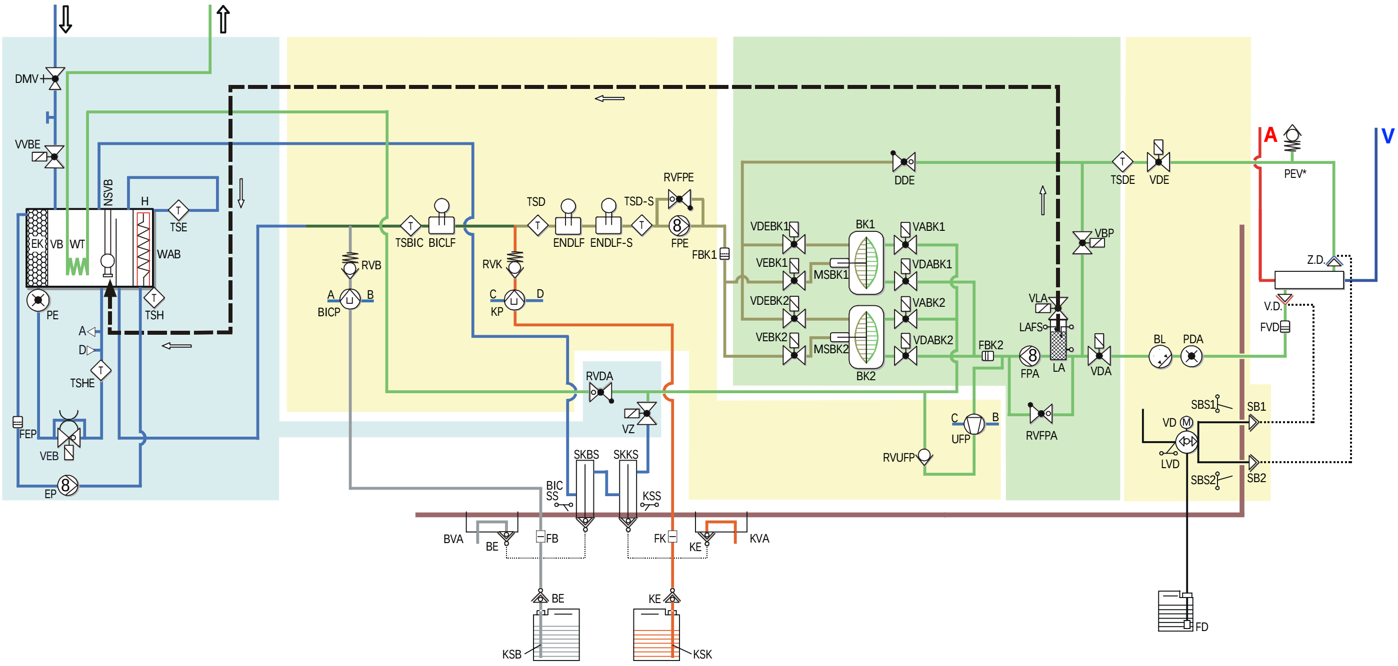


Fig. : Phase 2

Phase 3 With UFP running, a negative pressure of –100 mmHg is created at PDA. When this pressure is reached VD opens. The disinfectant is sucked into the hydraulic system by the UFP via the dialyser connectors. The circulation valve VZ is open and fluid flows into the upline tank of the water block WAB, because the throttle RVDA acts as a forward resistance. As soon as the correct volume is reached, the upline tank VB is filled up with fresh water (VVBE is controlled by NSVB).

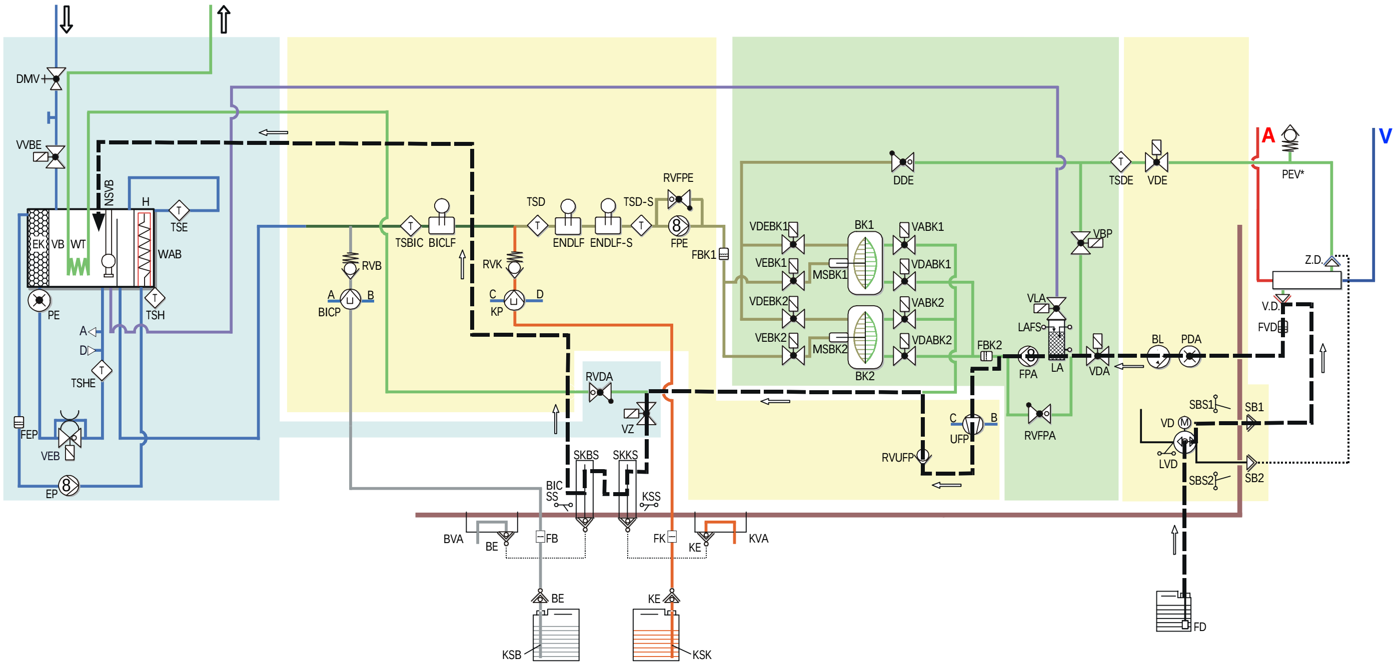


Fig. : Phase 3

Phase 4 The machine starts to recirculate the fluid, heating the system up to the desired temperature (e.g. 83 °C). Once this temperature is reached and a desired conductivity is reached (e.g. 2.2 mS/cm) the disinfection timer starts.

Phase 5 The machine recirculates the fluid, monitoring the temperature and conductivity until the disinfection time is reached. There is no flow of fluid to the drain during suction, heat-up and circulation. Then the machine starts with the VBICP test. The machine checks whether VVB and VBICP open and close properly. During the first step of this test VVB and VBICP are closed. With FPE and FPA still running this causes a negative pressure at PDA. VBICP then opens, causing a rapid increase in pressure at PDA.

Phase 6 The machine then starts to rinse with VZ closed until the rinsing time is reached, and the temperature has decreased below 40 °C and conductivity is below 0.1 mS/cm. Then the machine gives a message that asks the user to confirm that the machine is free of disinfectant and the disinfection is completed.

2.21 Block Diagram

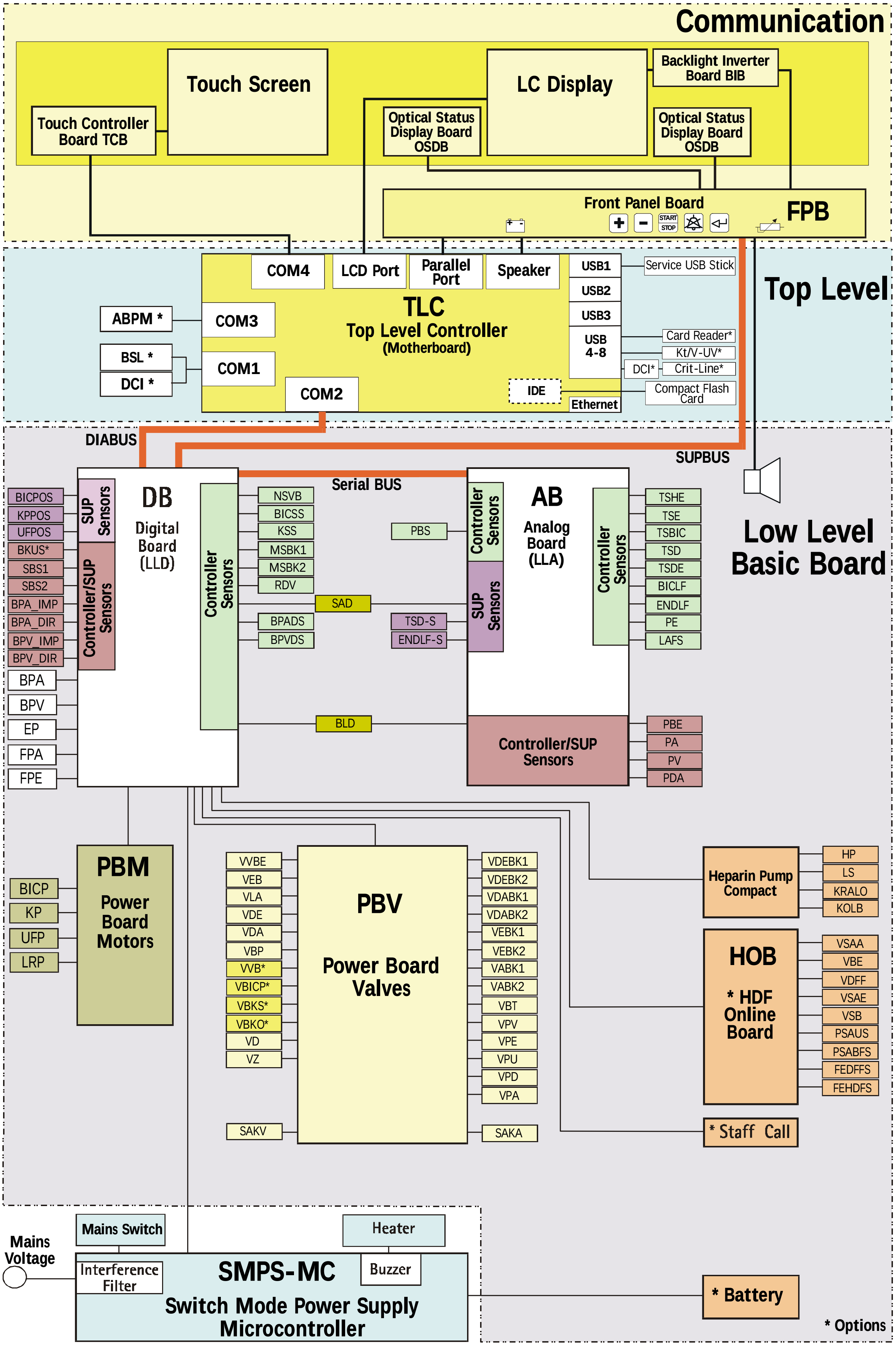


Fig. : Block Diagram

2.21.1 Legend Block Diagram

Digital Board DB

BPA	Arterial Blood Pump
BPV	Venous Blood Pump
EP	Degassing Pump
FPA	Outlet Flow Pump
FPE	Inlet Flow Pump
Supervisor	
BICPOS	Bicarbonate Pump Position Sensor
KPPOS	Concentrate Pump Position Sensor
UPPOS	UF Pump Position Sensor
Controller/Supervisor	
BKUS	Bottom Bicarbonate Cartridge Sensor
SBS1	Rinsing Bridge Connector Sensor 1
SBS2	Rinsing Bridge Connector Sensor 2
BPA_IMP	Arterial Blood Pump Motor Hall Sensor
BPA_DIR	Arterial Blood Pump Direction
BPV_IMP	Venous Blood Pump Motor Hall Sensor
BPV_DIR	Venous Blood Pump Direction
Controller	
NSVB	Level Sensor Upline Tank
BICSS	Bicarbonate Rinsing Connection Sensor
KSS	Concentrate Rinsing Connector Sensor
MSBK1	Membrane Position Sensor Balance Chamber 1
MSBK2	Membrane Position Sensor Balance Chamber 2
RDV	Venous Red Detector
SAD	Safety Air Detector
BPADS	Arterial Blood Pump Cover Switch
BPVDS	Venous Blood Pump Cover Switch

Analog Board AB

Controller	
PBS	Pressure Single Needle
TSHE	Heater Inlet Temperature Sensor
TSE	Degassing Temperature Sensor
TSBIC	Bicarbonate Temperature Sensor
TSD	Dialysate Temperature Sensor
TSDE	Dialyser Inlet Temperature Sensor
BICLF	Bicarbonate Conductivity
ENDLF	END Conductivity
PE	Degassing Pressure Sensor
LAFS	Air Separator Level Sensors
Supervisor	
TSD-S	Dialysate Temperature Sensor Supervisor
ENDLF-S	END Conductivity Supervisor

Controller/Supervisor

BLD	Blood Leak Detector
PBE	Pressure Sensor
PA	Arterial Pressure Sensor
PV	Venous Pressure Sensor
PDA	Pressure Sensor Dialysate Outlet

Power Board Motors PBM

BICP	Bicarbonate Pump
KP	Concentrate Pump
UFP	Ultrafiltration Pump
LRP	Level Regulation Pump

Power Board Valves PBV

VVBE	Upline Tank Inlet Valve
VEB	Degassing Bypass Valve
VLA	Air Separator Valve
VDE	Dialyser Inlet Valve
VDA	Dialyser Outlet Valve
VBP	Bypass Valve
VVB	Upline Tank Valve
VBICP	BIC Pump Valve
VBKS	BIC Concentrate Suction Rod Valve
VBKO	Top BIC Cartridge Valve
VD	Disinfection Valve
VZ	Circulation Valve
VDEBK1	Dialyser Inlet Valve Balance Chamber 1
VDEBK2	Dialyser Inlet Valve Balance Chamber 2
VDABK1	Dialyser Outlet Valve Balance Chamber 1
VDABK2	Dialyser Outlet Valve Balance Chamber 2
VEBK1	Inlet Valve Balance Chamber 1
VEBK2	Inlet Valve Balance Chamber 2
VABK1	Outlet Valve Balance Chamber 1
VABK2	Outlet Valve Balance Chamber 2
VBT	Blood Side Test Pressure Sensor Valve
VPV	Venous Pressure Sensor Valve
VPE	Inlet Pressure Sensor Valve
VPU	Up Pressure Sensor Valve
VPD	Down Pressure Sensor Valve
VPA	Arterial Pressure Sensor Valve
SAKV	Venous Tubing Clamp
SAKA	Arterial Tubing Clamp

Heparin Pump Compact

HP	Heparin Pump Compact
LS	Light Barrier Speed Monitoring
KRALO	Interlocking Sensor
KOLB	Syringe Plunger Sensor

HDF Online Board HOB

VSAA	Substitution Connection Outlet Valve (drain)
VBE	Filter Vent Valve
VDFF	DF Filter Valve
VSAE	Substitution Connection Inlet Valve
VSB	Substitution Bypass Valve
PSAUS	Port Substitution Outlet Sensor
PSABFS	Port Substitution Drain Sensor
FEDFFS	DF Filter Detection Sensor
FEHDFS	HD Filter Detection Sensor

2.22 Switch Mode Power Supply Microcontroller SMPS-MC

2.22.1 Block Diagram SMPS-MC

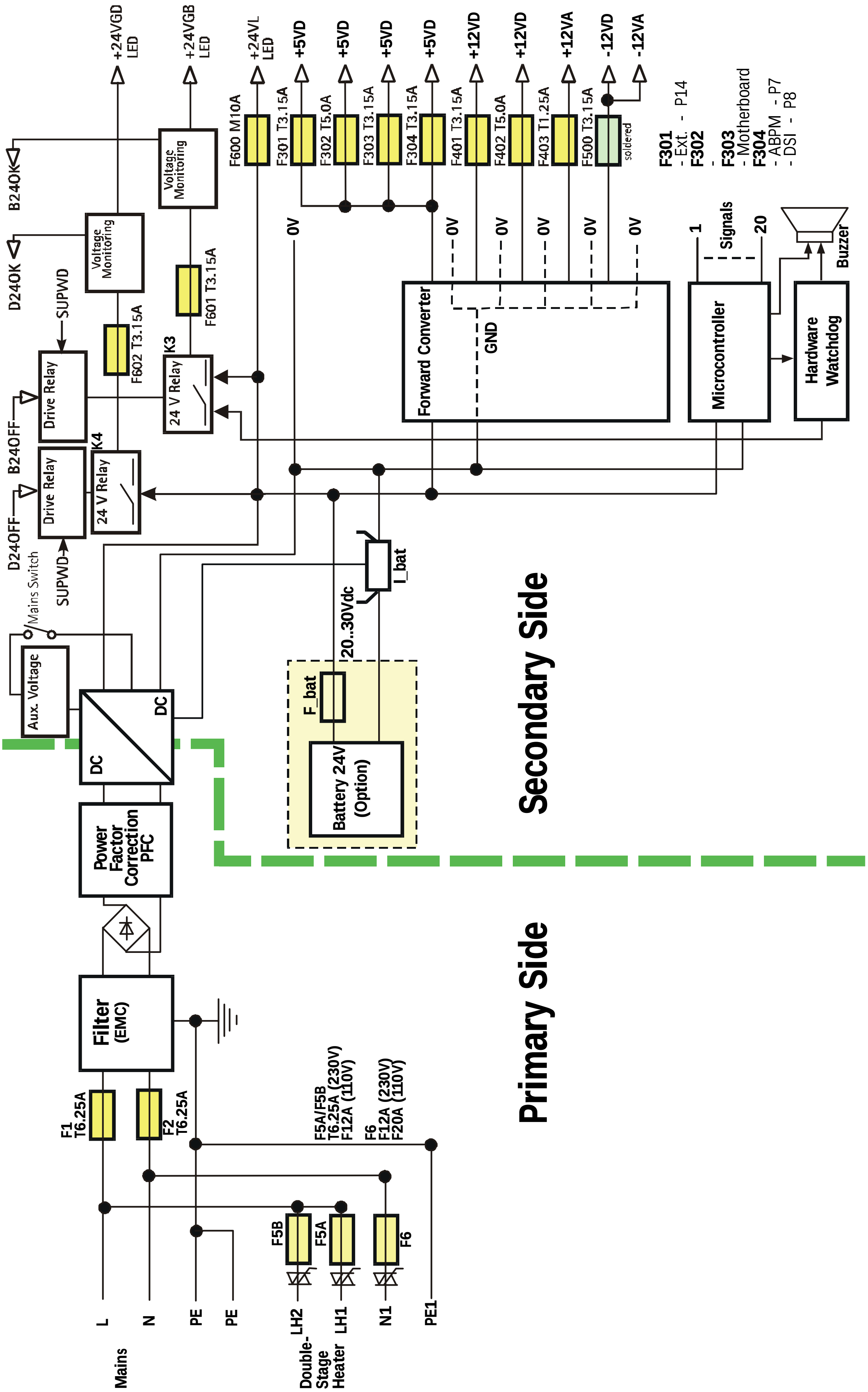


Fig. : Block Diagram Switch Mode Power Supply Microcontroller SMPS-MC

2.22.2 System Integration SMPS-MC

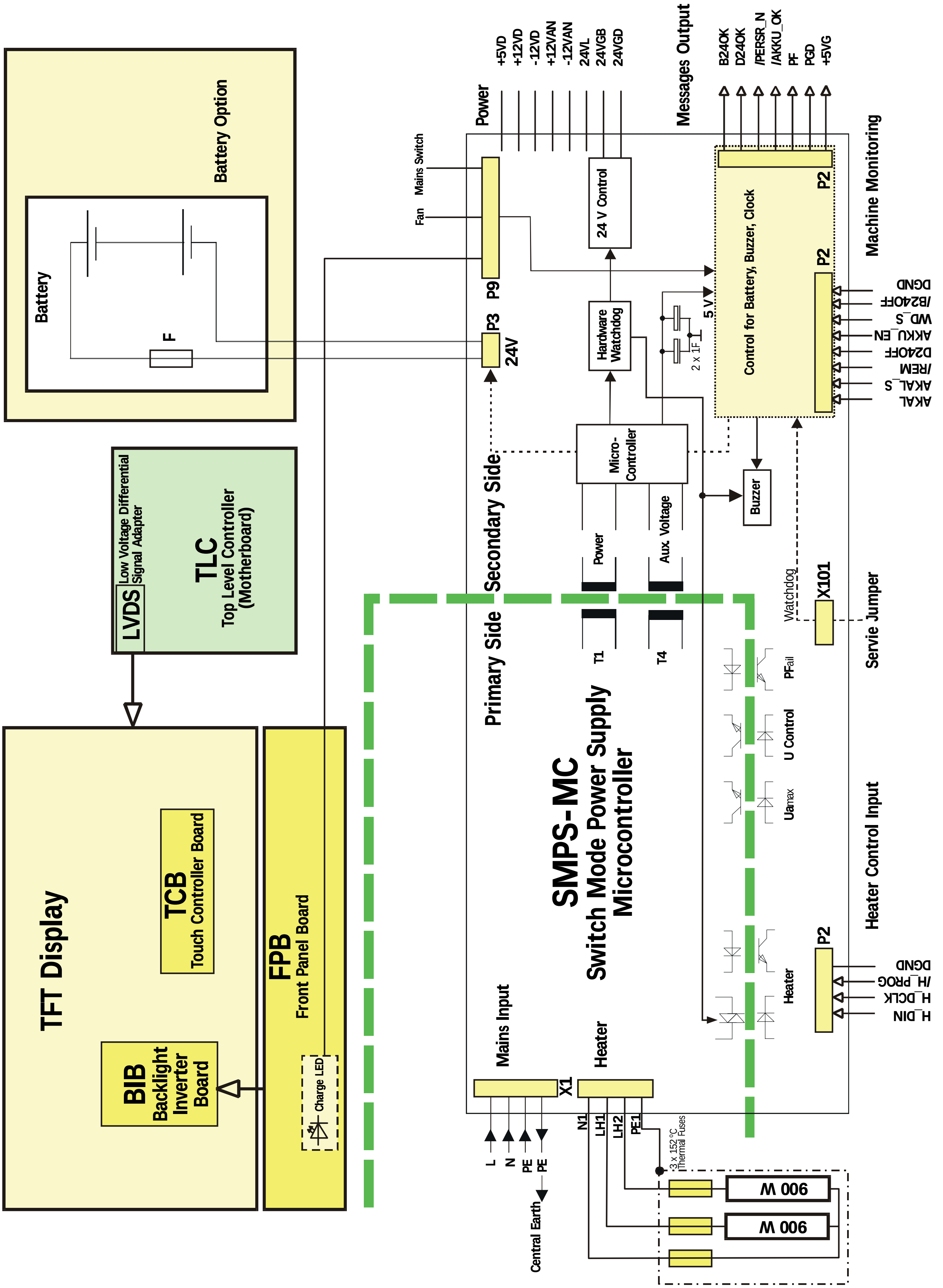


Fig. : System Integration

2.22.3 Component Layout SMPS-MC

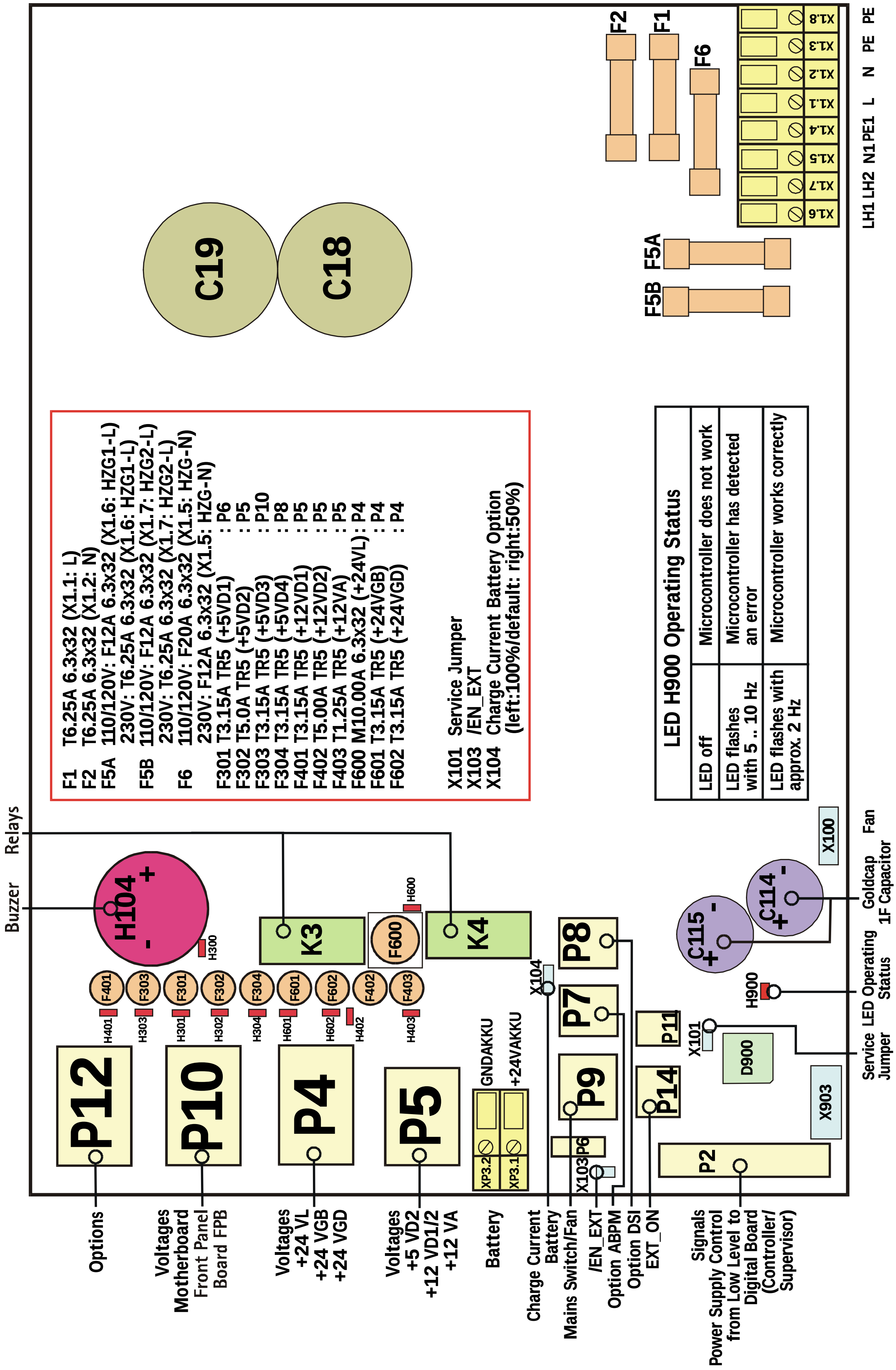


Fig. : Layout SMPS-MC

2.22.4 Wiring Diagram SMPS-MC with Battery Option

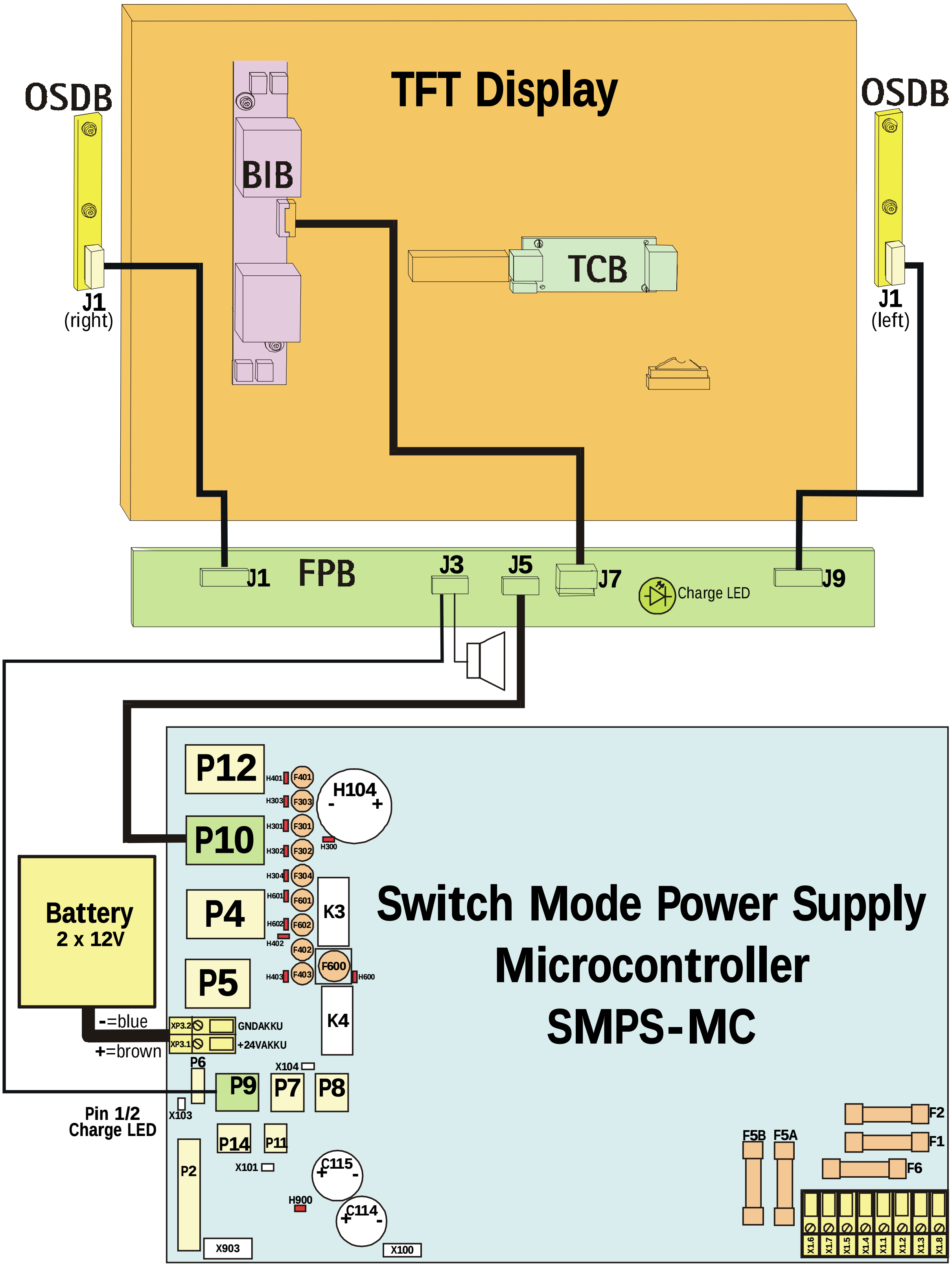


Fig. : Wiring Diagram SMPS-MC with Battery Option

Battery	2 x 12 V, 7 Ah
Fuse for Battery	10 AT (5x20), breaking capacity 1500 A, 150 Vdc
Jumper X104	**Charge Current for Batteries** Default: 50 % (right position)

2.22.5 Description SMPS-MC

The switch mode power supply microcontroller SMPS-MC is used in Dialog+ machines with software ≥ 9.xx.

Basic Components SMPS-MC

- Mains input, filter (EMC)
- Bridge rectifier
- PFC converter
- DC/DC converter
- Transformer
- 24 VL output (protected via F 600)
- 24 VGB output (switched via K3, protected via F601)
- 24 VGD output (switched via K4, protected via F602)
- DC/DC converter 24 V/+5 V (protected via F301/F302/F303/F304)
- DC/DC converter 24 V/+12 V (protected via F401/F402/F403)
- DC/DC converter 24 V/-12 V (electronically protected and via soldered fuse F500)
- Heater power circuit triac V29/V30
- Microcontroller (D900) for monitoring and heater control
- Signal interface P2
- Power connectors to the system components P4 ... P12
- Battery screw terminal to 24 V P3

SMPS-MC

The SMPS-MC (**S**witch **M**ode **P**ower **S**upply **M**icro**C**ontroller) is assembled in the rear door. The primary triggered switch mode power supply generates the following voltages on the secondary side: +5 V (5 V = 5.2 V); ±12 V and 24 V (24 V = 21.5 ... 29.07 V). The primary side has a wide range input for 120/230/240 V ± 10 %.
The SMPS-MC is not backwards compatible to the switch mode power supply SMPS.

Battery Option

The battery option is available in the machine ex works and can also be retrofitted. The blood side functions in therapy can be maintained with a battery supply (option) in case of a power failure. The charging circuit is integrated in the SMPS-MC and includes a deep discharge protection.

Mains Voltage

120/230/240 V ± 10 %, 50/60 Hz

Mains Switch ON/OFF

If the Dialog+ is switched off via the *Automatic Switch-Off* function in therapy, the machine is in standby mode, e.g. the Dialog+ can be switched on and off via the disinfection program.
The Dialog+ is only disconnected from mains if the mains plug is pulled out of the mains receptacle.

Switch-off in Therapy

The buzzer is activated three times if the Dialog+ is switched off in therapy.

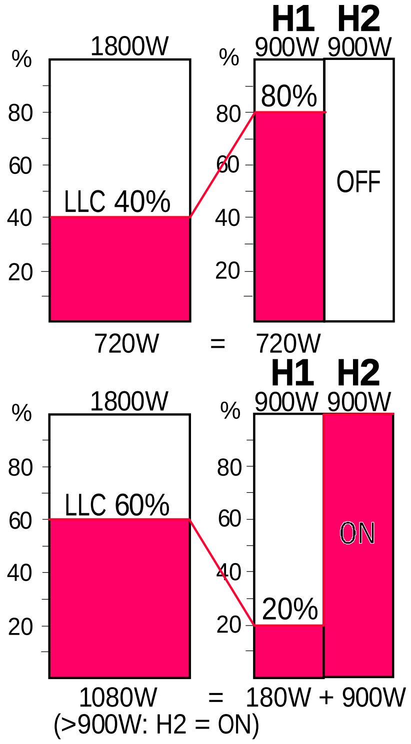
Mains Failure

The Dialog+ (with SMPS-MC) can be switched off and on again in battery operation approx. 16 min after mains failure.

Voltages

+5 VC	Controller power supply
+5 VD:	Digital
+5 VG:	buffered (generated from +12 VH)
+12 VH:	Aux. voltage
±12 VAN:	Analog
±12 VD:	Digital
+24 VGB:	Switched blood side
+24 VGD:	Switched dialysate side
+24 VL:	Power (uncontrolled)
GNDAN:	GND analog
GNDD:	GND digital
GNDH:	GND aux. voltage
GNDL:	GND power

Double-Stage Heater and Microcontroller



The SMPS-MC controls the double-stage heater **H1**/**H2** (2 x 900 W). The first heater circuit (heater **H1**, 900 W) is driven in 2 % steps. The second heater **H2** is switched with max. power (900 W) if 50% of **H1** is reached. **H1** is then controlled with half-wave-shapes, generated by the microcontroller **D900** from the SMPS-MC.

Example:

Set value of LLC = 40 % (based on 1800 W)

- H1 = 80 % (based on 900 W)
- H2 = switched off permanently

Set value of LLC = 60 % (based on 1800 W)

- H1 = 20 % (based on 900 W)
- H2 = switched on permanently

The microcontroller converts the predefined heater power from LLC into bit patterns (1 bit corresponds to a mains voltage half cycle) to control both heaters.

Hardware Watchdog (see also LED H900)

The hardware watchdog **HW-WD** switches the SMPS-MC in a safe condition if the microcontroller fails, i.e. the buzzer is activated, the heater and both voltages +24VGB/+24 VGD are switched off. The staff call is activated if present.

LED H900 Operating Status

3 Modes:

LED off :	Microcontroller is not working
LED flashes with 5 ... 10 Hz:	Microcontroller has detected an error
LED flashes with approx. 2 Hz:	Microcontroller is working correctly

24 V Outputs

The 24 V of the main converter supplies the following circuits:

- 24 VL via fuse F600
- 24 VGB via fuse F601 and relay K3
- 24 VGD via fuse F602 and Relay K4

Battery Management

The SMPS-MC has a battery management, with the following components:

- Screw terminal XP3.1 (+) and XP3.2 (-) for batteries
- Protection against incorrect polarity
- Electronic connection
- Deep discharge protection TES
- Charging current regulator
- Battery full detection
- Shut-down circuit for the battery test
- Enable signal **AKKU_EN**

All output voltages are maintained during a power failure if the signal **AKKU_EN** was set prior to the power failure. The secondary auxiliary voltage is also present. The battery is charged if mains voltage is present. The charging is performed via a body diode even without **AKKU_EN**. A comparator protects the battery from deep discharge by disconnecting the battery source from the circuit at a voltage < 22 V ±0.5 V via a MOSFETT switch.

+5 V Voltage

The 5 V DC/DC converter generates the 5 V voltage from the 24 V. The overvoltage protection circuit (crowbar) is triggered at 5.75 V ± 250 mV. A reset of the overvoltage protection circuit is possible only by switching the machine off and on again. The soldered fuse F300 disconnects the 24 V in case of a short circuit in the DC/DC converter.

+12 V Voltage

A DC/DC converter generates the –12 V voltage from the 24 V. The soldered fuse F500 disconnects the 24 V in case of a short circuit in the DC/DC converter.

2.22.6 Fuses

Fuse	Voltage	Rated Fuse Value Fuse Type	Connector
F1	L (Mains Input)	6.25 A (6.3 x 32)	X1.1
F2	N (Mains Input)	6.25 A (6.3 x 32)	X1.2
F5A	L (Heater 1, 900 W)	12 A (110/120 V) 6.25 A (230 V) (6.3 x 32)	X1.6
F5B	L (Heater 2, 900 W)	12 A (110/120 V) 6.25 A (230 V) (6.3 x 32)	X1.7
F6	N (Heater)	20 A (110/120 V) 12 A (230 V) (6.3 x 32)	X1.5
F301	+5 VD1	3.15 A (TR5)	P4/1
			P4/4
			P6/1
			P11/1
			P12/1
			P14/6
F302	+5 VD2	5 A (TR5)	P5/10
F303	+5 VD3	3.15 A (TR5)	P10/1
			P10/4
			P10/7
F304	+5 VD4	3.15 A (TR5)	P7/1
			P8/1
F401	+12 VD1	3.15 A (TR5)	P12/2
F402	+12 VD2	5 A (TR5)	X100/1
			P5/4
			P7/4
			P8/4
			P9/5
			P9/6
			P10/10
			P10/14
			P11/2
F403	+12 VD3	1.25 A (TR5)	P4/7
			P5/1
			P7/7
			P8/7
			P12/4
F600	+24 VL	10 A (6.3 x 32)	P4/10
			P4/13
			P5/8
			P12/10
F601	+24 VGB	3.15 A (TR5)	P4/11
			P4/14
			P5/7
			P12/13
F602	+24 VGD	3.15 A (TR5)	P4/12
			P4/15
			P12/14

Note: Soldered fuses (e.g. F300 or F500) must not be changed if they are defective, i.e. the complete SMPS-MC must be exchanged.

2.22.7 Signals

AKAL	Audible alarm (LLC)
AKAL_S	Audible alarm (LLS)
AKKU_EN	Enable battery operation (possible in therapy mode only)
AKKU_LADEN	Signal for external LED (on front panel board) – charging of battery
/AKKU_OK	Load status of the battery
B24OFF	+24 VGB ON/OFF (LLS)
B24OK	+24VGB OK
D24OFF	+24 VGD ON/OFF (LLS)
D24OK	+24VGD OK
/DIR_ON	Jumper X101 – is used to switch on the power supply without using the */REM* signal and deactivates the alarms. (The watchdog signal for the function of the heater (*H_DIN*) is still required to drive the heater.)
/EXT_ON	The machine can be switched on with this signal (see menu *1.26 Battery Option*: external *ON*).
EXT_STATE	Status for external switch-on possibility (e.g. central disinfection), simultaneously input and output; the signal is looped through (connector P14/3 = input).
H_DCLK	Clock signal for heater data from LLC. The *H_DCLK* Signal is an open-collector signal and is generated by the LLC. The *H_DCLK* Signal is used to send the data at *H_DIN* to the microcontroller. **0**, **1** Data clock
H_DIN	The *H_DIN* signal is an open-collector signal, is generated by the LLC and sent to the microcontroller (data to control the heater). **0** Half wave of mains voltage: heater switched off **1** Half wave of mains voltage: heater switched on
/H_PROG	Programming mode for heater data. The */H_PROG* signal is an open-collector signal and is generated by the LLC. **0** Programming mode **1** No programming mode
/MSWITCH	Mains switch
PERSR_N	Staff call from SMPS-MC
PF	Power fail (power failure)
/REM	Remote signal of LLC (clock on digital board)
WD_S	Watchdog LLS

2.22.8 Internal Signals

/PF	Power fail for the power supply monitoring
Watchdog	A watchdog is integrated to prevent a permanent unintentional drive of the heater in case of an LLC reset. The watchdog is retriggered by the LLC with < 2 s. The *H_DIN* signal is used for triggering. The watchdog prevents a drive of the heater for t = 10 s after the switch-on of the switch mode power supply. The watchdog has no safety function and is therefore not tested before the therapy starts.

Table of Contents

3. Self Test SW 9.xx

3.1 Microprocessor Unit MPU Test from Controller/Supervisor

The microprocessor unit MPU of the controller and supervisor are checked. The function of the internal MPU registers, flags and stacks is tested.

MPU Test Supervisor

The MPU test is performed in therapy mode and service mode after switch-on prior to the RAM and ROM test.

MPU Test Controller

The MPU test is performed during the boot phase after the RAM and ROM test. The operating system is not active in this phase.

Register Test

The following tests are performed:

- Read-write capability of the registers
- Cross-talk between the single bits
- Address ability of the registers
- Crosstalk between single words

Flag Test

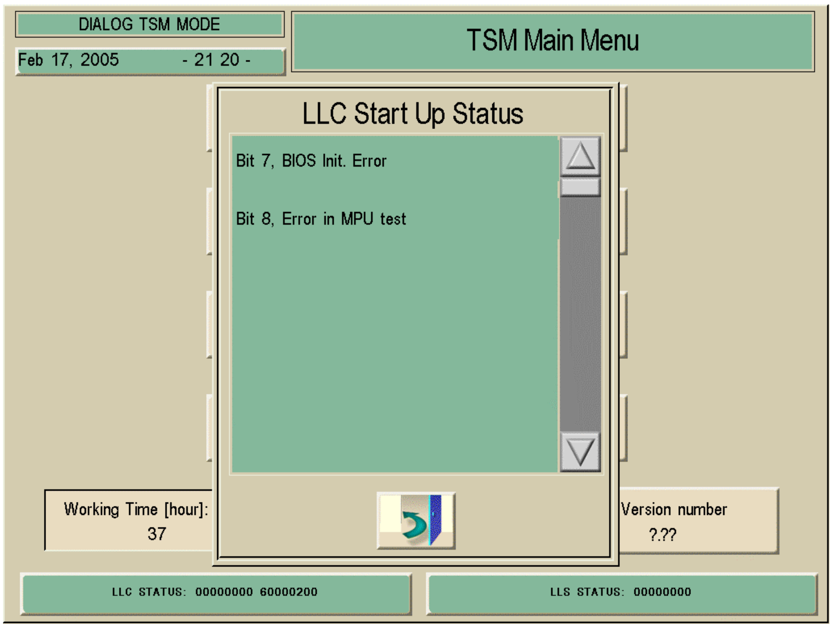
Set and Reset Capability
The test checks whether the flag can be set and reset correctly according to defined conditions.

Query Capability
The test checks whether the correctly set flags can also be evaluated correctly .

Stack Test

The function of the stack is tested by storing and reloading/reading a test pattern.

Reactions in Case of an Error of the MPU Test



Feb 17, 2005 - 21 20 -

Bit 7, BIOS Init. Error

Bit 8, Error in MPU test

Working Time [hour]: 37

Version number ?.??

LLC STATUS: 00000000 60000200

LLS STATUS: 00000000

Controller
If an error is detected during the MPU test the TLC terminates the start procedure – therapy can not be started. The error message is displayed in the TSM service program:

- Bit 7, BIOS init. error
- Bit 8, Error in MPU test

Supervisor
If an error is detected during the MPU test the following alarms are displayed:

In Therapy – Therapy Selection:

- *Hardware error RAM/ROM (SUP)*

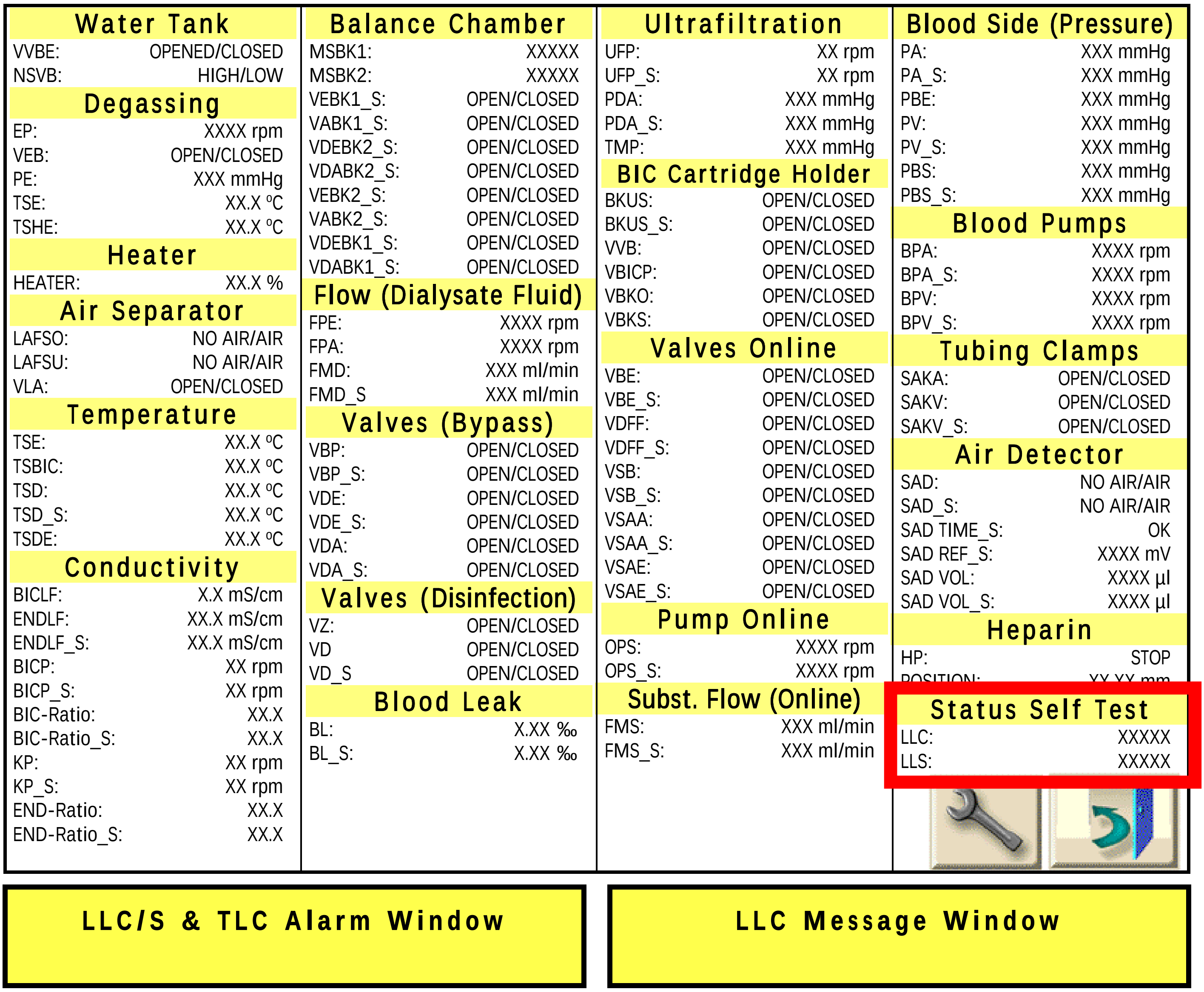
In TSM Service Program:

- *Error in MPU test*

3.2. Status Self Test in Service Overview

Display LLC/LLS Test Codes in Status Self Test

The test codes for the self test are displayed by LLC and LLS in the *Status Self Test* on the first page of the service overview (in therapy).



Water Tank
VVBE: OPENED/CLOSED
NSVB: HIGH/LOW

Degassing
EP: XXXX rpm
VEB: OPEN/CLOSED
PE: XXX mmHg
TSE: XX.X °C
TSHE: XX.X °C

Heater
HEATER: XX.X %

Air Separator
LAFSO: NO AIR/AIR
LAFSU: NO AIR/AIR
VLA: OPEN/CLOSED

Temperature
TSE: XX.X °C
TSBIC: XX.X °C
TSD: XX.X °C
TSD_S: XX.X °C
TSDE: XX.X °C

Conductivity
BICLF: X.X mS/cm
ENDLF: XX.X mS/cm
ENDLF_S: XX.X mS/cm
BICP: XX rpm
BICP_S: XX rpm
BIC-Ratio: XX.X
BIC-Ratio_S: XX.X
KP: XX rpm
KP_S: XX rpm
END-Ratio: XX.X
END-Ratio_S: XX.X

Balance Chamber
MSBK1: XXXXX
MSBK2: XXXXX
VEBK1_S: OPEN/CLOSED
VABK1_S: OPEN/CLOSED
VDEBK2_S: OPEN/CLOSED
VDABK2_S: OPEN/CLOSED
VEBK2_S: OPEN/CLOSED
VABK2_S: OPEN/CLOSED
VDEBK1_S: OPEN/CLOSED
VDABK1_S: OPEN/CLOSED

Flow (Dialysate Fluid)
FPE: XXXX rpm
FPA: XXXX rpm
FMD: XXX ml/min
FMD_S XXX ml/min

Valves (Bypass)
VBP: OPEN/CLOSED
VBP_S: OPEN/CLOSED
VDE: OPEN/CLOSED
VDE_S: OPEN/CLOSED
VDA: OPEN/CLOSED
VDA_S: OPEN/CLOSED

Valves (Disinfection)
VZ: OPEN/CLOSED
VD OPEN/CLOSED
VD_S OPEN/CLOSED

Blood Leak
BL: X.XX ‰
BL_S: X.XX ‰

Ultrafiltration
UFP: XX rpm
UFP_S: XX rpm
PDA: XXX mmHg
PDA_S: XXX mmHg
TMP: XXX mmHg

BIC Cartridge Holder
BKUS: OPEN/CLOSED
BKUS_S: OPEN/CLOSED
VVB: OPEN/CLOSED
VBICP: OPEN/CLOSED
VBKO: OPEN/CLOSED
VBKS: OPEN/CLOSED

Valves Online
VBE: OPEN/CLOSED
VBE_S: OPEN/CLOSED
VDFF: OPEN/CLOSED
VDFF_S: OPEN/CLOSED
VSB: OPEN/CLOSED
VSB_S: OPEN/CLOSED
VSAA: OPEN/CLOSED
VSAA_S: OPEN/CLOSED
VSAE: OPEN/CLOSED
VSAE_S: OPEN/CLOSED

Pump Online
OPS: XXXX rpm
OPS_S: XXXX rpm

Subst. Flow (Online)
FMS: XXX ml/min
FMS_S: XXX ml/min

Blood Side (Pressure)
PA: XXX mmHg
PA_S: XXX mmHg
PBE: XXX mmHg
PV: XXX mmHg
PV_S: XXX mmHg
PBS: XXX mmHg
PBS_S: XXX mmHg

Blood Pumps
BPA: XXXX rpm
BPA_S: XXXX rpm
BPV: XXXX rpm
BPV_S: XXXX rpm

Tubing Clamps
SAKA: OPEN/CLOSED
SAKV: OPEN/CLOSED
SAKV_S: OPEN/CLOSED

Air Detector
SAD: NO AIR/AIR
SAD_S: NO AIR/AIR
SAD TIME_S: OK
SAD REF_S: XXXX mV
SAD VOL: XXXX µl
SAD VOL_S: XXXX µl

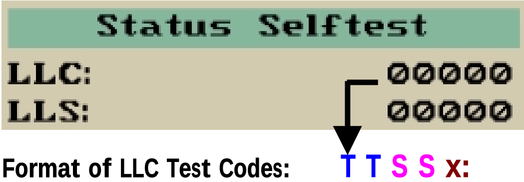
Heparin
HP: STOP
POSITION: XX.XX mm

Status Self Test
LLC: XXXXX
LLS: XXXXX

LLC/S & TLC Alarm Window

LLC Message Window

3.2.1 Set-Up Low Level Controller LLC Test Codes

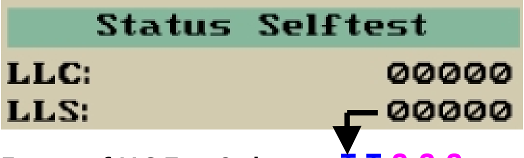

Status Selftest
LLC: 00000
LLS: 00000

Format of LLC Test Codes: T T S S x:

T T	LLC test code to LLS
S S	Performed test step
x	Number of performed repeats 0 ≤ x < repeats until error message
Examples	
11102	Third blood leak detector test: send signal to blood leak detector task
33701	Second BS pressure test terminated, because during autopriming, e.g. an LF error occurred.
37991	VD test passed after the second time.
LLC Test Codes Before the Individual Tests	
T T **00** x	Start test.
T T **01** x	Error: timeout (10 s) at "Before Test Start Wait for Test Code 0 from LLS".
T T **02** x	Test check prerequisites (if present, see respective tests).
T T **03** x	Error: Check timeout test prerequisites (if present, timeout time see respective tests).
T T **04** x	Wait for LLS test code from LLS.
T T **05** x	Error: timeout (10 s) at "Before Test Start Wait for LLS Test Code from LLS".
Test Codes of the Individual Tests	Range 10x .... 99x Not all test codes are displayed sequentially, due to the implementation. A higher test code always includes all the finalised subcodes with lower priority. In case of an error: The subcode always includes the subphase where the error occurred.

3.2.2 Set-Up Low Level Supervisor LLS Test Codes

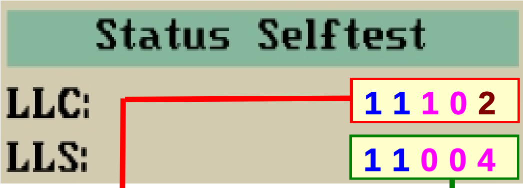
The test code is displayed as a numerical value ≥ 10000. If the value is < 9000, this is the required rinsing volume for the HDFO filter rinsing in ml. If the value is > 9000 and < 10000, the last three digits display the required HDFO filter rinsing volume in ml through the valves VSAA and VSAE (VSB is closed).


Status Selftest
LLC: 00000
LLS: 00000

Format of LLS Test Codes: T T S S S:
(Value ≥ 10000)

T T	LLS test code to LLC
S S S	Performed test step
Example:	
11104	Blood leak detector test: measure level for red and green

3.2.3 Example LLC/LLS Test Codes for Blood Leak Detector



Status Selftest

LLC: 11102

LLS: 11004

LLC Test Code:

11 (TT): Blood leak detector test

10 (SS): Send signal to blood leak task

2 (x): Third repetition (x = 0, 1, 2)

LLS Test Code:

11 (TT): Blood leak detector test

004 (SS): Measure level for red and green

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	1102x	**Prerequisites for Test:** Upline tank must be filled Timeout 2 min		
2.		Test code = **11** to LLS	Test code = **11** back to LLC	
3.	1110x	EV_TESTE_BLUTLECK_EIN to BlutleckTaskID	Test initialisation (VGD ON) Single measurement of green, Single measurement of red, then comparison of: red ≥ green + 0.2 V no timeout	11000 – 11003 11004
4.			Acknowledge with switch-off of VGD	11005 –
5.	1120x	Wait for D24OFF (timeout 30 s)		11011
6.			VGD ON	11012
7.	1130x	Wait for D24ON (timeout 30 s)		
8.	1199x	Completed		

3.2.4 Overview Test Codes

00	No tests
11	Blood leak detector
12	DFS pressure test
15	Integrity test HDF online (only for Dialog+ HDF online)
16	Alarm system
17	Monitoring of analog voltage ± 12 V
20	UF pump
21	End conductivity
22	Temperature TSD
25	SMPS-MC EEPROM
26	SMPS-MC service mode
27	SMPS-MC battery
28	SMPS-MC buzzer
30	SAD: Level test
31	SAD: Counter test
32	Pressure sensors blood side: Equality test for blood side pressure sensors
33	Pressure sensors blood side: Blood side pressure test
37	Disinfection Valve VD
40	Pressure test substitution line S-Online HDF online

3.3 Self Test in Preparation SW 9.xx Switch Mode Power Supply Microcontroller SMPS-MC

3.3.1 Service Mode (DIR_ON)

Configuration Switch mode power supply microcontroller SMPS-MC with and without battery
Test Code 26
Repeats Until Error Message 1
ID Error Message 1152: *Power supply service mode - no therapy*
Reaction to the Test Result in Preparation Error: X101 connected (/DIR_ON = *0*)

- **therapy not possible** because alarms deactivated, information text

OK: X101 open (/DIR_ON = *1*)

- Therapy possible

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.		**Prerequisites for Test:** none		
2.		Test code = 26 to LLS	Test code = 26 back to LLC	
3.	2610x		Switch-off of VGD and VGB	26001
4.		Wait for D24OFF and B24OFF (Timeout 15 s)		
5.		Set set point for heater to self test code #110		
6.	2620x	Wait for feedback of test result via BIOS (timeout 15 s)		
7.	2630x	Set set point of heater to 0		
8.	2699x	Completed	VGD ON VGB ON	

3.3.2 Battery

Configuration Switch mode power supply microcontroller SMPS-MC with and without battery
Test Code 27
Repeats Until Error Message 3
ID Error Message 1150: *Selftest error SMPS battery test*
Reaction to the Test Result in Preparation Error: Battery not present or not loaded

- Information text and **therapy possible**

OK: Battery present and loaded

- Therapy possible

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.		**Prerequisites for Test:** none		
2.		Test code = 27 to LLS	Test code = 27 back to LLC	
3.	2710x		Switch-off of VGD and VGB	27001
4.		Wait for D24OFF and B24OFF (Timeout 15 s)		
5.		Set set point for heater to self test code #112		
6.	2720x	Wait for feedback of test result via BIOS (timeout 15 s)		
7.	2730x	Set set point of heater to 0		
8.	2799x	Completed	VGD ON VGB ON	

3.3.3 EEPROM

Configuration Switch mode power supply microcontroller SMPS-MC with and without battery
Test Code 25
Repeats Until Error Message 1

ID Error Message 1154: *SMPS-EEPROM defective*
Reaction to the Test Result in Preparation Test is not performed at present

- Answer from SMPS-MC is *OK* because the EEPROM is not used at present

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.		**Prerequisites for Test:**		
2.		Test code = 25 to LLS	Test code = 25 back to LLC	
3.	2510x		Switch-off of VGD and VGB	25001
4.		Wait for D24OFF and B24OFF (Timeout 15 s)		
5.		Set set point for heater to self test code #113		
6.	2520x	Wait for feedback of test result via BIOS (timeout 15 s)		
7.	2530x	Set set point of heater to 0		
8.	2599x	Completed	VGD ON VGB ON	

3.3.4 Buzzer Test via LLS

Configuration Switch mode power supply microcontroller SMPS-MC with and without battery
Test Code 28
Repeats Until Error Message 3

ID Error Message 1145: *Self test error SMPS buzzer test*
Reaction to the Test Result in Preparation Error: buzzer defective

- Information text and **therapy possible**

OK:

- Therapy possible

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.		**Prerequisites for Test:** none		
2.		Test code = 10 to LLS	Test code = 10 back to LLC	
3.	2810x		Switch-off of VGD and VGB	28001
4.		Wait for D24OFF and B24OFF (Timeout 15 s)		
5.		Set set point for heater to self test code #115		
6.			Activate buzzer after approx. 1 s for 250 ms	28003
7.	2820x	Wait for feedback of test result via BIOS (timeout 15 s)		
8.	2830x	Set set point of heater to 0		
9.	2899x	Completed	VGD ON VGB ON	

3.3.5 Alarm System

Test Code	16
Repeats Until Error Message	1
ID Error Message	1167: *Sound + LED test failed*
Actions after Error	None (test is repeated immediately)

	LLC Test Code	**LLC Test Steps**	**LLS Test Steps**	**LLS Test Code**
	Code	**LLC**	**LLS**	**Code**
1.		**Prerequisites for Test:** No alarm activation		
2.		Test code = 16 to LLS	Test code = 16 back to LLC	
3.	1610x	**OSD LED OFF, Sound OFF** No alarm activation Timeout 60 s	**Start condition for the test:** 1. „OSD-LED OFF“ detected 2. „Sound OFF“ detected	16001
			Activation of the red OSD LED	16002
			Wait for feedback of the activation and switch-off of the LED	16003
			Wait for LED off	16004
4.			Acknowledge with switch-off of the power supply trigger, i.e. switch-off of VGD and VGB	16005 – 16010
5.	1620x	Wait for D24OFF and B24OFF (timeout 60 s since start of code 100)		
6.			Trigger ON	16011
7.	1630x	Wait for D24ON and B24ON (timeout 10 s)		
8.	1630x	**D24ON and B24ON:** Alarm activation LLC/TLC Activation test alarm with sound and OSD LED red (ID 1002)	Condition for the test: 1. „OSD LED red left and right ON“ detected 2. „Sound ON“ detected	16021
9.			Acknowledge with switch-off VGD	16022 – 16027
10.	1640x	Wait for D24OFF (timeout 60 s since start of code 200)		
11.			VGD ON	16028
12.	1650x	Wait for D24ON (timeout 10 s)		
13.	1699	Completed		

3.3.6 Monitoring of Analog Voltage ±12 V

Objective	Check the monitoring of the analog voltage ±12 V.
Test Code	17
Repeats Until Error Message	1
ID Error Message	1155: *±12 V not passed*
Actions after Error	None (test is repeated immediately)

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.		**Prerequisites for Test:** ± 12V voltage in limit range		
2.		Test code = 17 to LLS	Test code = 17 back to LLC	
3.			No test activation	17001 – 17003
4.	1710x	**Failure of voltage check** Timeout 15 s		
5.			Delete test activation for voltage 1: TEST1 set *low*	17011 – 17013
6.	1720x	**Voltage check OK** Timeout 15 s		
7.			Test activation for voltage 2: TEST2n set *low*	17021 – 17023
8.	1730x	**Failure of voltage check** Timeout 15 s		
9.			Delete test activation for voltage 2: TEST2n set *high*	17031
10.	1740x	**Voltage check OK** Timeout 15 s		
11.	1799	Completed		

3.3.7 Blood Leak Detector

Objective	The switch function between the LEDs and the PWM drive of the LEDs is tested.
Test Code	11
Repeats Until Error Message	3
ID Error Message	1156: *Blood leak test not OK*
Actions after Error	Rinse, repeat all tests

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	1102x	**Prerequisites for Test:** Upline tank must be filled Timeout 2 min		
2.		Test code = 11 to LLS	Test code = 11 back to LLC	
3.	1110x	EV_TESTE_BLUTLECK_EIN to BlutleckTaskID	Test initialisation (VGD ON) Single measurement of green, Single measurement of red, then comparison of: red ≥ green + 0.2 V no timeout	11000 – 11003 11004
4.			Acknowledge with switch-off of VGD	11005 –
5.	1120x	Wait for D24OFF (timeout 30 s)		11011
6.			VGD ON	11012
7.	1130x	Wait for D24ON (timeout 30 s)		
8.	1199x	Completed		

3.3.8 DFS Pressure Test (Table)

Objective	Pressure test of the balance system and function test of the valves, drive of UFP for function test of speed detection.
Test Code	12
Repeats until error message	1
ID Error Message	1157: *DF pressure test will be repeated*
Actions after error	Rinse, repeat all tests.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.		**Prerequisites for Test:** Upline tank must be filled		
2.		Test code = 12 to LLS	Test code = 12 back to LLC	
1	1220x	**Membrane Movement VDABK** FPE = 1500 ml·/min FPA = 20 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VABK1/2 --------- opened VDABK1/2 ---------------------------- closed VBP, VDA, VDE ----------------------- opened VLA --------------------- (5 s to vent) opened **Final Condition:** No further drop of the values for the balance chamber sensors or timeout 60 s	Wait until VLA is detected as opened	12000 12019
2	1221x	**Pressure build-up VDABK** FPE = 1500 ml·/min FPA = 20 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VABK1/2 -----------opened VDABK1/2----------------------------- closed VDE, VDA, VBP ----------------------- opened **Final Condition:** PDA ≥ +425 mmHg for 1 s or timeout 60 s	Wait until VLA is detected as closed	12020
3	1230x	**Pressure reduction UFP** FPE = 500 ml/min FPA = 100 ml/min **Valve Status:** VEBK1/2, VABK1/2 ----------------------opened VDABK1/2, VDEBK1/2 ------------------ closed VDE, VBP ---------------------------- opened VDA ---------------------------------- closed PDA ≤ +380 mmHg or timeout 60 s		12021
4	1235x	**VBP test** FPE = 800 ml/min FPA = 100 ml·/min **Valve Status:** VEBK1/2, VABK1/2, VDEBK1/2 -----------opened VDABK1/2----------------------------- closed VDE, VBP ----------------------------- closed VDA --------------------------------- opened Test timeout 30 s or wait for inversion of LLS_SELFTESTBIT from LLS	**Start condition for the test (2,5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. 300 mmHg < PDA < +450 mmHg Test 5 s, max. deviation ΔPDA < 25 mmHg, Acknowledge with inversion of LLS_SELFTESTBIT	12021 – 12026 12027 – 12036 12037 12038
5	1240x	**VDE/VDA test** FPE = 800 ml/min FPA = 100 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VABK1/2 --------- opened VDABK1/2 ---------------------------- closed VBP --------------------------------- opened VDA, VDE ----------------------------- closed Test timeout 60 s or wait for inversion of LLS_SELFTESTBIT from LLS	**Start condition for the test (2,5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. 300 mmHg < PDA < +450 mmHg Test 5 s, max. deviation ΔPDA < 25 mmHg, Acknowledge with inversion of LLS_SELFTESTBIT	12061 – 12066 12067 – 12076 12077 12078

6.	1245x	**Pressure build-up** VDABK FPE = 500 ml/min FPA = 100 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VABK1/2 --------- opened VDABK1/2 ---------------------------- closed VBP, VDA, VDE ----------------------- opened PDA ≥ +425*mmHg* for 1 s or timeout 60 s		12101
7.	1250x	**Pressure reduction with UFP** FPE = 800 ml/min FPA = 20 ml/min **Valve Status:** VEBK1/2, VDABK1/2------------------- opened VDEBK1/2, VABK1/2-------------------- closed VBP, VDE ---------------------------- opened VDA ---------------------------------- closed PDA ≤ +380 mmHg or timeout 60 s		12101
8.	1255x	**Membrane test** FPE = 800 ml/min FPA = 20 ml/min **Valve Status:** VEBK1/2, VDABK1/2------------------- opened VDEBK1/2, VABK1/2-------------------- closed VBP, VDE, VDA ----------------------- opened Test timeout 60 s or wait for inversion of LLS_SELFTESTBIT from LLS	**Start condition for the test (10 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. +300 mmHg < PDA < +450 mmHg Test 10 s, max. deviation ΔPDA < 25 mmHg, Acknowledge with inversion of LLS_SELFTESTBIT	12101 – 12121 12122 – 12131 12132 12133
9.	1260x	**Pressure build-up VABK** FPE = 500 ml/min FPA = 500 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VDABK1/2 -------- opened VABK1/2 ----------------------------- closed VBP, VDA, VDE ----------------------- opened PDA ≥ +425 mmHg for 1 s or timeout 60 s		12151
10.	1265x	**Membrane movement** FPE = 500 ml/min FPA = 1500 ml·/min **Valve Status:** VEBK1/2, VABK1/2 --------------------- closed VDEBK1/2, VDABK1/2 ----------------- opened VBP, VDA, VDE ----------------------- opened Test timeout 60 s or no increase of the values of the membrane position sensors		12151
11.	1270x	**Pressure reduction with UFP** FPE = 500 ml/min FPA = 500 ml/min **Valve Status:** VEBK1/2, VABK1/2 --------------------- closed VDEBK1/2, VDABK1/2 ----------------- opened VBP, VDE ---------------------------- opened VDA ---------------------------------- closed PDA ≤ +380 mmHg or timeout 60 s		12151

12.	1275x	**VEBK test** FPE = 800 ml/min FPA = 500 ml/min **Valve Status:** VEBK1/2, VABK1/2 --------------------- closed VDEBK1/2, VDABK1/2 ----------------- opened VBP, VDE, VDA ------------------------ opened Test timeout 60 s or wait for inversion of LLS_SELFTESTBIT from LLS	**Start condition for the test (5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. +300 mmHg < PDA < +450 mmHg Test 10 s, max. deviation ΔPDA < 25 mmHg, Acknowledge with inversion of LLS_SELFTESTBIT	12151 – 12161 12162 – 12181 12182 12183
13.	1280x	**Pressure reduction** FPE = 500 ml/min FPA = 500 ml/min **Valve Status:** VEBK1/2, VDEBK1/2 ------------------- opened VABK1/2, VDABK1/2------------------- opened VBP, VDA, VDE ------------------------ opened Timeout 60 s		12000
14.	1299	Completed		

3.3.8.1 DFS Pressure Test

General Comments

The closing function of VLA is tested implicitly together with all tests that generate an overpressure at PDA, because the overpressure is not built up and not maintained when VLA is open. Therefore an explicit test of VLA is not required. DFS pressure test:

- A controlled membrane movement is performed to the outlet side prior to the phase *Pressure build-up VDABK*.
- The FPE and FPA pumps are set to 1500 ml/min in phases with membrane movement. Thus a fast movement of the membrane is achieved.
- UFP is activated during the pressure build-up phase and thus tested.
- The evaluation of the pressure changes in a test interval is performed via the pressure at the end of the test interval. (The pressure difference to the minimum and maximum sensor value is created in the test interval.)
- VLA is opened for 5 s at the beginning of the test to ensure that the air separator is completely filled with water. Simultaneously the function for the monitoring of the current is checked.
- UFP is started during the pressure build-up phase.
- The acknowledgement of the single test steps in the DFS pressure test is performed via a bit in the internal communication (between LLS and LLC).

3.3.8.2 Membrane Movement/Pressure Build-up VDABK

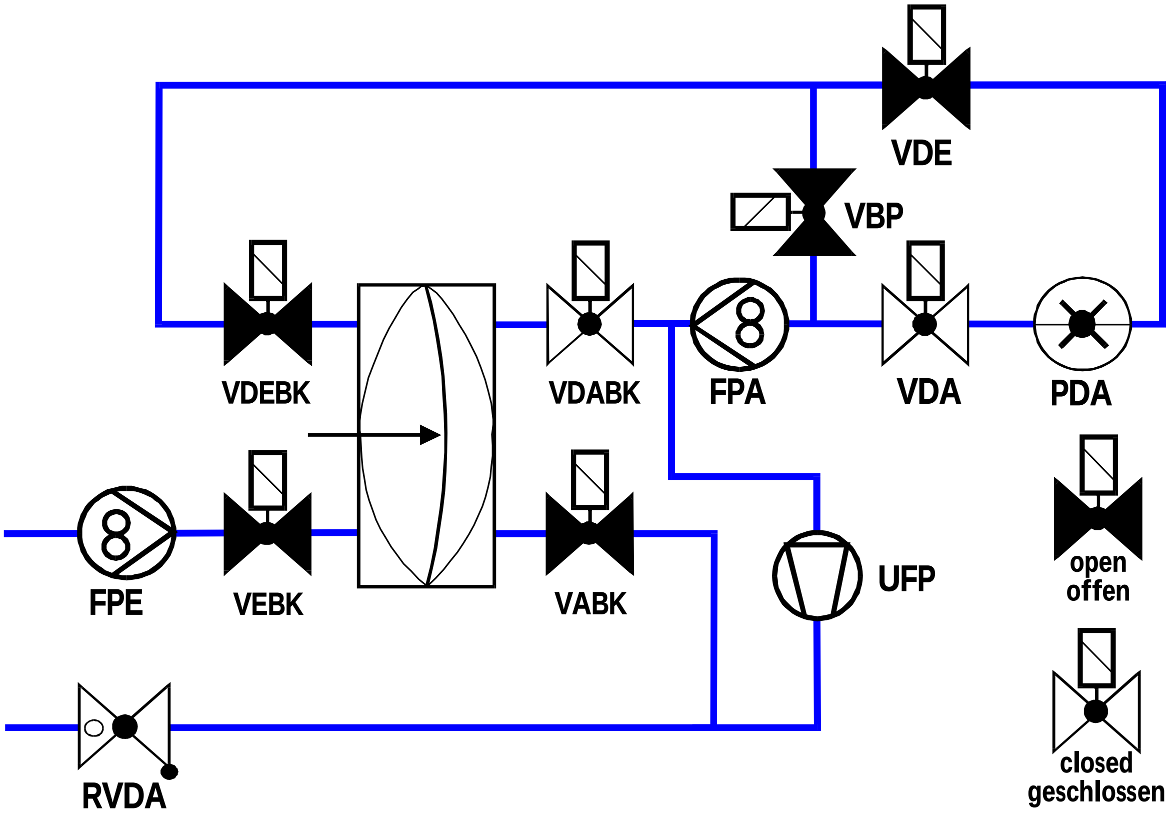


Fig. : Flow Diagram Membrane Movement/Pressure Build-up VDABK

The speed for FPE and FPA are slowly set in increments of 200 min^{-1} to a maximum flow of 1500 ml/min and 10 ml/min respectively. The membrane movement with the resulting pressure build-up is terminated after no further drop of the values for the balance chamber sensors is detected. The membrane is moved to the outlet.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1	1220x	**Membrane movement VDABK** FPE = 1500 ml/min FPA = 20 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VABK1/2 ------------opened VDABK1/2------------------------------ closed VDE, VDA, VBP ----------------------- opened VLA ---------------------- open to vent for 5 s **Final Condition:** No further drop of the values for the balance chamber sensors or timeout 60 s	Wait until VLA is detected as opened	12000 12019
2	1221x	**Pressure build-up VDABK** FPE = 1500 ml·/min FPA = 20 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VABK1/2 ------------opened VDABK1/2------------------------------ closed VDE, VDA, VBP ----------------------- opened **Final Condition:** PDA ≥ +425 mmHg for 1 s or timeout 60 s	Wait until VLA is detected as closed	12020

3.3.8.3 Pressure Reduction VDABK with UFP

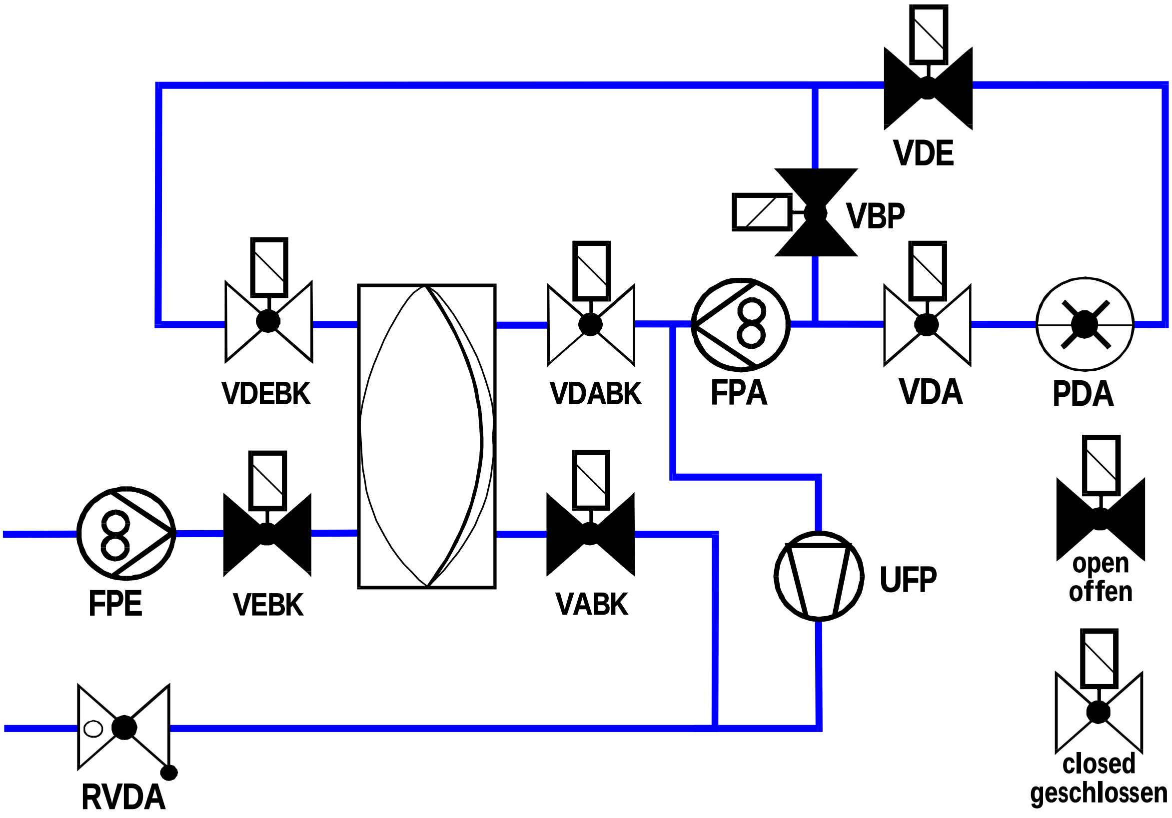


Fig. : Flow Diagram Pressure Reduction VDABK with UFP

The pressure at PDA is reduced ~~built-up~~ to ≤ 380 mmHg with the UF pump after the dialyser test circuit is closed. The UF pump is driven with 3000 ml/h. VDA is closed during this pressure reduction. Thus the UF pump strokes are damped via the extended flow path and no interferences are generated at PDA.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
3.	1230x	**Pressure reduction UFP** FPE = 500 ml/min FPA = 100 ml/min **Valve Status:** VEBK1/2, VABK1/2 -----------------------opened VDABK1/2, VDEBK1/2 ------------------- closed VDE, VBP ----------------------------- opened VDA ------------------------------------ closed **Final Condition:** PDA ≤ +380 mmHg or timeout 60 s		12021

3.3.8.4 VBP Test

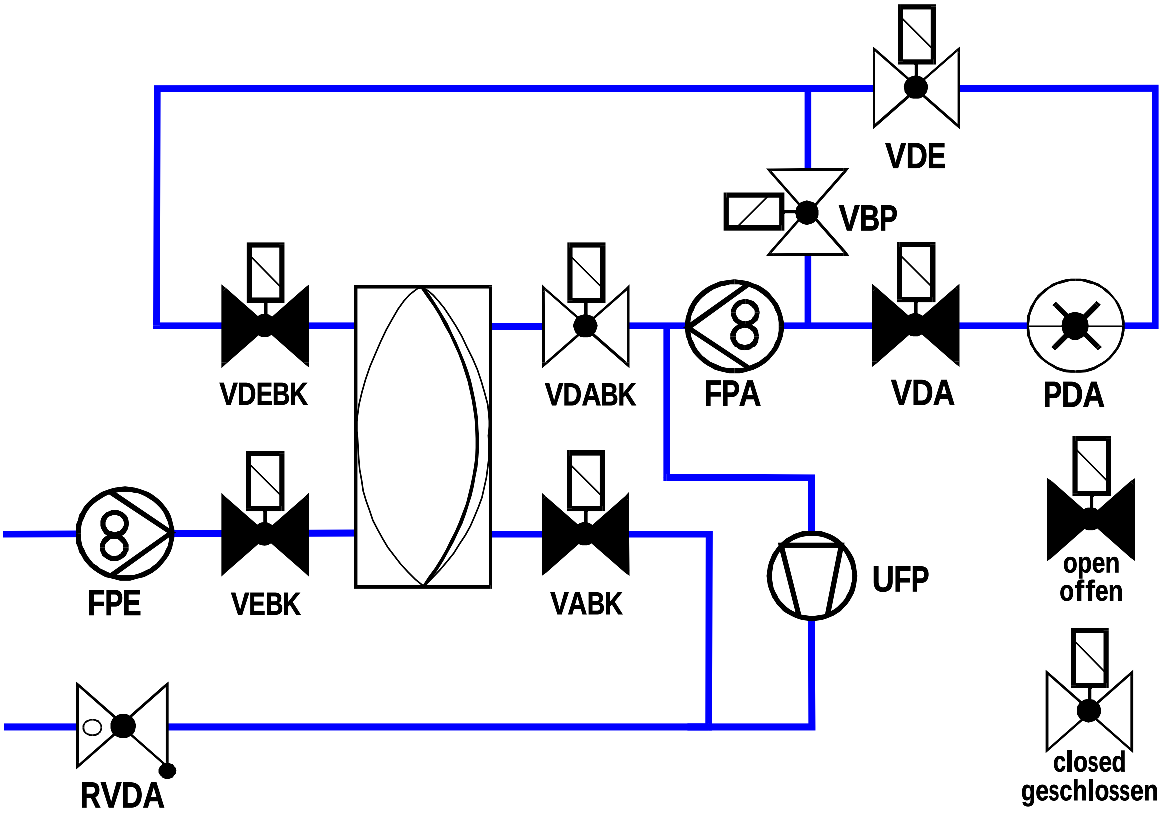


Fig. : Flow Diagram VBP Test

A pressure drop indicates a leakage at any component, e.g. rinse bridge, dialyser, UF pump, o-ring etc..

Test VDE/VBP	A leakage of the valves leads to a pressure increase at PDA.
Test VDABK	A leakage of the valve leads to a pressure increase at PDA.
Timeout	30 s

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
4.	1235x	**VBP test** FPE = 800 ml/min FPA = 100 ml/min **Valve Status:** VEBK1/2, VABK1/2, VDEBK1/2 ------------opened VDABK1/2------------------------------ closed VDE, VBP ------------------------------ closed VDA ---------------------------------- opened **Final Condition:** Test timeout 30 s or wait for inversion of LLS_SELFTESTBIT from LLS	**Start condition for the test (2.5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. 300 mmHg < PDA < +450 mmHg Test 5 s, max. deviation ΔPDA < 25 mmHg, Acknowledge with inversion of LLS_SELFTESTBIT	12021 – 12026 12027 – 12036 12037 12038

3.3.8.5 VDE/VDA Test

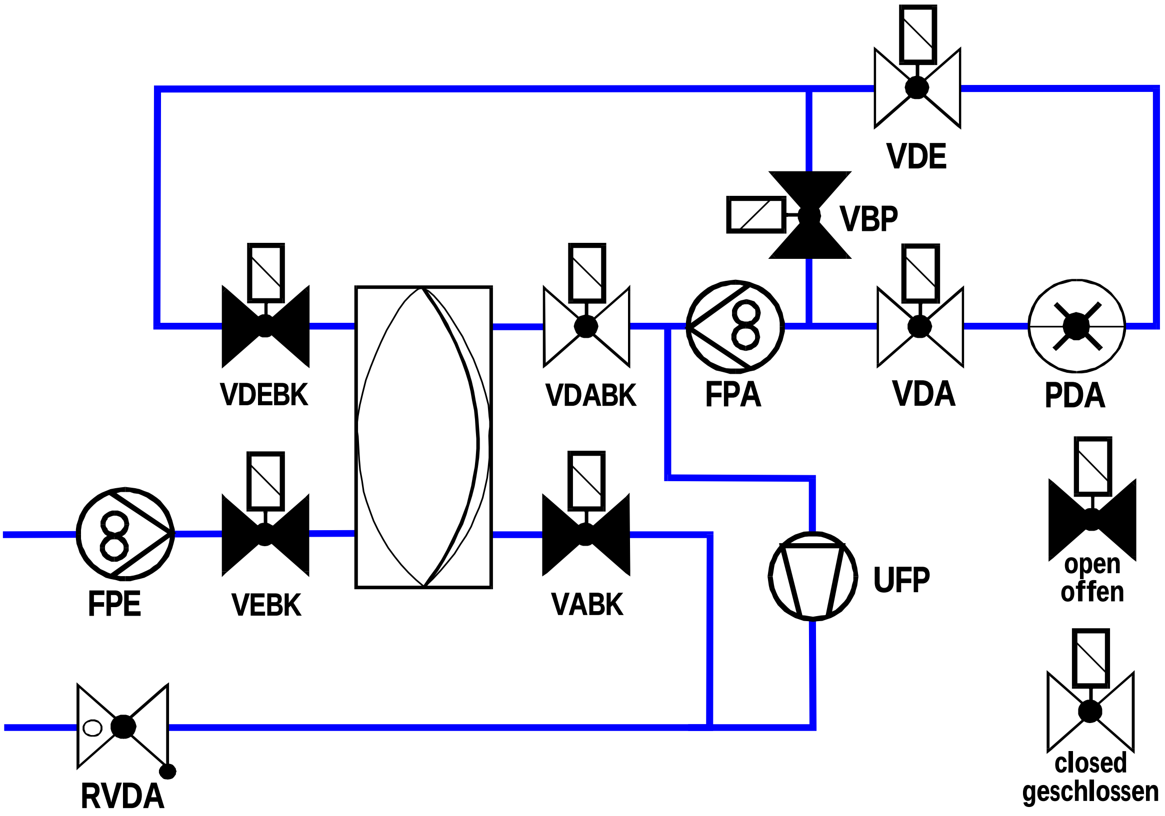


Fig. : Flow Diagram VDE/VDA Test

Test VDE/VDA A leakage of the valves leads to a pressure increase at PDA.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
5.	1240x	**VDE/VDA test** FPE = 800 ml/min FPA = 100 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VABK1/2 --------- opened VDABK1/2 ----------------------------- closed VBP ---------------------------------- opened VDA, VDE ----------------------------- closed **Final Condition:** Test timeout 60 s or wait for inversion of LLS_SELFTESTBIT from LLS	**Start condition for the test (2.5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. 300 mmHg < PDA < +450 mmHg Test 5 s, max. deviation ΔPDA < 25 mmHg, Acknowledge with inversion of LLS_SELFTESTBIT	12061 – 12066 12067 – 12076 12077 12078

3.3.8.6 Pressure Build-up VDABK

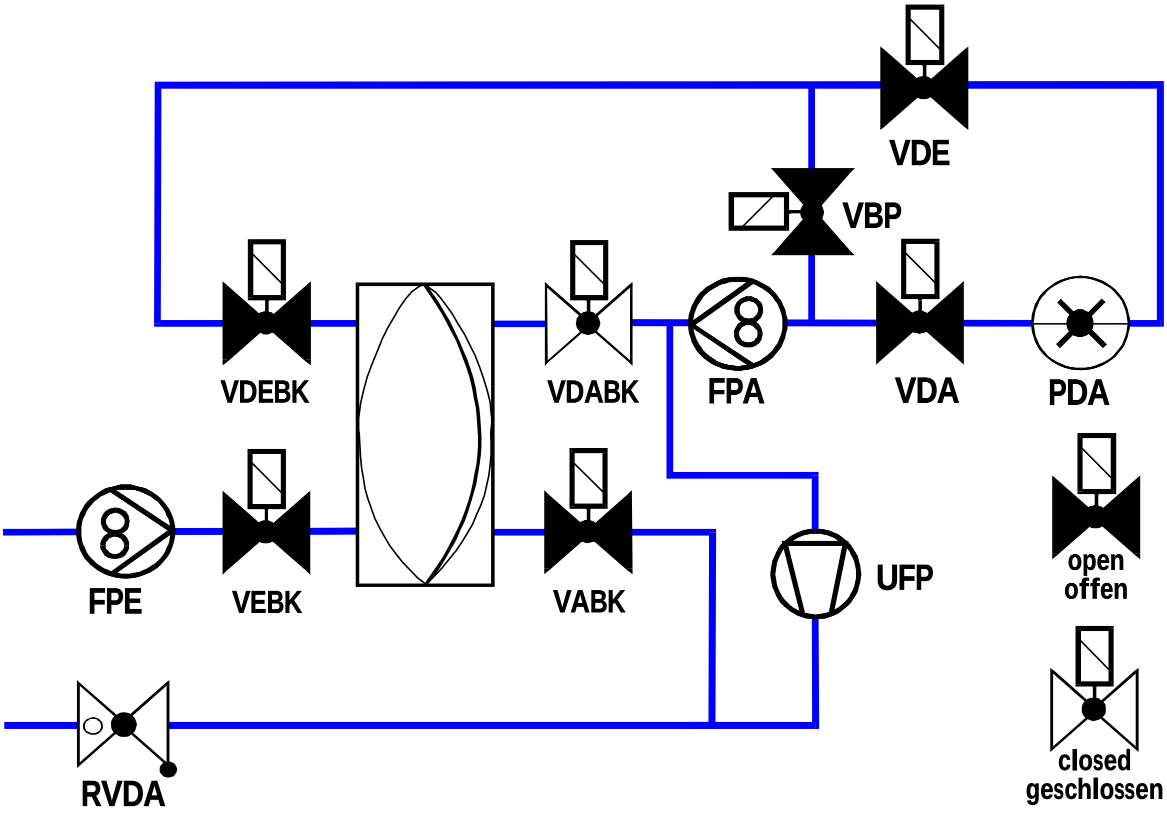


Fig. : Flow Diagram Pressure Build-up VDABK

If PDA < 425 mmHg: The speed for FPE and FPA is slowly set in increments of 200 min^{-1} in 250 ms to a maximum flow of 500 ml/min and 100 ml/min respectively.
The pressure build-up is completed if PDA is ≥ 425 mmHg for more than 1 s.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
6.	1245x	**Pressure build-up VDABK** FPE = 500 ml/min FPA = 100 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VABK1/2 --------- opened VDABK1/2 ----------------------------- closed VBP, VDA, VDE ----------------------- opened **Final Condition:** PDA ≥ +425 mmHg for 1 s or timeout 60 s		12101

3.3.8.7 Pressure Reduction Membrane Test with UFP

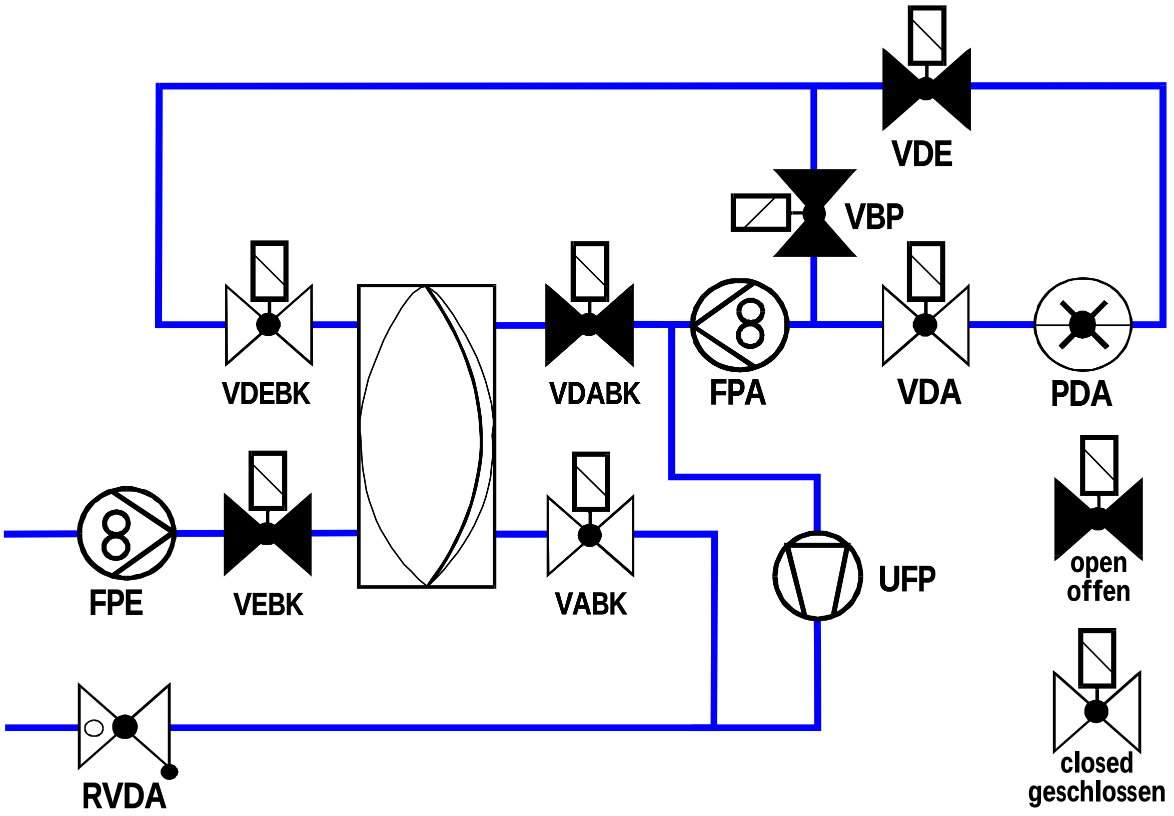


Fig. : Flow Diagram Pressure Reduction Membrane Test with UFP

The pressure at PDA is decreased to ≤ 380 mmHg with the UF pump after the dialyser test circuit is closed. The UF pump is driven with 3000 ml/h. VDA is closed during this pressure reduction. Thus the UF pump strokes are damped via the extended flow path and no interferences are generated at PDA.

During this pressure reduction the speeds for the following test are set to: FPE for a flow of 800 ml/min and FPA for 20 ml/min. Thus the membrane is pressed to the outlet side.

Timeout: 60 s

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
7.	1250x	**Pressure reduction with UFP** FPE = 800 ml/min FPA = 20 ml/min **Valve Status:** VEBK1/2, VDABK1/2 ------------------- opened VDEBK1/2, VABK1/2 -------------------- closed VBP, VDE ----------------------------- opened VDA ----------------------------------- closed **Final Condition:** PDA ≤ +380 mmHg or timeout 60 s		12101

3.3.8.8 Membrane Test

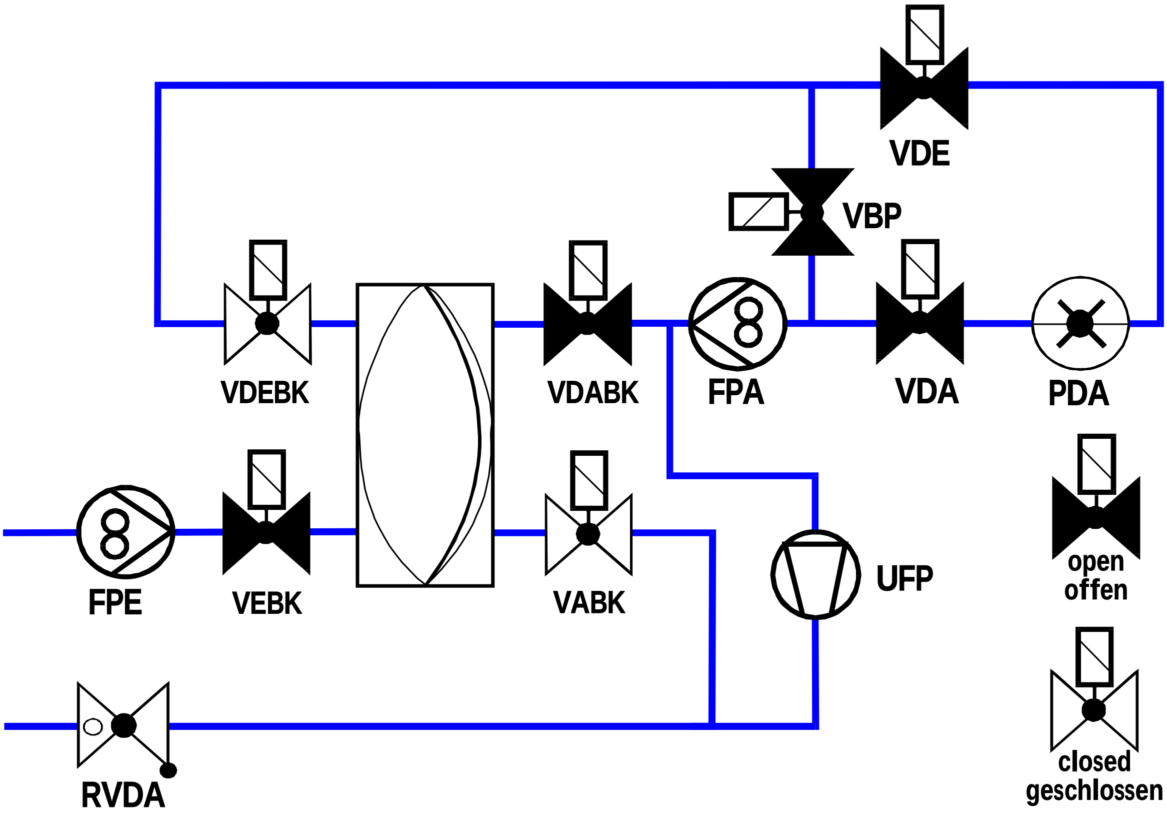


Fig. : Flow Diagram Membrane Test

Test Membrane	The membrane is loaded with a pressure of 1.3 bar due to the high speed of FPE with a flow of 800 ml/min. A leakage would cause a pressure increase at PDA. FPA runs with a slow speed during this test to prevent a back pressure.
Test VDEBK	A leakage of the valve leads to a pressure increase at PDA.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
8.	1255x	**Membrane test** FPE = 800 ml/min FPA = 20 ml/min **Valve Status:** VEBK1/2, VDABK1/2 ------------------- opened VDEBK1/2, VABK1/2 -------------------- closed VBP, VDE, VDA ------------------------ opened **Final Condition:** Test timeout 60 s or wait for inversion of LLS_SELFTESTBIT from LLS	**Start condition for the test (10 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. +300 mmHg < PDA < +450 mmHg Test 10 s, max. deviation ΔPDA < 25 mmHg, Acknowledge with inversion of LLS_SELFTESTBIT	12101 – 12121 12122 – 12131 12132 12133

3.3.8.9 Pressure Build-up VABK

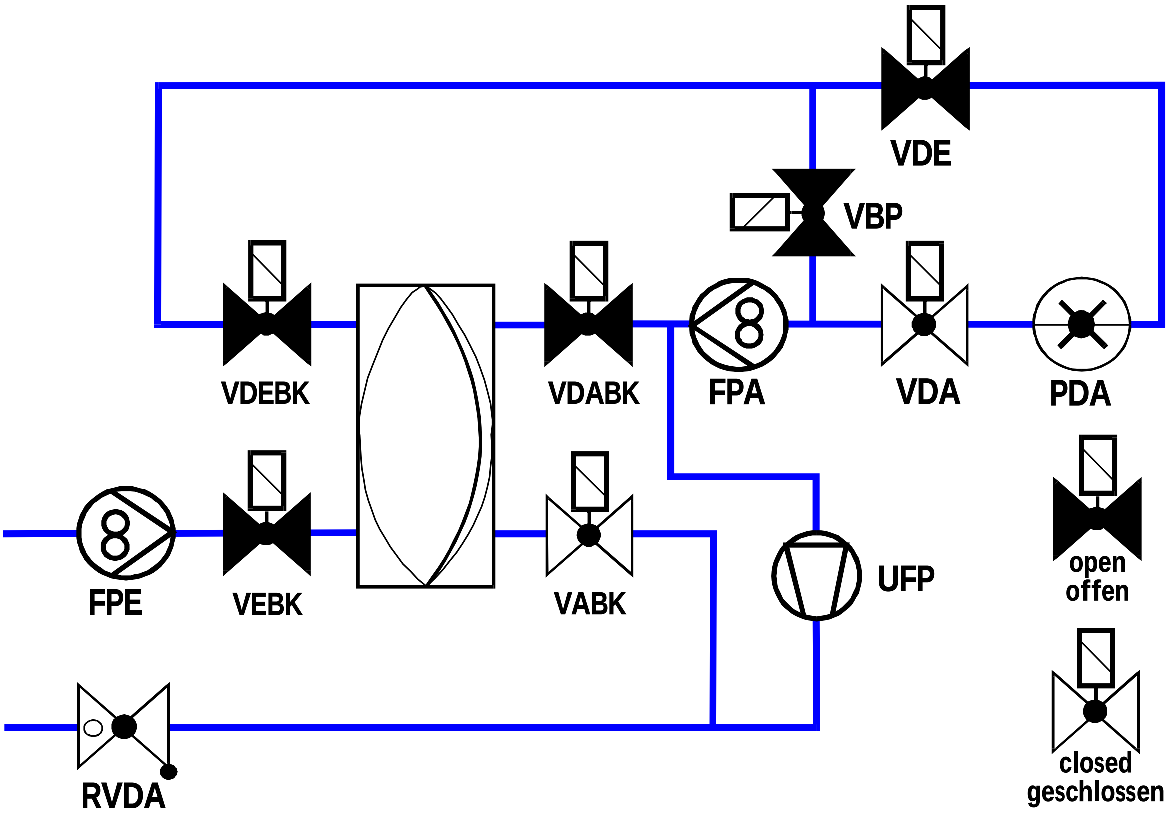


Fig. : Flow Diagram Pressure Build-up VABK

If PDA < 425 mmHg: the speed for FPE and FPA is slowly set in increments of 200 min^{-1} to a maximum flow of 500 ml/min and 100 ml/min respectively.
The pressure build-up is completed if PDA is ≥ 425 mmHg for more than 1 s.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
9.	1260x	**Pressure build-up VABK** FPE = 500 ml/min FPA = 500 ml/min **Valve Status:** VEBK1/2, VDEBK1/2, VDABK1/2 -------- opened VABK1/2 ------------------------------ closed VBP, VDA, VDE ------------------------ opened **Final Condition:** PDA ≥ +425 mmHg for 1 s or timeout 60 s		12151

3.3.8.10 Membrane Movement to Inlet Side

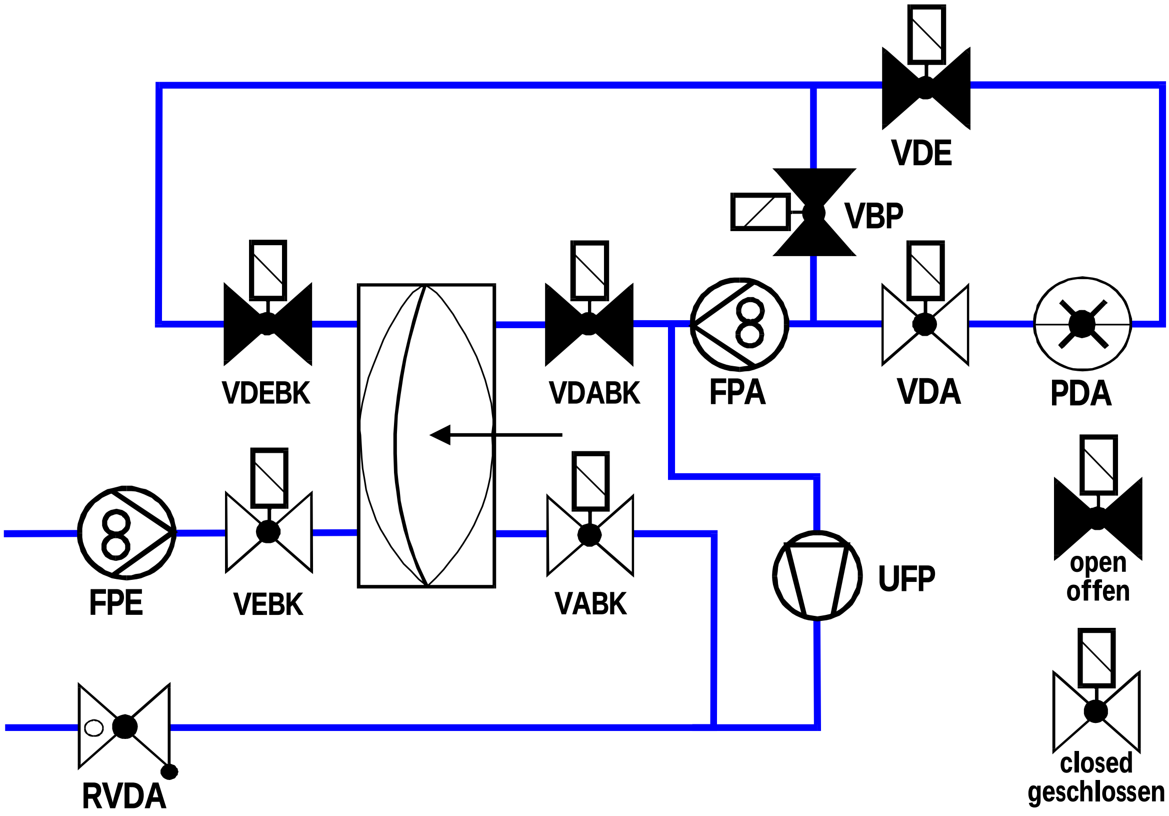


Fig. : Flow Diagram Membrane Movement to Inlet Side

The FPA pump is driven with 1500 ml/min and moves the membrane to the inlet side. Thus an overpressure is built up at the valves VABK1/2 for the next test step. If the membrane is not in end position: Only the pressure of the throttle DDE is built-up prior to the valves, due to the volume shift.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
10.	1265x	**Membrane movement** FPE = 500 ml/min FPA = 1500 ml/min **Valve Status:** VEBK1/2, VABK1/2 --------------------- closed VDEBK1/2, VDABK1/2 ----------------- opened VBP, VDA, VDE ------------------------ opened **Final Condition:** Test timeout 60 s or no increase of the values of the membrane position sensors		12151

3.3.8.11 Pressure Reduction VABK with UFP

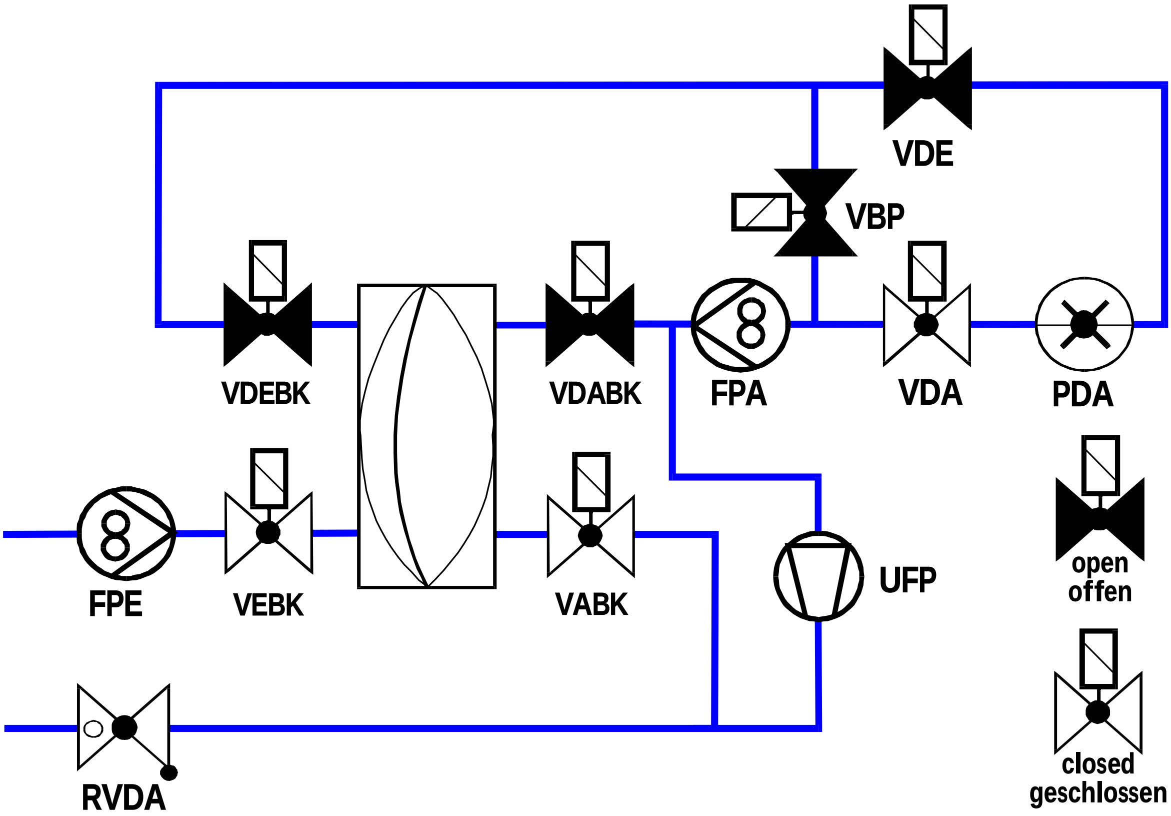


Fig. : Flow Diagram Pressure Reduction VABK with UFP

The pressure at PDA is reduced to ≤ 380 mmHg with the UF pump. The UF pump is driven with 3000 ml/h. VDA is closed during this pressure reduction. Thus the UF pump strokes are damped via the extended flow path and no interferences are generated at PDA. The valve VZ is opened so that the high pre-pressure at RVDA can be reduced to the outlet side and that a sufficient pressure gradient is present at VABK and UFP for the next test.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
11.	1270x	**Pressure reduction with UFP** FPE = 500 ml/min FPA = 500 ml/min **Valve Status:** VEBK1/2, VABK1/2 --------------------- closed VDEBK1/2, VDABK1/2 ----------------- opened VBP, VDE ----------------------------- opened VDA ----------------------------------- closed VZ ------------------------------------ opened **Final Condition:** PDA ≤ +380 mmHg or timeout 60 s		12151

3.3.8.12 VEBK Test

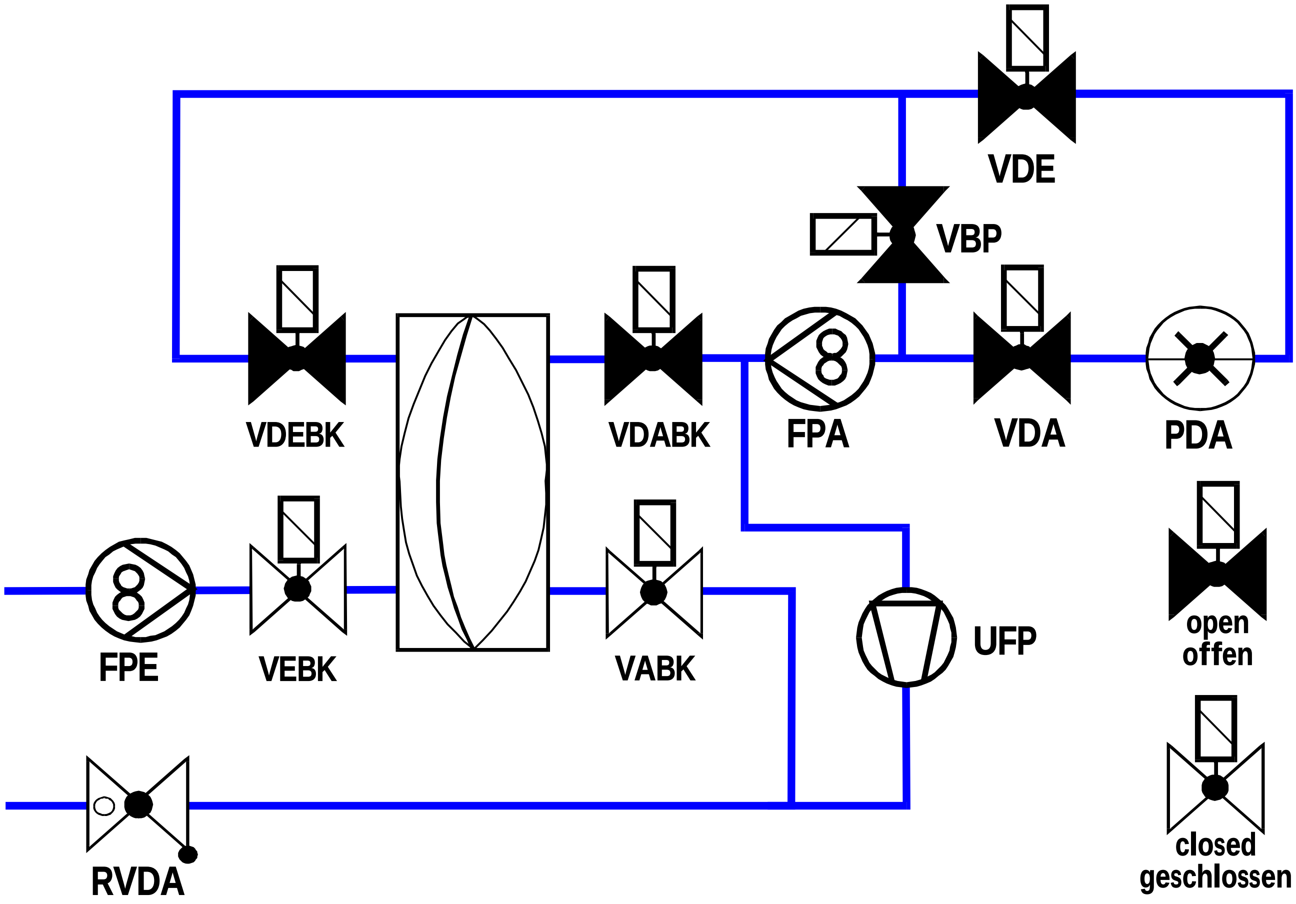


Fig. : Flow Diagram VEBK Test

Test VEBK1/2 VEBK is charged by the maximum delivery pressure from FPE (set at RVFPE). A leakage of the valves leads to a pressure increase at PDA.

Test VABK1/2 VABK is charged by the maximum delivery pressure from FPA (set at RVFPA). A leakage of the valves leads to a pressure increase at PDA.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
12.	1275x	**VEBK test** FPE = 800 ml/min FPA = 500 ml/min **Valve Status:** VEBK1/2, VABK1/2 --------------------- closed VDEBK1/2, VDABK1/2 ----------------- opened VBP, VDE, VDA ------------------------ opened **Final Condition:** Test timeout 60 s or wait for inversion of LLS_SELFTESTBIT from LLS	**Start condition for the test (5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. +300 mmHg < PDA < +450 mmHg Test 10 s, max. deviation ΔPDA < 25 mmHg, Acknowledge with inversion of LLS_SELFTESTBIT	12151 – 12161 12162 – 12181 12182 12183

3.3.8.13 Pressure Reduction

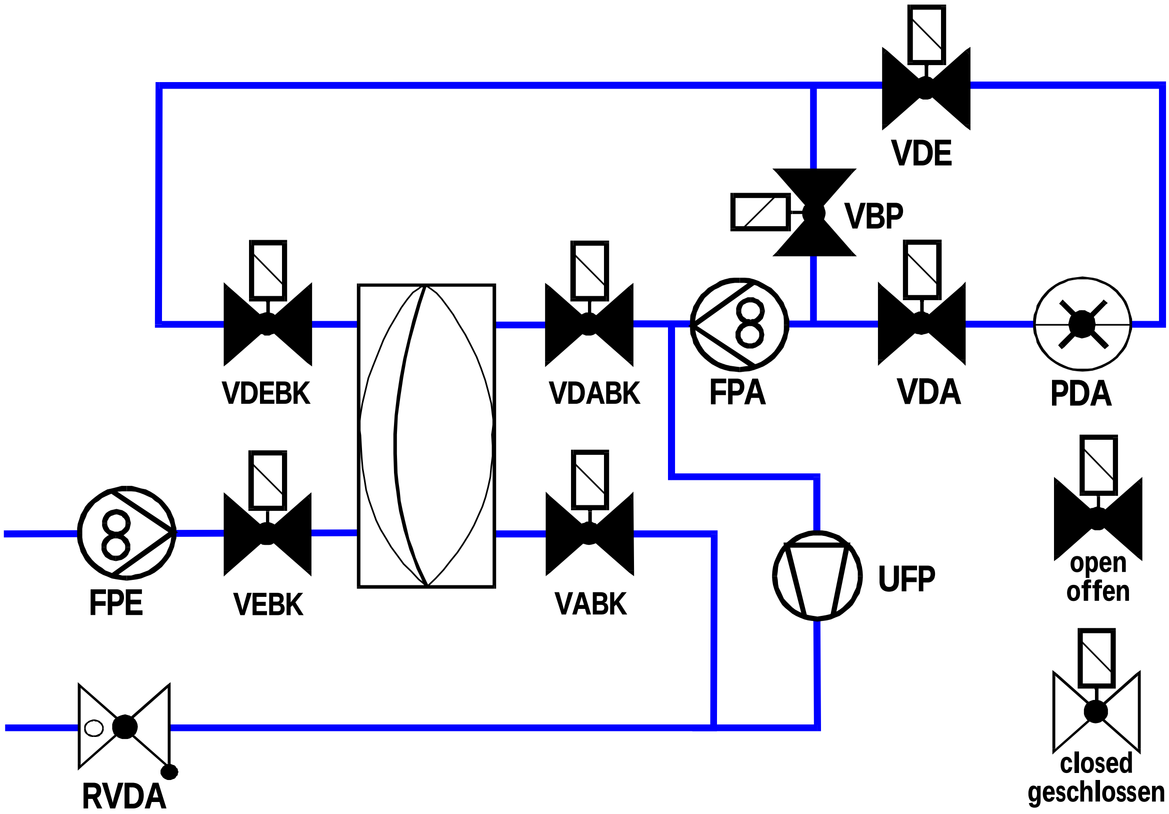


Fig. : Flow Diagram Pressure Reduction

A pressure level is set at PDA between –200 mmHg and +200 mmHg by opening all valves and driving the pumps accordingly.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
13.	1280x	**VEBK test** FPE = 500 ml/min FPA = 500 ml/min **Valve Status:** VEBK1/2, VDEBK1/2 ------------------- opened VABK1/2, VDABK1/2------------------- opened VBP, VDA, VDE ------------------------ opened Timeout 60 s		12000

3.3.9 Integrity Test HDF Online

Simultaneous pressure build-up of DF filter and HDF filter	
Objective	Detection of safety relevant ruptures, pressure test of the substitution system in the machine, pressure test of VBE/VSAE/VSAA. Air can not pass the semipermeable filter membrane at negative pressure of > -500 mmHg. To detect ruptures: One side of the filter is filled with air; On the other side a negative pressure < -270 mmHg is built up. If the pressure drop is < 20 mmHg in 3 min, safety relevant ruptures are not present. The final opening of VBP must be detected by LLS via PDA. Thus it is guaranteed that the filters were filled with air and VBE was opened.
Test code	15
Repeats until error message	1
ID error message	1151: *HDF online filter test failed!*
Actions after error	Rinse, repeat all tests

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	1502x	**Prerequisites for Test:** Upline tank must be filled, PSAUS, PSABF and BPV cover must be closed. Timeout 2 min		
2.		Test code = 15 to LLS	Test code = 15 back to LLC	
3.	1510x	**Pressure Reduction for VBE Test with FPA:** Pressure reduction with FPA until PDA < -300 mmHg **Valve Status:** VDEBK1/2, VEBK1/2 -------------------- closed VDABK1/2, VABK1/2------------------- opened VBE, VDFF, VDE, VSB-------------------- closed VBP, VDA, VSAE, VSAA----------------- opened Timeout 1 min		
4.	1515x	**VBE Pressure Test** **Valve Status:** VDEBK1/2, VEBK1/2 -------------------- closed VDABK1/2, VABK1/2-------------------- closed VBE, VDFF, VDE, VSB-------------------- closed VBP, VDA, VSAE, VSAA----------------- opened Test timeout 1 min or wait for switch-off VGD from LLS	**Start condition for the test (5 s):** 4. Correct valve position 5. UFP stopped (UF rate < 500 ml/h) 6. -450 mmHg < PDA < -150 mmHg Test 10 s, max. deviation ΔPDA < 50 mmHg, PDA < -100 mmHg, Acknowledge with switch-off of VGD	15001 – 15010 15011 15012 – 15018
5.	1520x	**Pressure Reduction for VSAE Test with UFP:** Pressure reduction with UFP until PDA < -300 mmHg **Valve Status:** VDEBK1/2, VEBK1/2 ------------------- opened VDABK1/2, VABK1/2-------------------- closed VBE, VDFF, VDE, VSB, VBP, VSAE--------- closed VDA, VSAA---------------------------- opened Timeout 1 min		
6.	1525x	**VSAE Pressure Test and OSP Test** FPE = 1000 ml/min **Valve Status:** VDEBK1/2, VEBK1/2 ------------------- opened VDABK1/2, VABK1/2-------------------- closed VBE, VDFF, VDE, VSB, VBP, VSAE--------- closed VDA, VSAA---------------------------- opened Test timeout 1 min or wait for switch-off VGD from LLS	**Start condition for the test (5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. PDA < -150 mmHg Test 10 s, max. deviation ΔPDA < 50 mmHg, PDA < -100 mmHg, Test delivery rate OSP at 200 ±15 ml/min Acknowledge with switch-off of VGD	15021 – 15030 15031, 15032 15033 15034 – 15039

7.	1530x	**Pressure Reduction for VSAA Test with UFP:** Pressure reduction with UFP until PDA < –300 mmHg **Valve Status:** VDEBK1/2, VEBK1/2 ------------------- opened VDABK1/2, VABK1/2-------------------- closed VBE, VDFF, VDE, VSB, VBP, VSAA -------- closed VDA, VSAE---------------------------- opened Timeout 1 min		
8.	1535x	**VSAA Pressure Test** FPE = 1000 ml/min **Valve Status:** VDEBK1/2, VEBK1/2 ------------------- opened VDABK1/2, VABK1/2-------------------- closed VBE, VDFF, VDE, VSB, VBP, VSAA -------- closed VDA, VSAE---------------------------- opened Test timeout 1 min or wait for switch-off VGD from LLS	**Start condition for the test (5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. PDA < -150 mmHg Test 10 s, max. deviation ΔPDA < 50 mmHg, PDA < -100 mmHg, Acknowledge with switch-off of VGD	15041 – 15050 15051 15052 – 15058
9.	1540x	**Pressure Equalisation for 60 s** **Valve Status:** VDEBK1/2, VEBK1/2 ------------------- opened VDABK1/2, VABK1/2-------------------- closed VBE, VDE ------------------------------ closed VDFF, VBP, VSB, VDA, VSAE, VSAA------ opened		
10.	1545x	**Filter Pressure Reduction with FPA:** Pressure reduction with FPA until PDA < –300 mmHg more than 4 s Opened VBE at PDA < –150 mmHg more than 2 s Close VBE at PDA > –150 mmHg **Valve Status:** VDEBK1/2 ----------------------------- closed VDABK1/2, VABK1/2------------------ opened VDE, VBP, VSAA------------------------ closed VDFF, VSB, VDA ----------------------- opened Timeout 3 min		
11.	1550x	Wait 1 s		
12.	1555x	**Filter Pressure Reduction with UFP:** Control negative pressure with UFP (–320 mmHg) PDA < -150 mmHg: VBE opened PDA > -10 mmHg: VBE closed **Valve Status:** VDEBK1/2 ----------------------------- closed VDABK1/2 ----------------------------- closed VDE, VBP, VSAA------------------------ closed VDFF, VSB, VDA ----------------------- opened Timeout 3 min		
13.	1560x	**Filter Pressure Test** **Valve Status:** VDEBK1/2 ----------------------------- closed VDABK1/2 ----------------------------- closed VDE, VBP, VSAA------------------------ closed VDFF, VSB, VDA, VBE ------------------ opened Test timeout 1 min or wait for switch-off VGD from LLS	**Start condition for the test (5 s):** 1. Correct valve position 2. UFP stopped (UF rate < 500 ml/h) 3. VBE opened 4. PDA < -250 mmHg Test 10 s, max. deviation ΔPDA < 50 mmHg, PDA < -200 mmHg, Acknowledge with switch-off of VGD	15101 – 15110 15111 15112 – 15118

14.	1565x	Opened VBP to acknowledge that air is really in the filter. Test timeout 1 min or wait for switch-off VGD from LLS	**Test Condition:** 1. Correct valve position 2. VBP, VBE opened 3. UFP stopped (UF rate < 500 ml/h) 4. PDA > -100 mmHg Acknowledge with switch-off of VGD	15120 15121 - 15127
15.	1580x	(Error) PSAUS and/or PSABF not closed		
16.	1599x	Completed		

The pressure reduction in the filters is first performed with FPA. The speed is controlled to build up a negative pressure of approx. -290 mmHg at PDA. If the pressure at PDA is < -300 mmHg the UF pump is switched on to reduce the pressure, and the balance chamber valves VDABK1/2 are closed.

Pressure reduction with FPA

PDA > -300 mmHg	100 ml/min ≤ FPA ≤ 1000 ml/min

Pressure reduction with UF pump

PDA > -300 mmHg	UF rate = 3000 ml/h
PDA > -320 mmHg	UF rate = 1000 ml/h

3.3.10 UF Pump

Objective	The function of the speed detection is tested.
Test code	20
Repeats until error message	1
ID error message	1158: *UF pump test will be repeated*
Actions after error	Repeat DFS pressure test and if necessary integrity test HDF online.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	2002x	**Prerequisites for Test:** Upline tank must be filled Timeout 2 min		
2.		Test code = 20 to LLS	Test code = 20 back to LLC	
3.	2010x	Set timeout timer	Test initialisation	20000 – 20004
4.			Since the start of the DFS pressure test more than 3 revolutions have been detected	20005
5.			Acknowledge with switch-off of VGD	20006 – 20011
6.	2020x	Wait for D24OFF (timeout 10 s)		
7.			VGD ON	20012
8.	2030x	Wait for D24ON (timeout 10 s)		
9.	2099x	Completed		

3.3.11 Conductivity

Objective	The function of the END-LF sensors is tested.
Test code	21
Repeats until error message	1
ID error message	1159: *Conductivity test not OK*
Actions after error	Rinse, repeat all tests.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.		Test Prerequisites - None:		
2.		Test code = 21 to LLS	Test code = 21 back to LLC	
3.	2110x		Test initialisation	21000 – 21004
4.			Evaluation of the LF value test After passing the DFS pressure test ENDLF-S must reach the following value: - ENDLF-S > ENDLF-S$_{\text{DFS-Pressure Test}}$ + 5 mS/cm - ENDLF-S ≥ 11.4 mS/cm - ENDLF-S ≤ 17.85 mS/cm	21005
5.			Acknowledge with switch-off of VGD	21066 – 21011
6.	2120x	Wait for D24OFF (timeout 10 s)		
7.			VGD ON	21012
8.	2130x	Wait for D24ON (timeout 10 s)		
9.	2199x	Completed		

ENDLF-S$_{\text{DFS-Pressure Test}}$ is stored at the beginning of the DFS pressure tests

3.3.12 Temperature TSD

Objective	The function of the TSD sensors is tested.
Test code	22
Repeats until error message	1
ID error message	1160: *Temperature test not OK*
Actions after error	Rinse, repeat all tests.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	2202x	Prerequisites for Test: If test temperature was not yet reached: - Set warning 1102 - Wait for max. 3 min to reach the test temperature Test temperature reached or wait time exceeded: - Delete warning 1102 - Perform test.		
2.		Test code = 22 to LLS	Test code = 22 back to LLC	
3.	2210x	If test temperature (>41 °C) was not yet reached: Test not passed otherwise: timeout - set timer	Test initialisation	22000 – 22004
4.			After the start of the preparation: TSD-S must exceed 41 °C and be < 50 °C. The heater is switched off at TSD-S > 41 °C	22005
5.			Acknowledge with switch-off of VGD	22006 – 22011
6.	2220x	Wait for D24OFF (timeout 10 s)		
7.			VGD ON	22012
8.	2230x	Wait for D24ON (timeout 10 s)		
9.	2299x	Completed		

3.3.13 SAD Level Test

The level test measures the test threshold, which LLC generates to drive the SAD with a permanent test pulse. This is compared with the calibrated test threshold ± 50 mV. If the measured test threshold is in this limit LLS switches off the +24 V for 3 s. This is detected by LLC as "test passed".

Test code	30
Repeats until error message	3
ID error message	1161: *SAD (Ref.) test not OK*
Actions after error	Return to window: Repeat blood line self test with ↵ key.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	3002x	**Test Prerequisites:** Blood side must not be stopped by TLC or LLC. If stopped: Message 1140 is displayed. No timeout.		
2.		Test code = 30 to LLS	Test code = 30 back to LLC	
3.	3010x	Set wait timer	Test initialisation	30000
4.	3020x	After 3 s signal EV_DAUERTEST_SAD_EIN send to BIOS-SAD-Task		
5.			If deviation SAD-Ref ≤ 50 mV then carry on	30001
6.			If deviation SAD-Ref ≤ 50 mV then acknowledge with switch-off VGB	30002
7.			Acknowledge with switch-off VGB	30003 - 30008
8.	3030x	Wait for B24OFF (timeout 10 s) If B24OFF signal EV_DAUERTEST_SAD_AUS send to BIOS-SAD-Task		
9.			VGB ON	30009
10.	3040x	Wait for B24ON (timeout 10 s)		
11.	3099x	Completed		

3.3.14 SAD Counter Test

The counter test measures the time base of the counter for the TIMECONTR signal. LLC triggers and a low pulse of 1666 µs is generated at the TIMECONTR signal, which is measured by LLS. If this pulse is in the range of 1666 µs ±30 µs LLS switches off the +24 VB for 3 s. This is detected by LLC as "test passed".

Test code	31
Repeats until error message	3
ID error message	1162: *SAD (Freq.) test not OK*
Actions after error	Return to window: Repeat blood line self test with ↵ key.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	3102x	**Prerequisites for Test:** Blood side must not be stopped by TLC or LLC. If stopped: Message 1140 is displayed. No timeout.		
2.		Test code = 31 to LLS	Test code = 31 back to LLC	
3.	3110x	Send signal EV_COUNTER_TEST_SAD to BIOS-SAD-Task	Test initialisation	31000
4.			If measurement of TIMECONTR pulse length 1629 µs ≤ t ≤ 1689 µs, then acknowledge with switch-off VGB	31001
5.			Acknowledge with switch-off VGB	31002 – 31007
6.	3120x	Wait for B24OFF (timeout 10 s)		
7.			VGB ON	31008
8.	3130x	Wait for B24ON (timeout 10 s)		
9.	3199x	Completed		

3.3.15 Equality Test for Blood Side Pressure Sensors

The pressure sensors are connected together via the filled tubing system with bag and thus have the same pressure level. Additionally the feedback of the level regulation valves, the level regulation pump LRP (PPR) and the SAKA are checked.

Objective	Test the equality of pressure sensors with opened tubing system.
Test code	32
Repeats until error message	3
ID error message	1163: *Blood side pressure sensor test not OK*
Actions after error	Return to window: Repeat blood line self test with ↵ key.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	3202x	**Prerequisites for Test:** **a)** Blood side must not be stopped by TLC or LLC. If stopped: Message 1140 is displayed. No timeout. **b)** If BS is not stopped HDFonline task must enable the start of the tests. A delay occurs only with autopriming (set pressure). Timeout 2 min		
2.		Test code = 32 to LLS	Test code = 32 back to LLC	
3.	3210x	LLC activates VBT, VPA, VPV, VPU and SAKA VPU must be activated to prevent a pressure equalisation to the environment and that the levels in the chambers do not change. VPE remains closed to prevent a pressure equalisation if PBE is not connected.	Test initialisation	32000
4.	3220x	Test timeout 60 s and wait for inversion of LLS_SELFTESTBIT from LLS	Check of current detection for VBT, VPA, VPV, VPE, VPD, SAKA and PPR Acknowledge with inversion of LLS_SELFTESTBIT	32001
5.	3230x	LLC deactivates VBT, VPA, VPV, SAKA and activates VPE		
6.	3240x	Test timeout 60 s and wait for inversion of LLS_SELFTESTBIT from LLS	Check of current detection for VBT, VPA, VPV, VPE, VPD, SAKA and PPR Acknowledge with inversion of LLS_SELFTESTBIT	32020
7.	3250x	LLC deactivates VBE and VPU VPD is activated PPR is activated with the PWM PPRLOW (PWM for line with small chamber, setting in TSM)		
8.		Initialise mean value storage for PA, PV, PBS and PBE	Check of current detection for VBT, VPA, VPV, VPE, VPD and PPR	32002
9.	3260x	Wait for inversion of LLS_SELFTESTBIT from LLS (timeout 15 s) Evaluate every 250 ms continuous mean value from the 4 values of PA, PV, PBS and PBE.	Save values from PA, PV, PBS, PBE and compare the pressure sensor PA, PV, PBE and PBS (if present):	32004
10.			$\lvert PV – PA \rvert$ must be $\le$ 20 mmHg. $\lvert PV – PBE \rvert$ must be $\le$ 20 mmHg or $\lvert PBE \rvert < 10$ mmHg.	32005
11.			$\lvert PV – PBS \rvert$ must be $\le$ 20 mmHg or $\lvert PBS \rvert < 10$ mmHg.	32006
12.			Acknowledge with inversion of LLS_SELFTESTBIT	32010
13.		Detected inversion of LLS_SELFTESTBIT Calculate mean value storage of PA, PV, PBS and PBE		
14.	3260x	(Error) received B24ON - mean value of PA and PV deviate more than ±40 mmHg.		
15.		(Error) the test prerequisites from HDFonline-Task are not given during one of the test steps (e.g. autopriming, HDF filter rinsing required after LF error).		
16.		Completed Close VPD		

3.3.16 Pressure Test Substitution Line S-Online HDF Online

If the substitution line s-online is connected at the beginning of the blood side self test and the filling of the tubing system is performed by the machine (autopriming): LLC performs a pressure test of the port connectors and the lines between the port and OSP. This tubing is connected with the pressure sensor PA via the arterial tubing adapter. The test is performed with positive pressure. The build-up is performed in the DFS system with FPE/FPA via a pressure drop at the throttle DDE and an opened VSAE. The pressure test is performed for s-online after the equality test of the pressure sensors in the blood side test block.

If autopriming is not performed s-online can not be tested. As an information LLS generates an alarm *Leakage Check S-Online* after the initial start of OSP in therapy. This information is generated even if the autopriming of the s-online test was not performed by LLC.

If the s-online is not connected during the pressure test this is not detected and a message to check the line is not generated after connection and the start of online.

Test code	40
Repeats until error message	1
ID error message	1166: *Self test substitution line failed*
Actions after error	Return to window: Repeat blood line self test with ↵ key.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	4002x	**Prerequisites for Test:** Blood side must not be stopped by TLC or LLC. If stopped: Message 1140 is displayed. No timeout.		
2.		Test code = 40 to LLS	Test code = 40 back to LLC	
3.	4010x	Opened VSAE	Test initialisation	40000
4.	4020x	Pressure build-up with FPE/FPA in chamber flow through mode via DDE until PA > 270 mmHg (no pressure control for pressure sensor PA!) Valve Status: VDFF, VDE, VDA, VSB, VSAA ------------------closed VBP, VSAE ---------------------------------opened Timeout *20 s*		
5.		**S-online Pressure Test** **Valve Status**: VSAE closed, BPA and OSP stopped	**Start condition for the test (for 5 s):** 1. Correct valve position (VSAE closed) 2. PA > 250 mmHg 3- PA < 500 mmHg	40001 – 40010
6.			Test 10 s, Averaging MeanPA, Determine MinPA and MaxPA Check –500 mmHg < PA < 500 mmHg, max. deviation ΔPA < 50 mmHg, -450 mmHg < PA < 450 mmHg,	40011
7.			Check: - MaxPA - MeanPA < 50 mmHg, - MeanPA - MinPA < 50 mmHg Acknowledge with switch-off VGB	40012 40013 – 40018
8.	4020x	Wait for B24OFF (timeout 30 s)		
9.			VGB ON	40019
10.	4030x	Wait for B24ON (timeout 15 s)		
11.	4070x	(Error) the test prerequisites from HDFonline task are not given during one of the test steps (e.g. autopriming, HDF filter rinsing required after LF error).		
12.	4099x	Completed		

3.3.17 Blood Side Pressure Retention Test

Objective	Pressure test of tubing system and control of the dynamics of the pressure sensors.
Test code	33
Repeats until error message	3
ID error message	1169: *Blood side leakage test not OK*
Actions after error	Return to window: Repeat blood line self test with ↵ key.

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.	3302x	**Prerequisites for Test:** **a)** Blood side must not be stopped by TLC or LLC. If stopped: Message 1140 is displayed. No timeout. **b)** If BS is not stopped HDFonline task must enable the start of the tests. A delay occurs only with autopriming (set pressure). Timeout 2 min		
2.		Test code = 33 to LLS	Test code = 33 back to LLC	
3.	3300x	Stop BPA	Test initialisation	33000
4.	3310x	Set BPA with ramp to delivery rate 200 ml/min, opened SAKV Timeout 90 s since subcode 100	Test SAKV opened	33001
5.			Test of BPA delivery rate at 185 ml/min < BPA < 215 ml/min Acknowledge by closing SAKV and saving PV	33013
6.			Test of BPA motor speed (Note: the motor pulses are used for alarm evaluation when detecting standstill.)	33014
7.	3330x	Wait for PV > +400 mmHg for 500 ms during the running of BPA. Pressure reached: - Stop BPA, close SAKV, open VBT - Initialise mean value storage for PA, PV, PBS and PBE Timeout 90 s since the start of subcode 100	Wait for PV > 390 mmHg no timeout	33015-33023
8.	3340x	Evaluate every 250 ms continuous mean value from the 4 values of PA, PV, PBS and PBE. Evaluate after 2.5 s mean values of PBS and PBE: **PBE connected, if** PBE mean value is min. 100 mmHg higher (from BS pressure test) than PBE mean value (from BS equality test of pressure sensors) and PBE and PV mean value deviate less than ± 40 mmHg (from BS equality test). **PBS connected, if** PBS mean value is min. 100 mmHg higher (from BS pressure test) than PBS mean value (from BS equality test of pressure sensors) and PBS and PV mean value deviate less than ± 40 mmHg (from BS equality test). |PA - PV| ≤ 20 mmHg	Opened SAKV	33024-33025
9.			PBE present, if: PBE ≥ PBE +100 mmHg from test 32, step 4 PBS present, if: PBS ≥ PBE +100 mmHg from test 32, step 4 Terminate if PBS not present for SNCO PV ≥ PV + 100 mmHg from test 32 step 20	33026
10.			Test SAKV closed, save PV	33027
11.			Test 10 s PV pressure drop < 20 mmHg and PV > 150 mmHg and |PA - PV| ≤ 20 mmHg otherwise return to 54 Acknowledge with inversion of LLS_SELFTESTBIT	33028 - 33038
12.	3340x	Wait for inversion of LLS_SELFTESTBIT from LLS (Timeout 35 s since start of subcode 400)		
13.		Close VBT	Test VBT closed	33039
14.			|PA - PV| ≥ 200 mmHg Acknowledge with inversion of LLS_SELFTESTBIT	33040
15.	3350x	Wait for inversion of LLS_SELFTESTBIT from LLS		

		(Timeout 10 s since start of subcode 400)		
16.	3360x	(Error) the test prerequisites from HDF online task are not given during one of the test steps (e.g. autopriming, HDF filter rinsing required after LF error).		
17.	3370x	(Error) during start up of BPA (subcode 200), PV > +400 mmHg		
18.	3399x	Completed		33041

3.3.18 Disinfection Valve VD

Objective Function test of the detection of the actual value for LLS.
The disinfection valve VD is opened shortly (t < 3 s) by LLC during the test. The opening must be detected by LLS.
The test is performed in *Preparation* if the dialyser couplings are not connected to the rinsing bridge anymore and the blood side pressure retention test was passed. If the test is not passed therapy is not possible.

Test code 37

Repeats until error message 3

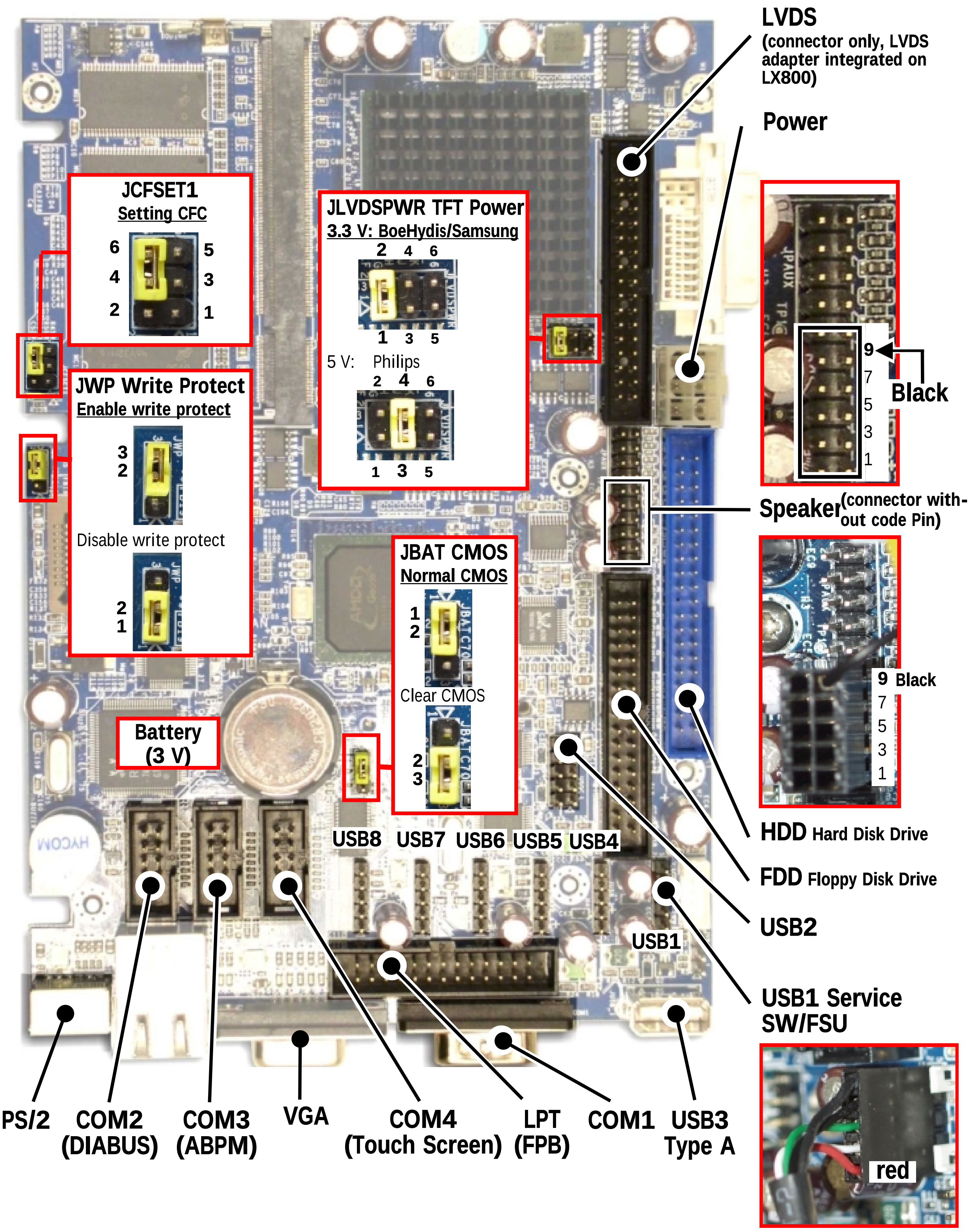
ID error message 1165: *Self test VD failed*

Actions after error None (repeat test until passed).

	LLC Test Code	LLC Test Steps	LLS Test Steps	LLS Test Code
1.		**Prerequisites for Test: None**		
2.		Test code = 37 to LLS	Test code = 37 back to LLC	
3.	3710x	Opened VD	Test initialisation	37000
4.			**Start condition for the test:** **1.** BS pressure retention test is passed (test code 33)	37001
5.			Detection valve opened	37002
6.	3720x	Close VD after 750 ms		
7.			Detection valve closed. The detected opening is acknowledged by the switch-off of VGB.	37003 – 37009
8.	3730x	Wait for B24OFF (timeout 7.5 s)		
9.			VGB ON	37010
10.	3730x	Wait for B24ON (timeout 5 s)		
11.	3780x	(Error) at start of test one or both couplings connected to rinsing bridge.		
12.	3799x	Completed		

3.4 LX800 Motherboard

The Dialog+ (software 9.xx) uses the LX800 motherboard. A compact flash card CFC is connected to the motherboard. The BIOS is described in paragraph 3.3.5.



3.4.1 IDE Interface LX800 Motherboard

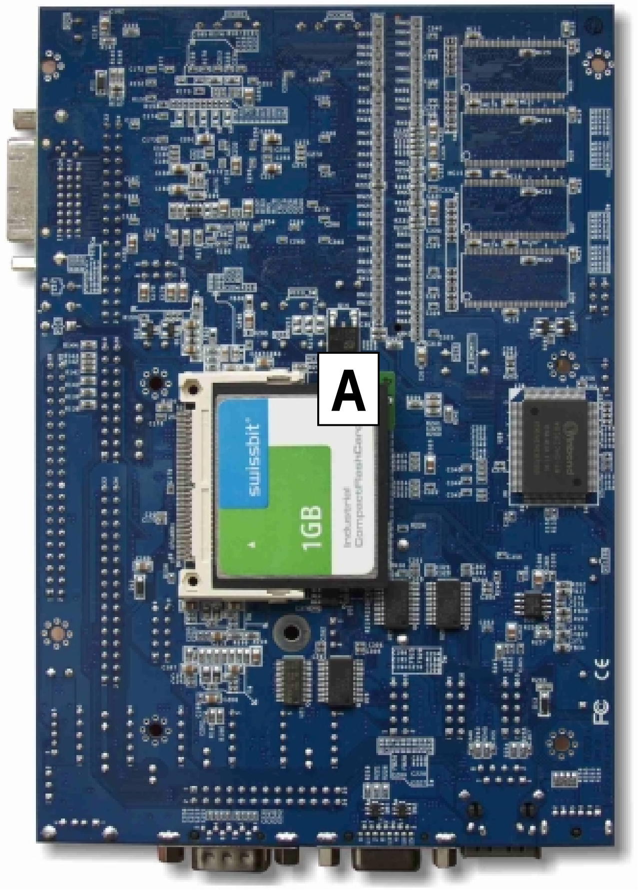


Fig.: LX800 Motherboard, Rear Side

The compact flash card CFC **A** is assembled on the rear side of the LX800 motherboard. The assignment of the IDE interface is listed in the table. The BIOS settings are in paragraph 3.4.5.

LX800 Assignment IDE Interface	
	IDE
Compact Flash Card CFC	**X**

3.4.2 COM Ports LX800 Motherboard

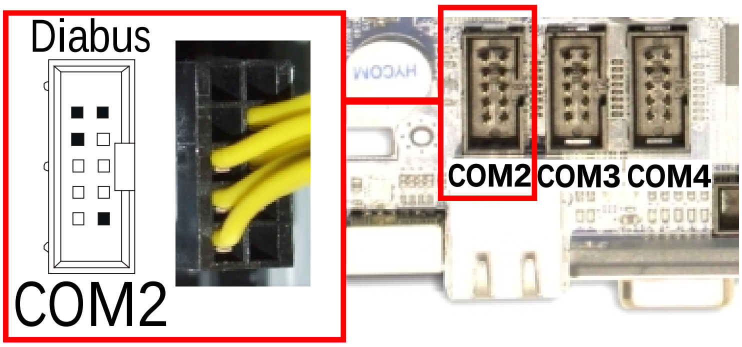


Fig.: COM Ports

The assignment of the COM ports is listed in the table. The assignment of the Diabus is shown additionally (left figure). The BIOS settings are in paragraph 3.4.5.

LX800 Assignment COM Ports			
	COM2	**COM3**	**COM4**
DIABUS	**X**		
ABPM		**X**	
Touch Screen			**X**

3.4.3 USB Ports LX800 Motherboard

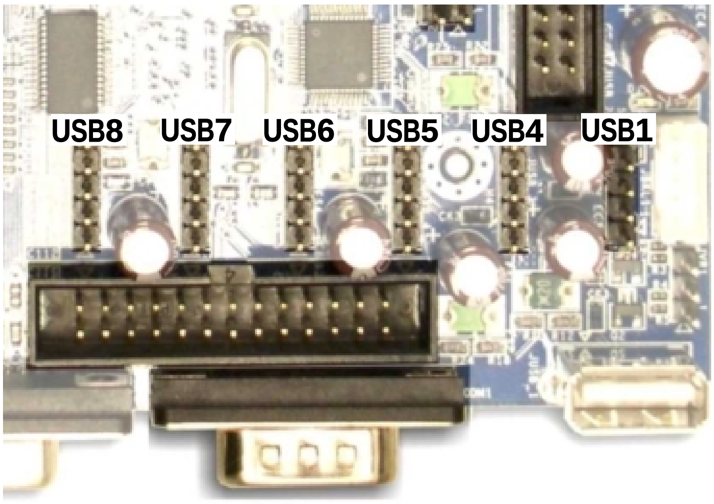


Fig.: USB Ports

The assignment of the USB ports is listed in the table. The USB ports 4 to 8 are freely selectable. The BIOS settings are in paragraph 3.4.5.

LX800 Assignment USB Ports				
	USB1	**USB2**	**USB3**	**USB4-8**
USB Service SW/FSU	**X**			
Card Reader				**X**
DSI (CritLine)				**X**
Adimea (Kt/V-UV)				**X**

3.4.4 Detection/Boot Sequence from Bootable USB Sticks

Use only USB sticks supplied by B. Braun as tool for the installation of the software.

Fig.: Start Screen during Installation of Software with **Installation** Logo

Fig.: Start Screen during Installation of Software with **B | BRAUN** Logo

Dialog+ machines detect automatically connected bootable USB sticks. This is indicated by the red **Installation** text in start screen.

The following may occur during the installation of the TLC software:

- a bootable USB stick is not detected or
- a bootable USB stick is detected, but it is not booted from the USB stick.

If the installation of the software can not be performed from the USB stick, the **B | BRAUN** logo is displayed in both cases on the start screen.

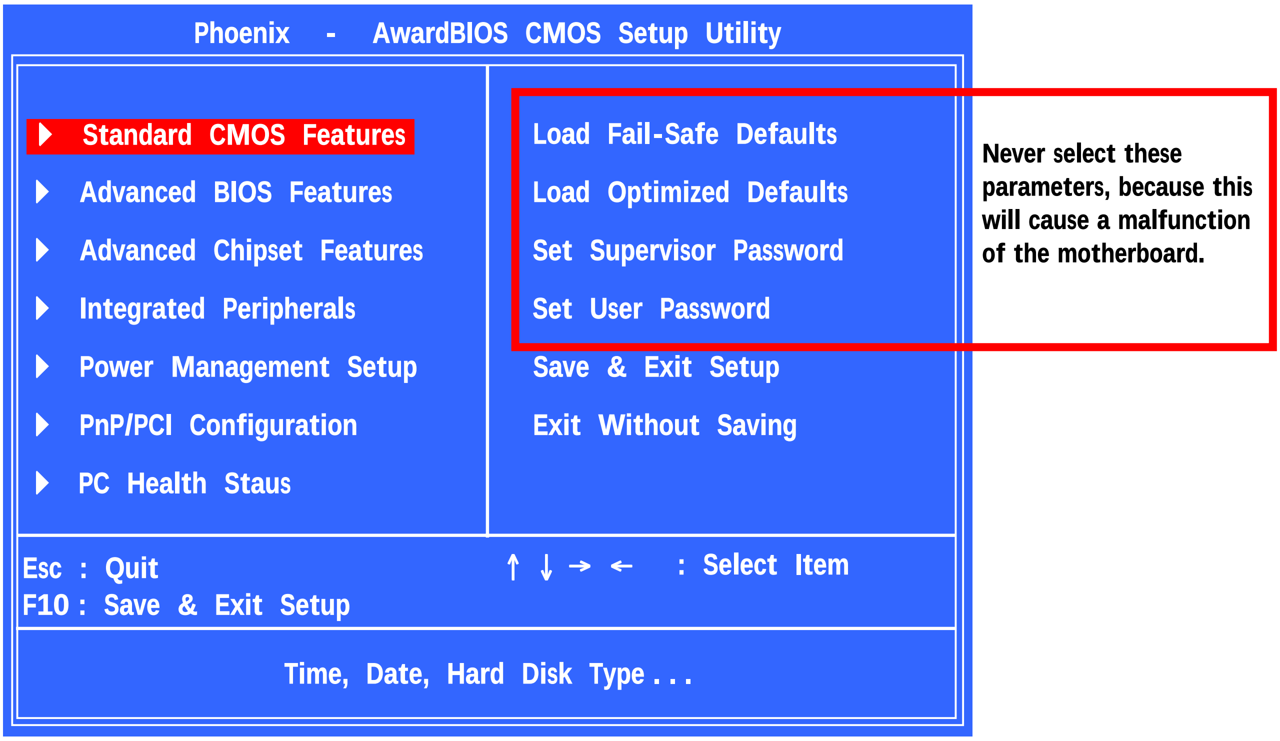
- switch the machine off and on again
- if necessary check boot sequence in the BIOS

3.4.5 BIOS Settings for LX800 Motherboard

BIOS Menu

The LX800 motherboard is delivered with a special default setting - Dialog+ with software ≥ 9.xx and CFC.

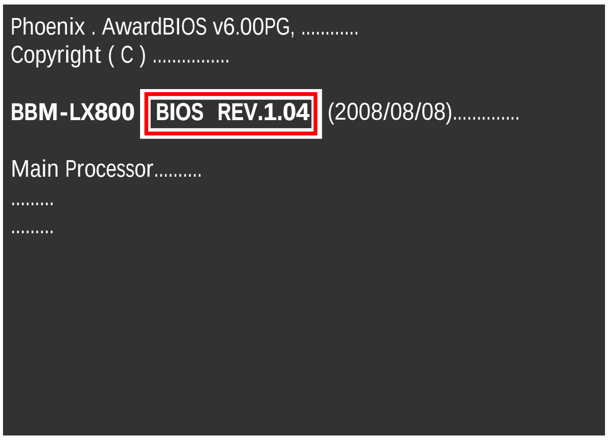
These settings are displayed in the following BIOS lists.



Never select these parameters, because this will cause a malfunction of the motherboard.

Fig.: Phoenix – AwardBIOS CMOS Setup Utility (Example)

BIOS Version Number



```
Phoenix . AwardBIOS v6.00PG, ...........
Copyright ( C ) ...............

BBM-LX800  BIOS  REV.1.04  (2008/08/08).............

Main Processor.........
.........
.........
```

The BIOS version number can be displayed as follows:

1. Connect PC keyboard to motherboard.
2. Switch on machine.
3. Press the *TAB* key when the **B | BRAUN** logo is displayed.
4. Press the ***Pause/Break*** key to stop the boot routine. The BIOS version is displayed, e.g. **BIOS Revision 1.04**.

3.4.5.1 Standard CMOS Features

	Dialog+ SW 9.xx **CFC/CR** Compact Flash Card/Card-Reader **(Default Setting)**
Date (mm:dd:yy)	Sun, mm:dd:yy
Time (hh:mm:ss)	hh:mm:ss
IDE Primary Master	[xxx xxx]
IDE HDD Auto-Detection	[Press Enter]
IDE Primary Master	[Auto]
Access Mode	[Auto]
Capacity	-
Cylinder	-
Head	-
Precomp	-
Landing Zone	-
Sector	-
IDE Primary Slave	[None]
Drive A	[None]
Drive B	[None]
Video	[EGA/VGA]
Halt On	[All, But Disk/Key]
Base Memory	640K
Extended Memory	252672K
Total Memory	253440K

3.4.5.2 Advanced BIOS Features

Virus Warning	[Disabled]
CPU Internal Cache	[Enabled]
First Boot Device	**[USB-HDD]**
Second Boot Device	**[HDD-0]**
Third Boot Device	[Disabled]
Boot Other Drive	[Disabled]
Swap Floppy Drive	[Disabled]
Boot Up Floppy Seek	[Disabled]
Boot Up NumLock Seek	[On]
Gate A20 Option	[Fast]
Typematic Rate Setting	[Disabled]
x Typematic Rate (Chars/Sec)	6
x Typematic Delay (Msec)	250
Security Option	[Setup]
OS Select For DRAM > 64MB	[Non-OS2]
Full Screen LOGO Show	[Enabled]
Small Logo(EPA) Show	[Disabled]
Onboard Lan Boot ROM	[Disabled]

3.4.5.3 Advanced Chipset Features

CPU Frequency	[Auto]
x Memory Frequency	[Auto]
CAS Latency	[Auto]
Video Memory Size	[8 M]
Output Display	**[Panel & CRT]**
Flat Panel Configuration	[Panel Enter]
Resolution	**[1024 x 768]**
Refresh Rate	[60 Hz]
HSYNC Polarity	[Normal High]
VSYNC Polarity Active	[Normal High]
SHFCLK Active Period	[Free Running]
LP Active Period	[Free Running]
Onboard Audio	[Disabled]
Onboard USB1.1	**[Enabled]**
Onboard USB2,0	**[Enabled]**
Onboard DIE	[Enabled]
Memory Hole At 15M-16M	[Disabled]

3.4.5.4 Integrated Peripherals

	Dialog+ SW 9.xx **CFC/CR** Compact Flash Card/Card-Reader **(Default Setting)**
Master Drive PIO Mode	[Auto]
Slave Drive PIO Mode	[Auto]
IDE Primary Master UDMA	[Auto]
IDE Primary Slave UDMA	[Auto]
IDE DMA Transfer Access	[Enabled]
IDE HDD Block Mode	[Enabled]
Onboard FDC Controller	[Enabled]
Onboard Serial Port 1	[3F8/IRQ4]
Onboard Serial Port 2	[2F8/IRQ3]
UART Mode Select	[Normal]
x RxD, TxD Active	Hi, Lo
x IR Transmission Delay	Enabled
x UR2 Duplex Mode	Half
x Use IR Pins	IR-Rx2Tx2
Onboard Parallel Port	[378/IRQ7]
Parallel Port Mode	[SPP]
x EPP Mode Select	EPP1.7
x ECP Mode Use DMA	3
Watch Dog Timer Select	[Disabled]
Onboard Serial Port 3	[3E8]
Serial Port 3 Use IRQ	[IRQ9]
Onboard Serial Port 4	[2E8]
Serial Port 4 Use IRQ	[IRQ5]

3.4.5.5 Power Management Setup

x ACPI Function	[Disabled]
Power Management	[Disabled]
** PM Timers **	
x Standby Mode	Disabled
x Suspend Mode	Disabled
HDD Power Down	[Disabled]
MODEM Use IRQ	[N/A]
PME Event Function	[Disabled]
Soft-Off by PWR-BTTN	[Instant-Off]
Power-On by Alarm	[Disabled]
x Time (hh:mm:ss) Alarm	0
IRQ Wakrup Events	[Press Enter]
IRQ1 (KeyBoard)	[OFF]
IRQ3 (COM 2)	[OFF]
IRQ4 (COM 1)	[OFF]
IRQ5 (LPT 2)	[OFF]
IRQ6 (Floppy Disk)	[OFF]
IRQ7 (LPT 1)	[OFF]
IRQ8 (RTC Alarm)	[OFF]
IRQ9 (IRQ2 Redir)	[OFF]
IRQ10 (Reserved)	[OFF]
IRQ11 (Reserverd)	[OFF]
IRQ12 (PS/2 Mouse)	[OFF]
IRQ13 (Coprocessor)	[OFF]
IRQ14 (Hard Disk)	[OFF]
IRQ15 (Reserved)	[OFF]

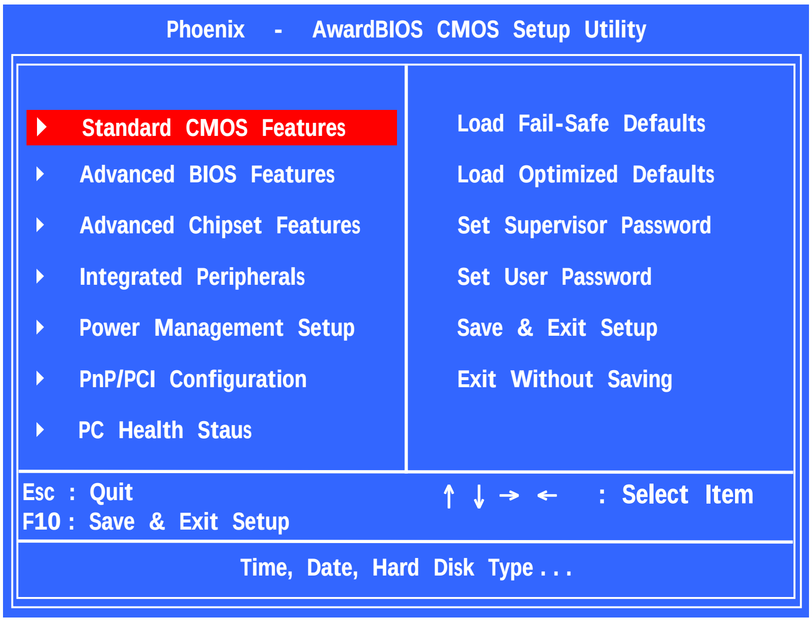
3.4.5.6 PnP/PCI Configuration

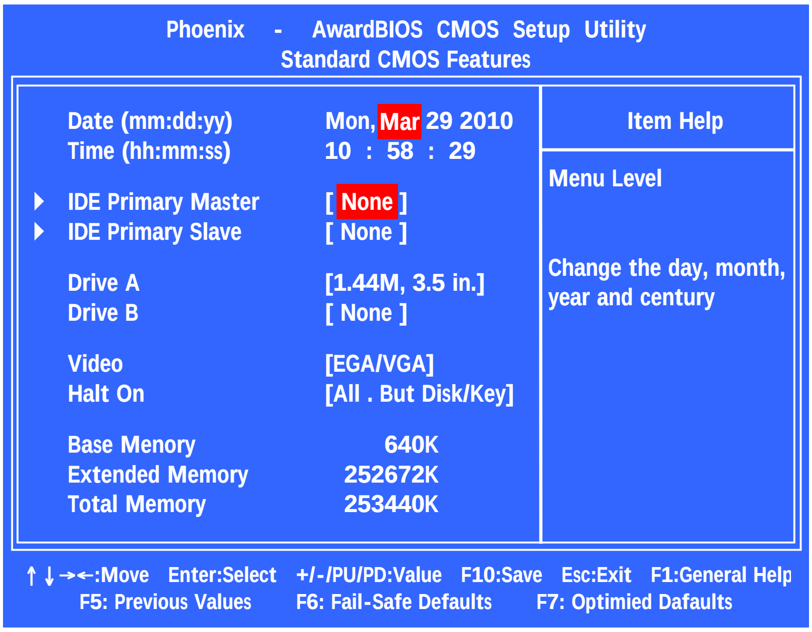
PNP OS Installed	[No]
Init Display First	[PCI Slot]
Reset Configuration Data	[Disabled]
Resources Controlled By	[Auto(ESCD)]
x IRQ Resources	Press Enter
x Memory Resources	Press Enter
PCI/VGA Palette Snoop	[Disabled]

3.4.5.7 PC Health Status

	Dialog+ SW 9.xx **CFC/CR** Compact Flash Card/Card-Reader **(Default Setting)**
CPU Temp	50°C
Vcore	1.26V
Vmem	2.60V
+3.3 V	3.39V
+5 V	5.13V
Load Fail-Safe Defaults	
Load Optimized Defaults	
Set Supervisor Password	
Set User Password	
Save Exit Setup	
Exit Without Saving	

3.4.5.8 Change Parameters in CMOS Setup




Phoenix - AwardBIOS CMOS Setup Utility
Standard CMOS Features

Date (mm:dd:yy) Mon, Mar 29 2010
Time (hh:mm:ss) 10 : 58 : 29
IDE Primary Master [None]
IDE Primary Slave [None]
Drive A [1.44M, 3.5 in.]
Drive B [None]
Video [EGA/VGA]
Halt On [All . But Disk/Key]
Base Menory 640K
Extended Memory 252672K
Total Memory 253440K

Item Help
Menu Level
Change the day, month, year and century

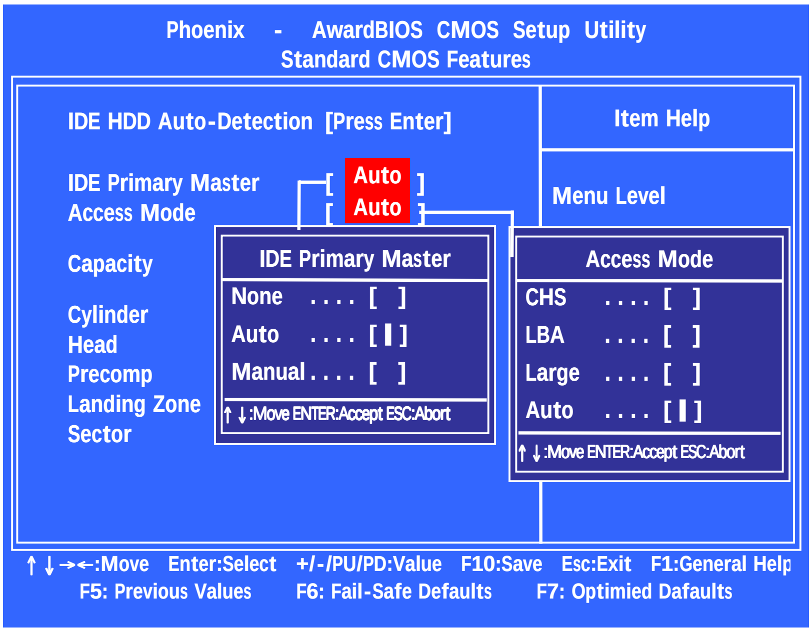
The LX800 motherboard is delivered ex works with a special default setting for a Dialog+ machine with a CFC.

If necessary, the BIOS setup must be adapted to the specific hardware present in a Dialog+ or Dialog Advanced machine. The example shows a general approach to change a parameter in the BIOS according to the BIOS setup table for the LX800 motherboard.

Example:
Change parameter in *Standard CMOS Features* for Dialog+ with HDD (CFC)

The example shows how the *IDE Primary Master* parameter is changed from *None* to *Auto* for a Dialog+ with a hard disk drive (CFC) (see paragraph 3.4.5.1 Standard CMOS Features).

1. Connect PC keyboard (with PS2 connector) to LX800 motherboard.
2. Switch on Dialog+ and press the ***Delete/Del*** key to enter the BIOS (when keyboard status LEDs shortly light up).
3. Press ***Enter*** key to go to the *Standard CMOS Features* menu.
4. Move down to *IDE Primary Master* with the ***Arrow*** key.



Phoenix - AwardBIOS CMOS Setup Utility
Standard CMOS Features

IDE HDD Auto-Detection [Press Enter]

IDE Primary Master [Auto]
Access Mode [Auto]

Capacity

Cylinder
Head
Precomp
Landing Zone
Sector

Item Help

Menu Level

IDE Primary Master
None . . . . [ ]
Auto . . . . [▌]
Manual . . . . [ ]
↑↓:Move ENTER:Accept ESC:Abort

Access Mode
CHS . . . . [ ]
LBA . . . . [ ]
Large . . . . [ ]
Auto . . . . [▌]
↑↓:Move ENTER:Accept ESC:Abort

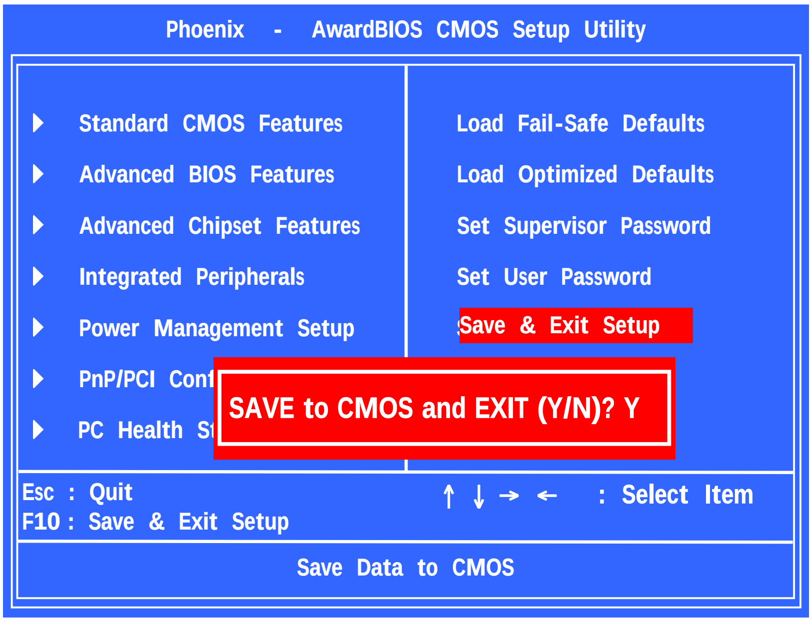
↑↓→←:Move Enter:Select +/-/PU/PD:Value F10:Save Esc:Exit F1:General Help
F5: Previous Values F6: Fail-Safe Defaults F7: Optimied Dafaults

5. Press ***Enter*** key to open *IDE Primary Master* window.

6. Move down to *Auto* with the ***Arrow*** key.

7. Press ***Enter*** key to accept. The *IDE Primary Master* window closes.

8. Check the *Auto* setting in the *Access Mode*.



Phoenix - AwardBIOS CMOS Setup Utility

- Standard CMOS Features
- Advanced BIOS Features
- Advanced Chipset Features
- Integrated Peripherals
- Power Management Setup
- PnP/PCI Conf
- PC Health S

Load Fail-Safe Defaults
Load Optimized Defaults
Set Supervisor Password
Set User Password
Save & Exit Setup

SAVE to CMOS and EXIT (Y/N)? Y

Esc : Quit
F10 : Save & Exit Setup
↑ ↓ → ← : Select Item

Save Data to CMOS

Save and Exit BIOS

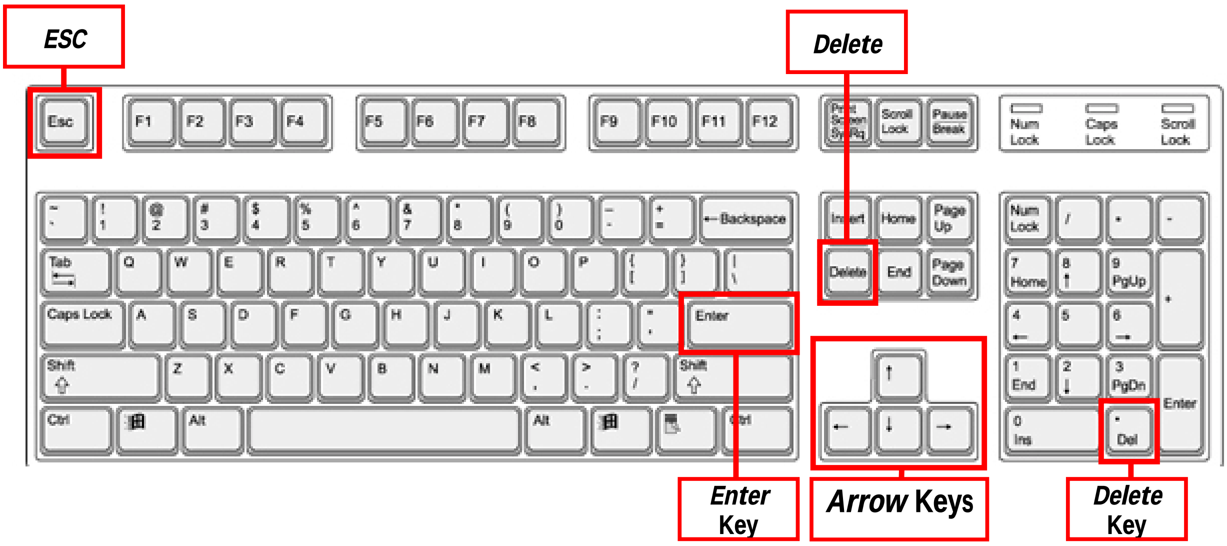
9. Press ***ESC*** key to go back to the *CMOS Setup Utility* menu.

   Note: In general you can use the ***ESC*** key to go back to the previous menu.

10. Select *Save & Exit Setup* menu with the ***Arrow*** keys.

11. Save changes and exit the *BIOS CMOS Setup* with ***Enter*** key.

    The changes in the *Standard CMOS Features* menu are saved to the *BIOS CMOS*.



3.5 Installation Software 9.xx

USB Stick for Treatment Support Settings

The system configuration saved on a USB stick (FSU utility) must only be downloaded to an other Dialog+ machine (with software ≥ 9.xx) after a software update if:

- the hardware matches and
- the machine has the identical software version number.

Activation of the Treatment Support Settings

The settings are only activated after the Dialog+ is switched off and on again. Check the settings after the Dialog+ was switched on again.

Service switch

The software is installed in the software update mode: digital board, service switch S1, position 3.

After software installation: turn service switch S1 to TSM service program mode (position 2)

After completion of all procedures turn back service switch S1 to therapy mode (position 0).

Default Table

The default values for the parameters depend on the machine status (see Dialog+ default table for SW 9.xx for a detailed overview).

Software Update

The customer specific default values of the machine must be documented in the default table prior to the installation of a new software. These values must be entered again after installation.

3.5.1 Document Customer Specific Default Values

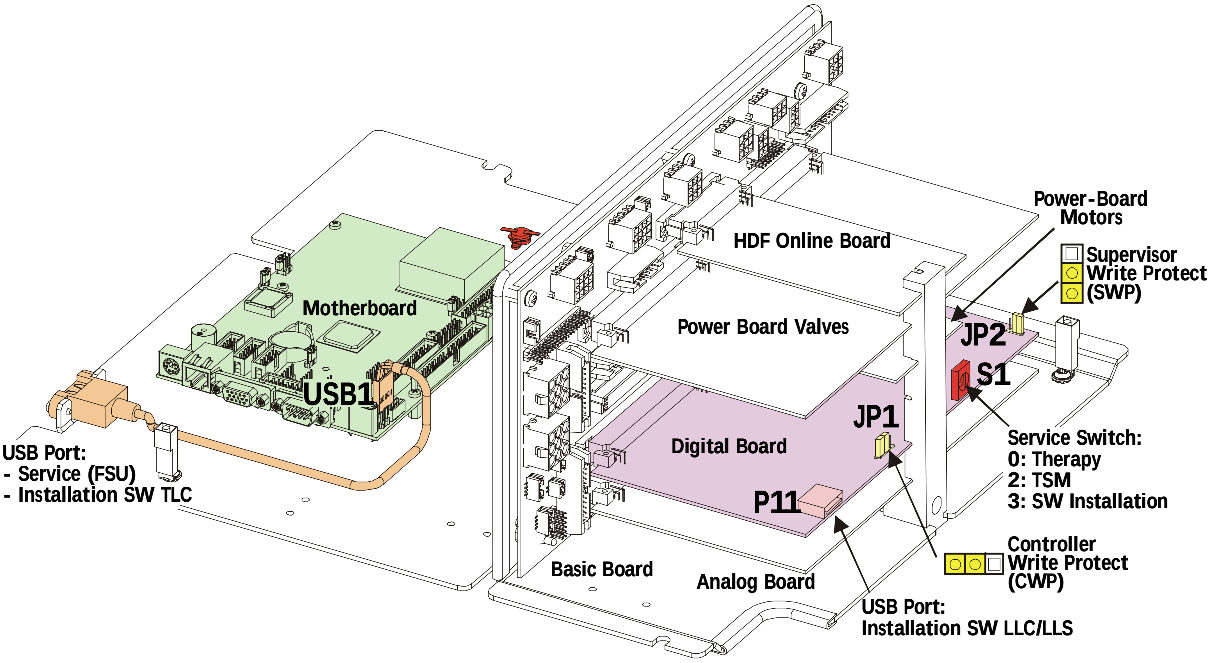


Fig. : Top Level Sub-Rack, Digital Board with Service Switch S1, USB Port P11 and Jumpers JP1/JP2

Enter the customer specific default values of the machine in the default table:

1. Open rear door.
2. Switch to TSM service program mode (on digital board DB, service switch S1 position 2).
3. Switch on Dialog+.
4. Document default values in default table.
5. Switch off Dialog+.

3.5.2 Installation Software LLC 9.xx and LLS 9.xx with USB Stick

The USB stick with the TLC/LLC/LLS software is required for the installation of the software LLC 9.xx and LLS 9.xx.

- Bootable USB stick with the TLC/LLC/LLS software

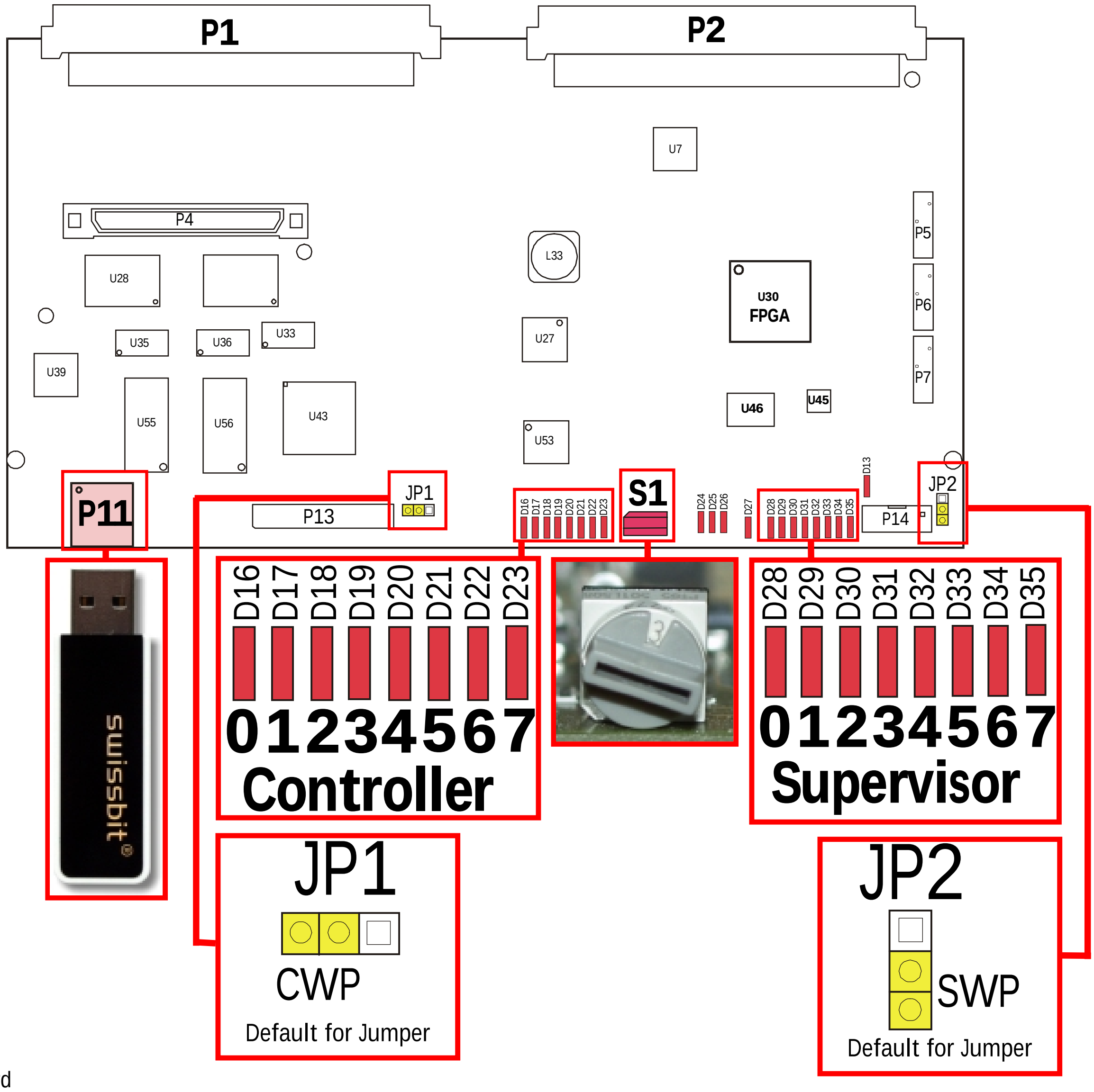


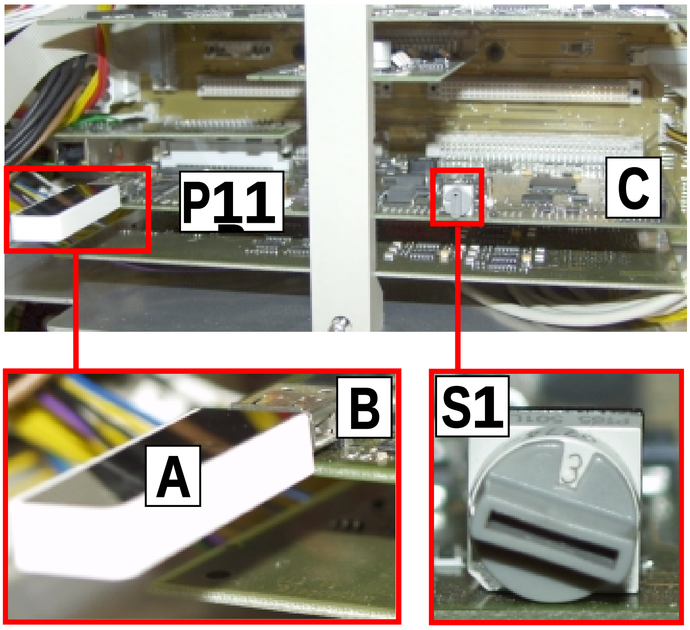
Fig. : Digital Board

P11 USB Type A for Installation of LLC/LLS SW with USB Stick

S1 **Service Switch:**
Position 0: Therapy Mode
Position 2: TSM Service Program Mode
Position 3: Software Installation/Update Mode

Controller LEDs 0 to 7 (D16 – D23)**:**
Status 0 – 7 for Installation of LLC Software
Jumper JP1 CWP:
Controller Write Protect

Supervisor LEDs 0 to 7 (D28 – D35)**:**
Status 0 – 7 for Installation of LLS Software
Jumper JP2 SWP:
Supervisor Write Protect

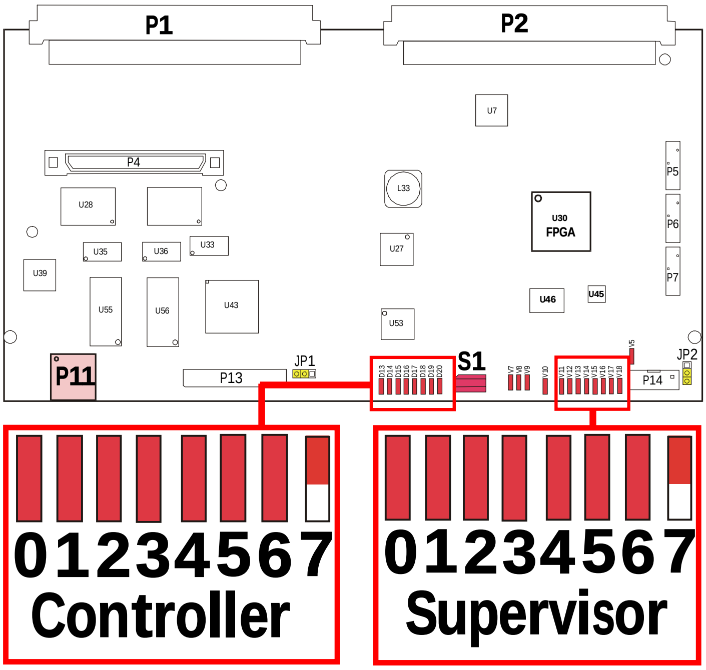


6. Connect USB stick **A** to USB port **B** (P11) on digital board **C**.

7. Turn service switch **S1** to position 3 – SW installation.

8. Switch on machine.

9. The USB stick is detected.



10. The LLC and LLS software is installed automatically.

    Both LLC/LLS LEDs show the installation progress:
    LED 0: Is off if firmware is not updated
    LED 1: Respective software is updated
    LED 2: Checksum and configuration files are loaded
    LED 3: USB stick consistency is verified
    LED 4: Binary files are loaded
    LED 5: Binary images are verified
    LED 6: Flash ROMs are programmed/under verification

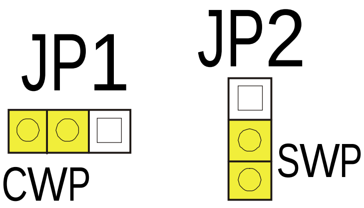
11. A successful software installation is indicated by:
    - **LEDs 7**: flashing
    - short beep from the SMPS-MC
    - **LED 0** : on (only if firmware is updated)
    - **LEDs 1 to 6**: on

12. Switch off machine.

13. Remove USB stick **A** from the USB port **B** on the digital board **C**.

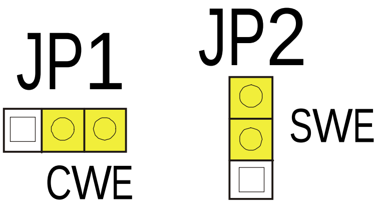
Setting for Jumpers JP1 and JP2

Firmware Update not Possible (Protected)



The firmware for the controller and supervisor is protected by the jumpers JP1 and JP2. The position for both jumpers are set to CWP/SWP (controller/supervisor write protect). The jumpers must be in this position to protect the LLC and LLS firmware.

Firmware Update Possible (Enabled)



The installation of the firmware is normally not required during the installation of LLC and LLS.

If the firmware has to be installed additionally, it will be indicated in the installation instructions. JP1 and JP2 have to be set to this position (Default CWE and SWE: controller/supervisor write enabled). Set the jumpers back to the CWP/SWP setting after installation.

3.5.3 Installation Software TLC 9.xx with USB Stick

The USB stick with the TLC/LLC/LLS software is required for the installation of the software TLC 9.xx.

If the TLC software has to be installed only:

- Open rear door.
- Switch to TSM service program mode (on digital board DB, service switch S1 position 2).
- Proceed with point 14.

- Bootable USB stick with the TLC/LLC/LLS software

14. Open front door.

15. Connect USB stick **A** to USB port **B** on the TLC sub-rack **C**.

16. Switch on machine.

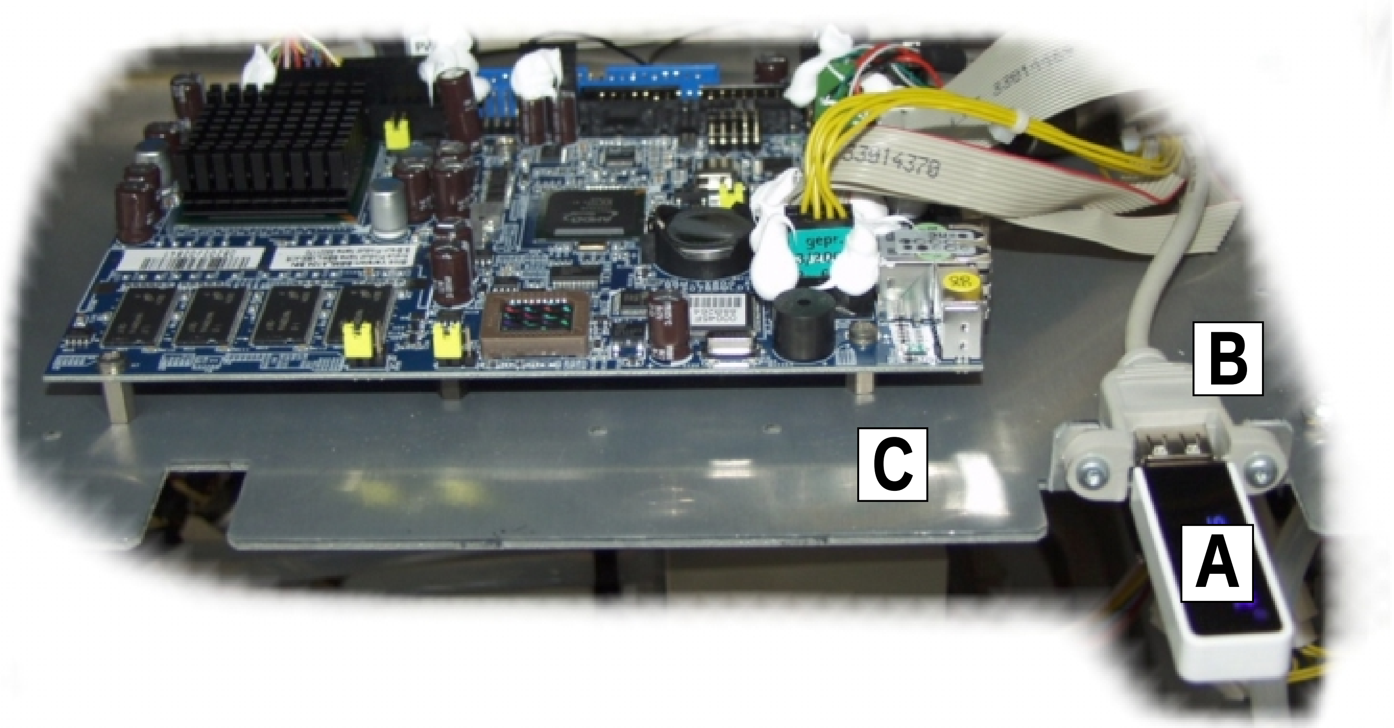
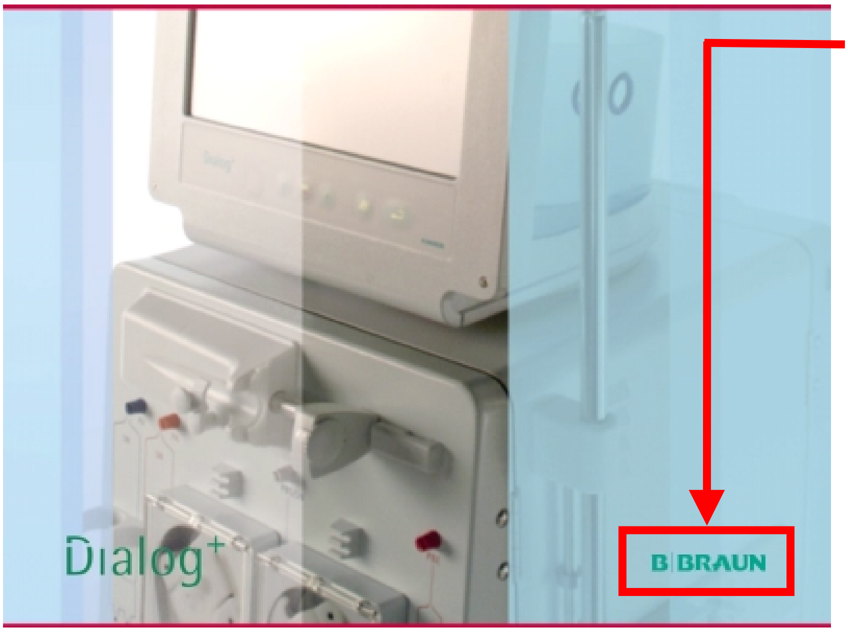


Fig.: Front View TLC Sub-Rack

USB Stick Detected

The system detects the bootable USB stick and boots from the USB stick (indicated by the red **Installation** text in the start screen).



USB Stick not Detected

The system does not detect the bootable USB stick (indicated by the green **B |BRAUN** logo in the start screen). If necessary disconnect the USB stick and reconnect.

17. Follow the software installation for TLC according to the information on the monitor:

- **Use hardware keys only: 🔕, or ↵**

  [AQ] (Alarm Acknowledgement) = NO = 🔕

  [EQ] (Enter) = YES = ↵

- **Do not connect and use a PC keyboard for the installation of the software.**

```
      *** You are about to install the Dialog/TLC V9.xx software. ***
              If you want to CONTINUE the Installation,
            LEAVE the installation USB stick in the socket,
               press Y or y and <CR> if keyboard is used
                               otherwise
                        press the EQ hardware key!
                If you want to SKIP the TLC installation
     press N or n and <CR> on keyboard or any other hardware key!
```

[EQ] Press ↵ to confirm and proceed with the installation of the TLC software.

[AQ] Press 🔕 if you want to terminate the installation of the software.

LX800 Motherboard

```
                *** Dialog V9.xx /TLC V9.xx installation ***
           Installation/setup of the Dialog/TLC runtime system.
  ------------------------------------------------------------------
                       Does the machine have:
         LX800 (NIBP: COM3=IRQ9 ECG: COM4=IRQ5) motherboard?
            If YES, press Y or y and <CR> if keyboard is used
                               otherwise
                        press the EQ hardware key!
     If NO, press N or n and <CR> on keyboard or any other hardware key!
```

[EQ] Press ↵ to select the LX800 motherboard.

```
        Selected motherboard: LX800 (NIBP: COM3=IRQ9 ECG: COM4=IRQ5)

                              Are you sure ?
            If YES, press Y or y and <CR> if keyboard is used
                               otherwise
                        press the EQ hardware key!
     If NO, press N or n and <CR> on keyboard or any other hardware key!
```

[EQ] Press ↵ to confirm the selected LX800 motherboard.

Compact Flash Card CFC

```
 Does the machine have:
CF-Card_Swissbit-SFCF1024H3BKZSA_I-MO-513_SID_1.00GB (h=16 s=63) harddisk?
            If YES, press Y or y and <CR> if keyboard is used
                               otherwise
                        press the EQ hardware key!
     If NO, press N or n and <CR> on keyboard or any other hardware key!
```

[EQ] Press ↵ to select the CFC.

```
Selected harddisk: CF-Card_Swissbit-SFCF1024H3BKZSA_I-MO-513_SID_1.00GB (h=16
s=63)

                              Are you sure ?
            If YES, press Y or y and <CR> if keyboard is used
                               otherwise
                        press the EQ hardware key!
     If NO, press N or n and <CR> on keyboard or any other hardware key!
```

[EQ] Press ↵ to confirm the selected CFC.

The following menu appears after the motherboard and the memory type were selected.

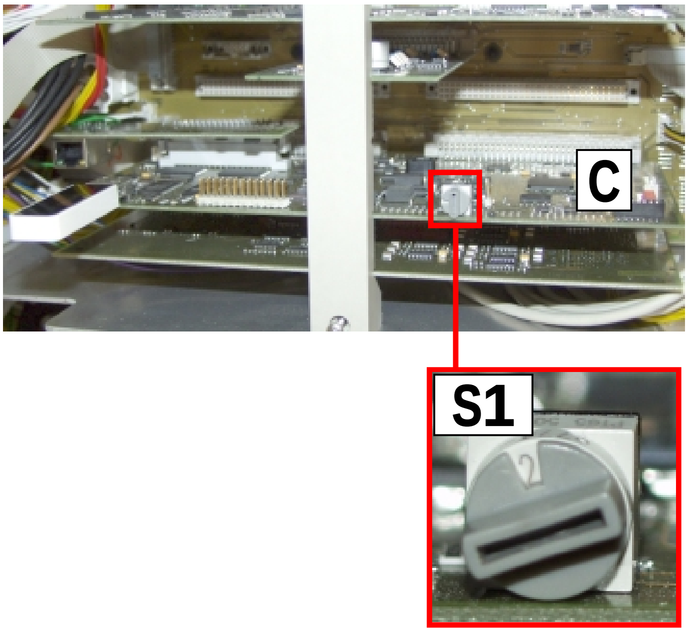
```
                         *** WARNING ! ***

    If you have any important files, SAVE them before the installation!

     TRENDS of previous treatments will be lost too, save them before
            the installation if they are needed in the future!

                If you want to CONTINUE the Installation
                press Y or y and <CR> if keyboard is used
                                otherwise
                        press the EQ hardware key!

     If you want to CANCEL the installation, press N or n and <CR>
                 on keyboard or any other hardware key!
```

[EQ] Press ↵ to confirm and proceed with the installation of the software.

[AQ] Press 🔕 if you want to terminate the installation of the software.

```
....
                  End of Dialog/TLC  SW INSTALLATION.

             The Dialog/TLC SW INSTALLATION has been completed.

                 The Dialog/TLC uses.....................

                          ......................


  Don't forget to set the operation mode switch to TSM mode (2) and check

                 in TSM all subsystems' version number.


Switch the power OFF and REMOVE the USB stick before starting the Dialog...
```

The TLC software was installed successfully.



18. Switch off the machine after the successful installation of the TLC software.

19. Remove USB stick.

20. Turn service switch **S1** (on digital board **C**) to position 2 - TSM.

3.5.4 Boot Machine /Check Version Number

21. Switch on machine.

22. Check whether machine boots correctly.

23. Open menu *Production Report*, *Version Number* and check the version numbers.

3.5.5 Select Options

All available options in TSM service program (*Production Report* and *Low Level Options*) must be selected again and saved with the OK button after the software installation.

Low Level Options

24. Select and activate all present options in the *Low Level Options* with the ✓O.K. button. Thus, the data is saved when quitting the menu.

Production Report

25. If necessary enter the serial number (see type plate *SN*) in the *Production Report* menu.

26. Select and activate all present options in the *Production Report* with the ✓O.K. button. Thus, the data is saved when quitting the menu.

3.5.6 Enter Customer Specific Default Values

The customer specific default values of the machine must be entered after the software installation.

27. Enter customer default values from default table and save

3.5.7 Enter Specific Parameters

The specific parameters must be entered again in the TSM service program and saved with the OK button after the software installation.

28. Enter the tube constants in menu *Calibration 2.13 Flow of BPA and BPV Pump*, *2.13.1 Tube Constants of BPA and BPV.*
BPA: 12306 [µl/head rotation]
BPV: 12306 [µl/head rotation]

29. Enter the stroke value in menu *Calibration 2.15 HDF Online Substitution Pump OSP.*
OSP: 8300 [µl/head rotation]

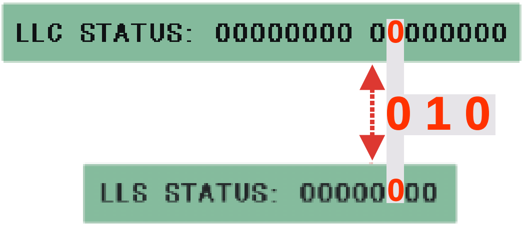
30. Enter the absolute low limit for PA in menu *Calibration 2.12 PV Alarm Window*, *PA Low Limit* and save with the calibration button (see default table).

31. Select the limit for the blood leak detector in menu *Calibration 2.7 Blood Leak Detector*, *BL Limit* (standard limit or AAMI limit).

32. Save in menu *File Operation*, *Save Calibration Data* after entering all constants and calibration data.

Pay attention to the LLC and LLS status windows when saving the calibration data. The bit sequence 0 1 0 must be identical in the LLC and LLS status windows during the saving procedure. The calibration data is saved only after the bit sequence 0 1 0 (see figure).

If an error occurs select corresponding window: error message is displayed (eliminate cause of trouble).



```
LLC STATUS: 00000000 00000000
LLS STATUS: 00000000
```

FSU USB-Stick for Treatment Support Settings

The system configuration saved on a USB stick (FSU utility) must only be downloaded to an other Dialog+ SW 9.xx machine after a software update if:

- **the hardware matches and**
- **the machine has the identical software version number.**

33. Set system configuration (customer specific values) or if available use the FSU USB stick with the system configuration.

34. Save settings.

35. Switch off machine.

3.5.8 Self Test

1. Turn service switch **S1** to position 0 - Therapy.
2. Start machine (fully equipped) in dialysis mode.
3. Insert line system – see instructions for use.
4. The machine must run without errors up to the message *Connect Patient*.

3.5.9 Test Run

5. Assemble the blood lines, perform preparation (insert heparin syringe and select 2 ml/h and use BIC cartridge if present).
6. Perform self test – according to instructions for use.
7. Press the icon to switch to therapy mode (*connect patient*). This icon is enabled after all self tests were performed successfully.
8. Insert the arterial and venous lines in the graduated cylinder.
9. Set the blood pump so that no blood side alarms are activated.
10. Start dialysis.
11. Check alarm function of SAD.

    (The ABPM function (if present) can be checked without a test run of the machine in preparation mode, without the concentrate pump.)
12. Terminate dialysis.
13. Perform disinfection/decalcification.
14. Remove blood lines, filter and heparin syringe.
15. Switch off Dialog+.

3.6 Field Service Utilities FSU

General

The FSU utility can be used in any mode. Exception: if the Dialog+ was switched off during therapy or end of therapy and was switched on again within 15 minutes.

Most of the utilities have the following features:

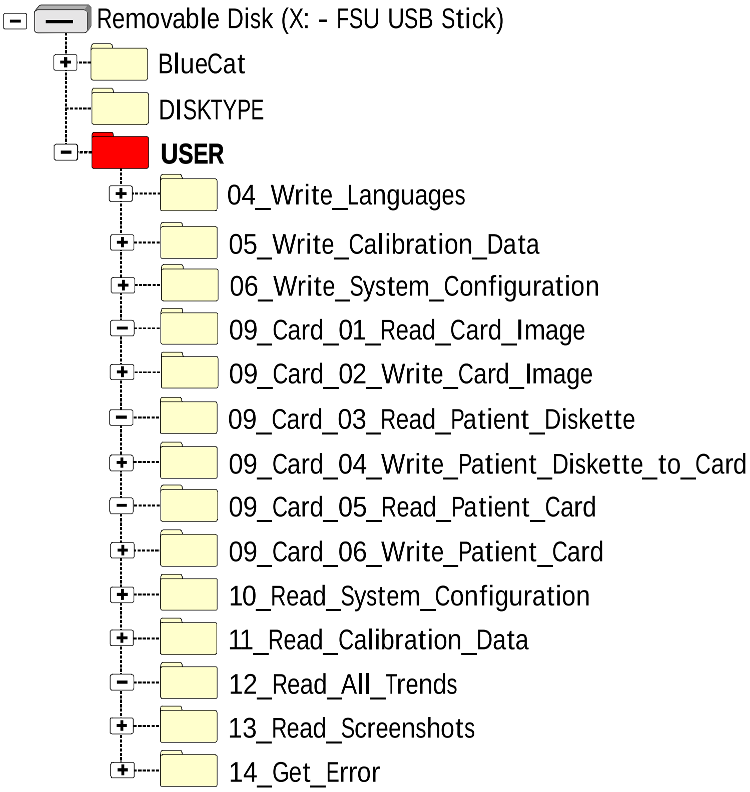
- messages are displayed during execution
- an *End of <utility name>* message is displayed after completion of a utility

3.6.1 FSU Directories and Subdirectories

BlueCat and DISKTYPE Directories
The BlueCat and DISKTYPE directories are used by the system operation of the FSU program only. Do not use, modify or delete these directories.

USER Directory
The USER directory is required for service technicians only. All user specific data/files from and to the Dialog+ machines are written and read to/from this directory (subdirectories).

The field service utilities has the following directory structure (see left figure).



Removable Disk (X: - FSU USB Stick)
- BlueCat
- DISKTYPE
- **USER**
  - 04_Write_Languages
  - 05_Write_Calibration_Data
  - 06_Write_System_Configuration
  - 09_Card_01_Read_Card_Image
  - 09_Card_02_Write_Card_Image
  - 09_Card_03_Read_Patient_Diskette
  - 09_Card_04_Write_Patient_Diskette_to_Card
  - 09_Card_05_Read_Patient_Card
  - 09_Card_06_Write_Patient_Card
  - 10_Read_System_Configuration
  - 11_Read_Calibration_Data
  - 12_Read_All_Trends
  - 13_Read_Screenshots
  - 14_Get_Error

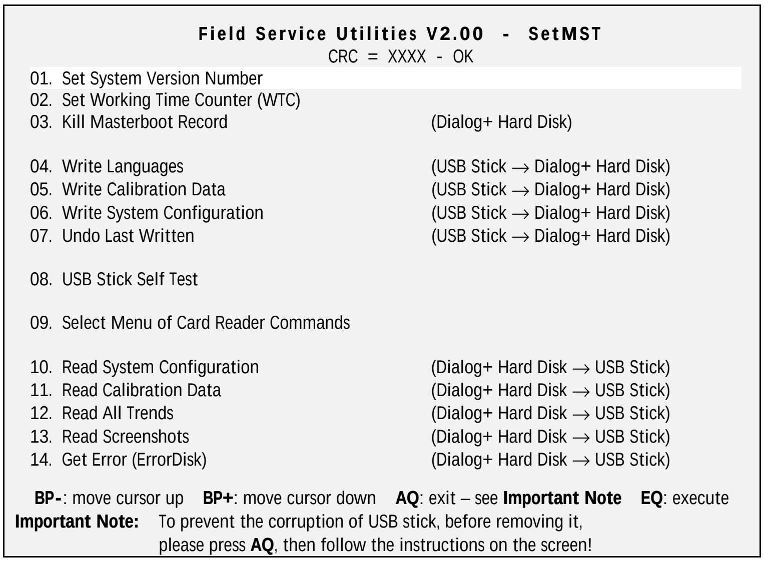
3.6.2 Start Field Service Utility FSU

TSM Service Mode Therapy Mode	**The service switch S1 on the digital board can be in position 0, 2 or 3. Turn back the service switch S1 to therapy mode (position 0) after terminating the field service utilities.**
Check of Initial Directories	**After switch-on the presence of the initial directories are checked. If one of these directories are not found (e.g. because they were accidentally deleted), an error window is displayed and the USB stick can not be used (use your backup copy).**
Backup Copy of FSU USB Stick Directories	**Copy the BlueCat, DISKTYPE and USER directory from the USB stick to a PC as a backup copy in case directories can not be found (e.g. because they were deleted by mistake).**
Self Test CRC	**The FSU program stops automatically in case of a self test error. The FSU is terminated. The corrupted USB stick must be exchanged before you continue with the FSU program.**
Prevent Corruption of USB Stick	**Do not disconnect the USB stick if the FSU menu is still active. Exit the FSU menu with the AQ /BP + hardware keys before you disconnect the USB stick.**

```
Please wait....

Checking USB stick consistency...
```

When the Dialog+ is switched on and the start window is displayed a self test is performed (a few seconds) for the USB stick.

1. Connect the USB stick to the USB port on the TLC sub-rack.
2. Switch on the Dialog+ in TSM service mode.
3. Wait for the consistency check of the FSU USB stick.



```
           Field Service Utilities V2.00  -  SetMST
                     CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                 (Dialog+ Hard Disk)

04. Write Languages                        (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                 (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration             (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                      (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration              (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                  (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                        (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                       (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                  (Dialog+ Hard Disk → USB Stick)

 BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:  To prevent the corruption of USB stick, before removing it,
                 please press AQ, then follow the instructions on the screen!
```

The main menu of the FSU is displayed. The following information is displayed in the header:

- Field service utilities Vn.nn" (n.nn is the version number)
- Set number of master (SetMST)
- CRC value with CRC status (CRC = XXXX – OK), i.e. CRC is OK

Hardware Keys

BP − : moves the cursor up

BP + : moves the cursor down

AQ : exits the FSU menu

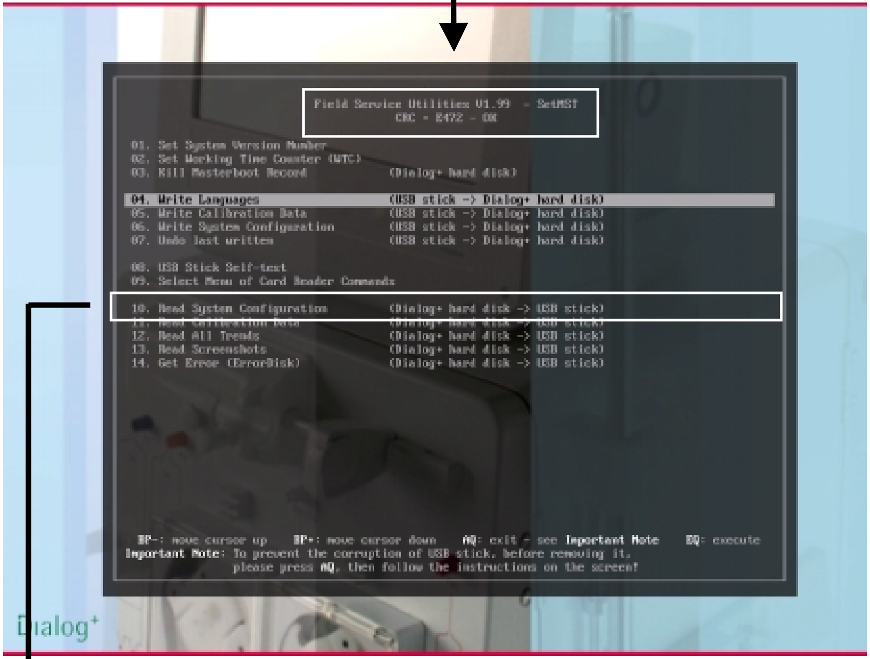
EQ ↵ : executes a selected utility

4. Press the **EQ** ↵ hardware key to execute the utility.
5. Press the **AQ** to exit the FSU program.

3.6.3 Set-Up FSU Main Menu

When the Dialog+ is switched on and the start window is displayed the self test for the USB stick is performed (a few seconds). In the start screen the *Field Service Utilities* menu appears after the CRC check (see header CRC=XXXX – OK).

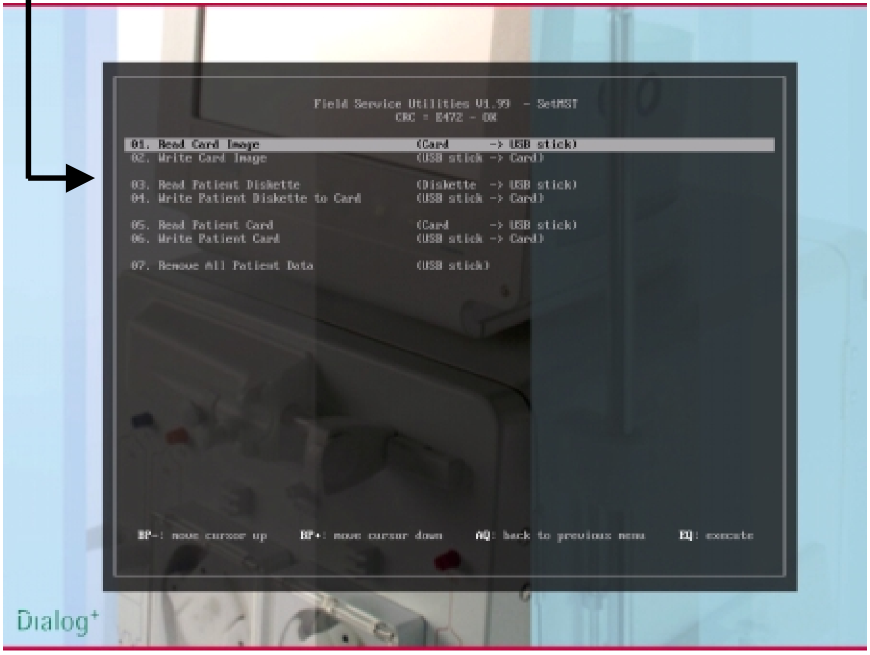
There are standard utilities in the main menu: set, write and read. A sub-menu can be selected for the card reader with the utilities: read and write.



```
        Field Service Utilities V1.99  - SetMST
                   CRC = E472 - OK

01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record          (Dialog+ hard disk)

04. Write Languages                 (USB stick -> Dialog+ hard disk)
05. Write Calibration Data          (USB stick -> Dialog+ hard disk)
06. Write System Configuration      (USB stick -> Dialog+ hard disk)
07. Undo last written               (USB stick -> Dialog+ hard disk)

08. USB Stick Self-test
09. Select Menu of Card Reader Commands

10. Read System Configuration       (Dialog+ hard disk -> USB stick)
11. Read Calibration Data           (Dialog+ hard disk -> USB stick)
12. Read All Trends                 (Dialog+ hard disk -> USB stick)
13. Read Screenshots                (Dialog+ hard disk -> USB stick)
14. Get Error (ErrorDisk)           (Dialog+ hard disk -> USB stick)

  BP-: move cursor up   BP+: move cursor down   AQ: exit - see Important Note   EQ: execute
Important Note: To prevent the corruption of USB stick, before removing it,
                please press AQ, then follow the instructions on the screen!
```

Main Menu Field Service Utilities

1. Connect the USB stick (with the FSU) to the USB port on the TLC sub-rack.
2. Switch on Dialog+.



```
        Field Service Utilities V1.99  - SetMST
                   CRC = E472 - OK

01. Read Card Image                 (Card      -> USB stick)
02. Write Card Image                (USB stick -> Card)

03. Read Patient Diskette           (Diskette  -> USB stick)
04. Write Patient Diskette to Card  (USB stick -> Card)

05. Read Patient Card               (Card      -> USB stick)
06. Write Patient Card              (USB stick -> Card)

07. Remove All Patient Data         (USB stick)

  BP-: move cursor up   BP+: move cursor down   AQ: back to previous menu   EQ: execute
```

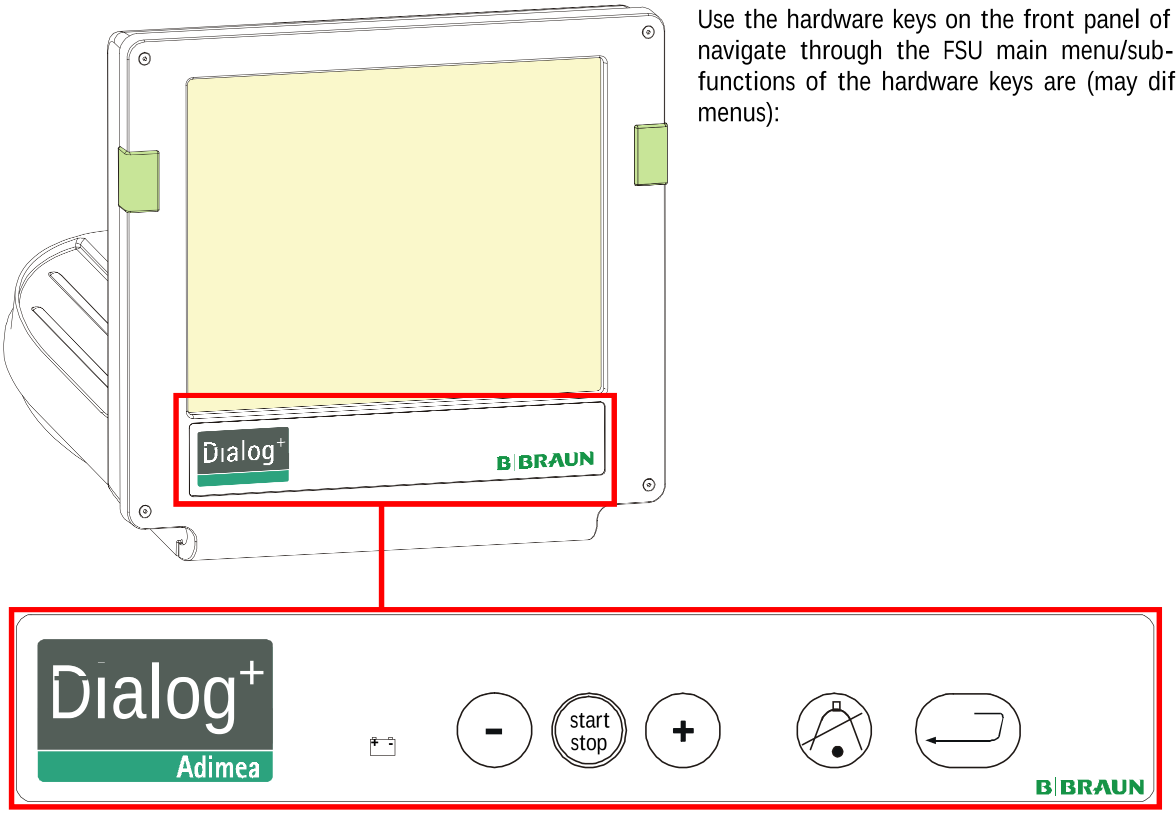
Sub-Menu Card Reader

The following sub-menu appears if *09 Select Menu of Card Commands* is selected in the Field Service Utilities main menu.

1. Press the **BP** + hardware key and move the cursor down to *09 Select Menu of Card Commands* in the main menu.
2. Press the **EQ** ↵ hardware key to execute the utility.
3. Press the **BP** + hardware key and move the cursor down to select a utility.

3.6.3.1 Hardware Keys for FSU

Use the hardware keys on the front panel of the TFT monitor to navigate through the FSU main menu/sub-menu. The general functions of the hardware keys are (may differ slightly in sub-menus):



Press the **BP** − hardware key to move the cursor up.

Press the **BP** start stop hardware key to select the next digit (e.g. during the setting of the working time counter).

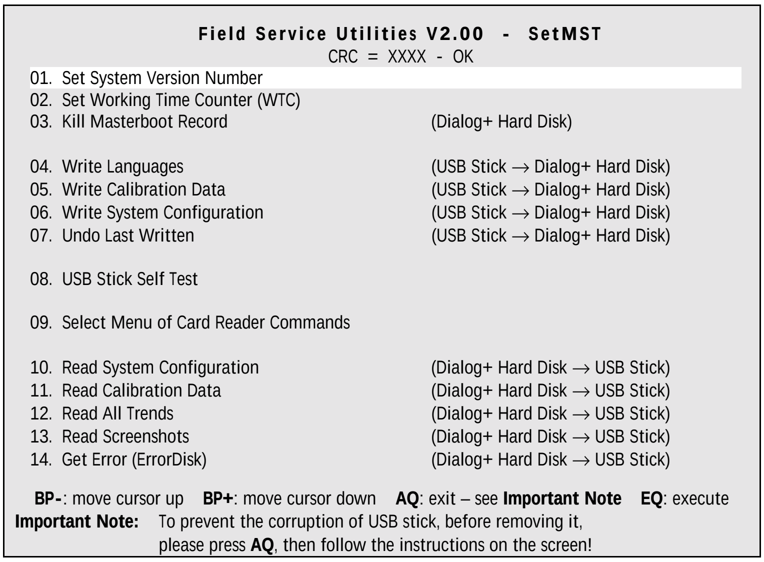
Press the **BP** + hardware key to move the cursor down.

Press the **AQ** hardware key to exit the FSU menu or to skip back to the previous menu.

Press the **EQ** ↵ hardware key to execute a selected utility.

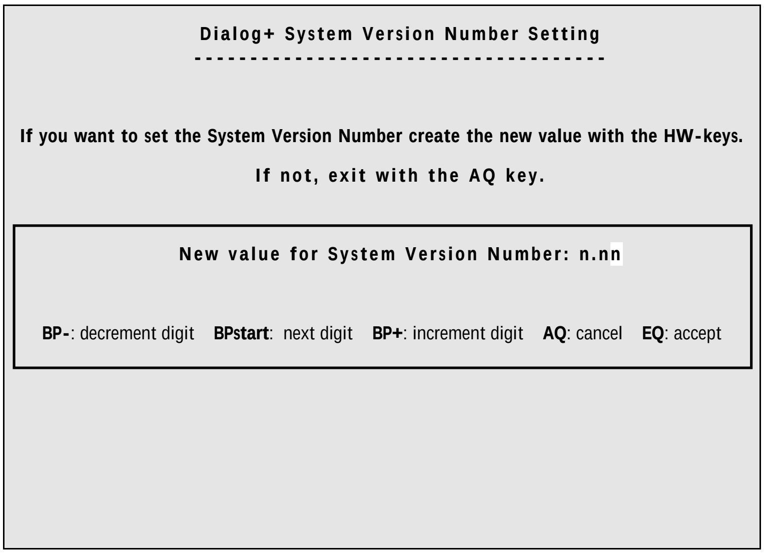
3.6.4 Set System Version Number

The *System Version Number* for the Dialog+ can be set with this utility. The utility is typically used after updating the LLC software, because the TLC software can not be accessed during the installation of the LLC. There is no file exchange between the USB stick and Dialog+ hard disk drive (CFC).



```
                    Field Service Utilities V2.00  -  SetMST
                              CRC = XXXX - OK
  01. Set System Version Number
  02. Set Working Time Counter (WTC)
  03. Kill Masterboot Record                       (Dialog+ Hard Disk)

  04. Write Languages                              (USB Stick → Dialog+ Hard Disk)
  05. Write Calibration Data                       (USB Stick → Dialog+ Hard Disk)
  06. Write System Configuration                   (USB Stick → Dialog+ Hard Disk)
  07. Undo Last Written                            (USB Stick → Dialog+ Hard Disk)

  08. USB Stick Self Test

  09. Select Menu of Card Reader Commands

  10. Read System Configuration                    (Dialog+ Hard Disk → USB Stick)
  11. Read Calibration Data                        (Dialog+ Hard Disk → USB Stick)
  12. Read All Trends                              (Dialog+ Hard Disk → USB Stick)
  13. Read Screenshots                             (Dialog+ Hard Disk → USB Stick)
  14. Get Error (ErrorDisk)                        (Dialog+ Hard Disk → USB Stick)

   BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
 Important Note:   To prevent the corruption of USB stick, before removing it,
                   please press AQ, then follow the instructions on the screen!
```

1. Press **EQ** ⏎ to execute the utility.
2. Press **AQ** to exit the FSU menu.



```
                 Dialog+ System Version Number Setting
                 -------------------------------------


 If you want to set the System Version Number create the new value with the HW-keys.

                      If not, exit with the AQ key.

              New value for System Version Number: n.nn


  BP-: decrement digit   BPstart: next digit   BP+: increment digit   AQ: cancel   EQ: accept
```

An input screen opens to set the new *System Version Number* with the following hardware keys:

BP − : decrements the current digit

BP + : increments the current digit

BP start stop : selects the next digit (from right to left)

AQ : cancels the operation, system version number is not changed

EQ ⏎ : sets the new system version number value

3. Set the new system version number with the **BP** −, **BP** + and **BP** start stop hardware keys.

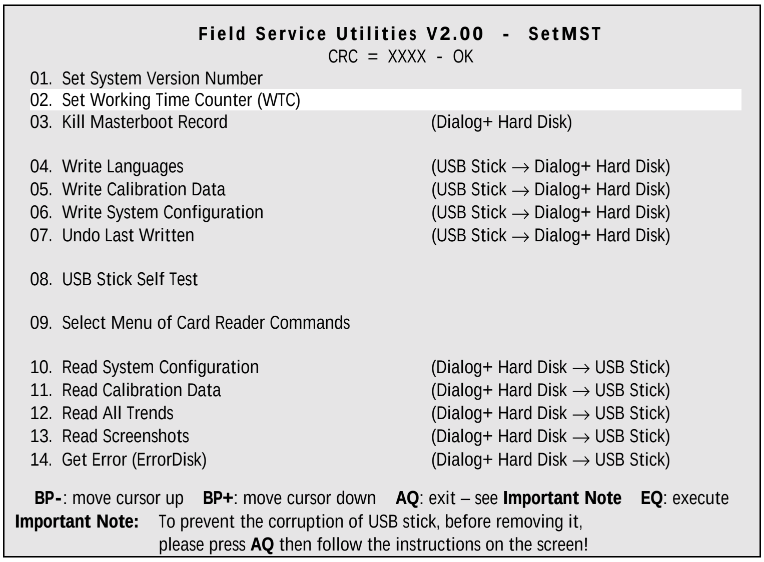
   Note: (n.nn = the version number)

4. Press **EQ** ⏎ to accept the entered value.

   The main menu is displayed after a few seconds.

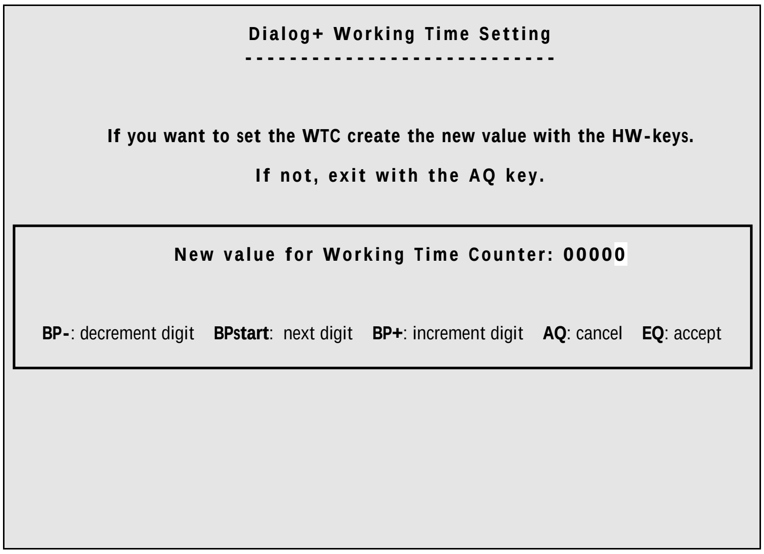
3.6.5 Set Working Time Counter (WTC)

The *Working Time Counter* for the Dialog+ can be set with this utility. The utility is typically used after replacing a hard disk drive (CFC). There is no file exchange between the USB stick and Dialog+ hard disk drive (CFC). In case of acceptance the new value is written to the Dialog+ hard disk drive (CFC) (TLC WTC files).



```
                 Field Service Utilities V2.00  -  SetMST
                            CRC = XXXX - OK
 01. Set System Version Number
 02. Set Working Time Counter (WTC)
 03. Kill Masterboot Record                  (Dialog+ Hard Disk)

 04. Write Languages                         (USB Stick → Dialog+ Hard Disk)
 05. Write Calibration Data                  (USB Stick → Dialog+ Hard Disk)
 06. Write System Configuration              (USB Stick → Dialog+ Hard Disk)
 07. Undo Last Written                       (USB Stick → Dialog+ Hard Disk)

 08. USB Stick Self Test

 09. Select Menu of Card Reader Commands

 10. Read System Configuration               (Dialog+ Hard Disk → USB Stick)
 11. Read Calibration Data                   (Dialog+ Hard Disk → USB Stick)
 12. Read All Trends                         (Dialog+ Hard Disk → USB Stick)
 13. Read Screenshots                        (Dialog+ Hard Disk → USB Stick)
 14. Get Error (ErrorDisk)                   (Dialog+ Hard Disk → USB Stick)

  BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:  To prevent the corruption of USB stick, before removing it,
                 please press AQ then follow the instructions on the screen!
```

1. Press **BP** + and move the cursor down to select the utility.
2. Press **EQ** ↵ to execute the utility.



```
                    Dialog+ Working Time Setting
                    ----------------------------


     If you want to set the WTC create the new value with the HW-keys.

                     If not, exit with the AQ key.

 ┌──────────────────────────────────────────────────────────────────────┐
 │              New value for Working Time Counter: 00000               │
 │                                                                      │
 │ BP-: decrement digit  BPstart: next digit  BP+: increment digit  AQ: cancel  EQ: accept │
 └──────────────────────────────────────────────────────────────────────┘
```

An input screen opens to set the new *Working Time Counter (WTC)* value with the following hardware keys:

BP − : decrements the current digit

BP + : increments the current digit

BP start stop : selects the next digit (from right to left)

AQ : cancels the operation, WTC is not changed

EQ ↵ : sets the new WTC value

3. Set the new working time counter with the **BP** −, **BP** + and **BP** start stop hardware keys.
4. Press **EQ** ↵ to accept the entered value.

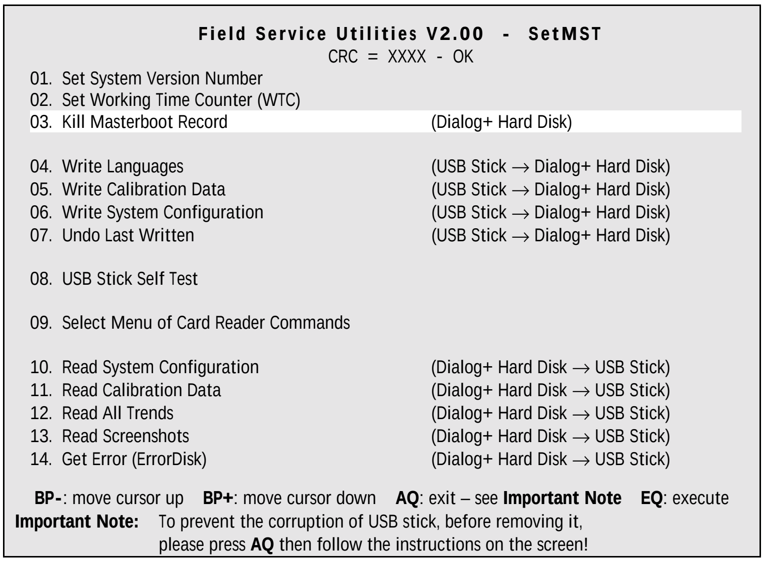
   The main menu is displayed after a few seconds.

3.6.6 Kill Masterboot Record

The *Undo Last Written* utility can not be used for restoring.

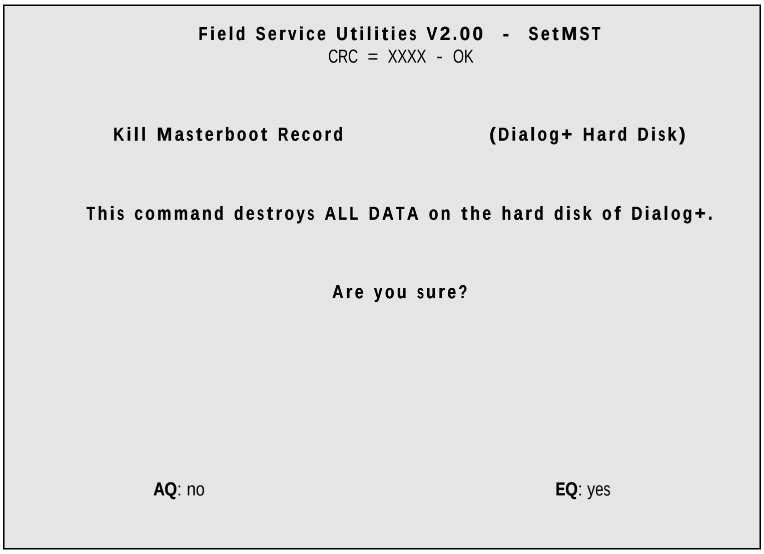
The utility deletes the contents of the masterboot record (first sector filled with 0x00) of the hard disk drive (CFC) of the Dialog+. This utility is typically used after replacing a hard disk drive (CFC) against a not empty CFC.

All data on the hard disk drive (CFC) is lost.
Do not switch off the machine immediately after using the *Kill Masterboot Record* utility. You must wait for the synchronisation between the operating system and CFC (until the main menu appears).



```
                 Field Service Utilities V2.00  -  SetMST
                           CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                (Dialog+ Hard Disk)

04. Write Languages                       (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration            (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                     (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration             (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                 (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                       (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                      (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                 (Dialog+ Hard Disk → USB Stick)

 BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:   To prevent the corruption of USB stick, before removing it,
                  please press AQ then follow the instructions on the screen!
```

1. Press **BP** + and move the cursor down to select the utility.
2. Press **EQ** ↵ to execute the utility.



```
                 Field Service Utilities V2.00  -  SetMST
                           CRC = XXXX - OK


        Kill Masterboot Record                  (Dialog+ Hard Disk)


      This command destroys ALL DATA on the hard disk of Dialog+.


                             Are you sure?




           AQ: no                                    EQ: yes
```

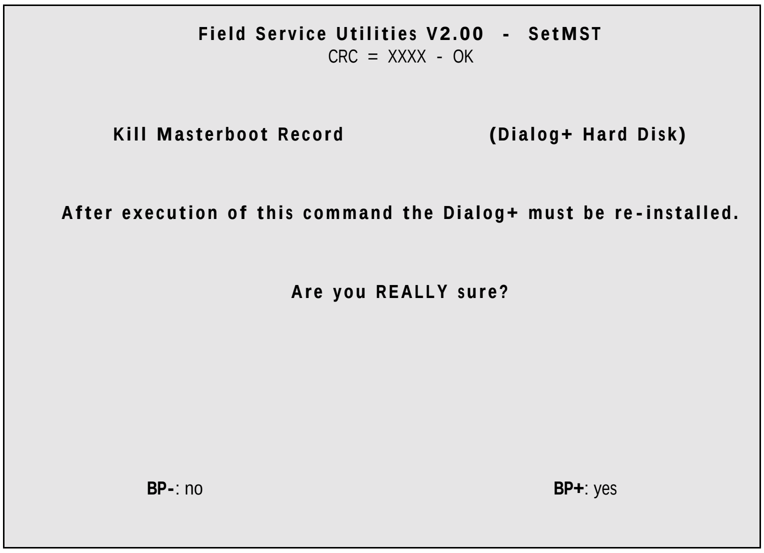
An input screen opens to confirm a deletion of the MBR of the *Masterboot Record* with the following hardware keys:

AQ : exit from the utility

EQ ↵: renewed query for confirmation

Press **EQ** ↵ if you are sure.

3. Press **AQ** if you do not want to delete the masterboot record.



```
Field Service Utilities V2.00  -  SetMST
CRC = XXXX - OK

Kill Masterboot Record                (Dialog+ Hard Disk)

After execution of this command the Dialog+ must be re-installed.

Are you REALLY sure?

BP-: no                                    BP+: yes
```

A second input screen opens to delete the MBR of the *Masterboot Record* with the following hardware keys:

BP − : NO, does not delete the MBR and the operation is cancelled

BP + : YES, deletes the MBR of the Dialog+ hard disk drive (CFC) (after second confirmation)

4. Press **BP** + if you are really sure. This will delete the masterboot record.

5. Press **BP** − to cancel the operation.

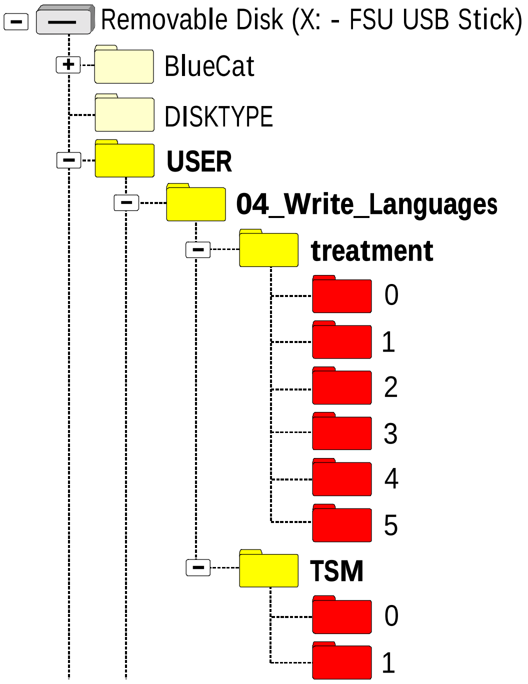
3.6.7 Write Utilities

The group of write utilities writes data files from the FSU USB stick to the Dialog+ hard disk drive (CFC). The following parameters can be written to the Dialog+ hard disk drive (CFC):

- Write Languages
- Write Calibration Data
- Write System Configuration
- Undo Last Written

3.6.7.1 Write Languages

The utility writes languages from the USB stick to the hard disk drive (CFC) of the Dialog+ machine.



If language files are not on the FSU USB stick

Languages have to be copied to the USB stick because by default the language directory is empty. Language files must be copied to the USER subdirectories of the USB stick from your PC.

Note: Do not mix up the places for the treatment language (0, 1, 2, 3, 4, 5) and the TSM language (0, 1).

Write Treatment Language or TSM Language

1. Connect the FSU USB stick to your PC.
2. Copy the required language files from the PC to the following directories:

Treatment Language
USB:\USER\04_Write_Languages\treatment\X*language.id*
USB:\USER\04_Write_Languages\treatment\X*language.tar.gz*

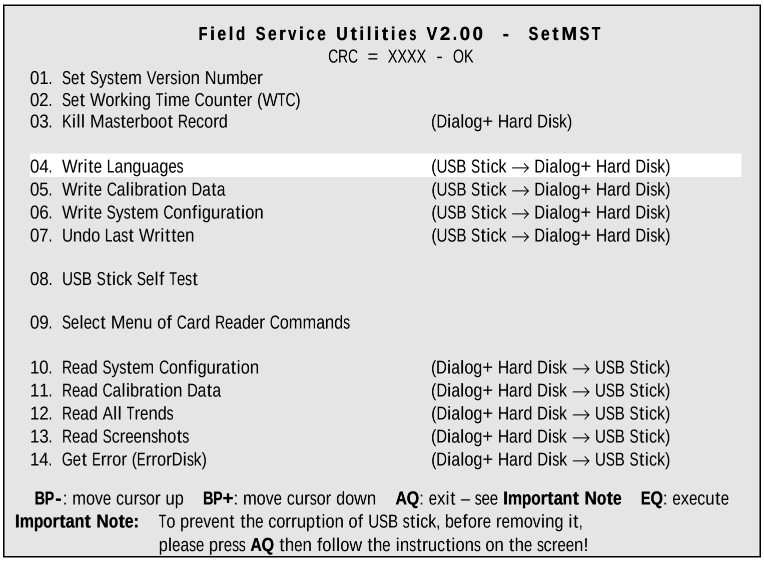
TSM Language
USB:\USER\04_Write_Languages\TSM\X*language.id*
USB:\USER\04_Write_Languages\TSM\X*language.tar.gz*

Note: The language files (*language.id* and *language.tar.gz*) are the outputs of the Windows Language Development Tool LDT.

Example Spanish Language ID
The following information is included in the *language.id* file (open with text editor):

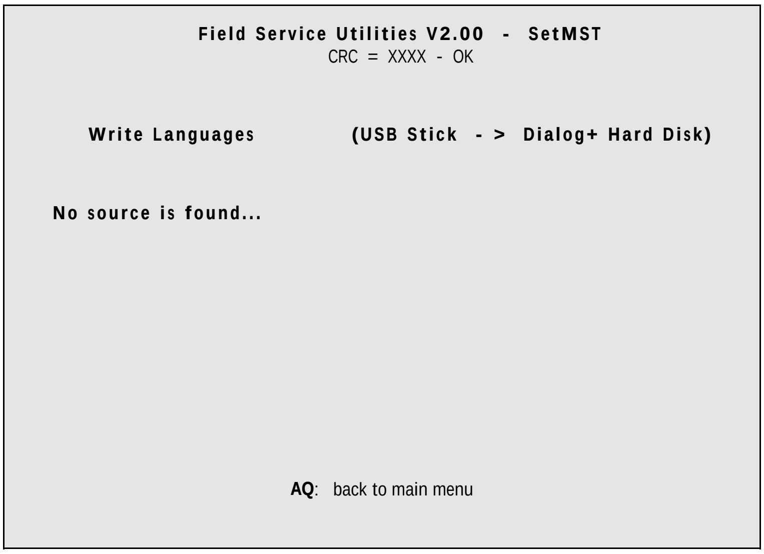
Spanish:	Spanish Language
Treat:	Treatment Language
%M %02d, %04y:	
Spanish:	Spanish Language
034.07.17:	**034** (country code), **07.17** (Dialog SW version number)

The last write procedure can be undone with the *07 Undo Last Written* utility. The Dialog+ can be switched off and on again between the write procedure and using the *07 Undo Last Written* utility.



```
Field Service Utilities V2.00  -  SetMST
CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                    (Dialog+ Hard Disk)

04. Write Languages                           (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                    (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration                (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                         (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration                 (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                     (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                           (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                          (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                     (Dialog+ Hard Disk → USB Stick)

BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:   To prevent the corruption of USB stick, before removing it,
                  please press AQ then follow the instructions on the screen!
```

1. Press **BP** + and move the cursor down to select the utility.
2. Press **EQ** ↵ to execute the utility.



```
Field Service Utilities V2.00  -  SetMST
CRC = XXXX - OK

Write Languages          (USB Stick  - >  Dialog+ Hard Disk)

No source is found...

AQ:  back to main menu
```

An input screen can open with the following information (see left figure), i.e. no languages were found on the USB stick because the language subdirectories are empty. Languages must be copied to the USB stick before you can write languages to the Dialog+ hard disk drive (CFC). Use the following hardware key:

3. Press **AQ** to go back to the main menu.

```
Field Service Utilities V2.00  -  SetMST
CRC = XXXX - OK

Write Languages          (USB Stick  - >  Dialog+ Hard Disk)

TREATMENT language:        Italian – TREAT – 039-07-15

Pressing BPStart will select this language for TREATMENT
Are you sure to install this language to Dialog+?

BPStart: select language for TREATMENT      AQ: no      EQ: yes
```

Languages must be downloaded to the USB stick before they can be written to the Dialog+ hard disk drive (CFC). An input screen opens to *Write Languages* (e.g. Italian) to the hard disk drive (CFC) with the following hardware keys:

BP start stop : if pressed before pressing the **EQ** HW key, the selected *Treatment Language* is set after copying as the active language

AQ : exit from the utility

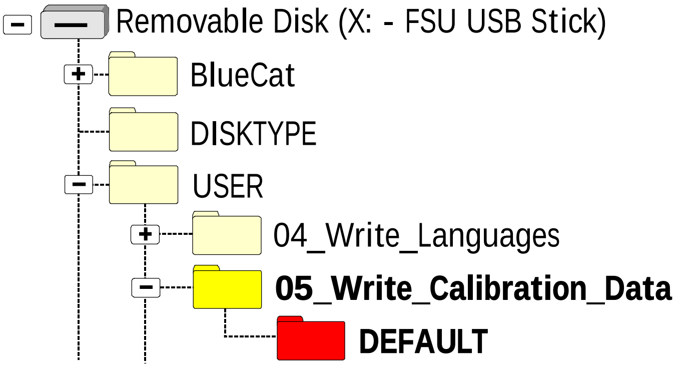
EQ ↵ : starts the execution of the language copying

After successfully copying the language to the CFC the version numbers of all languages available on the Dialog+ are displayed. The language selected for treatment is also marked.

4. Press **EQ** ↵ to continue.

3.6.7.2 Write Calibration Data

The utility writes the *Calibration Data* from the USB stick to the hard disk drive (CFC) of the Dialog+ machine.



If calibration data are not on the FSU USB stick

The calibration data must be read to the USB stick with the *11 Read Calibration Data* utility, because by default the directory is empty.

Write Calibration Data
USB:\USER\05_Write_Calibration_Data\DEFAULT*calib.dat.xxu*

Note: The *Calibration Data* file can be copied back to the Dialog+ machine only, if the serial number and main version number, saved in the *Calibration Data* file, are equal with the serial number and main version number reported by the Dialog+ machine.

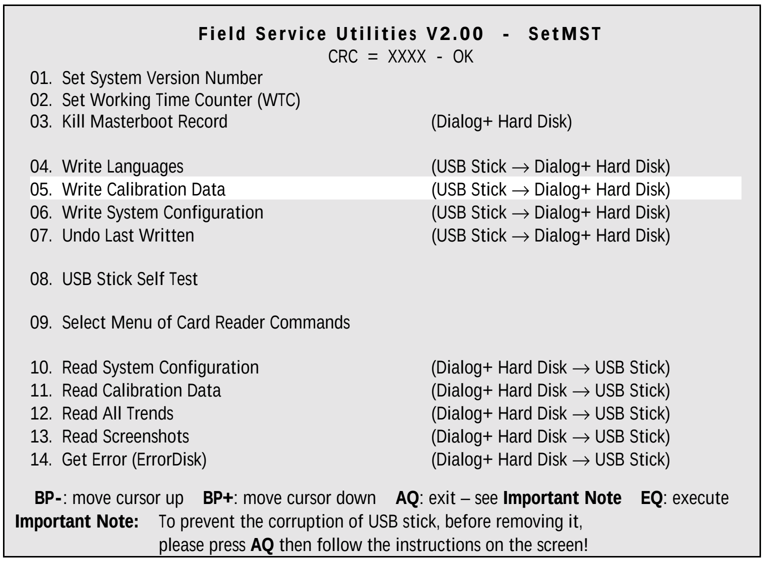
Write and Read Calibration Data

Write (download) the calibration data from the FSU USB stick to the same Dialog+ machine only.

The calibration data should be saved to the hard disk drive (CFC) **in the TSM service program: *TSM Main Menu*, *File Operations*, *Save Calibration Data*.**

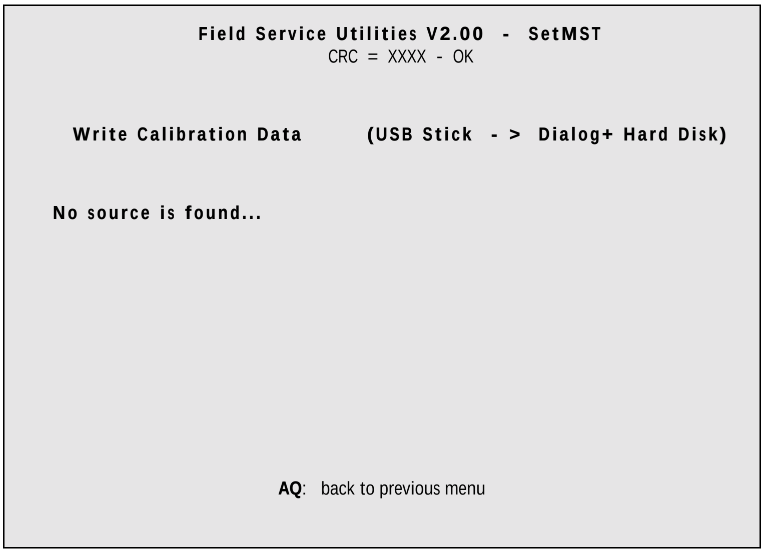
You should read (download) the calibration data from the respective Dialog+ to the USB stick before you start servicing the machine with the *Read Calibration Data* utility in the FSU menu.

The last write procedure can be undone with the *07 Undo Last Written* utility.



```
Field Service Utilities V2.00  -  SetMST
CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                (Dialog+ Hard Disk)

04. Write Languages                       (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration            (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                     (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration             (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                 (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                       (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                      (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                 (Dialog+ Hard Disk → USB Stick)

BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:  To prevent the corruption of USB stick, before removing it,
                 please press AQ then follow the instructions on the screen!
```

1. Press **BP** + and move the cursor down to select the utility.
2. Press **EQ** ↵ to execute the utility.



Field Service Utilities V2.00 - SetMST
CRC = XXXX - OK

Write Calibration Data (USB Stick -> Dialog+ Hard Disk)

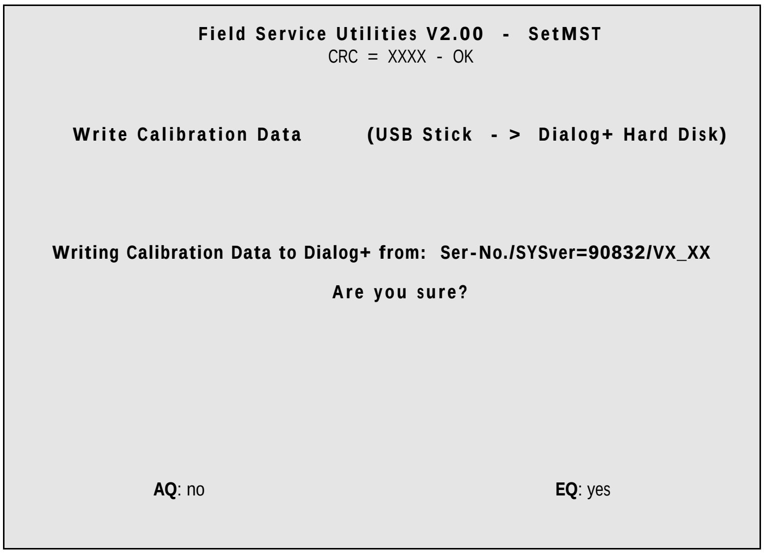
No source is found...

AQ: back to previous menu

The utility searches for sources. An input screen can open with the following information (see left figure), i.e. no sources were found on the USB stick because the calibration data subdirectories are empty. Calibration data must be read to the USB stick before you can write calibration data to the Dialog+ hard disk drive (CFC).

3. Press **AQ** to go back to the previous menu.

4. Use the *Read Calibration Data* utility to read the calibration data from the Dialog+ hard disk drive (CFC) to the USB stick.



Field Service Utilities V2.00 - SetMST
CRC = XXXX - OK

Write Calibration Data (USB Stick -> Dialog+ Hard Disk)

Writing Calibration Data to Dialog+ from: Ser-No./SYSver=90832/VX_XX

Are you sure?

AQ: no **EQ**: yes

An input screen opens to *Write Calibration Data* to the hard disk drive (CFC) with the following hardware keys:

AQ : No, calibration data are not written to Dialog+ hard disk drive (CFC), exit to main menu

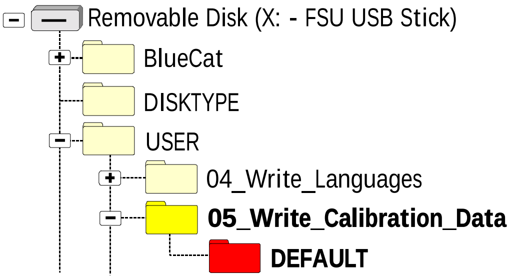
EQ : Yes, calibration data are written to Dialog+ hard disk drive (CFC)

Ser-No./SYSver=90832/VX_XX

The utility compares the serial number (Ser-No.) and the system version number (SYSver) stored in the calibration data file with the serial number and the system version number from the Dialog+. The calibration data file can be written only if they match.

Example

Ser-No.= 90832
SYSver = V8_20



The utility searches for input in the *05_Write_Calibration_Data*, *DEFAULT* subdirectory **and** in the results of the previously performed *11. Read Calibration Data* utility. If no file was found the following message is displayed:
No source...

If there are files (e.g. read from other Dialog+ machines) but there are no matching files, the following message is displayed:
No selectable source is found...

and the existing serial number/system version number pairs are displayed with the following message:
(not selectable)

If there is one matching file the following message is displayed:
Are you sure?

If there are more matching files (for the calibration data this is only possible if you read the calibration data with the *11. Read Calibration Data* utility and copy the result file manually to the *05_Write_Calibration_Data*, *DEFAULT* subdirectory): all existing serial number/system version number pairs are displayed (*DEFAULT* is displayed instead of the serial number if the subdirectory contains a *calib.dat.xxu* file). The user can select from the matching pairs only.

The pairs that do not match are displayed with the following message:
(not selectable)

5. Press **EQ** ↵ if you are sure. This will write the calibration data from the USB stick to the Dialog+ hard disk drive (CFC).

3.6.7.3 Write System Configuration

The utility writes the *System Configuration* from the USB stick to the hard disk drive (CFC) of the Dialog+ machine. The system configuration must be read to the USB stick with the *10 Read System Configuration* utility, because by default the directory is empty.

System Configuration

The system configuration saved on the FSU USB stick must be downloaded to an other Dialog+ machine only if:

- **the hardware matches and**
- **the identical TLC software version number is present.**

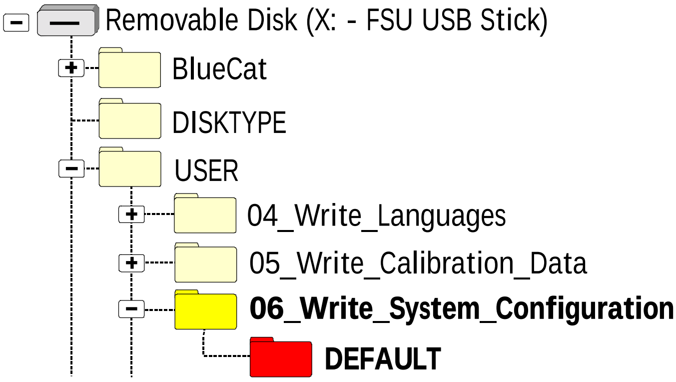
The last write procedure can be undone with the *07 Undo Last Written* utility.

USB Stick with Treatment Support Settings

Old treatment support settings must not be downloaded via a USB stick after a software update. If necessary download the new treatment support setting after an update.

Activation of the Treatment Support Settings

The settings are only activated after the Dialog+ is switched off and on again. Check the settings after the Dialog+ was switched on again.



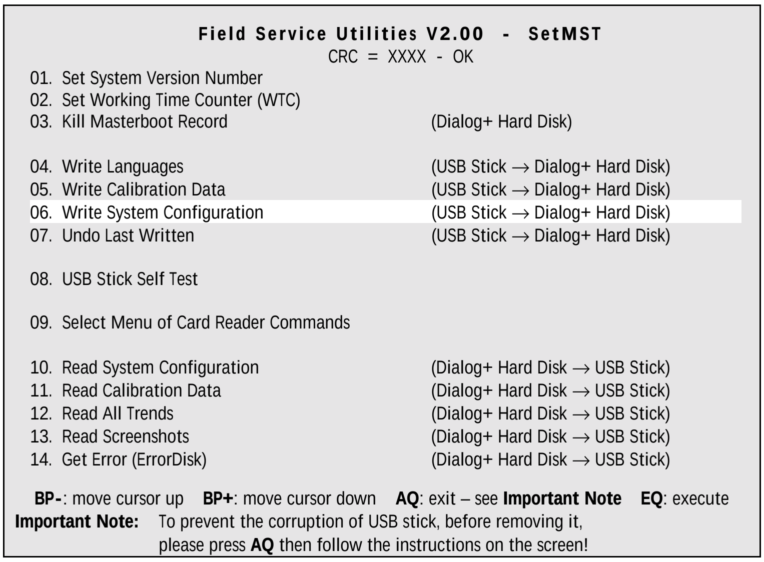
If system configuration is not on the FSU USB stick

The system configuration must be read to the USB stick with the *10 Read System Configuration* utility, because by default the directory is empty.

Write System Configuration

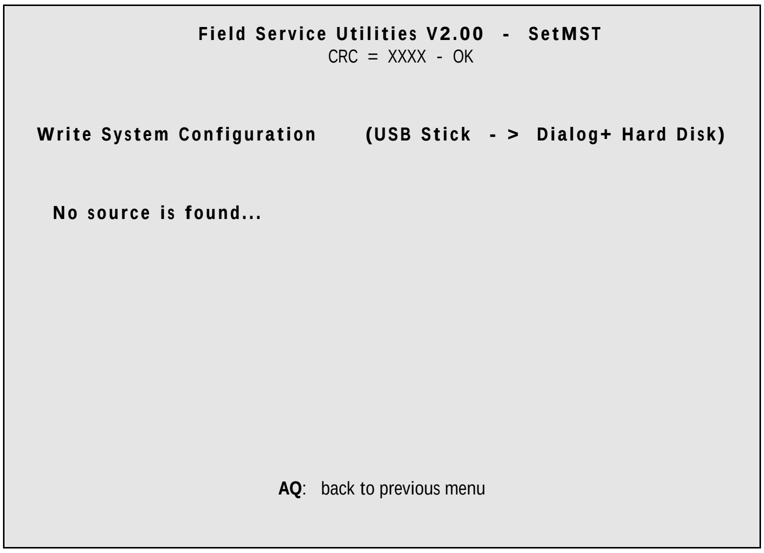
USB:\USER\06_Write_System_Configuration\DEFAULT*config.xxu*

Note: The *System Configuration* file can be copied back to the Dialog+ machine only, if the TLC version number, saved in the *System Configuration* file, is equal with the TLC version number reported by the Dialog+ machine.



```
                    Field Service Utilities V2.00  -  SetMST
                              CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                  (Dialog+ Hard Disk)

04. Write Languages                         (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                  (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration              (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                       (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration               (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                   (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                         (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                        (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                   (Dialog+ Hard Disk → USB Stick)

 BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:   To prevent the corruption of USB stick, before removing it,
                  please press AQ then follow the instructions on the screen!
```

1. Press the **BP** + hardware key and move the cursor down to select the utility.
2. Press the **EQ** ⏎ hardware key to execute the utility.



Field Service Utilities V2.00 - SetMST
CRC = XXXX - OK

Write System Configuration (USB Stick -> Dialog+ Hard Disk)

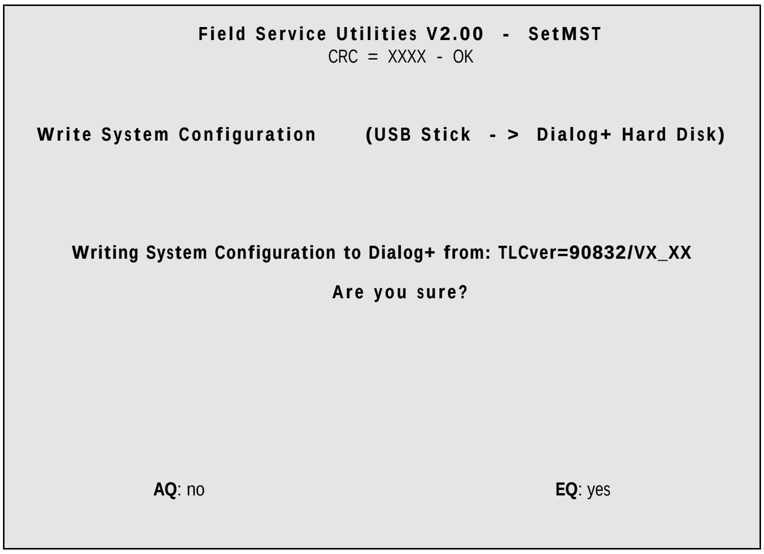
No source is found...

AQ: back to previous menu

The utility searches for sources. An input screen can open with the following information (see left figure), i.e. no sources were found on the USB stick because the system configuration data subdirectories are empty. System configuration data must be stored to the USB stick before you can write system configuration data to the Dialog+ hard disk drive (CFC).

3. Press **AQ** to go back to the previous menu.

4. Use the *Read System Configuration* utility to read the system configuration data from the Dialog+ hard disk drive (CFC) to the USB stick.



Field Service Utilities V2.00 - SetMST
CRC = XXXX - OK

Write System Configuration (USB Stick -> Dialog+ Hard Disk)

Writing System Configuration to Dialog+ from: TLCver=90832/VX_XX

Are you sure?

AQ: no **EQ**: yes

An input screen opens to *Write System Configuration* to the hard disk drive (CFC) with the following hardware keys:

AQ : No, system configuration file is not written to Dialog+, exit from the utility

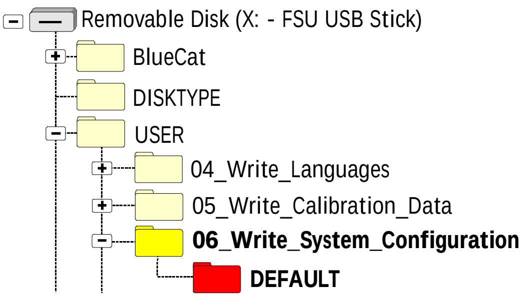
EQ Yes, system configuration file is written to Dialog+ hard disk drive (CFC)

TLCver=90832/VX_XX

The utility compares the top level controller version number (TLCver) stored in the system configuration file with the top level controller version number from the Dialog+. The system configuration file can be written only if they match.

Example

TLCver = V8_20 (top level controller version number)



Removable Disk (X: - FSU USB Stick)
- BlueCat
- DISKTYPE
- USER
  - 04_Write_Languages
  - 05_Write_Calibration_Data
  - **06_Write_System_Configuration**
    - **DEFAULT**

The utility searches for input in the *06_Write_System_ Configuration*, *DEFAULT* subdirectory **and** in the results of the previously performed *10. Read System Configuration* utility. If no file was found the following message is displayed: *No source…*

If there are files (e.g. read from other Dialog+ machines) but there are no matching files the following message is displayed: *No selectable source is found…*

and the existing serial number/top level controller version number pairs are displayed with the following message: *(not selectable)*

If there is one matching file the following message is displayed: *Are you sure?*

If there are more matching files (for the system configuration this is only possible if you read the system configuration data with the *10. Read System Configuration* utility and copy the result file manually to the *06_Write_System_Configuration*, *DEFAULT* subdirectory): all existing serial number/top level controller version number pairs are displayed (*DEFAULT* is displayed instead of the serial number if the subdirectory contains a *config.xxu* file). The user can select from the matching pairs only.

The pairs that do not match are displayed with the following message: *(not selectable)*

5. Press **EQ** ↵ if you are sure. This will write the system configuration data from the USB stick to the Dialog+ hard disk drive (CFC).

3.6.7.4 Undo Last Written

The content of the directory (directories) of the last write procedure is saved on the USB stick together with the serial number of the respective Dialog+ machine. The last write procedure can be undone (restored) with the *Undo Last Written* utility for the following write procedures:

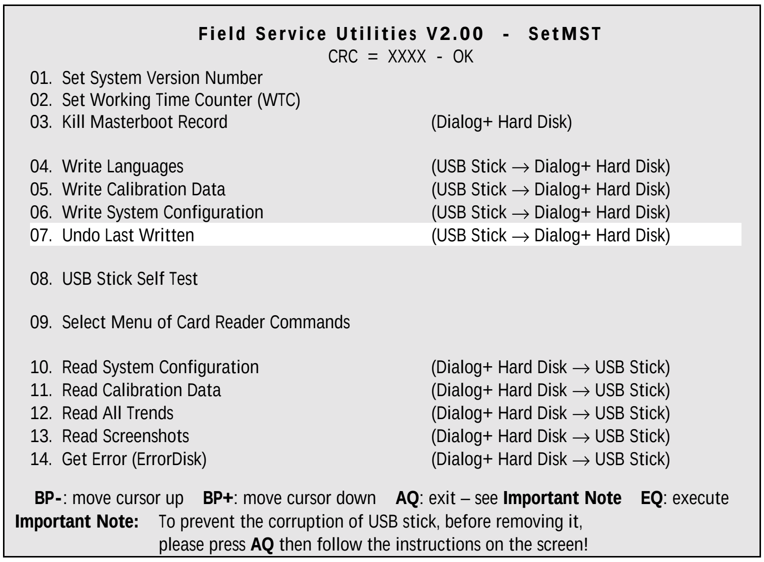
- Write Languages
- Write Calibration Data
- Write System Configuration

The *Undo Last Written* utility should be used immediately after a writing utility was performed by accident.

If the *Undo Last Written* utility is used after a *Write Calibration Data* or *Write System Configuration*: check and match not only the serial number but also the corresponding system version number or TLC version number.

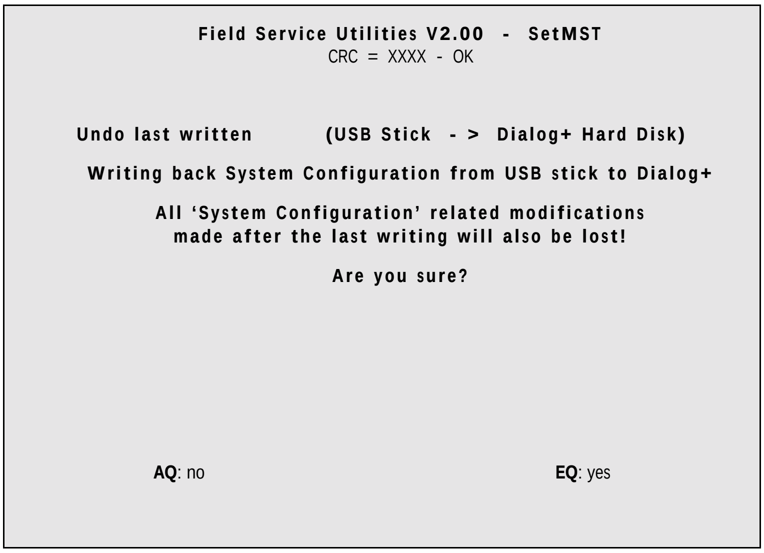
If a *Write…* utility is executed two times in a row the last (saved) and the current status are identical, i.e. in case you would use the *Undo Last Written* utility now there would be no difference between both versions.

The *Undo Last Written* utility can be applied only to the result of the last *Write…* utility and if the saved and the current serial number of the Dialog+ match.



```
              Field Service Utilities V2.00  -  SetMST
                         CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                (Dialog+ Hard Disk)

04. Write Languages                       (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration            (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                     (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration             (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                 (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                       (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                      (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                 (Dialog+ Hard Disk → USB Stick)

 BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:   To prevent the corruption of USB stick, before removing it,
                  please press AQ then follow the instructions on the screen!
```

1. Press the **BP** + hardware key and move the cursor down to select the utility.
2. Press the **EQ** ⏎ hardware key to execute the utility.



```
              Field Service Utilities V2.00  -  SetMST
                         CRC = XXXX - OK


      Undo last written        (USB Stick  - >  Dialog+ Hard Disk)

       Writing back System Configuration from USB stick to Dialog+

             All 'System Configuration' related modifications
               made after the last writing will also be lost!

                            Are you sure?




         AQ: no                                        EQ: yes
```

The *Undo Last Written* utility will undo the last written utility. The menu on the left shows an example of the undo utility for the system configuration.

AQ : No, system configuration file is not undone, exit from the utility

EQ ⏎: Yes, system configuration file is undone

3. Press **EQ** ⏎ if you are sure. This will undo the last written utility from the USB stick to the Dialog+ hard disk drive (CFC).

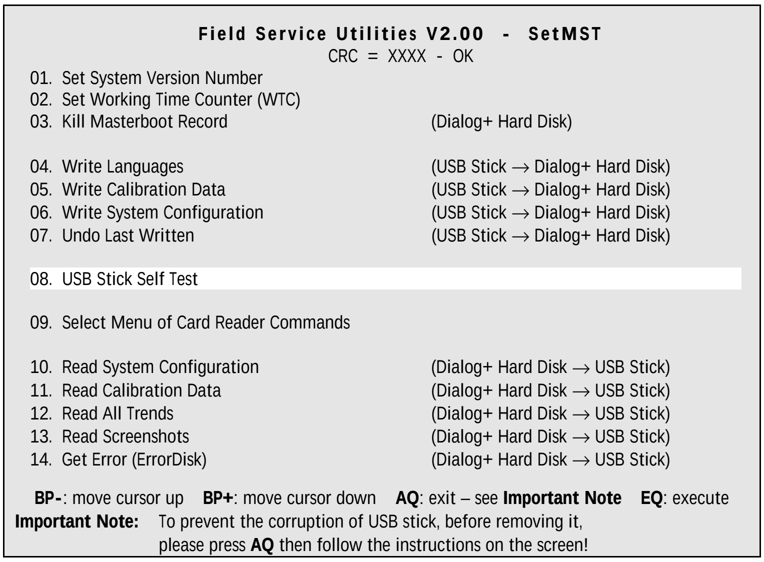
3.6.8 USB Stick Self Test

The *USB Stick Self Test* can be used to check the USB stick. The utility checks the consistency of the file systems.

Self test OK
In case of successful execution the calculated and the reference CRC are displayed before returning to the main menu.

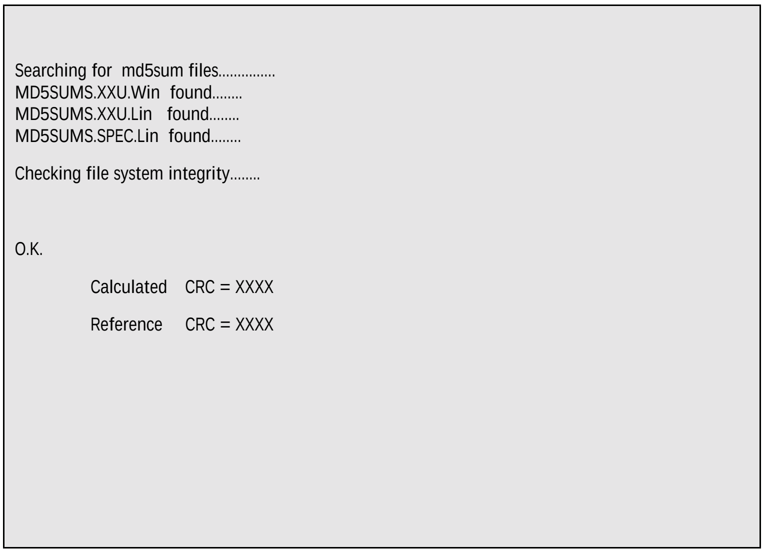
Self test failed
In case of any error the *Self test failed* message is displayed.

Failed Self Test
In case of a self test error the FSU stops automatically. Exit the program and exchange the damaged USB stick before you proceed with the FSU program.



```
                  Field Service Utilities V2.00  -  SetMST
                              CRC = XXXX - OK
 01. Set System Version Number
 02. Set Working Time Counter (WTC)
 03. Kill Masterboot Record                (Dialog+ Hard Disk)

 04. Write Languages                       (USB Stick → Dialog+ Hard Disk)
 05. Write Calibration Data                (USB Stick → Dialog+ Hard Disk)
 06. Write System Configuration            (USB Stick → Dialog+ Hard Disk)
 07. Undo Last Written                     (USB Stick → Dialog+ Hard Disk)

 08. USB Stick Self Test

 09. Select Menu of Card Reader Commands

 10. Read System Configuration             (Dialog+ Hard Disk → USB Stick)
 11. Read Calibration Data                 (Dialog+ Hard Disk → USB Stick)
 12. Read All Trends                       (Dialog+ Hard Disk → USB Stick)
 13. Read Screenshots                      (Dialog+ Hard Disk → USB Stick)
 14. Get Error (ErrorDisk)                 (Dialog+ Hard Disk → USB Stick)

  BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:  To prevent the corruption of USB stick, before removing it,
                 please press AQ then follow the instructions on the screen!
```

1. Press the **BP** + hardware key and move the cursor down to select the utility.
2. Press the **EQ** ↵ hardware key to execute the utility.



```
Searching for  md5sum files..............
MD5SUMS.XXU.Win  found........
MD5SUMS.XXU.Lin   found........
MD5SUMS.SPEC.Lin  found........

Checking file system integrity........


O.K.

           Calculated    CRC = XXXX

           Reference     CRC = XXXX
```

An input screen opens and the *USB Stick Self Test* is performed. The self test menu automatically returns to the main menu after the self test.

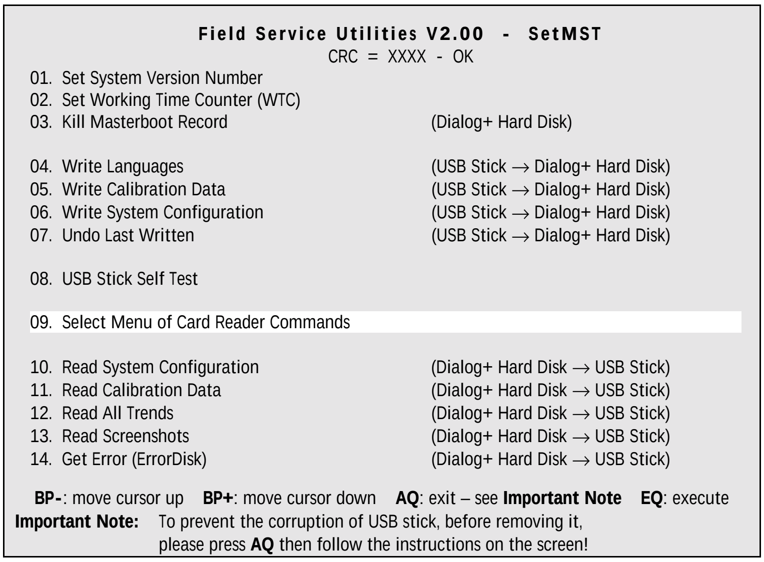
3.6.9 Card Reader Read/Write Utilities

The group of read and write utilities for the card reader is used:

- to read data from a card or diskette and to write them to a USB stick
- to read data from a USB stick and to write them to a card
- All card reader utilities are available in a sub-menu.

3.6.9.1 Select Menu of Card Reader Commands

Select the *09. Select Menu of Card Reader Commands* to open the sub-menu for the card reader utilities.



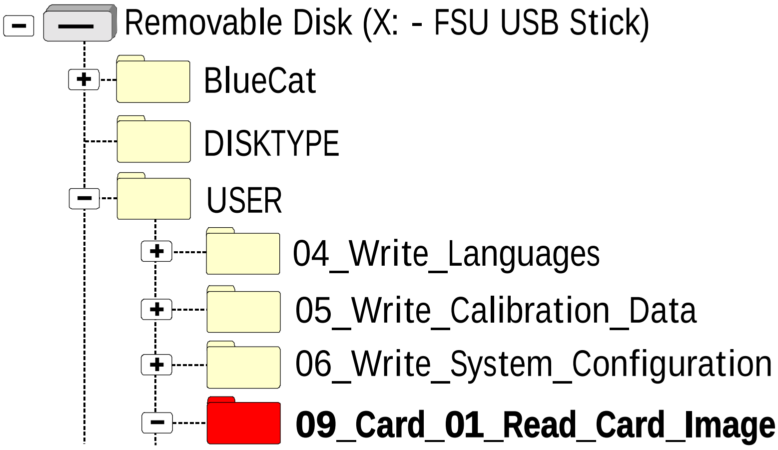
```
              Field Service Utilities V2.00  -  SetMST
                         CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                (Dialog+ Hard Disk)

04. Write Languages                       (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration            (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                     (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration             (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                 (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                       (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                      (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                 (Dialog+ Hard Disk → USB Stick)

 BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:  To prevent the corruption of USB stick, before removing it,
                 please press AQ then follow the instructions on the screen!
```

1. Press the **BP** + hardware key and move the cursor down to select the utility:

   09. Select Menu of Card Reader Commands.

2. Press the **EQ** ⏎ hardware key to execute the utility.

3.6.9.2 Read Card Image



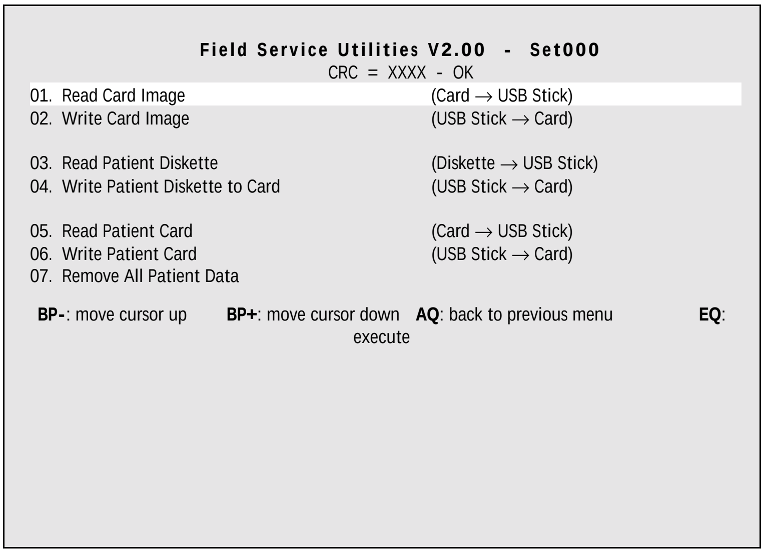
This utility reads card image from the card as a compressed *scard.img.zip* file to the FSU USB stick.

Read Card Image
USB:\USER\09_Card_01_Read_Card_Image\{YYYY-MM-DD.hh.mm.ss}\scard.img.zip

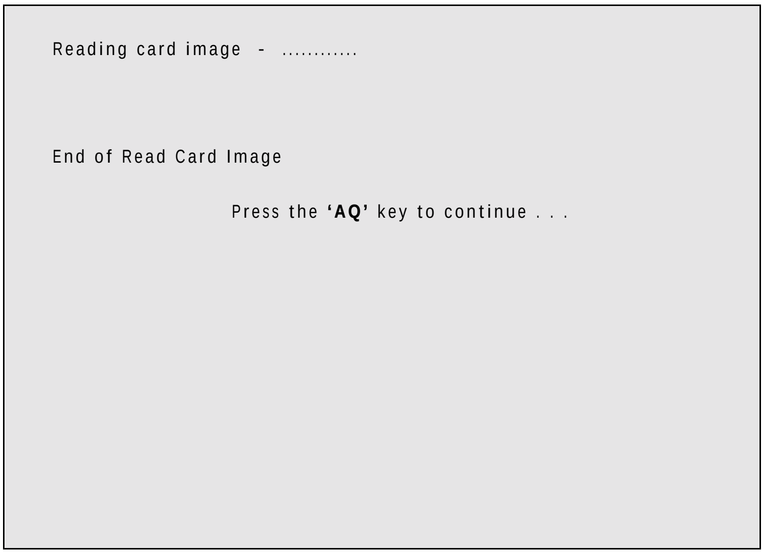
Example:
USB:\USER\09_Card_01_Read_Card_Image\{2007-08-30.15.34.12}*scard.img.zip*

Y Y Y Y :	Year 2007
M M :	08 month August
D D :	30 Thursday
h h :	15 hours
m m :	34 minutes
s s :	12 seconds

1. Press the **BP** + hardware key, move cursor down and select *09. Select Menu of Card Reader Commands* in the main menu.
2. Press the **EQ** ↵ hardware key to execute the utility.
   - Yes, card image is written to USB stick
3. Press the **AQ** hardware key to skip to the previous menu.
   - No, card image is not written to USB stick

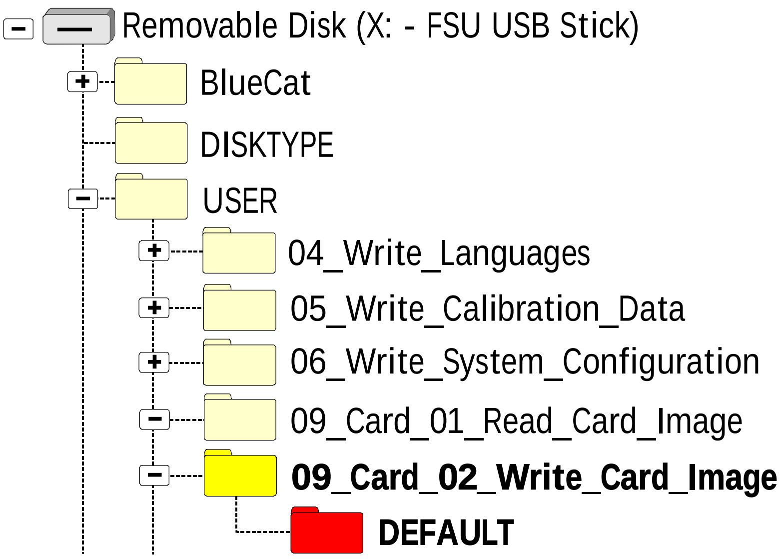


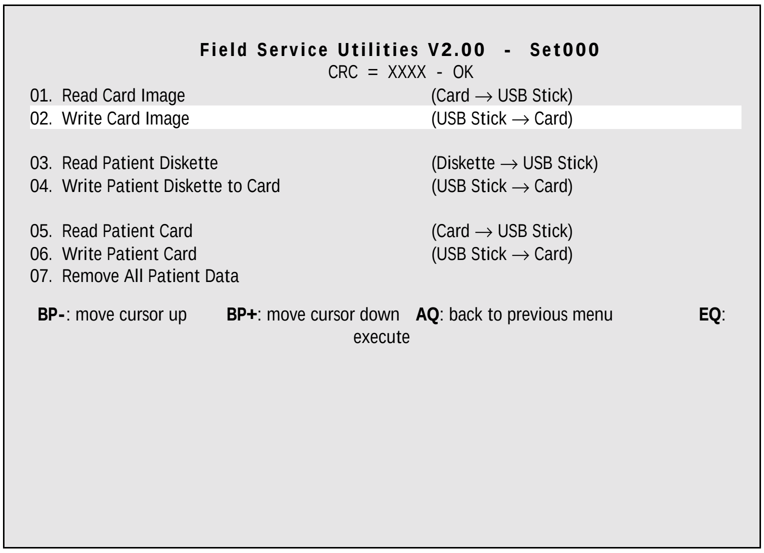
```
          Field Service Utilities V2.00  -  Set000
                       CRC = XXXX - OK
01. Read Card Image                     (Card → USB Stick)
02. Write Card Image                    (USB Stick → Card)

03. Read Patient Diskette               (Diskette → USB Stick)
04. Write Patient Diskette to Card      (USB Stick → Card)

05. Read Patient Card                   (Card → USB Stick)
06. Write Patient Card                  (USB Stick → Card)
07. Remove All Patient Data

 BP-: move cursor up    BP+: move cursor down   AQ: back to previous menu        EQ:
                             execute
```



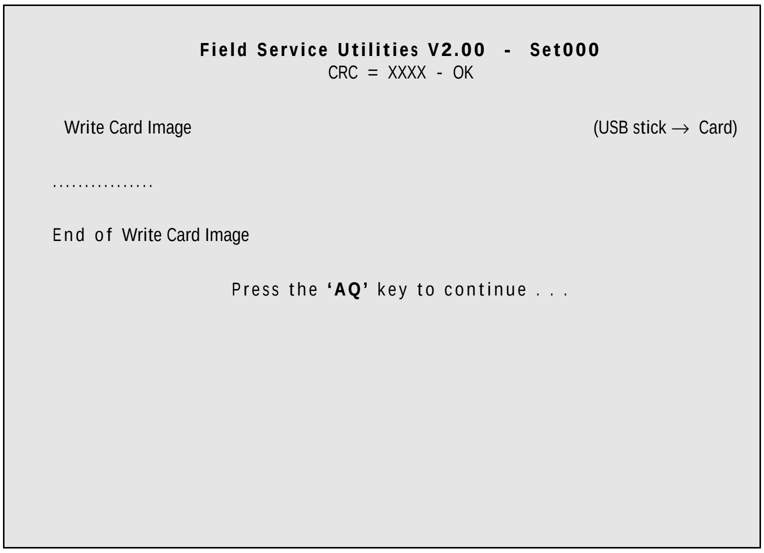
```
   Reading card image  -  ............


   End of Read Card Image

                  Press the 'AQ' key to continue . . .
```

3.6.9.3 Write Card Image





```
                 Field Service Utilities V2.00  -  Set000
                            CRC = XXXX - OK
01. Read Card Image                          (Card → USB Stick)
02. Write Card Image                         (USB Stick → Card)

03. Read Patient Diskette                    (Diskette → USB Stick)
04. Write Patient Diskette to Card           (USB Stick → Card)

05. Read Patient Card                        (Card → USB Stick)
06. Write Patient Card                       (USB Stick → Card)
07. Remove All Patient Data

 BP-: move cursor up   BP+: move cursor down   AQ: back to previous menu   EQ:
                               execute
```



```
                 Field Service Utilities V2.00  -  Set000
                            CRC = XXXX - OK

   Write Card Image                                  (USB stick → Card)

  ................

  End of Write Card Image

                 Press the 'AQ' key to continue . . .
```

This utility writes card images from the USB stick as a compressed *scard.img.zip* file to the card.

If file is not on FSU USB stick

Copy from the PC the compressed *scard.img.zip* file from the card image to the following USER subdirectory:

USB:\USER\09_Card_02_Write_Card_Image\DEFAULT\ *scard.img.zip*

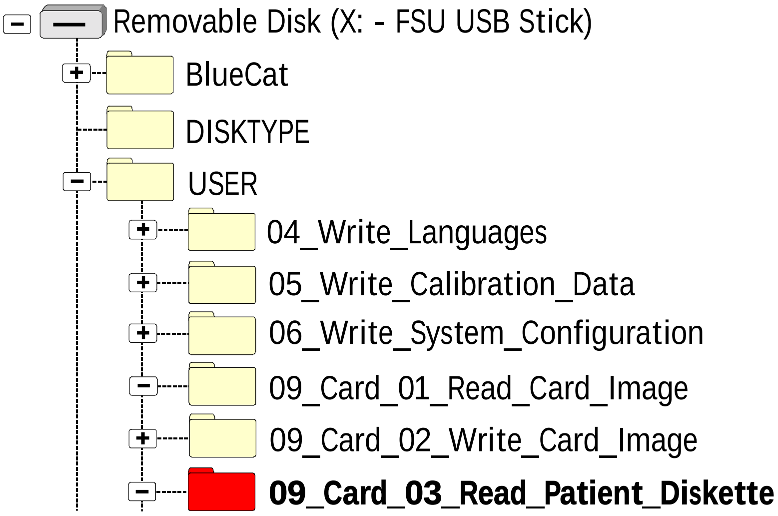
Note: This utility can not be used to copy the bioLogic RR activation card.

The process is aborted with the following message:

ABPS (bioLogic RR) Activation Card Image can not be written to card.

1. Press the **BP** + hardware key, move cursor down and select *09. Select Menu of Card Reader Commands* in the main menu.
2. Press the **BP** + hardware key and move the cursor down to select the utility.
3. Press the **EQ** ↵ hardware key to execute the utility.
   - Yes, card image is written to card
4. Press the AQ hardware key to skip to the previous menu.
   - No, card image is not written to card

3.6.9.4 Read Patient Diskette



Removable Disk (X: - FSU USB Stick)
- BlueCat
- DISKTYPE
- USER
  - 04_Write_Languages
  - 05_Write_Calibration_Data
  - 06_Write_System_Configuration
  - 09_Card_01_Read_Card_Image
  - 09_Card_02_Write_Card_Image
  - **09_Card_03_Read_Patient_Diskette**

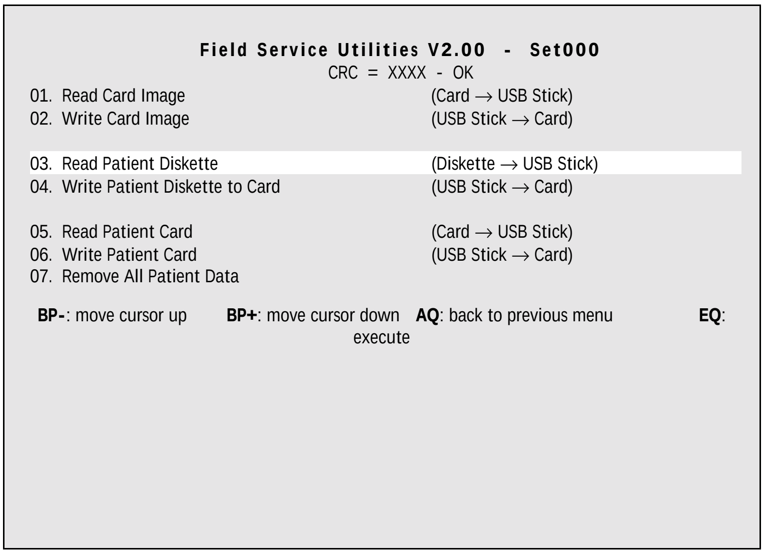
This utility reads patient files from the patient diskette as a compressed *patdisk.zip* file to the FSU USB stick.

Read Patient Diskette
USB:\USER\09_Card_03_Read_Patient_Diskette\
{Patient_Name}\patdisk.zip

Example:
USB:\USER\09_Card_03_Read_Patient_Diskette\
Michael_May*patdisk.zip*

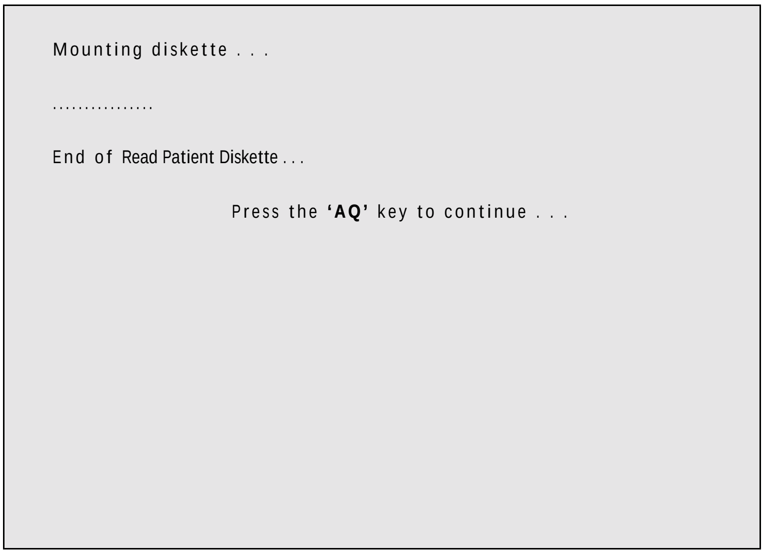
Patient_Name: Michael_May

Note: If the patient name is not found on the diskette, the *Unknown Patient* name is used.



```
                 Field Service Utilities V2.00  -  Set000
                           CRC = XXXX - OK
01. Read Card Image                            (Card → USB Stick)
02. Write Card Image                           (USB Stick → Card)

03. Read Patient Diskette                      (Diskette → USB Stick)
04. Write Patient Diskette to Card             (USB Stick → Card)

05. Read Patient Card                          (Card → USB Stick)
06. Write Patient Card                         (USB Stick → Card)
07. Remove All Patient Data

 BP-: move cursor up    BP+: move cursor down   AQ: back to previous menu        EQ:
                                  execute
```

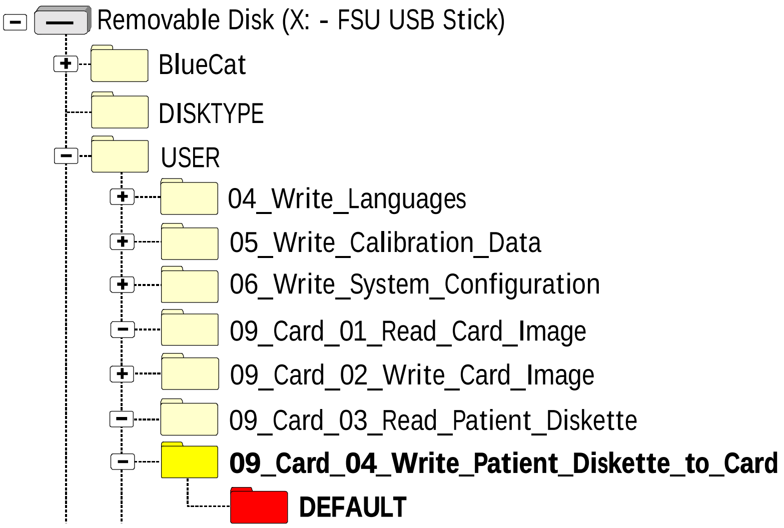
1. Press the **BP** + hardware key, move cursor down and select *09. Select Menu of Card Reader Commands* in the main menu.
2. Press the **BP** + hardware key and move the cursor down to select the utility.
3. Press the **EQ** ↵ hardware key to execute the utility.
   - Yes, patient diskette is read to USB stick
4. Press the **AQ** hardware key to skip to the previous menu.
   - No, patient diskette is not read to USB stick



```
   Mounting diskette . . .

   ................

   End of Read Patient Diskette . . .

                      Press the 'AQ' key to continue . . .
```

Remove all patient data from the FSU USB stick after service with the utility *07. Remove All Patient Data*. This will delete all patient data stored on the FSU USB stick.

3.6.9.5 Write Patient Diskette to Card



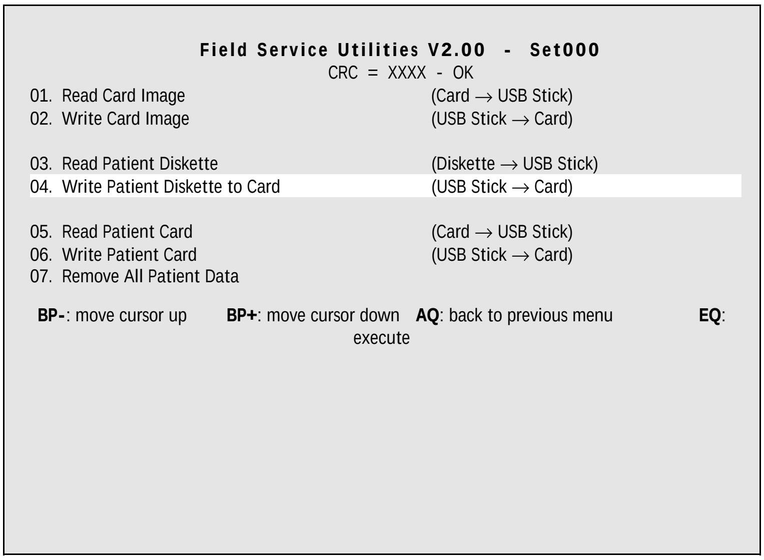
```
Removable Disk (X: - FSU USB Stick)
    BlueCat
    DISKTYPE
    USER
        04_Write_Languages
        05_Write_Calibration_Data
        06_Write_System_Configuration
        09_Card_01_Read_Card_Image
        09_Card_02_Write_Card_Image
        09_Card_03_Read_Patient_Diskette
        09_Card_04_Write_Patient_Diskette_to_Card
            DEFAULT
```

This utility writes the patient files from the USB stick as a compressed *patdisk.zip* file to the patient card, i.e. converts a patient diskette to a patient card.

If file is not on FSU USB stick

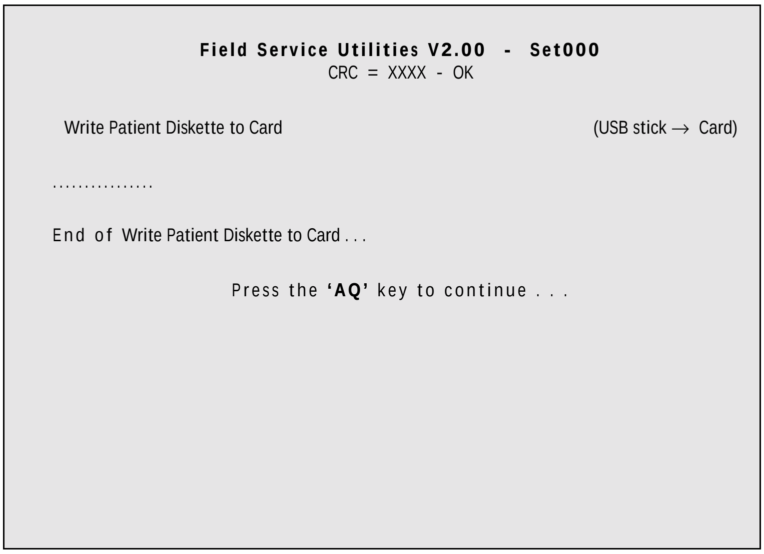
Copy from the PC the compressed *patdisk.zip* file from the patient diskette to the following USER subdirectory:

USB:\USER\09_Card_04_Write_Patient_Diskette_to_Card\DEFAULT*patdisk.zip*



```
              Field Service Utilities V2.00  -  Set000
                         CRC = XXXX - OK
01. Read Card Image                        (Card → USB Stick)
02. Write Card Image                       (USB Stick → Card)

03. Read Patient Diskette                  (Diskette → USB Stick)
04. Write Patient Diskette to Card         (USB Stick → Card)

05. Read Patient Card                      (Card → USB Stick)
06. Write Patient Card                     (USB Stick → Card)
07. Remove All Patient Data

 BP-: move cursor up    BP+: move cursor down   AQ: back to previous menu      EQ:
                              execute
```

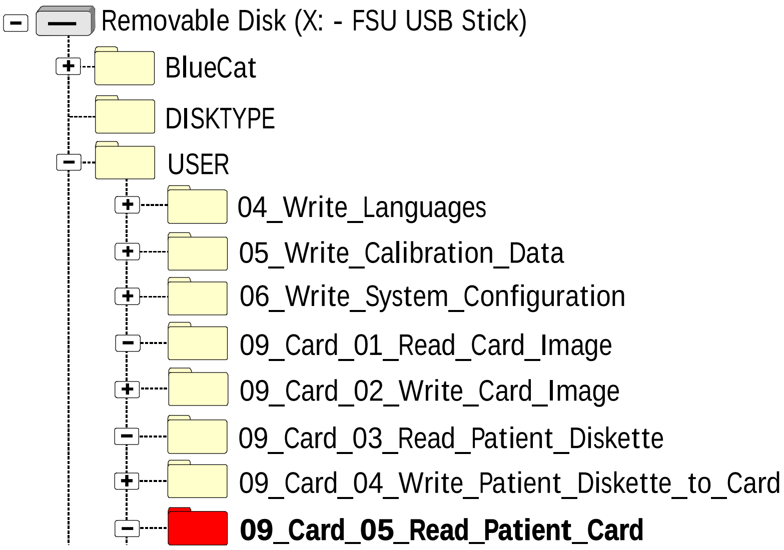
1. Press the **BP** + hardware key, move cursor down and select *09. Select Menu of Card Reader Commands* in the main menu.
2. Press the **BP** + hardware key and move the cursor down to select the utility.
3. Press the **EQ** ↵ hardware key to execute the utility.
   - Yes, USB stick (patient diskette) is written to patient card
4. Press the **AQ** 🔕 hardware key to skip to the previous menu.
   - No, USB stick (patient diskette) is not written to patient card



```
              Field Service Utilities V2.00  -  Set000
                         CRC = XXXX - OK

   Write Patient Diskette to Card                        (USB stick → Card)

  ................

  End of Write Patient Diskette to Card . . .

                  Press the 'AQ' key to continue . . .
```

Remove all patient data from the FSU USB stick after service with the utility *07. Remove All Patient Data*. This will delete all patient data stored on the FSU USB stick.

3.6.9.6 Read Patient Card



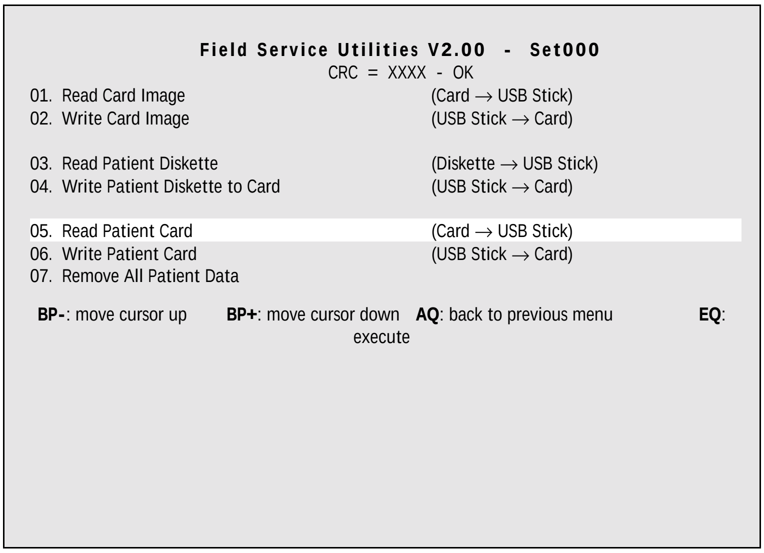
This utility reads patient files from the patient card as a compressed *patcard.zip* file to the FSU USB stick.

Read Patient Card
USB:\USER\09_Card_05_Read_Patient_Card\{Patient_Name}\patcard.zip

Example:
USB:\USER\09_Card_05_Read_Patient_Card\Michael_May*patcard.zip*

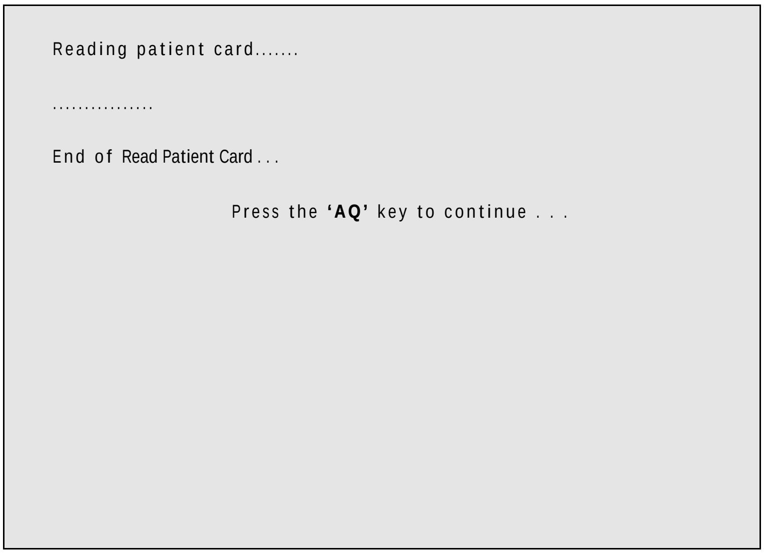
Patient_Name: Michael_May

Note: If the patient name is not found on the card, the *Unknown Patient* name is used.



```
Field Service Utilities V2.00  -  Set000
CRC = XXXX - OK
01.  Read Card Image                         (Card → USB Stick)
02.  Write Card Image                        (USB Stick → Card)

03.  Read Patient Diskette                   (Diskette → USB Stick)
04.  Write Patient Diskette to Card          (USB Stick → Card)

05.  Read Patient Card                       (Card → USB Stick)
06.  Write Patient Card                      (USB Stick → Card)
07.  Remove All Patient Data

BP-: move cursor up    BP+: move cursor down   AQ: back to previous menu        EQ:
                                  execute
```

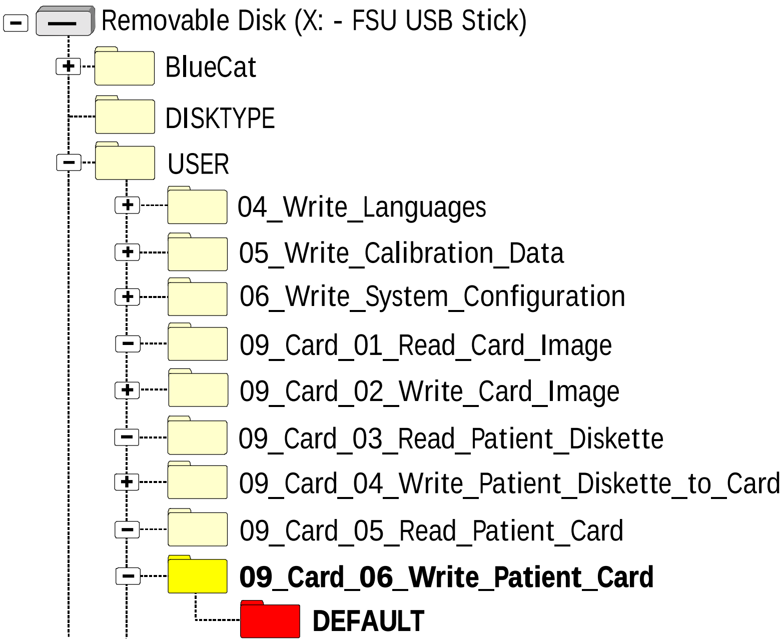
1. Press the **BP** + hardware key, move cursor down and select *09. Select Menu of Card Reader Commands* in the main menu.
2. Press the **BP** + hardware key and move the cursor down to select the utility.
3. Press the **EQ** ↵ hardware key to execute the utility.
   - Yes, patient card is read to USB stick
4. Press the **AQ** hardware key to skip to the previous menu.
   - No, patient card is not read to USB stick



```
Reading patient card.......

................

End of Read Patient Card . . .

             Press the 'AQ' key to continue . . .
```

Remove all patient data from the FSU USB stick after service with the utility *07. Remove All Patient Data*. This will delete all patient data stored on the FSU USB stick.

3.6.9.7 Write Patient Card

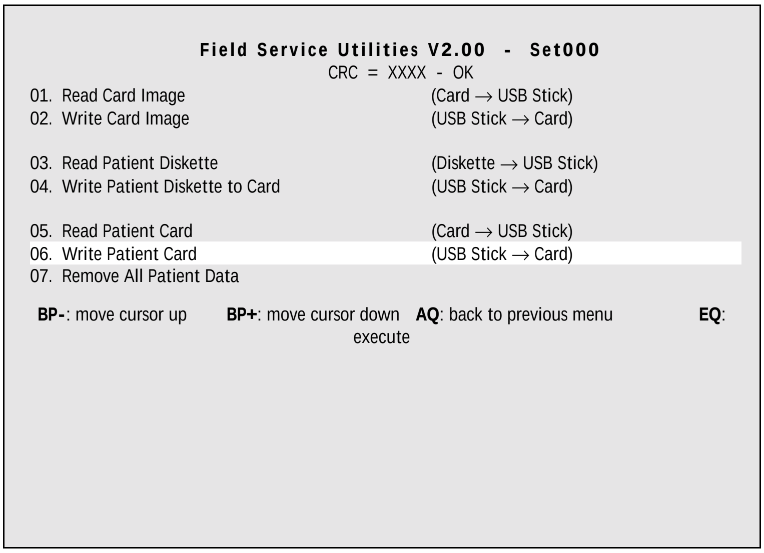


This utility writes patient files from the USB stick as a compressed *patcard.zip* file to the patient card.

If file is not on FSU USB stick

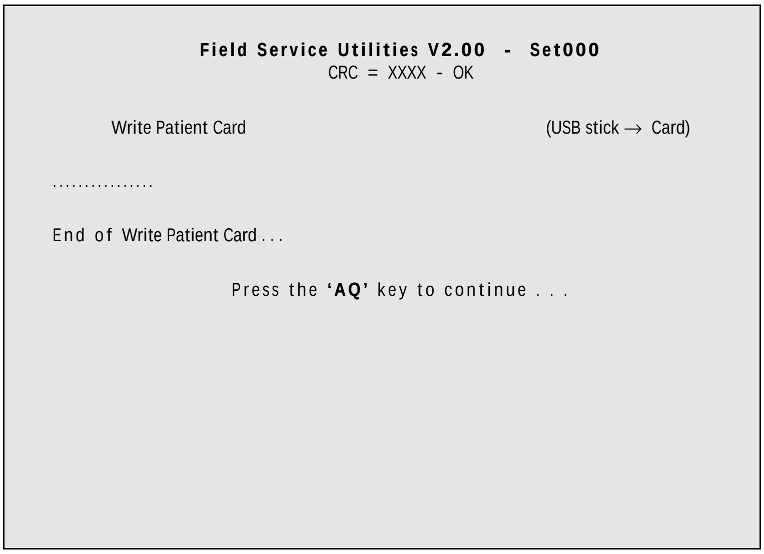
Copy on the PC, the compressed *patcard.zip* from the patient card file to the following USER subdirectory:

USB:\USER\09_Card_06_Write_Patient_Card\DEFAULT \patcard.zip



```
                 Field Service Utilities V2.00  -  Set000
                            CRC = XXXX - OK
01. Read Card Image                          (Card → USB Stick)
02. Write Card Image                         (USB Stick → Card)

03. Read Patient Diskette                    (Diskette → USB Stick)
04. Write Patient Diskette to Card           (USB Stick → Card)

05. Read Patient Card                        (Card → USB Stick)
06. Write Patient Card                       (USB Stick → Card)
07. Remove All Patient Data

 BP-: move cursor up   BP+: move cursor down   AQ: back to previous menu   EQ:
                                execute
```

1. Press the **BP** + hardware key, move cursor down and select *09. Select Menu of Card Reader Commands* in the main menu.
2. Press the **BP** + hardware key and move the cursor down to select the utility.
3. Press the **EQ** ↵ hardware key to execute the utility.
   - Yes, USB stick is written to patient card
4. Press the **AQ** hardware key to skip to the previous menu.
   - No, USB stick is not written to patient card



```
                 Field Service Utilities V2.00  -  Set000
                            CRC = XXXX - OK

        Write Patient Card                          (USB stick → Card)

   ................

   End of Write Patient Card . . .

                  Press the 'AQ' key to continue . . .
```

Remove all patient data from the FSU USB stick after service with the utility *07. Remove All Patient Data*. This will delete all patient data stored on the FSU USB stick.

3.6.9.8 Remove All Patient Data

Remove all patient data from the FSU USB stick after service with the utility *07. Remove All Patient Data*. This will delete all patient data stored on the FSU USB stick.

The service technician can store patient data on the USB stick by reading them from patient cards and patient diskettes. Additionally patient data can be copied manually to the *09_Write_Patient_Diskette_to_Card*, *DEFAULT* subdirectory and the *09_Write_Patient_Card*, *DEFAULT* sub-directories. If the patient data are not required anymore the service technician can remove them from the USB stick in one step by using the *07 Remove All Patient Data* utility. The utility will remove all the patient data from the FSU USB stick, except the patient card images.

The utility requires two confirmations.

First confirmation:
Are you sure?

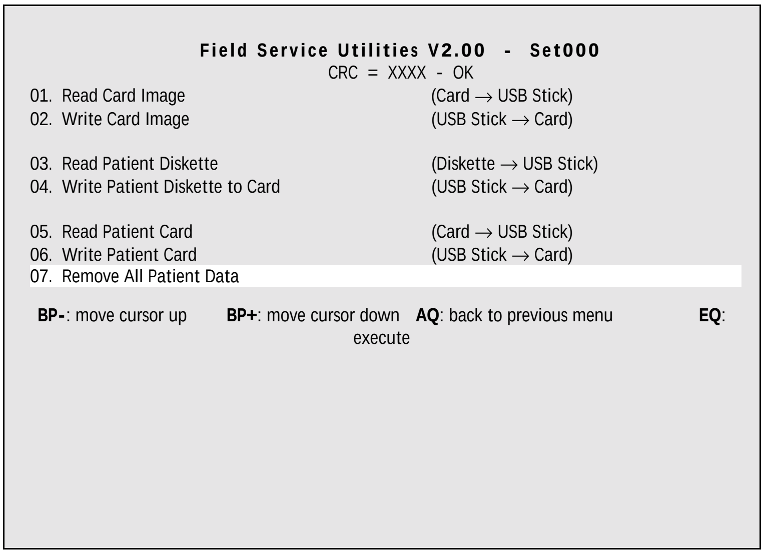
AQ 🔕: exit from the utility

EQ ↵: renewed query for confirmation

Second confirmation:
Are you REALLY sure?

BP −: exit from the utility

BP +: all patient data are deleted from the FSU USB stick.



Field Service Utilities V2.00 - Set000
CRC = XXXX - OK

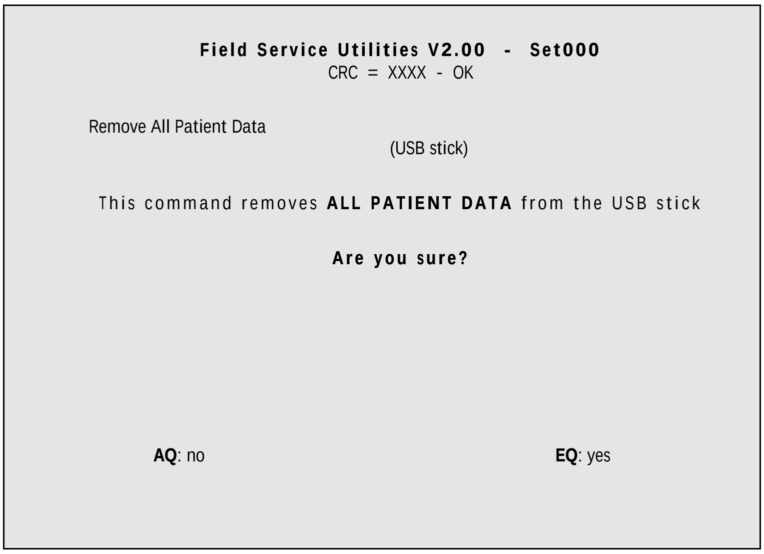
01. Read Card Image (Card → USB Stick)
02. Write Card Image (USB Stick → Card)

03. Read Patient Diskette (Diskette → USB Stick)
04. Write Patient Diskette to Card (USB Stick → Card)

05. Read Patient Card (Card → USB Stick)
06. Write Patient Card (USB Stick → Card)
07. Remove All Patient Data

BP-: move cursor up **BP+**: move cursor down **AQ**: back to previous menu **EQ**: execute

1. Press **EQ** ↵ to execute the utility.
2. Press **AQ** 🔕 to skip to the previous menu.



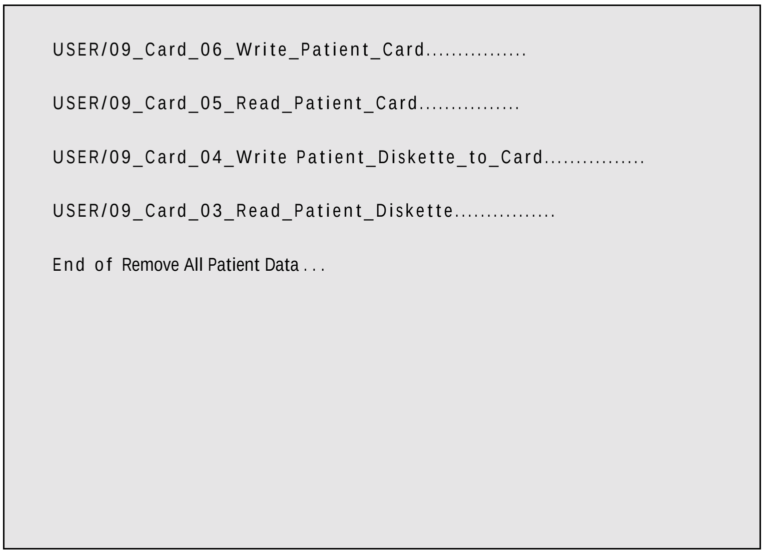
Field Service Utilities V2.00 - Set000
CRC = XXXX - OK

Remove All Patient Data
(USB stick)

This command removes **ALL PATIENT DATA** from the USB stick

Are you sure?

AQ: no **EQ**: yes



```
USER/09_Card_06_Write_Patient_Card................

USER/09_Card_05_Read_Patient_Card...............

USER/09_Card_04_Write Patient_Diskette_to_Card...............

USER/09_Card_03_Read_Patient_Diskette...............

End of Remove All Patient Data . . .
```

The *Remove All Patient Data* utility will delete all patient data from the FSU USB stick

AQ : No, all patient data are not deleted, exit from the utility

EQ ↵: Yes, all patient data are deleted

3. Press **EQ** ↵ if you are sure. This will delete all patient data from the FSU USB stick.

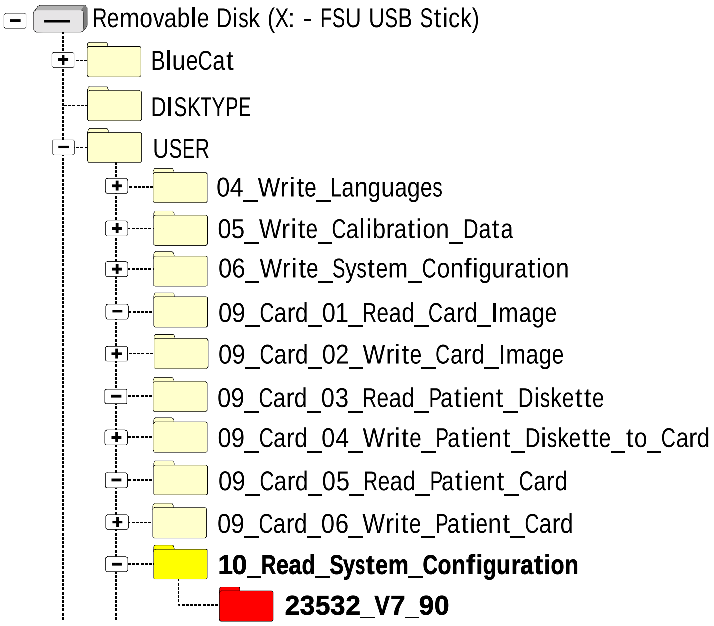
3.6.10 Read/Get Error Utilities

The group of read utilities reads data files from the Dialog+ hard disk drive (CFC) and writes them to the FSU USB stick.

3.6.10.1 Read System Configuration

The utility reads the system configuration from Dialog+ hard disk drive (CFC) and writes it to the USB stick. Files from different Dialog+ machines are placed in different subdirectories on the USB stick. The subdirectory name *USER/10_Read_System_Configuration/ <SERNUM>_<TLC Version>/* is created from the serial number and the TLC version number of the Dialog+ machine.

<SERNUM>_<TLC Version>
The subdirectory name is created from the serial number <SERNUM> and the TLC version number of the Dialog+ machine. If the serial number is not set on the Dialog+ <SERNUM> is equal to '-----'.



```
⊟ Removable Disk (X: - FSU USB Stick)
    ⊞ BlueCat
      DISKTYPE
    ⊟ USER
        ⊞ 04_Write_Languages
        ⊞ 05_Write_Calibration_Data
        ⊞ 06_Write_System_Configuration
        ⊟ 09_Card_01_Read_Card_Image
        ⊞ 09_Card_02_Write_Card_Image
        ⊟ 09_Card_03_Read_Patient_Diskette
        ⊞ 09_Card_04_Write_Patient_Diskette_to_Card
        ⊟ 09_Card_05_Read_Patient_Card
        ⊞ 09_Card_06_Write_Patient_Card
        ⊟ 10_Read_System_Configuration
              23532_V7_90
```

See the results in the subdirectories with the following path for the *System Configuration* file *config.xxu*.

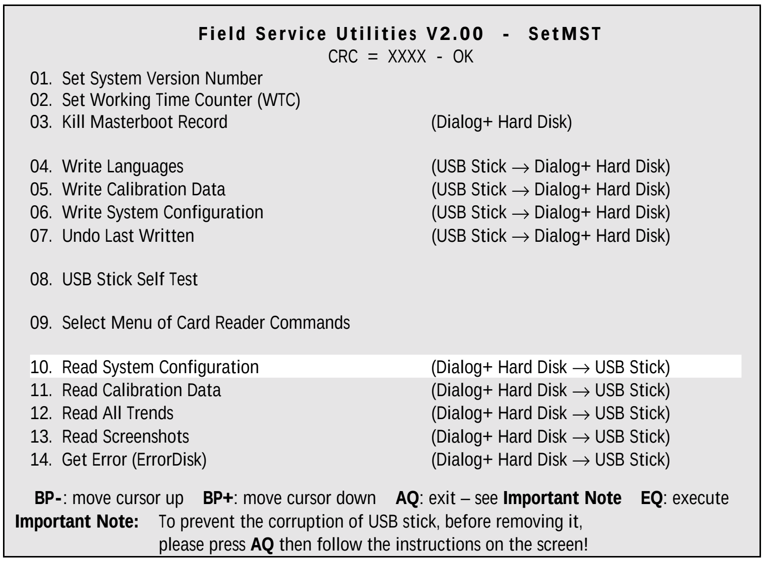
Read System Configuration

USB:\USER\10_Read_System_Configuration\{Serial Number}_{TLC Version}*config.xxu*

Example:

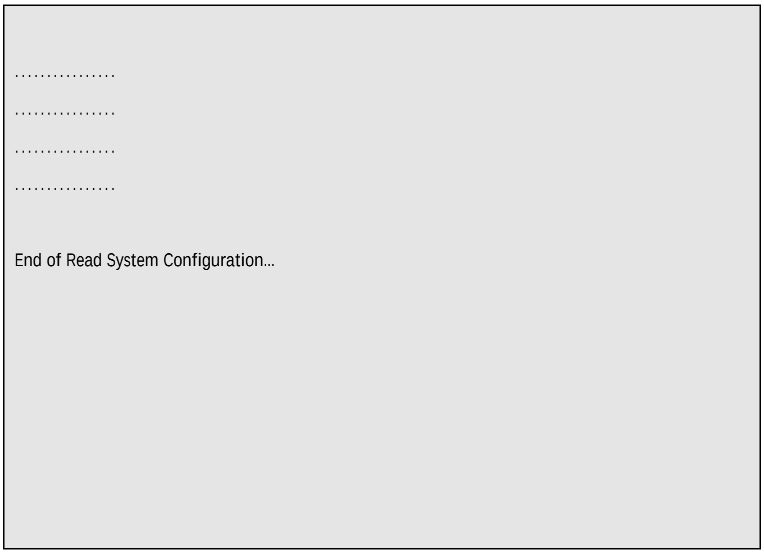
USB::\USER\10_Read_System_Configuration\23532_V7_90\ *config.xxu*

23532:	Serial Number of the Dialog+ machine
V7_90:	TLC software version



```
              Field Service Utilities V2.00  -  SetMST
                        CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                (Dialog+ Hard Disk)

04. Write Languages                       (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration            (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                     (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration             (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                 (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                       (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                      (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                 (Dialog+ Hard Disk → USB Stick)

 BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:   To prevent the corruption of USB stick, before removing it,
                  please press AQ then follow the instructions on the screen!
```

1. Press **BP** + and move the cursor down to select the utility.
2. Press **EQ** ↵ to execute the utility.



....

....

....

....

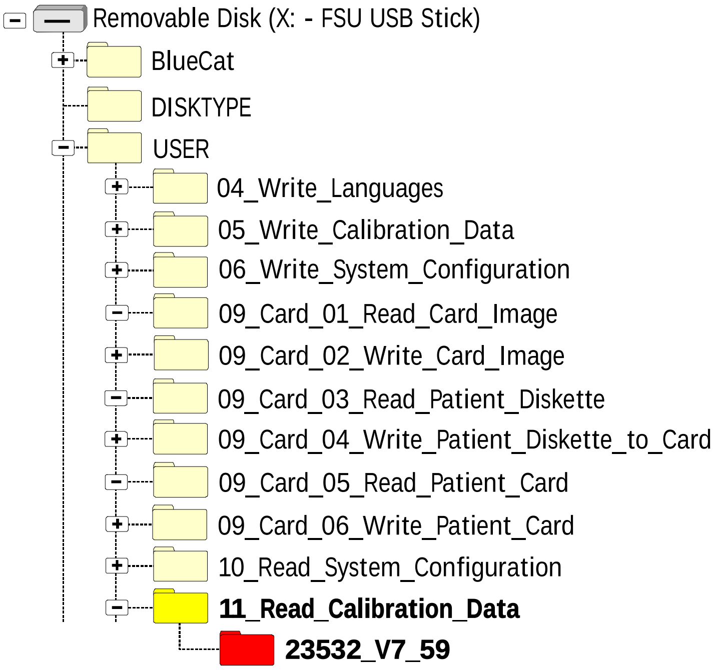
End of Read System Configuration...

An input screen opens and the system configuration is read from the Dialog+ hard disk drive (CFC) to the USB stick. The *Read System Configuration* menu automatically returns (a few seconds) to the main menu after *End of Read System Configuration...* is displayed.

3.6.10.2 Read Calibration Data

The utility reads the calibration data from Dialog+ hard disk drive (CFC) and writes it to the USB stick. Files from different Dialog+ machines are placed in different subdirectories on the USB stick. The subdirectory name *USER/11_Read_Calibration_Data/ <SERNUM>_<Main Version>/* is created from the serial number and the main version number of the Dialog+ machine.

<SERNUM>
The subdirectory name is created from the serial number <SERNUM> and the main version number of the Dialog+. If the serial number is not set on the Dialog+ <SERNUM> is equal to '-----'.



See the results in the directories with the following path for the *Calibration Data* file *calib.dat.xxu*.

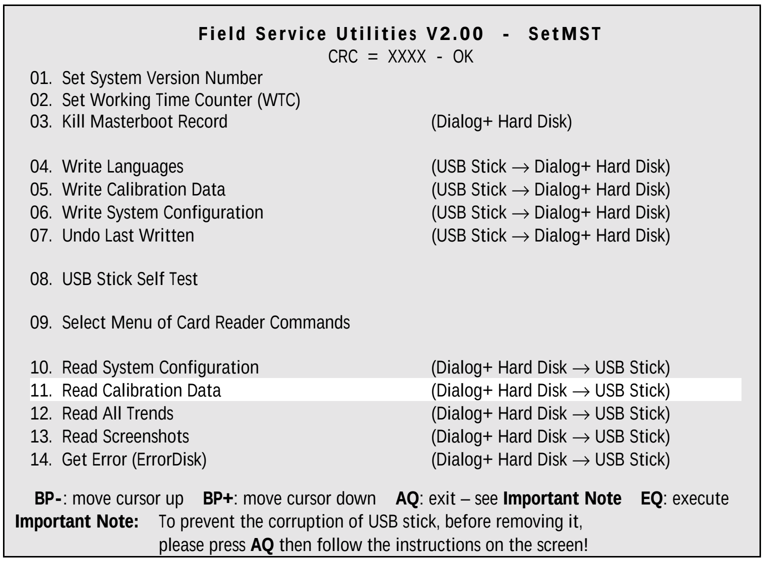
Read Calibration Data

USB:\USER\11_Read_Calibration_Data\{Serial Number}_{Main Version}\calib.dat.xxu

Example:

USB:\USER\11_Read_Calibration_Data\23532_V7_59\ *calib.dat.xxu*

23532:	Serial Number of the Dialog machine
V7_59:	Dialog+ main software version



```
                 Field Service Utilities V2.00  -  SetMST
                           CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                 (Dialog+ Hard Disk)

04. Write Languages                        (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                 (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration             (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                      (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration              (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                  (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                        (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                       (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                  (Dialog+ Hard Disk → USB Stick)

 BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:   To prevent the corruption of USB stick, before removing it,
                  please press AQ then follow the instructions on the screen!
```

1. Press the **BP** + hardware key and move the cursor down to select the utility.
2. Press the **EQ** ↵ hardware key to execute the utility.

....

....

....

....

End of Read Calibration Data...

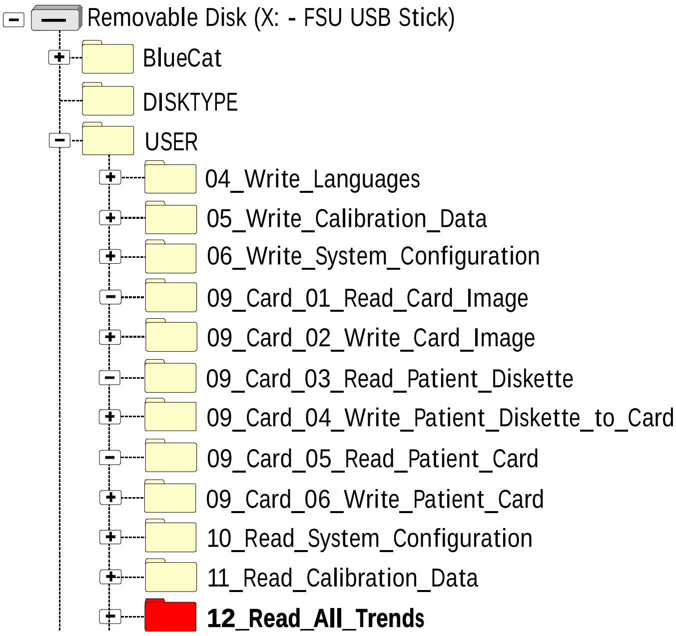
An input screen opens and the calibration data is read from the Dialog+ hard disk drive (CFC) to the USB stick. The *Read Calibration Data* menu automatically returns (a few seconds) to the main menu after *End of Read Calibration Data...* is displayed.

3.6.10.3 Read All Trends

A separate software program is required to analyse the trends, i.e. the Trend Viewer.

The utility reads all possible backup trend files on the Dialog+ hard disk drive (CFC) (max. 20 trends) and writes them to the USB stick. Files from different Dialog+ machines are placed in different subdirectories on the USB stick. The subdirectory name *USER/12_Read_All_Trends/ <SERNUM>/* is created from the serial number of the Dialog+ machine. Files from the same machine are placed in different subdirectories where the subdirectory names are created from the trend creation dates <*DATE*>.

<SERNUM>
The subdirectory name is created from the serial number <SERNUM> of the Dialog+. If the serial number is not set on the Dialog+ <SERNUM> is equal to '-----'.
<DATE>
The subdirectory name is created from a date. Format: YYYY-MM-DD.hh.mm.
In case of TRENDS: the date is the date of the trend start.



Removable Disk (X: - FSU USB Stick)
BlueCat
DISKTYPE
USER
04_Write_Languages
05_Write_Calibration_Data
06_Write_System_Configuration
09_Card_01_Read_Card_Image
09_Card_02_Write_Card_Image
09_Card_03_Read_Patient_Diskette
09_Card_04_Write_Patient_Diskette_to_Card
09_Card_05_Read_Patient_Card
09_Card_06_Write_Patient_Card
10_Read_System_Configuration
11_Read_Calibration_Data
12_Read_All_Trends

See the results in the directories with the following path for the *Read All Trends* file *tbd1.zip*.

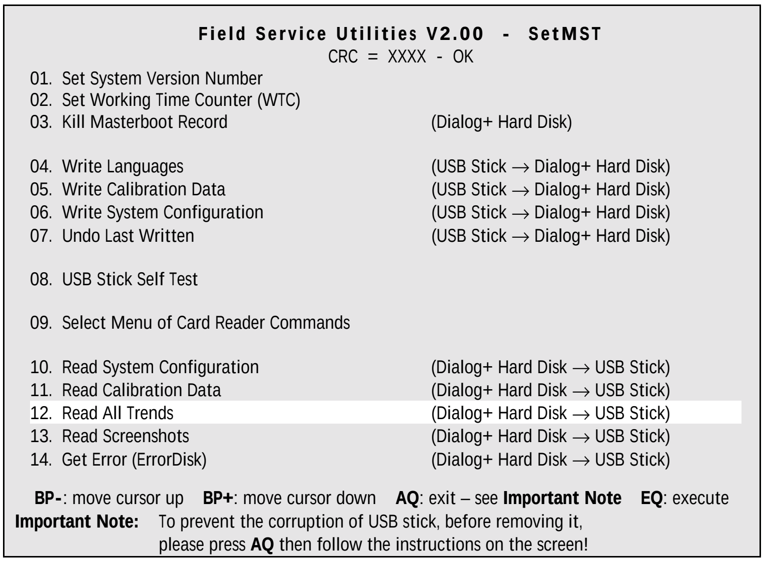
Read All Trends

USB:\USER\12_Read_All_Trends\{Serial Number}\{YYYY-MM-DD.hh.mm}\tbd1.zip

Example:

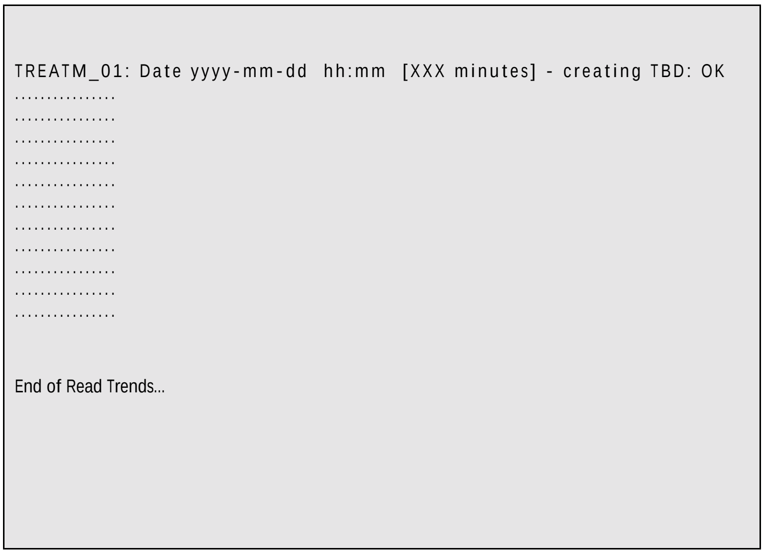
USB:\USER\12_Read_All_Trends\{Serial Number}\2007-09-12.14.25}*tbd1.zip*

Y Y Y Y :	Year 2007
M M :	09 month September
D D :	12 Wednesday
h h :	14 hours
m m :	25 minutes



```
Field Service Utilities V2.00  -  SetMST
CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                (Dialog+ Hard Disk)

04. Write Languages                       (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration            (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                     (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration             (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                 (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                       (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                      (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                 (Dialog+ Hard Disk → USB Stick)

BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:  To prevent the corruption of USB stick, before removing it,
                 please press AQ then follow the instructions on the screen!
```

1. Press the **BP** + hardware key and move the cursor down to select the utility.
2. Press the **EQ** ↵ hardware key to execute the utility.



```
TREATM_01: Date yyyy-mm-dd  hh:mm  [XXX minutes] - creating TBD: OK
................
................
................
................
................
................
................
................
................
................
................


End of Read Trends...
```

An input screen opens and all the trends are read from the Dialog+ hard disk drive (CFC) to the USB stick. The *Read Trends* menu automatically returns (a few seconds) to the main menu after *End of Read Trends...* is displayed.

3.6.10.4 Read Screenshots

The utility reads the screenshots from Dialog+ hard disk drive (CFC) and writes them to the USB stick. Files from different Dialog+ machines are placed in different subdirectories on the USB stick. The subdirectory names */USER/13_Read_Screenshots/ <SERNUM>/<DATE>/* are created from the serial numbers of the Dialog+ machines. Files from the same machine are placed in different subdirectories where the subdirectory names are created from the current date of reading *<DATE>*.

Create Screenshots

A keyboard is required to create screenshots. Connect a keyboard to the motherboard. Use the ALT + F5 key on the keyboard to take a screenshot.

<SERNUM>
The subdirectory name is created from the serial number <SERNUM> of the Dialog+. If the serial number is not set on the Dialog+ <SERNUM> is equal to '-----'.
<DATE>
The subdirectory name is created from a creation date. Format: YYYY-MM-DD.hh.mm.

See the results in the directories with the following path for the *Read Screenshots* files:

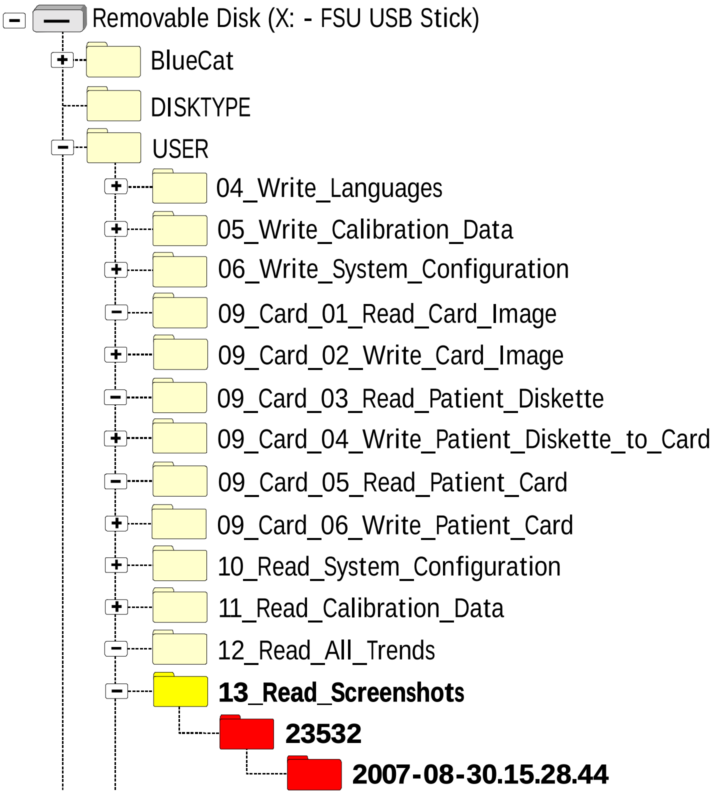
Read Screenshots

USB:\USER\13_Read_Screenshots\{Serial Number}\{YYYY-MM-DD.hh.mm.ss}\{DEFAULT and other directories}

Example:

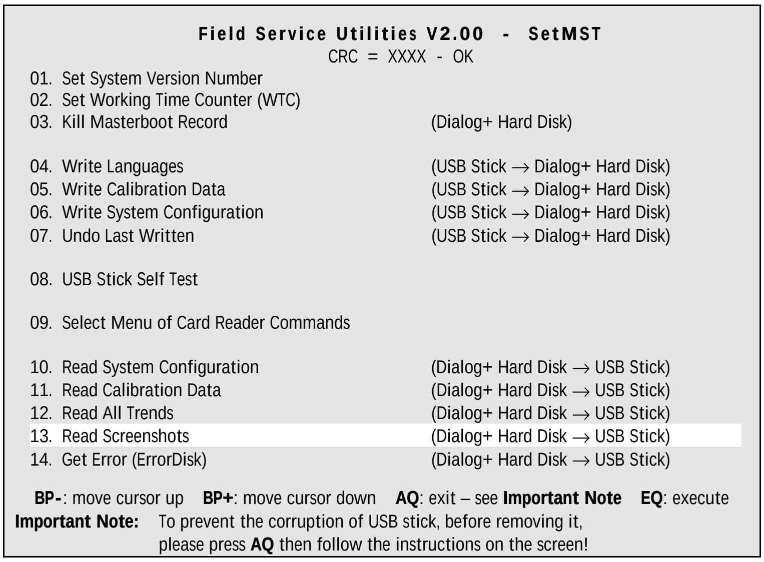
USB:\USER\13_Read_Screenshots\23532\2007-08-30.15.28.44\{DEFAULT and other directories}

2 3 5 3 2 :	Serial Number of the Dialog machine
Y Y Y Y :	Year 2007
M M :	08 month August
D D :	30 Thursday
h h :	15 hours
m m :	28 minutes
s s :	44 seconds



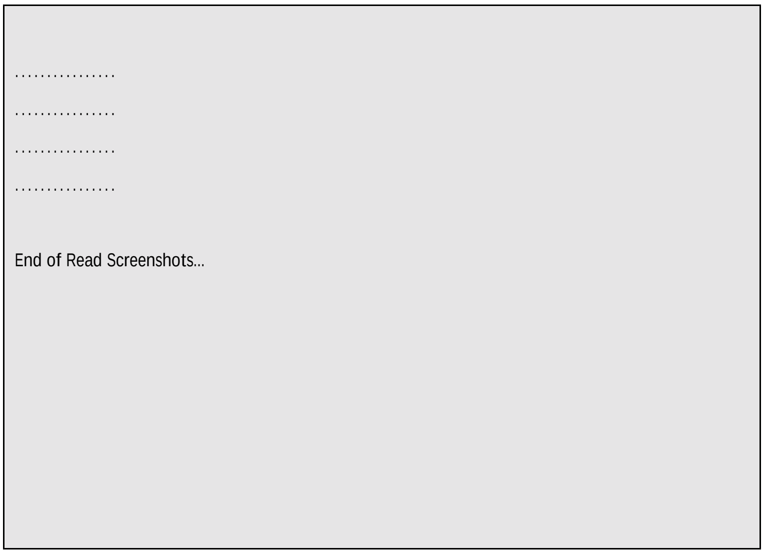
- Removable Disk (X: - FSU USB Stick)
  - BlueCat
  - DISKTYPE
  - USER
    - 04_Write_Languages
    - 05_Write_Calibration_Data
    - 06_Write_System_Configuration
    - 09_Card_01_Read_Card_Image
    - 09_Card_02_Write_Card_Image
    - 09_Card_03_Read_Patient_Diskette
    - 09_Card_04_Write_Patient_Diskette_to_Card
    - 09_Card_05_Read_Patient_Card
    - 09_Card_06_Write_Patient_Card
    - 10_Read_System_Configuration
    - 11_Read_Calibration_Data
    - 12_Read_All_Trends
    - **13_Read_Screenshots**
      - **23532**
        - **2007-08-30.15.28.44**

The screenshots are stored in vga*.zip files in the DEFAULT (and/or in other) subdirectories on the Dialog+. The vga*.zip files copied to USB stick are deleted from the Dialog+ hard disk drive (CFC) (similarly to the log files) but the subdirectory structure on the Dialog+ hard disk drive (CFC) is left untouched.



```
              Field Service Utilities V2.00  -  SetMST
                          CRC = XXXX - OK
  01. Set System Version Number
  02. Set Working Time Counter (WTC)
  03. Kill Masterboot Record                (Dialog+ Hard Disk)

  04. Write Languages                       (USB Stick → Dialog+ Hard Disk)
  05. Write Calibration Data                (USB Stick → Dialog+ Hard Disk)
  06. Write System Configuration            (USB Stick → Dialog+ Hard Disk)
  07. Undo Last Written                     (USB Stick → Dialog+ Hard Disk)

  08. USB Stick Self Test

  09. Select Menu of Card Reader Commands

  10. Read System Configuration             (Dialog+ Hard Disk → USB Stick)
  11. Read Calibration Data                 (Dialog+ Hard Disk → USB Stick)
  12. Read All Trends                       (Dialog+ Hard Disk → USB Stick)
  13. Read Screenshots                      (Dialog+ Hard Disk → USB Stick)
  14. Get Error (ErrorDisk)                 (Dialog+ Hard Disk → USB Stick)

  BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:   To prevent the corruption of USB stick, before removing it,
                  please press AQ then follow the instructions on the screen!
```

1. Press the **BP** + hardware key and move the cursor down to select the utility.
2. Press the **EQ** ↵ hardware key to execute the utility.



```
................

................

................

................


End of Read Screenshots...
```

An input screen opens and all the screenshots are read from the Dialog+ hard disk drive (CFC) to the USB stick. The *Read Screenshots* menu automatically returns (a few seconds) to the main menu after *End of Read Screenshots...* is displayed.

3.6.10.5 Get Error (ErrorDisk)

The error files can only be analysed by qualified personnel of B. Braun Avitum (e.g. development department) and should be provided only on special request.

The utility gets error information and log files from Dialog+ hard disk drive (CFC) and writes them to the USB stick. Files from different Dialog+ machines are placed in different subdirectories on the USB stick (VFAT partition). The subdirectory names */USER/14_Get Error/<SERNUM>/<DATE>/* are created from the serial numbers of the Dialog+ machines and from the current date of reading *<DATE>*.

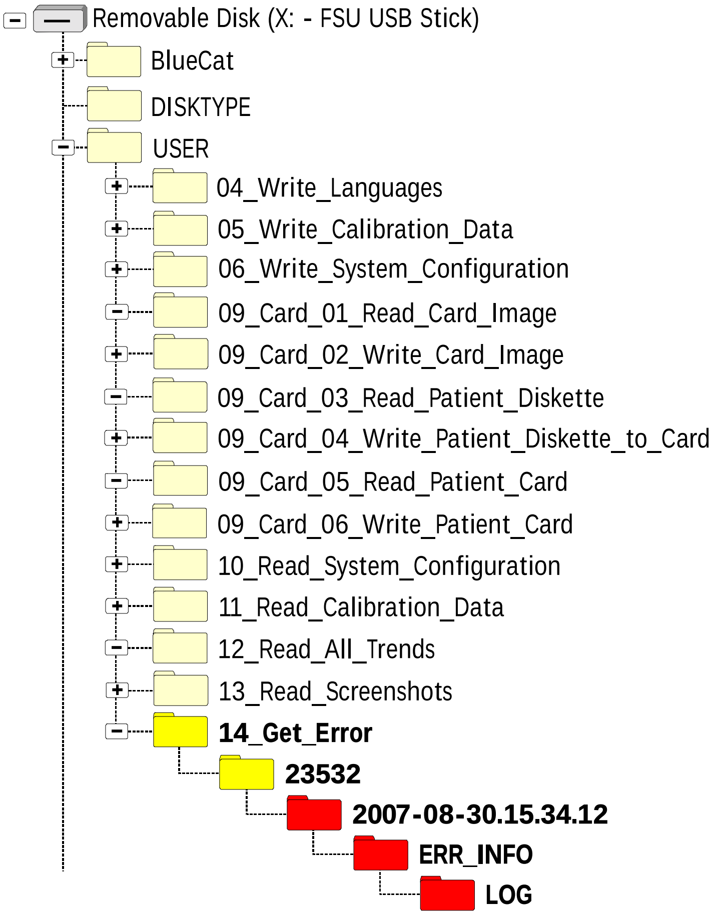
<SERNUM>

The subdirectory name is created from the serial number <SERNUM> of the Dialog+. If the serial number is not set on the Dialog+ <SERNUM> is equal to '-----'.

<DATE>

The subdirectory name is created from a date. Format: YYYY-MM-DD.hh.mm.ss.

In case of ERRDISK: the date is the date of the reading.



Removable Disk (X: - FSU USB Stick)
BlueCat
DISKTYPE
USER
04_Write_Languages
05_Write_Calibration_Data
06_Write_System_Configuration
09_Card_01_Read_Card_Image
09_Card_02_Write_Card_Image
09_Card_03_Read_Patient_Diskette
09_Card_04_Write_Patient_Diskette_to_Card
09_Card_05_Read_Patient_Card
09_Card_06_Write_Patient_Card
10_Read_System_Configuration
11_Read_Calibration_Data
12_Read_All_Trends
13_Read_Screenshots
14_Get_Error
23532
2007-08-30.15.34.12
ERR_INFO
LOG

See the results in the directories with the following path:

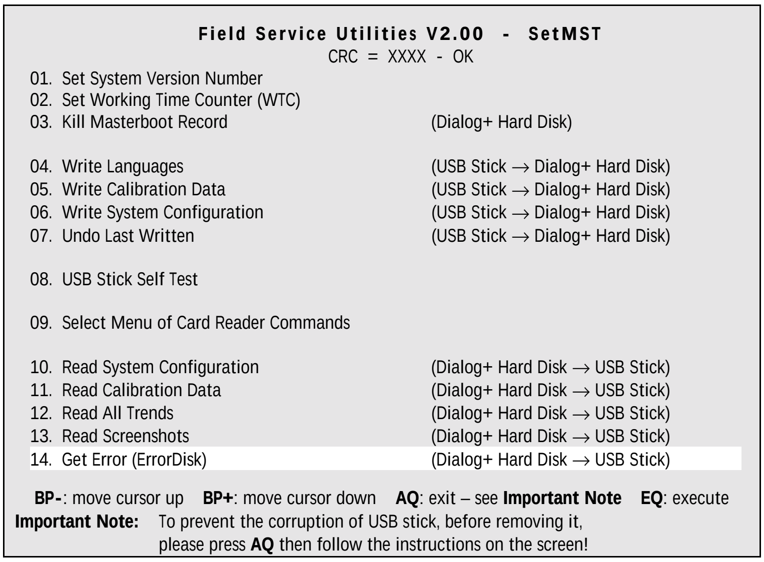
Get Error

USB:\USER\14_Get_Error\{Serial Number}\{YYYY-MM-DD.hh.mm.ss}\ERR_INFO

Example:

USB:\USER\14_Get_Error\23532\2007-08-30.15.34.12\ERR_INFO

23532:	Serial Number of the Dialog machine
YYYY:	Year 2007
MM:	08 month August
DD:	30 Thursday
hh:	15 hours
mm:	34 minutes
ss:	12 seconds
ERR_INFO:	Error information
LOG:	Log



```
              Field Service Utilities V2.00  -  SetMST
                         CRC = XXXX - OK
01. Set System Version Number
02. Set Working Time Counter (WTC)
03. Kill Masterboot Record                    (Dialog+ Hard Disk)

04. Write Languages                           (USB Stick → Dialog+ Hard Disk)
05. Write Calibration Data                    (USB Stick → Dialog+ Hard Disk)
06. Write System Configuration                (USB Stick → Dialog+ Hard Disk)
07. Undo Last Written                         (USB Stick → Dialog+ Hard Disk)

08. USB Stick Self Test

09. Select Menu of Card Reader Commands

10. Read System Configuration                 (Dialog+ Hard Disk → USB Stick)
11. Read Calibration Data                     (Dialog+ Hard Disk → USB Stick)
12. Read All Trends                           (Dialog+ Hard Disk → USB Stick)
13. Read Screenshots                          (Dialog+ Hard Disk → USB Stick)
14. Get Error (ErrorDisk)                     (Dialog+ Hard Disk → USB Stick)

  BP-: move cursor up   BP+: move cursor down   AQ: exit – see Important Note   EQ: execute
Important Note:   To prevent the corruption of USB stick, before removing it,
                  please press AQ then follow the instructions on the screen!
```

1. Press the **BP** + hardware key and move the cursor down to select the utility.
2. Press the **EQ** ↵ hardware key to execute the utility.

```
..........
..........
..........
..........

End of Error Disk...
```

An input screen opens and all the log files are read from the Dialog+ hard disk drive (CFC) to the USB stick. The *Get Error (ErrorDisk)* menu automatically returns (a few seconds) to the main menu *End of Error Disk...* is displayed.

3.6.11 FSU Handling of Errors

All utilities have the same error handling procedure:

- In case of an error generally an error message is displayed
- An error or warning message is displayed if an error occurs during the execution of a utility. To return to the main menu the service technician should press AQ or EQ according to the instruction on the screen.
- An error message is displayed in red at the bottom of the main menu:

  ERROR: Function returned error code = N
  N can be a varied number, e.g.:
  1: Error during directory creation, file copying, general error
  3: Source files are not found
  126: Function exists but not executable
  127: Function is missing
- The error message refers to the highlighted utility in the menu
- The error message is cleared at the next user input

3.6.12 Examination of Results

Deletion of Subdirectories

The <SERNUM>, <DATE>, <Patient Name> subdirectories and their contents (including sub-subdirectories) can be deleted without any problem.

Initial Directories

Do not delete the initial directories (that exist on the USB stick before the first use). Deletion makes the USB stick unusable. After the next switch-on a fatal error message is displayed (including the name of the missing directory). The missing directory must be restored to use the USB stick again.

Data collected from the Dialog+ and stored on the FSU USB stick can be examined on a PC with the following features:

- Windows operating system
- USB connection

Examine Data

- connect the USB stick to USB connector of the PC
- wait until Windows detects the USB stick
- open *My computer*
- the VFAT partition of the XXU stick appears as *Removable Disk X:*
- open the disk
- the results are in the following subdirectories:
  USER/XX_Read.....
  USER/14_Get_Error

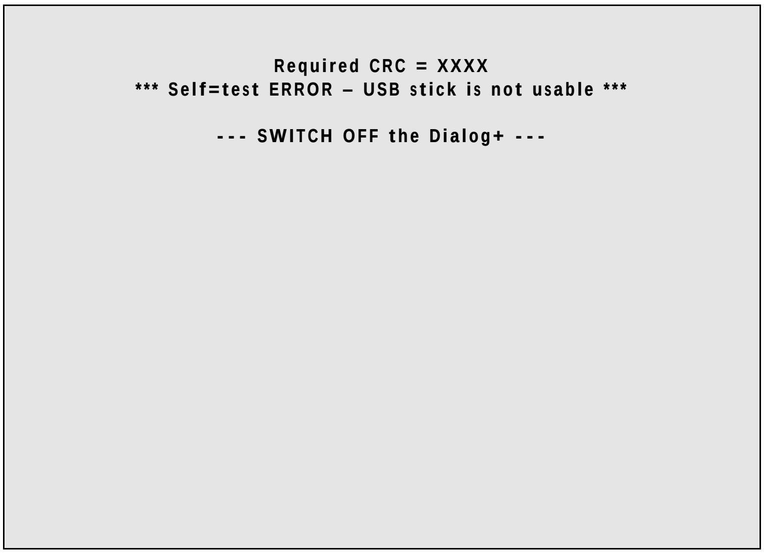
These files can be copied to any location on the PC (e.g. to use them for local examination) or can be deleted from the FSU USB stick.

3.6.13 Troubleshooting USB Stick

3.6.13.1 Field Service Utility Menu with Failed CRC Check

The FSU program stops automatically in case of a self test error. The corrupted USB stick must be exchanged before you continue with the FSU program.

The USB stick can be damaged permanently if the procedure to remove the USB stick is not observed.



```
Required CRC = XXXX
*** Self=test ERROR – USB stick is not usable ***

--- SWITCH OFF the Dialog+ ---
```

The following error message is displayed in case of a self test error.

Exchange the corrupted USB stick before you continue with the FSU program.

3.7 Default Table SW 9.xx

System Configuration

	Unit	HD	HDF Online	US Default	Modified
Dialysate Side Parameters					
Na Concentration/Conductivity Measurement Unit	-	mS/cm	mS/cm	mS/cm	
Acetate Mode Disabled	-	NO	YES	YES	
Default Conductivity Mode	-	BIC	BIC	BIC	
Stand-by Function Available in Preparation	-	YES	YES	NO	
Stand-by after Self Test/Rinsing	-	YES	YES	NO	
Maximum Stand-by Time	h:min	1:00	1:00	5:00	
Selected Acetate	-	B.BRAUN CONCENTRATE 1	B.BRAUN CONCENTRATE 1	B.BRAUN CONCENTRATE 1	
Selected Bicarbonate	-	BIC without NaCl	BIC without NaCl	BIC without NaCl	
Selected Acid	-	B.BRAUN ACID 1	B.BRAUN ACID 1	B.BRAUN ACID 1	
Temperature Measurement Unit	-	°C	°C	°C	
Dialysate Flow	ml/min	500	500	600	
Dialysate Temperature	°C	37.0	37.0	37.0	
Settings for Acetate Concentrate	**Unit**				
1st to 10th Concentrate Name	-		B.Braun Concentrate 1 – 10		
Conversion Factor	mS/cm per mmol/l		0.10500		
Default Value	mS/cm		14.0		
Settings for BIC					
1st Bicarbonate without NaCl	-		BIC without NaCl		
Conversion Factor	mS/cm per mmol/l		0.0950		
Default Value	mS/cm		3.0		
Acid Selection	-		B.Braun Acid 1		
2nd Bicarbonate with NaCl	-		BIC with NaCl		
Conversion Factor	mS/cm per mmol/l		0.0950		
Default Value	mS/cm		5.8		
Acid Selection	-		B.Braun Acid 2		
Setting for Acid	-				
1st to 20th Concentrate Name	-		B.Braun Acid 1 – 20		
Conversion Factor	mS/cm per mmol/l		0.10500		
Default Value	mS/cm		14.3		
Blood Side Parameters	**-**				
BS Pressure Test with Equalisation of Pressure	-	NO	NO	YES	
Default Blood Flow at End of Therapy	ml/min	100	100	200	
AV Line without Chamber is Possible	-	NO	NO	NO	
AV Line with PBE Connector	-	YES	YES	NO	
Min-Max Parameters					
Delta PA min.	mmHg	70	70	70	
Delta PA max.	mmHg	70	70	70	
Limit Maximum PBE	mmHg	700	700	700	
Limit Delta PBE	mmHg	150	150	600	
Limit Maximum TMP	mmHg	350	350	500	
Limits Low/High TMP	-	active	active	active	
Low Limit TMP	%	40	40	40	
High Limit TMP	%	40	40	40	
Minimum TMP Alarm Window	mmHg	20	20	20	
Extended TMP Limit Range Button is Displayed in Treatment	-	NO	NO	NO	
Select Extended TMP Limit Range	-	inactive	inactive	inactive	
Arterial Bolus Parameters					
Arterial Bolus Volume	ml	100	100	100	
Arterial Bolus with SAKA Support		NO	NO	NO	

	Unit	HD	HDF Online	US Default	Modified
Single Needle Parameters					
Single Needle Valve					
Limit Min. PA	mmHg	-200	-200	-200	
Max. Control Min. PV	mmHg	150	150	150	
Control Min. PV	mmHg	100	100	100	
Control Max. PV	mmHg	350	350	390	
Single-Needle Cross-Over					
Control PA	mmHg	-180	-180	-180	
Control PV	mmHg	360	360	360	
Heparin Parameters					
Treatment without Heparin	-	NO	NO	NO	
Heparin Measurement Unit	-	ml/h	ml/h	ml/h	
Conversion Factor Heparin (IE/ml)	-	1000	1000	1000	
Heparin Rate	ml/h	3.0	3.0	3.0	
Heparin Bolus Volume	ml	0.0	0.0	0.0	
Therapy Beginning Bolus	-	NO	NO	NO	
Selected Syringe Type	-	Omnifix 30 ml	Omnifix 30 ml	B-D 10 ml	

Syringe Table		
Heparin Pump Compact		Syringe Sizes: 10 ml to 30 ml
Syringe Type		**Inside Diameter [mm]**
Braun OPS	20 ml	19.00
Terumo	20/25 ml	20.10
Terumo	30/35 ml	22.57
B-D (for US)	10 ml	14.43
B-D	20 ml	18.90
B-D	30 ml	21.53
Monoject	20 ml	19.83
Dispomed	30 ml	22.17
Fresenius HS	30 ml	22.20
Omnifix	10 ml	16.05
Omnifix	20 ml	19.80
Omnifix	30 ml	22.00

	Unit	HD	HDF Online	US Default	Modified
Rinsing Parameters					
Priming without Recirculation	-	NO	NO	NO	
Filling BP Rate	ml/min	100	100	100	
Filling BP Volume	ml	700	700	500	
Automatic Rinse Program after Self Tests	-	YES	YES	YES	
User Message for BS Filled?	-	YES	YES	YES	
Rinsing Blood Flow	ml/min	200	200	200	
Rinsing Dialysate Flow	ml/min	500	500	600	
Rinsing Time by UFP	h:min	00:59	00:59	00:10	
Rinsing Rate by UFP	ml/h	203	203	600	
Rinsing Volume by UFP	ml	200	200	100	
Rinsing Time by BPA or BPV	h:min	-	00:30	-	
Rinsing Rate by BPA or BPV	ml/h	-	6000	-	
Rinsing Volume by BPA or BPV	ml	-	3000	-	
Blood Flow for Connecting Patient	ml/min	100	100	100	
UF Parameters					
Minimal UF Rate	ml/h	50	50	50	
UF Rate Compensation?	-	YES	YES	YES	
Max. Value of Upper Limit UF Rate	ml/h	3000	3000	3000	
Default Value of Upper Limit UF Rate	ml/h	2000	2000	2000	
UF Volume	ml	2000	2000	2000	
Therapy Time	h:min	04:00	04:00	03:30	
Gross UF Rate vs. Blood Flow	-	inactive	inactive	inactive	
	%	40	40	40	
Gross UF Rate vs. Blood Flow	-	active	active	active	
	%	30	30	30	
UF Profile Editor					

	Unit	HD	HDF Online	US Default	Modified
HDF/HF Online Parameters					
HDF Substitution Flow	ml/min	-	60	-	
HF Substitution Flow	ml/min	-	100	-	
HDF Dialysate Flow for Postdilution	ml/min	-	600	-	
HDF Dialysate Flow for Predilution	ml/min	-	700	-	
HDF/HF Infusion Bolus Volume	ml	-	100	-	
Post-/Predilution Selection	-	-	inactive	-	
Disinfection Parameters					
Disinfection after each Therapy	-	NO	YES	NO	
Automatic Preparation Start after Disinfection	-	NO	NO	NO	
Thermal Disinfection	-	YES	NO	YES	
Chemical Disinfection	-	YES	YES	YES	
Chemical Disinfection, Short	-	YES	NO	NO	
Central Thermal Disinfection	-	NO	NO	NO	
Central Manual Chemical Disinfection	-	NO	NO	NO	
Central Automatic Chemical Disinfection	-	NO	NO	NO	
Rinsing	-	NO	NO	YES	
Automatic Switch-On with Rinsing - No Weekly Schedule	-	inactive	inactive	inactive	
Switch-On Time	h:min	06:30	06:30	06:30	
Automatic Switch-On by Weekly Schedule	-	active	active	active	
Weekly Schedule	(see Table)				
Start on Sunday	-	inactive	inactive	active	
Start on Monday	-	active	active	inactive	
Auto Switch-On without daily confirmation	-	NO	NO	NO	
Maximum Out of Action Time	-	inactive	inactive	active	
Days	Days	0	0	2	
Hours/Minutes	h:min	08:00	08:00	00:00	
Disinfection Configuration Data Table	-	Citric Acid 50%	Citric Acid 50%	Citric Thermal	
Central Thermal: Inlet Flow	ml/min	250	250	250	
Central Thermal: Time	h:min	00:30	00:30	00:30	
Central Manual Chemical: Inlet Flow	ml/min	250	250	250	
Central Manual Chemical: Inlet Time	h:min	00:05	00:05	00:05	
Central Manual Chemical: Rinsing Flow	ml/min	800	800	800	
Central Manual Chemical: Rinsing Time	h:min	00:30	00:30	00:30	
Central Automatic Chemical: Inlet Volume	ml	260	260	260	
Central Automatic Chemical: Switch off for Retention without Automatic Switch-On	-	NO	NO	NO	
Central Automatic Chemical: Retention Time	h:min	00:20	00:20	00:20	
Central Automatic Chemical: Rinsing Flow	ml/min	800	800	800	
Central Automatic Chemical: Rinsing Time	h:min	00:30	00:30	00:30	
Rinsing: Inlet Flow	ml/min	800	800	800	
Rinsing: Time	h:min	00:02	00:02	00:02	
Filter Parameters					
Name	-	Diacap-Ultra	Diacap-Ultra	Diacap-Ultra	
Therapy Number	-	150	150	150	
Filter Operation Time	h	900	900	900	
Dialyser Parameters (Kt/V)					
Urea Distribution Volume Formula	-	Watson	Watson	Watson	
Height Measurement Unit of Watson Formula	-	cm	cm	cm	
Default Target Kt/V	-	1.20	1.20	1.20	
Default Setting for Treatment Mode Warning of Kt/V Target Projected Deviation	-	Warning active	Warning active	Warning inactive	
Kt/V Table - Manual Input: Setting Clean/Total Blood [%]	-	YES	YES	YES	
Warning for Saving Kt/V Volume enabled	-	NO	NO	NO	
Kt/V-UV					
Default Target Kt/V	-	1.20	1.20	1.20	
Kt/V Correction Mode	-	Single Pool	Single Pool	Single Pool	
Default Setting for Treatment Mode: Warning of Kt/V Target-Projected Deviation	-	Warning active	Warning active	Warning inactive	
Warning for Saving Kt/V Table	-	NO	NO	NO	
Timings					
Parameter Setting Window Disappearing Time	s	500	500	600	
Screen Saver Appearance	-	NO	NO	NO	
Appearing Time	s	600	600	600	

		Unit	HD	HDF Online	US Default	Modified
Language Selection						
English		-	active	active	active	
German		-	inactive	inactive	inactive	
Summer Time Setting (enter values accordingly)						
Begin of Summer Time		D/M/Y	dd.mm.yyyyy	dd.mm.yyyyy	dd.mm.yyyyy	
		h:min	xx:xx	xx:xx	xx:xx	
End of Summer Time		D/M/Y	dd.mm.yyyyy	dd.mm.yyyyy	dd.mm.yyyyy	
		h:min	xx:xx	xx:xx	xx:xx	
Time Difference		h:min	xx:xx	xx:xx	xx:xx	
ABPM						
Delete Button for Data		-	YES	YES	YES	
Auto Start of Cyclic Reading (from Patient Identification Media)		-	NO	NO	NO	
ABPM Cyclic Reading Stop at Entering Disinfection		-	YES	YES	YES	
Taking Over Limits from Patient's Parameters		-	YES	YES	YES	
bioLogic RR Comfort						
Guide Line Mode		-	NO	NO	-	
Suggested SYS Lower Limit		-	NO	NO	-	
bioLogic RR Algorithm ID		-	100	100	-	
Miscellaneous Parameters						
Click Sound		-	NO	NO	YES	
Warning and Writing (Saving) Patient Parameters		-	NO	NO	YES	
* Skip Self Tests * A skip of the self tests for servicing only!		-	NO	NO	NO	
Automatic Preparation Start		-	YES	YES	NO	
Data Validation with		-	Touch	Touch	Enter Key	
UF Profile Editing in Treatment		-	YES	YES	NO	
Manual Bypass Confirmation Window Enabled		-	NO	NO	YES	
End of Therapy Sound Duration		-	100 %	100 %	100 %	
Chopped Alarm Sound		-	NO	NO	NO	
Suppression of Warning Sounds in Preparation		-	NO	NO	NO	
Automatic Reinfusion Start at Entering End of Therapy		-	YES	YES	NO	
DCI						
Dianet Address		-	1	1	1	
Data Set		-	MPI 0.12	MPI 0.12	MPI 0.12	
DBI						
Baud Rate		kBaud	38.4	38.4	38.4	
User Logout Time		min	15 - ON	15 - ON	15 – ON	
Message Warning Time		min	15 - OFF	15 - OFF	15 - OFF	
Data Set	DBI 1.61	-	inactive	inactive	inactive	
	DBI 1.72	-	inactive	inactive	inactive	
	DBI 2.00	-	active	active	active	
	DBI 2.20	-	inactive	inactive	inactive	
	DBI 2.21	-	inactive	inactive	inactive	
DBI-WAN Interface – Network Name Configuration						
Pre-SN String is needed		-	-	-	d / YES	
SN String is needed		-	-	-	- / YES	
Post-SN String is needed		-	-	-	/ NO	
Network Name (max. 15 chars.)		-	-	-	d-	
Preventive Maintenance						
Warning for Preventive Maintenance Enabled		-	NO	NO	NO	
Load Interval		-	inactive	inactive	inactive	
Elapsed Month		-	inactive	inactive	inactive	
Setting Elapsed Month		months	12	12	12	
Elapsed Working Time Counter WTC		-	inactive	inactive	inactive	
Setting Elapsed WTC		hours	4000	4000	4000	

Production Report

	HD	HDF Online	US Default	Modified
Options				
ABPM	inactive	inactive	active	
DCI	inactive	inactive	inactive	
bioLogic RR®	inactive	inactive	inactive	
Kt/V	inactive	inactive	inactive	
Kt/V UV	inactive	inactive	inactive	
Card Reader	inactive	inactive	active	
HCT Crit-Line	inactive	inactive	inactive	
Low Level Options:				
Double Pump	1)	1)	1)	
Holder for BIC Cartridge	1)	1)	1)	
DF Filter	1)	1)	1)	
HDF Online	1)	1)	1)	
Battery	1)	1)	1)	
Nexadia-BSL (DBI)	1)	1)	1)	
WAN-BSL (DBI)	1)	1)	1)	

1) Setting depends on the configuration of the machine.

Blood Leak Detector Limit (2.7)

	HD	HDF Online	US Default	Modified
Standard Limit (0.5 ml/min at Haematocrite HK 0.45)	active	active	inactive	
AAMI Limit (0.35 ml/min at Haematocrite HK 0.25)	inactive	inactive	active	

Position Setting for BICP, KP and UFP (2.8.2)

	Unit	Default	US Default	Modified
BICP Parking	-	180	180	
KP Parking	-	180	180	
UFP Parking	-	180	180	
UFP Positive Pressure Test	-	270	270	
UFP Negative Pressure Test	-	90	90	

BICLF and ENDLF Ratio (2.10)

	Unit	Default	US Default	Modified
BICLF Ratio	-	25	25	
ENDLF Ratio	-	31	36	
BICLF Cart Ratio	-	35	35	

PV Alarm Window, PA Low Limit (2.12)

	Unit	Default	US Default	Modified
PV Alarm Window	mmHg	100	100	
PV Low Limit Position	mmHg	35	35	
PV Absolute Low Limit	mmHg	20	20	
PA Absolute Low Limit	mmHg	-200	-300	

Pump Head Selection (2.13)

	Unit	Default	US Default	Modified
Pump Head 8 x 12	-	active	active	
Pump Head 7 x 10	-	inactive	inactive	

BPA and BPV (2.13.1)

	Unit	Default	US Default	Modified
BPA	µl/Head Revolution	12306	12306	
BPV	µl/Head Revolution	12306	12306	

HDF Online Substitution Pump OSP (2.15)

	Unit	Default	US Default	Modified
OSP	µl/Head Revolution	8300	8300	

Level Regulation (2.16)

	Unit	Default	US Default	Modified
LRP (PPR) Slow	%	60	60	
LRP (PPR) Fast	%	100	100	

Weekly Disinfection Program

	Time	Method	Disinfectant	Time	Method	Disinfectant
Monday						
Night	-	-	-			
Morning	06:30	Chemical Long	Citric Acid 50%			
Tuesday						
Night	-	-	-			
Morning	06:30	Chemical Long	Citric Acid 50%			
Wednesday						
Night	-	-	-			
Morning	06:30	Chemical Long	Citric Acid 50%			
Thursday						
Night	-	-	-			
Morning	06:30	Chemical Long	Citric Acid 50%			
Friday						
Night	-	-	-			
Morning	06:30	Chemical Long	Citric Acid 50%			
Saturday						
Night	-	-	-			
Morning	-	-	-			
Sunday						
Night	-	-	-			
Morning	-	-	-			

US Weekly Disinfection Program

	Time	Method	Disinfectant	Time	Method	Disinfectant
Monday						
Night	-	-	-			
Morning	06:30	Rinsing	-			
Tuesday						
Night	-	-	-			
Morning	06:30	Rinsing	-			
Wednesday						
Night	-	-	-			
Morning	06:30	Rinsing	-			
Thursday						
Night	-	-	-			
Morning	06:30	Rinsing	-			
Friday						
Night	-	-	-			
Morning	06:30	Rinsing	-			
Saturday						
Night	-	-	-			
Morning	-	-	-			
Sunday						
Night	-	-	-			
Morning	-	-	-			

Disinfection Configuration Data (Standard Machine)

Chemical Disinfection (long or short)

Disinfectant		Reaction Time		Rinsing	Temperature	Conductivity
Name	Volume	Long	Short	Time		min.
(max. 20 Characters)	ml	h:min	h:min	h:min	°C	mS/cm
Citric Acid 50 %	120	0:15	0:05	0:05	83	2.2
Decalcification with Citric Acid 50 %	120	0:05	0:05	0:05	40	2
*** Peracetic acid 1 to < 5** *** Hydrogen peroxide 1 to < 35** *** Acetic acid 1 to < 10** (composition of concentrate [%])	90	0:20	0:20	0:25	40	0.1
# Tiutol™ KF	90	0:15	0:05	0:25	60	10,5
*** Puristeril® 340**	90	0:20	0:05	0:25	40	0.1
Doxan™	160	0:20	0:05	0:25	40	0.2
Dialox™	160	0:20	0:05	0:25	40	0.2
Peresal™	110	0:20	0:05	0:25	40	0.1
Citrosteril™	120	0:15	0:05	0:20	83	2.0
Maranon H™	90	0:20	0:05	0:25	40	10
Diasteril	90	0:15	0:05	0:15	80	0.5

* DF filter: a **max.** of 150 disinfections can be performed with Citric Acid 50 % or peracetic acid/hydrogen peroxide/acetic acid/Puristeril® 340

DF filter: a **max.** of 2 disinfections can be performed with Tiutol™ KF during the service life time (service life, 150 treatments/900 h), i.e.:

- Default: citro-thermal disinfection (thermal disinfection) with citric acid 50% after every treatment
- Option: after 50, 100 and 150 treatments (150 treatment and prior to exchange of filter) with Tiutol™ KF and then citro-thermal disinfection (after exchange of filter)

Disinfection Configuration Data (HDF Online Machine with Diacap Ultra)

Chemical Disinfection (long or short)

Disinfectant		Reaction Time		Rinsing	Temperature	Conductivity
Name	Volume	Long	Short	Time		min.
(max. 20 Characters)	ml	h:min	h:min	h:min	°C	mS/cm
Citric Acid 50 %	130	0:15	0:15	0:05	83	2.2
*** Peracetic acid 1 to < 5** *** Hydrogen peroxide 1 to < 35** *** Acetic acid 1 to < 10** (composition of concentrate [%])	120	0:20	0:20	0:25	40	0.1
# Tiutol™ KF	120	0:30	0:30	0:30	60	10.5
*** Puristeril® 340**	120	0:20	0:20	0:25	40	0.1

* DF filter: a **max.** of 150 disinfections can be performed with Citric Acid 50 % or peracetic acid/hydrogen peroxide/acetic acid/Puristeril® 340

DF filter: a **max.** of 2 disinfections can be performed with Tiutol™ KF during the service life time (service life, 150 treatments/900 h), i.e.:

- Default: citro-thermal disinfection (thermal disinfection) with citric acid 50% after every treatment
- Option: after 50, 100 and 150 treatments (150 treatment and prior to exchange of filter) with Tiutol™ KF and then citro-thermal disinfection (after exchange of filter)

US Disinfection Configuration Data

Chemical Disinfection (long or short)

Disinfectant		Reaction Time		Rinsing	Temperature	Conductivity
Name	Volume	Long	Short	Time		min.
(max. 20 Characters)	ml	h:min	h:min	h:min	°C	mS/cm
Citric Thermal	120	00:15	00:05	00:05	83	2.2
Decalcification Short	120	00:05	00:05	00:05	40	2.2
Bleach	90	00:15	00:05	00:25	30	5.0

Dialyser Filter Urea Clearance Data for Diacap®

DF1, DF2: Dialysate Flow
in ml/min

BF1, BF2, …. BF8: Blood Flow
in ml/min

Filter Name	DF1	BF1	BF2	BF3	BF4	BF5	BF6
(Default Filter on green)	DF2	100	200	300	400	500	600
Type	ml/min	ml/min					
Diacap LOPS 10	500	0	176	217	242	0	0
	800	0	0	0	0	0	0
Diacap LOPS 12	500	0	183	233	261	0	0
	800	0	0	0	0	0	0
Diacap LOPS 15	500	0	189	246	285	0	0
	800	0	0	0	0	0	0
Diacap LOPS 18	500	0	192	253	294	0	0
	800	0	0	0	0	0	0
Diacap LOPS 20	500	0	194	258	302	0	0
	800	0	0	0	0	0	0
Diacap HIPS 10	500	0	180	223	250	0	0
	800	0	0	0	0	0	0
Diacap HIPS 12	500	0	186	238	271	0	0
	800	0	0	0	0	0	0
Diacap HIPS 15	500	0	190	245	288	0	0
	800	0	0	0	0	0	0
Diacap HIPS 18	500	0	192	250	292	0	0
	800	0	0	0	0	0	0
Diacap HIPS 20	500	0	194	253	296	0	0
	800	0	0	0	0	0	0
Diacap HIFlo 18	500	0	0	257	298	0	0
	800	0	0	0	0	0	0
Diacap HIFlo 23	500	0	0	277	328	0	0
	800	0	0	0	0	0	0
xevonta Lo 10	500	0	184	236	276	0	0
	800	0	0	0	0	0	0
xevonta Lo 12	500	0	189	249	291	0	0
	800	0	0	0	0	0	0
xevonta Lo 15	500	0	194	267	311	0	0
	800	0	0	0	0	0	0
xevonta Lo 18	500	0	196	276	322	0	0
	800	0	0	0	0	0	0
xevonta Lo 20	500	0	198	281	329	0	0
	800	0	0	0	0	0	0
xevonta Lo 23	500	0	199	285	333	0	0
	800	0	0	0	0	0	0
xevonta Hi 10	500	0	186	241	290	0	0
	800	0	0	0	0	0	0
xevonta Hi 12	500	0	191	255	306	0	0
	800	0	0	0	0	0	0
xevonta Hi 15	500	0	197	272	329	0	0
	800	0	0	0	0	0	0
xevonta Hi 18	500	0	198	281	341	0	0
	800	0	0	0	0	0	0
xevonta Hi 20	500	0	199	287	349	0	0
	800	0	0	0	0	0	0
xevonta Hi 23	500	0	199	290	354	0	0
	800	0	0	0	0	0	0

3.8 Measures after Repair

3.8.1 Repair Matrix

		Exchanged/Repaired/Assembled Components/Groups	1. Automatic Blood Pressure Measurement: ABPM	2. Board, Analog: AB	3. Board, Basic: BB	4. Board, Digital: DB	5. Board, Front Panel: FPB	6. Board, HDF Online HOB	7. Board, Mother: TLC	8. Board, Optical Status Display: OSD	9. Board, Power Motors: PBM	10. Board, Power Valves: PBV	11. Compact Flash Card CFC	12. Coupling, Dialyser	13. Detector, Blood Leak: BL	14. Detector, Safety Air: SAD	15. Throttle: DBK	16. Throttle: DDE	17. Valve, Pressure Reducer: DMV	18. Chamber, Degassing: EK	19. Filter: FBK1; FBK2; FBIC; FVD; FB; FK	20. Filter, Hydrophobic: HFB	21. Heater	22. Clamp, Tubing: SAKV; SAKA	23. Rods, Concentrate Suction; o-ring	24. Manometer Connection; Protection Filter; Tubing	25. Membranes, MSBK1/2 (Balance Chamber)	26. Monitor (TFT Display)	27. Drive Unit, Gear Pump	28. Cable, Mains, with Mains Plug	29. SMPS-MC Components: Relay, Buzzer, Capacitor	30. SMPS-MC	31. Option ABPM	32. Option Adimea (Kt/V-UV)	33. Option Battery	34. Option Bedside-Link-Modul: BSL	35. Option BIC Cartridge Holder	36. Option DCI	37. Option DF-Filter	38. Option DSI (Crit-Line)	39. Option Card Reader	40. Option Staff Call	41. Level Regulation Module	42. Pump: BPA; BPV	43. Pump, Piston: BICP; KP	44. Pump, Piston: UFP	45. Pump, Heparin	46. Pump, Level Regulation: LRP (PPR)	47. Pump, Gear: EP; FPA; FPE	48. Nonreturn Valve: RVDA	49. Nonreturn Valve: RVFPA	50. Nonreturn Valve: RVFPE	51. Sensor, Pressure: PDA; PE	52. Sensor, Conductivity: BICLF; ENDLF	53. Sensor, Level, Upline Tank: NSVB	54. Sensor, Reed: BKUS	55. Sensor, Reed: PSAUS; PSABF, FEDFFS, FEDHDFS	56. Sensor, Reed SBS1, SBS2	57. Sensor, Temperature: TSBIC; TSD; TSD_S; TSDE	58. Sensor, Temperature: TSE; TSHE	59. Software, Installation/Update	60. Rinsing Bridge	61. Touch Screen	62. Valve: VEB; VVBE	63. Valve: VBE; VDFF; VSB; VSAE; VSAA	64. Valve: VBP; VDE; VDA; VZ; VLA	65. Valve: VD	66. Valve: VDEBK1; VEBK1; VEBK2; VDEBK2; VDABK1; VABK1; VABK2; VDABK2	67. Valve: VVB; VBICP; VBKO; VBKS ,BKUS
Tests and Measures to be Executed	3.8.2.1	Install Software		◆		◆							◆																							◆																													◆								
	3.8.2.2	Check System Configuration, Production Report and Set if Necessary		◆		◆			◆				◆		◆																																				◆																◆								
	3.8.2.3	Self Test		◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆		◆	◆	◆	◆	◆	◆	◆	◆	◆	◆		◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆		◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆			◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
	3.8.2.4	Conductivity Test Run, Temperature Comparison Measurement		◆	◆	◆																													◆						◆													◆			◆		◆	◆	◆									
	3.8.2.5	Test Run UF Comparison Measurement		◆	◆	◆		◆										◆			◆						◆																			◆				◆											◆							◆	
	3.8.2.6	Test Run	◆						◆		◆	◆			◆	◆	◆			◆		◆	◆	◆	◆	◆			◆		◆	◆	◆	◆		◆	◆	◆	◆	◆		◆	◆		◆		◆	◆	◆		◆	◆	◆		◆		◆	◆				◆		◆	◆	◆	◆		◆
	3.8.2.7	Electrical Safety Check								◆													◆						◆	◆	◆	◆																																					
	3.8.2.8	Perform Disinfection after repair	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆	◆
Tests and Calibrations to be Executed (see Dialog+ Service Manual, Chapter 4 and 5)	4.9.1.1	Buttons, Lamps and Sounds					◆			◆																		◆																																			◆						
	4.9.1.3	Touch Screen Calibration																										◆																																			◆						
	4.9.1.8	DBI Test (BSL) or DSI Test (Crit-Line) or DCI Test																																		◆		◆		◆																													
	4.9.2.1	Test 1.1 Staff Call, Alarms, Power Off																																								◆																											
	4.9.2.5	Test 1.5 Tubing Clamps																						◆																																													
	4.9.2.7	Test 1.7 Air Sensor SAD, Red Sensor														◆																																																					
	4.9.2.8	Test 1.8 Coupling Detectors																																																								◆											
	4.9.2.13	Test 1.13 Balance Chamber Valves																																																																		◆	
	4.9.2.14	Test 1.14 Bypass and Disinfection Valves																																																															◆			
	4.9.2.23	Test 1.23 BIC Cartridge Valves and Coupling Detectors																																			◆																															◆
	4.9.2.25	Test 1.25 HDF Online Valves and Detectors																																																						◆								◆				
	4.9.2.26	1.26 Option Battery																													◆	◆			◆																																		
	4.9.4.1	Calibration Pressure Sensors Blood Side PA, PV, PBE and PBS		◆																																							◆																										
	4.9.4.3	Calibration Pressure Sensors of Water Side PE and PDA		◆																																																	◆																
	4.9.4.4	Calibration Degassing TSE/TSHE		◆																																																								◆									
	4.9.4.5	Calibration Dialysis Temperature Sensors TSBIC and TSD/TSD_S/TSDE		◆																																																		◆					◆										
	4.9.4.6	Calibration Conductivity Sensors BICLF and ENDLF/ENDLF_S		◆																																																		◆					◆										
	4.9.4.7	Calibration Blood Leak Detector Type 2		◆											◆																																																						
	4.9.4.8	Calibration of Flow Rate UFP, BICP and KP				◆																																							◆	◆																							
	4.9.4.9	Calibration Safety Air Detector SAD Version Version 3				◆										◆																																																				
	4.9.4.10	Calibration BICLF and ENDLF Ratio				◆																																																															
	4.9.4.13	Calibration Flow Rate of BPA and BPV/OSP				◆																																																							◆								
	4.9.4.16	Calibration Inlet Flow Pump Nonreturn Valve RVFPE																																																		◆																	
	4.9.4.17	Calibration Dialysate Nonreturn Valve RVDA																																																◆																			
	4.9.4.18	Calibration Outlet Flow Pump Nonreturn Valve RVFPA																																																	◆																		
	4.9.4.19	Calibration Dialyser Inlet Throttle Valve DDE																◆																																																			
	4.9.4.20	Calibration Pressure Reducer Valve DMV																	◆																																																		
	4.9.4.21	Gap SAKA and SAKV																						◆																																													
	4.9.4.23	Setting Servomotor for Disinfection Valve VD																																																												◆					◆		
	5.1	Inspection Protocol for Automatic Blood Pressure Measurement ABPM	◆																																																																			

3.8.2 Tests and Measures to be Executed

It is recommended to use the repair matrix, the tests and measures and the execution protocol after servicing (e.g. repair, SW installation etc.).

All components are numbered alphabetically (from 1 to n) in the column *Points for Exchanged/Repaired Assembly Groups*. The respective calibrations, tests and measures in the matrix are assigned to each component (HW/SW) with a ◆ character. The executed measure can be documented in the execution protocol.

Risk of a patient infection due to a contamination of the manometer protection filter of the blood line system!
If the manometer protection filter of the blood line system was contaminated with blood and blood has entered the machine: replace the internal manometer protection filter, the tubing (between the filter and the manometer connector) and the manometer connector.

Tubing must be replaced only by the same tubing type/length and identical installation manner.
Make sure that the tubings in the machine are not kinked or twisted after servicing (e.g. if sub-racks are pulled out and inserted again). The tubing must not touch moving/rotating components (e.g. motors of gear pumps).

3.8.2.1 Install Software

1. The software must be installed according to the description in the service manual.

3.8.2.2 Check System Configuration, Production Report and Set if Necessary

The FSU USB stick with the system configuration can only be used if the hardware and software of the machine match.

1A System Configuration

- **System Configuration Present**
  Load the system configuration from the FSU USB stick and check all settings in the TSM service program.
- **Customer Specific System Configuration not Present)**
  Check system configuration and set system configuration according to user default.

1B Production Report

- Select and save/activate present options.

1C Calibration Data

- **Replacement of CFC**
  Save calibration data.
- **Replacement of Sensors/Detectors**
  Calibration, save calibration data.
- **Replacement of Digital Board**
  Download calibration data.
- **Replacement of Analog Board**
  Calibration, save calibration data.

1D LLC Calibrations
Check and set ratio, tubing constants BPA/BPV, OSP tubing type, check/set PA/PV limit values.

1E Working Time Counter

- Set working time counter.

1F Motherboard
Check and set BIOS.

3.8.2.3 Self Test

1. Start machine (fully equipped) in dialysis mode.
2. Insert line system – see instructions for use.
3. The machine must run without errors up to the message *Connect Patient*.

3.8.2.4 Conductivity Test Run, Temperature Comparison Measurement

1. Assemble the line system, perform preparation and self test – according to instructions for use.
2. Loop in a dialysis measurement system in the dialyser line.
3. Set 14.3 mS/cm, 37 °C (or the equivalent temperature in Fahrenheit).
4. Run the machine in main flow and compare the values (pay attention to the tolerances).

3.8.2.5 Test Run UF Comparison Measurement

Pay attention that the dialyser circuit is free of air.

1. Assemble the line system, perform preparation (insert heparin syringe and select 2 ml and use BIC cartridge if present).
2. Perform self test – according to instructions for use.
3. Press the icon to switch to therapy mode (*connect patient*). This icon is enabled after all self tests were performed successfully.

Simulation of Patient:

4. Fill a 250 ml graduated cylinder with water and document exact value (weight).
5. Set the UF volume to 125 ml and a therapy time to 00:15 h.
6. Insert the arterial and venous lines in the graduated cylinder.
7. Set the blood pump so that no blood side alarms are activated.
8. Start dialysis.
9. Check the UF volume after a dialysis time to > 0:15 h and compare the removed volume from the graduated cylinder with the displayed UF volume at the machine.
   (Permissible deviation: 3 % of the UF rate per hour. Example: corresponds to approx. ±4 ml at 125 ml UF volume after 15 minutes.)

3.8.2.6 Test Run

1. Assemble the line system, perform preparation (insert heparin syringe and select 2 ml/h and use BIC cartridge if present).
2. Perform self test – according to instructions for use.
3. Press the icon to switch to therapy mode (*connect patient*). This icon is enabled after all self tests were performed successfully.
4. Insert the arterial and venous lines in the graduated cylinder.
5. Set the blood pump so that no blood side alarms are activated.
6. Start dialysis.
7. Check alarm function of SAD.
   (The ABPM function can be checked without a test run of the machine in preparation mode.)

3.8.2.7 Electrical Safety Check

1. Electrical safety check according to EN 62353/EN 60601-1:
   - Protective earth resistance, equipment leakage current, patient leakage current.

3.8.2.8 Perform Disinfection after Repair

1. Select disinfection program.
2. Select disinfection type and start disinfection (depends on applied process and procedure in the dialysis centres, see chapter disinfection in the instructions for use).

3.8.2.9 Document the Executed Activities

1. The measures were executed correctly. Fill in the execution protocol after service (e.g. exchange of a component) and after executing all necessary measures according to the repair matrix.

3.8.3 Execution Protocol

Execution Protocol

Measures According to Repair Matrix			Measurement Values/ Executed Measures	NA	OK
3.8.2.1	**Install Software**		executed correctly	☐	☐
3.8.2.2	**Check System Configuration, Production Report and Set if Necessary**		executed correctly	☐	☐
3.8.2.3	**Self Test**		executed correctly	☐	☐
3.8.2.4	**Conductivity Test Run, Temperature Comparison Measurement:**	• Conductivity (14.3 ms/cm, ±0.2) • Temperature (37 °C, -1.5 +0.5)	.... **[mS/cm]** .... **[°C]**	☐	☐
3.8.2.5	**Test Run UF Comparison Measurement:**	• 15 min at UF rate 500 ml/h (3% ≈ ±4 ml)	.... **[ml]**	☐	☐
3.8.2.6	**Test Run**		executed correctly	☐	☐
3.8.2.7	**Electrical Safety Check:** **According to:** **IEC 62353/EN 60601-1/IEC 601-1**	• Protective Earth Resistance < 0.3 [Ω]: Potential equalization bolt Heater body (top) Rinsing bridge (dialyser inlet and outlet) Interior: front door (top left corner) Interior: rear door (top left corner) Interior: frame (rear) Interior: housing cover (top left) Monitor (one of the screws in the housing frame) • Equipment Leakage Current ≤ 0.5 [mA]: • Patient Leakage Current < 10 [µA] AC:	.... **[Ω]** (note highest value) .... **[mA]** .... **[µA]**	☐	☐
3.8.2.8	**Perform Disinfection after Repair**		executed correctly	☐	☐
4.	**Tests and Calibrations According to Service Manual** All text in { } brackets are general notes or execution information!		executed correctly	☐	☐
{4.9.1.1	Buttons, Lamps and Sounds}		Please use the repair matrix for the necessary tests and calibrations.		
{4.9.1.3	Touch Screen Calibration}				
{4.9.1.8	DBI Test or DSI Test or DCI Test}				
{4.9.2.1	Test 1.1 Staff Call, Alarms, Power Off}				
{4.9.2.5	1.5 Tubing Clamps}				
{4.9.2.7	Test 1.7 Air Sensor SAD, Red Sensor}				
{4.9.2.8	1.8 Coupling Detectors}				
{4.9.2.13	1.13 Balance Chamber Valves}				
{4.9.2.14	1.14 Bypass and Disinfection Valves}				
{4.9.2.19	1.19 Leak Test}				
{4.9.2.23	Test 1.23 BIC Cartridge Valves and Coupling Detectors}				
{4.9.2.25	1.25 HDF Online Valves and Detectors}				
{4.9.2.26	1.26 Option Battery				
{4.9.4.1	Calibration Pressure Sensors Blood Side PA, PV, PBE and PBS}				
{4.9.4.3	Calibration Pressure Sensors of Water Side PE and PDA}				
{4.9.4.4	Calibration Degassing TSE/TSHE}				
{4.9.4.5	Calibration Dialysis Temperature Sensors TSBIC and TSD/TSD_S/TSDE}				
{4.9.4.6	Calibration Conductivity Sensors BICLF and ENDLF/ENDLF_S}				
{4.9.4.7	Calibration Blood Leak Detector Type 3}				
{4.9.4.8	Calibration of Flow Rate UFP, BICP and KP}				
{4.9.4.9	Calibration Safety Air Detector SAD Version 3}				
{4.9.4.10	Calibration BICLF and ENDLF Ratio}				
{4.9.4.13	Calibration Flow Rate of BPA and BPV/OSP}				
{4.9.4.16	Calibration Inlet Flow Pump Nonreturn Valve RVFPE}				
{4.9.4.17	Calibration Dialysate Nonreturn Valve RVDA}				
{4.9.4.18	Calibration Outlet Flow Pump Nonreturn Valve RVFPA}				
{4.9.4.19	Calibration Dialyser Inlet Throttle Valve DDE}				
{4.9.4.20	Calibration Pressure Reducer Valve DMV}				
{4.9.4.21	Gap SAKA and SAKV}				
{4.9.4.23	Setting Servomotor for Disinfection Valve VD}				
{5.1	Inspection Protocol for Automatic Blood Pressure Measurement ABPM}				
The respective measures were executed correctly after servicing according to the repair matrix.			Name Service Technician: .... Date / Signature		

Table of Contents

4.1 Start TSM Service Program

TSM Service Program

Only activate the TSM service program for service activities. It is prohibited to connect a patient to the Dialog+ and to run a therapy if the TSM service program is activated in the Dialog+. If the TSM service program is activated the complete alarm system is disabled.

Therapy Mode

After completion of all procedures switch back to the therapy mode: digital board, service switch S1, position 0.

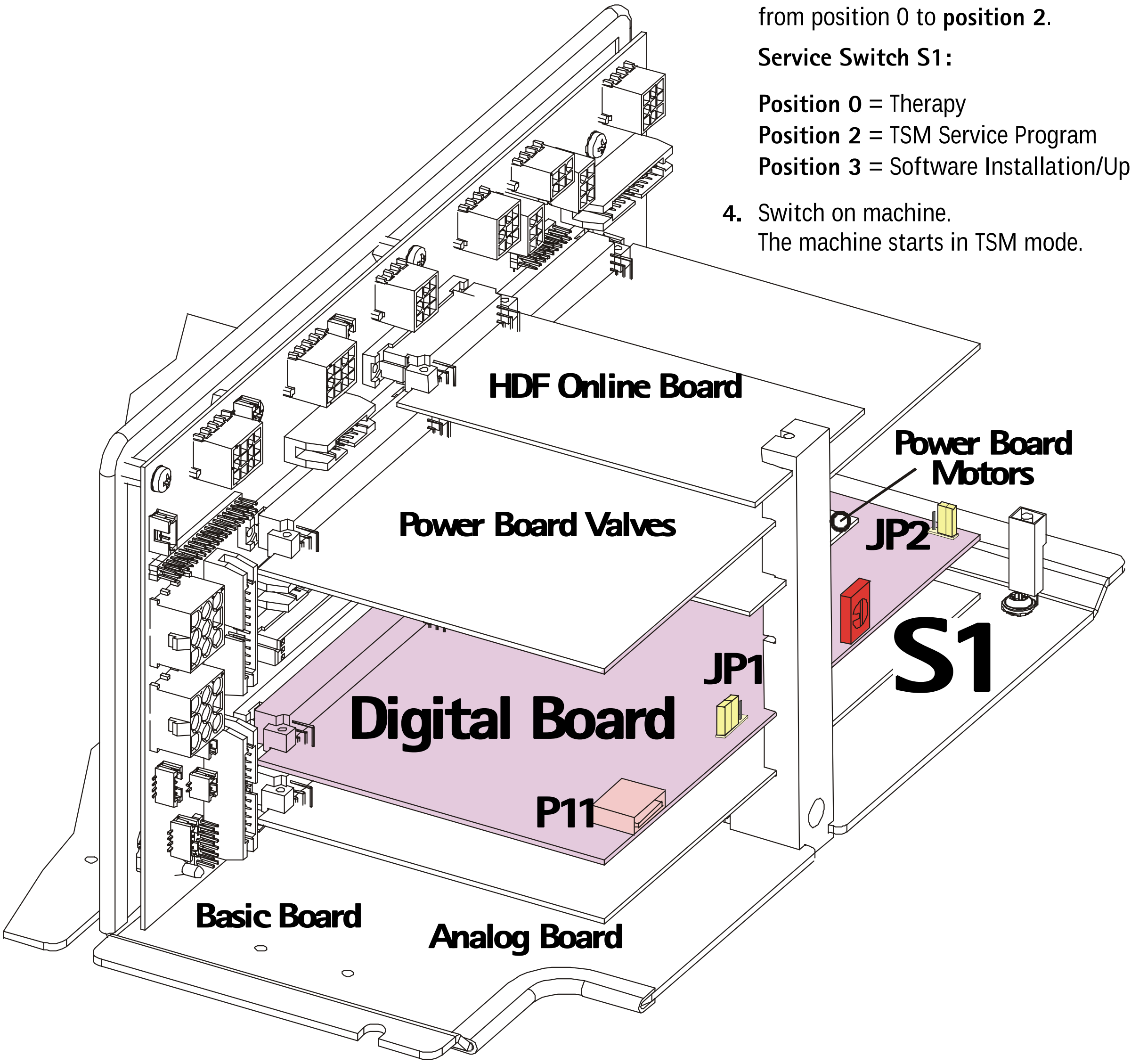
The *TSM Main Menu* (TSM = Technical Support and Maintenance) is used for servicing the machine. The TSM service program (*TSM Main Menu*) is started as follows:

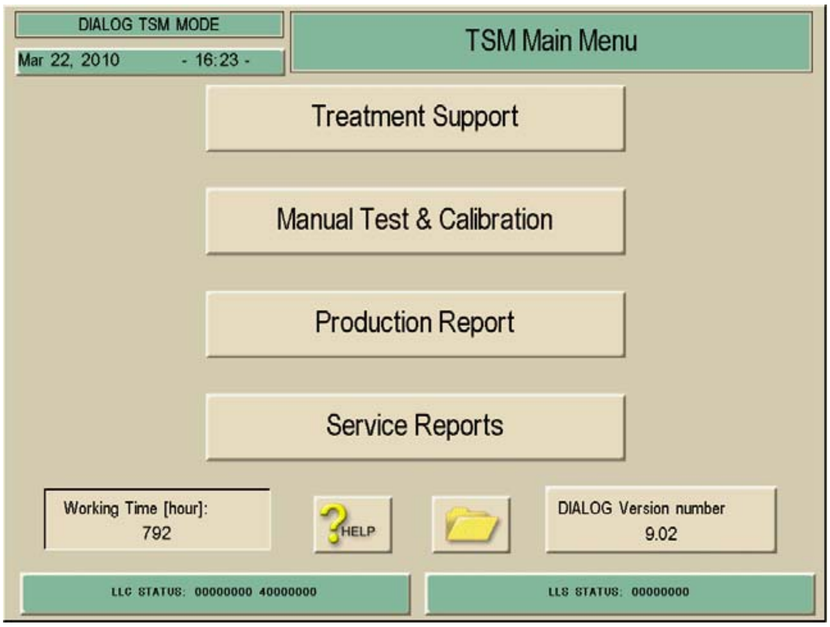
1. Switch off machine.
2. Open rear door.
3. On digital board DB: turn service switch S1 from position 0 to **position 2**.

   Service Switch S1:

   Position 0 = Therapy
   Position 2 = TSM Service Program
   Position 3 = Software Installation/Update

4. Switch on machine.
   The machine starts in TSM mode.





Mar 22, 2010 - 16:23 -

Working Time [hour]: 792

DIALOG Version number 9.02

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

The *TSM Main Menu* is displayed.

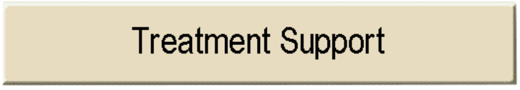
The date and time can be set in the *TSM Main Menu*.

The following four sub-menus can be selected:

- *Treatment Support*
- *Manual Test and Calibration*
- *Production Report*
- *Service Reports*

Mar 22, 2010 - 16:23 -

You can set the date and time of the machine by clicking on the field. The first click opens the *Minus/Plus* window for the *Date*; the second click opens the *Minus/Plus* window for the *Time*.

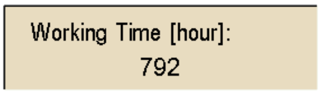


All basic parameters can be set for the therapy mode in the *Treatment Support* menu.

All manual tests and calibrations can be performed in the *Manual Test and Calibration* menu.

All machine specific data and options are available in the *Production Report* menu.

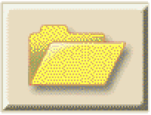
The *Operation Mode Report* menu can be selected in the *Service Report* menu.



Working Time [hour]: 792

The total working time of the machine is displayed in the *Working Time Counter* window. The total working time is stored on the compact flash card CFC.

- Activate additional information with the *HELP* icon.
  - Activate *HELP* icon
  - Select a sub-menu via touch screen.
    (A window with the help text is opened for the selected key.)



The *File Operations* menu can be activated with this icon.

DIALOG Version number 9.02

The current software/firmware versions are displayed in the Dialog Version Number menu. This menu can also be selected in the *Production Report*.

4.2 Quit TSM Service Program

TSM Service Program

Only activate the TSM service program for service activities. It is prohibited to connect a patient to the Dialog+ and to run a therapy if the TSM service program is activated in the Dialog+. If the TSM service program is activated the complete alarm system is disabled.

Therapy Mode

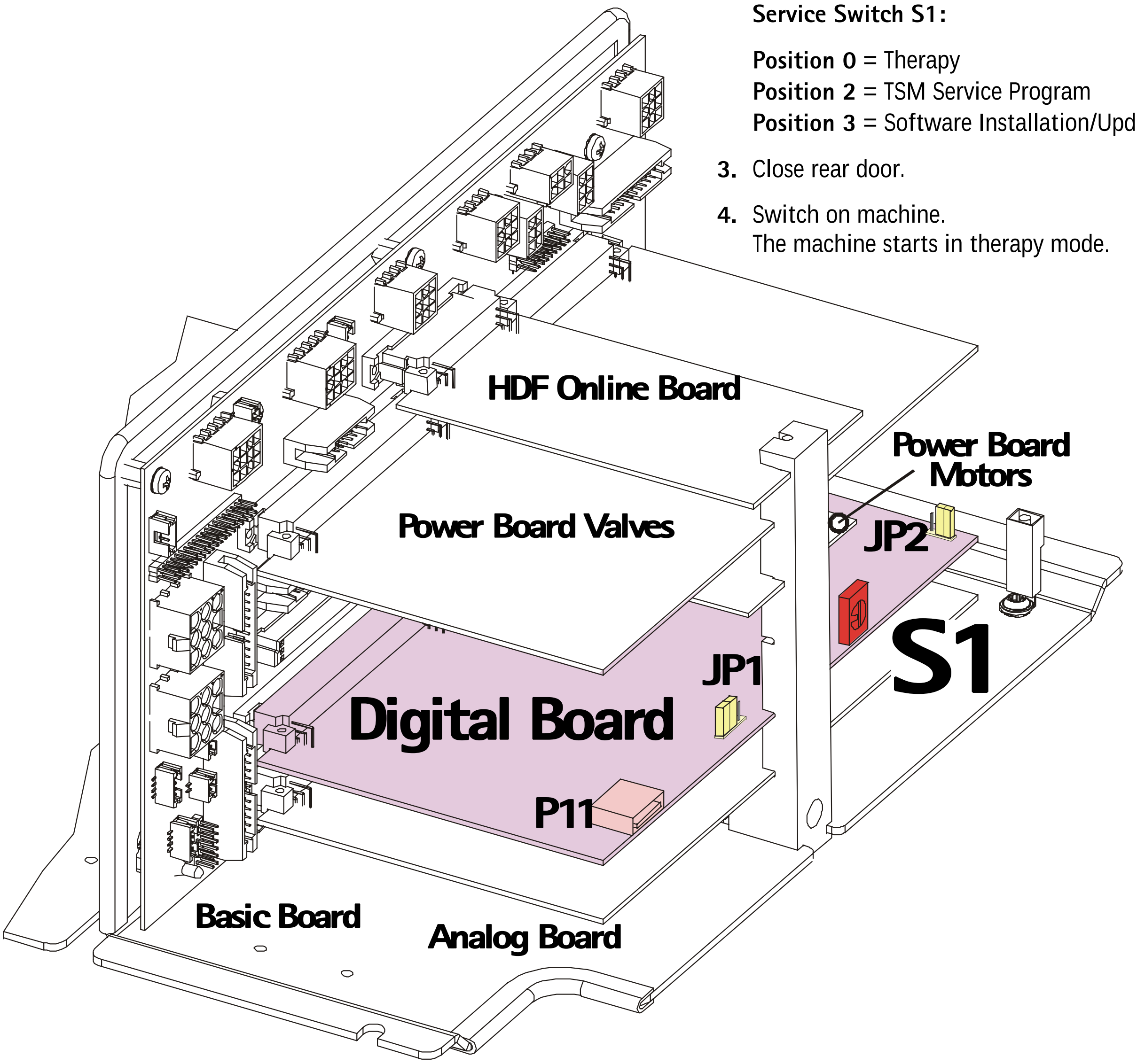
After completion of all procedures switch back to the therapy mode: digital board, service switch S1, position 0.

The following steps must be taken to quit the service program and to re-enter the therapy mode:

1. Switch off machine.
2. On digital board DB: turn service switch S1 from position 2 to **position 0** therapy mode.

   Service Switch S1:

   Position 0 = Therapy
   Position 2 = TSM Service Program
   Position 3 = Software Installation/Update
3. Close rear door.
4. Switch on machine.
   The machine starts in therapy mode.



4.3 Structure of TSM Service Program

TSM Service Program

Technical Support and Maintenance (SW 9.xx)

- **File Operations**
  - **Hard Disk Read/Write**
    - Save Calibration Data
    - Download Calibration Data
- **Treatment Support**
  - **System Configuration**
    - Dialysate Side Parameters
    - Blood Side Parameters
    - Min-Max Parameters
    - Arterial Bolus Parameters
    - Single Needle
    - Heparin Parameters
    - Rinsing Parameters
    - UF Parameters
    - HDF/HF Online Parameters
    - Disinfection Parameters
    - Filter Parameters
    - Dialyser Filter Parameters Kt/V
    - Kt/V-UV Parameters
    - Timings
    - Langauge Selection
    - ABPM Parameters
    - bioLogic RR GL Parameters
    - Summer Time Setting
    - Miscellaneous Parameters
    - DBI Parameters
    - DCI Parameters
    - Preventive Service
  - **Trends and Trend Groups**
- **Manual Test and Calibration**
  - **TL Manual Test and Calibration**
    - Buttons, Lamps and Sounds
    - Monitor Test
    - Touch Screen Calibration
    - Brightness
    - Card Reader and Card Check
    - USB Port Properties
    - Supervisor Window Test
    - File System Check
    - ABPM Maintenance
    - DBI Test
    - Kt/V-UV Sensor Test
    - DSI Test
  - **Low Level Manual Test**
    - Test 1.1 Staff Call/Alarms/Power Off
    - Test 1.2 Blood Pump Arterial
    - Test 1.3 Blood Pump Venous
    - Test 1.4 Heparin Pump
    - Test 1.5 Tubing Clamps
    - Test 1.6 Pressure Sensors (Blood Side)
    - Test 1.7 Safety Air Detector, Red Sensor
    - Test 1.8 Coupling Detectors
    - Test 1.9 Water Intake, Upline Tank and Flow Pump FPE
    - Test 1.10 Degassing and Heating
    - Test 1.11 Dialysis Temperature
    - Test 1.12 Concentrate Pumps and Conductivity
    - Test 1.13 Balance Chamber Valves
    - Test 1.14 By-Pass and Disinfection Valves
    - Test 1.15 Flow Pump FPA, Balance Chamber Sensors and Air Separator
    - Test 1.16 Pressure Water Part
    - Test 1.17 UF Pump
    - Test 1.18 Blood Leak Detector
    - Test 1.19 Leak Test
    - Test 1.20 Water Part (Overview)
    - Test 1.21 Emptying
    - {Test 1.22 HDF}
    - Test 1.23 BIC Cartridge Valves and Coupling Detectors
    - Test 1.24 HDF Online
    - Test 1.25 HDF Online Valves and Coupling Detectors
    - Test 1.26 Option Battery
    - Test 1.27 DFS Pressure Test of Therapy
    - Test 1.28 Front Panel Board FPB (LLS)
    - Test 1.29 Patient Leakage Current
    - Test 1.30 SMPS-MC Self Test
    - Test 1.31 Level Regulation
  - **Low Level Manual Calibration**
    - Calibration 2.1 Pressure Sensors (Blood Side)
    - {Calibration 2.2 Heparin Pump}
    - Calibration 2.3 Pressure Sensors (Water Side)
    - Calibration 2.4 Degassing Temperature
    - Calibration 2.5 Dialysis Temperature
    - Calibration 2.6 Conductivity
    - Calibration 2.7 Blood Leak Detector
    - Calibration 2.8 Flow of BICP, KP and UF Pump
      - Calibration 2.8.1 Stroke Value of BICP, KP and UFP
      - Calibration 2.8.2 Position Setting for BICP, KP and UFP
    - Calibration 2.9 Safety Air Detector SAD
    - Calibration 2.10 BICLF Ratio and ENDLF Ratio
    - {Calibration 2.11 Load Cell}
    - Calibration 2.12 PV Alarm Window, PA Low Limit
    - Calibration 2.13 Flow of BPA and BPV Pump
      - Calibration 2.13.1 Tube Constants of BPA and BPV
      - Calibration 2.13.2 Pump Head Selection
    - {Calibration 2.14 Substitution Pump}
    - Calibration 2.15 HDF Online Substitution Pump OSP
    - Calibration 2.16 Level Regulation Pump LRP
- **Production Report**
  - **Machine Delivery Data**
  - **Version Number Dialog**
  - **Option Icons**
    - ABPM
    - bioLogic RR
    - Card Reader
    - DCI
    - Kt/V
    - Kt/V-UV (Crit-Line)
    - HCT (Adimea)
  - **Low Level Options**
    - Double Pump
    - Holder for BIC Cartridge
    - DF Filter
    - HDF Online
    - Battery
    - Nexadia-BSL (DBI)
    - WAN-BSL (DBI)
- **Service Reports**
  - **Operation Mode Report**

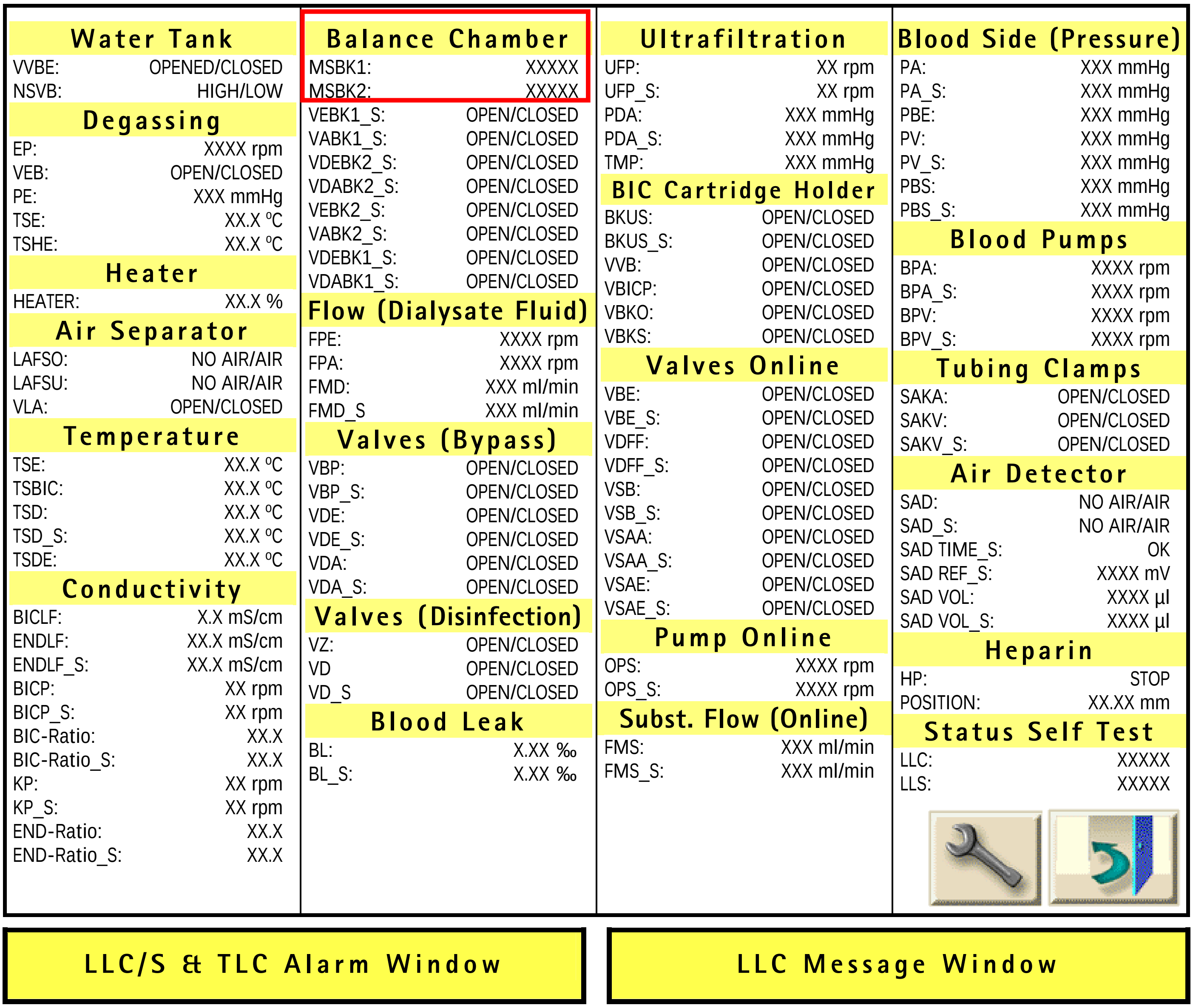
{ } : not applicable

Fig. : TSM Service Program

4.4 Service Overview in Therapy

The service overview can be selected in therapy with the *Service Key* icon. The second and third page of the service overview can be selected with the *service key* icon.

Click the *Door* icon to jump back to the initial menu.



Water Tank
VVBE: OPENED/CLOSED
NSVB: HIGH/LOW

Degassing
EP: XXXX rpm
VEB: OPEN/CLOSED
PE: XXX mmHg
TSE: XX.X °C
TSHE: XX.X °C

Heater
HEATER: XX.X %

Air Separator
LAFSO: NO AIR/AIR
LAFSU: NO AIR/AIR
VLA: OPEN/CLOSED

Temperature
TSE: XX.X °C
TSBIC: XX.X °C
TSD: XX.X °C
TSD_S: XX.X °C
TSDE: XX.X °C

Conductivity
BICLF: X.X mS/cm
ENDLF: XX.X mS/cm
ENDLF_S: XX.X mS/cm
BICP: XX rpm
BICP_S: XX rpm
BIC-Ratio: XX.X
BIC-Ratio_S: XX.X
KP: XX rpm
KP_S: XX rpm
END-Ratio: XX.X
END-Ratio_S: XX.X

Balance Chamber
MSBK1: XXXXX
MSBK2: XXXXX
VEBK1_S: OPEN/CLOSED
VABK1_S: OPEN/CLOSED
VDEBK2_S: OPEN/CLOSED
VDABK2_S: OPEN/CLOSED
VEBK2_S: OPEN/CLOSED
VABK2_S: OPEN/CLOSED
VDEBK1_S: OPEN/CLOSED
VDABK1_S: OPEN/CLOSED

Flow (Dialysate Fluid)
FPE: XXXX rpm
FPA: XXXX rpm
FMD: XXX ml/min
FMD_S XXX ml/min

Valves (Bypass)
VBP: OPEN/CLOSED
VBP_S: OPEN/CLOSED
VDE: OPEN/CLOSED
VDE_S: OPEN/CLOSED
VDA: OPEN/CLOSED
VDA_S: OPEN/CLOSED

Valves (Disinfection)
VZ: OPEN/CLOSED
VD OPEN/CLOSED
VD_S OPEN/CLOSED

Blood Leak
BL: X.XX ‰
BL_S: X.XX ‰

Ultrafiltration
UFP: XX rpm
UFP_S: XX rpm
PDA: XXX mmHg
PDA_S: XXX mmHg
TMP: XXX mmHg

BIC Cartridge Holder
BKUS: OPEN/CLOSED
BKUS_S: OPEN/CLOSED
VVB: OPEN/CLOSED
VBICP: OPEN/CLOSED
VBKO: OPEN/CLOSED
VBKS: OPEN/CLOSED

Valves Online
VBE: OPEN/CLOSED
VBE_S: OPEN/CLOSED
VDFF: OPEN/CLOSED
VDFF_S: OPEN/CLOSED
VSB: OPEN/CLOSED
VSB_S: OPEN/CLOSED
VSAA: OPEN/CLOSED
VSAA_S: OPEN/CLOSED
VSAE: OPEN/CLOSED
VSAE_S: OPEN/CLOSED

Pump Online
OPS: XXXX rpm
OPS_S: XXXX rpm

Subst. Flow (Online)
FMS: XXX ml/min
FMS_S: XXX ml/min

Blood Side (Pressure)
PA: XXX mmHg
PA_S: XXX mmHg
PBE: XXX mmHg
PV: XXX mmHg
PV_S: XXX mmHg
PBS: XXX mmHg
PBS_S: XXX mmHg

Blood Pumps
BPA: XXXX rpm
BPA_S: XXXX rpm
BPV: XXXX rpm
BPV_S: XXXX rpm

Tubing Clamps
SAKA: OPEN/CLOSED
SAKV: OPEN/CLOSED
SAKV_S: OPEN/CLOSED

Air Detector
SAD: NO AIR/AIR
SAD_S: NO AIR/AIR
SAD TIME_S: OK
SAD REF_S: XXXX mV
SAD VOL: XXXX µl
SAD VOL_S: XXXX µl

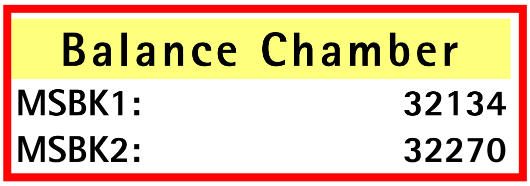
Heparin
HP: STOP
POSITION: XX.XX mm

Status Self Test
LLC: XXXXX
LLS: XXXXX

LLC/S & TLC Alarm Window

LLC Message Window

Fig.: First Page Service Overview in Therapy



Balance Chamber
MSBK1: 32134
MSBK2: 32270

Digit Range for MSBK1/2 in Therapy

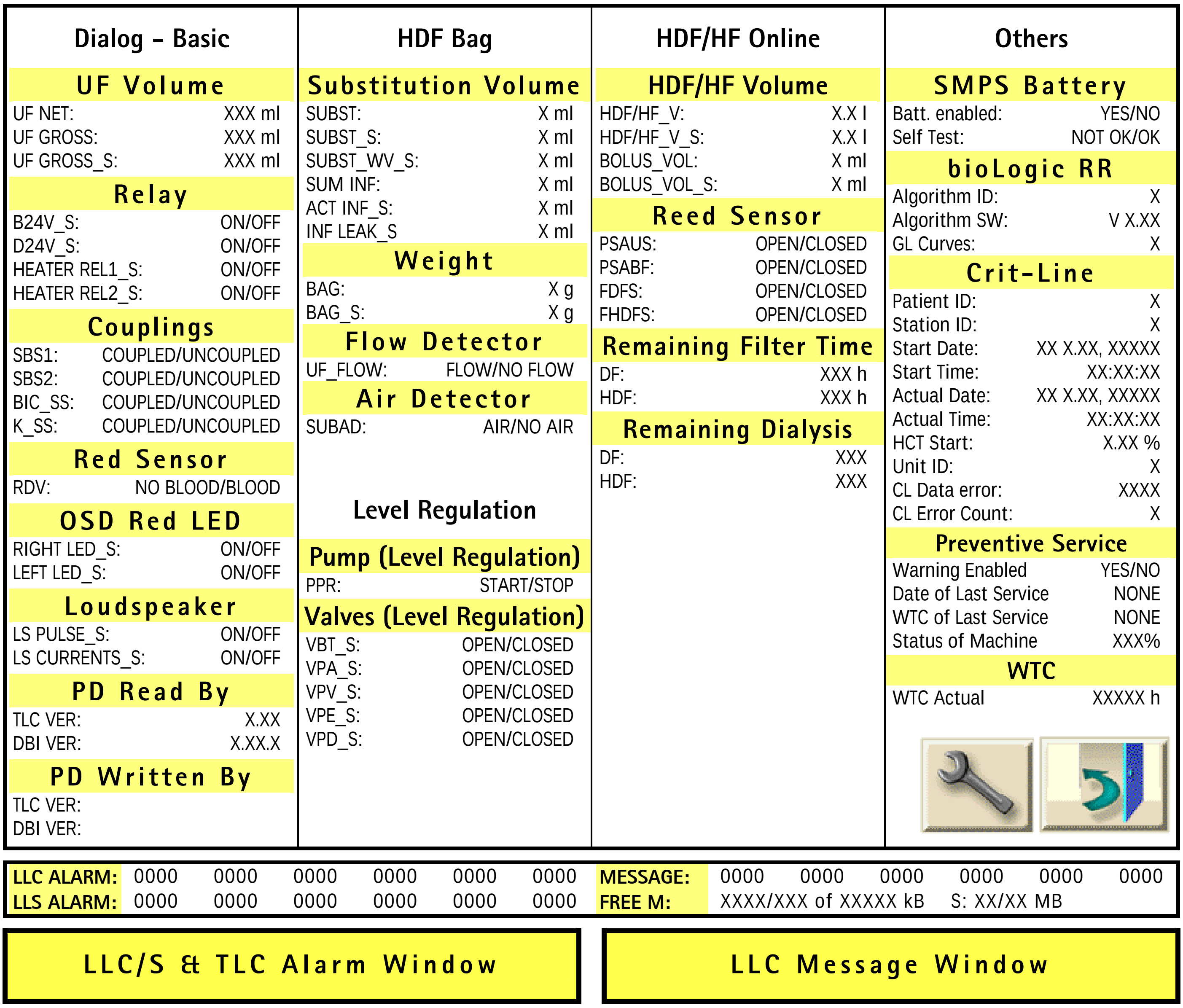
MSBK1/2
Min. Value: 10000
Max. Value: 35000
Differential Range: min. 7500

Malfunctions in the balance chamber can occur if:

- the values are out of limits
- the minimal difference from the detected min. value was not reached

The second page of the service overview can be selected with the *Service Key* icon.

Click the *Door* icon to jump back to the initial menu.



Dialog - Basic

UF Volume	
UF NET:	XXX ml
UF GROSS:	XXX ml
UF GROSS_S:	XXX ml
Relay	
B24V_S:	ON/OFF
D24V_S:	ON/OFF
HEATER REL1_S:	ON/OFF
HEATER REL2_S:	ON/OFF
Couplings	
SBS1:	COUPLED/UNCOUPLED
SBS2:	COUPLED/UNCOUPLED
BIC_SS:	COUPLED/UNCOUPLED
K_SS:	COUPLED/UNCOUPLED
Red Sensor	
RDV:	NO BLOOD/BLOOD
OSD Red LED	
RIGHT LED_S:	ON/OFF
LEFT LED_S:	ON/OFF
Loudspeaker	
LS PULSE_S:	ON/OFF
LS CURRENTS_S:	ON/OFF
PD Read By	
TLC VER:	X.XX
DBI VER:	X.XX.X
PD Written By	
TLC VER:	
DBI VER:	

HDF Bag

Substitution Volume	
SUBST:	X ml
SUBST_S:	X ml
SUBST_WV_S:	X ml
SUM INF:	X ml
ACT INF_S:	X ml
INF LEAK_S	X ml
Weight	
BAG:	X g
BAG_S:	X g
Flow Detector	
UF_FLOW:	FLOW/NO FLOW
Air Detector	
SUBAD:	AIR/NO AIR

Level Regulation

Pump (Level Regulation)	
PPR:	START/STOP
Valves (Level Regulation)	
VBT_S:	OPEN/CLOSED
VPA_S:	OPEN/CLOSED
VPV_S:	OPEN/CLOSED
VPE_S:	OPEN/CLOSED
VPD_S:	OPEN/CLOSED

HDF/HF Online

HDF/HF Volume	
HDF/HF_V:	X.X l
HDF/HF_V_S:	X.X l
BOLUS_VOL:	X ml
BOLUS_VOL_S:	X ml
Reed Sensor	
PSAUS:	OPEN/CLOSED
PSABF:	OPEN/CLOSED
FDFS:	OPEN/CLOSED
FHDFS:	OPEN/CLOSED
Remaining Filter Time	
DF:	XXX h
HDF:	XXX h
Remaining Dialysis	
DF:	XXX
HDF:	XXX

Others

SMPS Battery	
Batt. enabled:	YES/NO
Self Test:	NOT OK/OK
bioLogic RR	
Algorithm ID:	X
Algorithm SW:	V X.XX
GL Curves:	X
Crit-Line	
Patient ID:	X
Station ID:	X
Start Date:	XX X.XX, XXXXX
Start Time:	XX:XX:XX
Actual Date:	XX X.XX, XXXXX
Actual Time:	XX:XX:XX
HCT Start:	X.XX %
Unit ID:	X
CL Data error:	XXXX
CL Error Count:	X
Preventive Service	
Warning Enabled	YES/NO
Date of Last Service	NONE
WTC of Last Service	NONE
Status of Machine	XXX%
WTC	
WTC Actual	XXXXX h

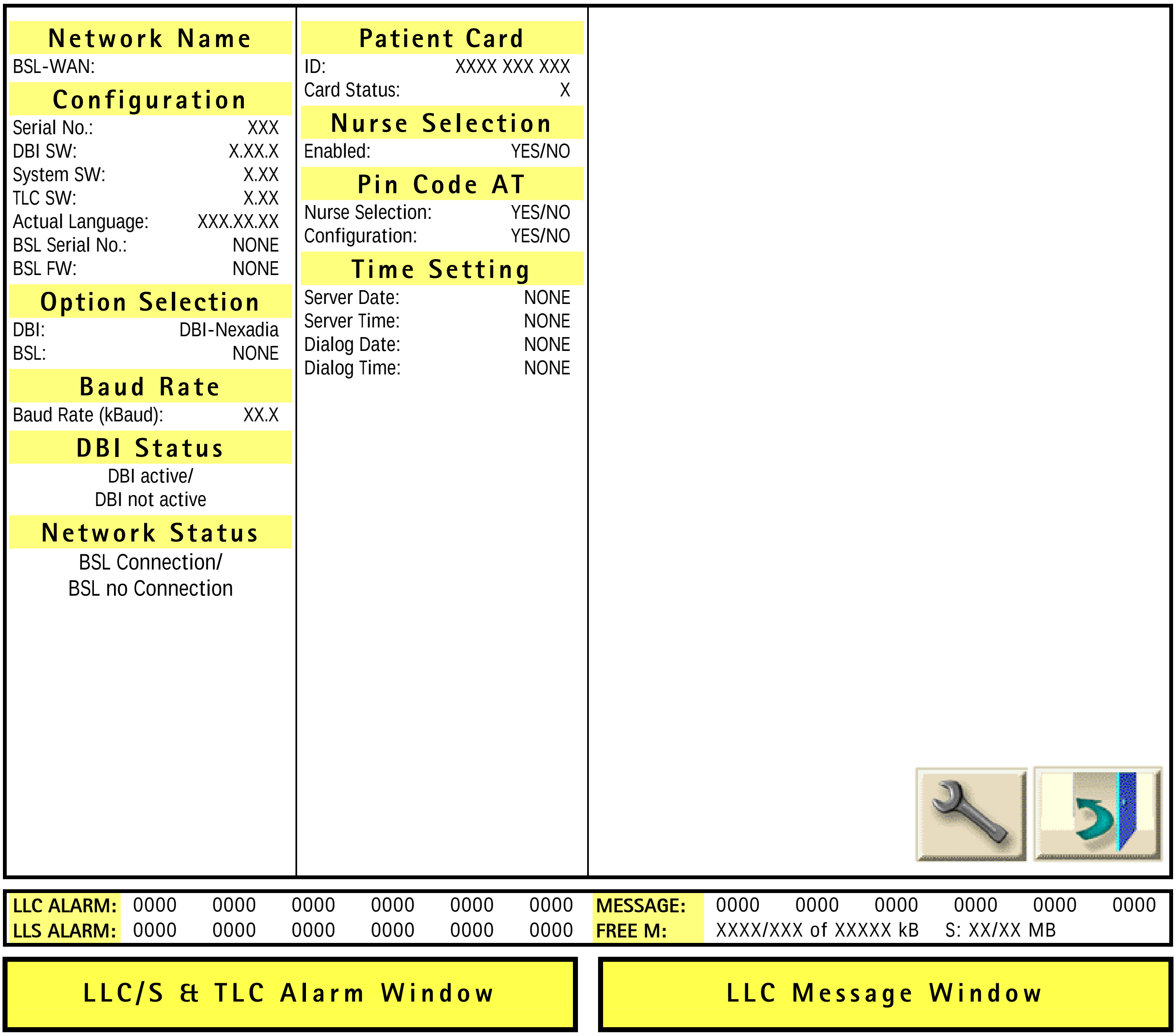
LLC ALARM:	0000	0000	0000	0000	0000	0000
LLS ALARM:	0000	0000	0000	0000	0000	0000

MESSAGE:	0000	0000	0000	0000	0000	0000
FREE M:	XXXX/XXX of XXXXX kB	S: XX/XX MB				

Fig.: Second Page Service Overview in Therapy

The third page of the service overview can be selected with the *Service Key* icon.

Click the *Door* icon to jump back to the initial menu.



Network Name
BSL-WAN:

Configuration
Serial No.: XXX
DBI SW: X.XX.X
System SW: X.XX
TLC SW: X.XX
Actual Language: XXX.XX.XX
BSL Serial No.: NONE
BSL FW: NONE

Option Selection
DBI: DBI-Nexadia
BSL: NONE

Baud Rate
Baud Rate (kBaud): XX.X

DBI Status
DBI active/
DBI not active

Network Status
BSL Connection/
BSL no Connection

Patient Card
ID: XXXX XXX XXX
Card Status: X

Nurse Selection
Enabled: YES/NO

Pin Code AT
Nurse Selection: YES/NO
Configuration: YES/NO

Time Setting
Server Date: NONE
Server Time: NONE
Dialog Date: NONE
Dialog Time: NONE

LLC ALARM:	0000	0000	0000	0000	0000	0000	**MESSAGE:**	0000	0000	0000	0000	0000	0000
LLS ALARM:	0000	0000	0000	0000	0000	0000	**FREE M:**	XXXX/XXX of XXXXX kB		S: XX/XX MB			

Fig.: Third Page Service Overview in Therapy

4.4.1 Legend Service Overview in Therapy

ACT INF_S:	Actual infusion supervisor (not applicable)
B24V_S:	24 V cut-off blood side supervisor (HP, BPA, BPV)
BAG:	Bag weight (not applicable)
BAG_S:	Bag weight supervisor (not applicable)
BIC_SS:	Bicarbonate rinsing connector sensor
BICLF:	Bicarbonate conductivity
BICP:	Bicarbonate pump
BICP_S:	Bicarbonate pump supervisor
BIC-RATIO:	Bicarbonate ratio
BIC-RATIO_S:	Bicarbonate ratio supervisor
BKUS:	BIC cartridge holder lower switch
BKUS_S:	BIC cartridge holder lower switch supervisor
BL:	Blood leak detector
BL_S:	Blood leak detector supervisor
BOLUS_VOL:	Bolus volume
BOLUS_VOL_S:	Bolus volume supervisor
BPA:	Arterial blood pump
BPA_S:	Arterial blood pump supervisor
BPV:	Venous blood pump
BPV_S:	Venous blood pump supervisor
DBI VER:	DBI version
D24V_S:	24 V cut-off dialysate side supervisor (VDA, VDE)
DF:	Remaining time for DF
ENDLF:	End conductivity
ENDLF_S:	End conductivity supervisor
END-RATIO:	End ratio
END-RATIO_S:	End ratio supervisor
EP:	Degassing pump
F(E)DFS:	Filter recognition DF filter sensor
F(E)HDFS:	Filter recognition HD filter sensor
FMS:	Substitution flow measurement
FMS_S:	Substitution flow low measurement supervisor
FPA:	Outlet flow pump
FPE:	Inlet flow pump
HDF/HF_V:	HDF/HF volume
HDF/HF_V_S:	HDF/HF volume supervisor
HDF:	Remaining time for HDF
HEATER REL1_S:	Heater relay 1 supervisor (not applicable)
HEATER REL2_S:	Heater relay 2 supervisor (not applicable)
HP:	Heparin pump
INF LEAK_S:	Infusion leakage supervisor (not applicable)
K_SS:	Concentrate rinsing connector sensor
KP:	Concentrate pump
KP_S:	Concentrate pump supervisor
LAFSO:	Top air separator level sensor
LAFSU:	Bottom air separator level sensor
LEFT LED_S:	Left LED from OSD
LLC:	Low level controller
LLS:	Low level supervisor
LS CURRENTS_S:	Loudspeaker current supervisor
LS PULSE_S:	Loudspeaker pulse supervisor
MSBK1:	Membrane position sensor balance chamber 1
MSBK2:	Membrane position sensor balance chamber 2
NSVB:	Level sensors upline tank

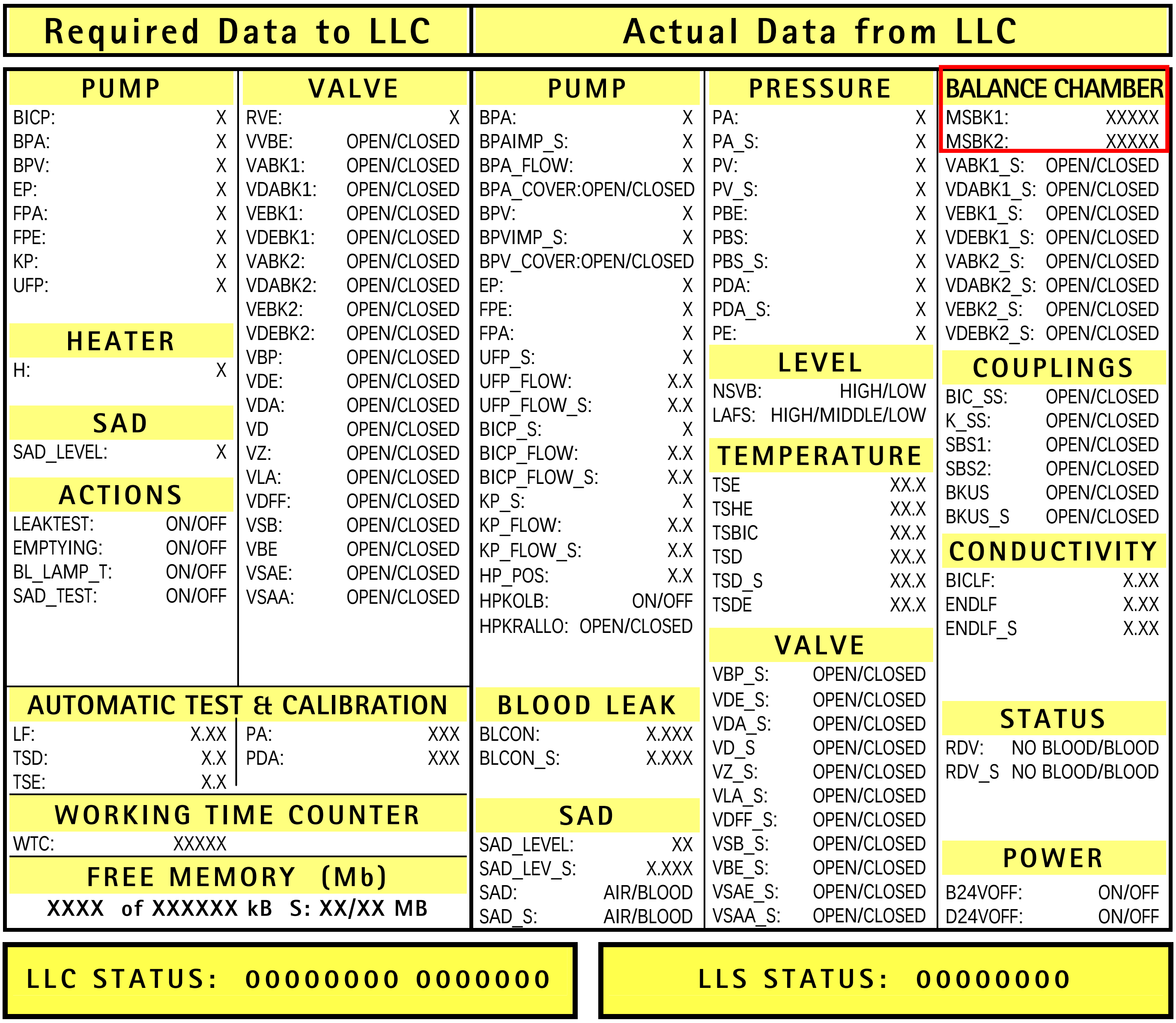
OSP:	Online substitution pump
OSP_S:	Online substitution pump supervisor
PA:	Arterial pressure sensor
PA_S:	Arterial pressure sensor supervisor
PBS:	Blood control pressure sensor
PBS_S:	Blood control pressure sensor supervisor
PDA:	Dialysate outlet pressure sensor
PDA_S:	Dialysate outlet pressure sensor supervisor
PE:	Degassing pressure sensor
POSITION:	Drive position
PSABF(S):	Substitution port drain sensor
PSAUS(S):	Substitution port outlet sensor
PV:	Venous pressure sensor
PV_S:	Venous pressure sensor supervisor
RDV:	Venous red detector
RVE:	Degassing control valve
RIGHT LED_S:	Right LED from OSD
SAD REF_S:	Safety air detector reference voltage supervisor
SAD TIME_S:	Safety air detector time control supervisor
SAD:	Safety air detector
SAD_S:	Safety air detector supervisor
SAKA:	Arterial tubing clamp
SAKV(-SG):	Venous tubing clamp currentless closed
SAKV(-SG)_S:	Venous tubing clamp currentless closed supervisor
SBS1:	Rinsing bridge connector sensor 1
SBS2:	Rinsing bridge connector sensor 2
SUBAD:	Substitution air detector (not applicable)
SUBST:	Substitution (not applicable)
SUBST_S:	Substitution supervisor (not applicable)
SUBST_WV_S:	Substitution weight volume supervisor (not applicable)
SUM INF:	Sum infusion (not applicable)
TLC VER:	TLC version
TMP:	Transmembrane pressure
TSBIC:	Bicarbonate temperature sensor
TSD:	Dialysate temperature sensor
TSD_S:	Dialysate temperature sensor supervisor
TSE:	Degassing temperature sensor
TSHE:	Heater inlet temperature sensor
TSDE:	Dialyser inlet temperature sensor
UF_Flow:	Ultrafiltration flow (not applicable)
UFP:	Ultrafiltration pump
UFP_S:	Ultrafiltration pump supervisor
VABK1_S:	Outlet valve balance chamber 1 supervisor
VABK2_S:	Outlet valve balance chamber 2 supervisor
VBE:	Vent filter valve
VBE_S:	Vent filter valve supervisor
VBICP:	BIC pump valve
VBKO:	BIC cartridge holder top Valve
VBKS:	BIC cartridge holder concentrate rod valve
VBP:	Bypass valve
VBP_S:	Bypass valve supervisor
VD:	Disinfection valve supervisor
VDA:	Dialyser outlet valve
VDABK1_S:	Dialyser outlet valve balance chamber 1 supervisor
VDABK2_S:	Dialyser outlet valve balance chamber 2 supervisor
VDA-S:	Dialyser outlet valve supervisor
VDE:	Dialyser inlet valve
VDEBK1_S:	Dialyser inlet valve balance chamber 1 supervisor
VDEBK2_S:	Dialyser inlet valve balance chamber 2 supervisor
VDE-S:	Dialyser inlet valve supervisor
VDFF:	DF filter valve

VDFF_S:	DF filter valve supervisor
VEBK1_S:	Inlet valve balance chamber 1 supervisor
VEBK2_S:	Inlet valve balance chamber 2 supervisor
VLA:	Air separator valve
VSAA:	Substitution outlet valve
VSAA_S:	Substitution outlet valve supervisor
VSAE:	Substitution inlet valve
VSAE_S:	Substitution inlet valve supervisor
VSB:	Substitution bypass valve
VSB_S:	Substitution bypass valve supervisor
VVB:	Upline tank valve
VVBE:	Upline tank inlet valve
VZ:	Circulation valve

Working Time Counter	Working time counter (WTC)
bioLogic RR	bioLogic RR Option
LLC ALARM	The low level controller alarms are displayed in a hexadecimal format. The corresponding bit alarms are shown in the LLC alarm window.
LLS ALARM	The low level supervisor alarms are displayed in a hexadecimal format. The corresponding bit alarms are shown in the LLS alarm window.
LLC MESSAGE	The LLC messages are displayed in a hexadecimal format. The corresponding bit messages are shown in the message window.
FREE MEMORY	Free RAM memory (DIMM/SIMM).
LLC/S & TLC Alarm Window	• Low level controller alarm text Window messages according to the LLC hex numbers from the LLC alarm window. • Low level supervisor alarm text Window messages according to the LLS hex numbers from the LLS alarm window. • Top level controller alarm messages Window according to the TLC hex numbers from the TLC alarm window.
LLC Message Window	LLC text messages according to the LLC message hex numbers from LLC message window.

4.5 Service Overview in TSM Service Program

The service overview can be selected with the key in the TSM service program.



Required Data to LLC

PUMP
BICP: X
BPA: X
BPV: X
EP: X
FPA: X
FPE: X
KP: X
UFP: X

HEATER
H: X

SAD
SAD_LEVEL: X

ACTIONS
LEAKTEST: ON/OFF
EMPTYING: ON/OFF
BL_LAMP_T: ON/OFF
SAD_TEST: ON/OFF

VALVE
RVE: X
VVBE: OPEN/CLOSED
VABK1: OPEN/CLOSED
VDABK1: OPEN/CLOSED
VEBK1: OPEN/CLOSED
VDEBK1: OPEN/CLOSED
VABK2: OPEN/CLOSED
VDABK2: OPEN/CLOSED
VEBK2: OPEN/CLOSED
VDEBK2: OPEN/CLOSED
VBP: OPEN/CLOSED
VDE: OPEN/CLOSED
VDA: OPEN/CLOSED
VD OPEN/CLOSED
VZ: OPEN/CLOSED
VLA: OPEN/CLOSED
VDFF: OPEN/CLOSED
VSB: OPEN/CLOSED
VBE OPEN/CLOSED
VSAE: OPEN/CLOSED
VSAA: OPEN/CLOSED

AUTOMATIC TEST & CALIBRATION
LF: X.XX
TSD: X.X
TSE: X.X
PA: XXX
PDA: XXX

WORKING TIME COUNTER
WTC: XXXXX

FREE MEMORY (Mb)
XXXX of XXXXXX kB S: XX/XX MB

Actual Data from LLC

PUMP
BPA: X
BPAIMP_S: X
BPA_FLOW: X
BPA_COVER:OPEN/CLOSED
BPV: X
BPVIMP_S: X
BPV_COVER:OPEN/CLOSED
EP: X
FPE: X
FPA: X
UFP_S: X
UFP_FLOW: X.X
UFP_FLOW_S: X.X
BICP_S: X
BICP_FLOW: X.X
BICP_FLOW_S: X.X
KP_S: X
KP_FLOW: X.X
KP_FLOW_S: X.X
HP_POS: X.X
HPKOLB: ON/OFF
HPKRALLO: OPEN/CLOSED

BLOOD LEAK
BLCON: X.XXX
BLCON_S: X.XXX

SAD
SAD_LEVEL: XX
SAD_LEV_S: X.XXX
SAD: AIR/BLOOD
SAD_S: AIR/BLOOD

PRESSURE
PA: X
PA_S: X
PV: X
PV_S: X
PBE: X
PBS: X
PBS_S: X
PDA: X
PDA_S: X
PE: X

LEVEL
NSVB: HIGH/LOW
LAFS: HIGH/MIDDLE/LOW

TEMPERATURE
TSE XX.X
TSHE XX.X
TSBIC XX.X
TSD XX.X
TSD_S XX.X
TSDE XX.X

VALVE
VBP_S: OPEN/CLOSED
VDE_S: OPEN/CLOSED
VDA_S: OPEN/CLOSED
VD_S OPEN/CLOSED
VZ_S: OPEN/CLOSED
VLA_S: OPEN/CLOSED
VDFF_S: OPEN/CLOSED
VSB_S: OPEN/CLOSED
VBE_S: OPEN/CLOSED
VSAE_S: OPEN/CLOSED
VSAA_S: OPEN/CLOSED

BALANCE CHAMBER
MSBK1: XXXXX
MSBK2: XXXXX
VABK1_S: OPEN/CLOSED
VDABK1_S: OPEN/CLOSED
VEBK1_S: OPEN/CLOSED
VDEBK1_S: OPEN/CLOSED
VABK2_S: OPEN/CLOSED
VDABK2_S: OPEN/CLOSED
VEBK2_S: OPEN/CLOSED
VDEBK2_S: OPEN/CLOSED

COUPLINGS
BIC_SS: OPEN/CLOSED
K_SS: OPEN/CLOSED
SBS1: OPEN/CLOSED
SBS2: OPEN/CLOSED
BKUS OPEN/CLOSED
BKUS_S OPEN/CLOSED

CONDUCTIVITY
BICLF: X.XX
ENDLF X.XX
ENDLF_S X.XX

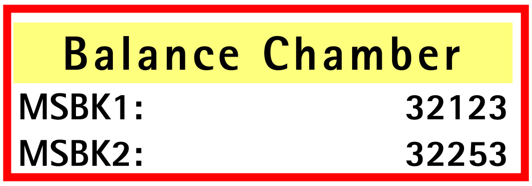
STATUS
RDV: NO BLOOD/BLOOD
RDV_S NO BLOOD/BLOOD

POWER
B24VOFF: ON/OFF
D24VOFF: ON/OFF

LLC STATUS: 00000000 0000000

LLS STATUS: 00000000

Fig.: Service Overview in TSM Service Program



Balance Chamber
MSBK1: 32123
MSBK2: 32253

Digit Range for MSBK1/2 in TSM

MSBK1/2

Min. Value:	11000
Max. Value:	34000
Differential Range:	min. 5500

Malfunctions in the balance chamber can occur if:

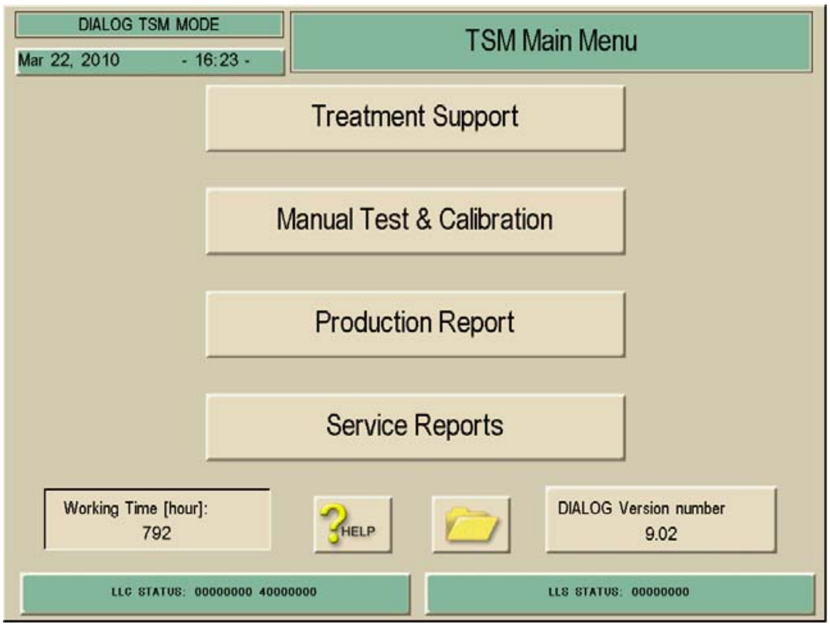
- the values are out of limits
- the minimal difference from the detected min. value was not reached

4.5.1 Legend Service Overview in TSM Service Program

B24VOFF:	24 V cut-off blood side (HP, BPA, BPV)
BIC_SS:	Bicarbonate rinsing connector sensor
BICLF:	Bicarbonate conductivity
BICP:	Bicarbonate pump
BICP_FLOW:	Bicarbonate pump flow
BICP_FLOW_S:	Bicarbonate pump flow supervisor
BICP_S:	Bicarbonate pump supervisor
BKUS:	Bottom BIC holder sensor
BKUS_S:	Bottom BIC holder sensor supervisor
BL_LAMP_T:	Blood leak detector lamp test
BLCON:	Blood leak detector
BLCON_S:	Blood leak detector supervisor
BPA:	Arterial blood pump
BPA_COVER:	Arterial blood pump cover
BPA_FLOW:	Arterial blood pump flow
BPAIMP_S:	Arterial blood pump pulse supervisor
BPV:	Venous blood pump
BPV_COVER:	Venous blood pump cover
BPVIMP_S:	Venous blood pump pulse supervisor
D24VOFF:	24 V cut-off dialysate side (VDA, VDE)
EMPTYING:	Emptying
ENDLF:	End conductivity
ENDLF_S:	End conductivity supervisor
EP:	Degassing pump
FPA:	Outlet flow pump
FPE:	Inlet flow pump
Free Memory:	Free RAM memory (DIMM/SIMM)
H:	Heater
HP_POS:	Heparin pump drive position
HPKOLB:	Heparin pump plate sensor
HPKRALLO:	Heparin pump claws
K_SS:	Concentrate rinsing connector sensor
KP:	Concentrate pump
KP_FLOW:	Concentrate pump flow
KP_FLOW_S:	Concentrate pump flow supervisor
KP_S:	Concentrate pump supervisor
LAFS:	Air separator level sensors
LEAKTEST:	Leakage test
LF:	Conductivity sensor
LLC STATUS:	Alarm messages low level controller
LLS STATUS:	Alarm messages low level supervisor
MSBK1:	Membrane position sensor balance chamber 1
MSBK2:	Membrane position sensor balance chamber 2
NSVB:	Level sensor upline tank
PA:	Arterial pressure sensor
PA_S:	Arterial pressure sensor supervisor
PBE:	Blood inlet pressure sensor
PBS:	Blood control pressure sensor
PBS_S:	Blood control pressure sensor supervisor
PDA:	Dialysate outlet pressure sensor
PDA_S:	Dialysate outlet pressure sensor supervisor
PE:	Degassing pressure sensor
PV:	Venous pressure sensor
PV_S:	Venous pressure sensor supervisor
RDV:	Venous red detector
RDV_S:	Venous red detector supervisor
RVE:	Degassing control valve

SAD:	Safety air detector
SAD_LEV_S:	Safety air detector supervisor level (voltage)
SAD_LEVEL:	Safety air detector level
SAD_S:	Safety air detector supervisor
SAD_TEST:	Safety air detector test
SBS1:	Rinsing bridge connector sensor 1
SBS2:	Rinsing bridge connector sensor 2
TSBIC:	Bicarbonate temperature sensor
TSD:	Dialysate temperature sensor
TSD_S:	Dialysate temperature sensor supervisor
TSE:	Degassing temperature sensor
TSHE:	Heater inlet temperature sensor
TSDE:	Dialyser inlet temperature sensor
UFP:	Ultrafiltration pump
UFP_FLOW:	Ultrafiltration pump flow
UFP_FLOW_S:	Ultrafiltration pump flow supervisor
UFP_S:	Ultrafiltration pump supervisor
VABK1:	Outlet valve balance chamber 1
VABK1_S:	Outlet valve balance chamber 1 supervisor
VABK2:	Outlet valve balance chamber 2
VABK2_S:	Outlet valve balance chamber 2 supervisor
VBE:	Filter vent valve
VBE_S:	Vent filter valve supervisor
VBP:	By-pass valve
VBP_S:	By-pass valve supervisor
VD:	Disinfection valve
VD_S:	Disinfection valve supervisor
VDA:	Dialyser outlet valve
VDABK1:	Dialyser outlet valve balance chamber 1
VDABK1_S:	Dialyser outlet valve balance chamber 1 supervisor
VDABK2:	Dialyser outlet valve balance chamber 2
VDABK2_S:	Dialyser outlet valve balance chamber 2 supervisor
VDA-S:	Dialyser outlet valve supervisor
VDE:	Dialyser inlet valve
VDEBK1:	Dialyser inlet valve balance chamber 1
VDEBK1_S:	Dialyser inlet valve balance chamber 1 supervisor
VDEBK2:	Dialyser inlet valve balance chamber 2
VDEBK2_S:	Dialyser inlet valve balance chamber 2 supervisor
VDE-S:	Dialyser inlet valve supervisor
VDFF:	DF filter valve
VDFF_S:	DF filter valve supervisor
VEBK1:	Inlet valve balance chamber 1
VEBK1_S:	Inlet valve balance chamber 1 supervisor
VEBK2:	Inlet valve balance chamber 2
VEBK2_S:	Inlet valve balance chamber 2 supervisor
VLA:	Air separator valve
VLA_S:	Air separator valve supervisor
VSAA:	Substitution outlet valve
VSAA_S:	Substitution outlet valve supervisor
VSAE:	Substitution inlet valve
VSAE_S:	Substitution inlet valve supervisor
VSB:	Substitution bypass valve
VSB_S:	Substitution bypass valve supervisor
VVBE:	Upline tank inlet valve
VZ:	Circulation valve
VZ_S:	Circulation valve supervisor
WTC:	Working time counter

4.6 File Operations



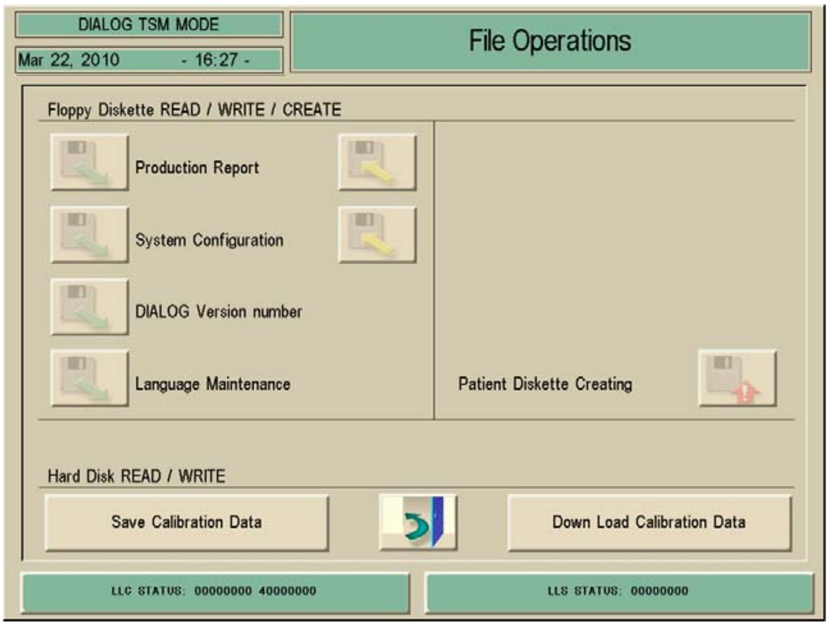
Mar 22, 2010 - 16:23 -

Working Time [hour]: 792

DIALOG Version number 9.02

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000



Mar 22, 2010 - 16:27 -

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

The *File Operations* menu is selected with the *File* icon in *TSM Main Menu*.

The following parameters can be selected:

Floppy Diskette Read/Write/Create
Not applicable.

Hard Disk (Compact Flash Card) Read/Write

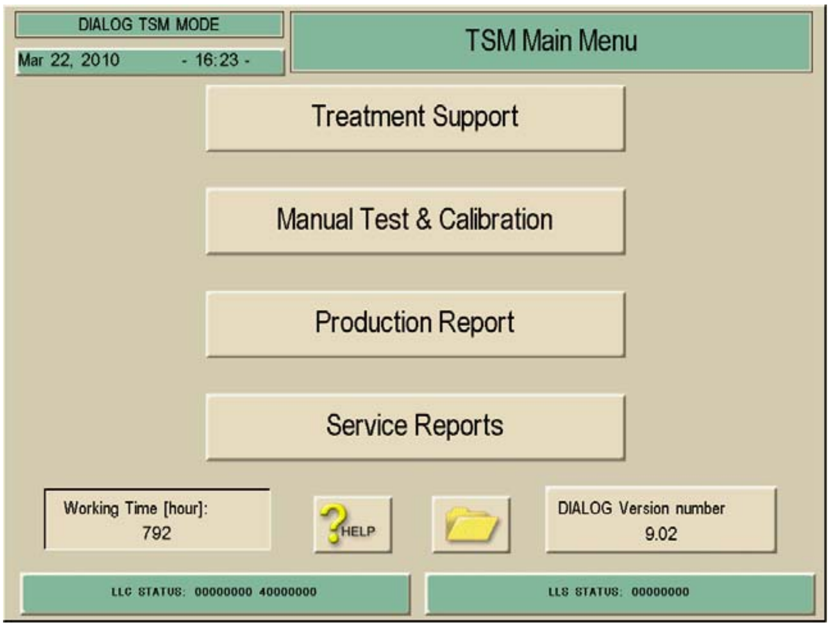
- Save Calibration Data
- Down Load Calibration Data

The Field Service Utilities FSU can be used for all relevant service activities. Details can be found in chapter 2 repair instructions.

4.6.1 Hard Disk Read/Write

Save Calibration Data	The calibration data must be saved to the compact flash card CFC (hard disk drive) by LLC/LLS after every calibration.
Down Load Calibration Data	The calibration data can be downloaded from the compact flash card CFC (hard disk drive) to the exchanged digital board DB.

4.6.2 Dialog Version Number



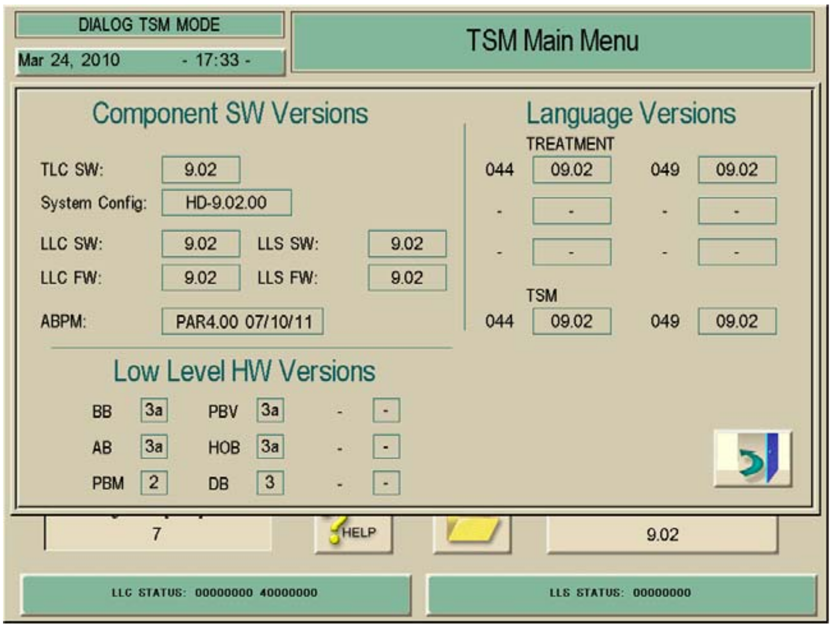
Mar 22, 2010 - 16:23 -

Working Time [hour]: 792

DIALOG Version number 9.02

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000



Mar 24, 2010 - 17:33 -

TLC SW: 9.02

System Config: HD-9.02.00

LLC SW: 9.02 LLS SW: 9.02

LLC FW: 9.02 LLS FW: 9.02

ABPM: PAR4.00 07/10/11

TREATMENT: 044 09.02 049 09.02; - - - -; - - - -

TSM: 044 09.02 049 09.02

BB 3a PBV 3a - -

AB 3a HOB 3a - -

PBM 2 DB 3 - -

7

9.02

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

The *Dialog Version Number* menu is selected with the *Dialog Version Number* window in *TSM Main Menu*. The current software/firmware versions are displayed. This menu can also be selected in the *Production Report*.

The following data can be checked:

Component Software Versions

The versions for the installed software/firmware are displayed.

- Top Level Controller Software TLC SW
- System Configuration
  (displays the system configuration version number for the haemodialysis machine)
- Low Level Controller Software LLC SW
- Low Level Controller Firmware LLC FW
- Low Level Supervisor Software LLS SW
- Low Level Supervisor Firmware LLS FW
- Automatic Blood Pressure Measurement ABPM (firmware for the ABPM module is displayed)

Language Versions

The installed languages are displayed.

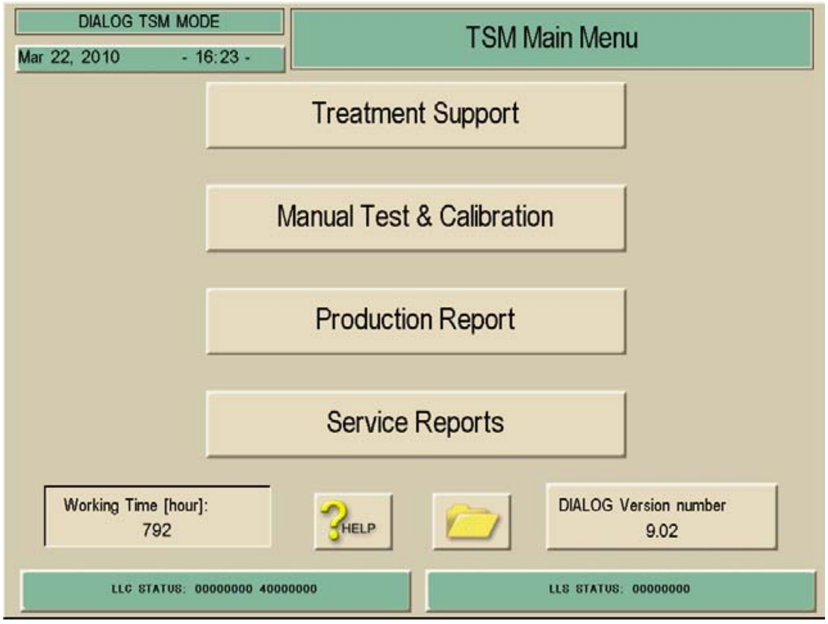
- Treatment
- TSM

Low Level Hardware Versions

The boards are displayed with the respective hardware versions, e.g. a HDF online machine. The displayed HW versions depend on the assembled boards in the machine.

- Basic Board **BB**
- Analog Board **AB**
- Power Board Motors **BPM**
- Power Board Valves **BPV**
- HDF Online Board **HOB**
- Digital Board **DB**

4.7 Treatment Support



Mar 22, 2010 - 16:23 -

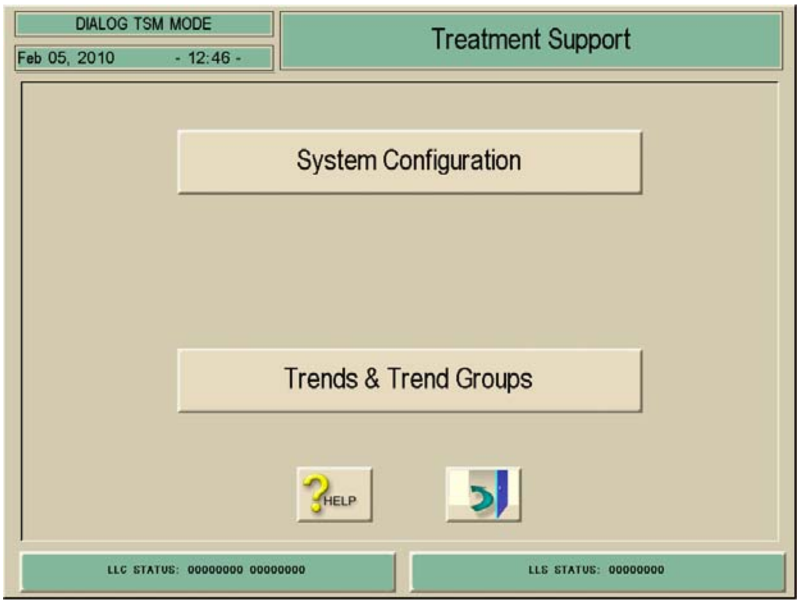
Working Time [hour]: 792

DIALOG Version number 9.02

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

1. Activate the *Treatment Support* menu with the *Treatment Support* key in menu *TSM Main Menu*. The following menu is opened.



Feb 05, 2010 - 12:46 -

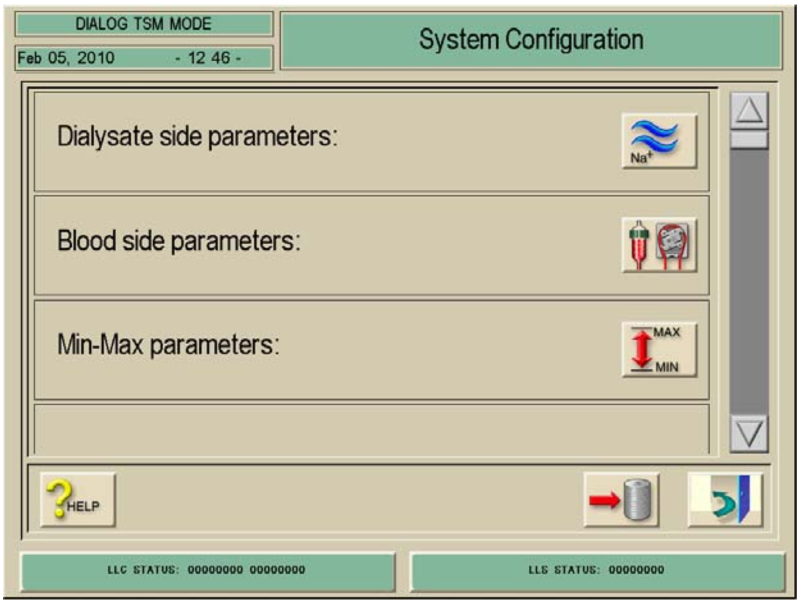
LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

Two sub-menus can be selected in the *Treatment Support* menu.

System Configuration	This is a special editor to set the configuration of the treatment mode (e.g. limits, default values). The new settings are valid after the restart of the machine.
Trends and Trend Groups	There are five trend groups, which can be selected for the treatment program. Every group has three treatment parameters.

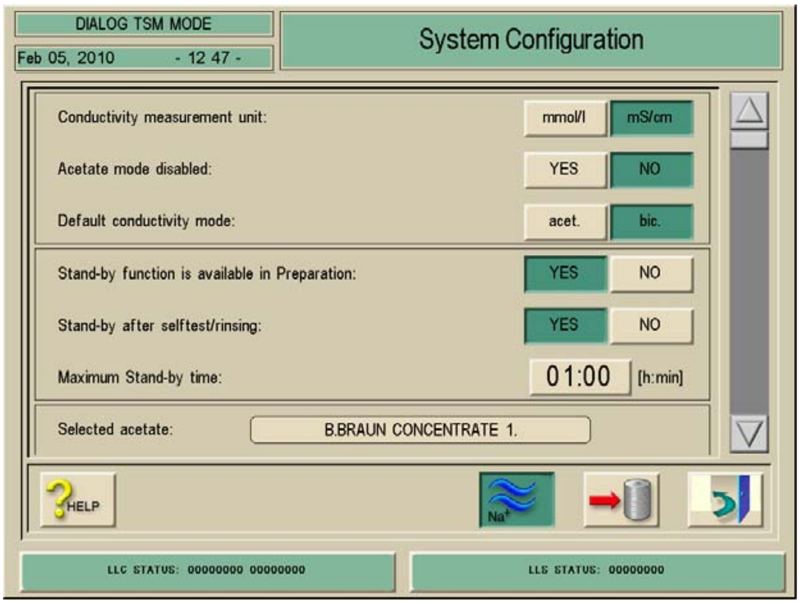
4.7.1 System Configuration



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*.
   The following menu is opened.

Scroll the various system configuration points up or down with the scroll bar. System configuration points can be selected (additional settings are activated if specific options are selected).

4.7.1.1 Dialysate Side Parameters



Conductivity measurement unit: mmol/l [✓ mS/cm]

Acetate mode disabled: YES [✓ NO]

Default conductivity mode: acet. [✓ bic.]

Stand-by function is available in Preparation: [✓ YES] NO

Stand-by after selftest/rinsing: [✓ YES] NO

Maximum Stand-by time: 01:00 [h:min]

Selected acetate: B.BRAUN CONCENTRATE 1.

The dialysate fluid parameters can be set in the *Dialysate Side Parameters* menu.

1. Activate the *Dialysate Side Parameters* menu with the *Dialysate Side Parameters* icon. The following menu is opened.

The following parameters can be set:

- Conductivity measurement unit
- Acetate Mode Disabled
- Default Conductivity Mode
- Stand-by Function is Available in Preparation
- Stand-by after Self Test
- Maximum Stand-by Time
- Selected Acetate (only necessary if mmol/l is selected)
- Selected Bicarbonate/Selected Acid (only necessary if mmol/l is selected)
- Temperature Measurement unit
- Dialysate Flow
- Dialysate Temperature

Conductivity Measurement Unit

Make sure that the corresponding conversion factor is set and assigned correctly:

- **conversion factor for the conductivity unit mS/cm**
- **conversion factor for the concentration unit mmol/l.**

You can either select conductivity [mS/cm] or sodium concentration [mmol/l] for the conductivity measurement unit. If sodium concentration [mmol/l] is selected a corresponding conversion factor must be entered. Activate the *ACET* or *BIC* icon to enter the corresponding conversion factor.

1. Click the *mmol/l* or *mS/cm* key to select a measurement unit.

Acetate Mode Disabled

The acetate mode can be disabled.

1. Click the *YES* key to disable the acetate mode.

Default Conductivity Mode

The bicarbonate dialysis is the standard factory setting. You can preselect either acetate or bicarbonate for the standard dialysis operation mode.

1. Click either the *Bic* or *Acet* key for the standard setting.

Stand-by Function is Available in Preparation

The stand-by function is available during preparation.

1. Click the *NO* key to disable the stand-by function in preparation.

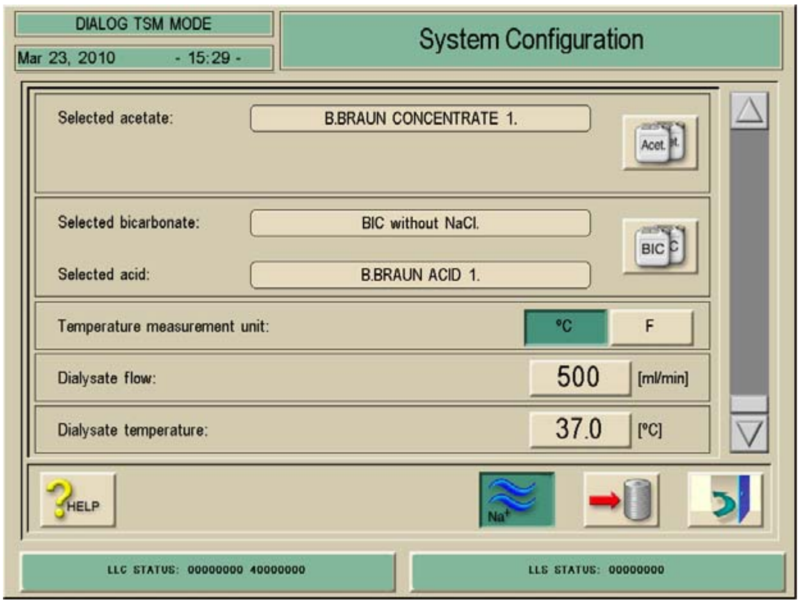
Stand-by after Self Test/Rinsing

The function is activated after the self test/rinsing.

Maximum Stand-by Time

You can set the maximum duration of the stand-by state.

Selected Acetate



DIALOG TSM MODE
Mar 23, 2010 - 15:29 -
System Configuration

Selected acetate: B.BRAUN CONCENTRATE 1.

Selected bicarbonate: BIC without NaCl.

Selected acid: B.BRAUN ACID 1.

Temperature measurement unit: °C F

Dialysate flow: 500 [ml/min]

Dialysate temperature: 37.0 [°C]

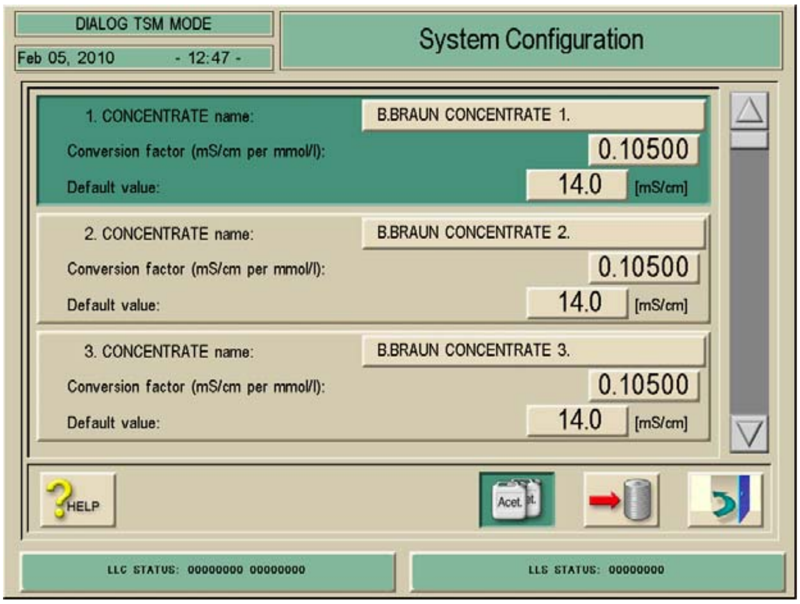
LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

There are 10 acetate concentrate names and the conversion factors for the conversion of conductivity values for concentrate of sodium ions.

If necessary the name and the conversion factor [mS/cm per mmol/l] can be set, for the selected acetate type.

1. Click the ACET icon to activate the *Selected Acetate* menu.



DIALOG TSM MODE
Feb 05, 2010 - 12:47 -
System Configuration

1. CONCENTRATE name: B.BRAUN CONCENTRATE 1.
Conversion factor (mS/cm per mmol/l): 0.10500
Default value: 14.0 [mS/cm]

2. CONCENTRATE name: B.BRAUN CONCENTRATE 2.
Conversion factor (mS/cm per mmol/l): 0.10500
Default value: 14.0 [mS/cm]

3. CONCENTRATE name: B.BRAUN CONCENTRATE 3.
Conversion factor (mS/cm per mmol/l): 0.10500
Default value: 14.0 [mS/cm]

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

The following menu is opened. You can activate a concentrate for therapy by pressing a free section of the window.

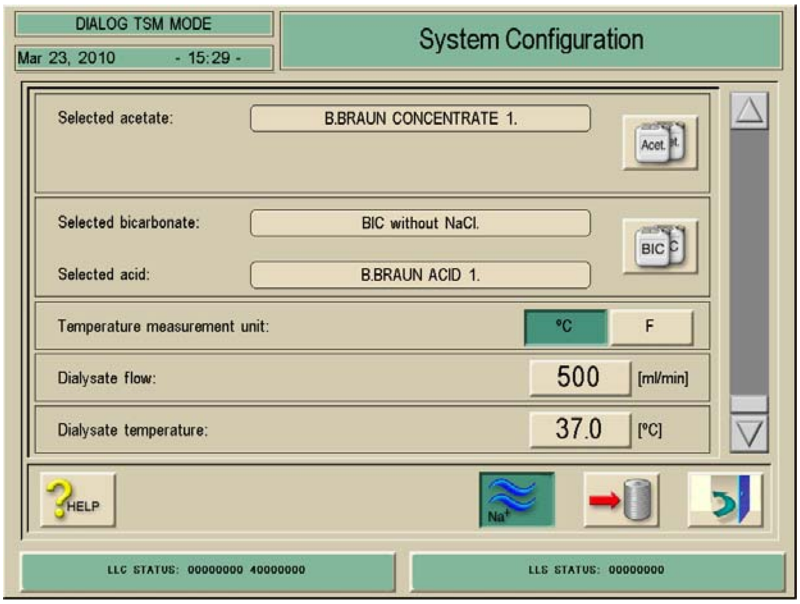
2. Click the *Concentrate* window if necessary to edit a concentrate name. This name is displayed in therapy mode.
3. Click the *Conversion* window if necessary to change the conversion factor [mS/cm per mmol/l].

Conversion Factor:

$$\frac{\text{Conductivity mS/cm (Standard Value)}}{\text{NaCl Concentration mmol/l (Measured Value)}} = \text{Conversion Factor}$$

4. Click the *Default Value* window if necessary to change the value [mS/cm].

Selected Bicarbonate/Selected Acid



DIALOG TSM MODE

Mar 23, 2010 - 15:29 -

System Configuration

Selected acetate: B.BRAUN CONCENTRATE 1.

Selected bicarbonate: BIC without NaCl.

Selected acid: B.BRAUN ACID 1.

Temperature measurement unit: °C F

Dialysate flow: 500 [ml/min]

Dialysate temperature: 37.0 [°C]

LLC STATUS: 00000000 40000000

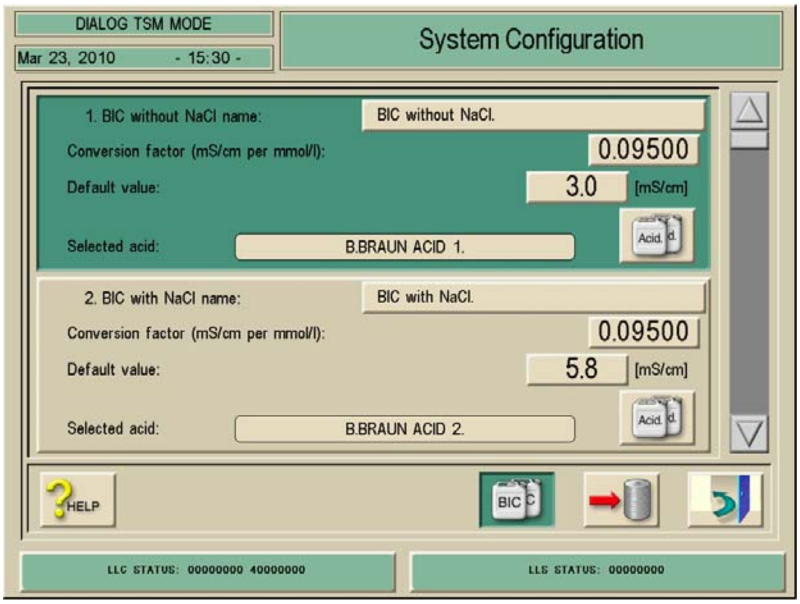
LLS STATUS: 00000000

There are 20 concentrate names and the conversion factors for the conversion of conductivity values.

If necessary the name and the conversion factor [mS/cm per mmol/l] can be set, for the selected bicarbonate type.

1. Click the *BIC* icon to activate the menu for:
   - *BIC without NaCl*
   - *BIC with NaCl.*

BIC without NaCl



DIALOG TSM MODE

Mar 23, 2010 - 15:30 -

System Configuration

1. BIC without NaCl name: BIC without NaCl.

Conversion factor (mS/cm per mmol/l): 0.09500

Default value: 3.0 [mS/cm]

Selected acid: B.BRAUN ACID 1.

2. BIC with NaCl name: BIC with NaCl.

Conversion factor (mS/cm per mmol/l): 0.09500

Default value: 5.8 [mS/cm]

Selected acid: B.BRAUN ACID 2.

LLC STATUS: 00000000 40000000

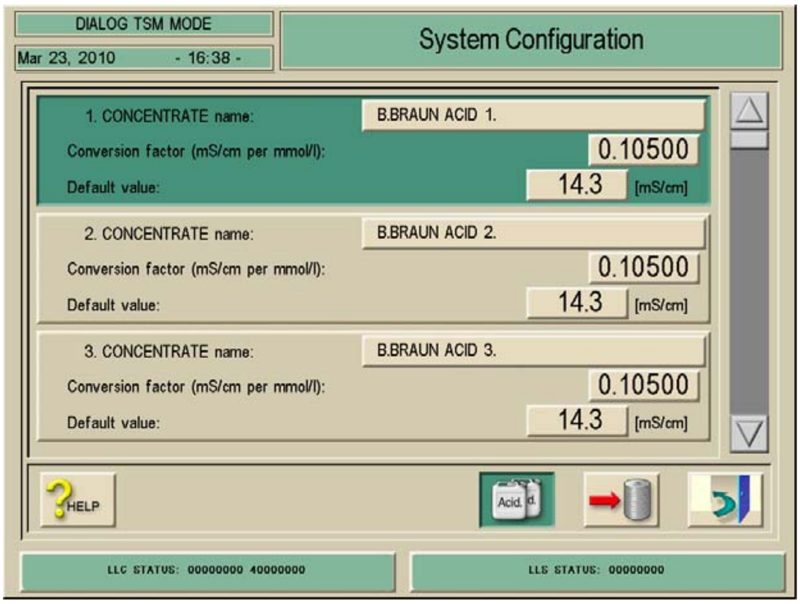
LLS STATUS: 00000000

The current bicarbonate type without NaCl can be selected:

- Bicarbonate without NaCl (2 - 4 mS/cm)

Activate *BIC without NaCl* by pressing a free section of the window.

1. Click the *BIC without NaCl* window if necessary to edit the bicarbonate name.
2. Click the *Conversion* window if necessary to change the conversion factor [mS/cm per mmol/l].
3. Click the *Default Value* window if necessary to change the value [mS/cm].
4. Click the ACID icon if necessary to edit the following parameters:
   - Acid Concentrate Name
   - Conversion Factor [mS/cm per mmol/l]
   - Default Value



DIALOG TSM MODE

Mar 23, 2010 - 16:38 -

System Configuration

1. CONCENTRATE name: B.BRAUN ACID 1.

Conversion factor (mS/cm per mmol/l): 0.10500

Default value: 14.3 [mS/cm]

2. CONCENTRATE name: B.BRAUN ACID 2.

Conversion factor (mS/cm per mmol/l): 0.10500

Default value: 14.3 [mS/cm]

3. CONCENTRATE name: B.BRAUN ACID 3.

Conversion factor (mS/cm per mmol/l): 0.10500

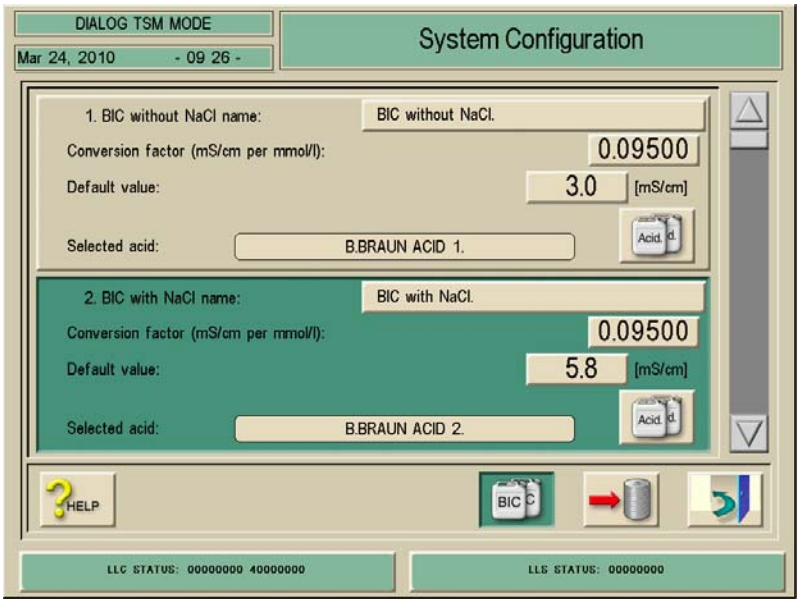
Default value: 14.3 [mS/cm]

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

BIC with NaCl

Machines with a BIC Cartridge Option
It is prohibited to use (select/activate) a bicarbonate concentrate with NaCl if the machine has a BIC cartridge holder.
The unit mmol/l (NaCl concentration) must not be used if bicarbonate concentrate with NaCl is applied.

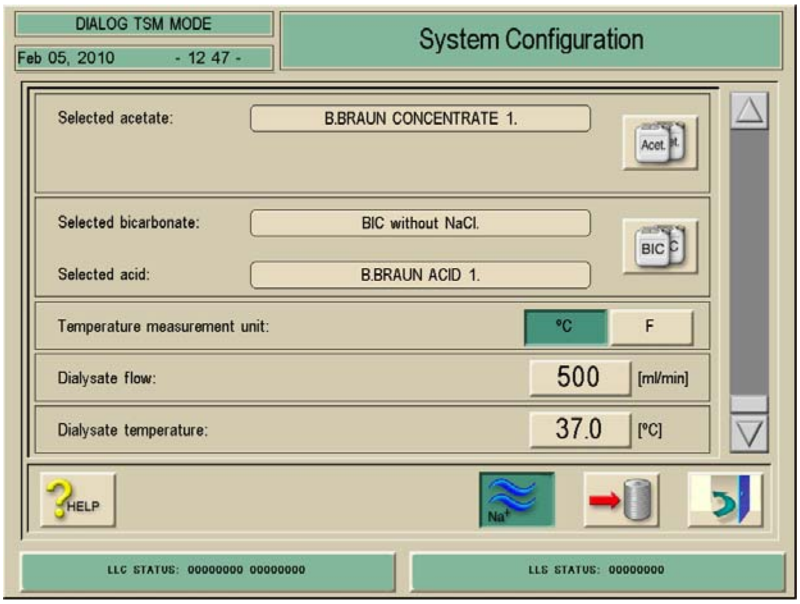


DIALOG TSM MODE
Mar 24, 2010 - 09 26 -
System Configuration

1. BIC without NaCl name: BIC without NaCl.
Conversion factor (mS/cm per mmol/l): 0.09500
Default value: 3.0 [mS/cm]
Selected acid: B.BRAUN ACID 1.

2. BIC with NaCl name: BIC with NaCl.
Conversion factor (mS/cm per mmol/l): 0.09500
Default value: 5.8 [mS/cm]
Selected acid: B.BRAUN ACID 2.

LLC STATUS: 00000000 40000000
LLS STATUS: 00000000



DIALOG TSM MODE
Feb 05, 2010 - 12 47 -
System Configuration

Selected acetate: B.BRAUN CONCENTRATE 1.

Selected bicarbonate: BIC without NaCl.
Selected acid: B.BRAUN ACID 1.

Temperature measurement unit: °C F
Dialysate flow: 500 [ml/min]
Dialysate temperature: 37.0 [°C]

LLC STATUS: 00000000 00000000
LLS STATUS: 00000000

You can select the current bicarbonate type with NaCl:

- Bicarbonate with NaCl (4 - 7 mS/cm)

The *BIC with NaCl* is activated by pressing a free section of the window.

The current acetate concentrate can be selected. The name and the conversion factor [mS/cm per mmol/l] can be entered if necessary for the different acetate concentrates.

1. Click the *BIC with NaCl* window if necessary to edit the bicarbonate name.
2. Click the *Conversion* window if necessary to change the conversion factor [mS/cm per mmol/l].
3. Click the *Default Value* window if necessary to change the value [mS/cm].
4. Click the ACID icon if necessary to edit the following parameters:
   - Acid Concentrate Name
   - Conversion Factor [mS/cm per mmol/l]
   - Default Value
5. Scroll down to the end to set further parameters.

Temperature Measurement Unit

You can set the temperature measurement unit between ^{0}C and F.

1. Click the *F* key to set to Fahrenheit.

Dialysate Flow

You can preset the dialysate flow for therapy.

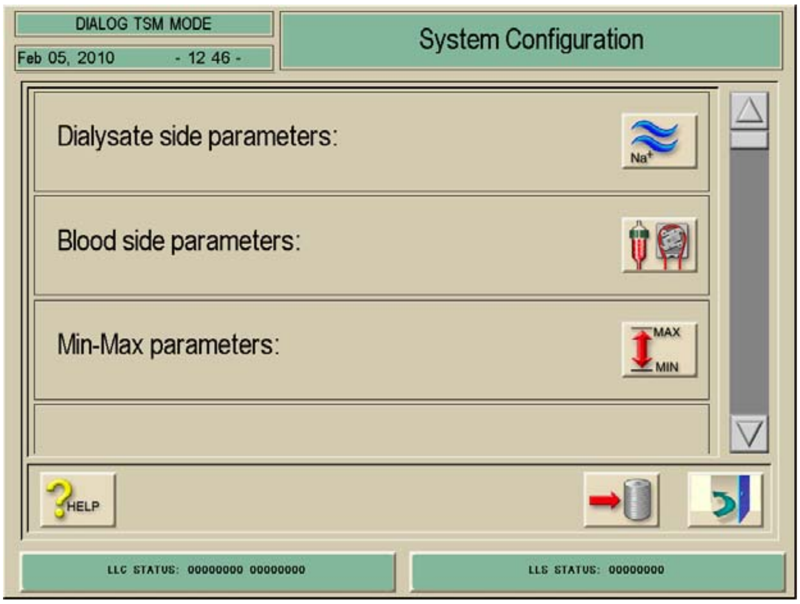
1. Click the *ml/min* key to set the dialysate flow.

Dialysate Temperature

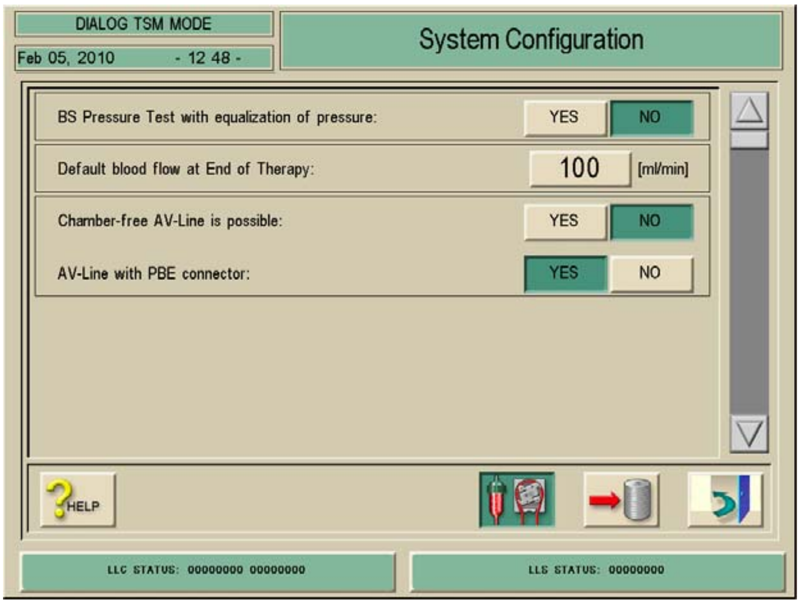
You can set the dialysate temperature for therapy.

1. Click the ^{0}C key to set the dialysate temperature.

4.7.1.2 Blood Side Parameters



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. Use the scroll bar until the following menu appears.



BS Pressure Test with equalization of pressure: YES [✓ NO]

Default blood flow at End of Therapy: 100 [ml/min]

Chamber-free AV-Line is possible: YES [✓ NO]

AV-Line with PBE connector: [✓ YES] NO

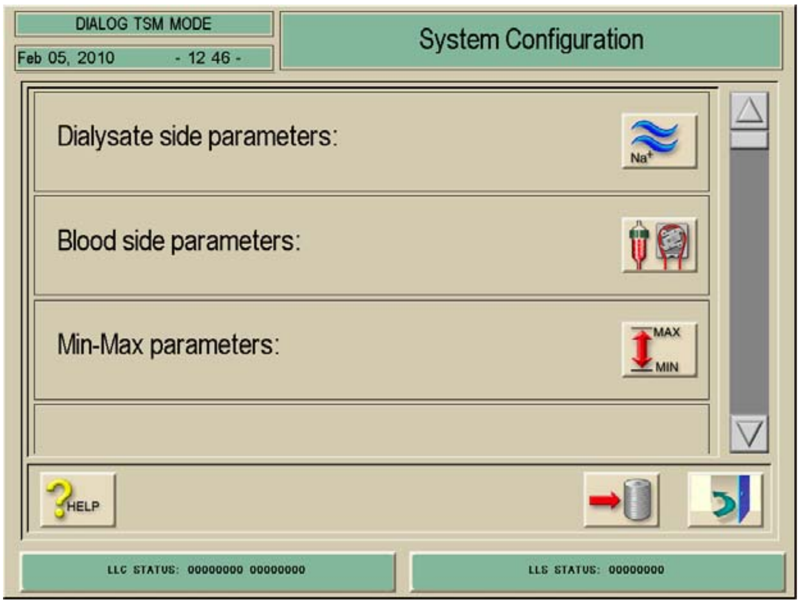
2. Activate the *Blood Side Parameters* menu with the *Blood Side* icon. The following menu is opened.

The following parameters can be set:

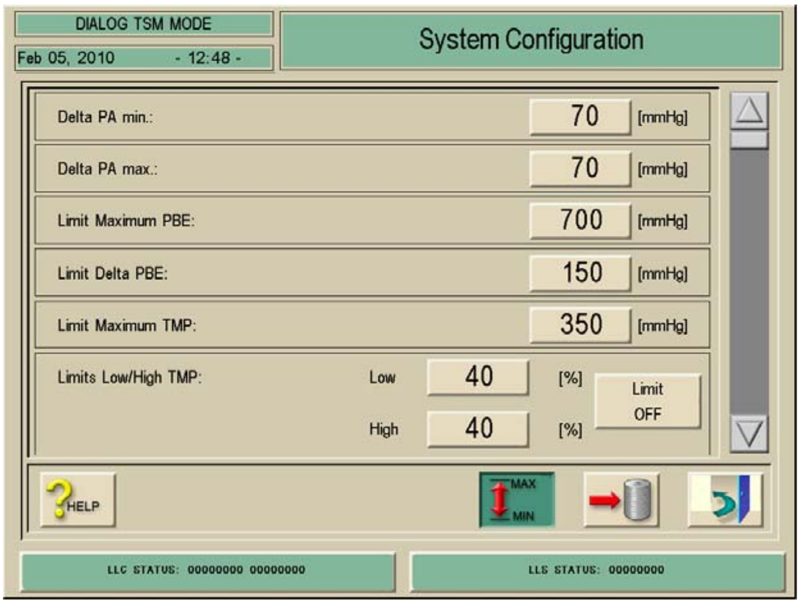
- Blood Side BS Pressure Test with Equalisation of Pressure
- Default Blood Flow at End of Therapy
- Chamber-free AV Line is Possible
- AV Line with PBE Connector

Blood Side BS Pressure Test with Equalisation of Pressure	**YES** If the *YES* key is pressed: The system performs a relief (equalisation) of the pressure at the end of the blood side BS pressure test via the main flow (dialyser). **NO** If the *NO* key is pressed: The system does not perform a relief (equalisation) of the pressure at the end of the blood side BS pressure test (venous tubing clamp SAKV opens and some fluid escapes from the venous line, as before).
Default Blood Flow at End of Therapy	You can preselect the blood flow which will be preset at the end of a therapy. 1. Click the *ml/min* key to set the default blood flow at the end of a therapy.
Chamber-free AV Line is Possible	**YES** The chamber symbols can not be selected in the level regulation menu in therapy. The selected *Chamber-free AV Line* appears. **NO** The chamber symbols can be selected in the level regulation menu in therapy. The selected *Chamber-free AV Line* does not appear.
AV Line with PBE Connector	**YES** Activate if AV lines with PBE pressure connection are used. **NO** Do not activate if AV lines without PBE pressure connection are used.

4.7.1.3 Min-Max Parameters



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. Use the scroll bar until the following menu appears.



Delta PA min.: 70 [mmHg]
Delta PA max.: 70 [mmHg]
Limit Maximum PBE: 700 [mmHg]
Limit Delta PBE: 150 [mmHg]
Limit Maximum TMP: 350 [mmHg]
Limits Low/High TMP: Low 40 [%] High 40 [%] Limit OFF

2. Activate the *Min-Max Parameters* menu with the *MIN-Max* icon. The following menu is opened.

The following parameters can be set in the *Min-Max Parameters* menu:

- Delta PA min.
- Delta PA max.
- Limit Maximum PBE
- Limit Delta PBE
- Limit Maximum TMP
- Limits Low/High TMP
- Extended TMP Limit Range Key is Displayed in Treatment
- Select Extended TMP Limit Range

Delta PA min. You can set the lower relative alarm limit for the PA limit window.

Delta PA max. You can set the upper relative alarm limit for the PA limit window.

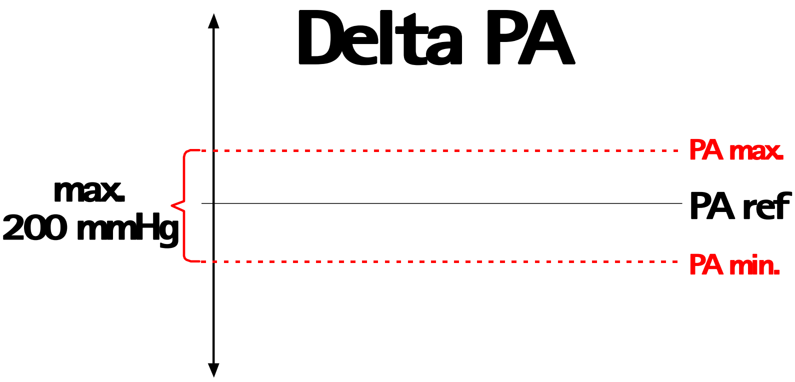
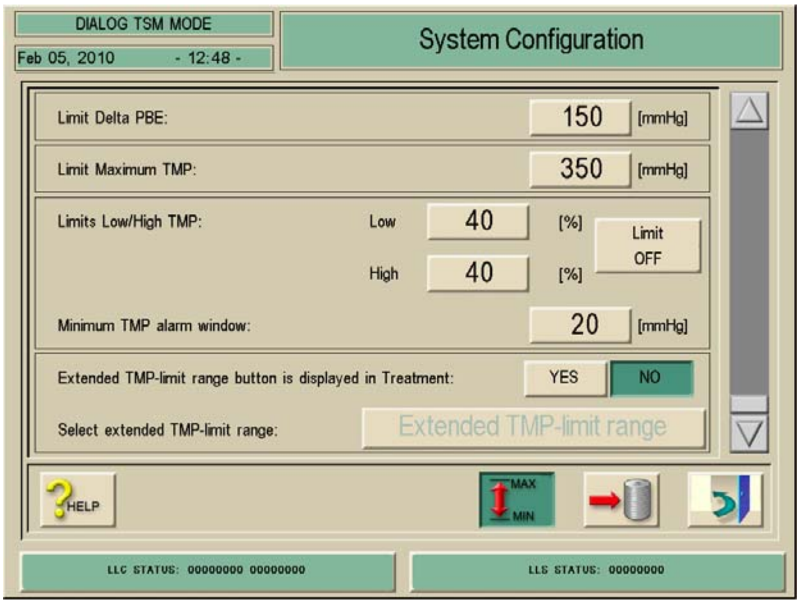


Fig.: Limit Window for PA

Limit Maximum PBE	The maximum limit for the monitoring of PBE in therapy can be set.
Limit Delta PBE	The permissible changes for PBE during therapy can be set.
Limit Maximum TMP	The maximum upper TMP limit for the monitoring in therapy can be set. This value is always active if no relative monitoring is active (see description for *Limits Low/High*).
Limits Low/High TMP	The relative lower and upper limit can be set in % for TMP monitoring in therapy.
	Limit OFF: (activated) Monitoring is not performed
	Limit OFF: (deactivated) Monitoring is performed
Minimum TMP Alarm Window	The limit window is at least as large as predefined independent of the relative low and high limit. The default is 20 mmHg and can be changed in the limits of 20 to 100 mmHg.


DIALOG TSM MODE
Feb 05, 2010 - 12:48 -
System Configuration

Limit Delta PBE: 150 [mmHg]

Limit Maximum TMP: 350 [mmHg]

Limits Low/High TMP: Low 40 [%] High 40 [%]

Minimum TMP alarm window: 20 [mmHg]

Extended TMP-limit range button is displayed in Treatment: YES NO

Select extended TMP-limit range: Extended TMP-limit range

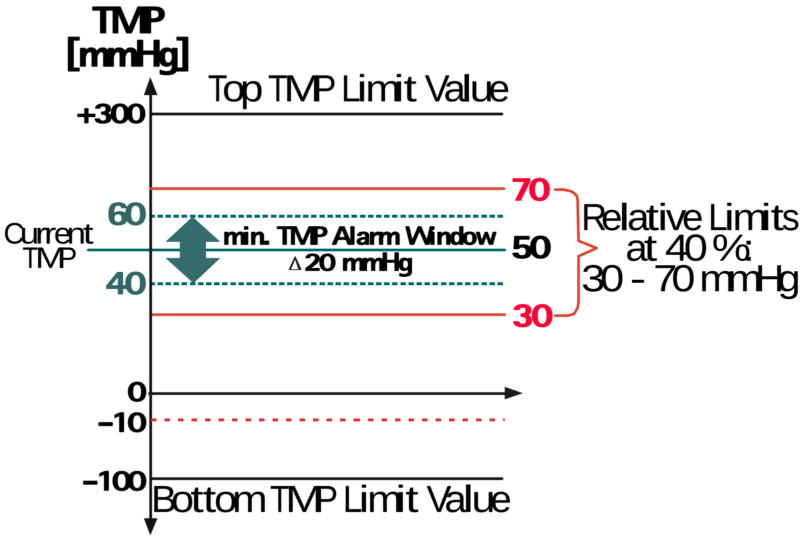
LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

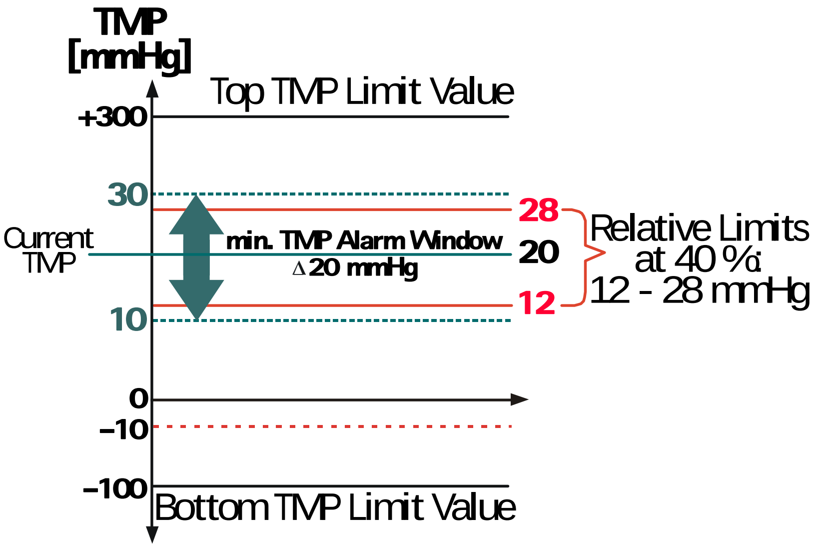
3. Use the scroll bar until the following menu appears.

Extended TMP Limit Range Key **is Displayed in Treatment**	The user can select the extended TMP range.
NO	The *Extended TMP Limit Range* key can not be selected/enabled (shaded) if *NO* is selected.
YES	The *Extended TMP Limit Range* key can be selected/enabled (highlighted) if *YES* is selected.
Select Extended TMP Limit Range	If the key was selected, the extended TMP limit range can be preselected during the start of the therapy via the *Extended TMP Limit Range*.
If the key is not pressed	The TMP low limit range is set min. –10 mmHg.
If the key is pressed	The TMP limit range is extended to –100 mmHg (absolute TMP value).

Standard TMP Limit Range



Example A



Example B

If the *Standard TMP Limit Range* key is not pressed:

- the TMP low limit range is set min. –10 mmHg.

If the normal window limits are reached:

- a warning message is displayed (in alarm window)
- a warning tone is activated.
- treatment is not interrupted

Once the TMP reaches -10 mmHg:

- a warning message is displayed (in alarm window)
- a warning tone is activated
- an additional information is displayed
- treatment is not interrupted

The absolute limit value is -100 mmHg.

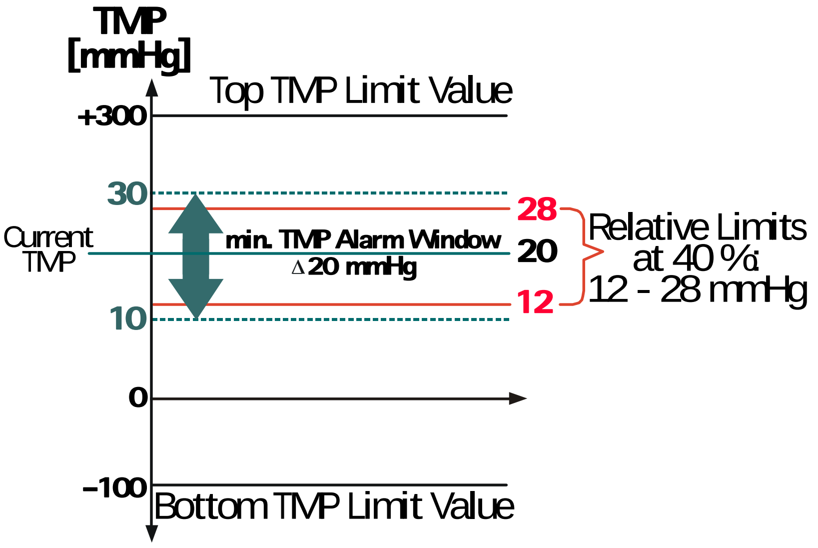
Once the absolute TMP value is reached:

- an alarm is activated
- an alarm tone is activated
- treatment is interrupted
- machine is switched to bypass

In example **A** the min. TMP alarm window (40 to 60 mmHg) is smaller than the relative limits of 30 to 70 mmHg. Thus the relative limits are valid.

In example **B** the min. TMP alarm window (10 to 30 mmHg) is larger than the relative limits of 12 to 28 mmHg. Thus the limits of the min. TMP alarm window are valid.

Extended TMP Limit Range



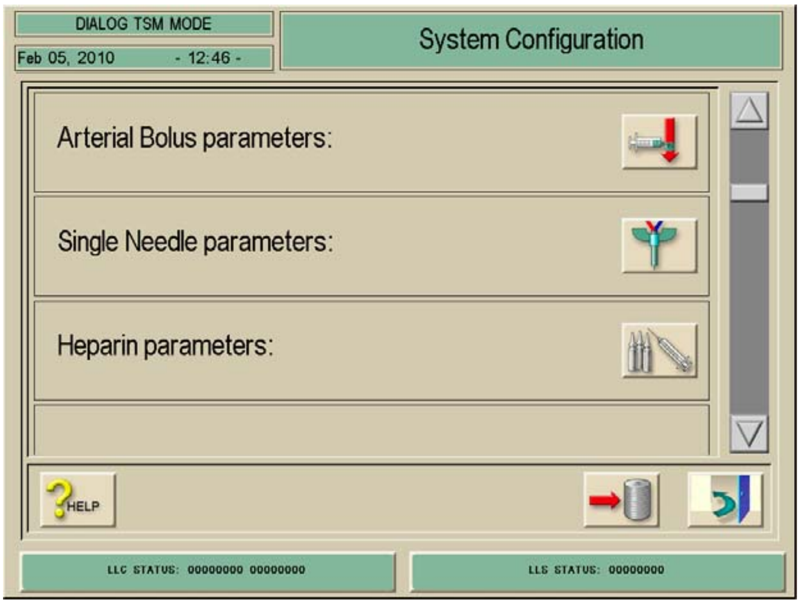
If the *Extended TMP Limit Range* key is pressed:

- the TMP limit range is extended to –100 mmHg (absolute TMP limit).

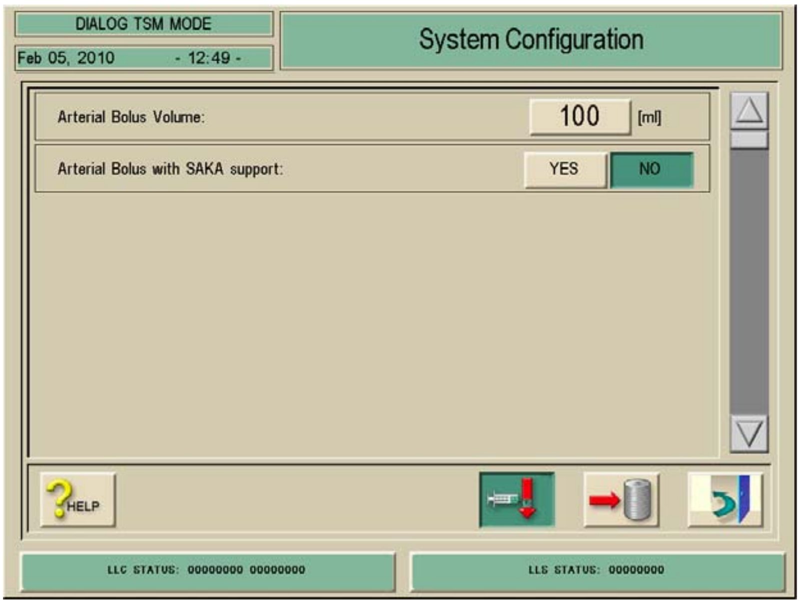
Once this absolute TMP limit is reached:

- an alarm is activated
- an alarm tone is activated
- a warning message is not displayed anymore
- treatment is interrupted
- machine is switched to bypass

4.7.1.4 Arterial Bolus Parameters



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. Use the scroll bar until the following menu appears.



Arterial Bolus Volume: 100 [ml]

Arterial Bolus with SAKA support: YES [✓ NO]

2. Activate the *Arterial Bolus Parameters* menu with the *Arterial Bolus* icon. The following menu is opened.

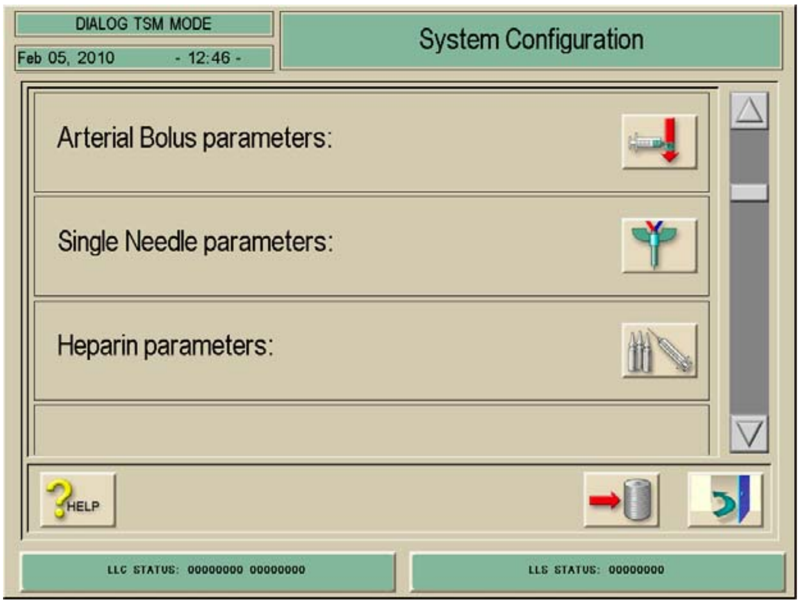
The following parameters can be set in the *Arterial Bolus Parameters* menu:

- Arterial Bolus Volume
- Arterial Bolus with SAKA Support

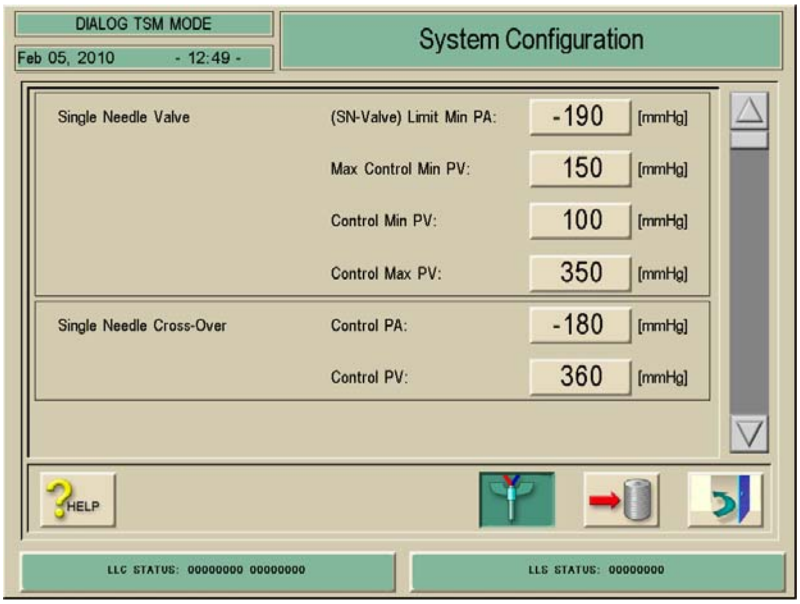
Arterial Bolus Volume	The volume for an arterial bolus can be set.
Arterial Bolus with SAKA Support	The arterial tubing clamp SAKA can be used to support an arterial bolus in the *Arterial Bolus Parameters* menu. Prerequisites are:

- Arterial tubing clamp SAKA present
- An arterial line system with infusion access is present between the SAKA and blood pump

4.7.1.5 Single-Needle Parameters



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. Use the scroll bar until the following menu appears.



Single Needle Valve
(SN-Valve) Limit Min PA: -190 [mmHg]
Max Control Min PV: 150 [mmHg]
Control Min PV: 100 [mmHg]
Control Max PV: 350 [mmHg]

Single Needle Cross-Over
Control PA: -180 [mmHg]
Control PV: 360 [mmHg]

2. Activate the *Single-Needle Parameters* menu with the *Single-Needle* icon.

The following parameters can be set:

Single-Needle Valve (Control Pressures)

- (Single-Needle SN Valve) Limit Min PA
- Max Control Min PV
- Control Min PV
- Control Max. PV

Single-Needle Cross-Over (Control Pressures)

- Control PA
- Control PV

Single-Needle Valve

(Single-Needle SN Valve) Limit Minimum PA
The minimum limit of the arterial pressure PA can be set for the single-needle valve mode.

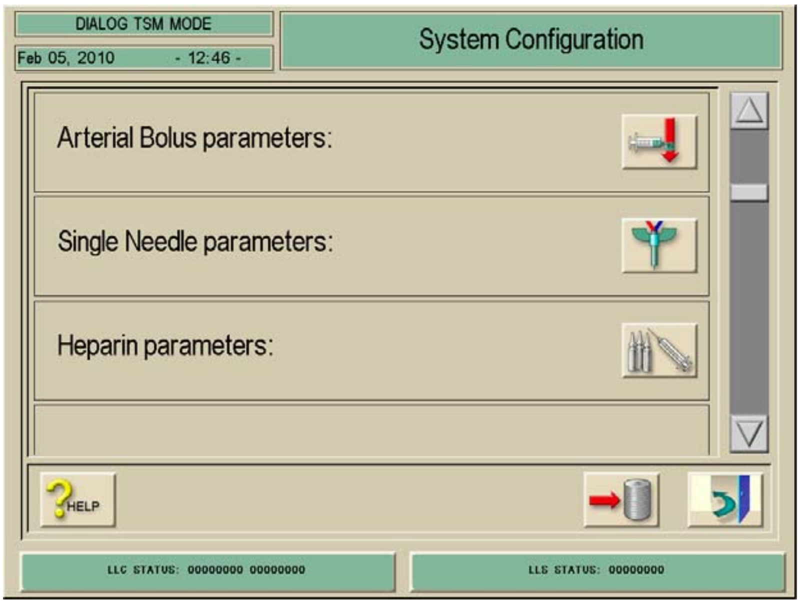
Maximum Control Minimum PV
The maximum lower venous control pressure can be set for the *Single-Needle Valve* option. For safety reasons it is necessary to limit the maximum value for the lower venous control pressure for the SN valve. The maximum setting is 150 mmHg (default setting).

Furthermore the control pressure PV can be set. Thereby the blood pump is started/stopped and the venous tubing clamp currentless closed SAKV-SG is opened/closed.

Single-Needle Cross-Over

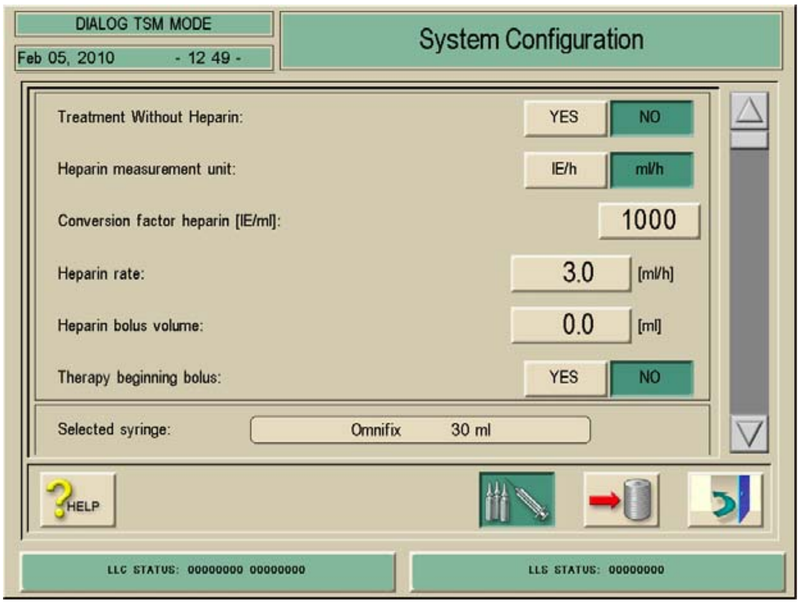
The control pressures for PA and PV can be set for single-needle cross-over.

4.7.1.6 Heparin Parameters



You can set the parameters in the Heparin Parameters menu and select a syringe type.

1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened.



Treatment Without Heparin: YES [✓ NO]
Heparin measurement unit: IE/h [✓ ml/h]
Conversion factor heparin [IE/ml]: 1000
Heparin rate: 3.0 [ml/h]
Heparin bolus volume: 0.0 [ml]
Therapy beginning bolus: YES [✓ NO]
Selected syringe: Omnifix 30 ml

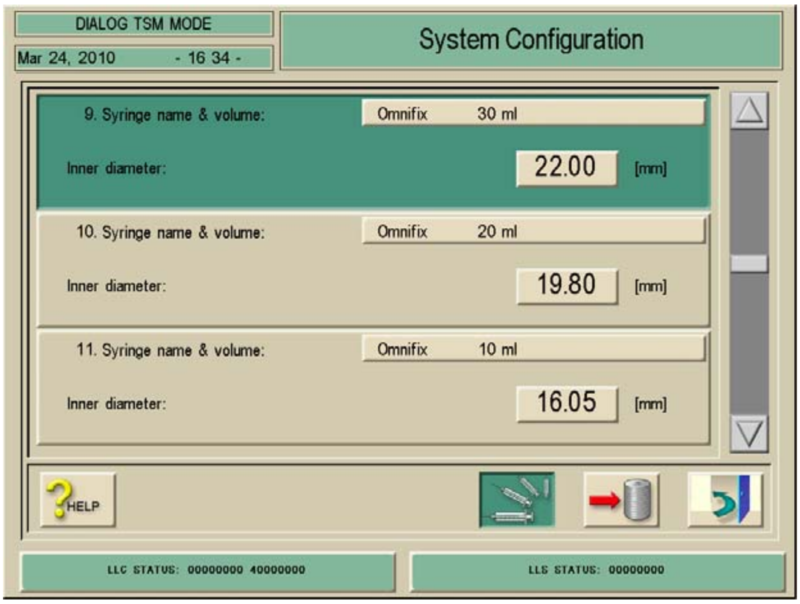
2. Activate the *Heparin Parameters* menu with the *Heparin Parameters* icon. The following menu is opened.

The following parameters can be set:

- Treatment without heparin
- Heparin measurement unit
- Conversion factor heparin [IE/ml]
- Heparin rate
- Heparin bolus volume
- Therapy beginning bolus
- Selected syringe

Treatment Without Heparin	**YES** The treatment is not started with heparin if the YES key is selected, i.e. the default is set to treatment start without heparin. The heparin pump alarms are disabled. **NO** The treatment is started with heparin if the NO key is selected, i.e. the default is set to treatment start with heparin. The heparin pump alarms are enabled.
Heparin Measurement Unit	The measurement unit [IE/H] or [ml/h] can be selected for heparin.
Conversion Factor Heparin [IE/ml]	You can set the conversion factor ([IE/ML] depending on the mixing ratio, if the amount of heparin should be displayed in international units (IE). The conversion factor describes the quantity of IE in 1 ml solution, e.g. 1000 IE represent in 1 ml solution 1000 IE heparin.
Heparin Rate	The heparin rate can be set to [IE/h] or [ml/h], depending on the selected unit.
Heparin Bolus Volume	You can select the bolus volume for the heparin bolus.
Therapy Beginning Bolus	An automatic bolus can be administered at the beginning of a therapy. The heparin bolus is performed by the venous red detector RDV.

Selected Syringe	The selected syringe type is used in therapy.
Heparin Pump Compact	You can set the syringe name and the inner diameter of the syringe.



9. Syringe name & volume: Omnifix 30 ml
Inner diameter: 22.00 [mm]

10. Syringe name & volume: Omnifix 20 ml
Inner diameter: 19.80 [mm]

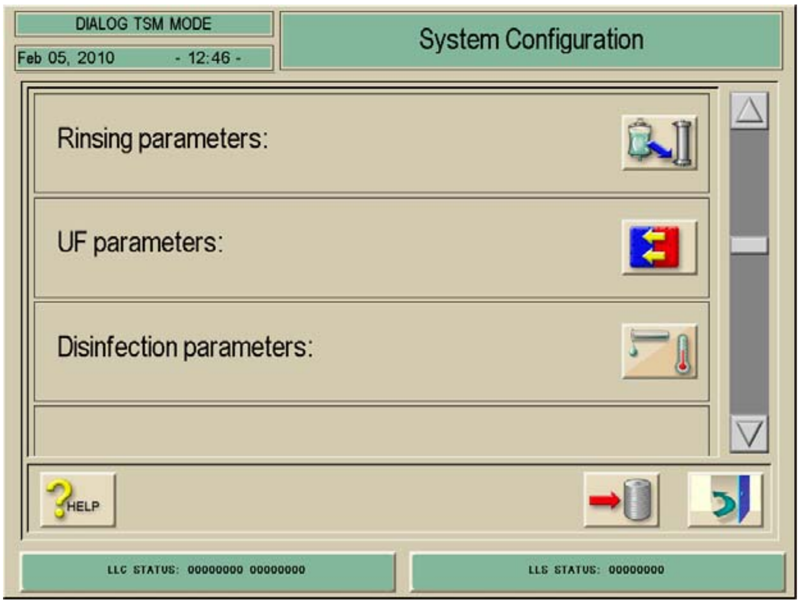
11. Syringe name & volume: Omnifix 10 ml
Inner diameter: 16.05 [mm]

3. Activate the *Selected Syringe* menu with the *Selected Syringe* icon. The following menu is opened.

4.7.1.7 Rinsing Parameters

The *Rinsing Parameters* can be set in the *Rinsing Parameters* menu.

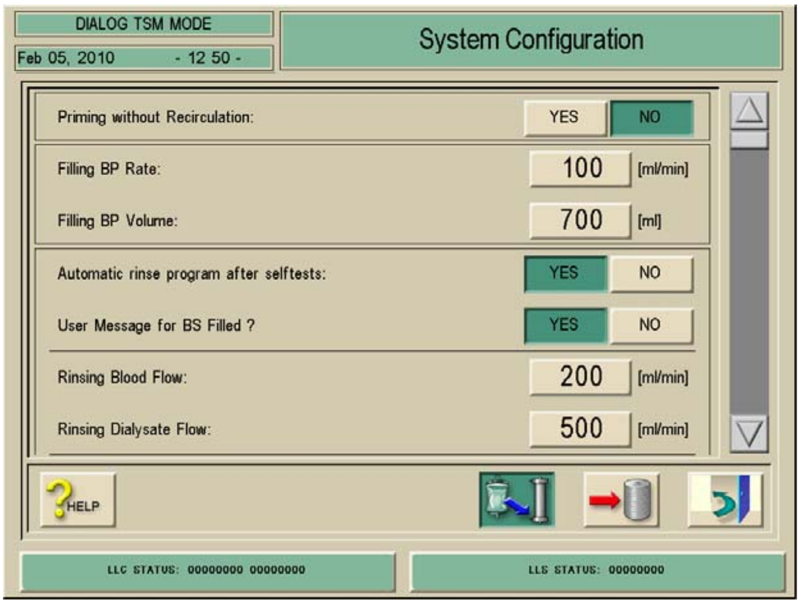
1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar).



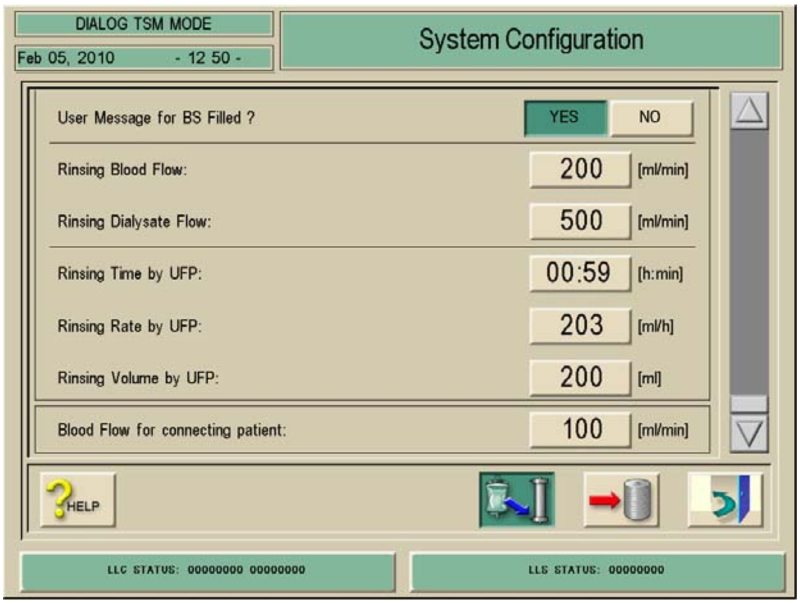
2. Activate the *Rinsing Parameters* menu with the *Rinsing Parameters* icon. The following menu is displayed.

The following parameters can be set:

- Priming without Recirculation
- Filling BP Rate
- Filling BP Volume
- Automatic Rinse Program after Self Tests
- User Message for BS Filled?
- Rinsing Blood Flow
- Rinsing Dialysate Flow
- Rinsing Time by UFP
- Rinsing Rate by UFP
- Rinsing Volume by UFP
- Blood Flow for Connecting Patient



Priming without Recirculation: YES [✓ NO]
Filling BP Rate: 100 [ml/min]
Filling BP Volume: 700 [ml]
Automatic rinse program after selftests: [✓ YES] NO
User Message for BS Filled ? [✓ YES] NO
Rinsing Blood Flow: 200 [ml/min]
Rinsing Dialysate Flow: 500 [ml/min]



User Message for BS Filled ? [✓ YES] NO
Rinsing Blood Flow: 200 [ml/min]
Rinsing Dialysate Flow: 500 [ml/min]
Rinsing Time by UFP: 00:59 [h:min]
Rinsing Rate by UFP: 203 [ml/h]
Rinsing Volume by UFP: 200 [ml]
Blood Flow for connecting patient: 100 [ml/min]

Priming without Recirculation

If YES is activated
The blood pump stops 120 ml before the required filling volume. The 120 ml is used for the blood pump self test. A warning message is not activated. Thus a connection of the disposable for recirculation is not necessary after filling. An automatic start of the rinsing is prohibited.

Filling BP Rate

You can set the BP rate to fill the blood line system (BS) for all rinsing modes.

Filling BP Volume

You can set the filling/rinsing volume for the A/V system.

With Rinsing Out of Machine
The filling of the dialyser is started after the filling BP volume is reached (e.g. 500 ml; min. 500 ml/standard 700 ml).

With Bag Rinsing
The blood pump BPA is stopped after the filling BP volume is reached (e.g. 500 ml). This allows the changing from two bags to one bag.

Automatic Rinse Program after Self Tests

If YES is Activated
The rinsing is automatically performed directly after the BS self tests.

If NO is Activated
The rinsing must be started manually after the BS self tests.

User Message for BS Filled?

If YES is Activated
A user message is displayed after the rinsing of the machine:

The BS system is filled until the ⏎ key is pressed and the filling BP volume is completed. Thus the level can be set. Then the dialyser can be turned to fill the DF side.

If NO is Activated
The filling of the dialyser is automatically started after the *Filling BP Volume* is finished.

Rinsing Blood Flow

You can set the blood flow for rinsing. After the self tests BPA delivers a longitudinal flow during rinsing. This depends on the rinsing mode.

Longitudinal rinsing (along the dialyser):
- Blood side inlet/outlet
- Water side inlet/outlet

Cross rinsing (through the dialyser membrane):
- Blood side to water side

Note
Interdependencies when changing parameters:

Change	Automatic Adaptation from
Rinsing Time	Rate
Rate	Rinsing Time
Rinsing Volume	Rate

Rinsing Dialysate Flow

You can set the dialysate flow for the rinsing of the dialyser in preparation.

Rinsing Time by UFP

You can set the rinsing time (for bag rinsing without substitution line (s-online)). Thus rinsing via the dialyser membrane is possible. After the termination of the rinsing time, rinsing is performed with min. UF.

Rinsing Rate by UFP

You can set the rinsing rate for the UFP to reach the *Rinsing Volume by UFP*. The *Rinsing Time by UFP* is automatically recalculated.

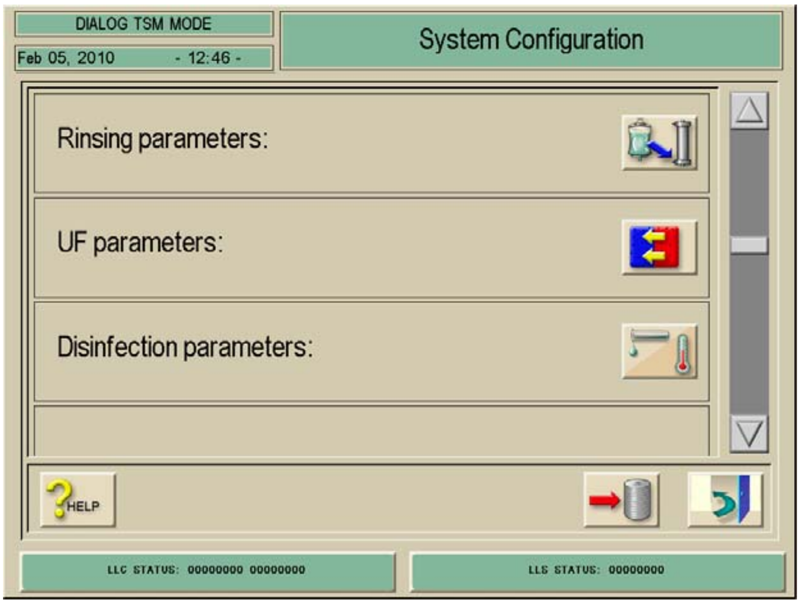
Rinsing Volume by UFP

You can set the rinsing volume (via the dialyser membrane) for the *Rinsing Time by UFP*. The *Rinsing Rate by UFP* is automatically recalculated.

Blood Flow for Connecting Patient

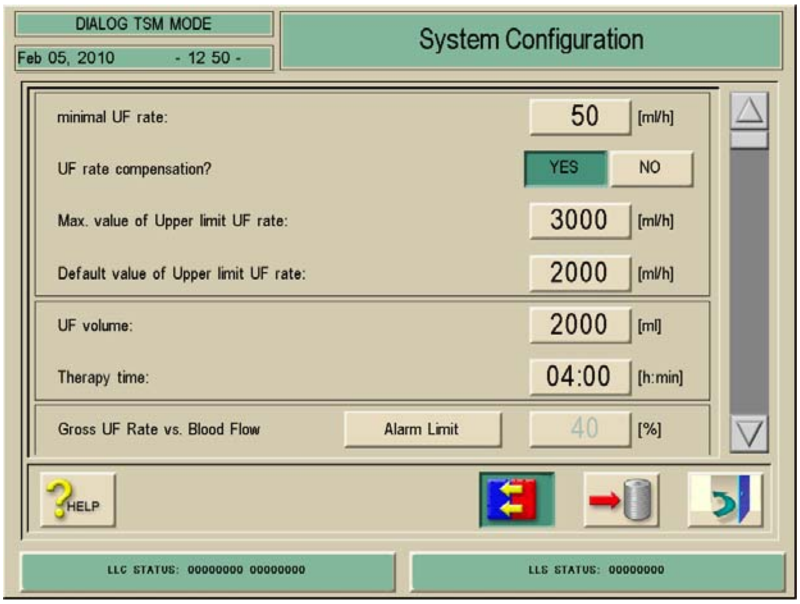
You can set the blood flow for connecting the patient (in therapy). The blood pump BPA is started with this rate when the therapy is started.

4.7.1.8 UF Parameters



The dialysate fluid parameters can be set in the *UF Parameters* menu.

1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar).



minimal UF rate: 50 [ml/h]
UF rate compensation? YES NO
Max. value of Upper limit UF rate: 3000 [ml/h]
Default value of Upper limit UF rate: 2000 [ml/h]
UF volume: 2000 [ml]
Therapy time: 04:00 [h:min]
Gross UF Rate vs. Blood Flow Alarm Limit 40 [%]

2. Activate the *UF Parameters* menu with the *UF Parameters* icon. The following menu is opened.

The following parameters can be set:

- Minimal UF Rate
- UF Rate Compensation?
- Max. Value of Upper Limit UF Rate
- Default Value of Upper Limit UF Rate
- UF Volume
- Therapy Time
- Gross UF Rate vs. Blood Flow - Alarm Limit
- Gross UF Rate vs. Blood Flow - Warning Limit
- UF Profile Editor

Minimal UF-Rate	You can set the minimal UF rate.
UF Rate Compensation?	*If YES is Activated* If the *Minimal UF Rate* is active the UF rate is recalculated to reach the required UF volume.
Max. Value of Upper Limit UF Rate	You can set the maximum value of the upper limit for the UF rate.
Default Value of Upper Limit UF Rate	You can set the default value of the upper limit for the UF rate.
UF Volume	You can set the UF volume.
Therapy Time	You can set the therapy time.
Gross UF Rate vs. Blood Flow – Alarm Limit	You can set and activate an alarm limit, i.e. an alarm (red) is activated if the limit is reached. The alarm limit can only be changed if the warning limit was changed in advance. The alarm can be acknowledged with the key. **Setting Range** The alarm limit can not be set lower than the warning limit (even if the warning limit is deactivated).

Gross UF Rate vs. Blood Flow – Warning Limit

You can set and activate a warning limit, i.e. a warning (yellow) is activated if the limit is reached.

Setting Range
The alarm limit can not be set lower than the warning limit (even if the warning limit is deactivated).

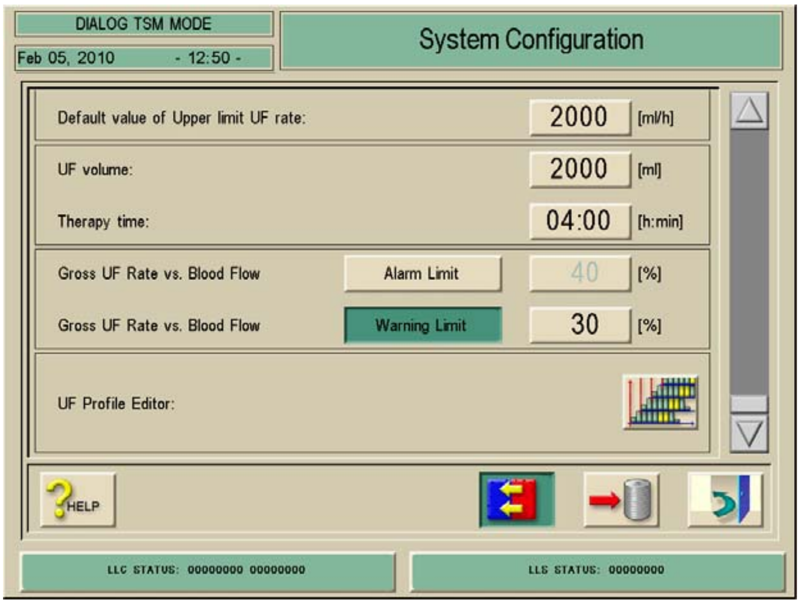
There are no limit alarms for HDF machines in predilution.

Alarm Limit/Warning Limit

Alarm Limit	Warning Limit	
deactivated	deactivated	No alarm/no warning in therapy
deactivated	activated	Warning in therapy if limit is exceeded
activated	deactivated	Alarm in therapy if limit is exceeded
activated	activated	Alarm and warning in therapy if limit is exceeded

UF Profile Editor

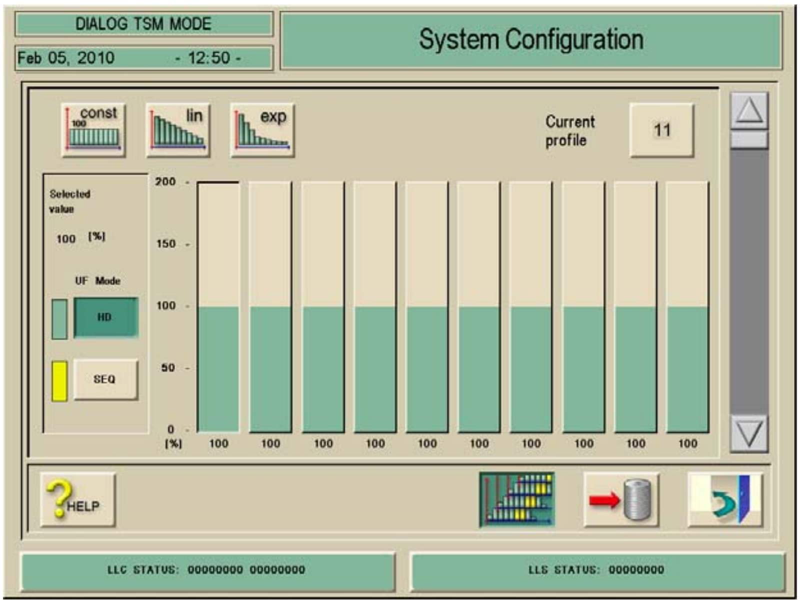
The UF profile can be edited in the *UF Profile Editor*. Editing can be performed in the therapy mode and in the TSM service program.


DIALOG TSM MODE
Feb 05, 2010 - 12:50 -
System Configuration

Default value of Upper limit UF rate: 2000 [ml/h]
UF volume: 2000 [ml]
Therapy time: 04:00 [h:min]
Gross UF Rate vs. Blood Flow Alarm Limit 40 [%]
Gross UF Rate vs. Blood Flow Warning Limit 30 [%]
UF Profile Editor:

LLC STATUS: 00000000 00000000
LLS STATUS: 00000000

Press the *UF Profile Editor* icon to open the *UF Profile Editor* menu.


DIALOG TSM MODE
Feb 05, 2010 - 12:50 -
System Configuration

Current profile 11
Selected value 100 [%]
UF Mode HD

LLC STATUS: 00000000 00000000
LLS STATUS: 00000000

CONST (Constant)
If this key is activated all intervals of the profile are set to 100%.

LIN (Linear)
If this key is activated only the first interval can be set. A linear adaptation is calculated for the remaining process.

EXP (Exponential)
If this key is activated only the first interval can be set. An exponential adaptation is calculated for the remaining process.

Note If both the *LIN* and *EXP* keys are not activated the response of the graph can be selected individually. If an interval is changed the remaining intervals are adapted accordingly. The last interval can not be modified, because this setting is calculated from the previous interval settings.

Current Profile No.
The profile selected with this key is displayed and can be modified. Additionally to 10 standard profiles 20 further profiles can be activated, displayed and modified.

Profile No. 0
This is a constant 100% profile.

Profile No. 1 to 9
These profiles are pre-defined.

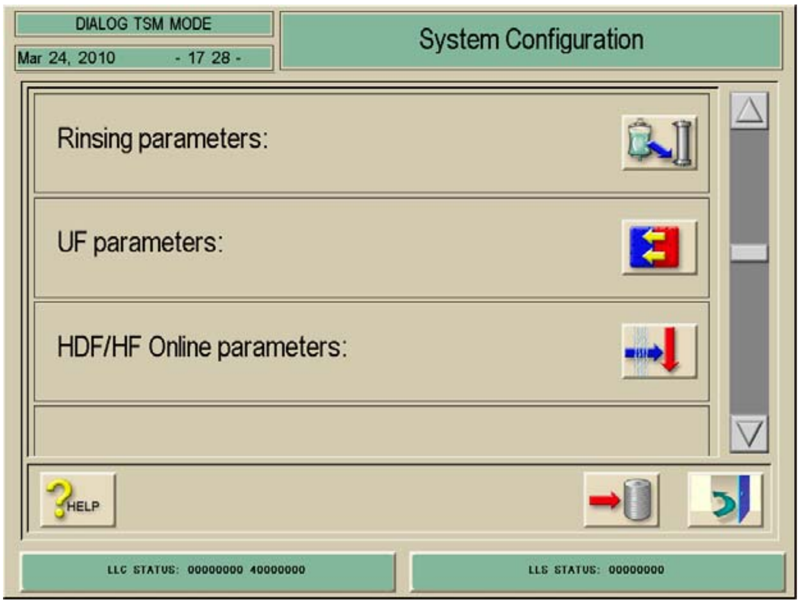
Profile No. 10
A profile which was edited in therapy and stored to a chip card (card reader option).

Profile No. 11 to 30
These profiles can be edited in the TSM service program and stored under a number.

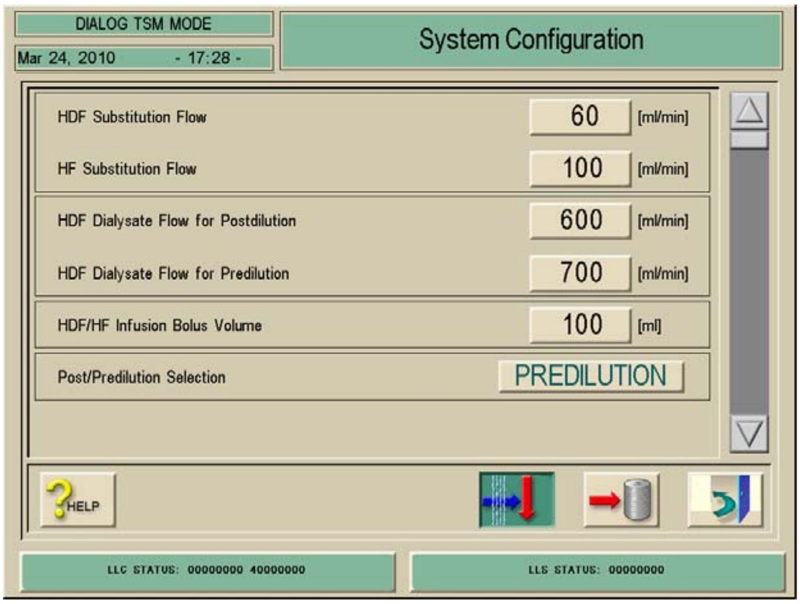
UF Mode HD
The UF process of the activated interval is set to HD with the *HD* key.

UF Mode Sequential SEQ
The UF process of the activated interval is set to sequential with the *SEQ* key.

4.7.1.9 HDF/HF Online Parameters



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. Use the scroll bar until the following menu appears (only HDF online machines).



HDF Substitution Flow 60 [ml/min]
HF Substitution Flow 100 [ml/min]
HDF Dialysate Flow for Postdilution 600 [ml/min]
HDF Dialysate Flow for Predilution 700 [ml/min]
HDF/HF Infusion Bolus Volume 100 [ml]
Post/Predilution Selection PREDILUTION

2. Activate the *HDF/HF Online Parameters* menu with the *HDF/HF Online Parameters* icon. The following menu is opened.

The following parameters can be set.

- HDF Substitution Volume
- HF Substitution Volume
- HDF Dialysate Flow for Postdilution
- HDF Dialysate Flow for Predilution
- HDF/HF infusion bolus volume
- Post/Predilution Selection

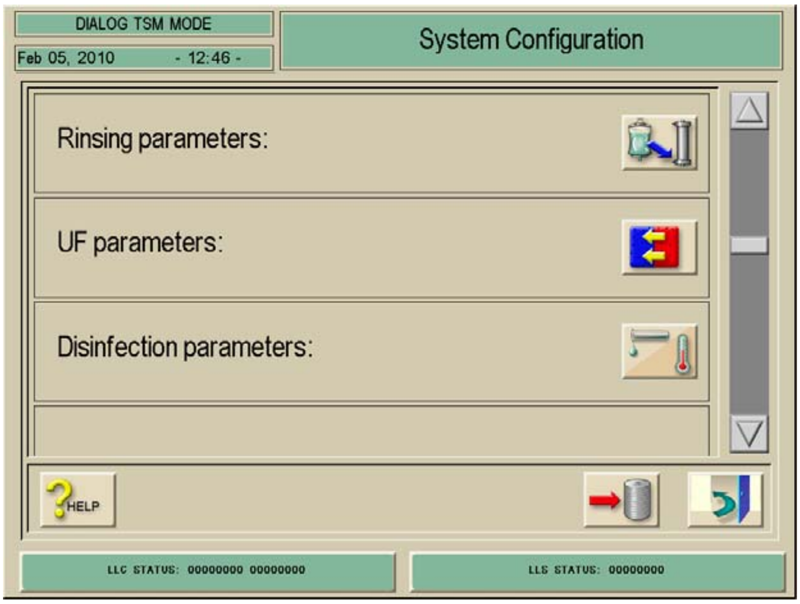
HDF Substitution Volume	The HDF substitution volume can be set.
HF Substitution Volume	The HF substitution volume can be set.
HDF Dialysate Flow for Postdilution	The HDF dialysate flow for postdilution can be set.
HDF Dialysate Flow for Predilution	The HDF dialysate flow for predilution can be set.
HDF/HF Infusion Bolus Volume	The HDF/HF infusion bolus volume can be set.
Post/Predilution Selection	You can set predilution for a HDF/HF online therapy by activating the *Predilution* key.

4.7.1.10 Disinfection Parameters

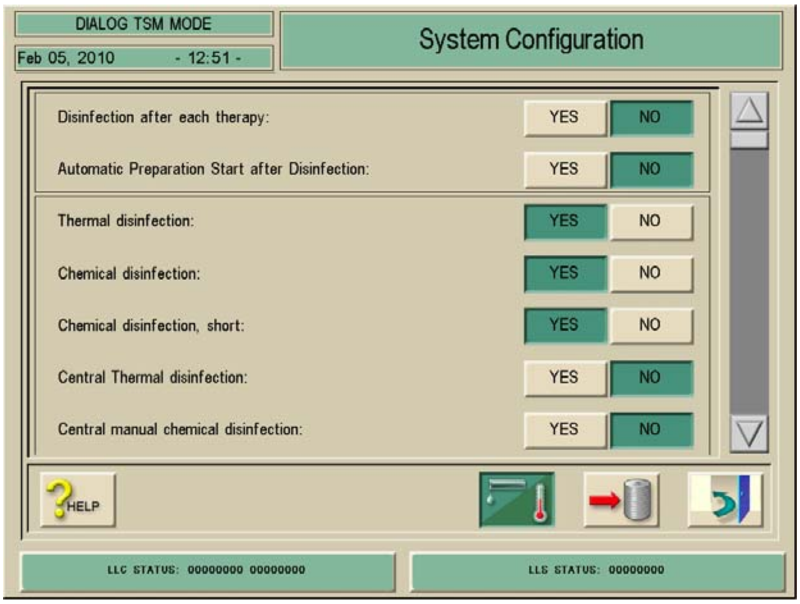
Disinfection after servicing in TSM
Before disinfection: rinse the machine to remove residual dialysate or concentrate in the system.

The disinfection parameters can be set in the *Disinfection Parameters* menu.

1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar).



2. Activate the *Disinfection* menu with the *Disinfection Parameters* icon. The following menu is displayed.



Disinfection after each therapy: YES [✓ NO]
Automatic Preparation Start after Disinfection: YES [✓ NO]
Thermal disinfection: [✓ YES] NO
Chemical disinfection: [✓ YES] NO
Chemical disinfection, short: [✓ YES] NO
Central Thermal disinfection: YES [✓ NO]
Central manual chemical disinfection: YES [✓ NO]

3. Scroll the menu with the scroll bar.

The following parameters can be set:

- Disinfection after each Therapy
- Automatic Preparation Start after Disinfection
- Thermal Disinfection
- Chemical Disinfection
- Chemical Disinfection, Short
- Central Thermal Disinfection
- Central Manual Chemical Disinfection
- Central Automatic Chemical Disinfection
- Rinsing
- Auto Switch-On with Rinsing (No Weekly Schedule)
  - Switch-On Time
- Auto Switch-On by Weekly Schedule
  - Weekly Schedule
  - Start on Sunday/Start on Monday
- Auto Switch-On without Daily Confirmation
- Maximum Out of Action Time (Day/Hour/Minutes)
- Disinfection Configuration Data Chemical (long), Chemical (short)
- Disinfection Configuration Data Central Thermal, Central Chemical, Rinsing

Disinfection after each Therapy

If the *YES* key is activated, a disinfection must be performed after every therapy.

Automatic Preparation Start after Disinfection

YES
After disinfection and rinsing the *Preparation* and the self tests are started.

NO
After disinfection and rinsing the disinfection method is terminated.

Thermal Disinfection

You can enable the thermal disinfection with the *YES* key in the disinfection program or disable with the *NO* key. If you select the *NO* key the thermal disinfection icon is not displayed in the disinfection program.

Chemical Disinfection

You can enable the chemical disinfection with the *YES* key in the disinfection program or disable with the *NO* key. If you select the *NO* key the chemical disinfection icon is not displayed in the disinfection program.

Short Chemical Disinfection

You can enable the short chemical disinfection with the *YES* key in the disinfection program or disable with the *NO* key. If you select the *NO* key the short chemical disinfection icon is not displayed in the disinfection program.

Central Thermal Disinfection

The inlet feed-line and the machine are disinfected with hot water, if the central facility loop-line is also disinfected with hot water (> 85°C).

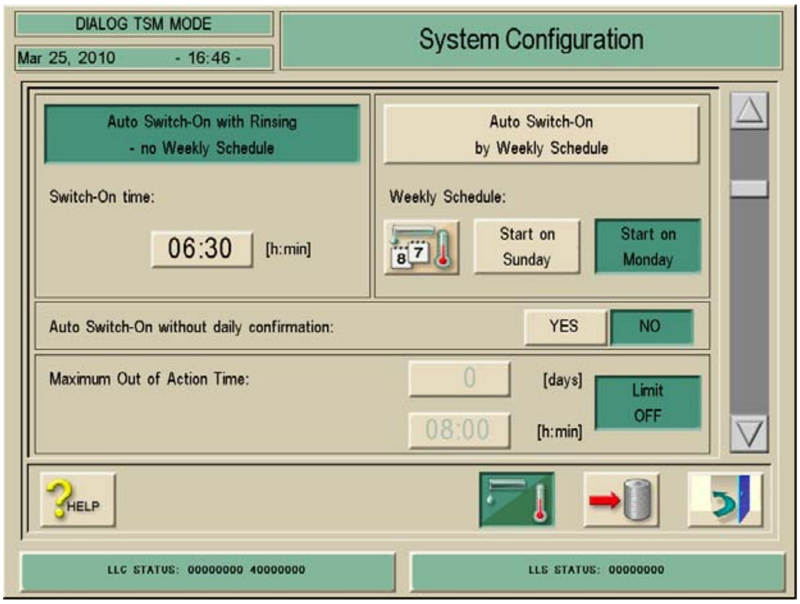
Central Chemical Disinfection

The inlet feed-lines are disinfected with chemical disinfectants, if the central facility loop-line is also disinfected with chemical disinfectants.

Rinsing

Rinsing of disinfectant residues: e.g. a disinfection was performed in the evening and the residues are rinsed in the morning.

Auto Switch-On with Rinsing – No Weekly Schedule



Switch-On time: 06:30 [h:min]

Auto Switch-On without daily confirmation: NO

Maximum Out of Action Time: 0 [days] 08:00 [h:min]

The parameters for the switch-on without a weekly schedule can be set in the menu *Auto Switch-On with Rinsing - No Weekly Schedule*.

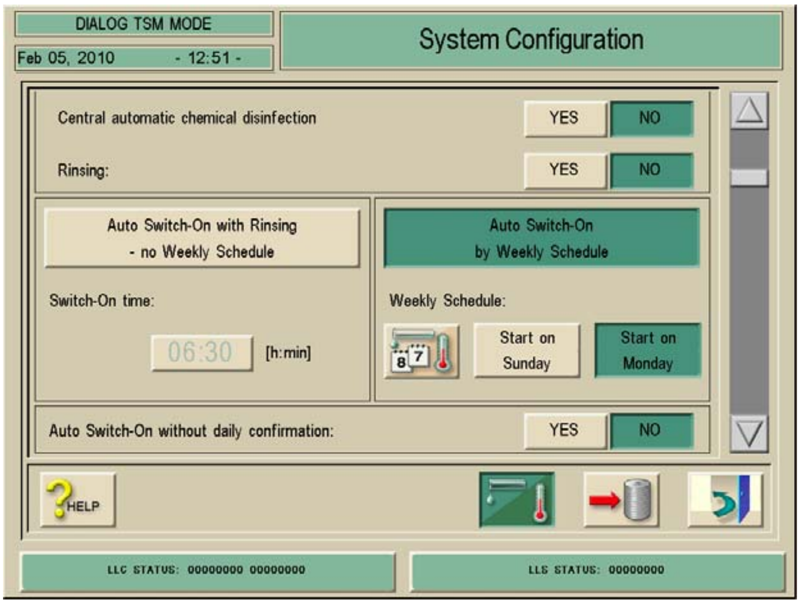
The keys for *Auto Switch-On with Rinsing - No Weekly Schedule* and *Auto Switch-On by Weekly Schedule* are interlocked.

The machine is rinsed after the preselected switch-on time. The key is only enabled if the function is selected.

Switch-On Time

The switch-on time can be set (without a weekly schedule).

Auto Switch-On by Weekly Schedule

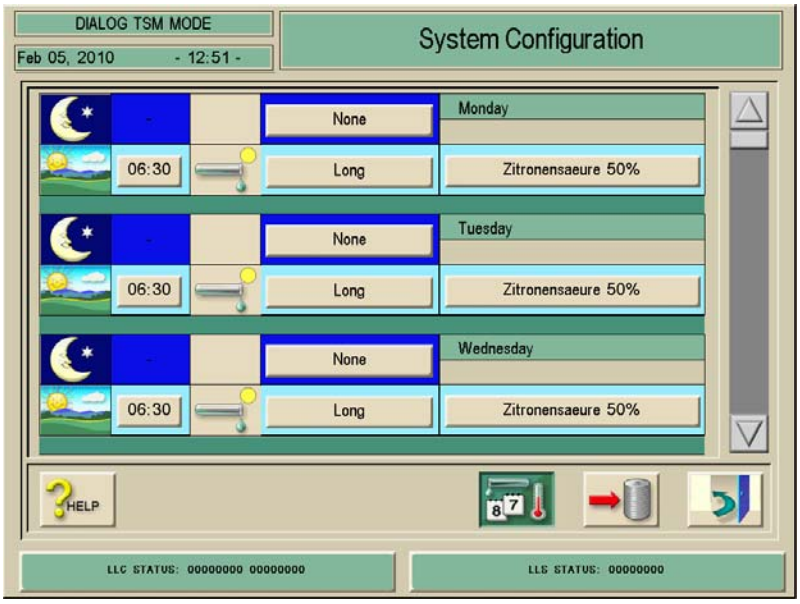


The parameters for the switch-on and the weekly schedule can be set in the menu *Auto Switch-On by Weekly Schedule*.

The keys for *Auto Switch-On with Rinsing - No Weekly Schedule* and *Auto Switch-On by Weekly Schedule* are interlocked.

Start on Sunday/Start on Monday

The table for the weekly schedule can either start with Sunday or Monday.



Weekly Schedule

The parameters for the weekly schedule can be set in the *Weekly Schedule* menu.

The selected disinfection method is performed according to the preselected *Weekday* and *Time* parameters:

- Monday, Tuesday .... Sunday
- Night (Moon Symbol), Dialog switches off after disinfection is completed
- Day (Sun Symbol), Dialog does not switch off and remains in *Rinsing*
- Switch-On Time
- Disinfection Method
- Disinfectants

The table can also be modified by the user in the therapy/disinfection mode.

Auto Switch-On without Daily Confirmation

If YES is Activated
No confirmation required for the automatic switch-on at the end of each disinfection.

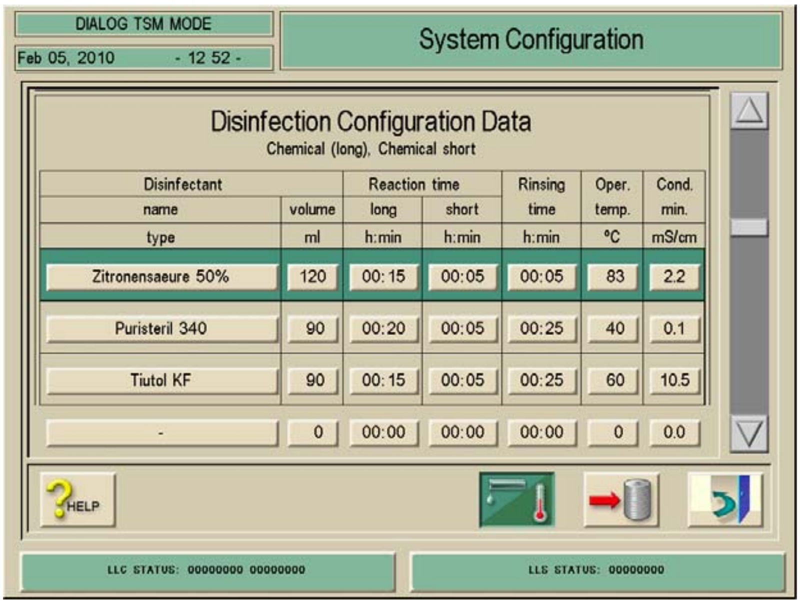
If NO is Activated
A confirmation is required for the automatic switch-on at the end of each disinfection.

Maximum Out of Action Time

Limit OFF
The function is activated if the *Limit OFF* key is not pressed.

The *Limit OFF* key is activated in the default setting, the parameter keys are disabled, i.e. parameter values can not be set.

Disinfection Configuration Data
Chemical (long), Chemical (short)



DIALOG TSM MODE

Feb 05, 2010 - 12 52 -

System Configuration

Disinfection Configuration Data

Chemical (long), Chemical short

Disinfectant		Reaction time		Rinsing	Oper.	Cond.
name	volume	long	short	time	temp.	min.
type	ml	h:min	h:min	h:min	°C	mS/cm
Zitronensaeure 50%	120	00:15	00:05	00:05	83	2.2
Puristeril 340	90	00:20	00:05	00:25	40	0.1
Tiutol KF	90	00:15	00:05	00:25	60	10.5
-	0	00:00	00:00	00:00	0	0.0

LLC STATUS: 00000000 00000000

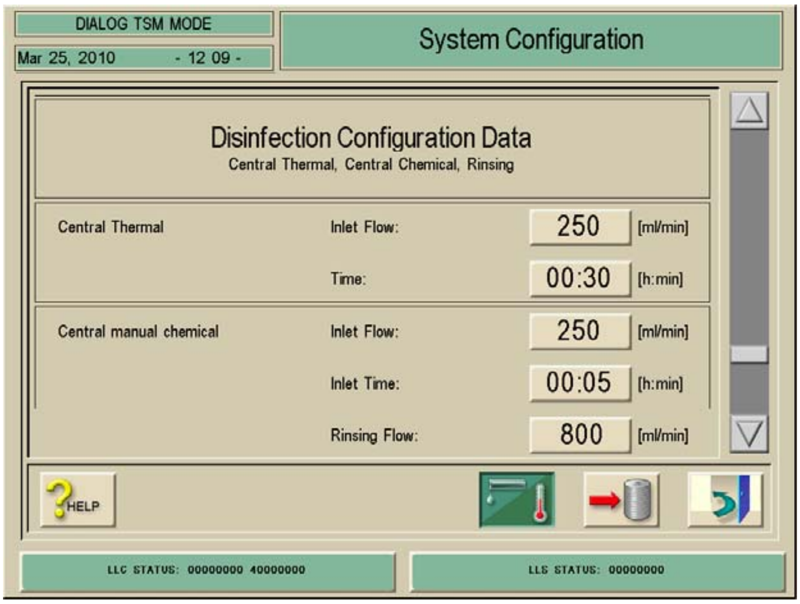
LLS STATUS: 00000000

The parameters for the disinfectants are set in the *Disinfection Configuration Data, Chemical (Long), Chemical (Short)* table. The following parameters are available:

- Disinfectant Name, Type and Volume
- Reaction Time Long/Short
- Rinsing Time
- Operating Temperature
- Minimum Conductivity

Details can be found in Chapter 3 repair instructions.

Disinfection Configuration Data
Central Thermal, Central Chemical, Rinsing



DIALOG TSM MODE

Mar 25, 2010 - 12 09 -

System Configuration

Disinfection Configuration Data

Central Thermal, Central Chemical, Rinsing

Central Thermal Inlet Flow: 250 [ml/min]

Time: 00:30 [h:min]

Central manual chemical Inlet Flow: 250 [ml/min]

Inlet Time: 00:05 [h:min]

Rinsing Flow: 800 [ml/min]

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

The parameters for the water inlet system can be set in the menu *Disinfection Configuration Data, Central Thermal, Central Chemical, Rinsing*.

Central Thermal:

- Inlet Flow
- Time

Central Manual Chemical:

- Inlet Flow
- Inlet Time
- Rinsing Flow
- Rinsing Time

Central Automatic Chemical:

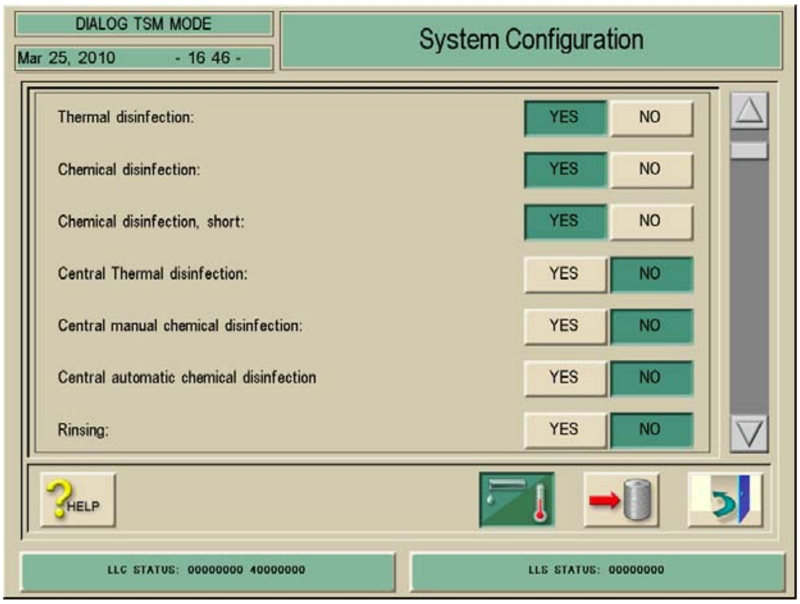
- Inlet Volume
- Switch-off for Retention without Automatic Switch-on
- Retention Time
- Rinsing Flow
- Rinsing Time

Rinsing:

- Inlet Flow
- Time

Central Automatic Chemical Disinfection

The hypochlorite disinfectant Tiutol KF must be applied (mixing ratio maximum 65 ml Tiutol KF per litre).
The user is responsible to integrate the dialysis machine in the dialysis centre's central water loop system, if the *Central Automatic Chemical Disinfection* is used.
The retention time must be ≤ 10 hours if the retention is disabled, i.e. the *Retention Time* is set to *YES*, thus, no *Central Automatic Chemical Disinfection*.



Thermal disinfection: [✓ YES] NO
Chemical disinfection: [✓ YES] NO
Chemical disinfection, short: [✓ YES] NO
Central Thermal disinfection: YES [✓ NO]
Central manual chemical disinfection: YES [✓ NO]
Central automatic chemical disinfection YES [✓ NO]
Rinsing: YES [✓ NO]

This disinfection method can be used for the disinfection of the water inlet line in dialysis centres with central water loop systems.

A defined inlet volume (disinfectant) from the water loop line is sucked in as follows (see dotted lines in the flow diagram):

- **FPA/UFP** decrease the water level in the upline tank **VB** to the lower level sensor **NSVB**
- The upline tank **VB** (approx. 260 ml inlet volume) is filled with disinfectant to the upper level sensor **NSVB**, due to the water pressure at **VVBE** from
- the central water loop system
- Filling is repeated until the preselected volume is reached
- Retention time (machine is switched off)
- Rinsing via **VB**, **RVE**, **VLA**, **LA** and **FPA** to the outlet

Phase 1

- machine is filled and emptied 5 times, i.e the disinfectant is volume controlled and sucked in and emptied by the central water loop line

Phase 2

- cyclic rinsing (time controlled -- rinsing time and rinsing flow

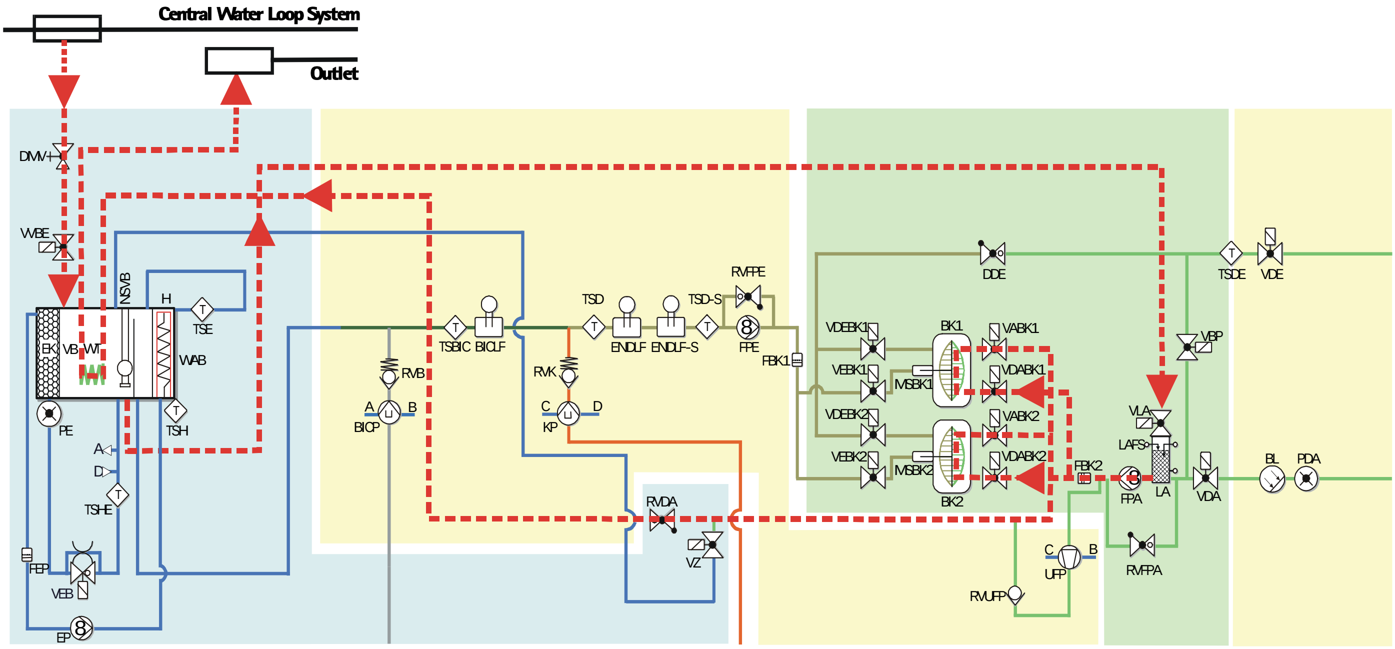
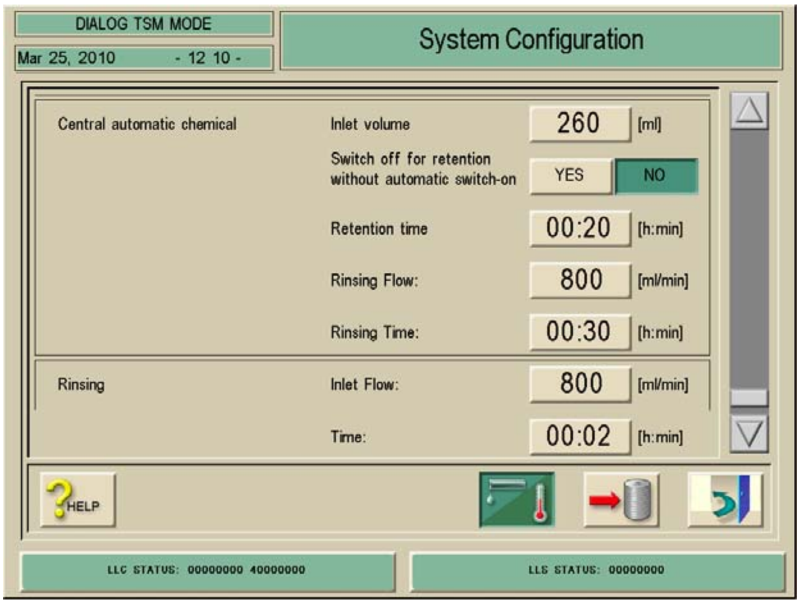


Fig.: Flow Diagram - Central Automatic Chemical Disinfection of Water Inlet



Central automatic chemical

Inlet volume 260 [ml]

Switch off for retention without automatic switch-on YES NO

Retention time 00:20 [h:min]

Rinsing Flow: 800 [ml/min]

Rinsing Time: 00:30 [h:min]

Rinsing

Inlet Flow: 800 [ml/min]

Time: 00:02 [h:min]

Central Automatic Chemical

Inlet Volume

The inlet volume can be selected.

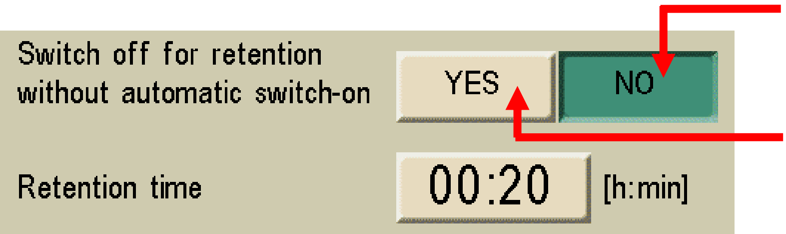
Switch-off for retention without automatic switch-on

NO – (i.e.: the automatic switch-on of the machine is performed)

The retention time of the disinfectant in the machine is according to the preset retention time.

YES – (i.e.: the automatic switch-on of the machine is not performed)

The retention time of the disinfectant in the machine depends on the switch-off time and from the manual switch-on of the machine by the user.



Switch off for retention without automatic switch-on YES NO

Retention time 00:20 [h:min]

Retention Time

If *NO* was selected

The retention time is enabled and can be selected.

If *YES* was selected

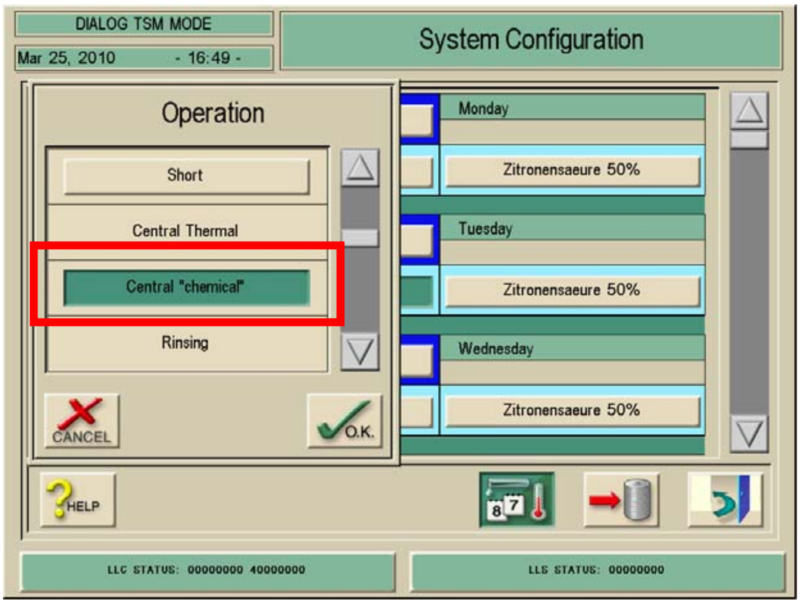
The retention time is disabled and can not be selected. The retention time must be ≤ 10 hours for manual retention.

Rinsing Flow

The rinsing flow can be selected.

Rinsing Time

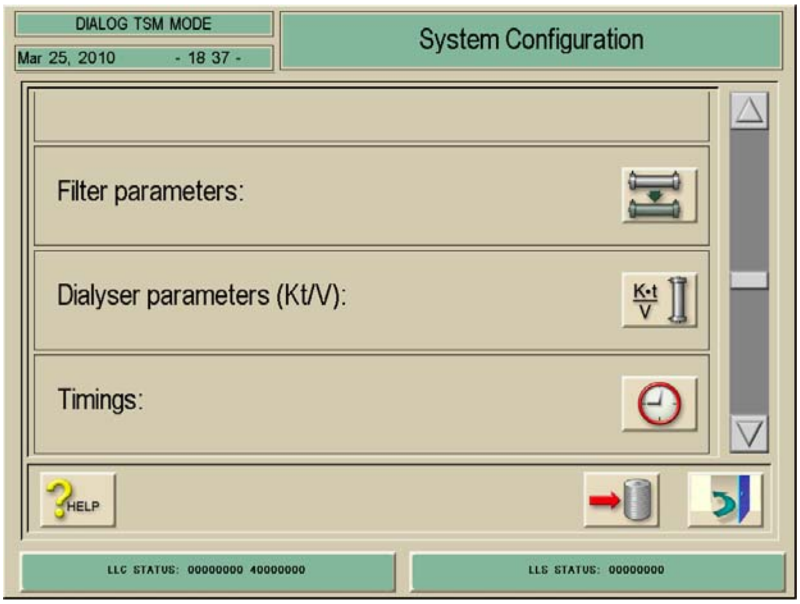
The rinsing time can be selected.



Central Chemical

A central chemical mode can be selected for the automatic switch-on in the weekly schedule.

4.7.1.11 Filter Parameters

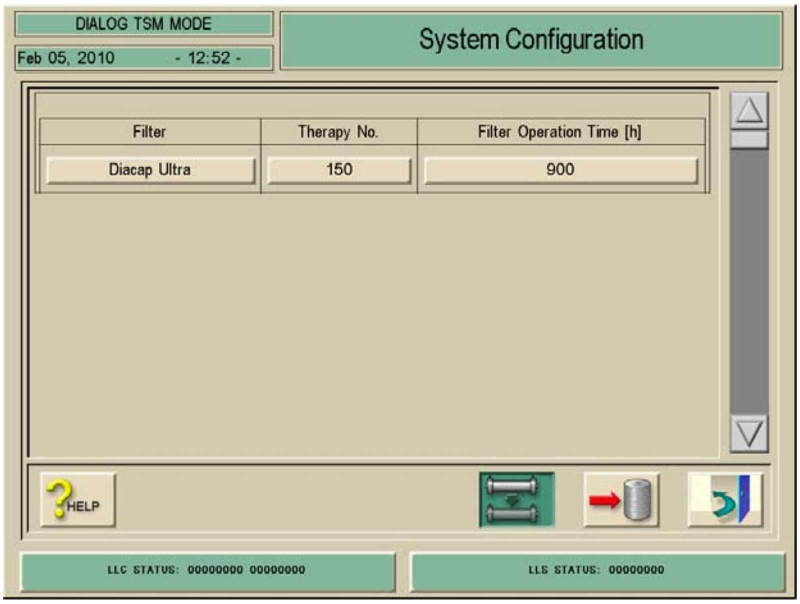


Mar 25, 2010 - 18 37 -

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. Use the scroll bar until the following menu appears.



Feb 05, 2010 - 12:52 -

Filter	Therapy No.	Filter Operation Time [h]
Diacap Ultra	150	900

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

2. Activate the *Filter Parameters* menu with the *Filter* icon.

The following parameters can be set for HDF online and DF filters:

- Filter Type, e.g. Diacap-Ultra
- Therapy No. (number of therapies)
- Filter Operation Time [h]

Filter The filter type can be entered, e.g. Diacap-Ultra.

Therapy Number The number of therapies can be set for the DF/HDF filters.

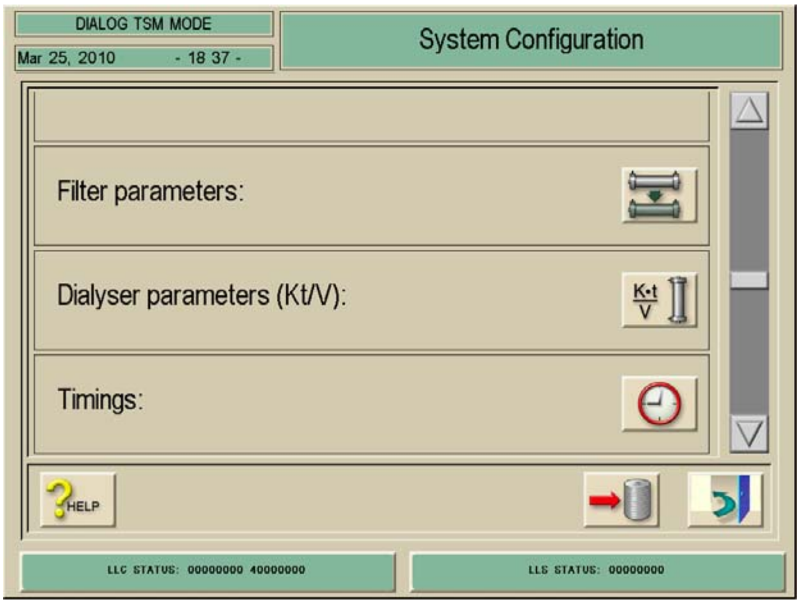
The following messages are displayed before *Preparation*, after the life-time data for therapy numbers/filter operation time is expired (one of the first three lines are selected/displayed depending on the filter/s which is/are expired):

<Check the DF Filter!> or
<Check the HDF Filter!> or
<Check the DF and HDF Filter!> or
<Check the life-time data on the service screen!>
<Do you want to continue with an expired filter?>

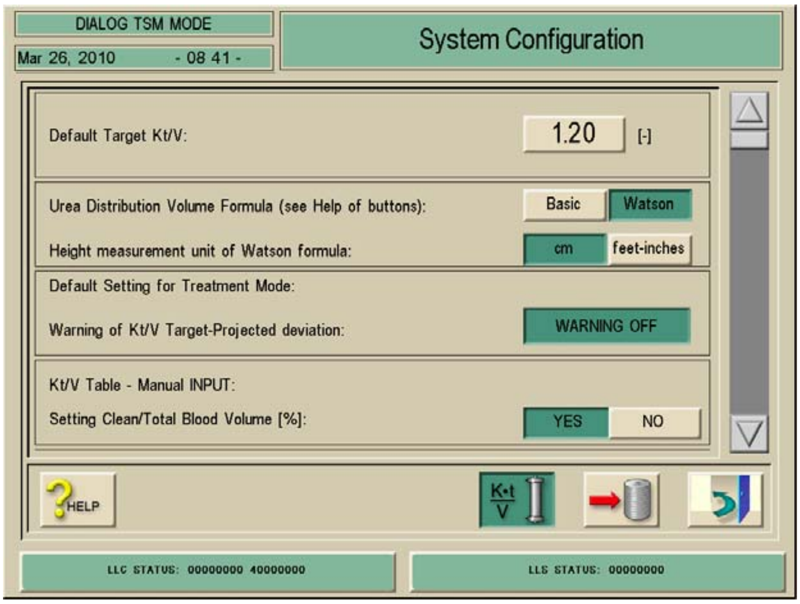
The message must be acknowledged with the ↵ key.

Filter Operation Time [h] The operating hours can be set for the intended operation time of the DF/HDF filters. The operating hour counter is active when *DF Preparation* is active.

4.7.1.12 Dialyser Parameters (Kt/V)



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. Use the scroll bar until the following menu appears.



Default Target Kt/V: 1.20 [-]

Urea Distribution Volume Formula (see Help of buttons): Basic Watson

Height measurement unit of Watson formula: cm feet-inches

Default Setting for Treatment Mode:

Warning of Kt/V Target-Projected deviation: WARNING OFF

Kt/V Table - Manual INPUT:

Setting Clean/Total Blood Volume [%]: YES NO

2. Activate the *Dialyser Parameters (Kt/V)* menu with the *Dialyser* icon.

The following parameters can be set.

- Default Target Kt/V
- Urea Distribution Volume Formula
- Height Measurement Unit of Watson Formula
- Default Setting for Treatment Mode: Warning of Kt/V Target Projected Deviation
- Kt/V Table - Manual INPUT: Setting Clean Blood Volume [%] Enabled
- Warning for Saving Kt/V Table
- Dialyser Filter Urea Clearance Data

If Nexadia-BSL is selected
Only the first parameter point *Default Target Kt/V* is displayed, but Kt/V is still active in Nexadia-BSL.

If WAN-BSL is selected
No display, Kt/V is not active in WAN-BSL, i.e. empty screen.

Default Target Kt/V The target value is the Kt/V value at the end of a therapy. The target is set by the user.

Urea Distribution Volume Formula Kt/V can be calculated with one of two different equations.

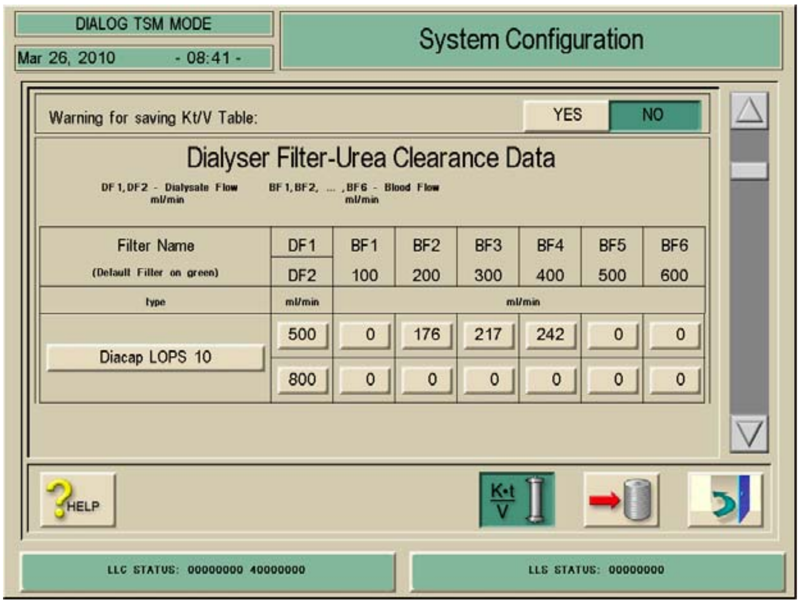
Urea Distribution Volume Formula (Basic)
The calculation is according to the following equation:
V (litres) = 0.58 x Dry Weight (kg)

Urea Distribution Volume Formula (Watson)
The calculation is according to the following Watson equation:

Male:
V (litres)=2.447 – 0.09516 x Age (years) + 0.1074 x Height (cm or feet/inch) + 0.3362 x Dry Weight (kg)

Female:
V (litres)=-2.097 + 0.1069 x Height (cm or feet/inch) + 0.2466 x Dry Weight (kg)

Height Measurement Unit of Watson Formula	The unit [cm] or [Feet/Inch] can be selected.
Default Setting for Treatment Mode: Warning of Kt/V Target Projected Deviation	If the calculated Kt/V from the set parameters is smaller than the set target value a message is activated.
Kt/V Table – Manual INPUT: Setting Clean Blood Volume [%] Enabled	If YES is Activated The ratio can be edited subsequently in therapy for adaptation to the calculated Kt/V value.
Warning for Saving Kt/V Table	A warning message can be enabled for saving the Kt/V table.



Warning for saving Kt/V Table: YES [✓ NO]

Dialyser Filter-Urea Clearance Data

DF1,DF2 - Dialysate Flow ml/min BF1,BF2, ... ,BF6 - Blood Flow ml/min

Filter Name (Default Filter on green)	DF1	BF1	BF2	BF3	BF4	BF5	BF6
	DF2	100	200	300	400	500	600
type	ml/min	ml/min					
Diacap LOPS 10	500	0	176	217	242	0	0
	800	0	0	0	0	0	0

LLC STATUS: 00000000 40000000

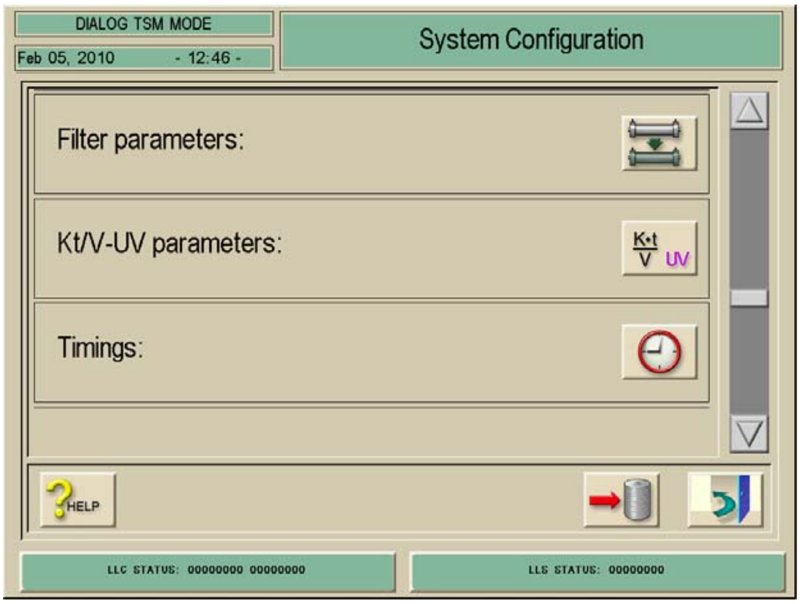
LLS STATUS: 00000000

Dialyser Filter Urea Clearance Data

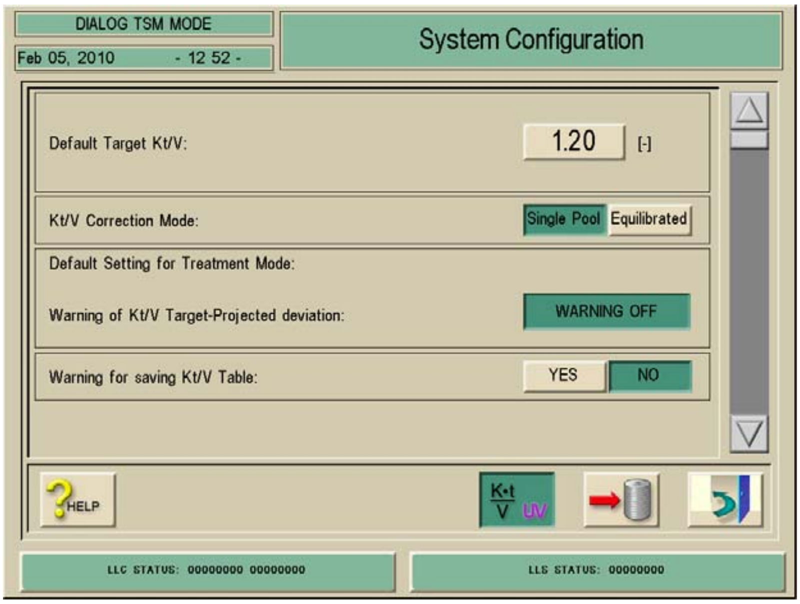
The Kt/V is approximately calculated via the *Dialyser Filter Urea Clearance Data* for the selected dialyser (see table, use scroll bar to see table).

Details can be found in Chapter 3 repair instructions.

4.7.1.13 Kt/V-UV Parameters



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. Use the scroll bar until the following menu appears.



Default Target Kt/V: 1.20 [-]

Kt/V Correction Mode: Single Pool Equilibrated

Default Setting for Treatment Mode:

Warning of Kt/V Target-Projected deviation: WARNING OFF

Warning for saving Kt/V Table: YES NO

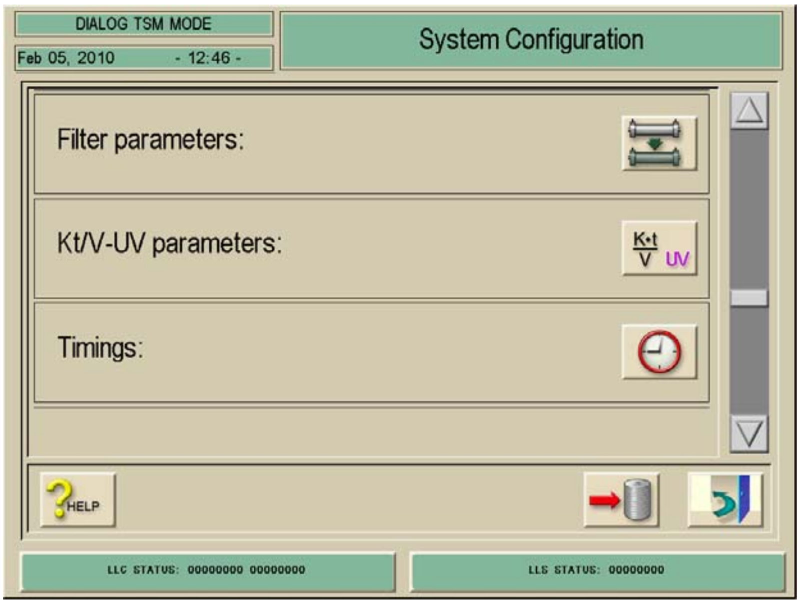
2. Activate the *Kt/V-UV Parameters* menu with the *Kt/V-UV* icon.

The following parameters can be set.

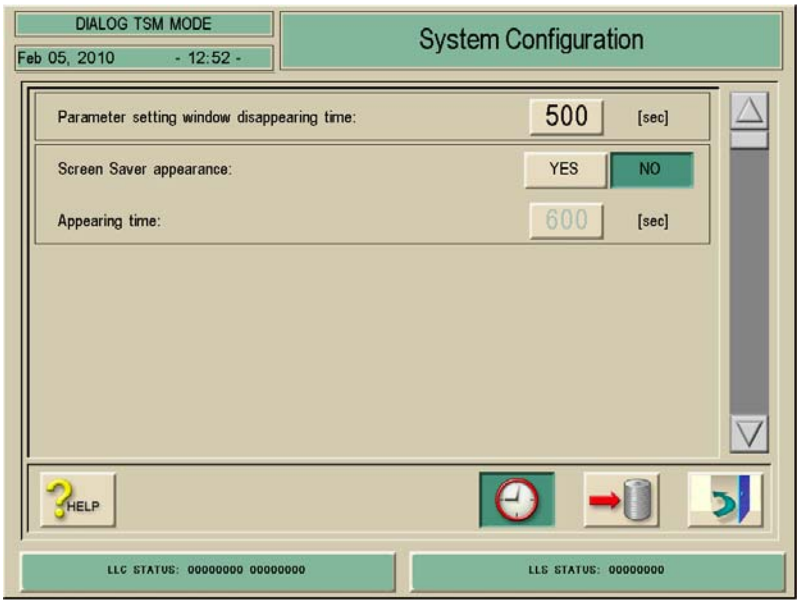
- Default Target Kt/V
- Kt/V Correction Mode
- Single Pool / Equilibrated
- Default Setting for Treatment Mode: Warning of Kt/V Target-Projected Deviation
- Warning for Saving Kt/V Table

Default Target Kt/V	The target value is the required Kt/V value at the end of a therapy. The target is set by the user.
Kt/V Correction Mode	For Kt/V-UV, i.e. Adimea option.
Single Pool / Equilibrated	The Single Pool parameter or the Equilibrated parameter can be selected according to the requirements of the physician/customer.
Default Setting for Treatment Mode: Warning of Kt/V Target-Projected Deviation	If the calculated Kt/V from the set parameters is smaller than the set target value, a message is activated.
Warning for Saving Kt/V Table	A warning message can be enabled for saving the Kt/V table.

4.7.1.14 Timings



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar):



Parameter setting window disappearing time: 500 [sec]

Screen Saver appearance: YES NO

Appearing time: 600 [sec]

2. Activate the *Timings* menu with the *Timings* icon. The following menu is displayed.

The following parameters can be set:

- Parameter setting window disappearing time
- Screen saver appearance
- Appearing time

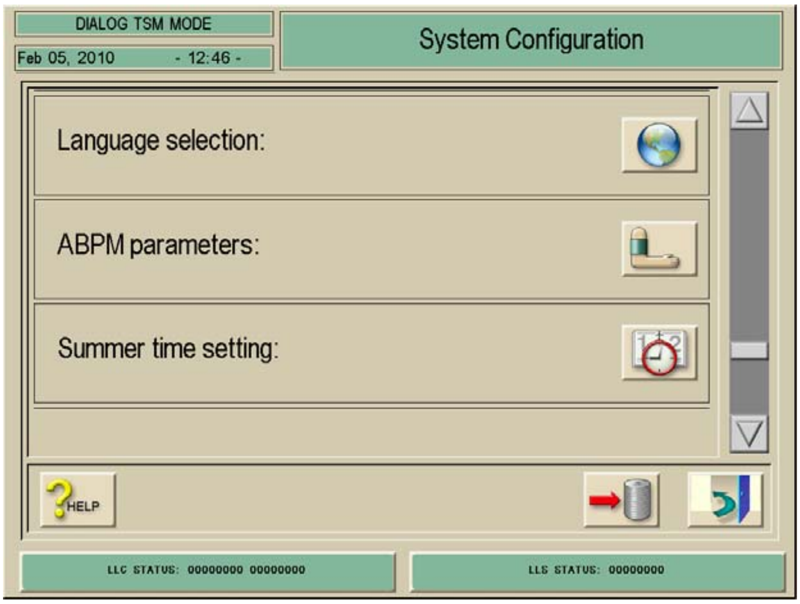
Parameter Setting Window Disappearing Time You can set the automatic disappearing time for the *Parameter Setting Window* (lower screen in therapy).

Screen Saver Appearance You can activate a screen saver with the *YES* key. The actual image on the screen is then replaced by the screen saver, according to the preset time. The original image appears in case of an alarm or if the screen is touched. The following screen savers are activated:

Therapy selection:	B.Braun logo, date, time
Preparation:	B.Braun logo, time, status line
Therapy and end of therapy:	Time cake, remaining time, status line
Disinfection:	Time cake, disinfection mode, phase

Appearing Time You can set the appearance time of the Screen Saver.

4.7.1.15 Language Selection

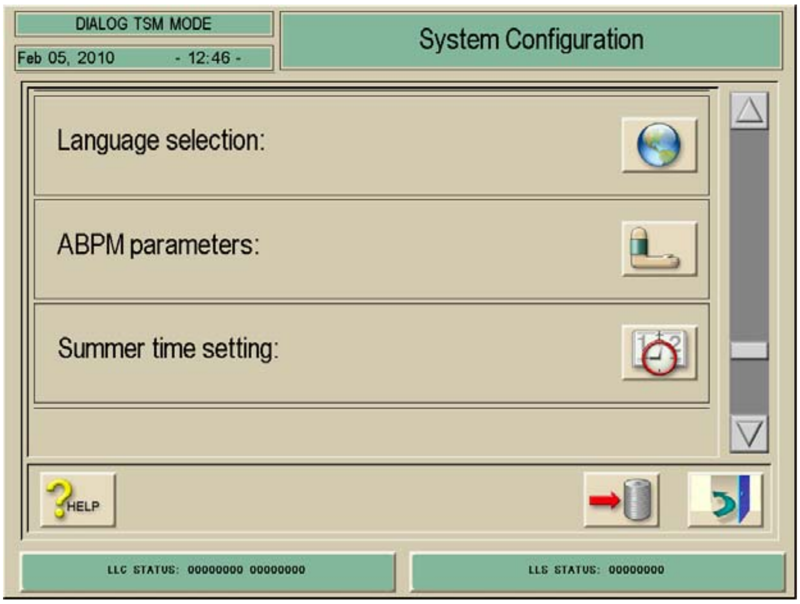


1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar).

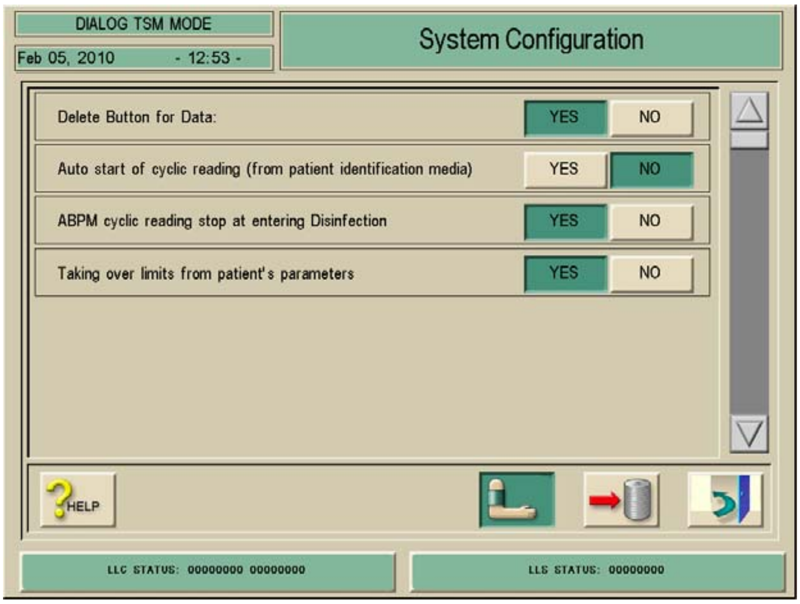
2. Activate the *Language Selection* menu with the *Language Selection* icon.
3. Select the *English* or *German* language or an additional available language.
4. The following menu is displayed (or if available additional languages).

If English is selected the therapy and TSM language is English. If German is selected the therapy and TSM language is German. If an additional language is selected this language is used in therapy. The TSM language is English.

4.7.1.16 Automatic Blood Pressure Measurement ABPM



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar).



Delete Button for Data:	● YES	○ NO
Auto start of cyclic reading (from patient identification media)	○ YES	● NO
ABPM cyclic reading stop at entering Disinfection	● YES	○ NO
Taking over limits from patient's parameters	● YES	○ NO

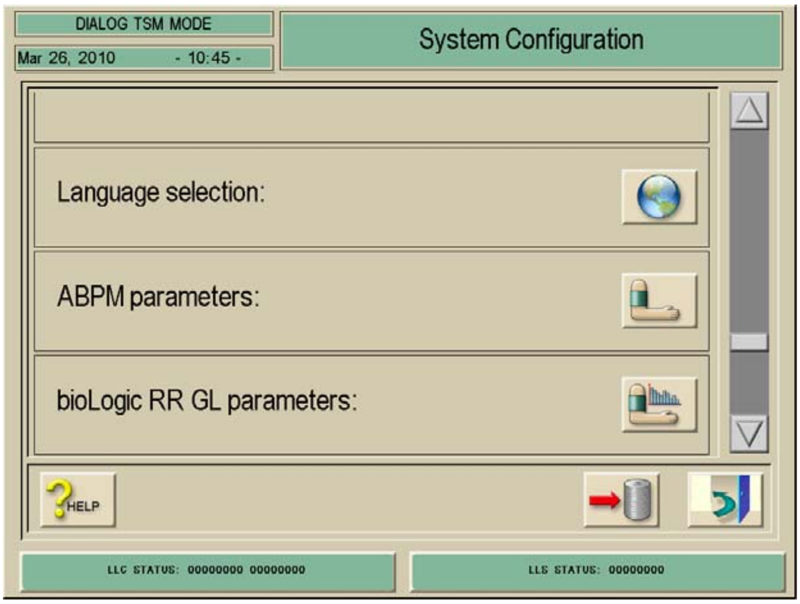
2. Activate the *ABPM Parameters* menu with the *ABPM Parameters* icon. The following menu is opened and displayed.

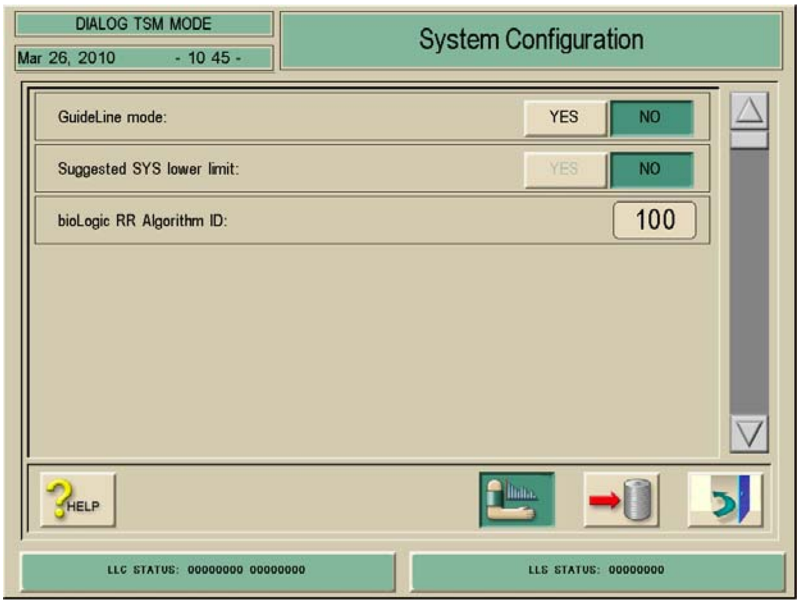
The following parameters can be set:

- Delete Key Data
- Auto Start of Cyclic Reading (from Patient Identification Media)
- ABPM Cyclic Reading Stop at Entering Disinfection
- Taking Over Limits from Patient's Parameters

Delete Key Data	*If YES* is Activated In therapy a delete key is displayed in the ABPM menu. The measurement data can be deleted in the table. *If NO* is Deactivated The measurement data is saved in the table until the end of therapy and can not be deleted.
Auto Start of Cyclic Reading (from Patient Identification Media)	*NO* The cyclic blood pressure measurement must always be selected manually. *YES* If the cyclic blood pressure measurement is on the patient chip card, ABPM is automatically activated at the beginning of a new therapy.
ABPM Cyclic Reading Stop at Entering Disinfection	The cyclic reading of the ABPM is stopped at entering the disinfection.
Taking Over Limits from Patient's Parameters	The limit values in therapy, e.g. for systole/diastole can be stored on a patient chip card. These limit values are taken over if the patient chip card is read.

4.7.1.17 bioLogic RR® GL Parameters





GuideLine mode: YES [✓ NO]

Suggested SYS lower limit: YES [✓ NO]

bioLogic RR Algorithm ID: 100

1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar).
2. Activate the *bioLogic RR® Comfort* menu with the *bioLogic RR® Comfort* icon. The following menu is opened and displayed.

bioLogic RR® GL (GL: Guide-Line)
Note: bioLogic RR GL = bioLogic RR Comfort

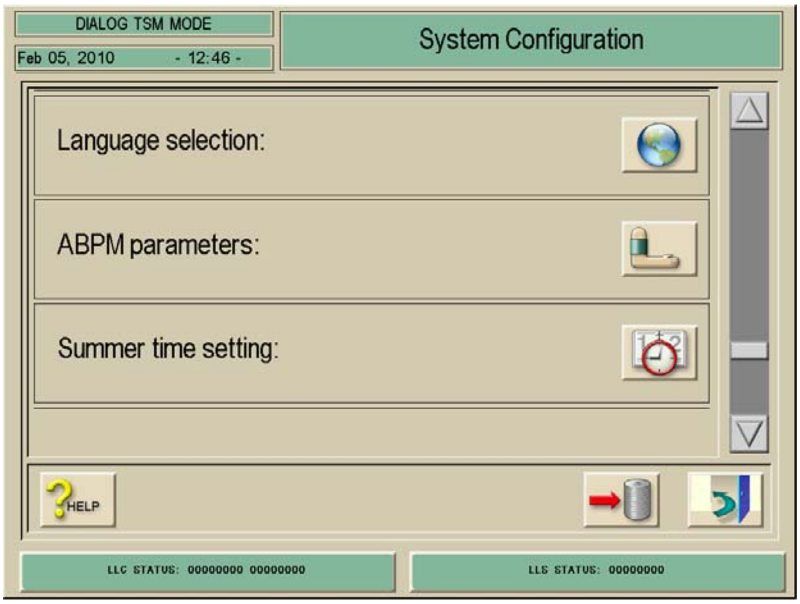
The parameters for the bioLogic RR® Comfort can be set in the *System Configuration*, *bioLogic RR® Parameters* menu, if the option was already selected and activated in the *Production Report* menu.

The following parameters can be set:

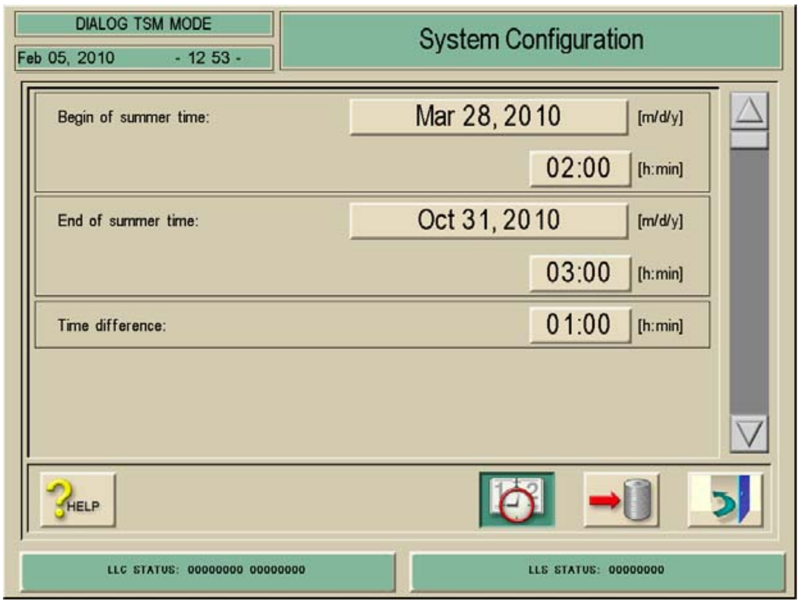
- Guide Line Mode
- Suggested SYS (Systolic) Lower Limit
- bioLogic RR Algorithm ID

Guide Line Mode	Press *YES* key to enable the *Guide Line* (GL) mode of the bioLogic RR® Comfort option. If *NO* is selected the bioLogic RR® Comfort option is used without the guide line (GL) mode.
Suggested SYS (Systolic) Lower Limit	If *Guide Line Mode*: *YES* The suggested systolic lower limit can be selected. The suggested systolic lower limit can be used in therapy to set the SYS lower limit. If *Guide Line Mode*: *NO* The suggested systolic lower limit can not be selected (see bottom figure).
bioLogic RR Algorithm ID	*ID Number 200* The ID number 200 indicates that the *Guide Line Mode* is enabled and can be used in therapy. *ID Number 100* The ID number 100 indicates that the *Guide Line Mode* is not enabled and can not be used in therapy.

4.7.1.18 Summer Time Setting



1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar).



Begin of summer time: Mar 28, 2010 [m/d/y] 02:00 [h:min]

End of summer time: Oct 31, 2010 [m/d/y] 03:00 [h:min]

Time difference: 01:00 [h:min]

2. Activate the *Summer Time Setting* menu with the *Summer Time Setting* icon. The following menu is displayed.

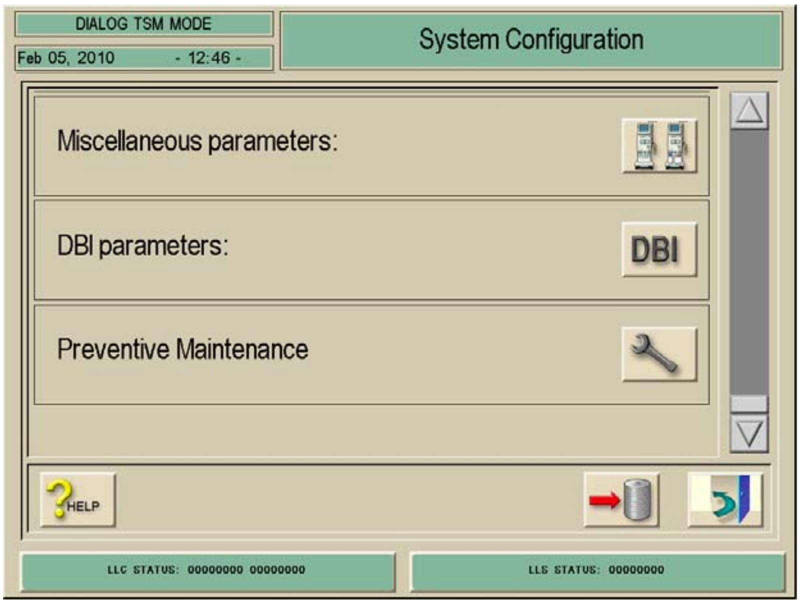
The following parameters can be set:

- Begin of summer time
- End of summer time
- Time difference

Begin of Summer Time	If necessary you can set the start of the summer time (date and hour).
End of Summer Time	If necessary you can set the end of the summer time (date and hour).
Time Difference	If necessary you can set the time difference between summer and winter time.

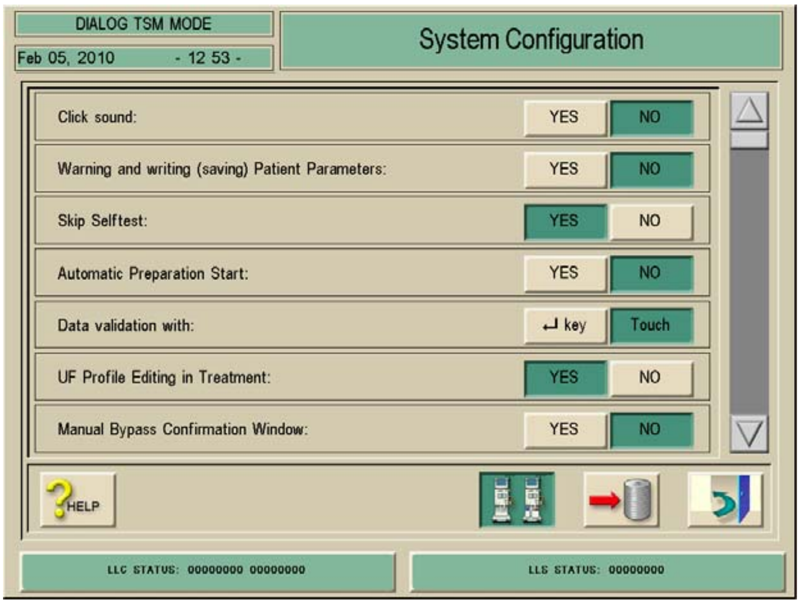
Note: The *Time Difference* should be set to 00:00 for countries where daylight saving time is not applicable.

4.7.1.19 Miscellaneous Parameters



Further parameters can be set in the *Miscellaneous Parameters* menu.

1. Activate the *System Configuration* menu with the *System Configuration* key in menu *Treatment Support*. The following menu is opened and displayed (scroll with scroll bar).



Click sound: YES [✓ NO]
Warning and writing (saving) Patient Parameters: YES [✓ NO]
Skip Selftest: [✓ YES] NO
Automatic Preparation Start: YES [✓ NO]
Data validation with: ↵ key [✓ Touch]
UF Profile Editing in Treatment: [✓ YES] NO
Manual Bypass Confirmation Window: YES [✓ NO]

2. Activate the *Miscellaneous Parameters* menu with the *Miscellaneous Parameters* icon. The following menu is displayed.

The following parameters can be set:

- Click Sound
- Warning and Writing (Saving) Patient Parameters
- Skip Self Tests
- Automatic Preparation Start
- Data Validation with
- UF Profile Editing in Treatment
- Manual Bypass Confirmation Window
- End of Therapy Sound Duration
- Chopped Alarm Sound
- Suppression of Warning Sounds in Preparation
- Automatic Reinfusion Start at Entering End of Treatment

Click Sound

If you activate the *YES* key a click sound is activated if a key or the touch screen is pressed.

Warning and Writing (Saving) Patient Parameters

If you click the *YES* key you can generate a warning message to save the patient data in the following cases:

- The patient data was loaded from the data media
- The therapy was terminated without saving the patient data

Skip Self Tests

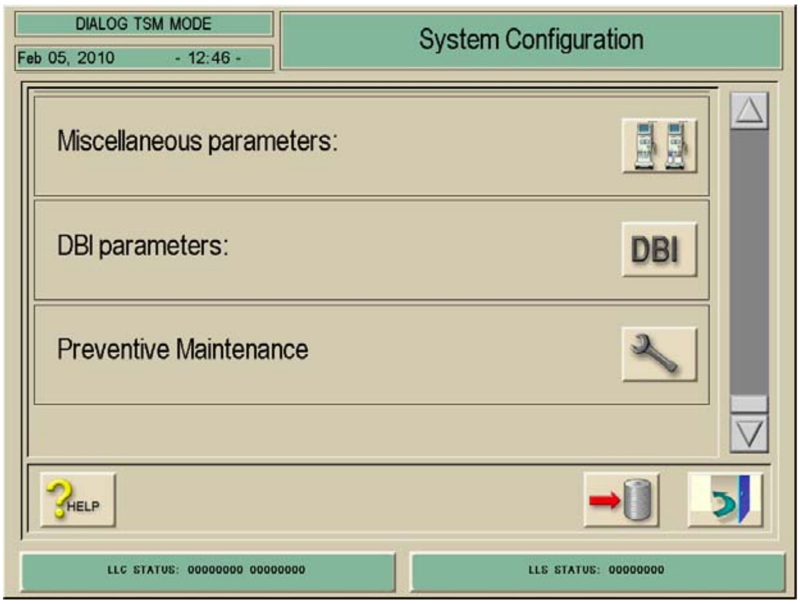
It is only permitted to activate the *Skip Self Test* function for servicing.
It is prohibited to run a therapy with a patient if the *Skip Self Test* function is activated.
The self test must be passed successfully prior to a therapy.

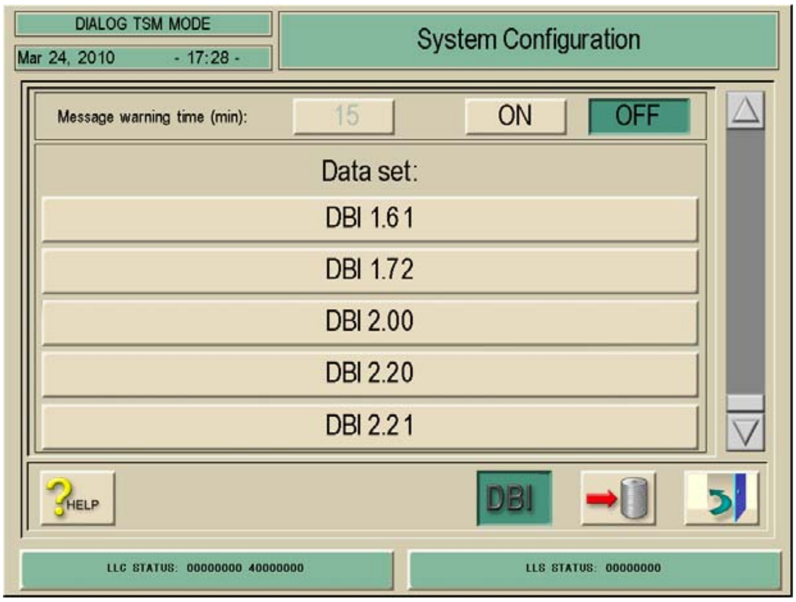
Automatic Preparation Start	Preparation is started after the machine is switched on, if the machine was in therapy selection mode when switched off.
Data Validation with	**Data validation with the ↵ Key:** The confirmation of the data validation for the UF profiles is performed via the ↵ key. **Data validation with the Touch:** The confirmation of the data validation for the UF profiles is performed via the ✓O.K. key (touch screen) in the menu.
UF Profile Editing in Treatment	The editing of the UF profiles can be performed in treatment.
Manual Bypass Confirmation Window	The confirmation window for bypass can be enabled with YES. Thus every bypass switching must be confirmed manually.
End of Therapy Sound Duration	The duration of the sound can be reduced at the end of a therapy.
Chopped Alarm Sound	Two different alarm tones can be selected. **NO** • Standard continuous alarm sound **YES** • Chopped alarm sound
Suppression of Warning Sounds in Preparation	Some warning sounds can be suppressed during preparation. See instructions for use (chapter 4.3) for details.
Automatic Reinfusion Start at Entering End of Treatment	A window is automatically opened at the end of therapy. This window must be confirmed at the end of the therapy for the reinfusion of the blood.

4.7.1.20 DBI Parameters

DBI parameters can be set in the *Dialog Bedside-Link Interface DBI Parameters* menu.

1. Activate the System Configuration menu with the System Configuration key in menu Treatment Support. The following menu is opened and displayed (scroll with scroll bar).





Message warning time (min): 15 ON OFF

The DBI menu is present and can be opened if DBI Nexadia was selected in the Production Report, Low Level Options. Various DBI parameters can be selected in the DBI Parameters menu.

Baud Rate (kBaud)

The default for the Baud rate is 38.4 kBaud.

Automatic User Logout Time (min)

An automatic user logout time can be set and activated. After the automatic logout the user has to log in again before he is able to confirm any messages, medications or checklist entries.

Message Warning Time (min)

A message warning time can be set and activated. Thereby it is possible to inform users of any unconfirmed messages, medications or checklist entries, before the end of a therapy.

Note:

The data set must be set according to the support of the Nexadia software.

Data Set DBI 1.61 (applicable for Nexadia)

Data Set DBI 1.72 (not applicable)

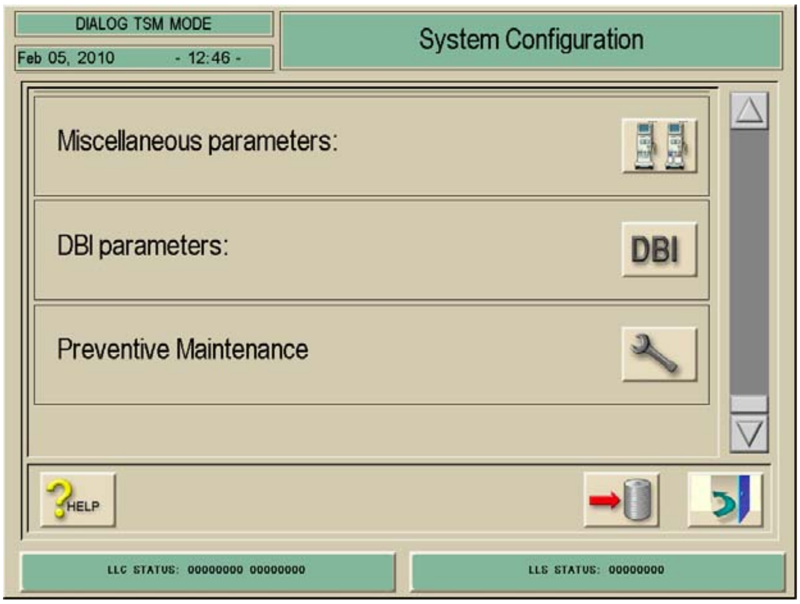
Data Set DBI 2.00 (default)

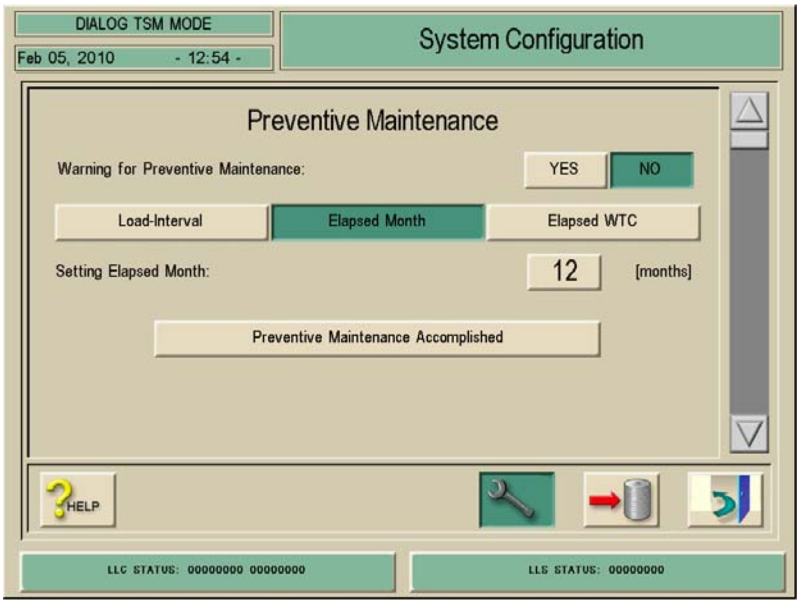
Data Set DBI 2.20 (not applicable)

Data Set DBI 2.21

The data set DBI 2.21 is required for the extension of the Nexadia functionality, e.g. support of the option bioLogic RR Comfort and Adimea; the mmol/l unit can be used. The Nexadia protocol must be supported by the host computer.

4.7.1.21 Preventive Maintenance





Warning for Preventive Maintenance: NO

Elapsed Month

Setting Elapsed Month: 12 [months]

Preventive maintenance parameters can be set in the *Preventive Maintenance* menu.

1. Activate the System Configuration menu with the System Configuration key in menu Treatment Support. The following menu is opened and displayed (scroll with scroll bar).
2. Activate the *Preventive Maintenance* menu with the *Preventive Maintenance* icon. The following menu is displayed.

You can define an interval for a preventive maintenance PM. If this feature is selected (YES): the user is informed about the necessity of a preventive maintenance. A warning message is displayed in the transition phase end of treatment/start of disinfection. The message is displayed according to the following conditions:

- once if status is ≤ 5 % of set condition
- every time if set condition is expired

The following warning message is displayed:

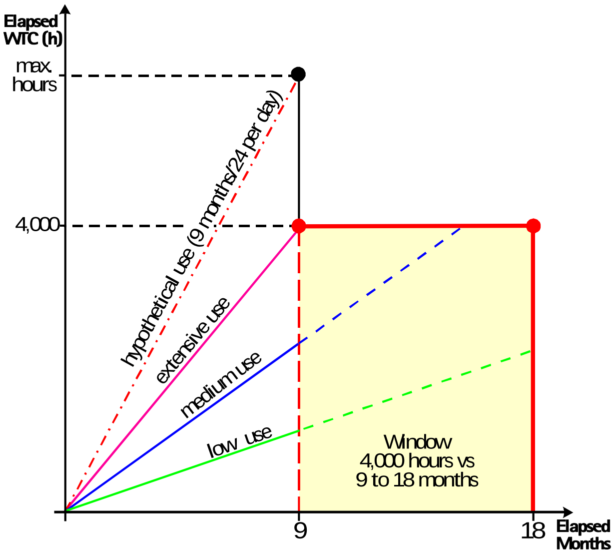
Preventive Maintenance Recommended
The set preventive maintenance interval is expired.
Please inform your service technician.

One of three modes can be selected to calculate the next preventive service.

Load-Interval

A warning message is enabled under the following defined conditions:

- *YES* is selected
- the user is never warned in the first 9 month period
- the user is always warned after a 18 month period
- the user is warned between a 9 to 18 month period if the working time is more than 4,000 hours after the last reset.



Elapsed Months

A warning message is enabled if *YES* is selected and the preselected period of months is expired.

Note: The manufacturer recommends an annual preventive maintenance and the replacement of the wear and tear parts from the preventive maintenance kit.

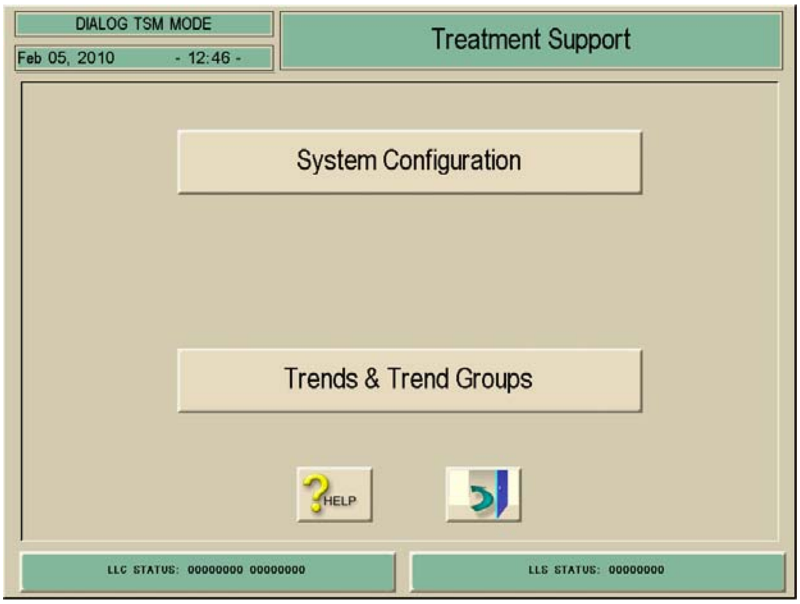
Elapsed WTC (Working Time Counter)

A warning message is enabled if *YES* is selected and the set working time is elapsed.

Preventive Maintenance Accomplished

Press the *Preventive Maintenance Accomplished* key and then the *Save* icon after the preventive maintenance was performed. Consequently a new preventive service period is started again after the machine is switched off and on.

4.7.2 Trends and Trend Groups



Six different trend groups can be selected for the treatment mode. Three treatment parameters can be configured individually for each group.

1. Activate the *Treatment Support* menu with the *Treatment Support* key in the *TSM Main Menu*. The following menu is opened.

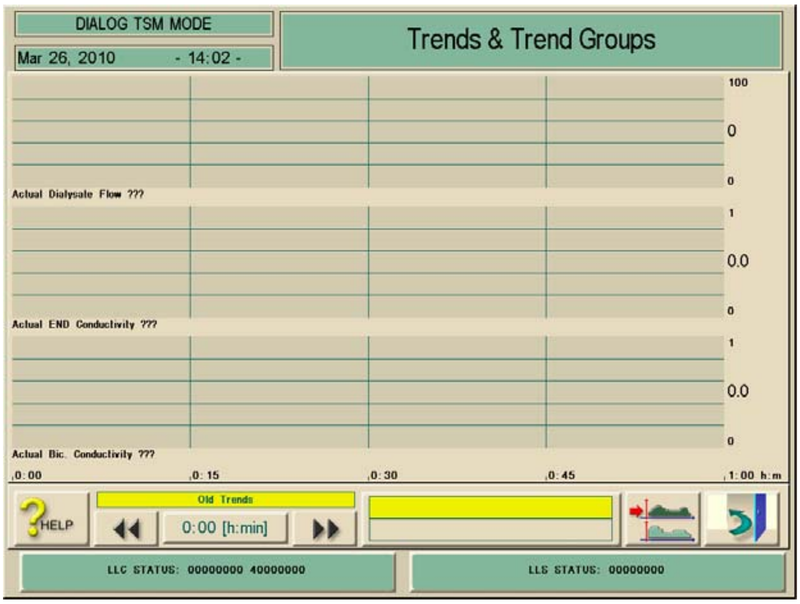
The following settings can be selected:

- Cursor (left and right)
- Time display
- Selection of trend groups

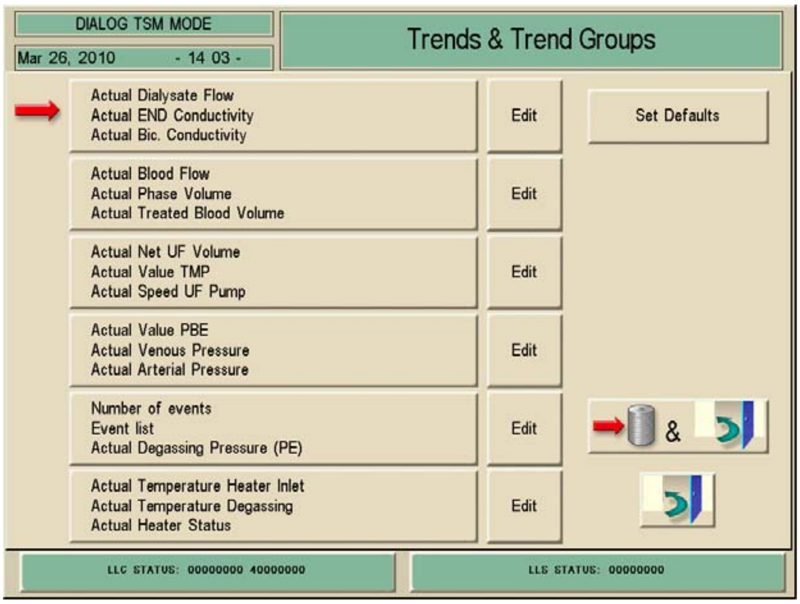
Cursor (left and right) The last treatment results can be displayed. You can shift the time base in one minute increments with the left or right cursor. The time is displayed in the *Time Display* window. A specific time can be selected in the graphics with the time base. Thus the corresponding events can be displayed.

Time Display You can position the time base on a certain treatment time. The corresponding events can be displayed.

Selection of Trend Groups You can select the *Trend Groups* menu. Six different graphic blocks can be selected. Three treatment parameters for each block can be configured individually.



2. Activate the *Trend and Trend Groups* menu with the *Trend and Trend Groups* key in the *Treatment Support* menu. The following menu is opened and displayed.
3. Activate the *Trend History* menu with the *Trend History* window.



Actual Dialysate Flow
Actual END Conductivity
Actual Bic. Conductivity

Actual Blood Flow
Actual Phase Volume
Actual Treated Blood Volume

Actual Net UF Volume
Actual Value TMP
Actual Speed UF Pump

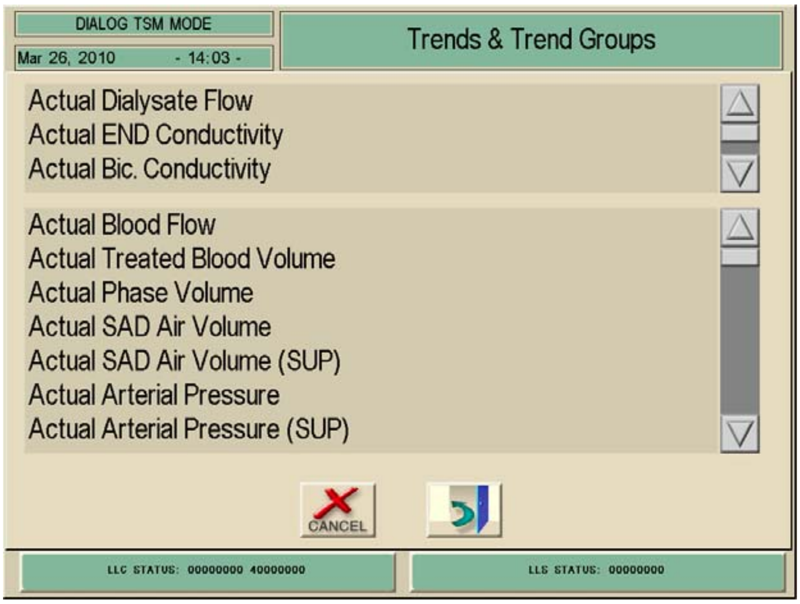
Actual Value PBE
Actual Venous Pressure
Actual Arterial Pressure

Number of events
Event list
Actual Degassing Pressure (PE)

Actual Temperature Heater Inlet
Actual Temperature Degassing
Actual Heater Status

Six trend groups are available. The trend group with the red arrow can be selected.

4. Activate the *Trend Groups* menu with the *Trend Groups* icon.



Actual Dialysate Flow
Actual END Conductivity
Actual Bic. Conductivity

Actual Blood Flow
Actual Treated Blood Volume
Actual Phase Volume
Actual SAD Air Volume
Actual SAD Air Volume (SUP)
Actual Arterial Pressure
Actual Arterial Pressure (SUP)

Edit Key

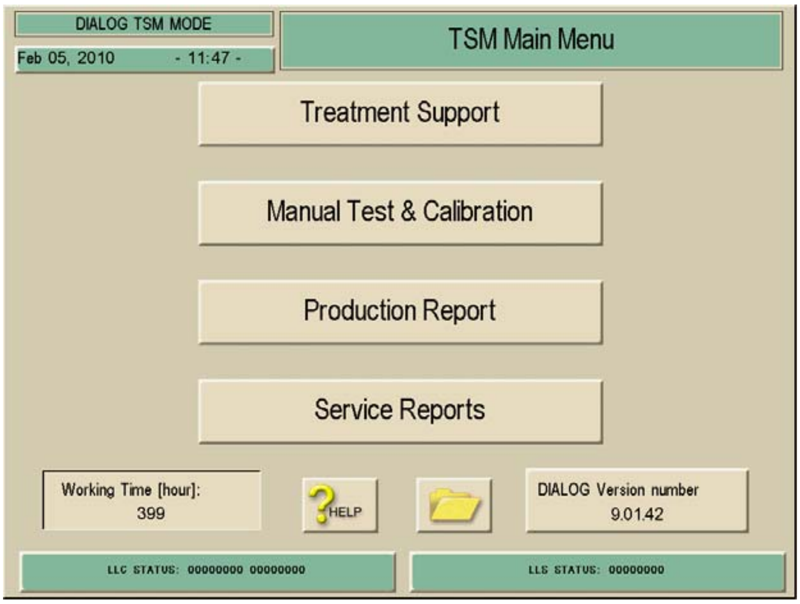
Three treatment parameters can be selected for one group from a parameter list.

5. Activate the *Edit* menu with the *Edit* icon.

6. The treatment parameters in the six trend groups can be modified.

7. The default parameters can be reset with the *Set Defaults* window.

4.8 Manual Test and Calibration



Feb 05, 2010 - 11:47 -

Working Time [hour]: 399

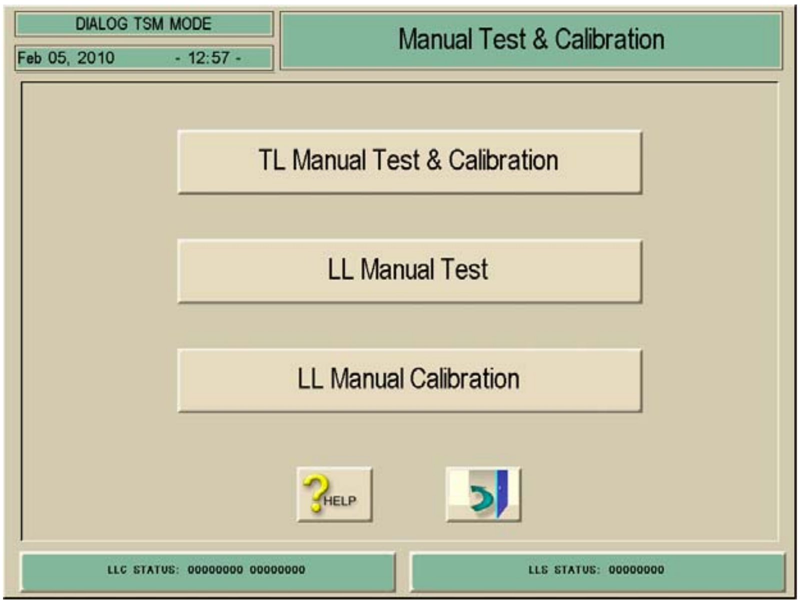
DIALOG Version number 9.01.42

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

The menu contains test and calibration functions. The user can test all basic operations and calibrate components (e.g. sensors and pumps).

The *TSM Main Menu* appears after the machine is switched on.



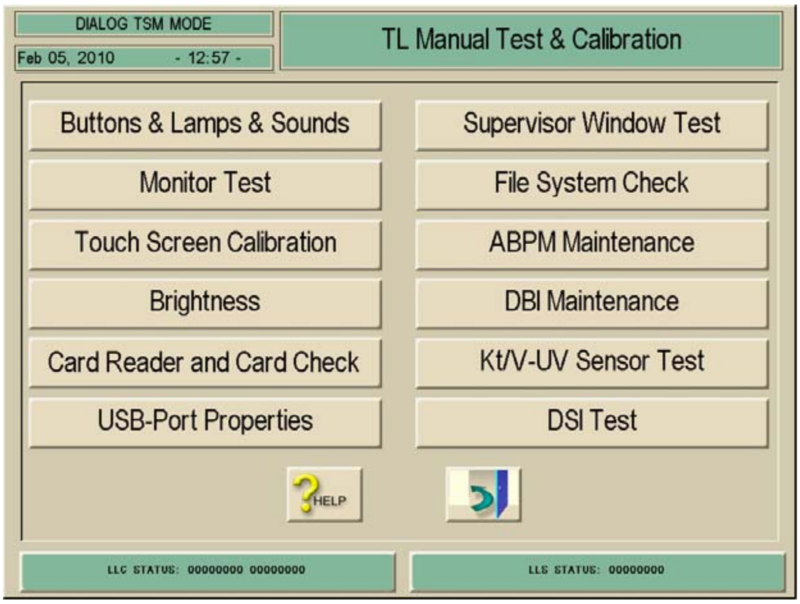
Feb 05, 2010 - 12:57 -

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

1. Activate the *Manual Test and Calibration* menu with the *Manual Test and Calibration* key in the *TSM Main Menu*. The following menu is opened.

4.8.1 Top Level Manual Test and Calibration



Feb 05, 2010 - 12:57 -

LLC STATUS: 00000000 00000000

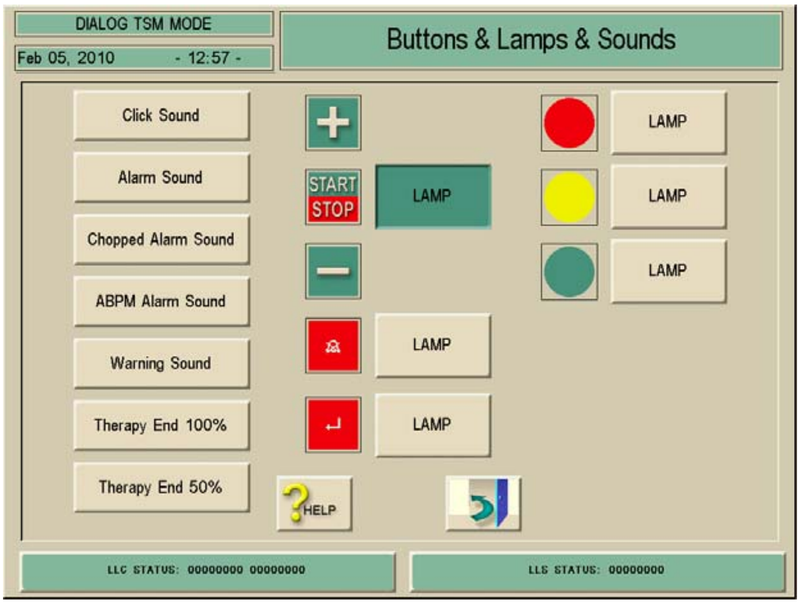
LLS STATUS: 00000000

You can perform functional tests, a touch screen calibration, and the test of present options in the *Top Level Manual Test and Calibration* menu.

1. Activate the *TL Manual Test and Calibration* menu with the *TL Manual Test and Calibration* key.

- Buttons, Lamps and Sounds
- Monitor Test
- Touch Screen Calibration
- Brightness
- Card Reader and Card Check (Option Card Reader)
- USB Port Properties
- Supervisor Window Test
- File System Check
- ABPM Maintenance (Option ABPM)
- DBI Maintenance (Option Nexadia-BSL)
- Kt/V-UV Sensor Test (Option Adimea)
- DSI Test (Option Crit-Line)

4.8.1.1 Buttons, Lamps and Sounds



1. Activate the *Buttons, Lamps and Sounds* menu with the *Buttons, Lamps and Sounds* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.

In the *Buttons, Lamps and Sounds* menu the following functions can be tested:

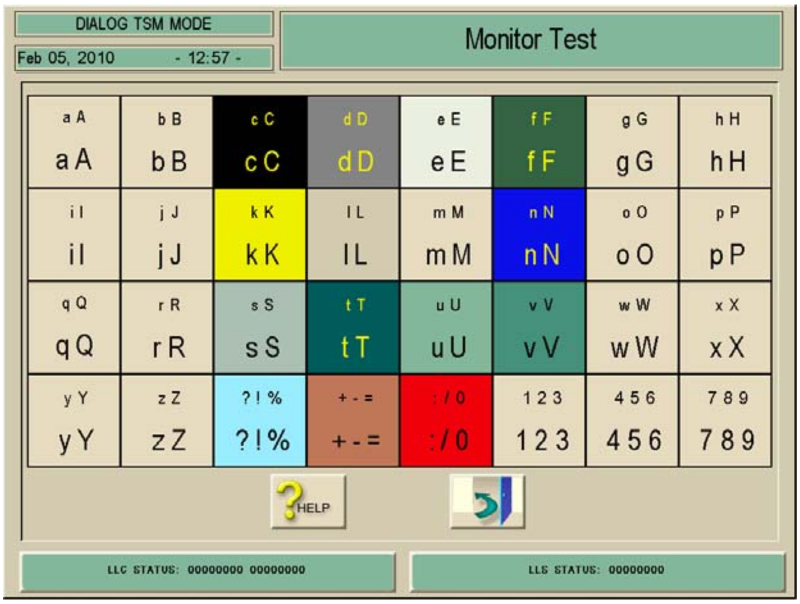
- different sounds
- LEDs for start stop / 🔕 / ↵ (on front panel board FPB)
- LEDs for signal lamps (on optical status display boards OSDs)

Click Sound	The *Click* sound can be checked.
Alarm Sound	The *Alarm* sound can be checked.
Chopped Alarm Sound	The *Chopped Alarm* sound can be checked.
ABPM Alarm Sound	The *ABPM Alarm* sound can be checked.
Warning Sound	The *Warning* sound can be checked.
Therapy End 100%	The *Therapy End 100 %* sound can be checked.
Therapy End 50%	The *Therapy End 50 %* sound can be checked.
+	Check + key for blood pump.
START STOP	Check start stop key/lamp for blood pump.
−	Check − key for blood pump.
🔕	Check alarm 🔕 (confirm) key and lamp (LED).
↵	Check ↵ (enter) key and lamp (LED).
🔴	Check red LED for signal lamp (on optical status display boards OSD).
🟡	Check yellow LED for signal lamp (on optical status display boards OSD).
🟢	Check green LED for signal lamp (on optical status display boards OSD).

4.8.1.2 Monitor Test

A table appears with all colours. Every square contains an alphanumerical character with different character fonts. The brightness and the contrast of the monitor can be checked with this test image.

1. Activate the *Monitor Test* menu with the *Monitor Test* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.



DIALOG TSM MODE

Feb 05, 2010 - 12:57 -

Monitor Test

a A a A	b B b B	c C c C	d D d D	e E e E	f F f F	g G g G	h H h H
i l i l	j J j J	k K k K	l L l L	m M m M	n N n N	o O o O	p P p P
q Q q Q	r R r R	s S s S	t T t T	u U u U	v V v V	w W w W	x X x X
y Y y Y	z Z z Z	? ! % ? ! %	+ - = + - =	: / 0 : / 0	1 2 3 1 2 3	4 5 6 4 5 6	7 8 9 7 8 9

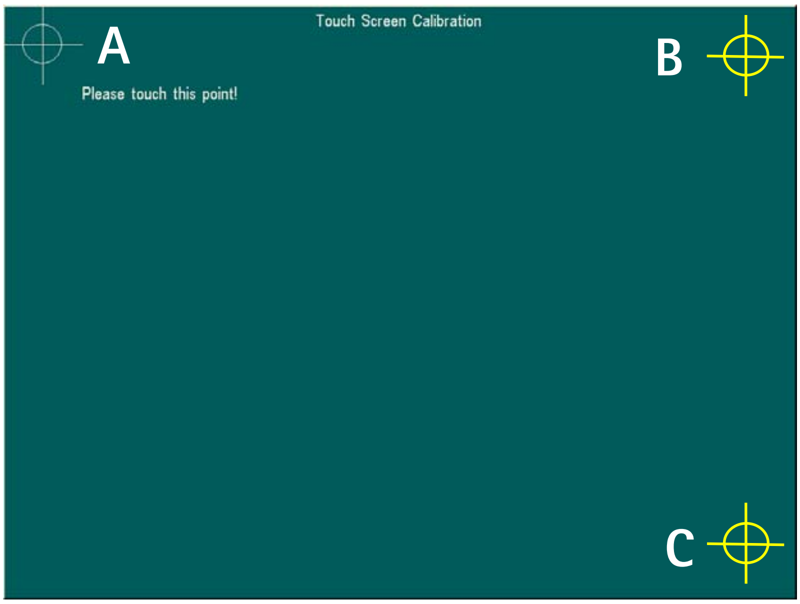
LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

4.8.1.3 Touch Screen Calibration

The touch screen can be calibrated in the *Touch Screen Calibration* menu.

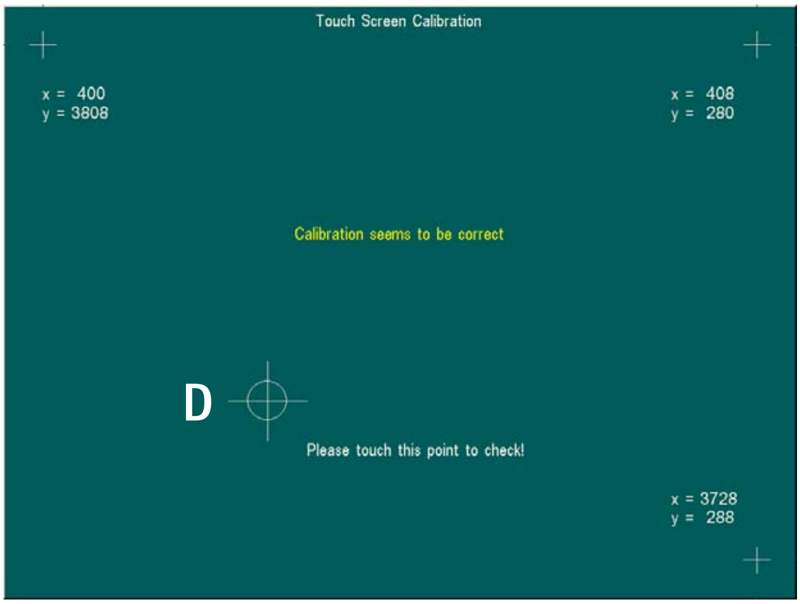
The active part of the touch screen is displayed in the figure. Four points are used (**A**, **B**, **C** and **D**) for the calibration. The touch area is defined by the calibration.
Tip on the cross wires to ensure an accurate setting during calibration.



Touch Screen Calibration

Please touch this point!

1. Activate the *Touch Screen Calibration* menu with the *Touch Screen Calibration* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.
2. Tip the cross wires **A** in the upper left corner. The first calibration point is defined.
3. Tip the cross wires **B**. The second calibration point is defined.
4. Tip the cross wires **C**. The third calibration point is defined.



Touch Screen Calibration

x = 400
y = 3808

x = 408
y = 280

Calibration seems to be correct

Please touch this point to check!

x = 3728
y = 288

The following message is displayed:
Calibration seems to be correct!

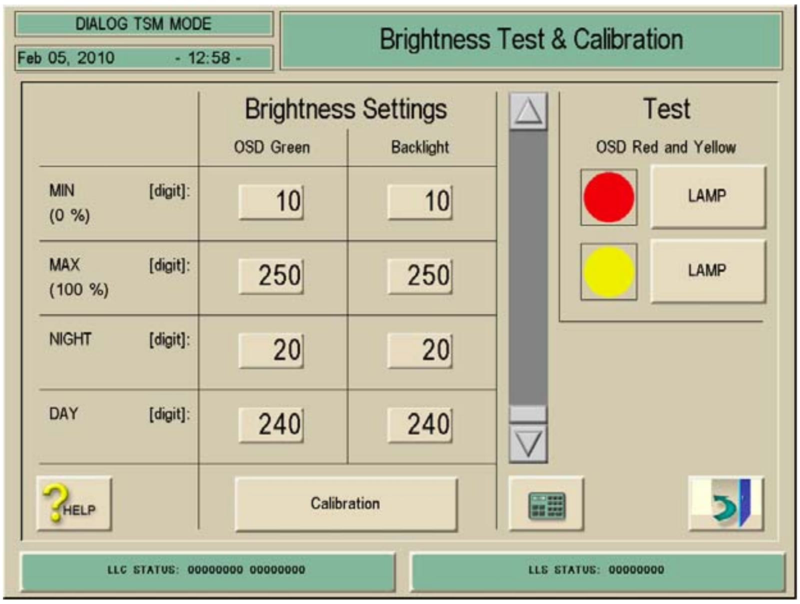
5. Tip the cross wires **D** to check the calibration. The following message is displayed if the calibration was successful:
   Calibration OK
   The calibration data is stored. The *TL Manual Test and Calibration* menu is automatically displayed again.
6. Switch the Dialog+ off and on again. The new calibration data are loaded for the touch screen.
7. Check the touch screen.

Download Default Setting

If the touch screen is out of function (e.g. after a faulty calibration) the default setting for the touch screen can be downloaded.

1. Press the + key of the blood pump (on the keyboard membrane of the TFT housing) three times in the *TSM Main Menu*.
2. Switch machine off and on again. The old default setting is loaded.

4.8.1.4 Brightness Calibration



		OSD Green	Backlight
MIN (0 %)	[digit]:	10	10
MAX (100 %)	[digit]:	250	250
NIGHT	[digit]:	20	20
DAY	[digit]:	240	240

Parameters can be set and tests can be performed in the *Brightness and Test Calibration* menu.

1. Activate the *Brightness* menu with the *Brightness* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.

If a button was pressed the field remains highlighted.

If a value is changed the *Calibration* button must be pressed to take over the new value.

If a *MIN* or *MAX* value was set the minimum and/or maximum limits for *NIGHT/DAY* are adapted.

Brightness Settings

OSD Green Parameter (for green LED)

MIN (0%)

The minimum brightness (digits) for the green LEDs on the optical status display OSD boards can be set.

MAX (100%)

The maximum brightness (digits) for the green LEDs on the optical status display OSD boards can be set.

NIGHT

The night brightness (digits) for the green LEDs on the optical status display OSD boards can be set.

DAY

The day brightness (digits) for the green LEDs on the optical status display OSD boards can be set.

Backlight Parameter

MIN (0%)

The minimum brightness (digits) for the backlight can be set.

MAX (100%)

The maximum brightness (digits) for the backlight can be set.

NIGHT

The night brightness (digits) for the backlight set.

DAY

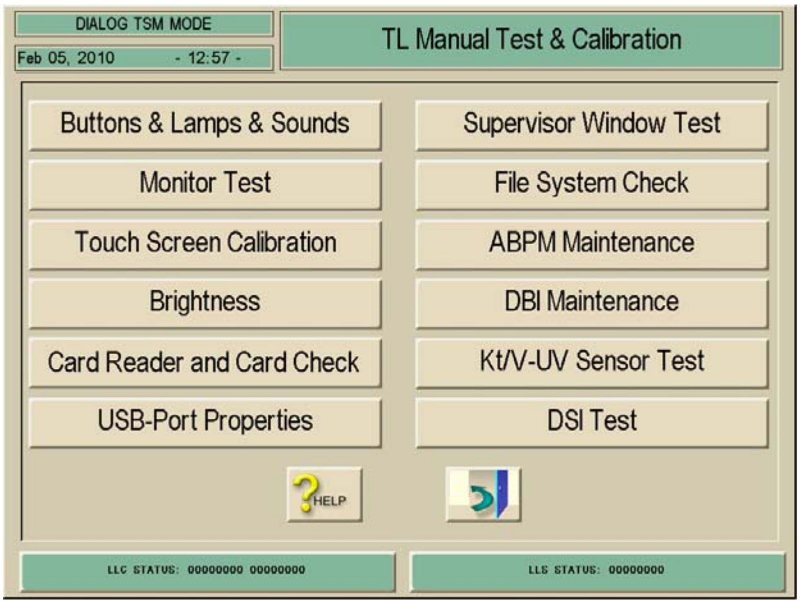
The day brightness (digits) for the backlight set.

Test

OSD Red and Yellow (for Signal Lamps)

The red and yellow LED of the optical status display OSD can be checked, i.e. switched ON and OFF.

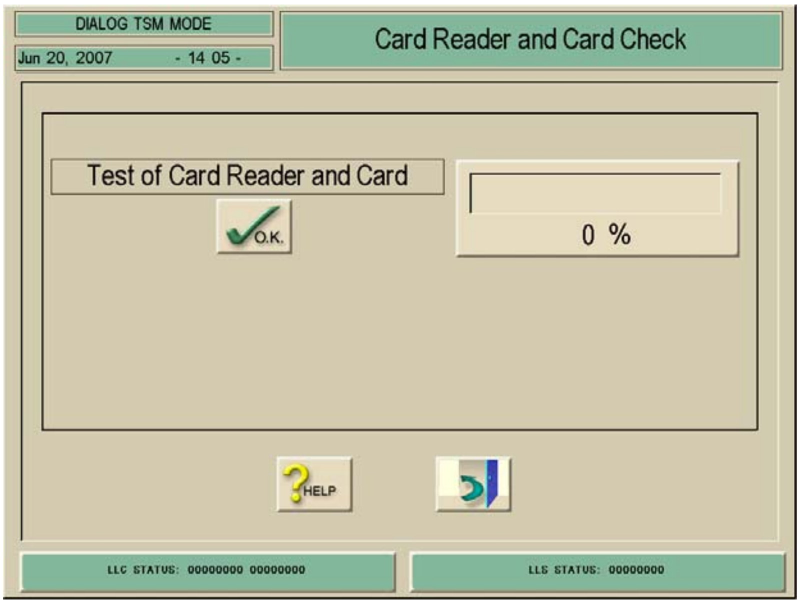
4.8.1.5 Card Reader and Card Check



The card reader and the card can be checked in the *Card Reader and Card Check* menu.

The *Card Reader and Card Check* key is displayed in this menu if the card reader is present in the machine and the option was selected/activated in the *Production Report* menu.

1. Activate the *Card Reader and Card Check* menu with the *Card Reader and Card Check* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.

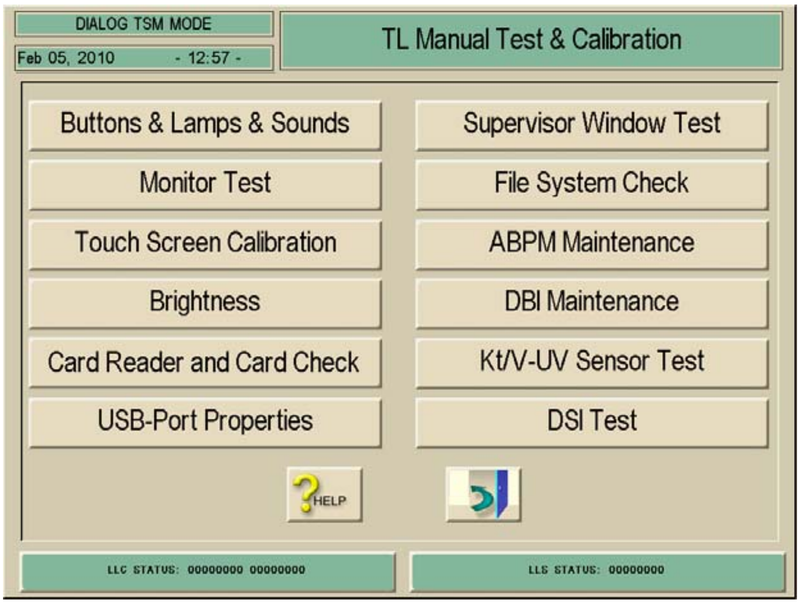


Both card reader and chip card can be checked if a chip card is inserted in the card reader and the test is started with the OK key. The chip card must be inserted with the contacts facing upwards.

Note

- Use an empty service chip card (art. no. 7703856) for the test and not a patient chip card.
- Do not remove the chip card from the card reader during the test.

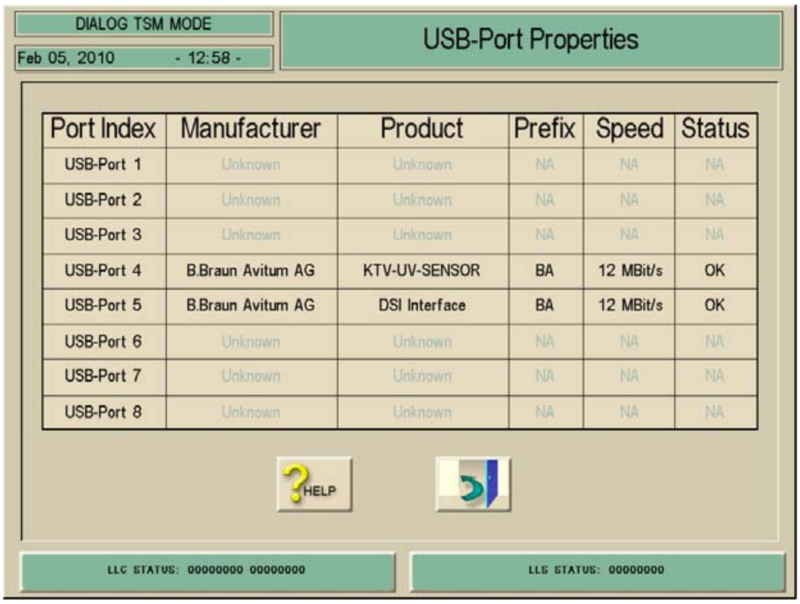
4.8.1.6 USB-Port Properties



All devices connected to the motherboard can be checked in the *USB Port Properties* menu.

All devices connected to the USB ports of the motherboard are displayed in a table if the *USB Port Properties* key is pressed in the *TL Manual Test and Calibration* menu. There are two different tables depending on the type of motherboard connected.

1. Activate the *USB Port Properties* menu with the *USB Port Properties* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.



Port Index	Manufacturer	Product	Prefix	Speed	Status
USB-Port 1	Unknown	Unknown	NA	NA	NA
USB-Port 2	Unknown	Unknown	NA	NA	NA
USB-Port 3	Unknown	Unknown	NA	NA	NA
USB-Port 4	B.Braun Avitum AG	KTV-UV-SENSOR	BA	12 MBit/s	OK
USB-Port 5	B.Braun Avitum AG	DSI Interface	BA	12 MBit/s	OK
USB-Port 6	Unknown	Unknown	NA	NA	NA
USB-Port 7	Unknown	Unknown	NA	NA	NA
USB-Port 8	Unknown	Unknown	NA	NA	NA

Motherboard on Top Level Sub-Rack

The table displays all USB ports available on the motherboard with the corresponding USB port properties.

Port Index
The USB ports (1 through 8) on the motherboard.

- Ports 1 through 3 are internally assigned and can not be used for options
- Ports 4 through 8 can be chosen freely for options that are connected to a USB port

Manufacturer
The name of the USB device manufacturer.

Product
The name of the USB device product.

Prefix
The first two characters of the serial number of the USB device.

Speed
The maximum speed of the USB port.

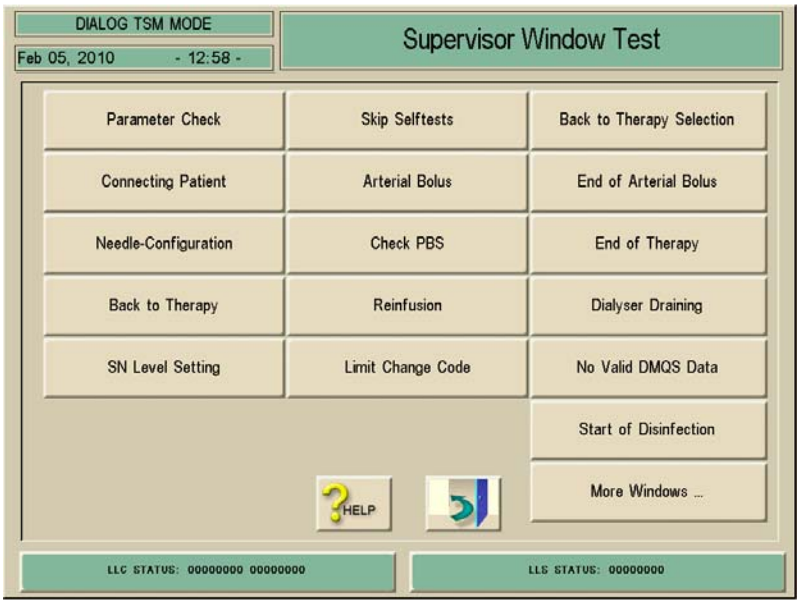
Status

OK
The connected USB device is in the valid USB device list.

Not OK
The connected USB device is not in the valid USB device list.

4.7.1.7 Supervisor Window Test

The position and data of the selected supervisor window is displayed. You can close the window with the *Cancel* key.



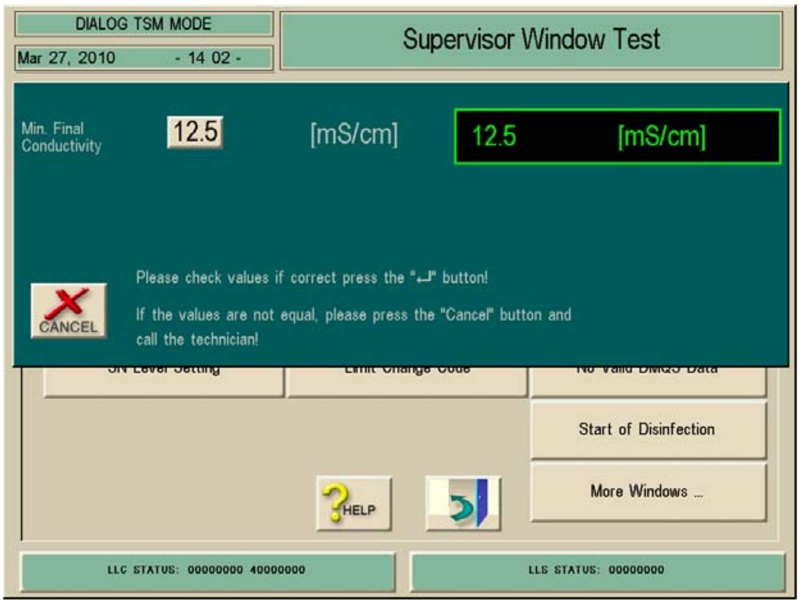
1. Activate the *Supervisor Window Test* menu with the *Supervisor Window Test* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.

The following supervisor windows can be checked:

- Parameter Check
- Connecting Patient
- Needle Configuration
- Back to Therapy
- SN Level Setting
- Skip Self Tests
- Arterial Bolus
- Check PBS
- Reinfusion
- Limit Change Code
- Back to Therapy Selection
- End of Arterial Bolus
- End of Therapy
- Dialyser Draining
- No Valid DMQS Data
- Start of Disinfection

More Windows ...:
- Multi Window
- UF Volume and Max. UF Rate
- Multi Window MW with Substitution Volume
- Multi Window MW with Single Needle
- Min. Max. Final Conductivity

A parameter check is displayed as an example.
The supervisor window for the *Min. Max. Final Conductivity* is displayed. You can either close the supervisor window with the CANCEL key or select and acknowledge the single parameters and close the supervisor window with the ↵ key.



Min. Final Conductivity 12.5 [mS/cm] 12.5 [mS/cm]

Please check values if correct press the "↵" button!

If the values are not equal, please press the "Cancel" button and call the technician!

2. Activate the *Parameter Check* window with the *Parameter Check* key. The following menu is displayed.

3. Press the CANCEL key to close the supervisor window.

   or

   Press the ↵ key to select and acknowledge the single parameters and close the supervisor window.

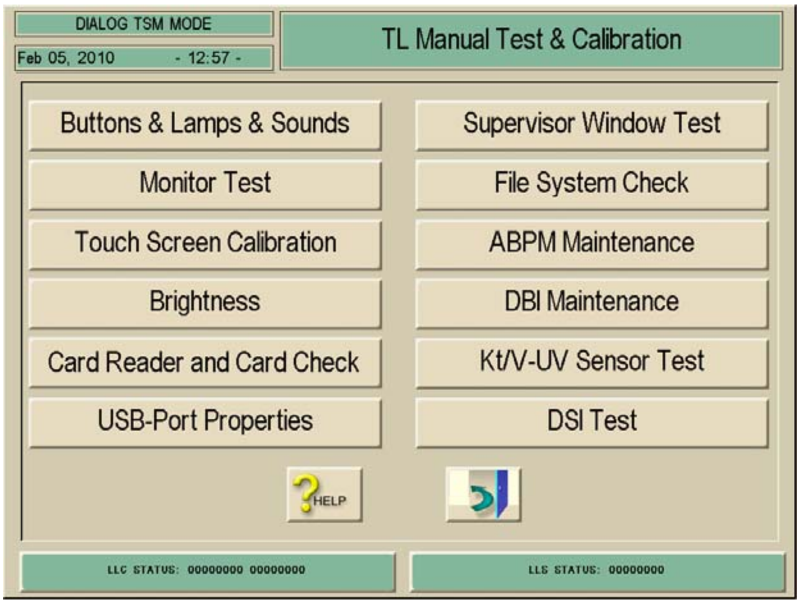
4.7.1.8 File System Check

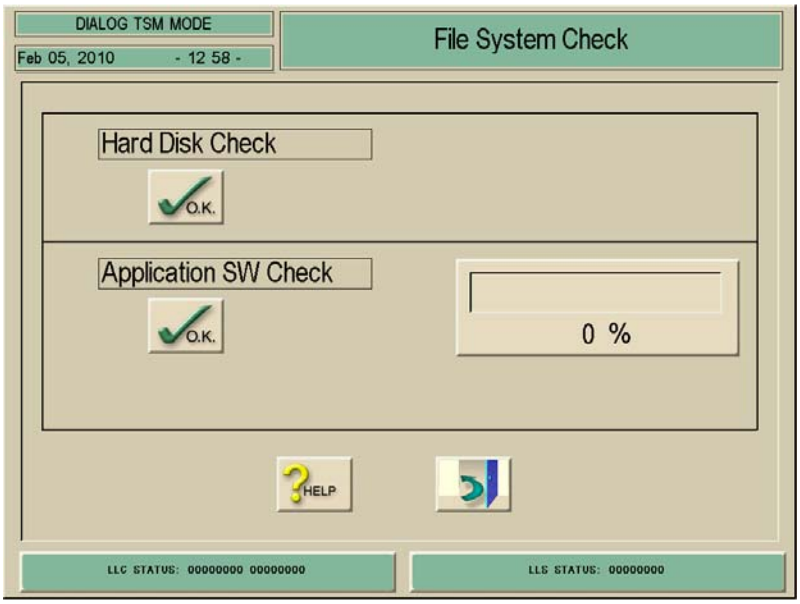
Press the O.K. key to start the check of the Dialog file system. This function reads all executable files and creates a check value. If it does not equal with the original check value a warning message is displayed.

1. Activate the *Test System Check* menu with the *Test System Check* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.
2. Press the O.K. key of the *Hard Disk Check* (for the compact flash card) to test the hard disk drive.

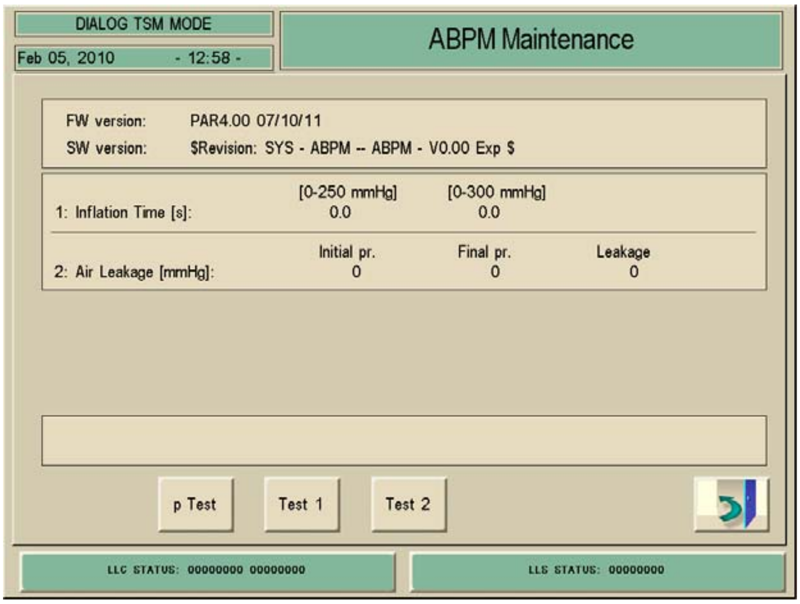
   or

   Press the O.K. key of the *Application SW Check* to test the application software.





4.8.1.9 ABPM Maintenance



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FW version: PAR4.00 07/10/11
SW version: $Revision: SYS - ABPM -- ABPM - V0.00 Exp $

	[0-250 mmHg]	[0-300 mmHg]	
1: Inflation Time [s]:	0.0	0.0	
	Initial pr.	Final pr.	Leakage
2: Air Leakage [mmHg]:	0	0	0

LLC STATUS: 00000000 00000000
LLS STATUS: 00000000

1. Activate the *ABPM Maintenance* menu with the *ABPM Maintenance* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.

The *ABPM Maintenance* menu is used for the function test of the Dialog automatic blood pressure measurement ABPM option. The cuff is replaced by a 500 ml measurement chamber.

The following functions can be tested:

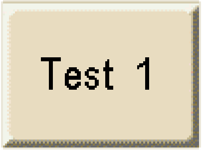
- P Test Pressure Comparison Test
- Test 1 Inflation Time
- Test 2 Air Leakage

See chapter 5 technical safety inspection and preventive maintenance: inspection protocol for the automatic blood pressure measurement ABPM and the execution procedure for the measurement inspection.

Pressure Comparison Test

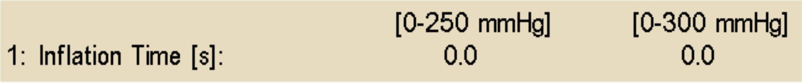
The *P Test* key activates and deactivates the pressure comparison test of the ABPM. The *P Test* is used to compare the pressure value of the pressure sensor with a reference instrument.
A reference instrument (accuracy ≤ ± 0.5 mmHg) is required for the comparison test of the pressure sensor.

Inflation Time [s]



The *Test 1* key activates and deactivates the inflation time. Thus the inflation time of the pump is tested up to 300 mmHg, i.e.:

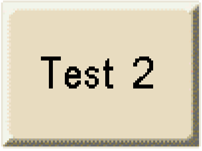
- 0 - 250 mmHg
- 0 - 300 mmHg



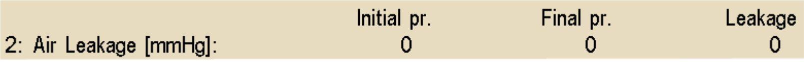
	[0-250 mmHg]	[0-300 mmHg]
1: Inflation Time [s]:	0.0	0.0

The measurement chamber is connected to the ABPM system via the pressure tubing. A pressure is built up to 300 mmHg.

Air Leakage [mmHg]



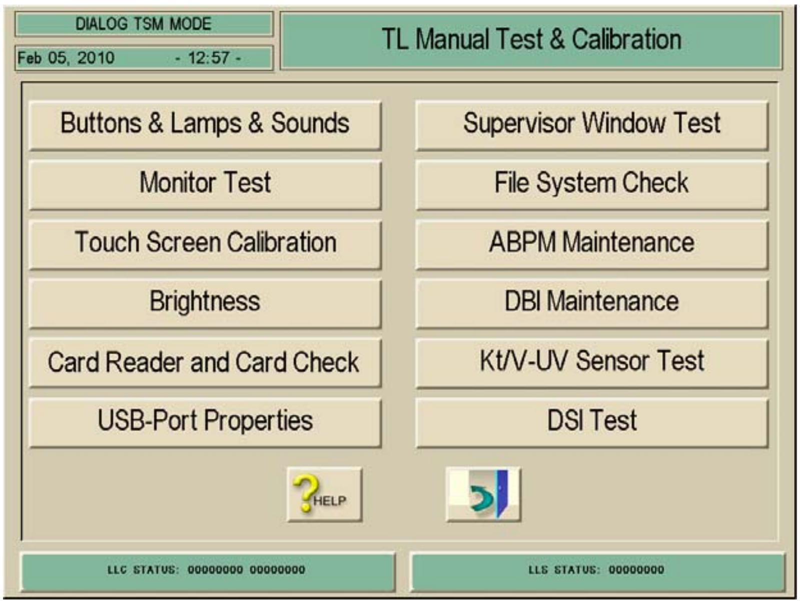
The *Test 4* key activates and deactivates the air leakage test (3 minutes). Thus the pneumatic integrity of the ABPM system is tested.

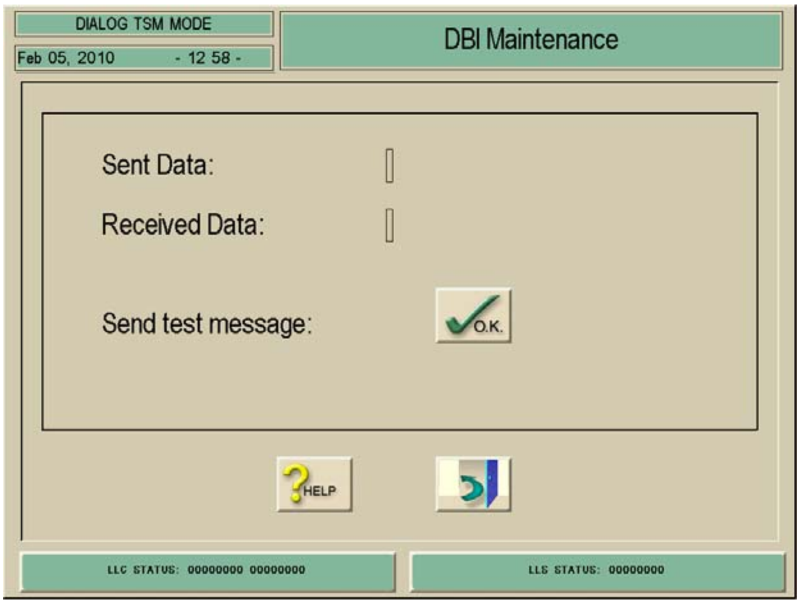


	Initial pr.	Final pr.	Leakage
2: Air Leakage [mmHg]:	0	0	0

The measurement chamber is connected to the ABPM system via the pressure tubing. A pressure is built up to 300 mmHg and is held for 3 minutes.

4.8.1.10 DBI Maintenance





If the DBI option (for Nexadia/WAN-BSL (Bedside Link) Network) was selected in the menu *Production Report/Low Level Options* the *Dialog Bedside-Link Interface DBI Maintenance* button is displayed.

The RS 232 port (COM1) on the motherboard can be tested (*Sent Data* and *Received Data*) in the *DBI Maintenance* menu. A test plug **A** (art. no. 7703473) is required to perform the DBI test.

1. Connect the test plug **A** to the RS 232 port (COM1) on the motherboard.
2. Switch on machine.
3. Open the *DBI Maintenance* menu with the *DBI Maintenance* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.
4. Press the ✓O.K. key to start test.

   Note: The DBI test can be repeated by pressing the ✓O.K. key. If the DBI test is repeated the sent data pattern is different (≠ *1234567890*).

Sent Data

The sent data are displayed.

Received Data

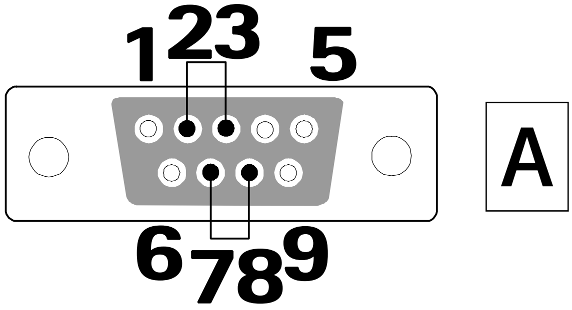
The received data are displayed.

Comparison of Data

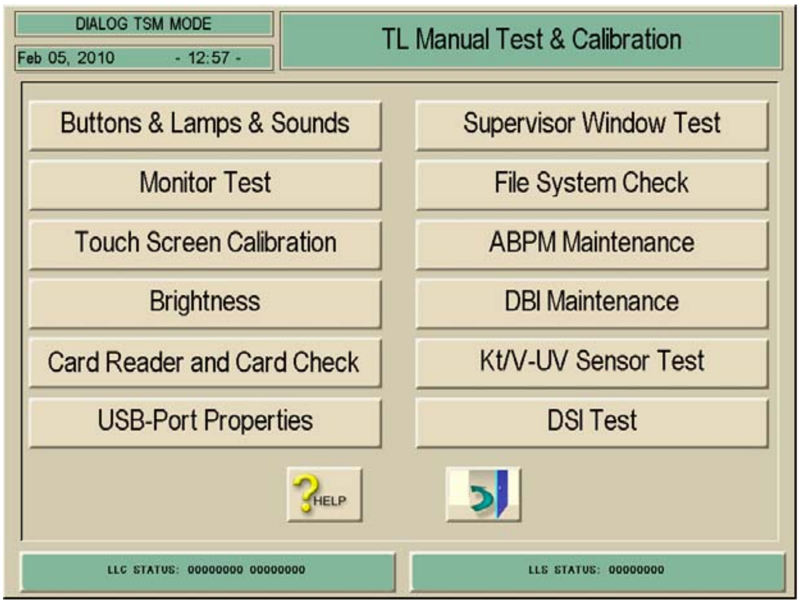
If the *Sent Data* and *Received Data* are identical, the test was successful.

5. Switch off machine after successful test.
6. Remove the test plug from the RS 232 port.

Pin Assignment RS 232 Test Plug (Soldering Side)



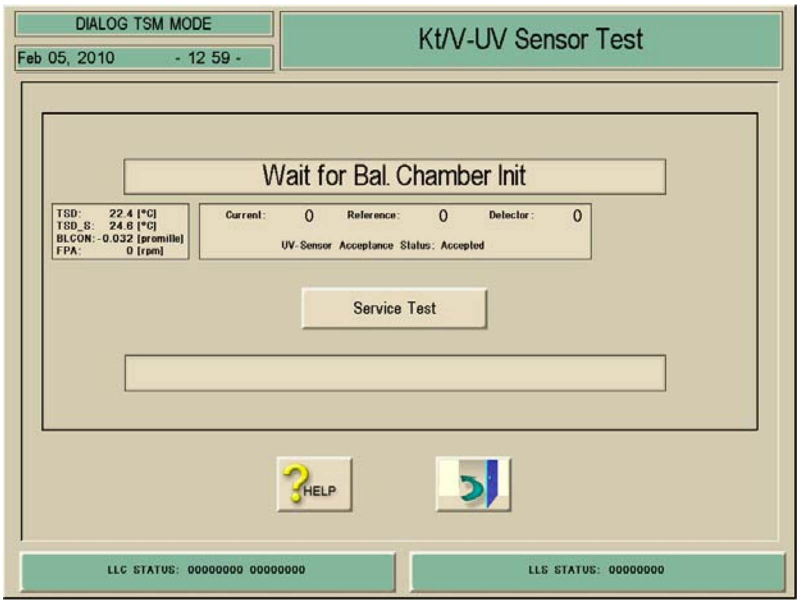
4.8.1.11 Kt/V-UV Sensor Test



Feb 05, 2010 - 12:57 -

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000



Feb 05, 2010 - 12 59 -

Wait for Bal. Chamber Init

TSD: 22.4 [°C]
TSD_S: 24.6 [°C]
BLCON: -0.032 [promille]
FPA: 0 [rpm]

Current: 0 Reference: 0 Detector: 0

UV-Sensor Acceptance Status: Accepted

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

The Kt/V-UV sensor (option Adimea) can be checked and tested in the *Kt/V-UV Sensor Test* menu.

The *Kt/V-UV Sensor Test* key is displayed in this menu if the Kt/V-UV sensor is present in the machine and the option was selected/activated in the *Production Report* menu.

1. Activate the *Kt/V-UV Sensor Test* menu with the *Kt/V-UV Sensor Test* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.

Kt/V-UV Sensor Test

The Kt/V-UV sensor can be tested in the Kt/V-UV Sensor Test menu.

The machine is prepared for the test after pressing the Kt/V-UV Sensor Test key. The following test steps are performed:

- Sensor Init
- TSD Sensor Calibration Check
- Wait for Bal. Chamber Init
- Balance Chamber Init
- Rinsing
- Temperature Check
- Bubble Free Check
- Stopping Dialysate Flow
- **Ready for Test**

Ready for Test

If the test was successful, *Ready for Test* is displayed.

Service Test

Press Service Test to start the test for the UV sensor. The single test steps are displayed in a window. The following test steps are performed:

- Checking Acceptance Status
- Cold sensor - <n>*
- System Identification (100%) - <n>*
- System Identification (75%) - <n>*
- Calibration - <n>*

(* number of measurement cycles are indicated with <n>)

Test OK

Test OK is displayed if the test was successful.

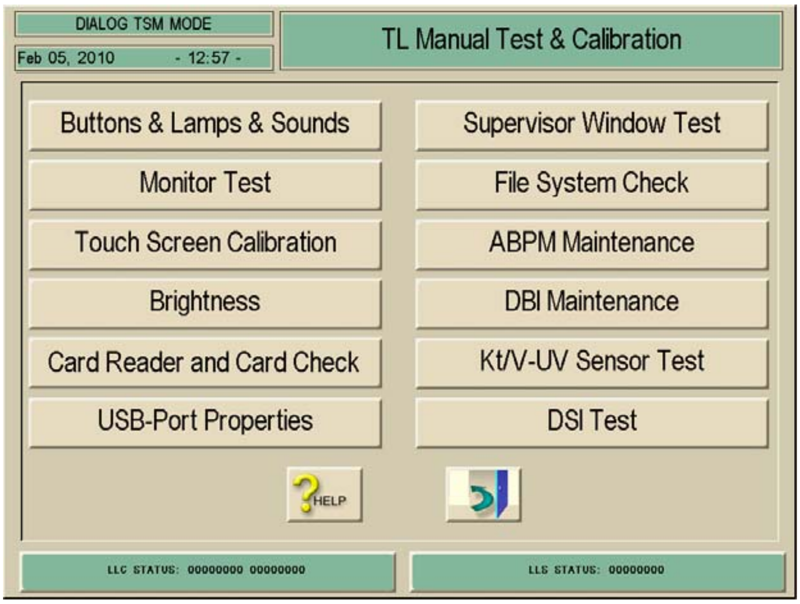
Required Current

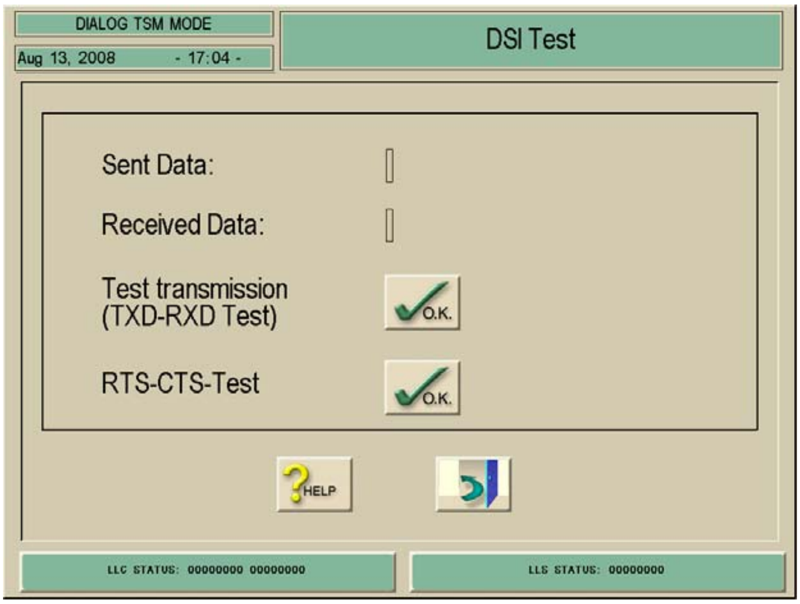
The LED requires a certain current for optimal working conditions. This current is automatically adapted to the LED. The current is displayed as digit value together with the corresponding reserve digits (residual digits). This value must be ≤4000 digits (maximum service life).

Example:

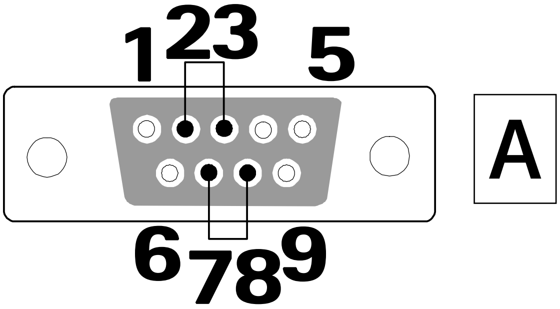
Required current:	1332 (digit)
Reserve:	2668 (digit)
Total digits:	4000

4.8.1.12 Dialog Serial Interface DSI Test





Pin Assignment RS 232 Test Plug (Soldering Side)



If the Crit-Line option (HCT) was selected in the menu *Production Report* and a DSI was detected at a USB port of the motherboard, the *Dialog Serial Interface DSI Test* button is displayed.

The DSI interface (RS 232) can be tested (*Sent Data* and *Received Data*) in the *DSI Test* menu. A test plug **A** (art. no. 7703473) is required to perform the DSI test.

Note

The DSI test can be performed correctly only if a test plug is connected to the DSI interface (RS 232).

1. Connect test plug **A** to the RS 232 socket of the DSI.
2. Switch on machine.
3. Activate the *DSI Test* menu with the *Dialog Serial Interface DSI* key in the *TL Manual Test and Calibration* menu. The following menu is displayed.

   Note: The DSI test can be repeated by pressing the ✓ key. If the DBI test is repeated the sent data pattern is different (≠ *1234567890*).

Test Transmission (TXD-RXD Test)
(Transmit eXchange Data–Received eXchange Data)

The TXD-RXD test can be performed with the OK key. The sent data and the received data must match.

4. Press the ✓ key to start *TXD-RXD Test*.

If the *Sent Data* and *Received Data* are identical, the test was successful.

RTS-CTS Test
(Request to Send - Clear to Send)

The RTS-CTS test can be performed with the OK key. The sent data and the received data must match.

5. Press the ✓ key to start *RTS-CTS Test*.

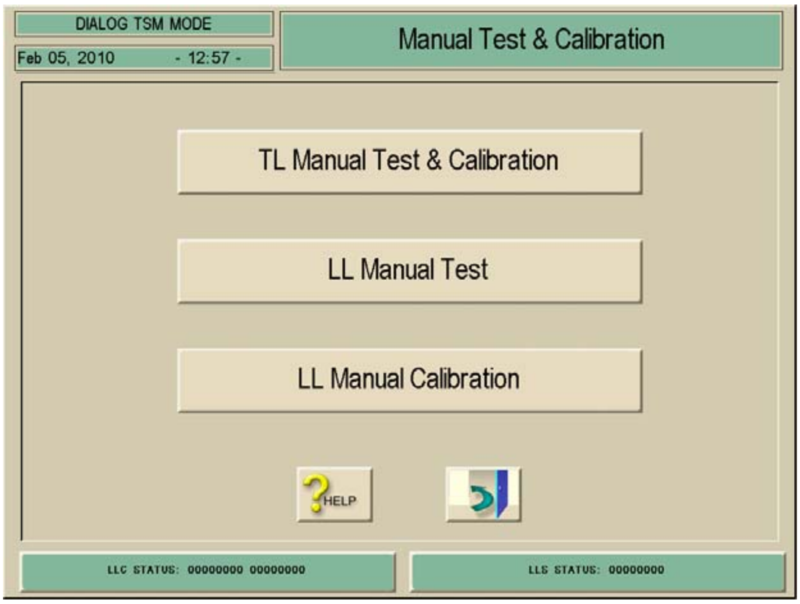
If the *Sent Data* and *Received Data* are identical, the test was successful.

6. Switch off machine after successful test.
7. Remove the test plug from the DSI interface.

4.8.2 Low Level Manual Test

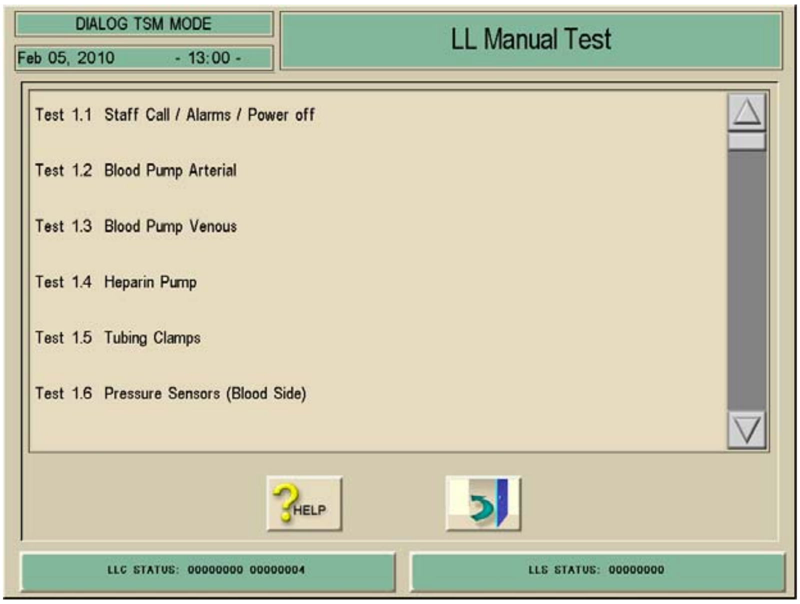
You can test the function of the low level controller LLC sensors, pumps and valves. You can select a test menu and check a single (or where applicable combined) sensor, pump and valve. The components are displayed in graphics (position and corresponding value is displayed). Additionally you can directly skip to the *Low Level Calibration* menu with a *Calibration* key.

1. Activate the *Manual Test and Calibration* menu with the *Manual Test and Calibration* key in the *TSM Main Menu*. The following menu is displayed.
2. Activate the *LL Manual Test* menu with the *LL Manual Test* key in the *Manual Test and Calibration* menu. The following menu is displayed (if necessary use scroll bar).



LLC STATUS: 00000000 00000000

LLS STATUS: 00000000



LLC STATUS: 00000000 00000004

LLS STATUS: 00000000

The following tests can be selected:

- 1.1 Staff Call, Alarms, Power off
- 1.2 Blood Pump Arterial
- 1.3 Blood Pump Venous
- 1.4 Heparin Pump
- 1.5 Tubing Clamps
- 1.6 Pressure Sensors (Blood Side)
- 1.7 Air Sensor, Red Sensor
- 1.8 Coupling Detectors
- 1.9 Water Intake, Upline Tank and Flow Pump FPE
- 1.10 Degassing and Heating
- 1.11 Dialysis Temperature
- 1.12 Concentrate Pumps and Conductivity
- 1.13 Balance Chamber Valves
- 1.14 Bypass and Disinfection Valves
- 1.15 Flow Pump FPA, Balance Chamber and Air Separator
- 1.16 Pressure Water Part
- 1.17 UF Pump
- 1.18 Blood Leak
- 1.19 Leak Test
- 1.20 Water Part (Overview)
- 1.21 Emptying
- 1.22 HDF
- 1.23 BIC Cartridge Valve and Coupling Detectors
- 1.24 HDF Online
- 1.25 HDF Online Valves and Coupling Detectors
- 1.26 Option Battery
- 1.27 DFS Pressure Test of Therapy
- 1.28 Front Panel Board FPB (LLS)
- 1.29 Patient Leakage Current
- 1.30 SMPS-MC Self Tests
- 1.31 Level Regulation

Function of the Software Keys and Icons

The function of the software keys and icons are as follows:

HELP

Press the *HELP* key to see the help information of the menu.

The menu can be closed with the *Exit Door* key.

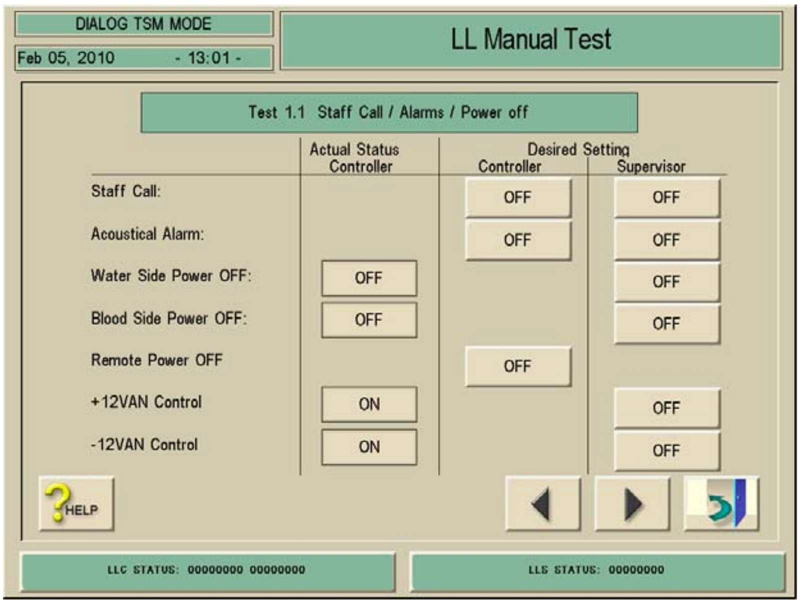
◀ ▶

If required, the previous menu or the next menu can be selected with the *Previous* and *Next Arrow* keys.

Calibration

If required, a corresponding calibration menu can be selected in certain *LL Manual Test* menus. The calibration procedures are described in paragraph *4.8.3 Low Level Manual Calibration*.

4.8.2.1 Test 1.1 Staff Call, Alarms, Power Off



	Actual Status Controller	Desired Setting Controller	Desired Setting Supervisor
Staff Call:		OFF	OFF
Acoustical Alarm:		OFF	OFF
Water Side Power OFF:	OFF		OFF
Blood Side Power OFF:	OFF		OFF
Remote Power OFF		OFF	
+12VAN Control	ON		OFF
-12VAN Control	ON		OFF

1. Activate the *Staff Call/Alarms/Power Off* menu with the *Staff Call/Alarms/Power Off* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

- Staff Call/
- Acoustical Alarm
- Water Side Power OFF
- Blood Side Power OFF
- Remote Power OFF
- +12 VAN Control
- -12 VAN Control

Staff Call/Acoustical Alarm

The staff call can be activated with the *PRUF/PRUF-S* signal and the acoustical alarm can be switched separately with the *ACAL/ACAL-S* signal by the controller and supervisor.

Water Side Power OFF

The low level supervisor can test the power off for the 24 V supply voltage with the *D24OFF-S* signal for the dialysate side power off. The feedback to the controller (ON/OFF) shows whether the voltage was switched.

Blood Side Power OFF

The low level supervisor can test the power off for the 24 V supply voltage with the *B24OFF-S* signal for the blood side power off. The feedback to the controller (ON/OFF) shows whether the voltage was switched.

Remote Power OFF

The REMOTE signal for the remote power off can be activated by the controller. The machine is switched off by the internal real time clock RTC. The machine is switched on again after the shortest time period (approx. 64 s) has expired. The machine can be switched on immediately, if the machine is switched off and on again.

±12 VAN Control

The digital board has an integrated voltage monitoring for the analog ±12 VAN from the SMPS-MC. A self test for the ±12 VAN is performed during preparation. The ±12 VAN voltages are detuned during the test.

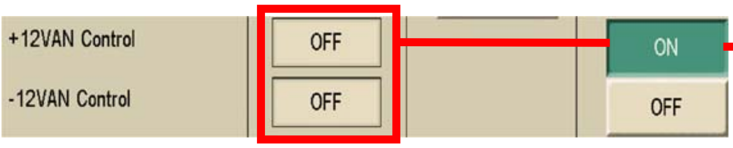
Supervisor OFF

±12 VAN for the controller are ON, i.e. voltages are present.

ON = Voltage OK

+12 VAN Control / Supervisor ON

ON = Test activated

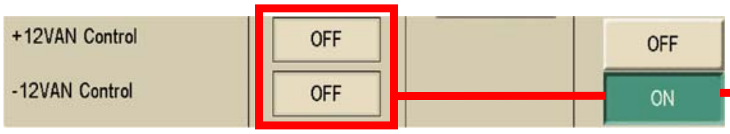


+12VAN Control	OFF	ON
-12VAN Control	OFF	OFF

±12 VAN Test:
- +12 VAN > 13 V
- -12 VAN > -11 V

-12 VAN Control / Supervisor ON

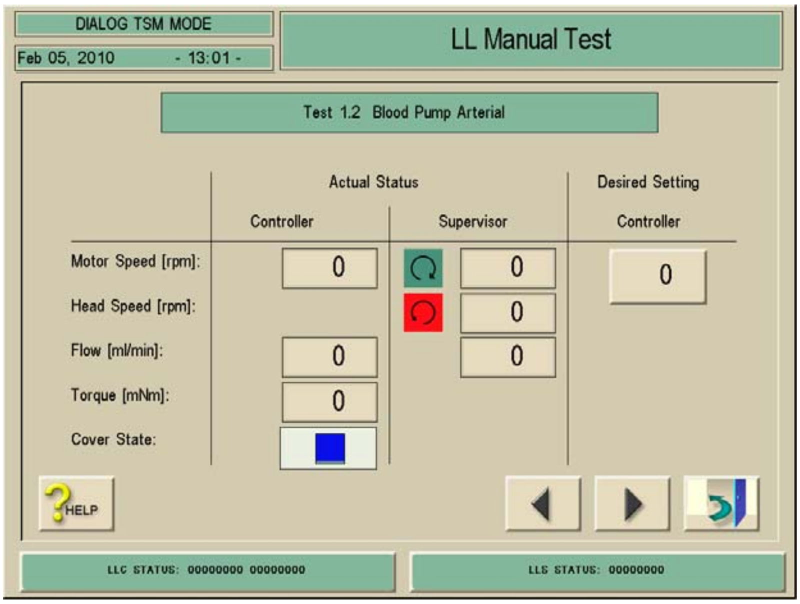
ON = Test activated



+12VAN Control	OFF	OFF
-12VAN Control	OFF	ON

±12 VAN Test:
- +12 VAN < 11 V
- -12 VAN < -13 V

4.8.2.2 Test 1.2 Blood Pump Arterial



DIALOG TSM MODE

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LL Manual Test

Test 1.2 Blood Pump Arterial

	Actual Status			Desired Setting
	Controller		Supervisor	Controller
Motor Speed [rpm]:	0	🟩	0	0
Head Speed [rpm]:		🟥	0	
Flow [ml/min]:	0		0	
Torque [mNm]:	0			
Cover State:	🟦			

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

1. Activate the *Blood Pump Arterial* menu with the *Blood Pump Arterial* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

- Motor Speed
- Head Speed
- Flow
- Torque
- Cover State

Motor Speed The motor speed is displayed by the controller and supervisor. The direction of rotation is displayed by a direction of rotation symbol:

🟩 Green: Correct direction of rotation

🟥 Red: Reverse direction of rotation

Head Speed The head speed is displayed by the supervisor. The direction of rotation for the roller is displayed by a direction of rotation symbol:

🟩 Green: Correct direction of rotation

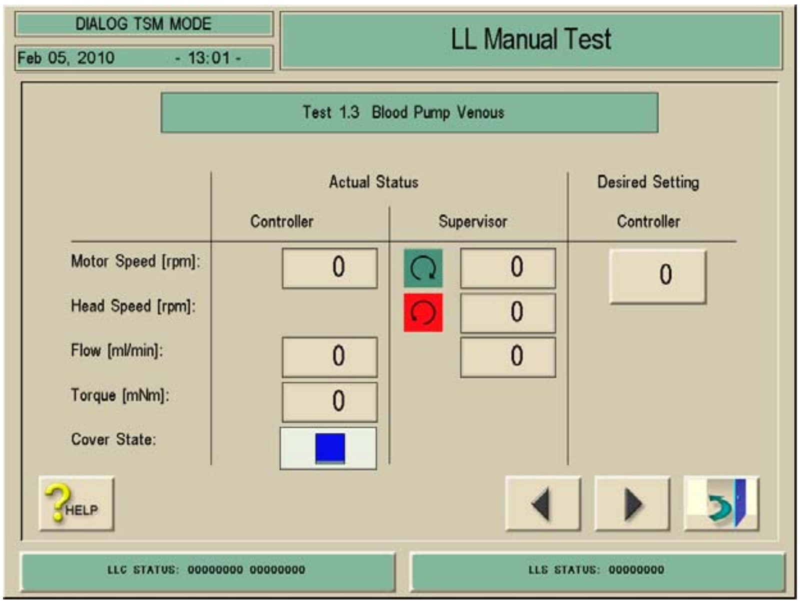
🟥 Red: Reverse direction of rotation

Flow The controller and supervisor display the calculated flow rate, based on the pump speed and the tube constant.

Torque The motor torque is displayed by the controller.

Cover State If the pump cover is opened the blood pump **BPA** is stopped. The controller detects and displays the opened pump cover.

4.8.2.3 Test 1.3 Blood Pump Venous



DIALOG TSM MODE

Feb 05, 2010 - 13:01 -

LL Manual Test

Test 1.3 Blood Pump Venous

	Actual Status		Desired Setting
	Controller	Supervisor	Controller
Motor Speed [rpm]:	0	↻ 0	0
Head Speed [rpm]:		↺ 0	
Flow [ml/min]:	0	0	
Torque [mNm]:	0		
Cover State:	■		

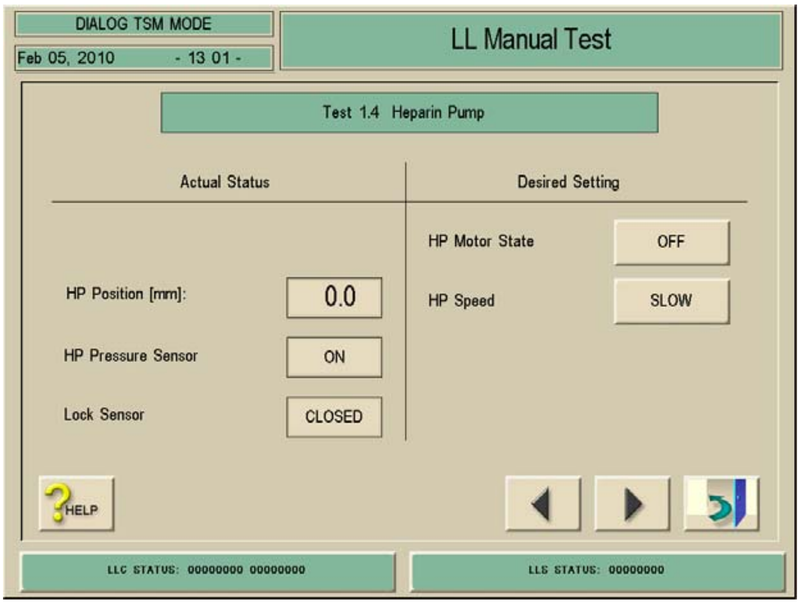
LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

1. Activate the *Blood Pump Venous* menu with the *Blood Pump Venous* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

Motor Speed	The motor speed is displayed by the supervisor. The direction of rotation is displayed by a direction of rotation symbol:
↻	Green: Correct direction of rotation
↺	Red: Reverse direction of rotation
Head Speed	The head speed is displayed by the supervisor. The direction of rotation for the roller is displayed by a direction of rotation symbol:
↻	Green: Correct direction of rotation
↺	Red: Reverse direction of rotation
Flow	The controller and supervisor display the calculated flow rate, based on the pump speed and the tube constant.
Torque	The motor torque is displayed by the controller.
Cover State	If the pump cover is opened the blood pump **BPV**/substitution pump is stopped immediately. The controller detects and displays the opened pump cover.

4.8.2.4 Test 1.4 Heparin Pump



HP Position [mm]: 0.0

HP Pressure Sensor: ON

Lock Sensor: CLOSED

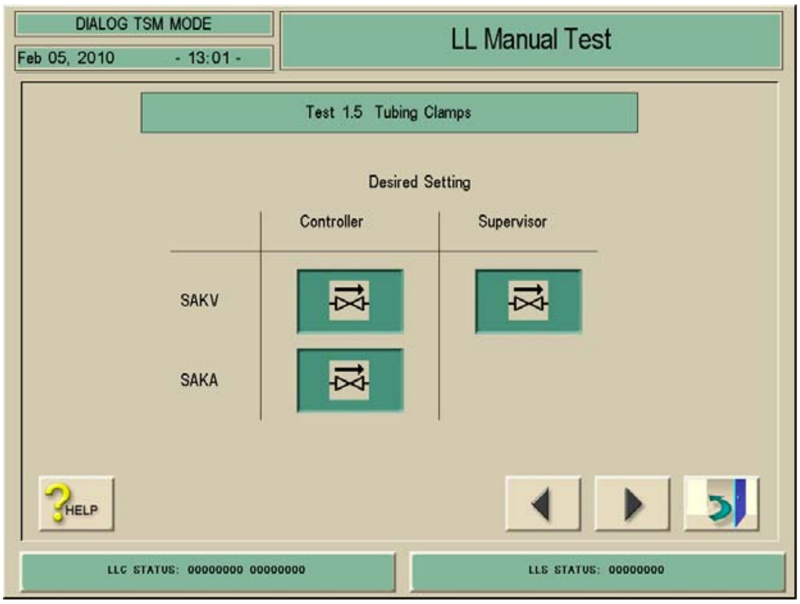
HP Motor State: OFF

HP Speed: SLOW

1. Activate the *Heparin Pump* menu with the *Heparin Pump* key in the *LL Manual Test* menu. The following menu is displayed for the heparin pump Compact.
2. Check the functions with the appropriate keys.

HP Position	The forward feed distance is displayed in mm (only if the syringe is inserted and locked). The counter is reset if the lock sensor is opened. The distance is detected from the signal of the light barrier on the motor axle.
HP Syringe Sensor	The sensor for the sensor plate of the syringe detects an inserted syringe.
Lock Sensor	Sensor to open the clasp nut. (The clasp nut is assembled on the drive spindle and limits the max. pressure load of the heparin pump).
HP Motor State	Activates/switches off the heparin pump.
HP Speed	Selection between slow and fast forward feed.

4.8.2.5 Test 1.5 Tubing Clamps



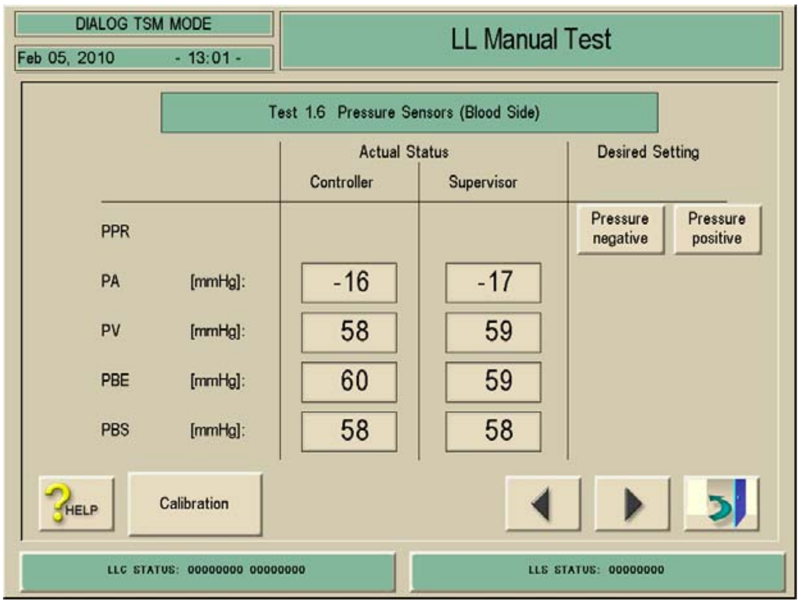
1. Activate the *Tubing Clamps* menu with the *Tubing Clamps* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

Tubing Clamps SAKV and SAKA

The venous tubing clamp **SAKV** and arterial tubing clamp **SAKA** can be closed and opened. Thereby the switch function and leakage test (pressure - clamp gap, time) can be tested.

The closed clamp gap is set to 1.4 mm + 0.1 mm.

4.8.2.6 Test 1.6 Pressure Sensors (Blood Side)



DIALOG TSM MODE

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LL Manual Test

Test 1.6 Pressure Sensors (Blood Side)

		Actual Status Controller	Actual Status Supervisor	Desired Setting
PPR				Pressure negative Pressure positive
PA	[mmHg]:	-16	-17	
PV	[mmHg]:	58	59	
PBE	[mmHg]:	60	59	
PBS	[mmHg]:	58	58	

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

1. Activate the *Pressure Sensors (Blood Side)* menu with the *Pressure Sensors (Blood Side)* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can skip directly to the calibration of the sensors by pressing the Calibration key.

Level Regulation Pump LRP (PPR)

Pressure negative Pressure positive

The pressure for the pressure sensors can be set with the *Pressure Negative* and *Pressure Positive* keys. The pressures are increased or decreased via the level regulation pump (diaphragm pump).

Pressure Sensors

The pressure sensors **PA**, **PV** and **PBE** are displayed.

PBS Value

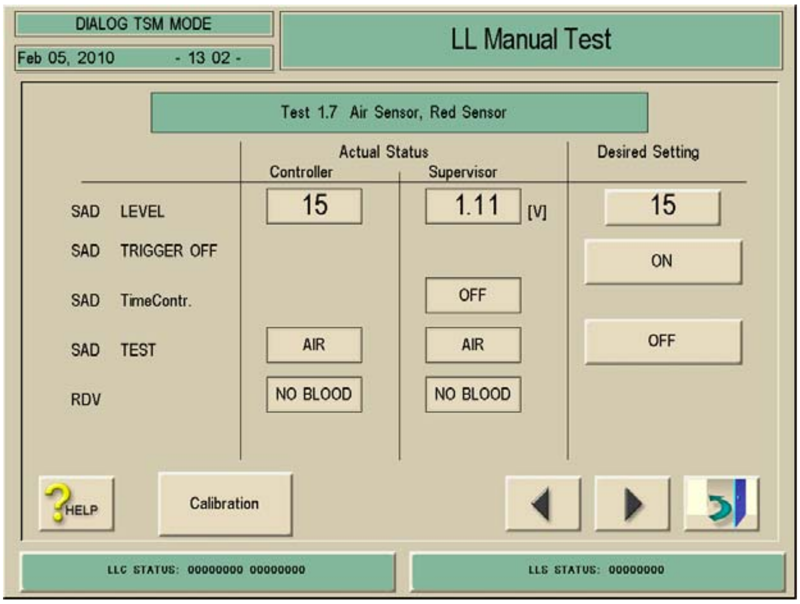
Machine with Single Pump

The value for PBS is 0.

Machine with Double

Double Pump must be activated in *Production Report*, *Low Level Options*. A value for PBS is displayed.

4.8.2.7 Test 1.7 Air Sensor SAD, Red Sensor



SAD LEVEL 15 1.11 [V] 15
SAD TRIGGER OFF ON
SAD TimeContr. OFF
SAD TEST AIR AIR OFF
RDV NO BLOOD NO BLOOD

1. Activate the *Air Sensor, Red Sensor* menu with the *Air Sensor, Red Sensor* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can skip directly to the calibration of the safety air detector **SAD** by pressing the Calibration key.

SAD Level

The calibration level (example KS = 48) on the SAD is entered for the SAD (version 2) with a fixed alarm level. The alarm level is automatically set to 15 digits after the calibration value is entered. The test level is calculated by adding 5 digits to the calibration level (test level = KS + 5 digits). You can find the detailed description and procedure for the calibration of the SAD version 2 in the menu: *LL Manual Calibration*, *Calibration 2.9 Safety Air Detector SAD*.

SAD Trigger OFF

The cyclic measurement of the controller can be checked with the *SAD TRIGGER OFF* key.

SAD Time Control

The cyclic measurement is checked by the controller and must be detected by the supervisor with the *SAD Time Contr.*

SAD Test

Activate the internal test of the safety air detector **SAD** with the *SAD TEST* key (the switch level is automatically increased). The sensitivity can be changed to check the switching point.

AIR

A tubing filled with air is inserted in the SAD

If the *SAD TEST* ON is activated *AIR* must be detected.

NO AIR

A tubing filled with fluid is inserted in the SAD

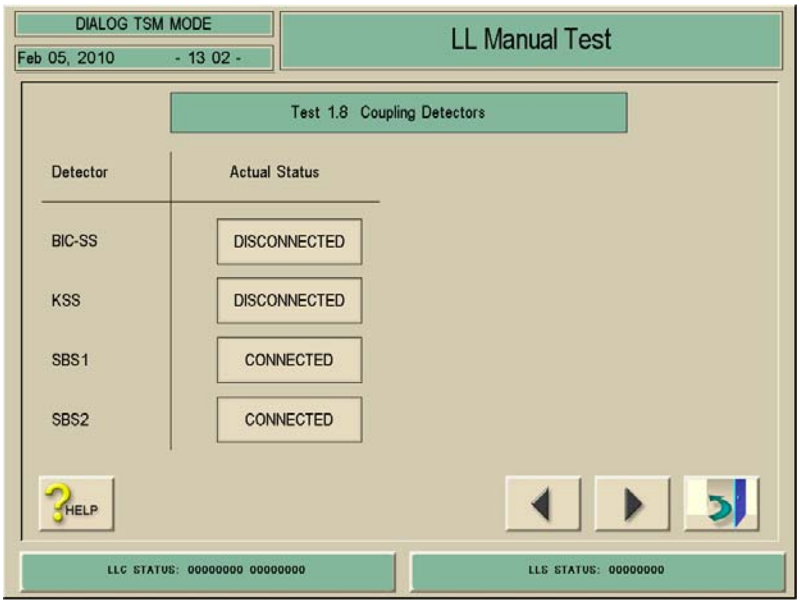
If the *SAD TEST* OFF is activated *NO AIR* must be detected.

RDV

The light path is interrupted

NO BLOOD (Controller/Supervisor) changes to *BLOOD (Controller/Supervisor)*.

4.8.2.8 Test 1.8 Coupling Detectors



DIALOG TSM MODE

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LL Manual Test

Test 1.8 Coupling Detectors

Detector	Actual Status
BIC-SS	DISCONNECTED
KSS	DISCONNECTED
SBS1	CONNECTED
SBS2	CONNECTED

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

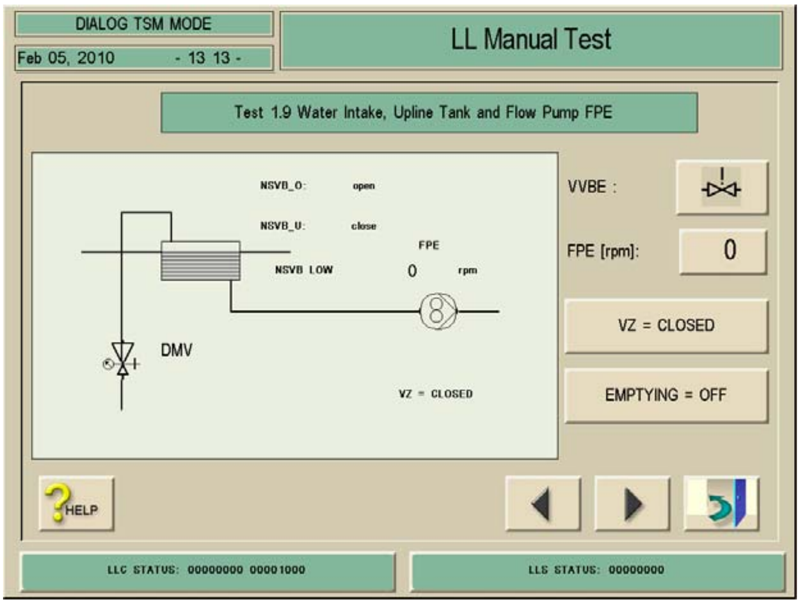
1. Activate the *Coupling Detectors* menu with the *Coupling* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions of the reed contacts with the appropriate couplings.

You can check the actual status of the reed sensors.

Detectors

BICSS	Bicarbonate rinsing connection sensor.
KSS	Concentrate rinsing connector sensor.
SBS1	Rinsing bridge connector sensor (dialyser coupling).
SBS2	Rinsing bridge connector sensor (dialyser coupling).

4.8.2.9 Test 1.9 Water Inlet, Upline Tank and Flow Pump FPE


DIALOG TSM MODE

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LL Manual Test

Test 1.9 Water Intake, Upline Tank and Flow Pump FPE

NSVB_O: open

NSVB_U: close

FPE 0 rpm

VZ = CLOSED

VVBE :

FPE [rpm]: 0

VZ = CLOSED

EMPTYING = OFF

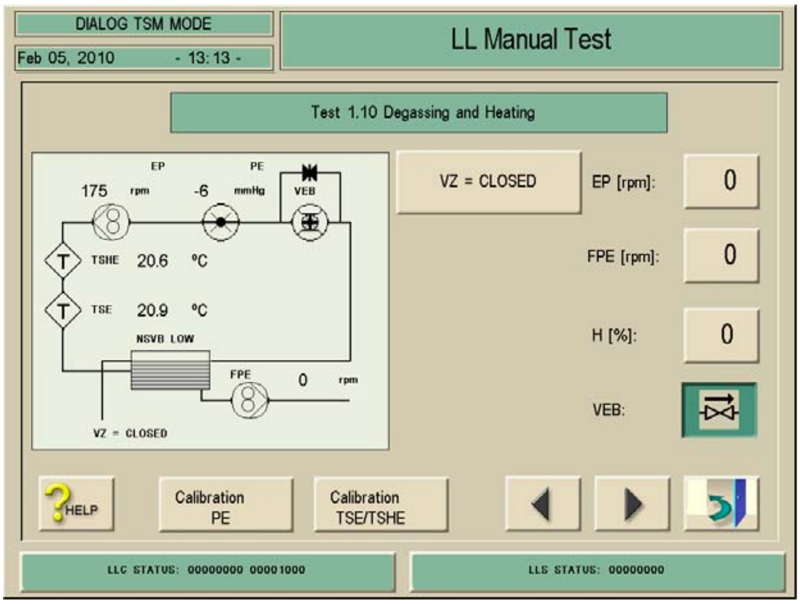
LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Water Inlet* menu with the *Water Inlet* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

Valve VVBE	You can set the flow of the upline tank control valve **VVBE**. **VVBE** must guarantee a flow of ≥ 1200 ml/min at a water inlet pressure of approx. 0.9 bar.
Level Sensor NSVB	The level of the upline tank **VB** is displayed on the screen by the level sensors (**NSVB_O** high sensor and **NSVB_U** low sensor).
Flow Pump FPE	If the upline tank is full the valve **VVBE** is closed automatically. If the flow pump **FPE** is activated **FPA** is also switched on, to allow an unrestricted flow through the balance chambers.
Emptying	The degassing pump **PE** is permanently switched on to allow a circulation in both compartments of the upline tank. **VEB** is opened. If the emptying is activated to drain the machine the pumps are switched on for a short period and **VVBE** closed. All balance chamber valves are opened and the outlet flow pump **FPA** works in main flow with the same speed as the inlet flow pump **FPE**. The degassing pump **EP** runs and the degassing bypass valve **VEB** is open.

4.8.2.10 Test 1.10 Degassing and Heating



DIALOG TSM MODE

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LL Manual Test

Test 1.10 Degassing and Heating

EP 175 rpm

PE -6 mmHg

TSHE 20.6 °C

TSE 20.9 °C

NSVB LOW

FPE 0 rpm

VZ = CLOSED

EP [rpm]: 0

FPE [rpm]: 0

H [%]: 0

VEB:

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Degassing and Heating* menu with the *Degassing and Heating* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can skip directly to the calibration of the pressure sensor **PE** or the temperature sensor **TSHE/TSE** by pressing the appropriate Calibration PE or Calibration TSE/TSHE key. **TSHE** is calibrated together with **TSE**.

The components of the degassing and heating circuit can be tested step by step.

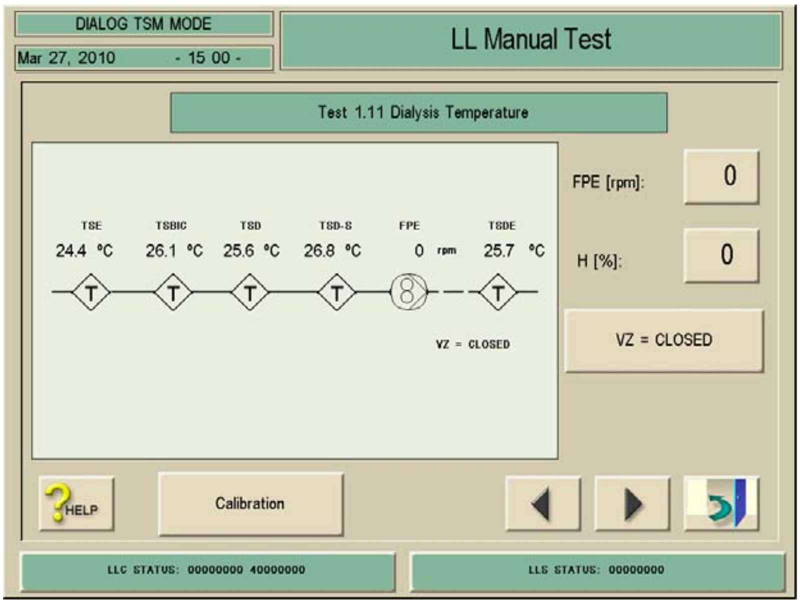
All balance chamber valves are switched so that one half of the balance chamber is open and the other side closed to position the membrane.

The flow pump **FPE** and **FPA** have the same speed and work in main flow. If the speed of **FPE** is set the degassing pump **EP** starts automatically with a higher speed.

The heater **H** is stopped if the degassing pump **EP** < 500 rpm, the degassing temperature sensor **TSE** > 89 °C or the upline tank VB is empty.

The degassing pump **EP** must be able to build up a flow of > 1200 ml/min at a negative pressure of - 500 mmHg.

4.8.2.11 Test 1.11 Dialysis Temperature



TSE 24.4 °C
TSBIC 26.1 °C
TSD 25.6 °C
TSD-S 26.8 °C
FPE 0 rpm
TSDE 25.7 °C

FPE [rpm]: 0
H [%]: 0
VZ = CLOSED

1. Activate the *Dialysis Temperature* menu with the *Dialysis Temperature* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can skip directly to the calibration of the temperature sensors **TSBIC, TSD, TSD-S, TSDE** by pressing the Calibration key.

The dialysate is heated up with the set heater power **H** %.

The flow pumps **FPE/FPA** work with the set speed. The balance chambers are opened and the machine works in main flow.

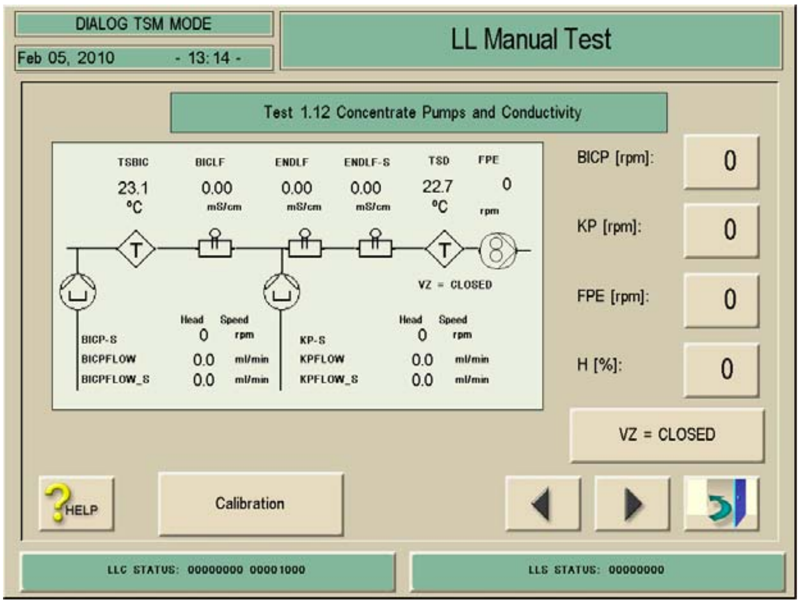
The temperature must be controlled by the heater to a stable set-point to test the temperature sensors.

If you open the circulation valve **VZ** a closed flow circuit is achieved (via the upline tank). Increase the speed [rpm] until the flow pump **FPE** has built up a flow of 750 ml/min.

The measurement range is as follows:

TSE, TSD, **TSBIC**:	0 to 100 °C
TSD-S:	30 to 55 °C
TSDE:	30 to 55 °C

4.8.2.12 Test 1.12 Concentrate Pumps and Conductivity



DIALOG TSM MODE

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LL Manual Test

Test 1.12 Concentrate Pumps and Conductivity

BICP [rpm]: 0

KP [rpm]: 0

FPE [rpm]: 0

H [%]: 0

VZ = CLOSED

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Concentrate Pumps and Conductivity* menu with the *Concentrate Pumps and Conductivity* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can skip directly to the calibration of the conductivity sensors **BICLF/ENDLF** by pressing the Calibration key.

You can set the pumps **BICP/KP**, flow pump **FPE** and the heater power **H** %.

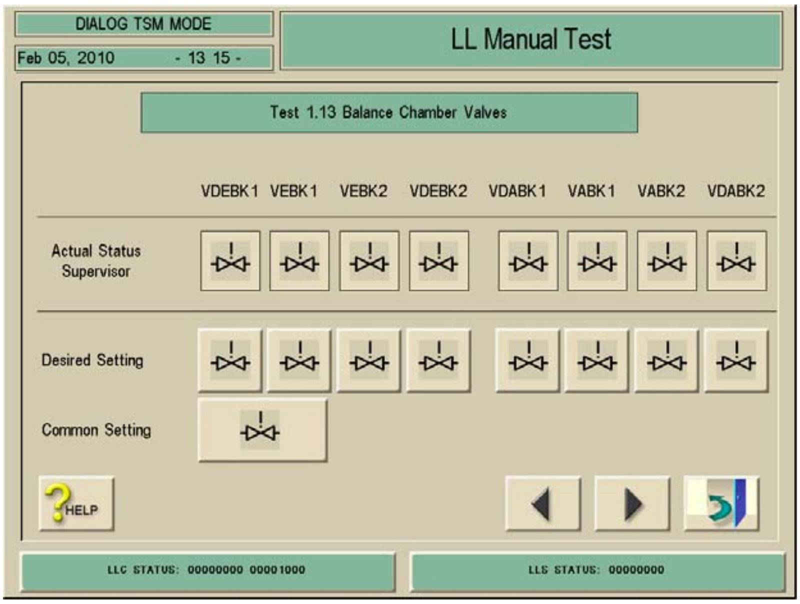
All balance chamber valves are open and the flow pump **FPA** works with the same speed as **FPE**.

The machine is in main flow. The machine can suck-in concentrate with the concentrate pumps **BICP/KP** for the preparation of the conductivity to test the conductivity sensors **BICLF/ENDLF/ENDLF-S**.

You can connect a measurement instrument at the dialyser couplings or between **FPE** and the balance chamber.

The supervisor displays the head speed **BICP-S/KP-S** of the concentrate pumps. Increase the speed [rpm] until the flow pump **FPE** has built up a flow of 750 ml/min. Thereby the pulsating flow of the pumps have no influence on the conductivity measurement.

4.8.2.13 Test 1.13 Balance Chamber Valves



LLC STATUS: 00000000 00001000

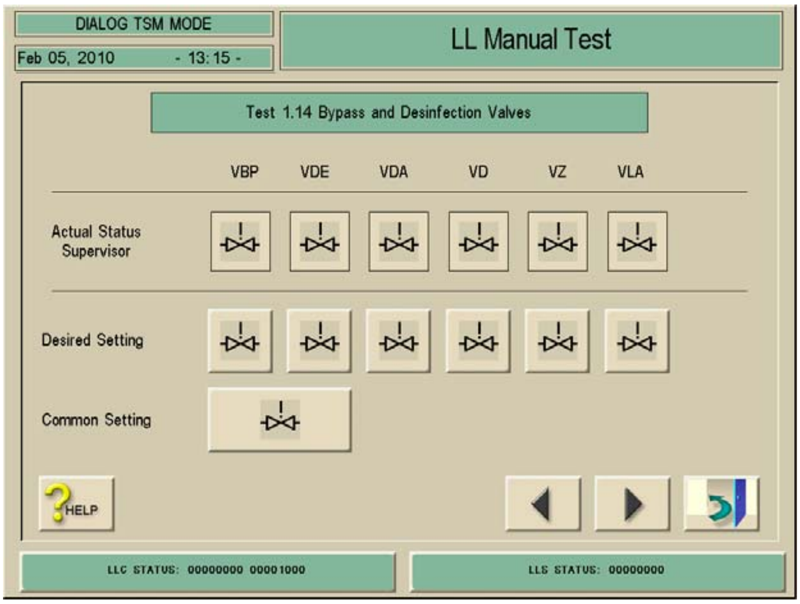
LLS STATUS: 00000000

1. Activate the *Balance Chamber Valves* menu with the *Balance Chamber Valves* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can activate a single valve or combined setting via the controller. The actual condition is displayed by the supervisor. The following valves can be activated:

Valves	**VDEBK1/2**	Dialyser inlet valve 1/2 balance chamber
	VEBK1/2	Inlet valve 1/2 balance chamber
	VDABK1/2	Dialyser outlet valve 1/2 balance chamber
	VABK1/2	Outlet valve 1/2 balance chamber

4.8.2.14 Test 1.14 Bypass and Disinfection Valves

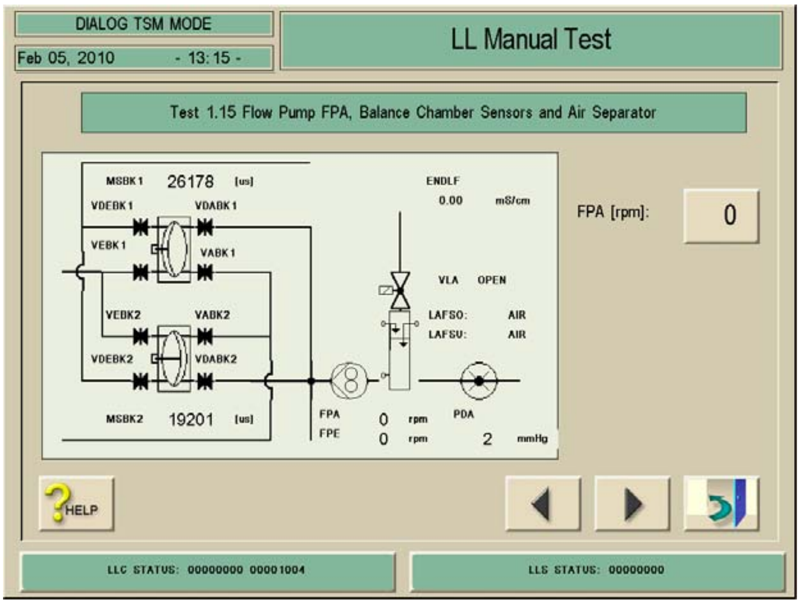


1. Activate the *Bypass and Disinfection Valves* menu with the *Bypass and Disinfection Valves* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can activate a single valve or combined setting via the controller. The actual condition is displayed by the supervisor. The following valves can be activated:

Valves	**VBP**	Bypass valve
	VDE	Dialyser inlet valve
	VDA	Dialyser outlet valve
	VD	Disinfection valve
	VZ	Circulation valve
	VLA	Air separator valve

4.8.2.15 Test 1.15 Flow Pump FPA, Balance Chamber Sensors and Air Separator



MSBK1 26178 [us]

MSBK2 19201 [us]

ENDLF 0.00 mS/cm

VLA OPEN

LAFSO: AIR

LAFSU: AIR

FPA 0 rpm

FPE 0 rpm

PDA 2 mmHg

FPA [rpm]: 0

LLC STATUS: 00000000 00001004

LLS STATUS: 00000000

1. Activate the *Flow Pump FPA, Balance Chamber Sensors and Air Separator* menu with the *Flow Pump FPA, Balance Chamber Sensors and Air Separator* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

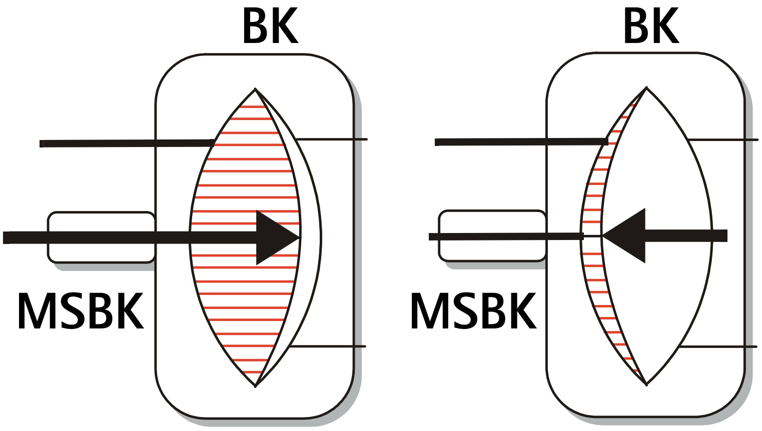


Fig. : Switch Point MSBK1/2

If the test (initialisation) is started the switching point of the membrane position sensor balance chambers **MSBK1/2** are detected. If the maximum stroke of **MSBK1/2** is reached the balance chamber valves are automatically switched (see figure).

Phase 1

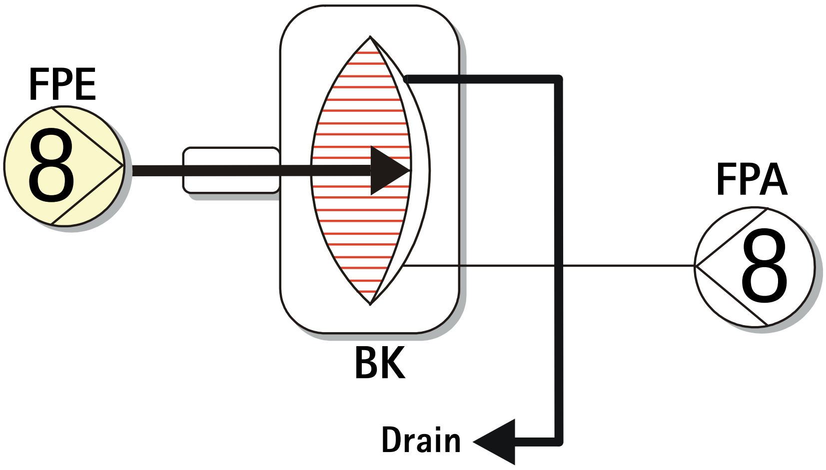


Fig. : Filling Cycle Balance Chamber Phase 1

If you set the flow pump **FPA** the left side of one of the balance chambers is filled by the flow pump **FPE**. Simultaneously the fluid in the right side of the balance chamber is emptied to the drain.

Phase 2

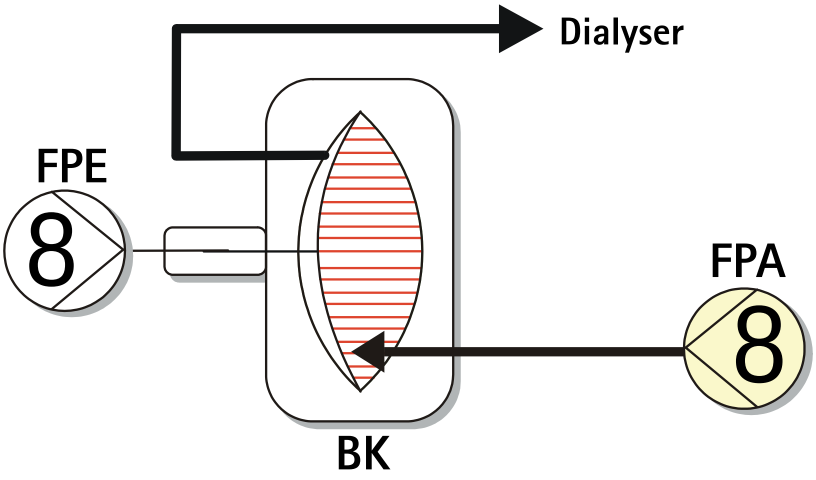


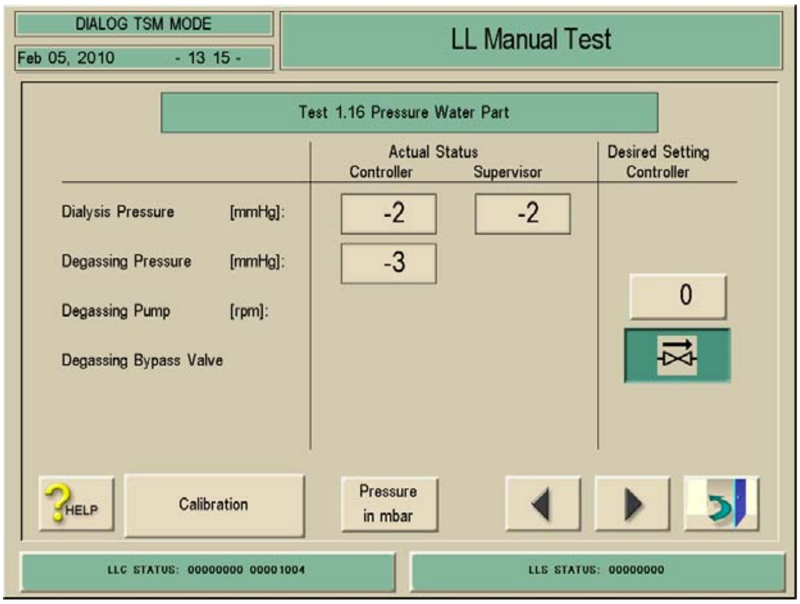
Fig. : Filling Cycle Balance Chamber Phase 2

The right side of the balance chamber is filled with the fluid from the dialyser by the flow pump **FPA**. Simultaneously the fresh fluid in the left side of the balance chamber is delivered into the dialyser circuit.

The concentrate pump **KP** is set to a fixed speed of 20 rpm during this test. Thereby a final conductivity **ENDLF** of > 0.5 mS/cm is obtained if concentrate is connected.

This conductivity is required to test the level sensors in the air separator **LA**. If the lower level sensor **LAFSU** is activated the air separator valve **VLA** is opened and the balance chamber valves are switched. Thereby **FPE** delivers fluid into the dialyser circuit. **VLA** is only closed and switched to normal operation if the top level sensor **LAFSO** detects fluid.

4.8.2.16 Test 1.16 Pressure Water Part



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LL Manual Test

Test 1.16 Pressure Water Part

	Actual Status Controller	Actual Status Supervisor	Desired Setting Controller
Dialysis Pressure [mmHg]:	-2	-2	
Degassing Pressure [mmHg]:	-3		
Degassing Pump [rpm]:			0
Degassing Bypass Valve			

LLC STATUS: 00000000 00001004

LLS STATUS: 00000000

1. Activate the *Pressure Water Part* menu with the *Pressure Water Part* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can skip directly to the calibration of the pressure sensors **PE** and **PDA** by pressing the Calibration key.

The degassing pump **EP** can be set. The degassing bypass valve **VEB** can be opened/closed.

The pressure at the degassing pressure sensor **PE** can be set with the degassing pump **EP** and the degassing bypass valve **VEB**.

The pressure at the outlet dialysate pressure sensor **PDA** is set manually with a syringe at the dialyser couplings.

Pressure in mbar The pressure can be displayed in mmHg or in mbar, depending on selection.

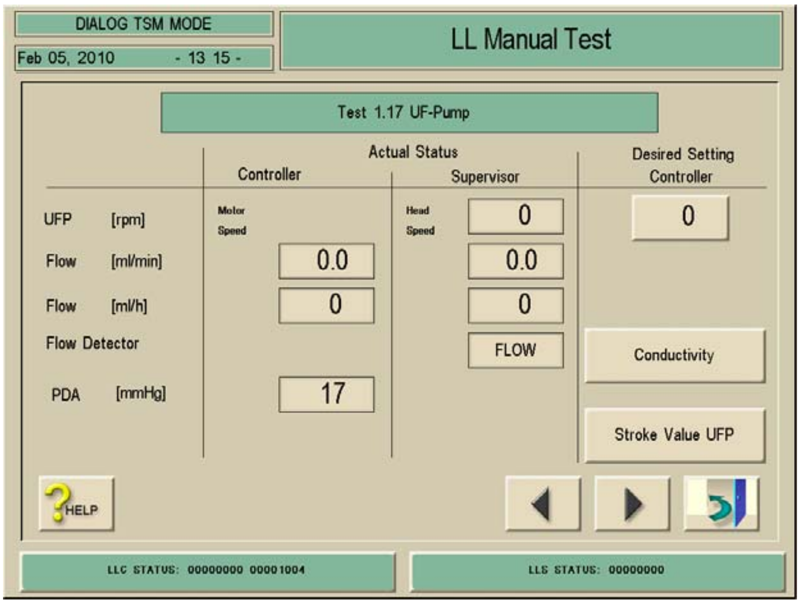
Conversion Factor mmHg to mbar

Conversion Factor = 1.3332

Example:

-100 mmHg	approx. –133 mbar
–400 mmHg	approx. –533 mbar

4.8.2.17 Test 1.17 UF Pump



	Actual Status Controller	Actual Status Supervisor	Desired Setting Controller
UFP [rpm]		0	0
Flow [ml/min]	0.0	0.0	
Flow [ml/h]	0	0	
Flow Detector		FLOW	
PDA [mmHg]	17		

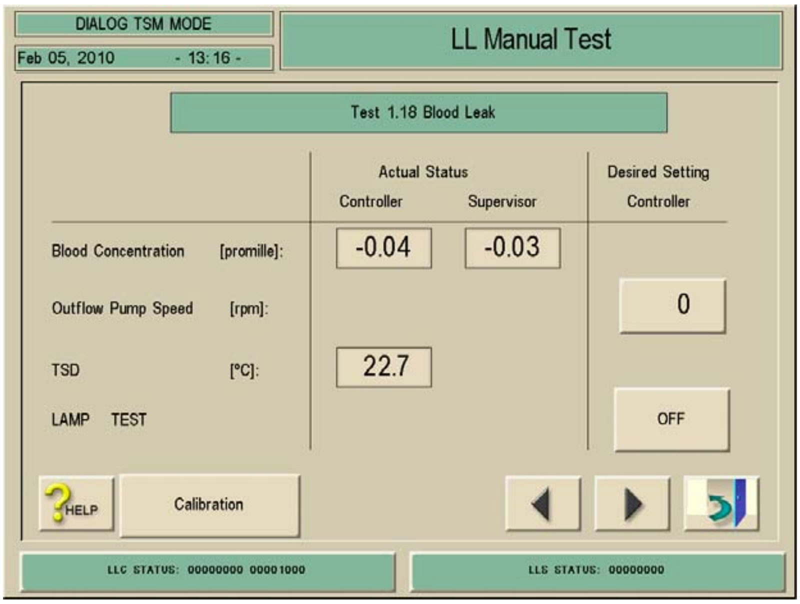
1. Activate the *UF Pump* menu with the *UF Pump* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can set the speed of the **UF** pump **UFP**. The head speed and the calculated flow are displayed. At the beginning of the test the balance chambers are initialised. The flow pumps **FPE/FPA** are activated to reach the inlet pressure for **UFP**, set by the value of the throttle **DDE**.

Flow Detector Not applicable.

Stroke Value UFP The *Stroke Value UFP* should not be used in a normal case, because **UFP** must be calibrated (see LL Manual calibration).

4.8.2.18 Test 1.18 Blood Leak



	Actual Status Controller	Actual Status Supervisor	Desired Setting Controller
Blood Concentration [promille]:	-0.04	-0.03	
Outflow Pump Speed [rpm]:			0
TSD [°C]:	22.7		
LAMP TEST			OFF

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Blood Leak Detector* menu with the *Blood Leak Detector* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can check the following functions of the blood leak detector:

- Red and green LED
- Receiver circuit
- Optical efficiency of the detector block

You can skip directly to the calibration of the blood leak detector by pressing the Calibration key.

Blood Leak Detector

The blood leak detector performs an automatic calibration of the zero point with a reference diode.

The blood leak detector can be checked and calibrated. The rinsing block must have an even temperature for calibration. If both dialyser couplings are connected to the rinsing bridge the flow pumps **FPA/FPE** work in main flow.

If only one coupling is connected **FPE** is stopped. The test solution can be drawn in by the second coupling via **FPA**. The first calibration point must be performed with clean water from the water treatment system.

A function test and a calibration are performed for the blood leak detector.
If an actual value is out of limits during the function test, the blood leak detector has to be exchanged.
Check the blood leak detector after a citro-thermal disinfection (*LL Manual Test*, *Test 1.18 Blood Leak Detector*).
Close front and rear door for the function test to prevent light irradiation on the sensor.

Leakages

Air and micro-bubbles can lead to false measurement values in the measurement line and can cause fluctuation of the actual value.
If air is visible check the complete system for leaks in menu 1.20 Test Water Part. After the initialisation phase rinse the blood leak detector approx. 1 min and then perform a leakage test of the system in menu 1.19 Leak Test.

Check Blood Leak Detector

Exchange the blood leak detector if one of these three values is out of limits.

1. Connect both dialyser couplings to the rinsing bridge.
2. Select menu 1.18 in TSM to perform a function check of the blood leak detector.
3. Rinse the blood leak detector BL for approx. 1 min at the beginning of the rinsing time with outlet flow pump **FPA** (approx. 1400 rpm). Thereby possible air bubbles in the system are removed.
4. Rinse blood leak detector for approx. 15 to 30 min with **FPA,** approx. 1000 rpm to warm up the complete system to a temperature of approx. 40 °C.
5. The *LED Test* is activated with the *LED TEST OFF* key. The *OFF* key switches to the *RED* key as soon as the key is pressed.

   The *red LED* is tested after 10 s. The controller value for the switched off *red LED* must be as follows (the supervisor value is uncritical):

red LED	Actual Status Controller
Blood Concentration	< 4.00

6. Press the *LED TEST RED* key to switch to the *green LED*. The *RED* key switches to the *GREEN* key.

   The *green LED* is tested. The controller value for the switched off *green LED* must be as follows (the supervisor value is uncritical):

green LED	Actual Status Controller
Blood Concentration	> 2.06

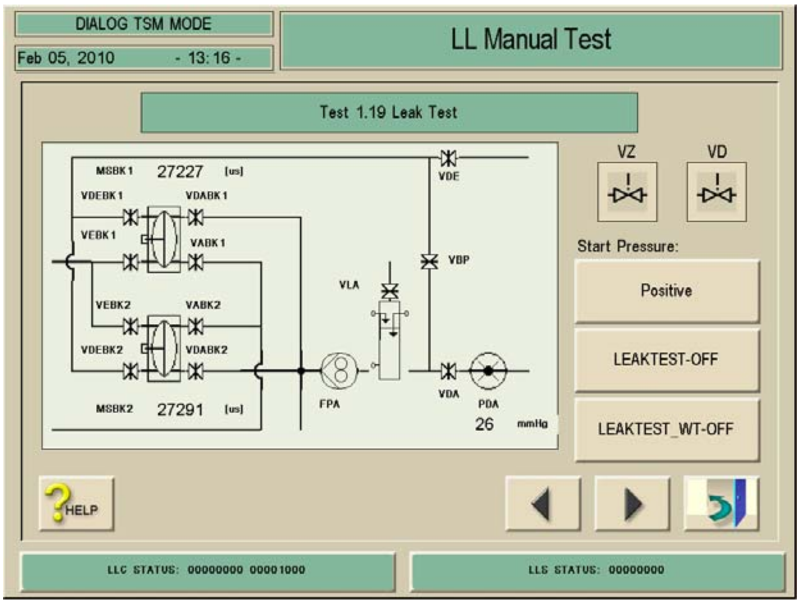
7. The actual controller values for the *red LED* and the *green LED* must be divided.

   Note: The calculated value of **red LED** divided by **green LED** is displayed briefly after the key *LAMP TEST* is switched back to OFF.

   The calculated value must be in the following limits (to the first decimal digit/round off):

red LED / green LED
1.15 - 1.44

4.8.2.19 Test 1.19 Leak Test



LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Leak Test* menu with the *Leak Test* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can run a leakage test for the balance chamber system, the bypass valve **VBP** and the main flow valves **VDE/VDA**, the air separator valve **VLA** and the UF pump **UFP**. The leakage test can be started with a positive or negative pressure. The flow system must be filled with water prior to the leakage test (if necessary fill in menu *1.20 Water Part Overview*).

Leak Test

The following components are tested:

Membrane position sensors:	**MSBK1/2**
Balance chamber valves:	**VDEBK1/2, VDABK1/2, VEBK1/2, VABK1/2**
Bypass valve:	**VBP**
Dialyser in/output valves:	**VDE, VDA**
Disinfection valve:	**VD**
Air separator valve:	**VLA**
* Membrane leak proof test:	**VDEBK/VABK** (opened) **VDABK/VEBK/VLA** (closed)

(*If *Start Pressure Positive* was set: An additional membrane leak proof test is performed after the second test step.)

Start Pressure Positive

If the test is activated for the dialysate circuit an automatic leakage test is performed. The test is started with a positive test pressure and then followed by a negative test pressure.

If the test is started with a positive test pressure an additional test step is performed after the second test step. This additional step performs a leak proof test of the membranes. The valves have the following position during the test:

- **VDEBK/VABK**: opened
- **VDABK/VEBK/VLA**: closed

The test pressure is present in the inlet balance chamber during this test. The membrane seals the outlet of the test circuit. A defective membrane would cause a pressure drop.

HDF Online

HDF online machines: the two additional test steps **2a** and **2b** are performed after the membrane test. Thus the valves **VDFF**, **VSB**, **VSAE** and **VSAA** and the substitution port are checked.

Start Pressure Negative

If the test is activated for the dialysate circuit an automatic leakage test is performed. The test is started with a negative test pressure and then followed by a positive test pressure.

LLC Alarm

The leakage test consists of three test steps. If an error occurs an LLC alarm is activated (LLC Status 00020000).

Test Procedure Positive Test Pressure

- A positive pressure is built up with the **FPE** pump.
- The pump is stopped and the valves closed if the set-point pressure for **PDA** = +400 mmHg is reached.
- The **PDA** reference value is stored after a wait state of 5 s.
- This reference value is compared with the actual value after 30 s.
- If the deviation is < 10 mmHg the next test step is performed.

Test Step 1

VLA, **VEBK1/2, VABK1/2**---------------- closed

Test Step 2

VLA, VDEBK1/2, VDABK1/2 ------------- closed

Note
Only if start pressure was positive

After the second test step a leak proof test of the membranes is performed. The valves have the following position:

VDEBK/VABK: --------------------------- opened
VDABK/VEBK/VLA: ---------------------- closed

Test Step 2a

Note
Test step 2a and 2b only for HDF online machines.

VLA Air separator valve: ----------------- closed
VDFF DF filter valve: --------------------- closed
VSB Substitution bypass valve: ----------- closed
VSAE Substitution connection inlet valve: - closed

Test Step 2b

VLA Air separator valve: ----------------- closed
VDFF DF filter valve : -------------------- closed
VSB Substitution bypass valve: ----------- closed
VSAA Substitution connection outlet valve: closed

Test Step 3

VLA, **VDE, VDA** ------------------------ closed

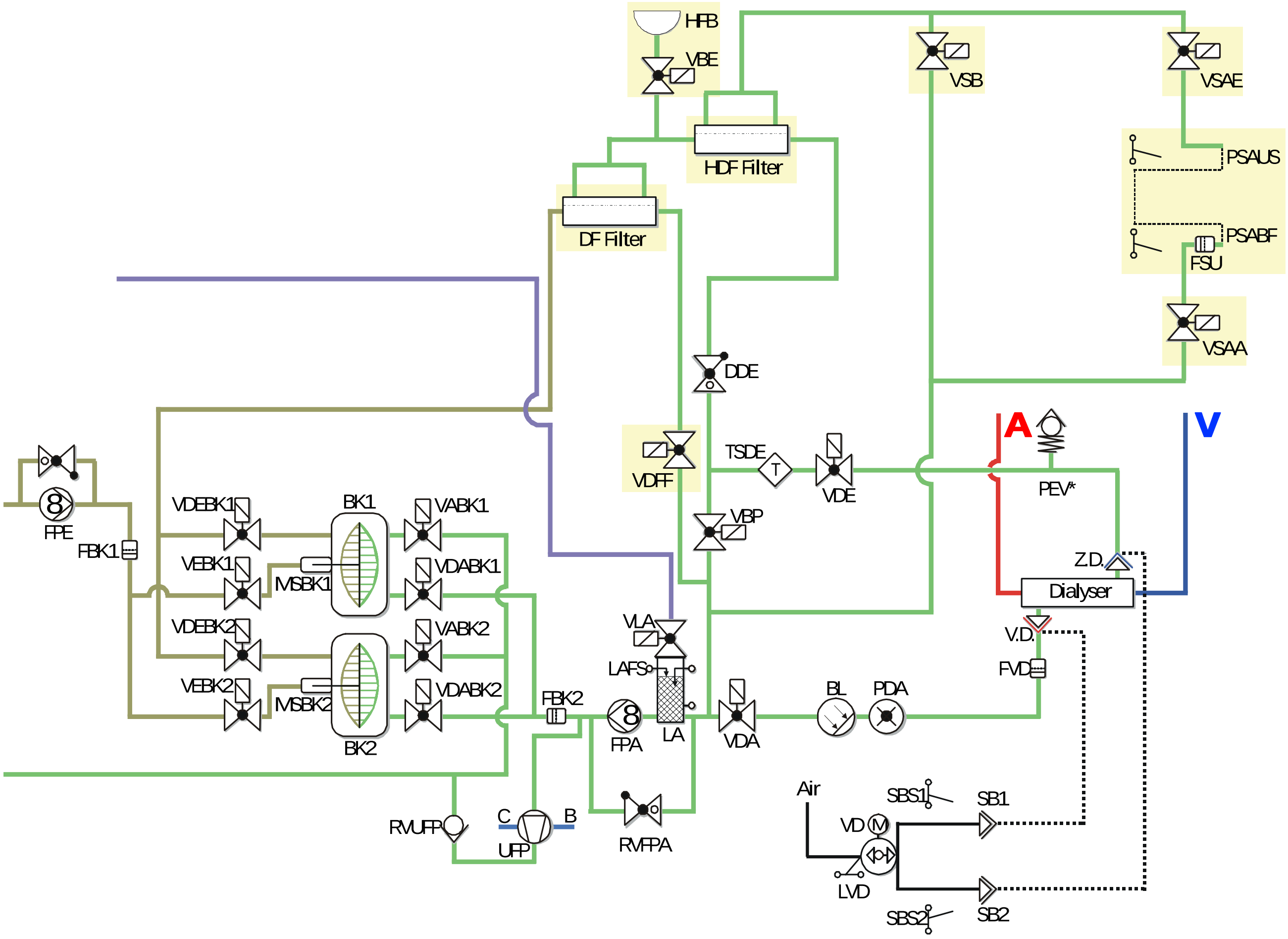


Fig.: Excerpt Flow Diagram for HDF Online

Negative Test Pressure Test Steps 1 to 3

The valve switching is identical with the above description.

- Negative pressure is built up with the UF pump after the third test step.
- The pump is stopped and the valves are closed if the set-point pressure for **PDA** = - 400 mmHg is reached.
- The **PDA** reference value is stored after a wait state of 5 s.
- This reference value is compared with the actual value after 30 s.
- If the deviation is < 10 mmHg the next test step is performed.

Leak Test Heat Exchanger

The following component is tested:

Heat Exchanger: **WT**

Manual Leakage Test Heat Exchanger (WT)

a) Rinse the flow circuit with water prior to the leakage test, to prevent air bubbles in the test area.

b) Close all valves in the Dialog (switch off machine).

c) Connect a manometer and a syringe filled with water to the water outlet.

d) Build up a test pressure 400 mmHg (+ 50 mmHg) with the syringe and close with tubing clamp.

e) Check pressure drop. The pressure drop must be < 50 mmHg in 30 s.

Leak Test Heat Exchanger (WT)

a) Rinse water circuit to prevent air bubbles.

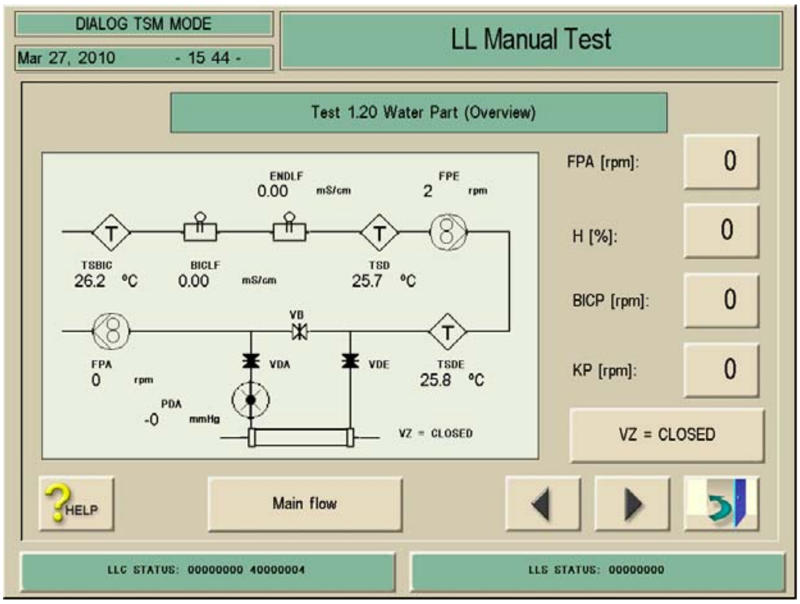
b) Close the outlet.

c) Activate test.

The **FPE** builds up a pressure.

d) Check pressure drop. The pressure drop must be < 50 mmHg in 30 s.

4.8.2.20 Test 1.20 Water Part (Overview)



FPA [rpm]: 0

H [%]: 0

BICP [rpm]: 0

KP [rpm]: 0

VZ = CLOSED

LLC STATUS: 00000000 40000004

LLS STATUS: 00000000

1. Activate the *Water Part (Overview)* menu with the *Water Part (Overview)* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can set the speed for the flow pump **FPE/FPA**. The heater power **H %** can be set in %. The speed of the concentrate pumps **BICP/KP** can be set manually. After starting this menu the balance chamber is initialised. Then the flow pump **FPE** is set to the same speed as **FPA**. The balance chamber valves are switched automatically.

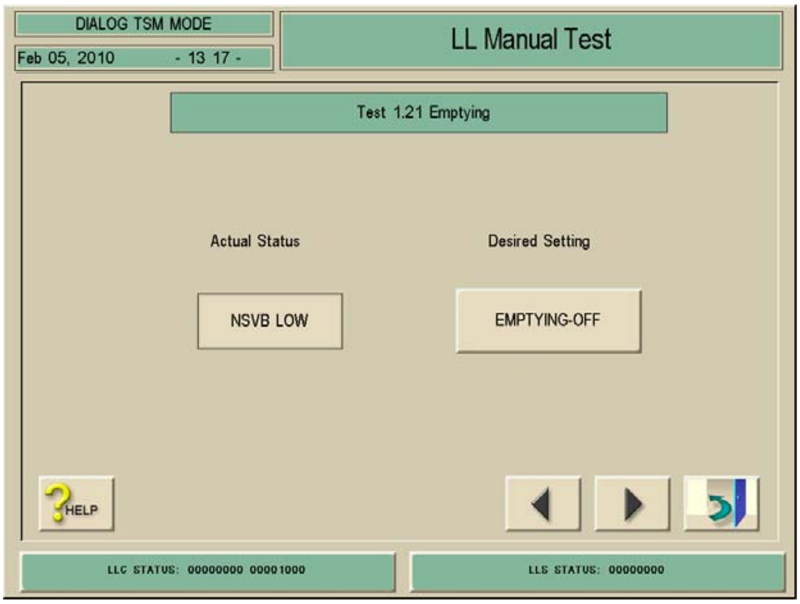
Main Flow

The machine can be switched between main flow and bypass for servicing.

Main Flow
Valves **VDA/VDE** are open (valve symbols are black).
Valve **VBP** is closed (valve symbol is white).

Bypass
Valves **VDA/VDE** are closed (valve symbols are white).
Valve **VBP** is open (valve symbol is black).

4.8.2.21 Test 1.21 Emptying



Actual Status: NSVB LOW

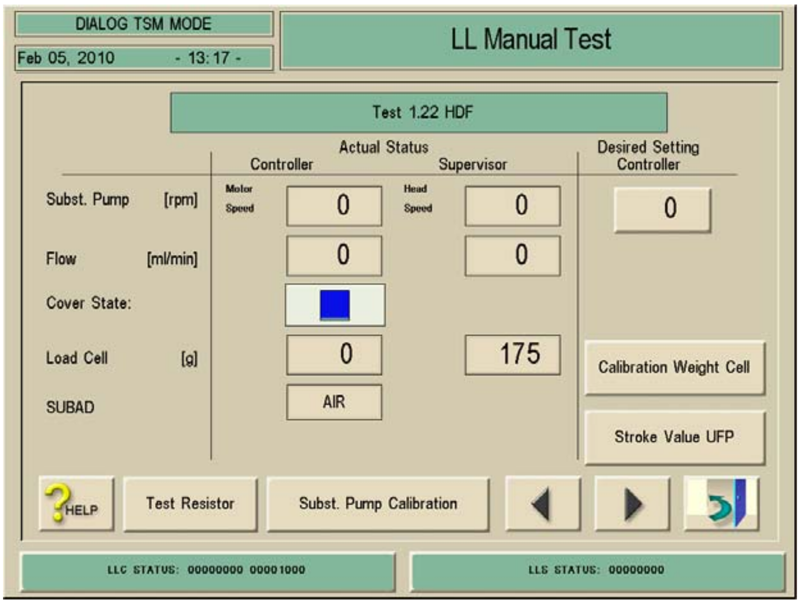
Desired Setting: EMPTYING-OFF

1. Activate the *Emptying* menu with the *Emptying* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can drain the system. After the emptying key is activated the drain procedure is started. The actual value, i.e. the fluid level of the upline tank **VB** is displayed by the level sensors **NSVB**.

Start the *Emptying ON* at least three times and manually clamp the bypass (tubing) to ensure a sufficient emptying (for transportation).

4.8.2.22 Test 1.22 HDF



DIALOG TSM MODE

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LL Manual Test

Test 1.22 HDF

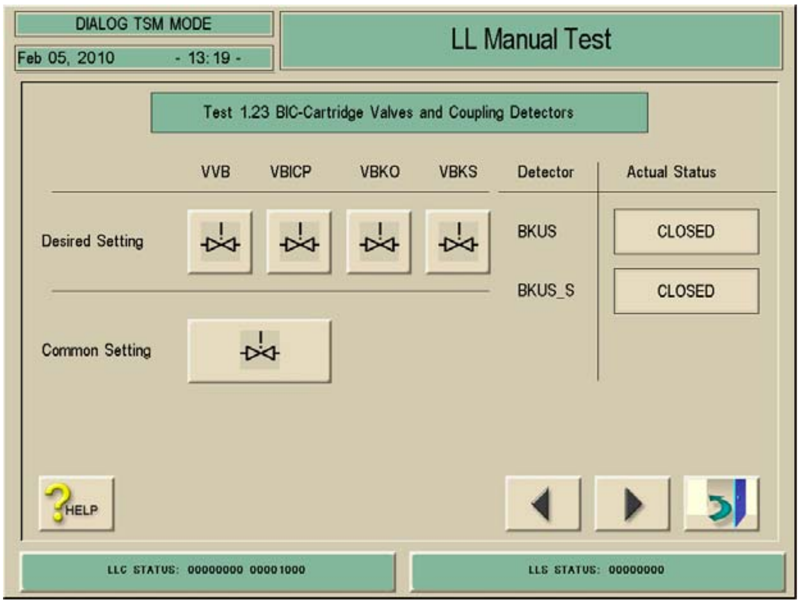
	Actual Status Controller		Actual Status Supervisor	Desired Setting Controller
Subst. Pump [rpm]	Motor Speed	0	Head Speed 0	0
Flow [ml/min]		0	0	
Cover State:		🟦		
Load Cell [g]		0	175	
SUBAD		AIR		

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

Not applicable.

4.8.2.23 Test 1.23 BIC Cartridge Valves and Coupling Detectors

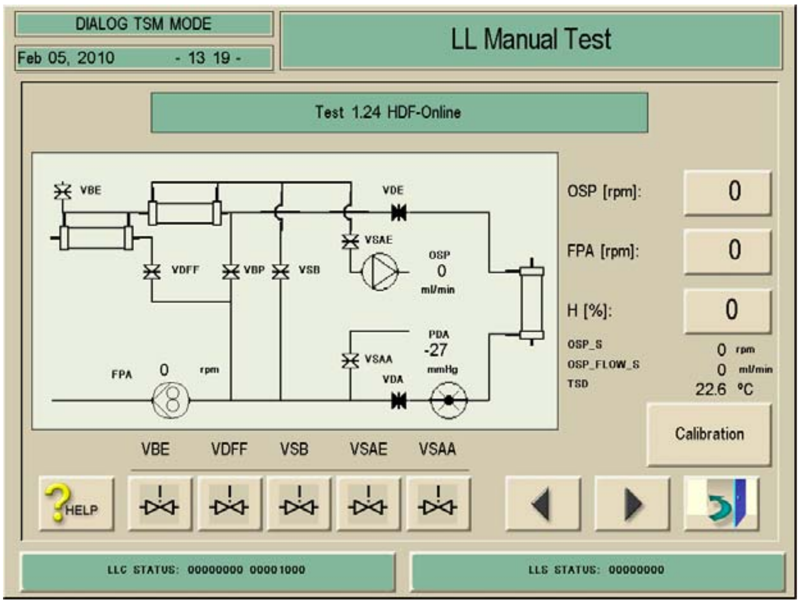


1. Activate the *BIC Cartridge Valves and Coupling Detectors* menu with the *BIC Cartridge Valves and Coupling Detectors* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

Valves VVB, VBICP, VBKO, VBKS	The valves **VVB**, **VBICP**, **VBKO** and **VBKS** can be switched either separately or together.
Detectors BKUS, BKUS_S	The status of the reed sensor (*OPEN/CLOSED*) is displayed.

4.8.2.24 Test 1.24 HDF Online

Exchange Intervals:
The HFB filter must be exchanged on an annual basis.



DIALOG TSM MODE
Feb 05, 2010 - 13 19 -
LL Manual Test
Test 1.24 HDF-Online

OSP [rpm]: 0
FPA [rpm]: 0
H [%]: 0
OSP_S 0 rpm
OSP_FLOW_S 0 ml/min
TSD 22.6 °C

LLC STATUS: 00000000 00001000
LLS STATUS: 00000000

1. Activate the *HDF Online* menu with the *HDF Online* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can check the function of the HDF online substitution pump *OSP (BPV)* and the additional valves.

Online Substitution Pump OSP (BPV)

The function of the HDF online substitution pump *OSP (BPV)* can be checked.

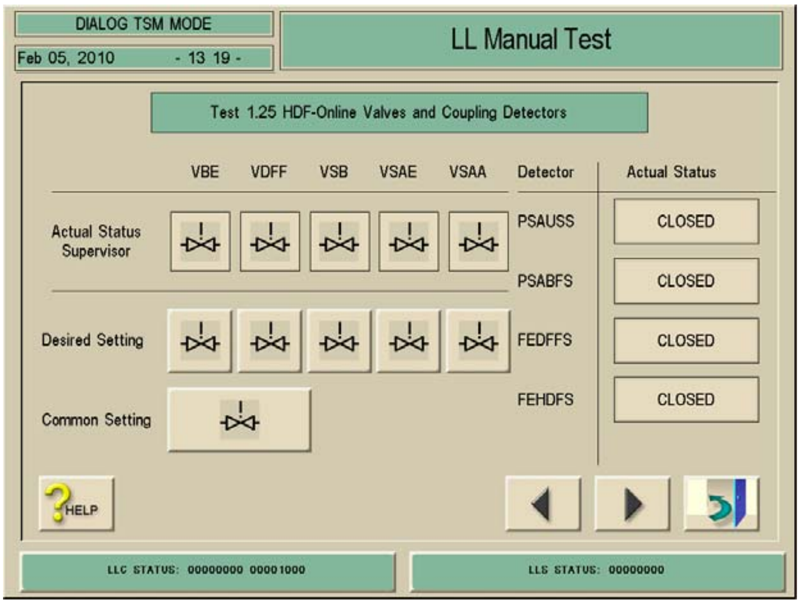
Valves VBE, VDFF, VSB, VSAE, VSAA

The flow path through both filters (**DF** and **HDF**) can be set via the valves.

Before operation in main flow the DF filter inlet must be vented via **VDFF**, because the membranes of the **DF** filter and **HDF** filter are impermeable to air.

Valve **VBE** can only be opened if **PDA** < -100 mmHg to prevent fluid penetration.

4.8.2.25 Test 1.25 HDF Online Valves and Coupling Detectors



DIALOG TSM MODE

Feb 05, 2010 - 13 19 -

LL Manual Test

Test 1.25 HDF-Online Valves and Coupling Detectors

Detector	Actual Status
PSAUSS	CLOSED
PSABFS	CLOSED
FEDFFS	CLOSED
FEHDFS	CLOSED

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *HDF Online Valves and Coupling Detectors* menu with the *HDF Online Valves and Coupling Detectors* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can activate and deactivate the HDF online valves.

Valves
VBE, VDFF, VSB, VSAE, VSAA

You can either activate or deactivate a single valve with the *Desired Setting* icon or all valves **VBE**, **VDFF**, **VSB**, **VSAE**, **VSAA** with the *Common Setting* icon. Thus the feedback from the LLS can be checked.

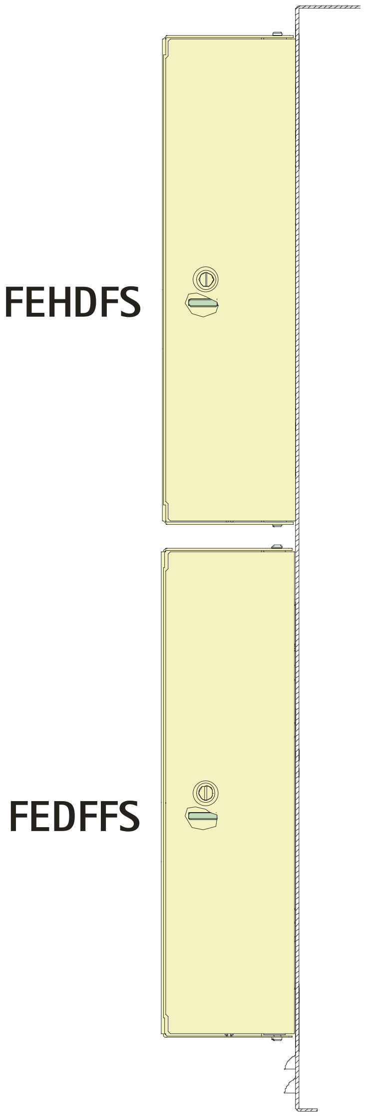
Detectors

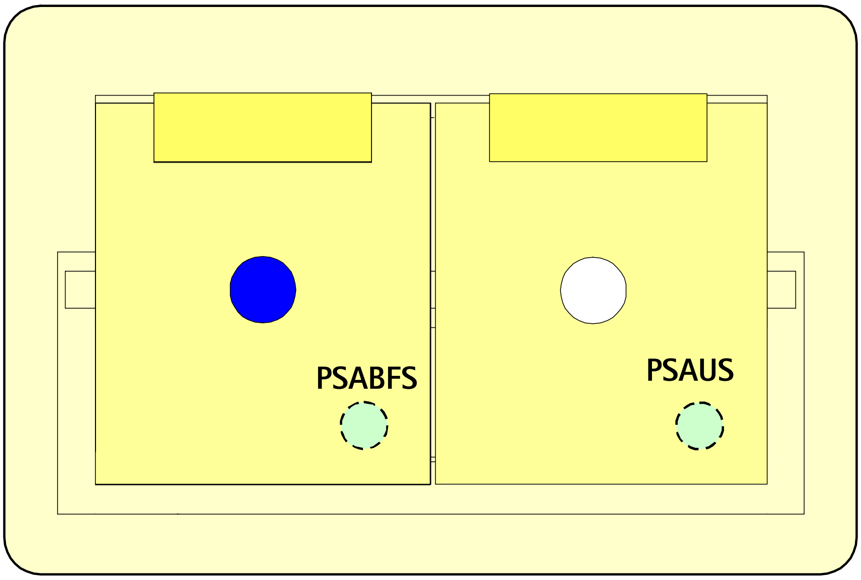
PSAUSS (substitution port outlet sensor)
The status of the additional coupling sensor **PSAUS** can be checked.

PSABFS (substitution port drain sensor)
The status of the additional coupling sensor **PSABFS** can be checked.

FEDFFS (filter recognition DF filter)
The status of the additional coupling sensor **FEDFFS** can be checked.

FEHDFS (filter recognition HDF filter)
The status of the additional coupling sensor **FEHDFS** can be checked.



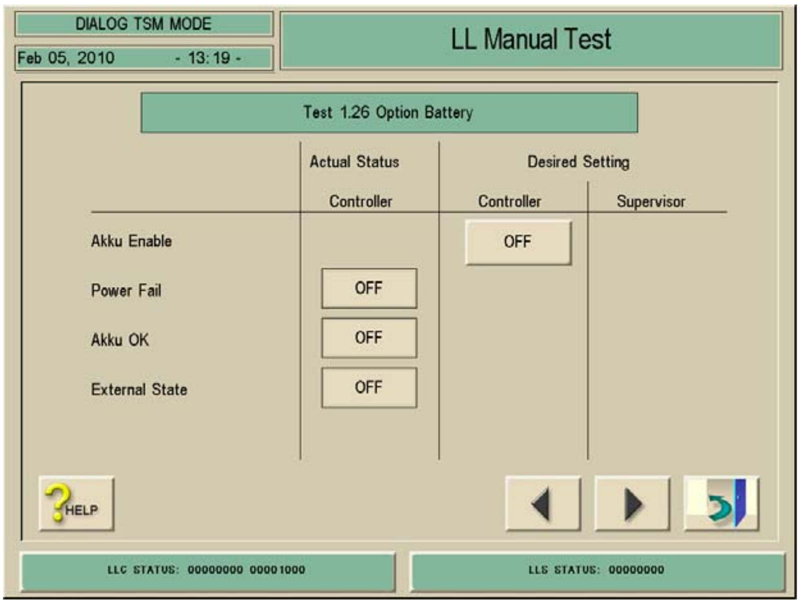


4.8.2.26 Test 1.26 Option Battery

Charge Batteries

To guarantee battery operation the batteries may have to be charged for several hours if the Dialog was not connected to mains for a longer period.

If the batteries are empty the charge time is > 8 hours to guarantee a battery running time of at least 20 minutes.



	Actual Status	Desired Setting	
	Controller	Controller	Supervisor
Akku Enable		OFF	
Power Fail	OFF		
Akku OK	OFF		
External State	OFF		

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Option (Rechargeable) Battery* menu with the *Option (Rechargeable) Battery* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

The enable parameter can be set and the following parameters can be checked:

Setting

- *Akku Enable* (battery enable, *AKKU_EN* signal)

Check

- *Power Fail* (PF signal)
- *Akku OK* (battery OK, *AKKU_OK* signal)
- *External State* (*EXT_STATE* signal)

Akku Enable (Battery Enable)

The enable signal is set to **ON** by the LLC in therapy. Thus indicating to the power supply that the battery operation can be enabled in the case of a power breakdown. In all other operating modes (with the exception of therapy) the *Akku Enable* (battery enable, AKKU_EN signal) is set to **OFF**, i.e. the machine is switched off in case of a power breakdown.

1. Battery charged (charge LED off), i.e. *Akku OK* (battery OK) = *ON*
2. Set *Akku Enable* (battery enable) to *ON*.
3. Disconnect machine from mains with mains plug.

A three-tone signal is activated via the buzzer from the switch mode power supply to indicate that the machine is running in battery operation.

- Blood pump(s) run(s)
- Monitor is on
- Power Fail = *ON*
- *Akku OK* (battery OK) changes from *ON* to *OFF*

Power Fail

The switch mode power supply sends the signal to the LLC indicating a power failure.

OFF	Mains voltage present (and in the tolerance limits)
ON	Mains voltage not present (or out of tolerance limits)

Akku OK (Battery OK)

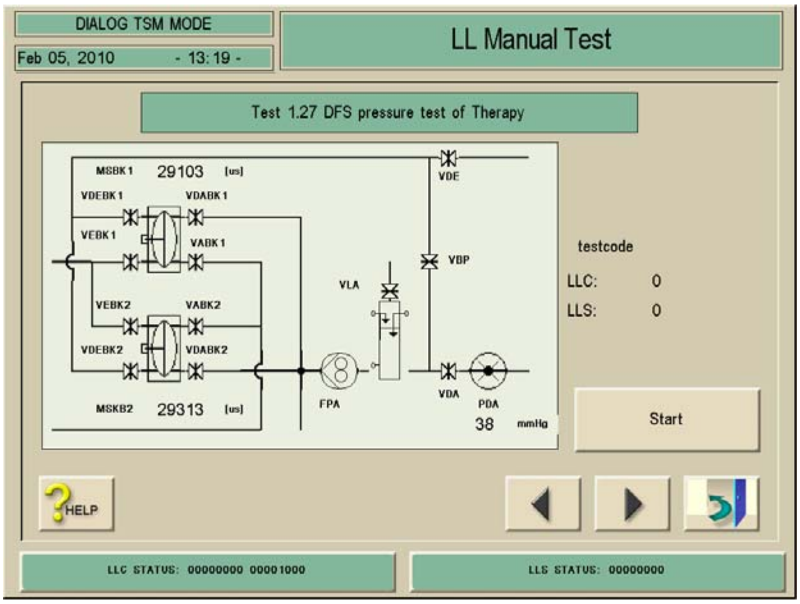
ON	Battery capacity ≥ required capacity for 20 minutes battery running time
OFF	Battery capacity < required capacity for 20 minutes battery running time

External State

Indicates if machine was switched on externally.

ON	Machine was switched on externally

4.8.2.27 Test 1.27 DFS Pressure Test of Therapy



Feb 05, 2010 - 13:19 -

Test 1.27 DFS pressure test of Therapy

MSBK1 29103 [us]

MSKB2 29313 [us]

PDA 38 mmHg

testcode

LLC: 0

LLS: 0

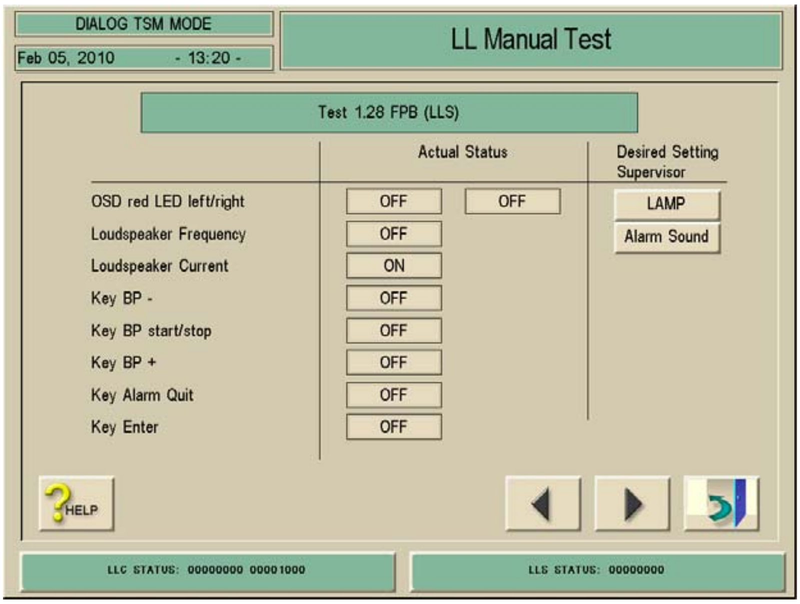
LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *DFS Pressure Test of Therapy* menu with the *DFS Pressure Test of Therapy* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

Start Key	You can activate the DFS pressure test with the *Start* key from the self test in *Preparation*.
Stop Key	The test run can be terminated with the *Stop* key. The key jumps back to *Start* in case of an error or at the end of the pressure test.
Test Code	The test codes for LLC and LLS are displayed for all test phases. In case of an error the defective components can be determined with the help of the test description.

4.8.2.28 Test 1.28 Front Panel Board FPB (LLS)


DIALOG TSM MODE

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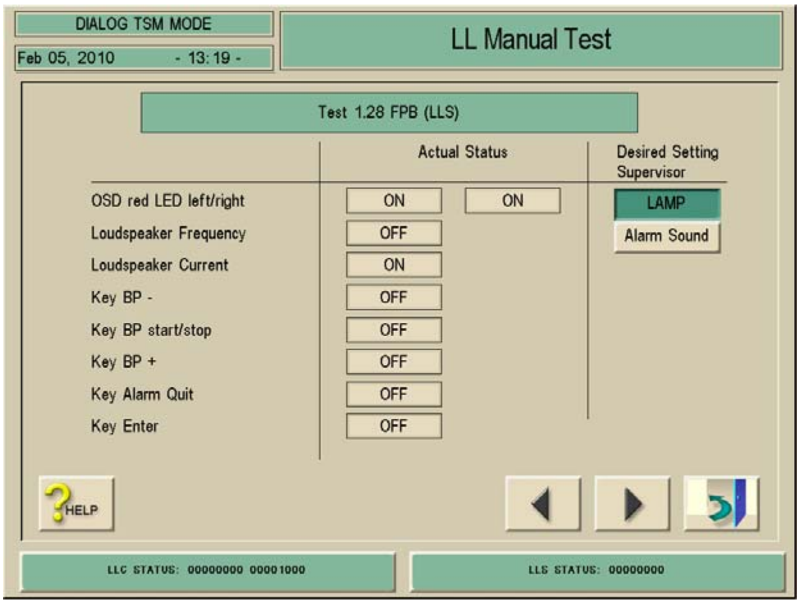
LL Manual Test

Test 1.28 FPB (LLS)

	Actual Status		Desired Setting Supervisor
OSD red LED left/right	OFF	OFF	LAMP
Loudspeaker Frequency	OFF		Alarm Sound
Loudspeaker Current	ON		
Key BP -	OFF		
Key BP start/stop	OFF		
Key BP +	OFF		
Key Alarm Quit	OFF		
Key Enter	OFF		

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000


DIALOG TSM MODE

Feb 05, 2010 - 13:19 -

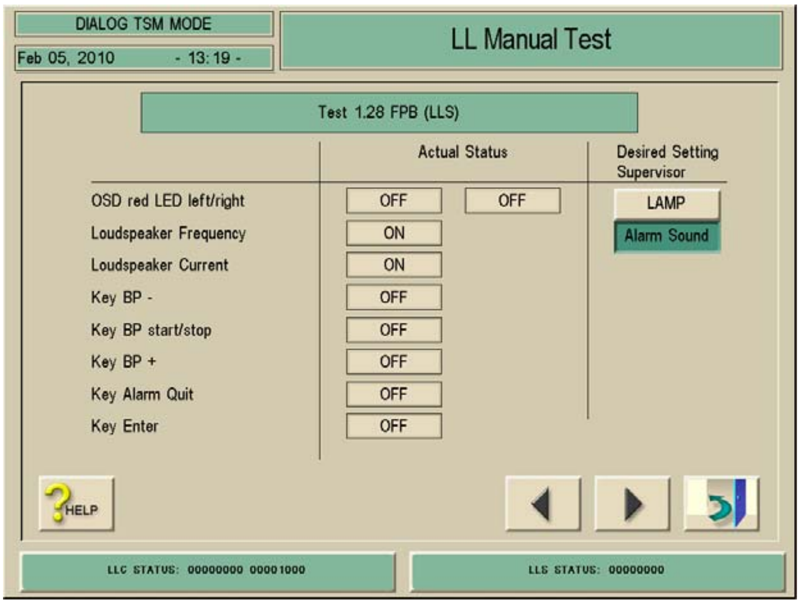
LL Manual Test

Test 1.28 FPB (LLS)

	Actual Status		Desired Setting Supervisor
OSD red LED left/right	ON	ON	LAMP
Loudspeaker Frequency	OFF		Alarm Sound
Loudspeaker Current	ON		
Key BP -	OFF		
Key BP start/stop	OFF		
Key BP +	OFF		
Key Alarm Quit	OFF		
Key Enter	OFF		

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000


DIALOG TSM MODE

Feb 05, 2010 - 13:19 -

LL Manual Test

Test 1.28 FPB (LLS)

	Actual Status		Desired Setting Supervisor
OSD red LED left/right	OFF	OFF	LAMP
Loudspeaker Frequency	ON		Alarm Sound
Loudspeaker Current	ON		
Key BP -	OFF		
Key BP start/stop	OFF		
Key BP +	OFF		
Key Alarm Quit	OFF		
Key Enter	OFF		

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Front Panel Board FPB* menu with the *Front Panel Board FPB* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

You can check the LEDs and keys on the front panel board FPB via the supervisor LLS.

Lamp

- OSD Red LED Left/Right

If you press the *Lamp* key the red LEDs on the OSD boards are switched on (*OFF/ON*) and checked with a feedback from the red LEDs to the supervisor LLS.

Alarm Sound

- Loudspeaker Frequency

If you press the *Alarm Sound* key the loudspeaker is switched on and checked with a feedback (*Loudspeaker Frequency ON*) from the loudspeaker to the supervisor LLS.

If the loudspeaker is not connected the *Loudspeaker Frequency* stays *OFF*.

Test Blood Pump Keys

- *Blood Pump – Key*

Press the − key on the front panel board FPB and wait for switching (*OFF/ON*).

- *Blood Pump START/STOP Key*

Press the start stop key on the front panel board FPB and wait for switching (*OFF/ON*).

- *Blood Pump + Key*

Press the + key on the front panel board FPB and wait for switching (*OFF/ON*).

Test Alarm Quit/Enter Key

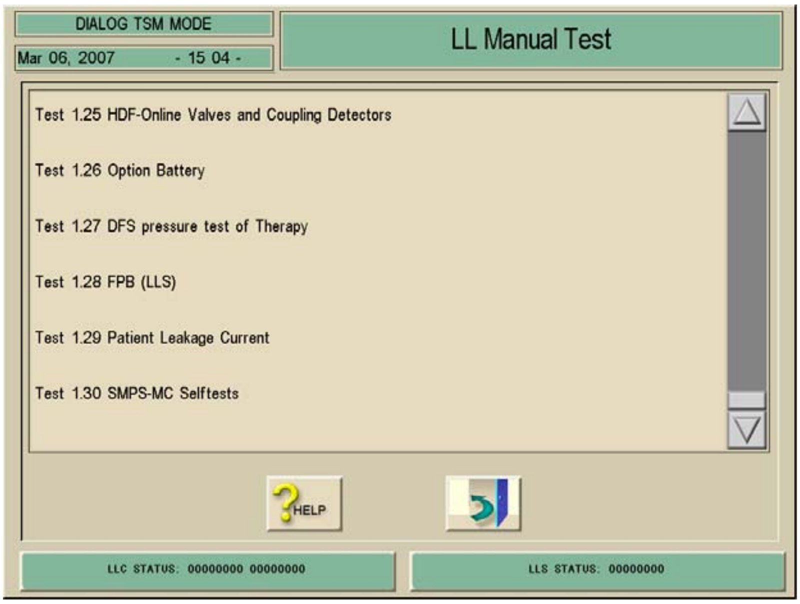
- *Alarm Key*

Press the 🔕 key on the front panel board FPB and wait for switching (*OFF/ON*).

- *Enter Key*

Press the ↵ key on the front panel board FPB and wait for switching (*OFF/ON*).

4.8.2.29 Test 1.29 Patient Leakage Current

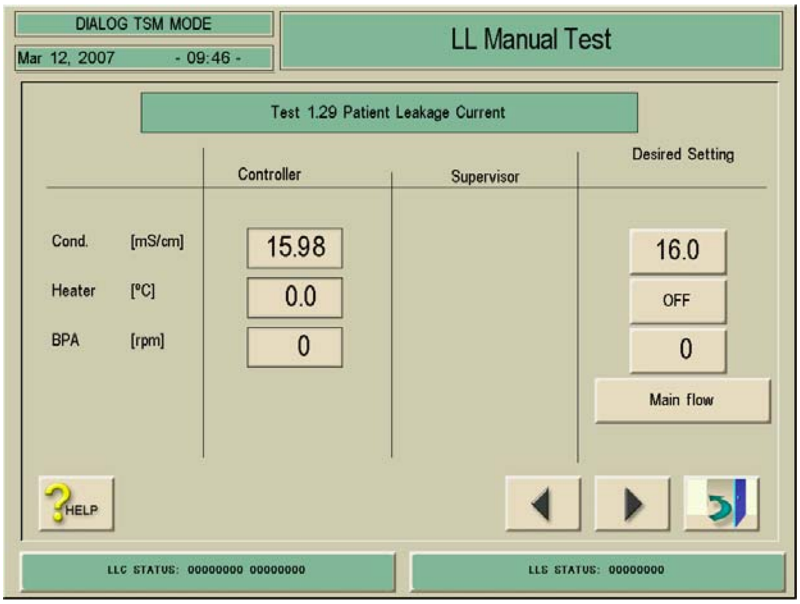


1. Activate the *Patient Leakage Current* menu with the *Patient Leakage Current* key in the *LL Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.

Patient Leakage Current

You can set all required parameters for the measurement of the patient leakage current in the menu. The following parameters and functions are available:

- Automatic control of the conductivity after entering the set point value (default: max. conductivity setting).
- Heater can be switched on and off manually (automatic switch-off at 60 °C).
- Possibility to switch from Main Flow to Bypass (default: main flow).
- Set point can be set for the speed of the blood pump (default 0)
- Display of the conductivity and temperature
- DF flow between 500 – 600 ml/min depending on pump



		Controller	Supervisor	Desired Setting
Cond.	[mS/cm]	15.98		16.0
Heater	[°C]	0.0		OFF
BPA	[rpm]	0		0
				Main flow

Conductivity

The conductivity can be activated for the measurement of the patient leakage current.

Heater

The heater can be switched on for the measurement of the patient leakage current. The heater is controlled with 100 % until it reaches 60 °C and is then switched off.

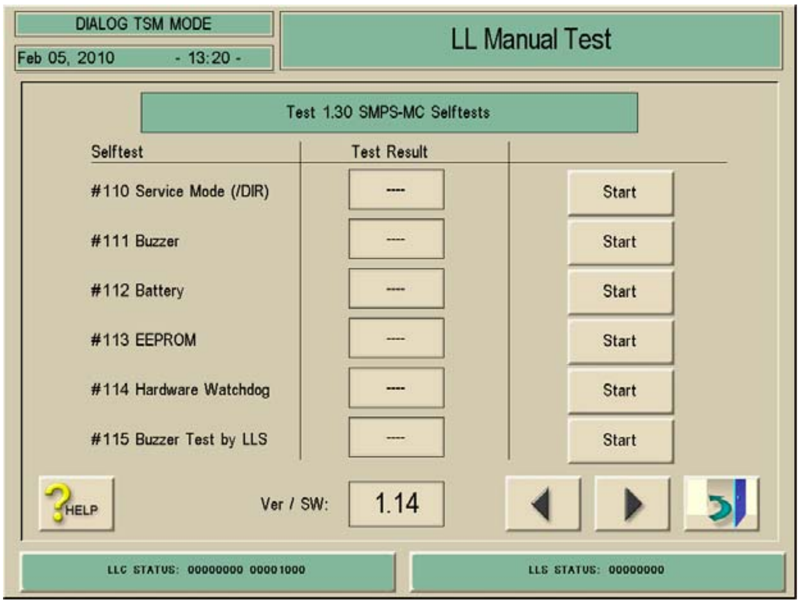
BPA

The blood pump can be activated additionally if the measurement is performed with tubing set (line).

Main Flow

The machine can be switched between main flow and bypass.

4.8.2.30 Test 1.30 SMPS-MC Self Tests



DIALOG TSM MODE

Feb 05, 2010 - 13:20 -

LL Manual Test

Test 1.30 SMPS-MC Selftests

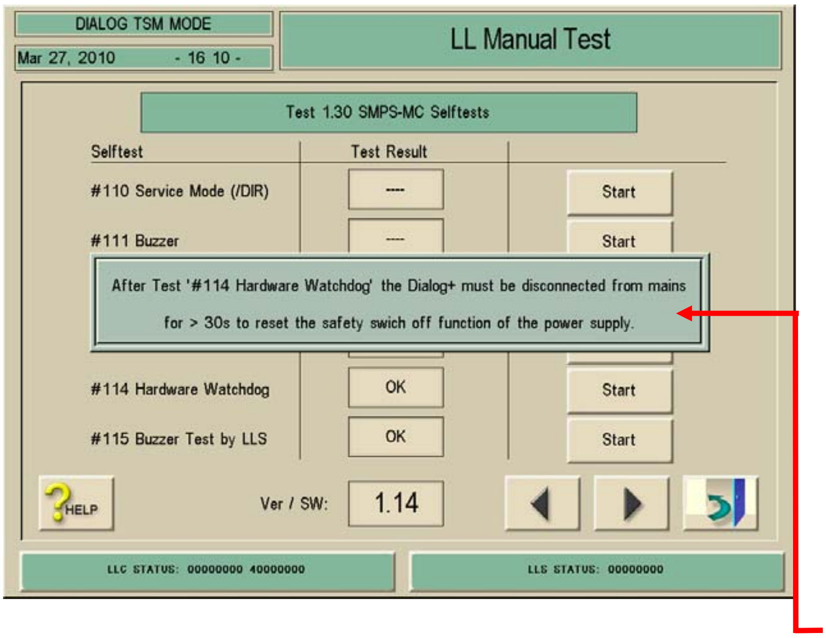
Selftest	Test Result	
#110 Service Mode (/DIR)	----	Start
#111 Buzzer	----	Start
#112 Battery	----	Start
#113 EEPROM	----	Start
#114 Hardware Watchdog	----	Start
#115 Buzzer Test by LLS	----	Start

Ver / SW: 1.14

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Test 1.30 SMPS-MC Self Tests* menu with the *SMPS-MC Self Tests* key in the *Low Level Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.



DIALOG TSM MODE

Mar 27, 2010 - 16 10 -

LL Manual Test

Test 1.30 SMPS-MC Selftests

Selftest	Test Result	
#110 Service Mode (/DIR)	----	Start
#111 Buzzer	----	Start
#114 Hardware Watchdog	OK	Start
#115 Buzzer Test by LLS	OK	Start

After Test '#114 Hardware Watchdog' the Dialog+ must be disconnected from mains for > 30s to reset the safety swich off function of the power supply.

Ver / SW: 1.14

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

The switch mode power supply microcontroller SMPS-MC can be tested with the self test functions in this menu.

The relays K3/K4 are deactivated during all self tests.

The self tests are described in detail on the next page.

#110 Service Mode (/DIR)

#111 Buzzer

#112 Battery

Note: #112 Battery is performed only if the battery option is present.

#113 EEPROM

#114 Hardware Watchdog

Note: This window appears if the *#Test 114* was performed. The safety switch-off of the SMPS-MC must be reset after the test, i.e. the machine must be disconnected from mains for > 30 s (disconnect mains plug from mains receptacle).

#115 Buzzer Test by LLS

Ver/SW

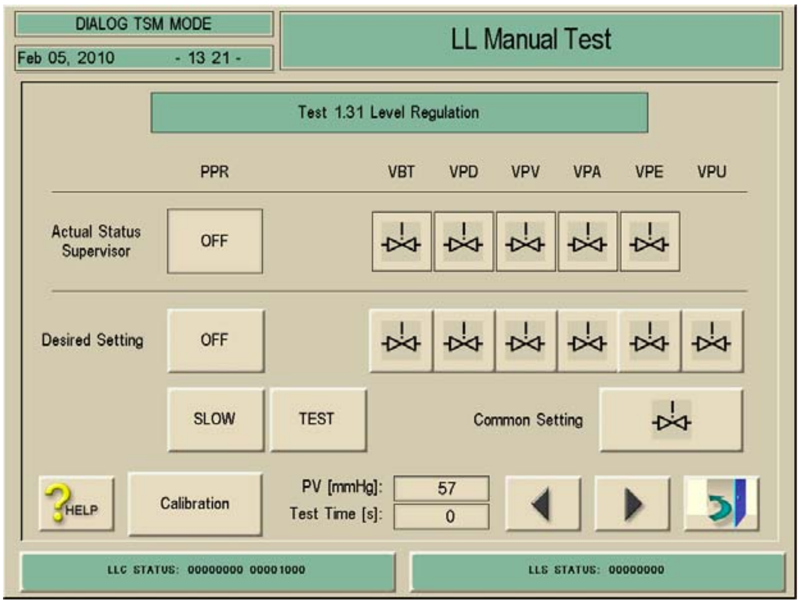
The software version of the SMPS-MC is displayed.

4.8.2.30.1 Self Tests SMPS-MC

Relays K3/K4 are deactivated during all self tests.

No.	Test	Description	Reaction SMPS-MC	Reaction Dialog+
-	Flash memory	Microcontroller of SMPS-MC checks the flash memory	Condition: • Machine connected to mains Response: • Power-On reset + CRC Condition: • Mains switch ON Response: • Watchdog timer reset + CRC Error in flash: • Switch-on not possible, quick flashing of the operating status LED H900 (5 .. 10 Hz)	
110	Service mode (/DIR_ON)	Microcontroller of SMPS-MC checks the operating mode	Service jumper X101 connected • TSM mode (alarms deactivated) Service jumper X101 not connected • Therapy mode (alarms activated)	if /DIR_ON = 0 (service jumper X101 connected): • Therapy is rejected • Error message is generated
111	Buzzer test (the buzzer is tested via LLS in # 115)	Microcontroller of the SMPS-MC checks the function of the buzzer (without drive/activation from LLS)		
112	Battery test (is performed only if option is present)	Check whether battery is connected and if connected, check whether battery is charged sufficiently	OK: • Battery present and charged sufficiently not OK: • Battery not present or not charged sufficiently	if not OK: • Warning is generated • Therapy still possible
113	EEPROM	Microcontroller of the SMPS-MC checks the EEPROM memory (EEPROM currently not used)		
114	Hardware watchdog WD	In TSM service program only A simulated microcontroller failure tests the function of the hardware watchdog (the trigger signals for the hardware WD are switched off)	Condition: • Trigger HW-WD Response: • Buzzer and staff call ON • +24 VGX OFF • Heater OFF Only a reset of the microcontroller (enable voltage) deactivates the alarm (mains connector must be disconnected from the mains > 30 s) **If switch-off time < 30 s** Mains plug was connected again without waiting more than 30 s. LED H900 on SMPS-MC continues to flash - Remove fuse on battery rack -- LED H900 goes out. - Insert again the fuse.	
115	Buzzer test via LLS	Microcontroller of SMPS-MC checks the function of the buzzer	The +24 VGB and +24 VGD are always switched off during this test (a communication between LLS and SMPS-MC is not possible without this switch-off) • LLC informs LLS via DIABUS • LLC sends #115 to SMPS-MC • LLS must activate AKAL-S within 5 s OK: • Buzzer OK. not OK: • Buzzer not OK.	if not OK: • Warning is generated • Therapy still possible

4.8.2.31 Test 1.31 Level Regulation


DIALOG TSM MODE

Feb 05, 2010 - 13 21 -

LL Manual Test

Test 1.31 Level Regulation

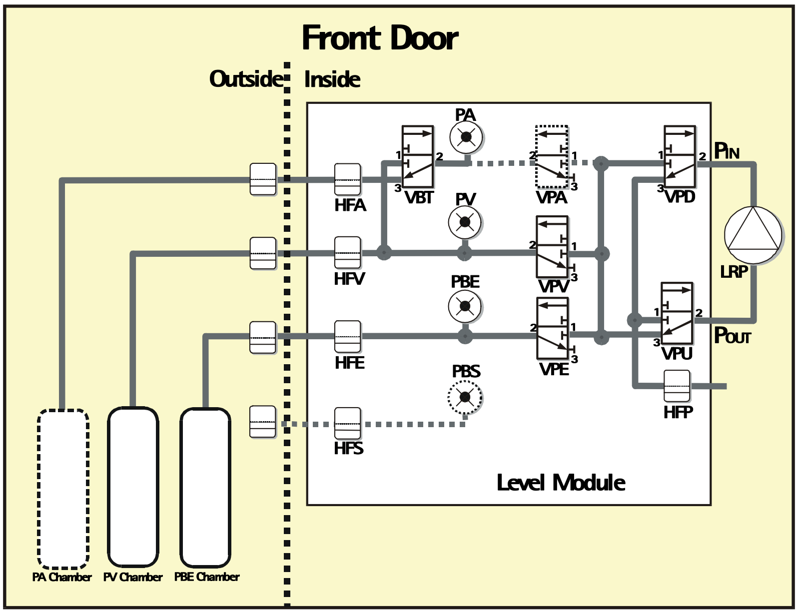
PV [mmHg]: 57

Test Time [s]: 0

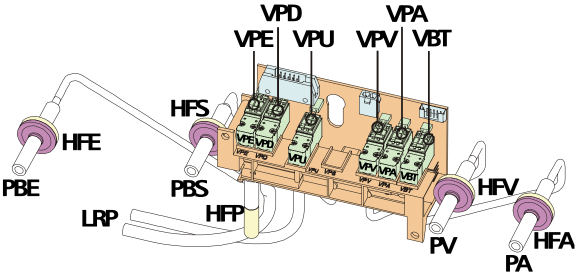
LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *Test 1.31 Level Regulation* menu with the *Level Regulation* key in the *Low Level Manual Test* menu. The following menu is displayed.
2. Check the functions with the appropriate keys.



The valves VPE, VPD, VPU, VPV, VPA, and VBT are all assembled on the level regulation module. All valves can be activated and tested. The manometer connectors must be opened for the test.



Actual Status Supervisor	**LRP (PPR) OFF/ON** The supervisor must detect correctly the current status of the level regulation pump LRP (PPR).
Desired Setting	**OFF/ON** The level regulation pump LRP (PPR) can be switched on and off.
Slow/Fast	The desired value for the LRP can be switched between a *Slow* and a *Fast* setting.
Test	The delivery of the LRP can be checked with the *Test* key. A measurement chamber must be connected to PV. LRP stops when 500 ml are reached and the required time for the pressure build-up is displayed.

4.8.3 Low Level Manual Calibration

4.8.3.1 General Calibration Information

Specifications for Measurement Instruments

Measurement instruments (e.g. dialysis measurement instrument) used to calibrate Dialog machines are subject to regular inspections or if necessary calibration by the respective manufacturer or by a certified calibration lab.

Pressure

For ABPM
- Accuracy ≤ 0.8 mmHg

Pressure

For PV, PA, PBS, PBE
- Accuracy $\leq \pm 1$ mmHg

Temperature

- Temperature accuracy: $\leq \pm 0.2$ °C
- Temperature resolution minimum 0.1 °C

Conductivity

- Temperature coefficient $\alpha = 2.10$ %/°C (set)
- Reference temperature $T_{Ref} = 25$ °C (set)
- Correct cell constant (set)
- Conductivity accuracy: $\leq \pm 0.1$ mS/cm
- Conductivity resolution 0.01 mS/cm

Balance

- Measurement range >200 g, accuracy < 0.5 g

Manometer

For PE and PDA:
- Accuracy Class ≤ 0.5

For DMV, RVFPA, RVFPE, DDE and RVDA:
- Accuracy Class ≤ 1.0

Flow Meter

4 % of final value:
- 1.1 l/min, approx. ± 44 ml/min

Hardware Keys

Various keys (software keys and hardware keys) are used during calibration. The hardware keys (on the front panel board) can be used via the keyboard membrane (see figure). The function and significance of the hardware keys are as follows.

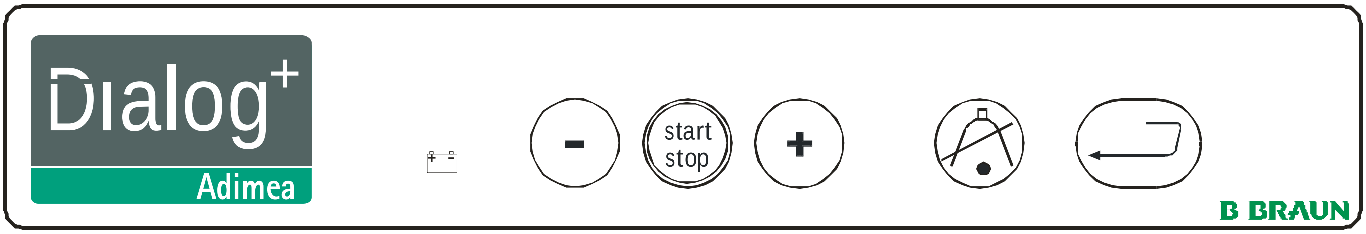


Fig. : Symbols of Hardware Keys on Keyboard Membrane of Monitor

−

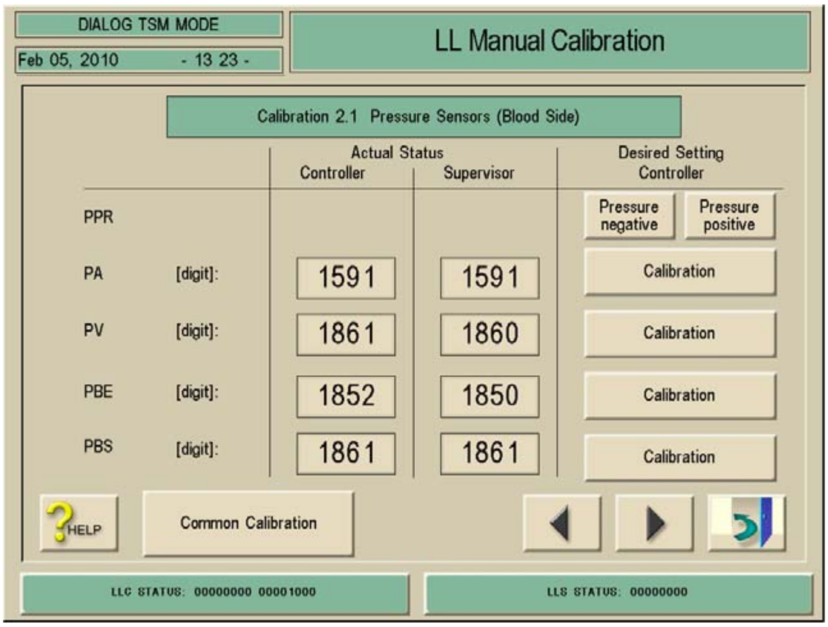
Input values can be decreased in increments with the displayed hardware key as an alternative to the software key on the touch screen.

+

Input values can be increased in increments with the displayed hardware key as an alternative to the software key on the touch screen.

The service overview can be selected in the TSM with the hardware key.

Software Keys and Icons



DIALOG TSM MODE

Feb 05, 2010 - 13 23 -

LL Manual Calibration

Calibration 2.1 Pressure Sensors (Blood Side)

		Actual Status Controller	Supervisor	Desired Setting Controller	
PPR				Pressure negative	Pressure positive
PA	[digit]:	1591	1591	Calibration	
PV	[digit]:	1861	1860	Calibration	
PBE	[digit]:	1852	1850	Calibration	
PBS	[digit]:	1861	1861	Calibration	

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

The software keys and icons are displayed in the respective menus of the TSM service program and can be used via the touch screen. The procedure for calibration of the sensors is similar in all *Low Level Manual Calibration* menus.

Example

Select the menu via the following menus:

- *TSM Main Menu*
- *Manual Test and Calibration*
- *Low Level Manual Calibration*
- *Calibration 2.1 Pressure Sensors (Blood Side)*

Function of the Software Keys and Icons

The function of the software keys and icons are as follows:

HELP

Press the *HELP* key to see the help information of the menu.

Calibration

A single sensor can be selected for calibration with the *Calibration* key. A lower calibration window is opened (see second figure).

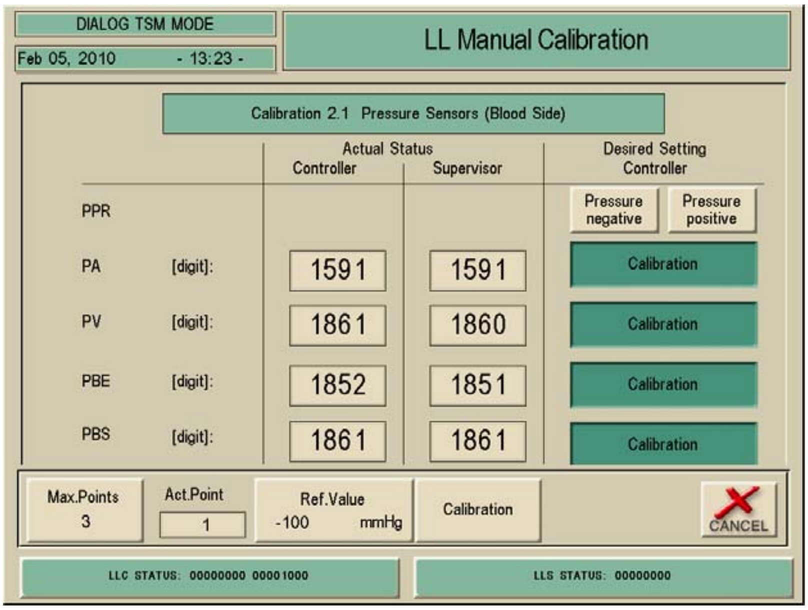
Common Calibration

A combined sensor calibration can be selected with the *Common Calibration* key. A lower calibration window is opened (see second figure on next page).

◀ ▶

If required, the previous calibration menu or the next calibration menu can be selected with the *Previous* and *Next Arrow* keys.

The menu can be closed with the *Exit Door* key.

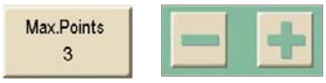


		Actual Status Controller	Actual Status Supervisor	Desired Setting Controller
PPR				Pressure negative / Pressure positive
PA	[digit]:	1591	1591	Calibration
PV	[digit]:	1861	1860	Calibration
PBE	[digit]:	1852	1851	Calibration
PBS	[digit]:	1861	1861	Calibration

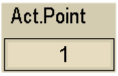
The Common Calibration key was selected. A calibration window is opened (bottom section of the menu).

Function of the Software Keys und Icons

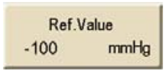
The function of the software keys und icons during calibration are as follows:



The max. number of calibration points is displayed, e.g. three calibration points. Click on key: the number of calibration points can be modified with the -/+ keys. We recommend keeping the suggested number or increasing only, do not decrease the number.



The actual calibration point is displayed, e.g. first calibration point.

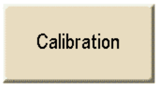


The suggested reference value is displayed for the first calibration point.

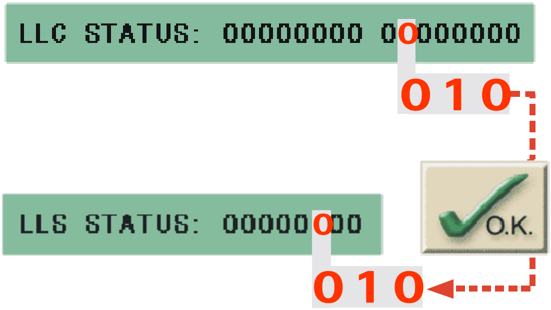
If the reference value key is pressed, an input keypad is displayed. The value from the measurement instrument can be entered. The entered value must be in the permissible limits (e.g. –100 to 500 mmHg).

The entered value can be cancelled and the window is closed.

The entered value can be confirmed with the OK key and the window is closed.



The calibration point with the entered calibration value can be confirmed and the calibration value is saved. The sensor values must be checked in therapy mode (service overview) after calibration.



The calibration procedure is completed and the new calibration data are stored in the LLC and LLS.

Note: Pay attention to the LLC and LLS status windows. The bit sequence 0-1-0 must be identical in the LLC and LLS status windows during the saving procedure. The calibration data is saved only after the bit sequence 0-1-0 (see figure).

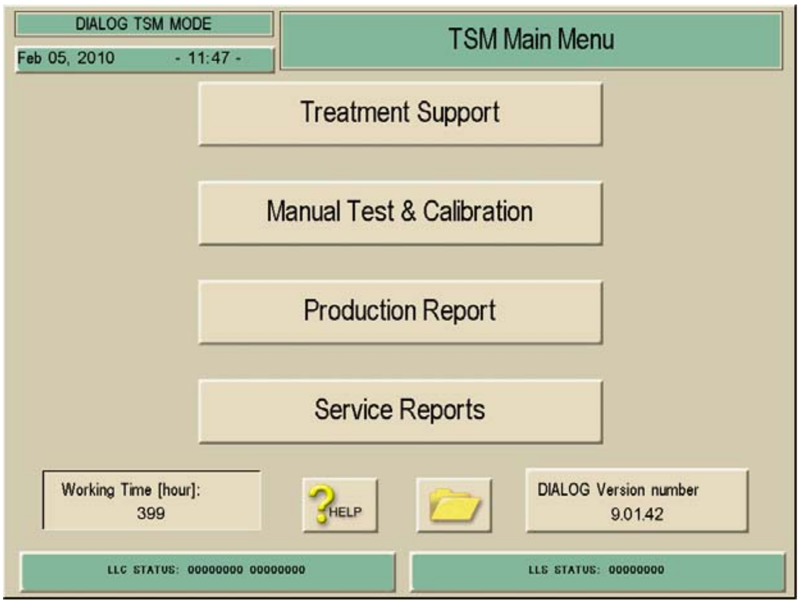
Save the calibration data to the compact flash card before exiting the TSM service program: *TSM Main Menu*, *File Operations*, *Save Calibration Data*.

A calibration procedure can be terminated. The existing calibration data are maintained in the LLS and LLC.

Conversion Table Voltage/Digits

	Controller/Supervisor (12 bit)
Voltage	0 to 5 V
Digits	0 to 4095

4.8.3.2 Select Low Level Manual Calibration



Feb 05, 2010 - 11:47 -

Working Time [hour]: 399

DIALOG Version number 9.01.42

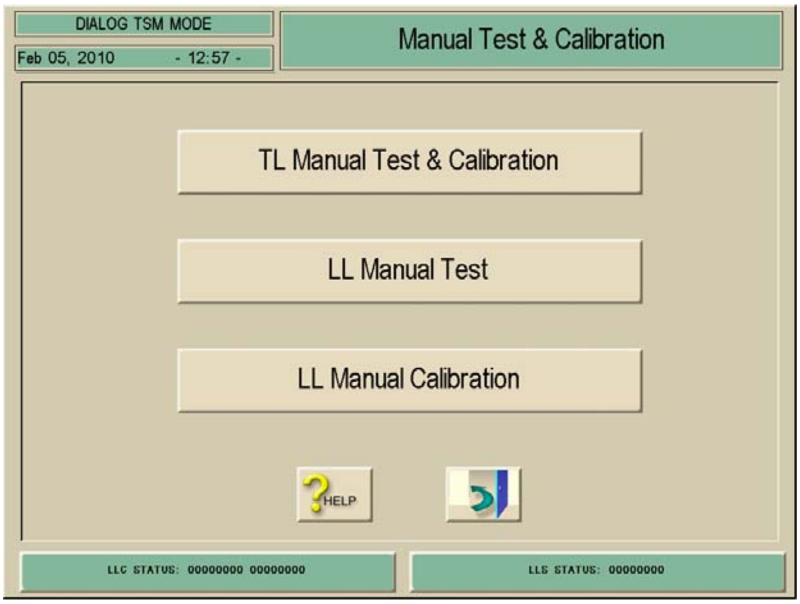
LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

You can calibrate all sensors in the *LL Manual Calibration* menu. The number of calibration points is preset.

Some sensors have the possibility to run a combined or a single calibration.

The *TSM Main Menu* is displayed after the machine is switched on (set service switch S1 to position 2, on digital board).

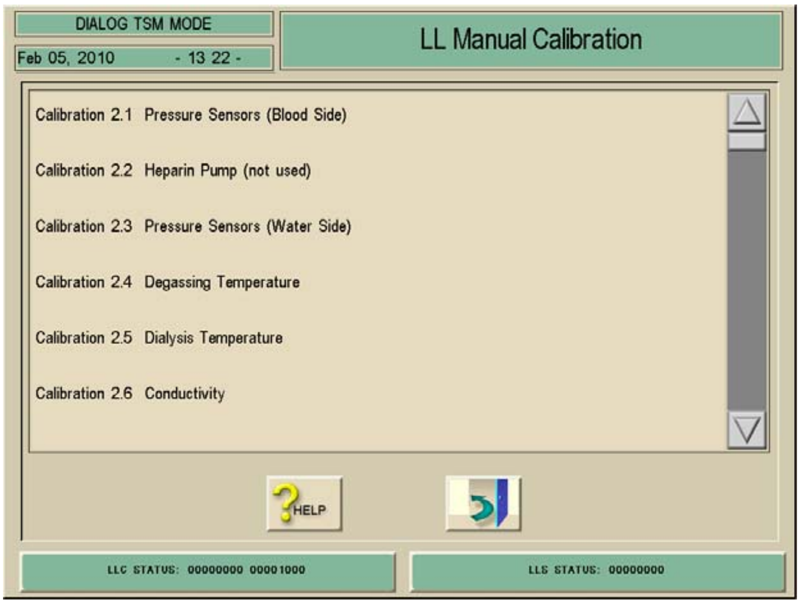


Feb 05, 2010 - 12:57 -

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

1. Activate the *Manual Test & Calibration* menu with the *Manual Test & Calibration* key in the *TSM Main Menu*. The following menu is displayed.



Feb 05, 2010 - 13 22 -

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

2. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu. The following menu is displayed.

The following low level calibrations can be selected:

- 2.1 Pressure Sensors (Blood Side)
- 2.2 Heparin Pump (not applicable)
- 2.3 Pressure Sensors (Water Side)
- 2.4 Degassing Temperature
- 2.5 Dialysis Temperature
- 2.6 Conductivity
- 2.7 Blood Leak Detector
- 2.8 Flow of BICP, KP and UF
- 2.9 Safety Air Detector SAD
- 2.10 BICLF Ratio and ENDLF Ratio
- 2.11 Load Cell (not applicable)
- 2.12 PV Alarm Window, PA Low Limit
- 2.13 Flow of BPA and BPV Pump
- 2.14 Substitution Pump (not applicable)
- 2.15 HDF Online Substitution Pump OSP
- 2.16 Level Regulation

4.8.3.3 Calibration Pressure Sensors Blood Side PA, PV, PBE and PBS

Prior to Calibration

- Use calibrated measurement instrument
- Wait until Dialog has reached working temperature

You can calibrate the following pressure sensors of the blood side either separately or combined:

- **PA** arterial pressure sensor
- **PV** venous pressure sensor
- **PBE** blood inlet pressure sensor
- **PBS** blood control pressure sensor

After a calibration compare the pressure sensor values in the test menu. The sensor values are displayed in digits (see conversion table).

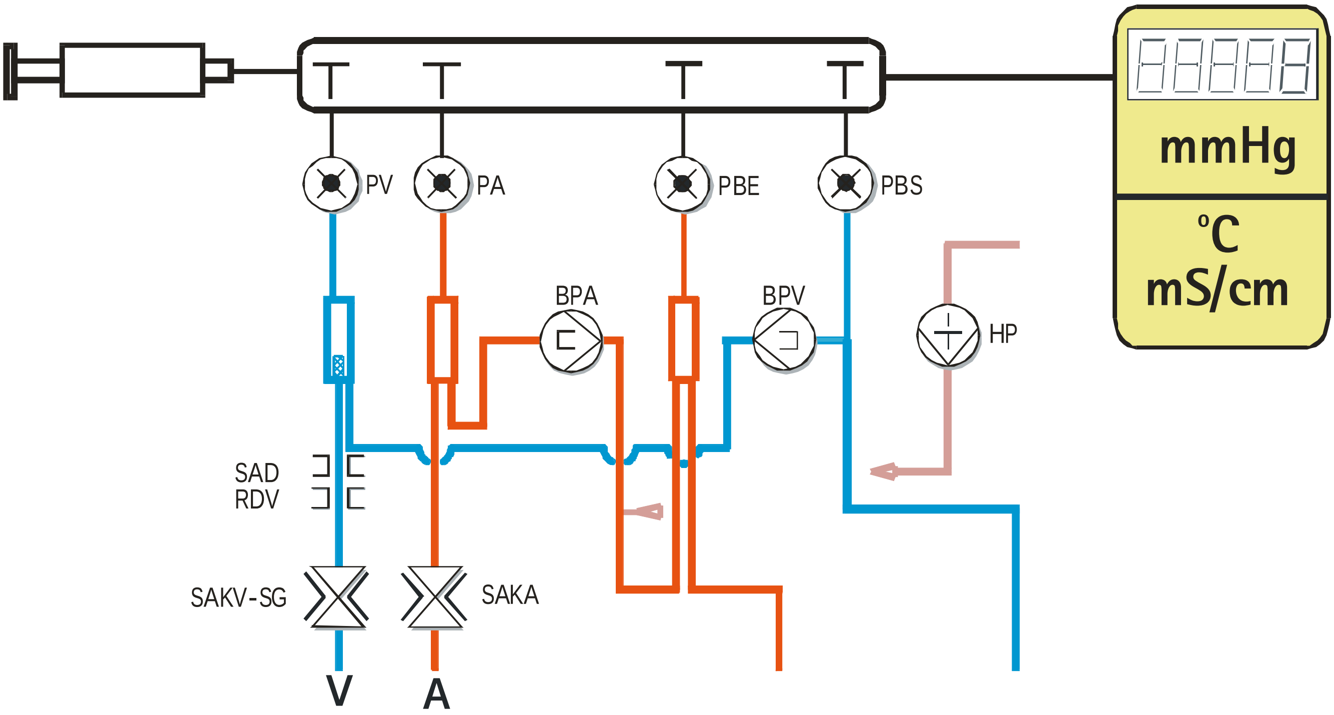
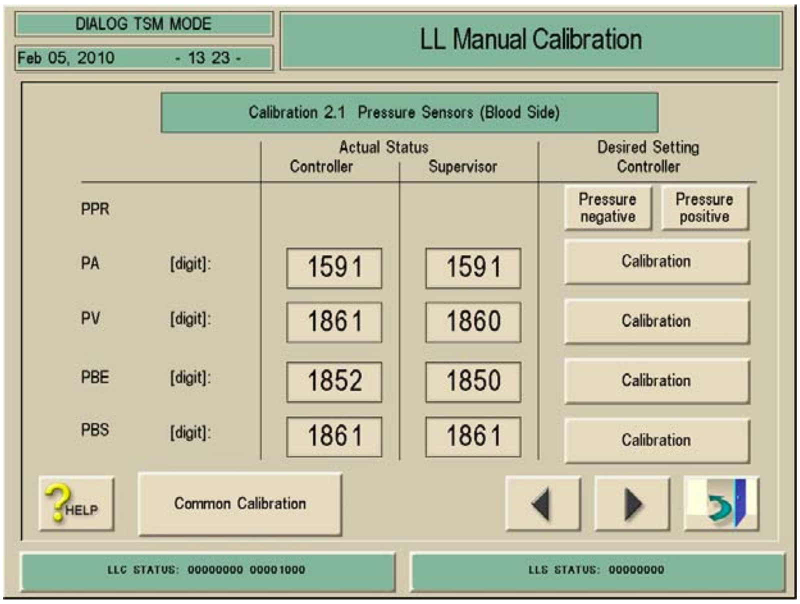


Fig. : Single Needle Version

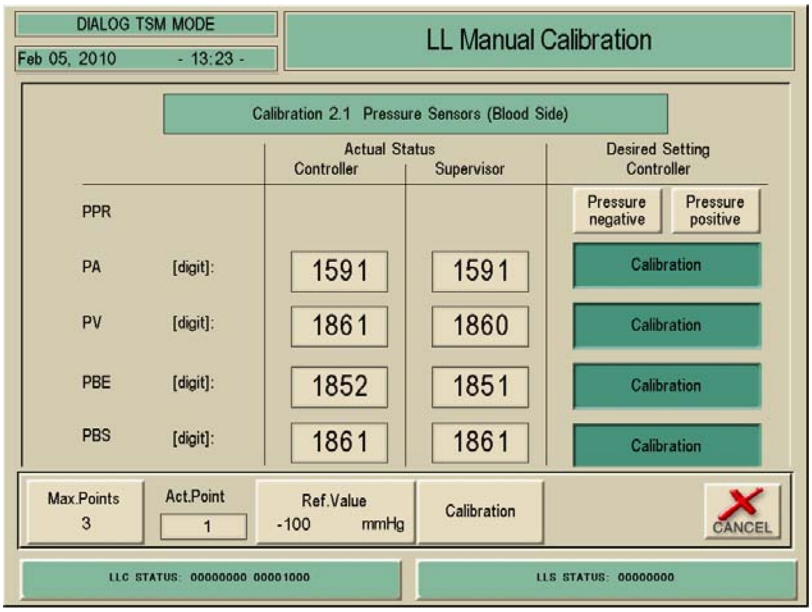


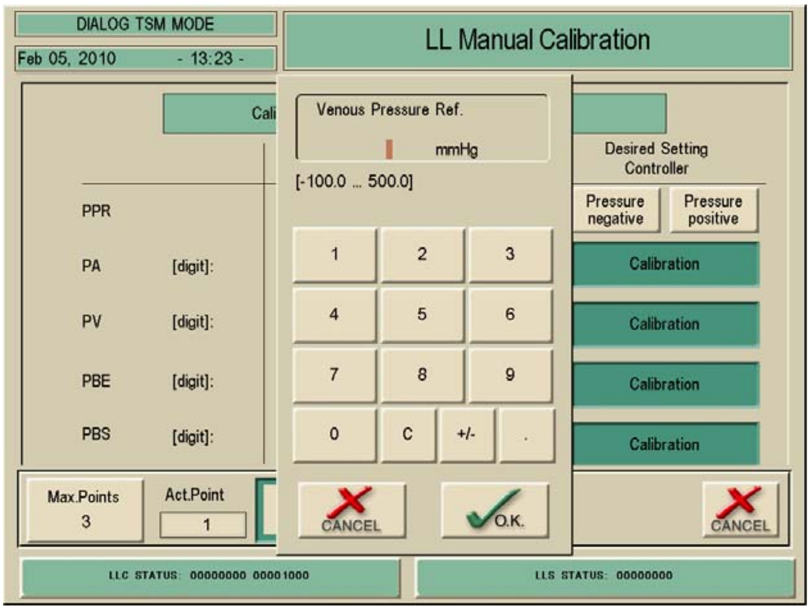
		Actual Status Controller	Actual Status Supervisor	Desired Setting Controller
PPR				Pressure negative Pressure positive
PA	[digit]:	1591	1591	Calibration
PV	[digit]:	1861	1860	Calibration
PBE	[digit]:	1852	1850	Calibration
PBS	[digit]:	1861	1861	Calibration

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the LL Manual Calibration menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Pressure Sensors Blood Side* menu by pressing on the line *Calibration 2.1 Pressure Sensors Blood Side*. The following menu is displayed.





A common calibration or a single calibration can be performed for the pressure sensors.

Common Calibration

Press the Common Calibration key for a combined calibration of the pressure sensors **PA**, **PV**, **PBE** and **PBS**. A calibration window is opened if the key is selected. The common calibration of all blood pressure sensors is recommended. The menu shows the *Common Calibration*.

Single Calibration

Press an individual Calibration key for a single calibration of the pressure sensor **PA, PV, PBE** or **PBS**. A calibration window is opened if the key is selected.

Press the Ref.Value -100 mmHg key to enter a reference value. A keypad is opened if the key is selected.

Pay attention to the negative or positive sign during the enter of the reference value.

- Pressure measurement instrument (e.g. HDM 99 or equivalent)
- Syringe
- Stopcock system with lines (770203A) or tubing/tubing clamp

3. Connect the pressure measurement instrument, syringe and stopcock system.
4. Connect the tubing to the respective pressure sensors **PA, PV**, **PBE** and/or **PBS** (option).
5. Press Common Calibration key.

PA/PV/PBE/PBS Calibration Point -100 mmHg

6. Build up a pressure of -100 mmHg (+10 mmHg) with a syringe and clamp the tube.
7. Press Ref.Value key.

   Wait until digits are stable.
8. Enter the stable value from the pressure measurement instrument as reference value.
9. Confirm with the Calibration key.

PA/PV/PBE/PBS Calibration Point 0 mmHg

10. Remove syringe for the 0 mmHg calibration (open to atmosphere).

    Wait until digits are stable.

11. Confirm the reference value 0 mmHg with the Calibration key.

PA/PV/PBE/PBS Calibration Point +500 mmHg

12. Connect syringe and build up a pressure of +500 mmHg (-10 mmHg) and clamp the tube.

13. Press Ref.Value key.

14. Enter the stable value from the pressure measurement instrument as reference value.

    Wait until digits are stable.

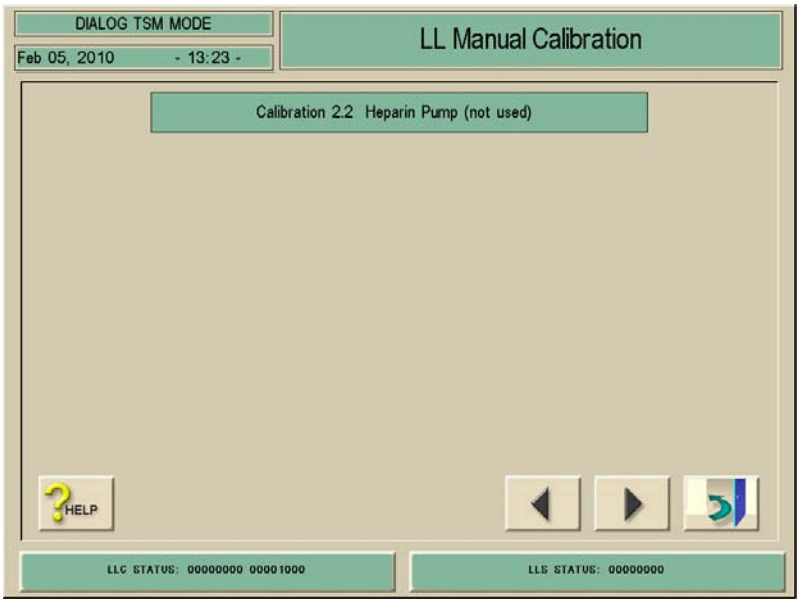
15. Confirm with the Calibration key.

    Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).

16. Confirm and store completed calibration with ✓O.K. key.

17. Remove pressure measurement instrument, syringe and tubing.

4.8.3.4 Heparin Pump



DIALOG TSM MODE

Feb 05, 2010 - 13:23 -

LL Manual Calibration

Calibration 2.2 Heparin Pump (not used)

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

Not applicable.

4.8.3.5 Calibration Degassing Pressure Sensor PE

Prior to Calibration

- Use calibrated manometer (or pressure measurement instrument)
- Position the manometer at the same level (see **A** in bottom figure) as the degassing pressure sensor **PE**
- Keep the extra tubings as short as possible for calibration
- Wait until Dialog has reached working temperature

You can calibrate the degassing pressure sensor **PE**. Build up the negative pressure in the degassing circuit with a syringe.

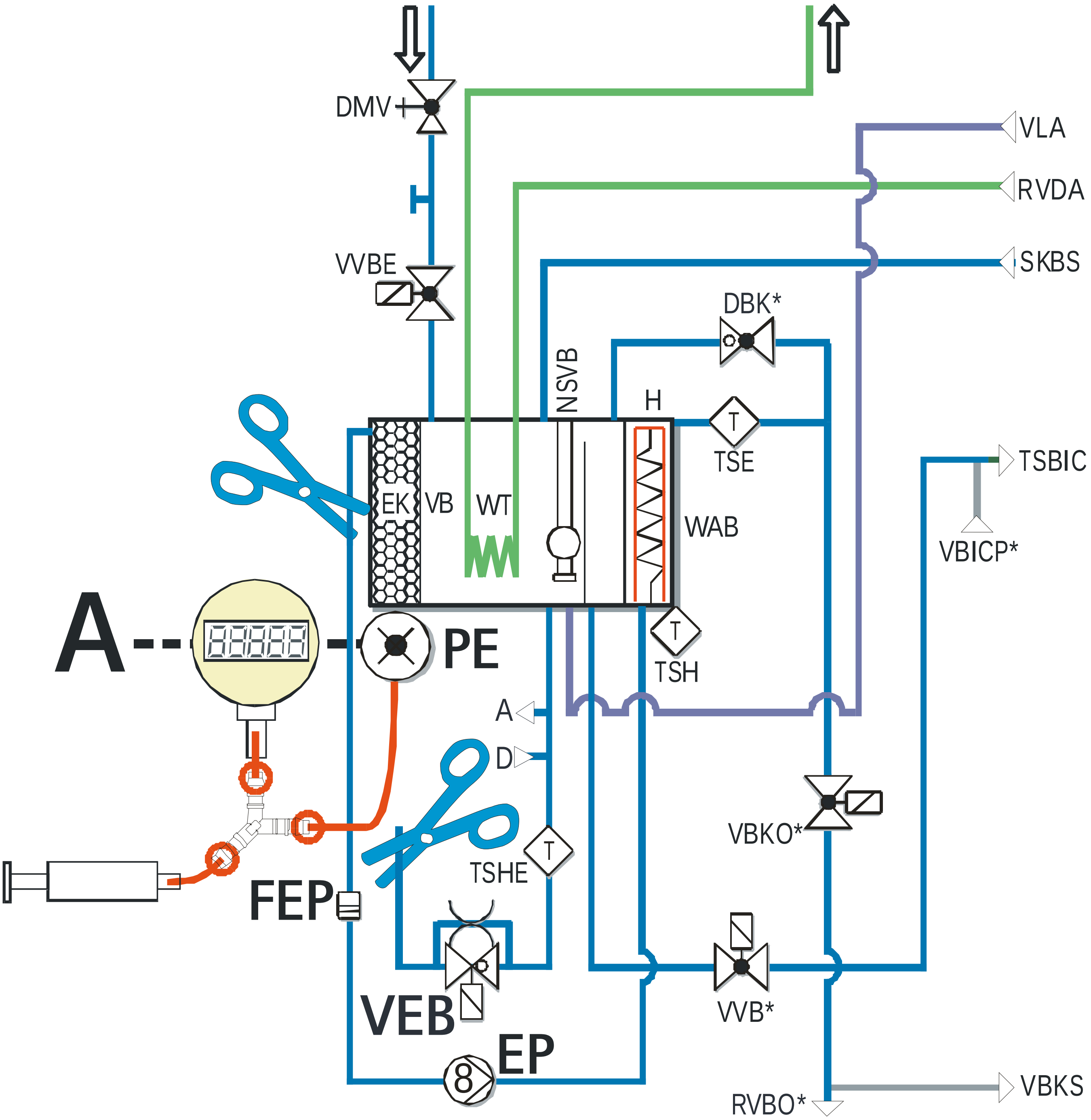


Fig.: Degassing Circuit and PE

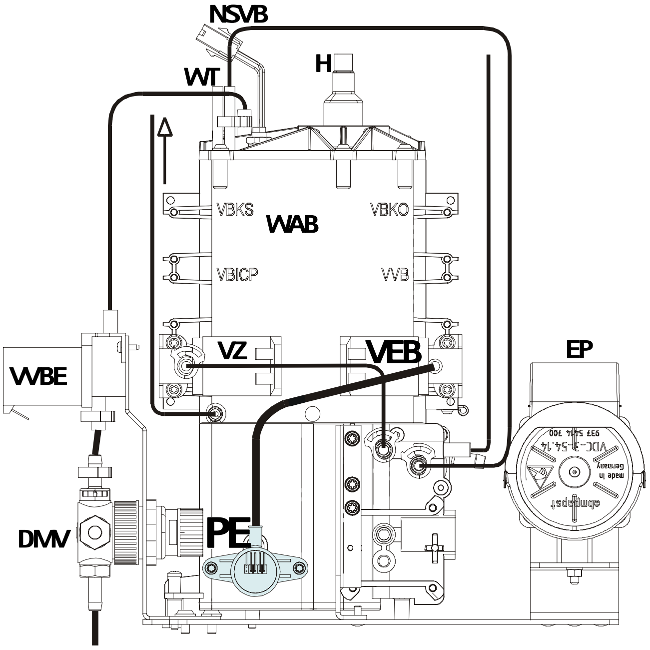


Fig.: Original Tubing Water Sub-Rack (rear view)

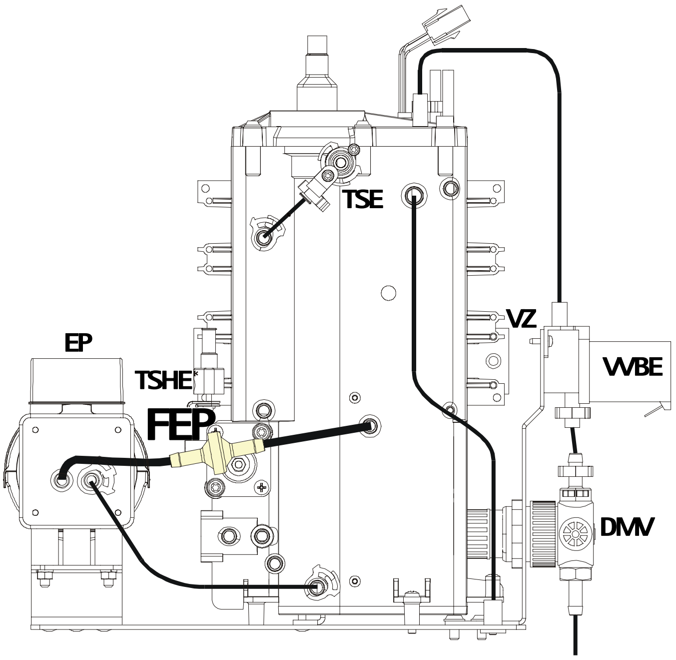


Fig.: Original Tubing Water Sub-Rack (front view)

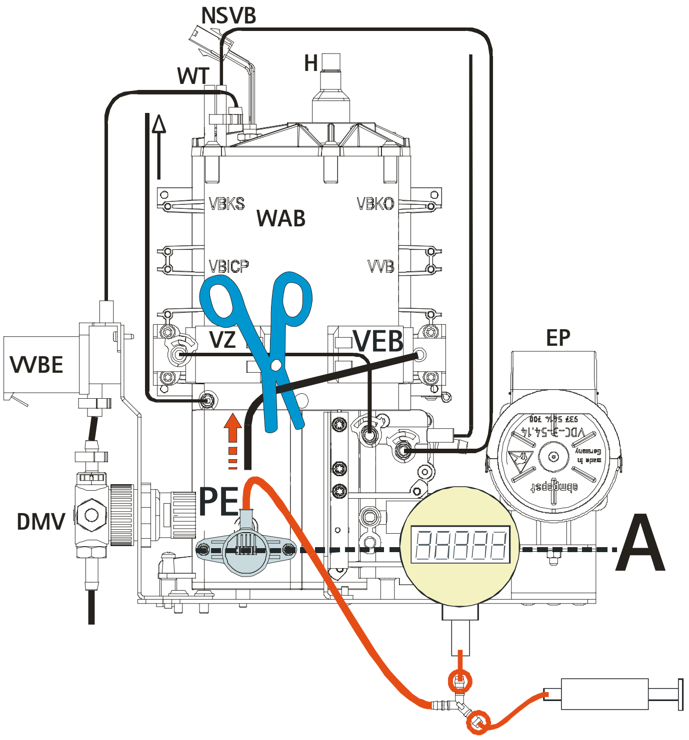


Fig.: Water Sub-Rack with Loop-In for Manometer at PE and Tubing Clamp at VEB (rear view)

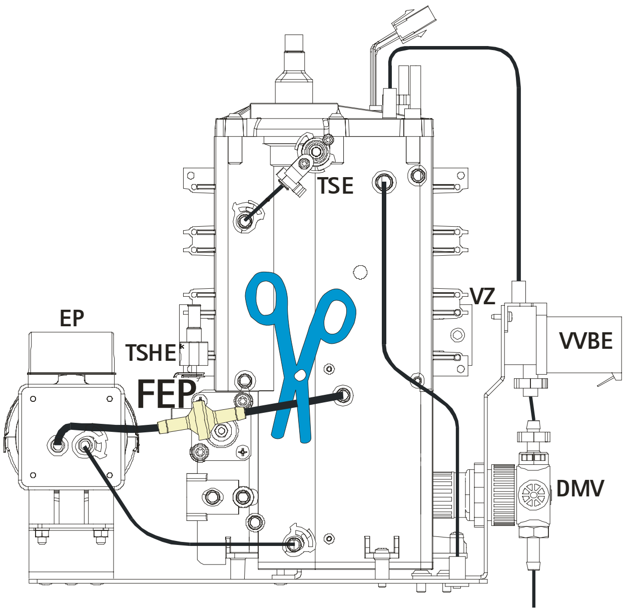


Fig.: Water Sub-Rack with Tubing Clamp between FEP and EP (front view)

The calibration for the degassing pressure sensor **PE** is performed with a two point calibration (-400 mmHg/-533 mbar and –100 mmHg/-133 mbar).

The calibration can be performed either with a manometer or a pressure measurement instrument. The calibration is described with a manometer. The measurement unit *mmHg* or *mbar* can be selected for calibration.

Conversion Factor mmHg to mbar

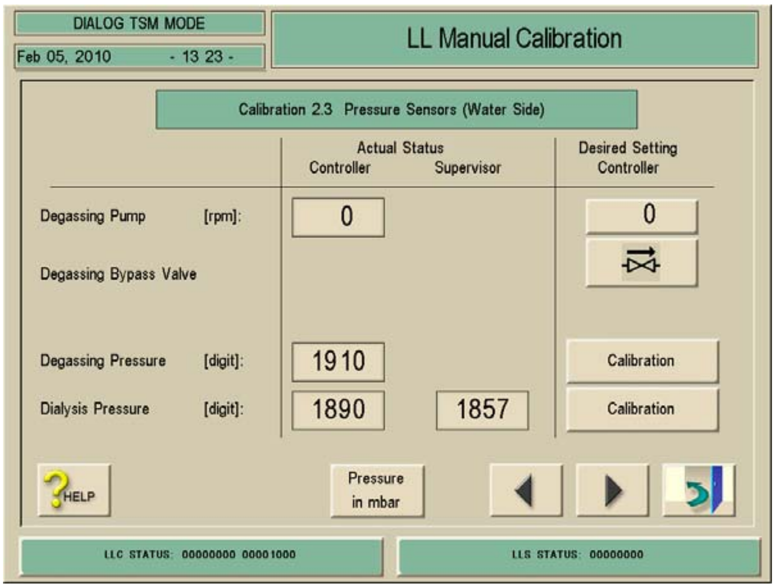
Conversion Factor = 1.3332

Example:

-100 mmHg	approx. –130 mbar
–400 mmHg	approx. –530 mbar

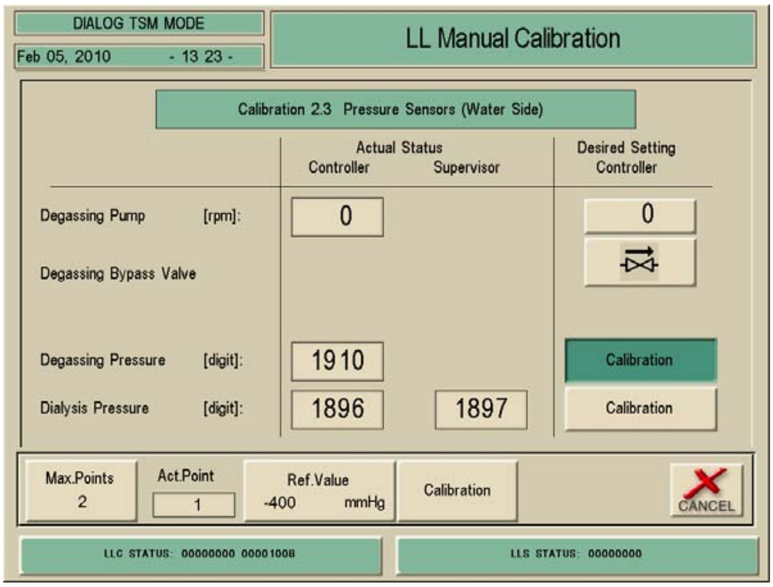
- Manometer or pressure measurement instrument
- Syringe
- Y piece
- Tubing and tubing clamps

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Pressure Sensors (Water Side)* menu by pressing on the line *Calibration 2.3 Pressure Sensors (Water Side)*. The following menu is displayed.



DIALOG TSM MODE
Feb 05, 2010 - 13 23 -
LL Manual Calibration
Calibration 2.3 Pressure Sensors (Water Side)

	Actual Status Controller	Actual Status Supervisor	Desired Setting Controller
Degassing Pump [rpm]:	0		0
Degassing Bypass Valve			
Degassing Pressure [digit]:	1910		Calibration
Dialysis Pressure [digit]:	1890	1857	Calibration



DIALOG TSM MODE
Feb 05, 2010 - 13 23 -
LL Manual Calibration
Calibration 2.3 Pressure Sensors (Water Side)

	Actual Status Controller	Actual Status Supervisor	Desired Setting Controller
Degassing Pump [rpm]:	0		0
Degassing Bypass Valve			
Degassing Pressure [digit]:	1910		Calibration
Dialysis Pressure [digit]:	1896	1897	Calibration

Max.Points 2
Act.Point 1
Ref.Value -400 mmHg

Pay attention to the negative sign during the enter of the reference value.

Prevent offset during calibration
Pay attention that there is no fluid in the tubing to the manometer.

3. Clamp tubing at filter degassing pump **FEP** inlet.
4. Clamp tubing between degassing bypass valve **VEB** and degassing pressure sensor **PE** and pull off tubing from the degassing pressure sensor **PE**.
5. Connect a manometer and a syringe to the **PE** sensor, using a Y-piece and extra tubing.

   If required.
6. You can set the measurement unit to mbar with the Pressure in mbar key if you want to perform a calibration in mbar.

PE Calibration Point –400 mmHg
–530 mbar

7. Press *Degassing Pressure PE* Calibration key.
8. Use a syringe to create a negative pressure of (reading on manometer display):
   - -400 mmHg ±10 mmHg
   - -530 mbar ±13 mbar
9. Press Ref.Value key.
10. Enter the stable value from the manometer as reference value.

    Wait until digits are stable.
11. Confirm with Calibration key.

PE Calibration Point –100 mmHg
–130 mbar

12. Use syringe and create a negative pressure of (reading on manometer display):
    - -100 mmHg ±10 mmHg
    - -130 mbar ±13 mbar
13. Press Ref.Value key.
14. Enter the stable value from the manometer as reference value.

    Wait until digits are stable.
15. Confirm with Calibration key.
16. Confirm and store complete calibration procedure with ✓O.K. key.

    Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).
17. Remove calibration devices.
18. Reconnect tubings.
19. Check function in TSM menu *Test 1.16 Pressure Water Part*:
    - Open degassing bypass valve **VEB** and set speed of degassing pump **EP** to 1,500 rpm
    - **PE** should show a of approx. < -35 mmHg/-50 mbar
    - Close **VEB** and increase speed to 2,100 rpm
    - **PE** should show a value of approx. < -500 mmHg/-670 mbar

4.8.3.5.1 Calibration Degassing Pressure Sensor PE for Machines at High Altitudes of >1,000 m

For calibration point -400 mmHg/-530 mbar
If the Dialog machine is used at high altitudes (>1,000 m above sea level), an offset of +75 mmHg/+100 mbar per 1000 m must be used for the calibration of the degassing pressure sensor **PE**.

Measurement unit mmHg
1,000 m altitude: –325 mmHg (–400 mmHg + 75 mmHg offset = –325 mmHg)
2,000 m altitude: –250 mmHg (–400 mmHg + 150 mmHg offset = –250 mmHg)
3,000 m altitude: –175 mmHg (–400 mmHg + 225 mmHg offset = –175 mmHg)

Measurement unit mbar
1,000 m altitude: –430 mbar (–530 mbar + 100 mbar offset = –430 mbar)
2,000 m altitude: –330 mbar (–530 mbar + 200 mbar offset = –330 mbar)
3,000 m altitude: –230 mbar (–530 mbar + 300 mbar offset = –230 mbar)

Example for Calibration at 1,000 m Altitude

1. Clamp tubing at filter degassing pump **FEP**.
2. Clamp tubing between degassing bypass valve **VEB** and degassing pressure sensor **PE** and pull off tubing from the degassing pressure sensor **PE**.
3. Connect a manometer and a syringe to the **PE** sensor, using a Y-piece and extra tubing.

PE Calibration Point –400 mmHg
–530 mbar

4. Press the *Degassing Pressure PE* Calibration key.
5. Use syringe and create a negative pressure, e.g. at 1,000 m altitude:
   - –325 mmHg ±10 mmHg (-400 mmHg plus offset +75 mmHg/1,000 m)
   - -430 mbar ±13 mbar (-530 mbar plus offset +100 mbar/1,000 m)
6. Press Ref.Value key.
7. Enter the stable reference value:
   - –325 mmHg ±10 mmHg (-400 mmHg plus offset +75 mmHg/1,000 m)
   - –430 mbar ±13 mbar (-530 mbar plus offset +100 mbar/1,000 m)

   Wait until digits are stable.
8. Confirm with Calibration key.

PE Calibration Point 0 mmHg
0 mbar

11. Remove syringe (0 mmHg/0 mbar).
12. Press Ref.Value key.
13. Enter 0 mmHg/0 mbar.

    Wait until digits are stable.
14. Confirm with Calibration key.
15. Confirm and store complete calibration procedure with ✓O.K. key.

    Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).
16. Remove calibration devices.
17. Reconnect tubings.

4.8.3.6 Calibration Dialysate Outlet Pressure Sensor PDA

Prior to Calibration

- Use calibrated manometer (or pressure measurement instrument)
- Position the manometer at the same level as the dialysate outlet pressure sensor **PDA** (see figure, **A**)
- Keep the extra tubings as short as possible for calibration
- Wait until Dialog has reached working temperature

You can calibrate the dialysate outlet pressure sensor **PDA**. Build up the negative or positive pressure in the dialysate circuit with a syringe. Pay attention to the position of **VDA**, it must be closed or the tubing must be clamped manually.

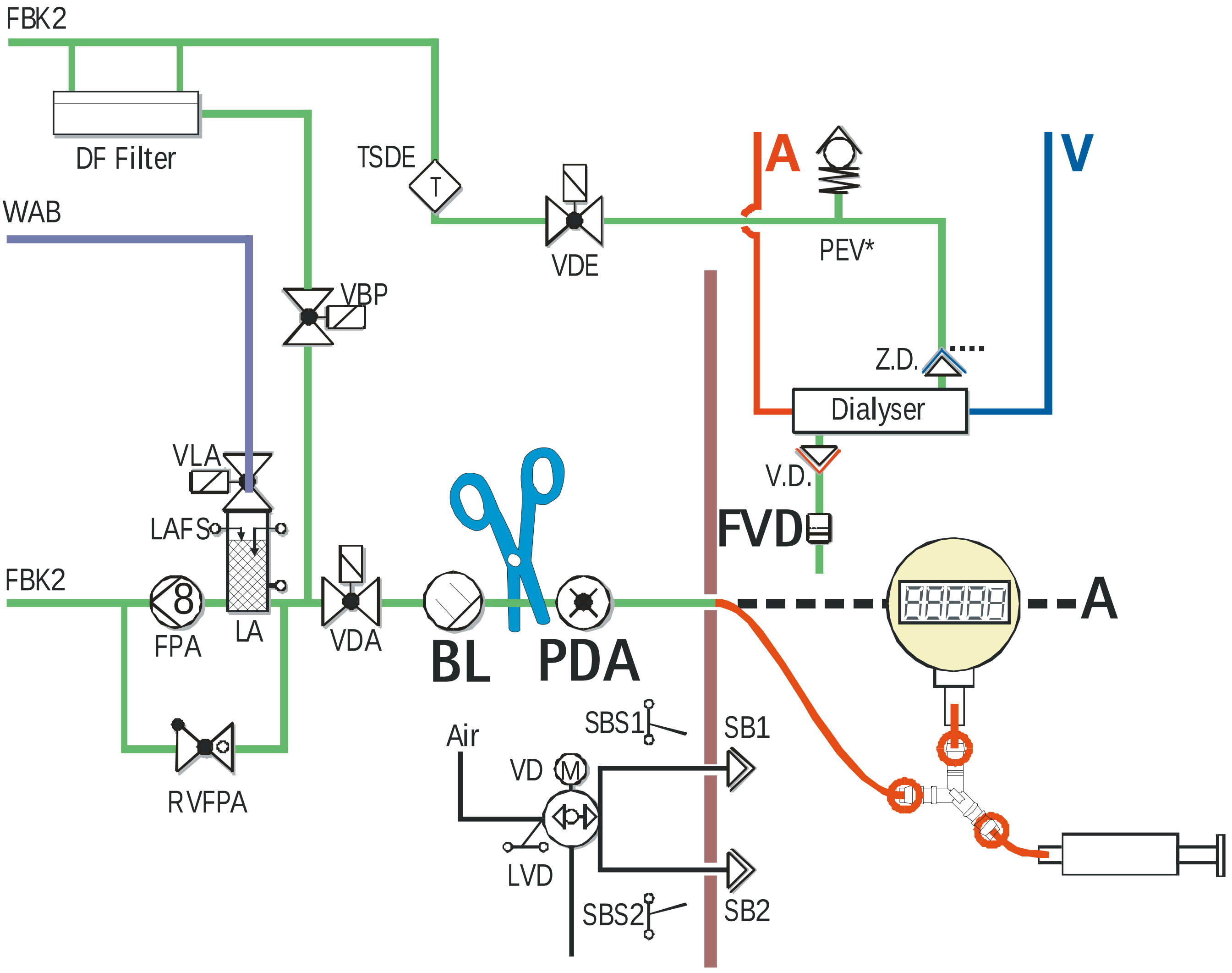


Fig.: Dialysate Circuit and PDA

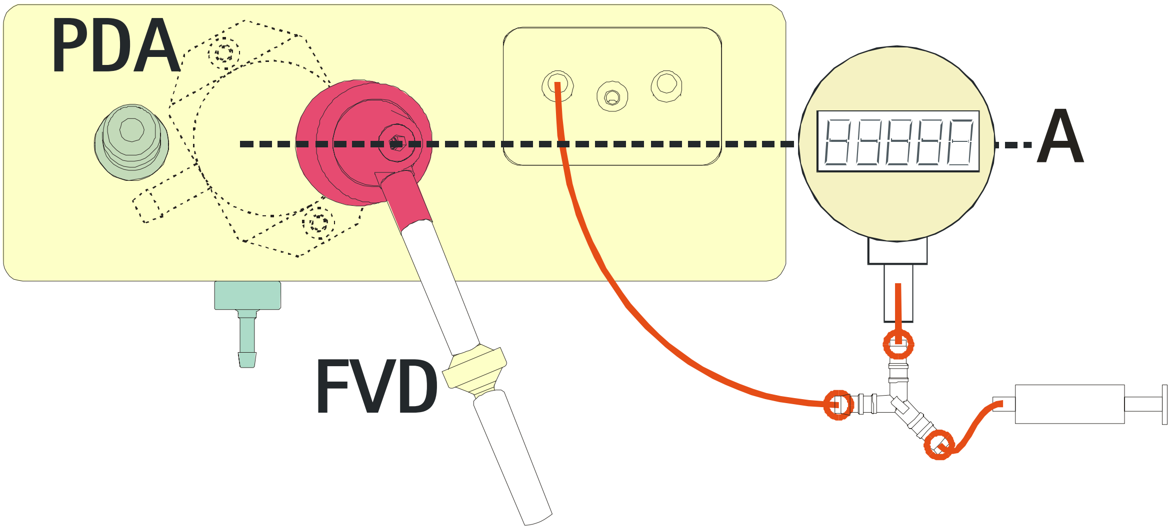


Fig.: Rinsing Bridge with Loop-In for Manometer/Syringe

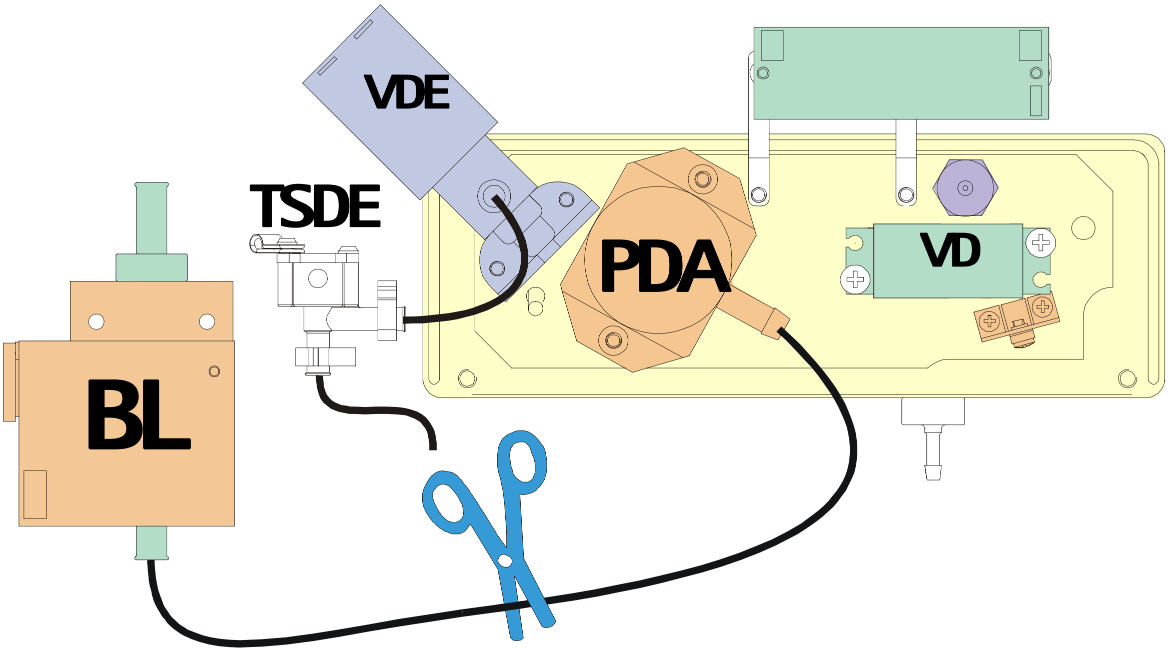


Fig.: Rinsing Bridge with Tubing Clamp between BL and PDA

Pay attention that there is no fluid in the tubing to the manometer. Ensure that the manometer and connection tubing are at the same level as the dialysate outlet pressure sensor **PDA**.

The calibration for the dialysate outlet pressure sensor **PDA** is performed with a three point calibration (-400 mmHg/-533 mbar, 0 mmHg/0 mbar and +400 mmHg/+533 mbar).

The calibration can be performed either with a manometer or a pressure measurement instrument. The calibration is described with a manometer. A measurement unit mmHg or mbar can be selected for calibration.

Conversion Factor mmHg to mbar
Conversion Factor = 1.3332

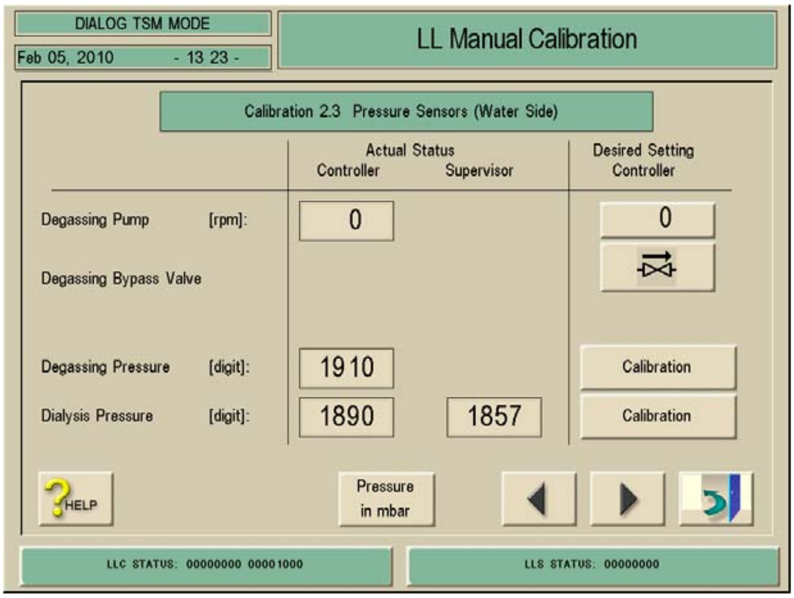
Example:

–400 mmHg	approx. –530 mbar
0 mmHg	0 mbar
+400 mmHg	approx. +530 mbar

- Manometer or pressure measurement instrument
- Syringe
- Y piece
- Tubing and tubing clamp

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.

2. Activate the *Pressure Sensors Water Side* menu by pressing on the line *Calibration 2.3 Pressure Sensors Water Side*. The following menu is displayed.



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Degassing Pump [rpm]: 0 0

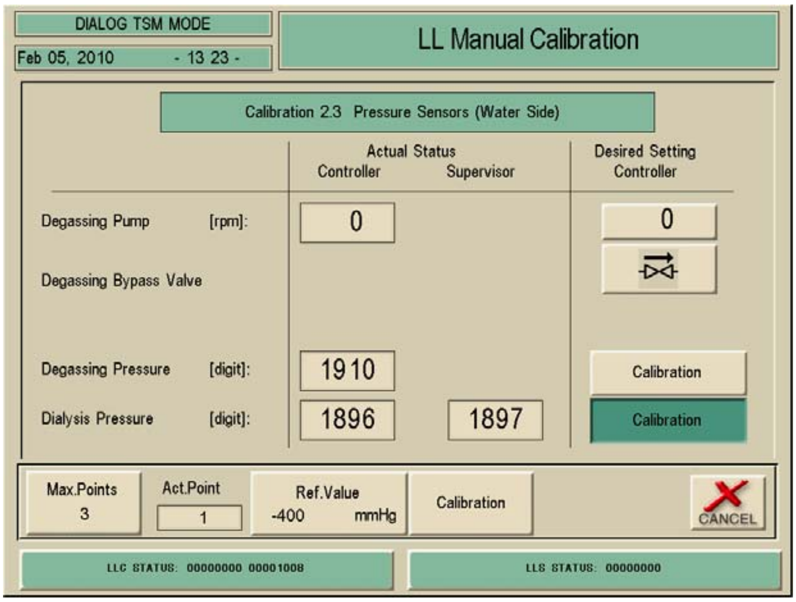
Degassing Bypass Valve

Degassing Pressure [digit]: 1910

Dialysis Pressure [digit]: 1890 1857

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000



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Degassing Pump [rpm]: 0 0

Degassing Bypass Valve

Degassing Pressure [digit]: 1910

Dialysis Pressure [digit]: 1896 1897

Max.Points 3

Act.Point 1

Ref.Value -400 mmHg

LLC STATUS: 00000000 00001008

LLS STATUS: 00000000

Pay attention to the negative or positive sign during the enter of the reference value.

Prevent offset during calibration
Pay attention that there is no fluid in the tubing to the manometer.

3. Disconnect tubing (to filter **FVD**) from rinsing bridge.
4. Connect manometer and a syringe to the left tubing connector outlet (red dialyser coupling) on rinsing bridge.
5. Clamp tubing between blood leak detector **BL** and dialysate outlet pressure sensor **PDA**.
6. Set measurement unit to mbar with the Pressure in mbar key if you want to perform a calibration in mbar.

PDA Calibration Point –400 mmHg
–530 mbar

7. Press *Dialysis Pressure PDA* Calibration key.
8. Press Max.Points 2 key and enter a third calibration point.
9. Use a syringe to create a negative pressure of (reading on manometer display):
   - -400 mmHg ±10 mmHg
   - -530 mbar ±13 mbar
10. Press Ref.Value key.
11. Enter the stable value from the manometer as reference value.

    Wait until digits are stable.
12. Confirm with the Calibration key.

PDA Calibration Point 0 mmHg
0 mbar

13. Open syringe to atmosphere for 0 mmHg/0 mbar calibration.
14. Press Ref.Value key.
15. Enter the value "0" from the manometer as reference value.

    Wait until digits are stable.
16. Confirm with the Calibration key.

PDA Calibration Point +400 mmHg
+ 530 mbar

17. Use the syringe to create a positive pressure of (reading on manometer display):
    - +400 mmHg ±10 mmHg
    - +530 mbar ±13 mbar
18. Press Ref.Value key.
19. Enter the stable value from the manometer as reference value.

    Wait until digits are stable.
20. Confirm with Calibration key.
21. Confirm and store complete calibration procedure with ✓ O.K. key.

    Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).
22. Remove calibration devices.
23. Reconnect tubings.

4.8.3.7 Calibration Degassing Temperature Sensor TSE/ Heater Inlet Temperature Sensor TSHE

Prior to Calibration

- Position the heater inlet temperature sensor **TSHE** next to **TSE** (see figure redirect heater inlet temperature sensor **TSHE**, next page)
- Use calibrated measurement instrument
- Wait until Dialog has reached working temperature

The degassing temperature **TSE** and the heater inlet temperature sensor **TSHE** are calibrated together. The following calibration points are used:

TSE / TSHE: 30 °C, 40 °C, 85 °C

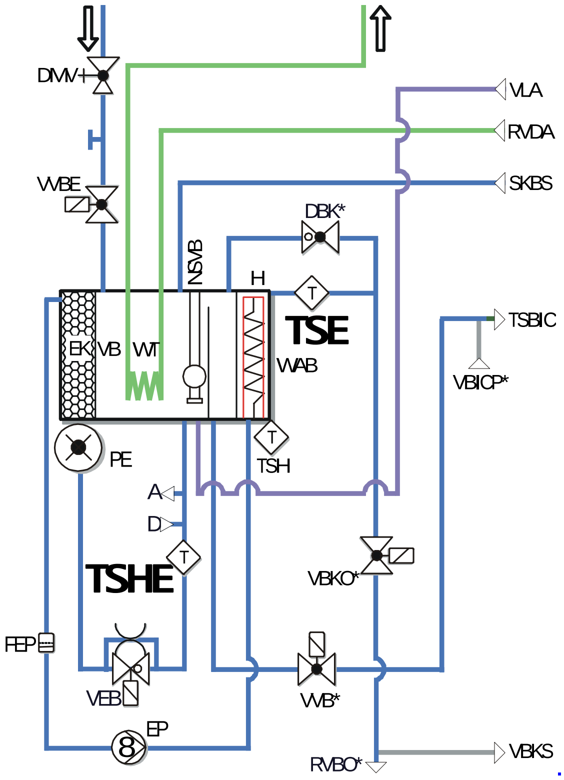


Fig.: Temperature Circulation

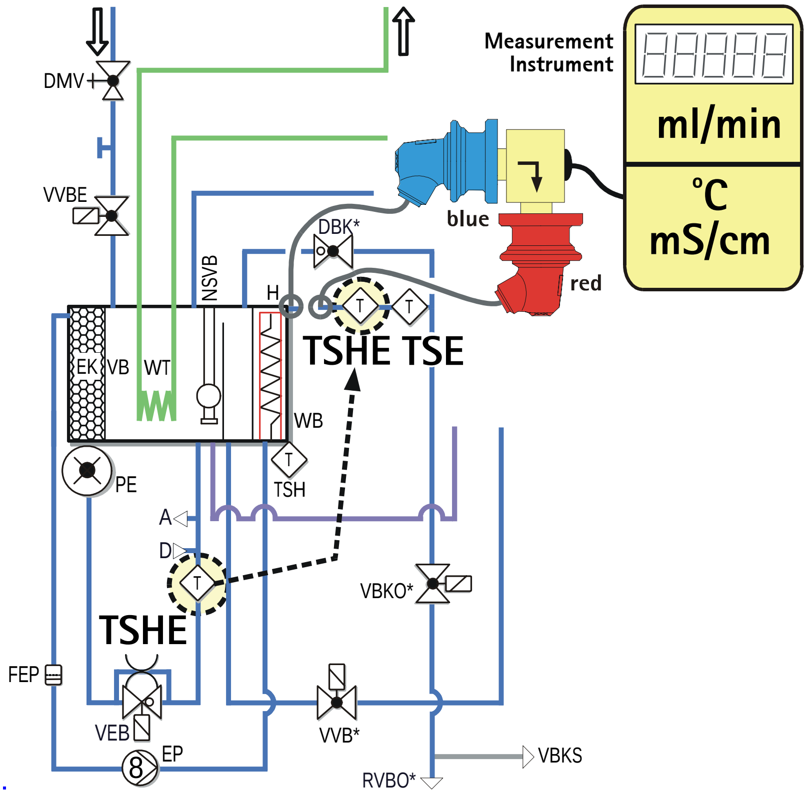


Fig.: Loop-In Point and TSHE in Line with TSE for Calibration

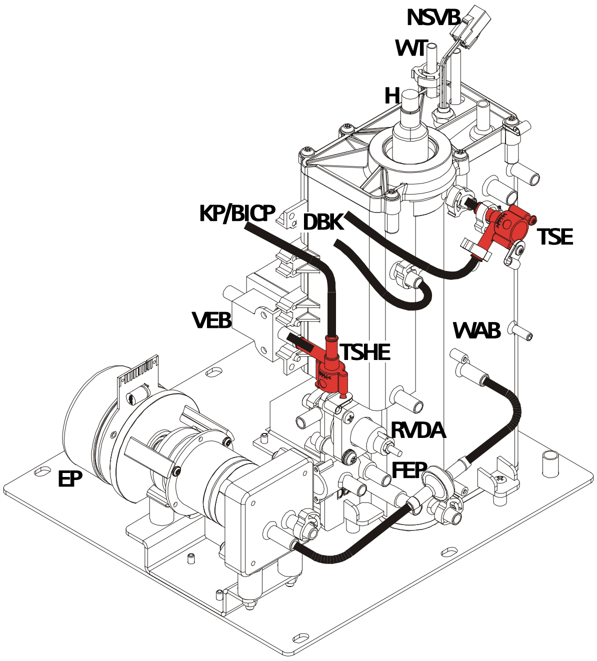
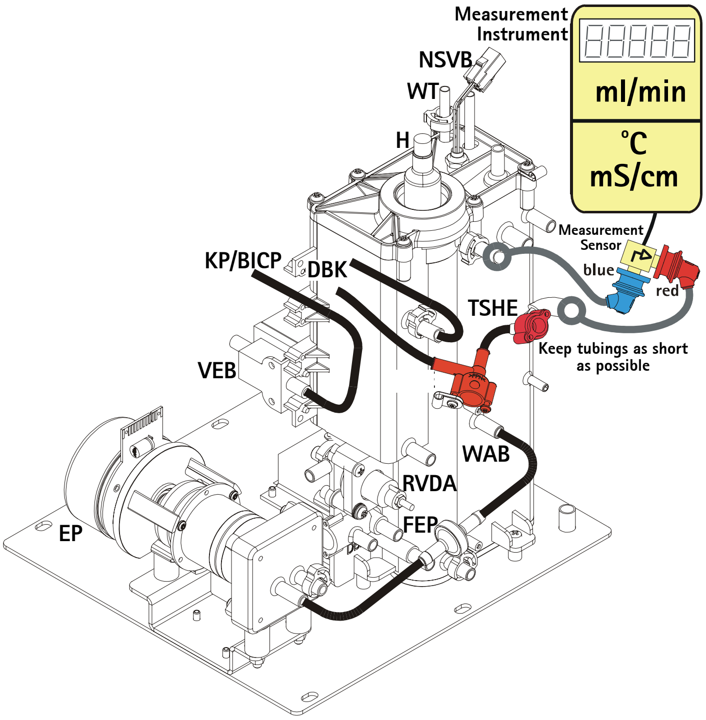


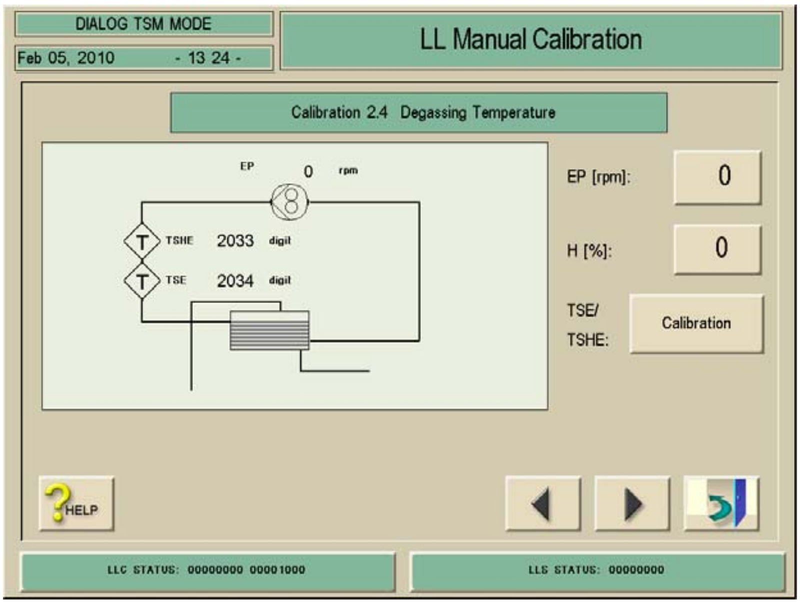
Fig.: Original Tubing Water Sub-Rack for TSE/TSHE



Keep tubings as short as possible

Fig.: Water Sub-Rack with TSHE in Line with TSE for Calibration

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Degassing Temperature* menu by pressing on the line *Calibration 2.4 Degassing Temperature.* The following menu is displayed.


DIALOG TSM MODE

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LL Manual Calibration

Calibration 2.4 Degassing Temperature

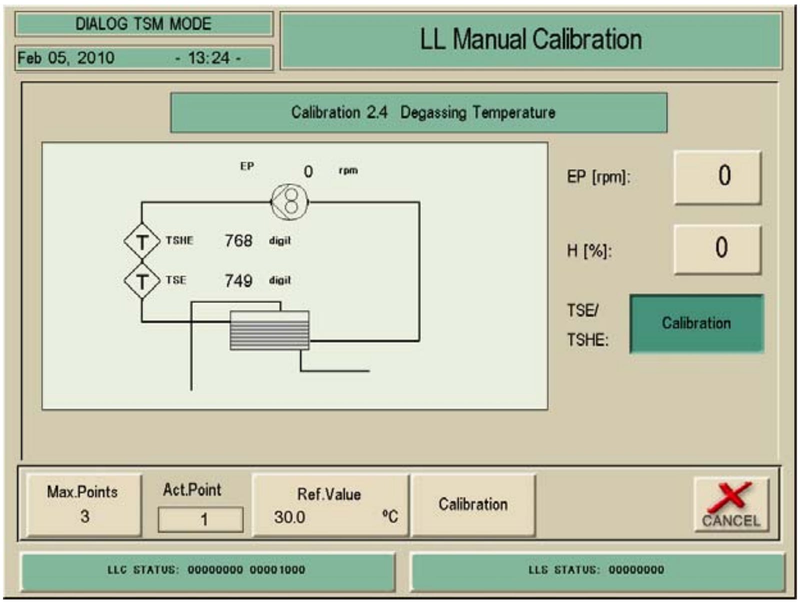
EP [rpm]: 0

H [%]: 0

TSE/TSHE: Calibration

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000


DIALOG TSM MODE

Feb 05, 2010 - 13:24 -

LL Manual Calibration

Calibration 2.4 Degassing Temperature

EP [rpm]: 0

H [%]: 0

TSE/TSHE: Calibration

Max.Points 3

Act.Point 1

Ref.Value 30.0 °C

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

- Temperature measurement instrument (e.g. HDM 99 or equivalent)
- Adapter set (coupling/tubing/dialyser couplings)

3. Position the heater inlet temperature sensor **TSHE** (on the water sub-rack) next to **TSE** (see previous page).
4. Connect the adapter set between the heater inlet temperature sensor **TSHE** and water block **WAB**.

   Note: Pay attention to correct flow direction of temperature sensor **TSHE**.
5. Connect temperature measurement instrument to adapter set.
6. Set degassing pump **EP** to 1800 rpm.
7. Press *TSE/TSHE* Calibration key.

TSE/TSHE Calibration Point 30 °C

8. Increase heater power (in %) slowly, until a stable temperature value of 30 °C (±2 °C) is displayed at the temperature measurement instrument.

   Wait until temperature is stable, i.e. 0.1 °C for at least 10 s.
9. Press Ref.Value key.
10. Enter the stable value from the temperature measurement instrument as reference value.

Wait until digits are stable.

11. Confirm with the Calibration key.

TSE/TSHE Calibration Point 40 °C

12. Increase heater power (in %) slowly, until a stable temperature value of 40 °C (±2 °C) is displayed at the temperature measurement instrument.

    Wait until temperature is stable, i.e. 0.1 °C for at least 10 s.

13. Press Ref.Value key.
14. Enter the stable value from the measurement instrument as reference value.
15. Confirm with the Calibration key.

TSE/TSHE Calibration Point 85 °C

16. Slowly increase heater power (in %), until a stable temperature value of 85 °C (±2 °C) is displayed at the temperature measurement instrument.

    Wait until temperature is stable, i.e. 0.1 °C for at least 10 s.

17. Press Ref.Value key.
18. Enter the stable value from the temperature measurement instrument.
19. Confirm with the Calibration key.
20. Confirm and store complete calibration procedure with ✓O.K. key.

    Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).

21. Set heater power to 0% and rinse briefly with flow pump **FPE** to cool down the water (menu 1.9, in *Low Level Manual Test*) and to prevent scalding.
22. Stop degassing pump **EP** and flow pump **FPE**, and disconnect adapter set.
23. Reassemble the heater inlet temperature sensor **TSHE** to the original position (see previous page).

    Note: Pay attention to correct flow direction of temperature sensor **TSHE**.

4.8.3.8 Calibration Temperature Sensors TSBIC/TSD/TSD-S and TSDE

The conductivity sensors BICLF and ENDLF/ENDLF-S have to be calibrated after every calibration of the temperature sensors TSBIC/TSD/TSDS/TSDE (in menu (*LL Manual Calibration, Calibration 2.6 Conductivity*).

Temperature Measurement Instrument (e.g. HDM 99 or equivalent)

Technical Data:

- Temperature accuracy: ≤ ±0.2 °C
- Temperature resolution minimum 0.1 °C
- Use calibrated temperature measurement instrument

Prior to Calibration

- Wait until Dialog has reached working temperature

The following calibration points are used:

- Calibration points **TSBIC/TSD/TSD-S/TSDE**: 30 °C, 38 °C, 50 °C
- Temperature oscillation range: ± 1 digit/0.1 °C (displayed value of Dialog) over 10 s, i.e. the temperature should be constant over a time period of 10 s to be considered stable.

Measurement of the Temperature and the Conductivity

The measurement sensor for temperature and conductivity of the measurement instrument is connected between **FPE** and the inlet to the balance chamber (see figure).

Measurement of the Flow

Connect the dialyser couplings to a flow sensor.

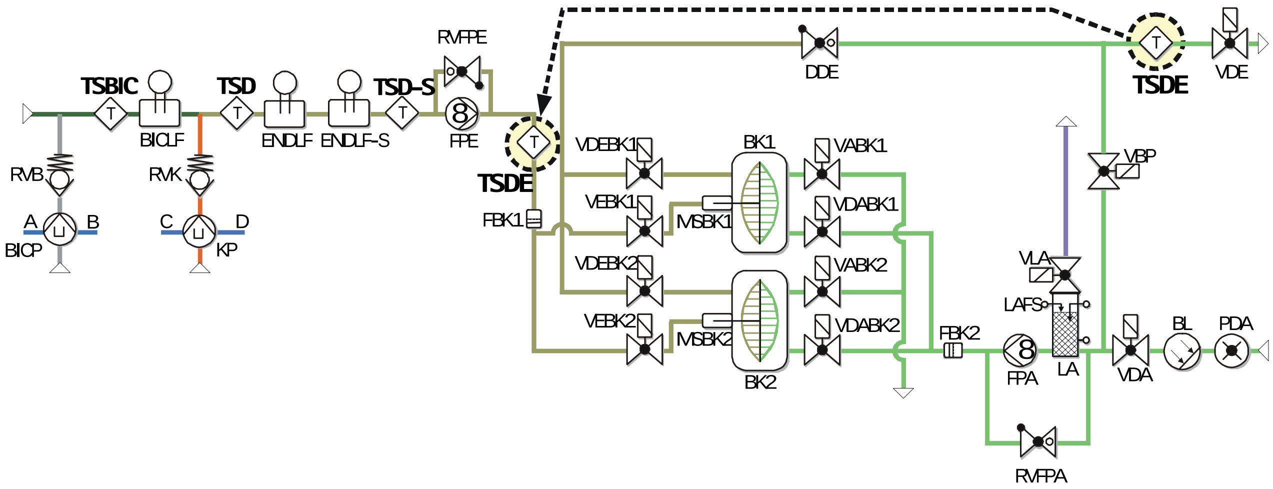


Fig.: Assemble TSDE from Rinsing Bridge to FBK1 on UF Sub-Rack

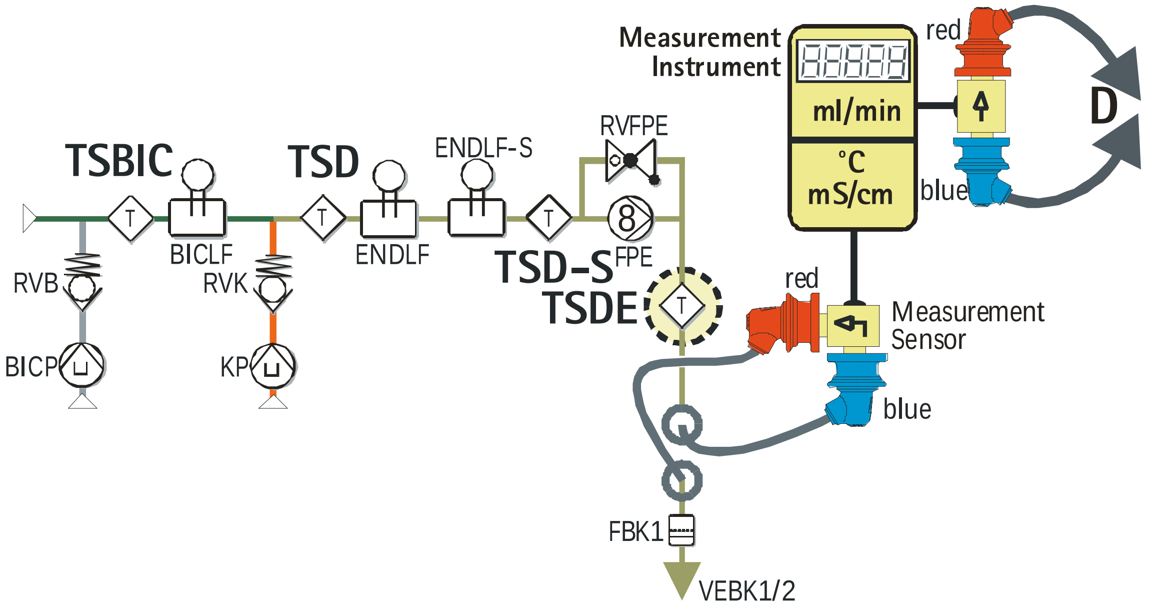


Fig.: Dialysate Preparation with Loop-In Point for TSBIC/TSD/TSD-S and TSDE Calibration

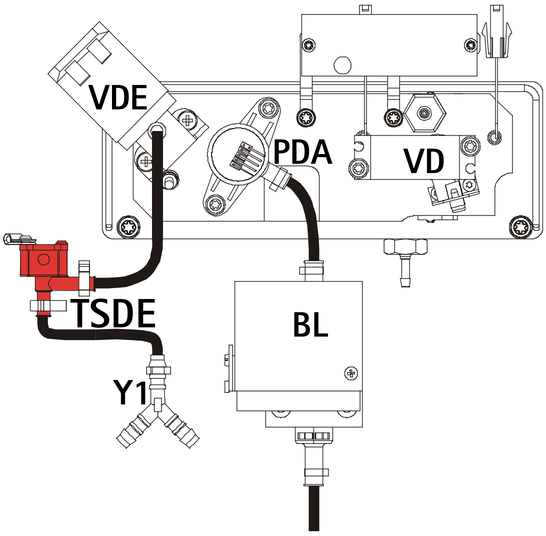


Fig.: Original Tubing Rinsing Bridge with TSDE

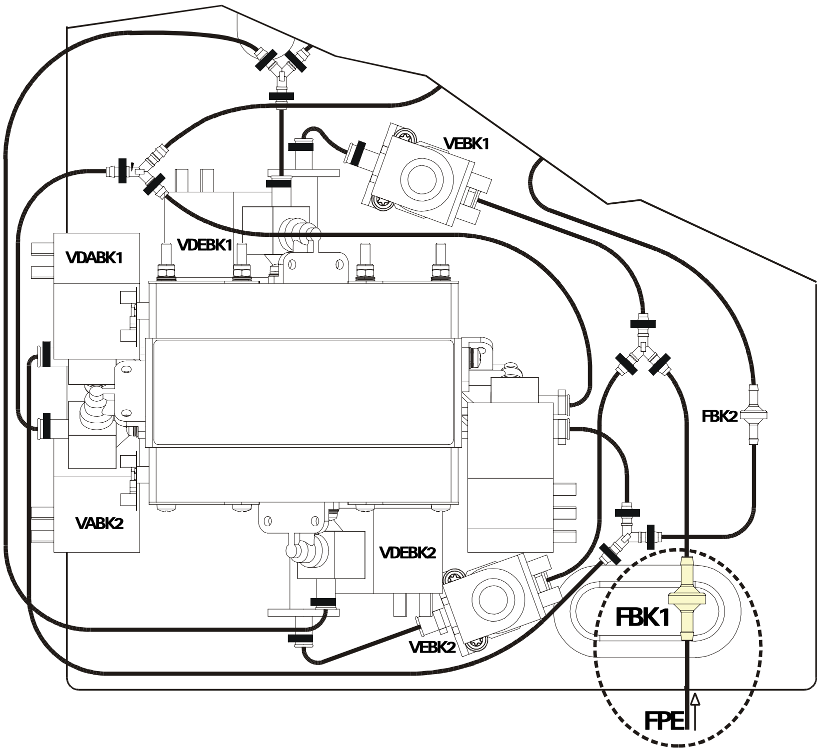


Fig.: Original Tubing UF Sub-Rack with FBK1

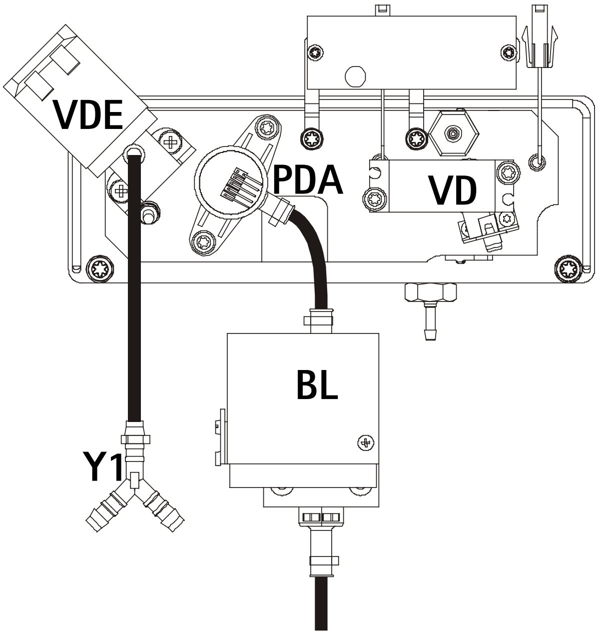


Fig.: Tubing Rinsing Bridge with Removed TSDE

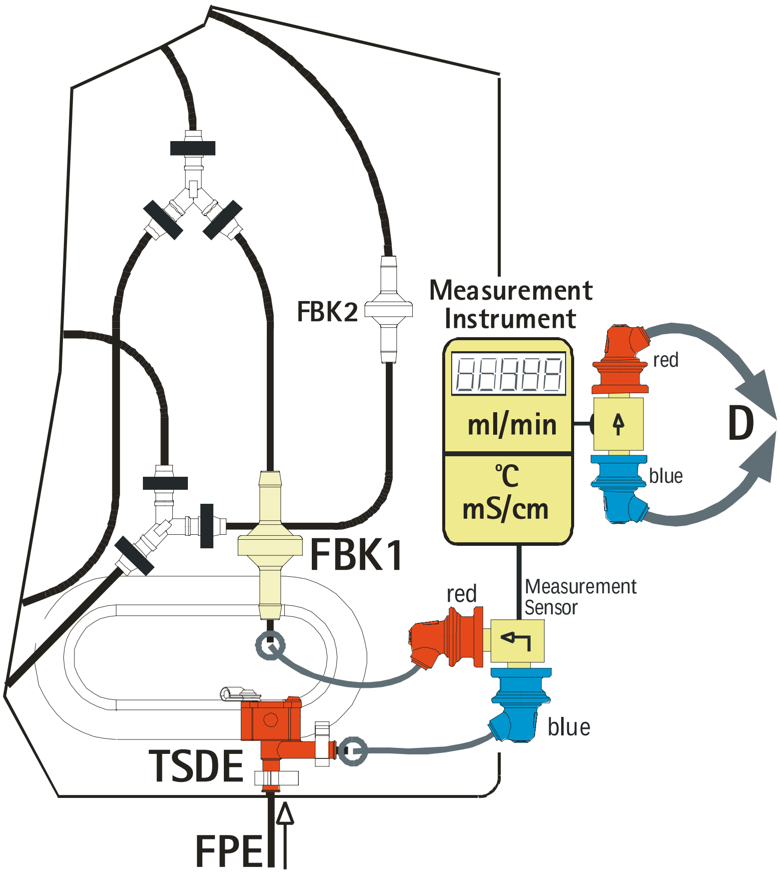
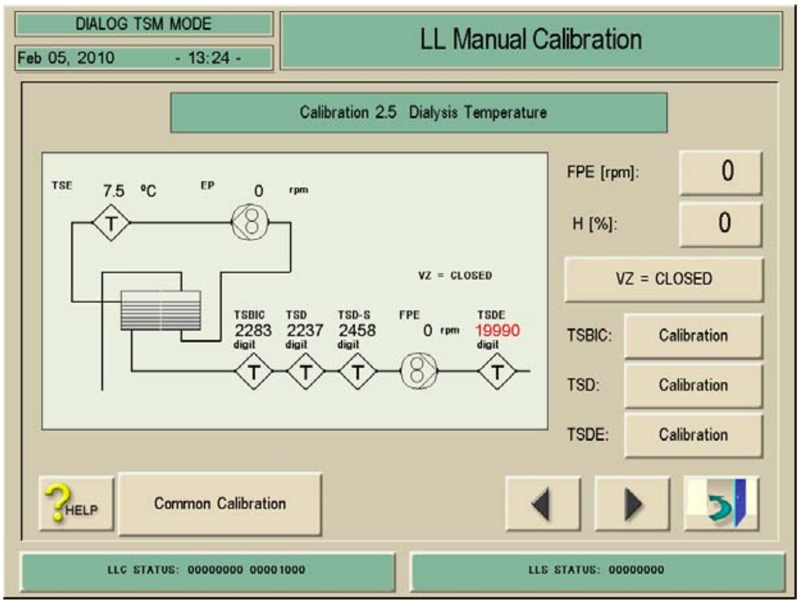
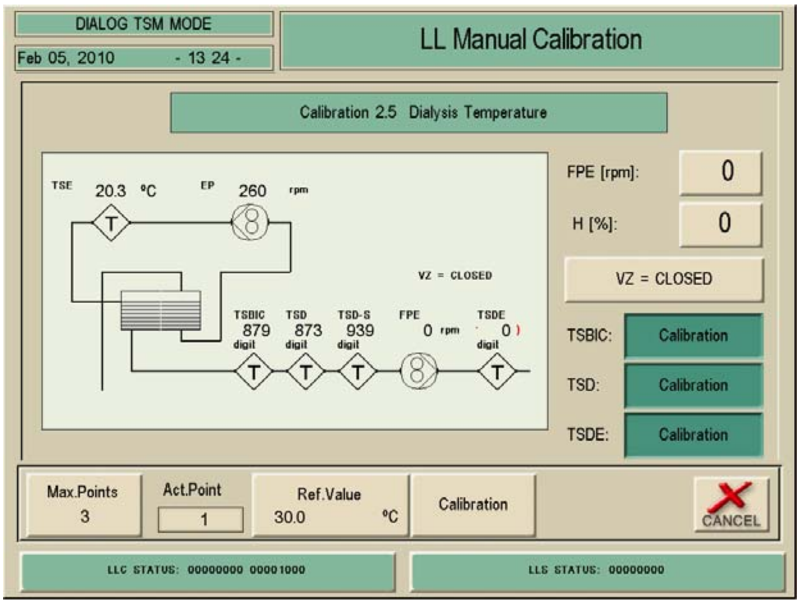


Fig.: UF Sub-Rack with TSDE in Line with TSBIC/TSD/TSD-S (on DF Sub-Rack) for Calibration





1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Dialysis Temperature* menu by pressing on the line *Calibration 2.5 Dialysis Temperature.* The following menu is displayed.

- Measurement instrument (e.g. HDM 99 or equivalent)
- Adapter set (coupling, tubing, dialyser couplings)

3. Remove **TSDE** from rinsing bridge and connect at the outlet of **FPE** (tubing going to **FBK1**).

   Note: Pay attention to correct flow direction of temperature sensor **TSDE**.
4. Connect measurement instrument between **TSDE** and **FBK1**.
5. Connect dialyser couplings to flow meter.
6. Increase slowly the speed of **FPE**, until a flow of 750 ml/min ±50 ml/min is reached.
7. Press Common Calibration key for a combined calibration of **TSBIC**, **TSD/TSD-S** and **TSDE** (The circulation valve **VZ** stays closed).

Calibration Point 30 °C

8. Increase slowly heater power (in %) until a stable temperature value of 30 °C ±2 °C is displayed at the temperature measurement instrument.

Note: Pay attention to the maximum fluctuation of ±0.1 °C over 10 s at the temperature measurement instrument.

9. Press Ref.Value key.

Wait until digits are stable.

10. Enter the stable value from the temperature measurement instrument as reference value.

11. Confirm with Calibration key.

Calibration Point 38 °C

12. Increase slowly heater power until a stable temperature value of 38 °C ±2 °C is displayed at the temperature measurement instrument.

Note: Pay attention to the maximum fluctuation of ±0.1 °C over 10 s at the temperature measurement instrument.

Write down the value of the heater power, because this value is required for the calibration of the conductivity.

13. Press Ref.Value key.

Wait until digits are stable.

14. Enter the stable value from the temperature measurement instrument as reference value.

15. Confirm with Calibration key.

Calibration Point 50 °C

16. Increase slowly heater power until a stable temperature value of 50 °C ±2 °C is displayed at the temperature measurement instrument.

Note: Pay attention to the maximum fluctuation of ±0.1 °C over 10 s at the temperature measurement instrument.

The flow can be reduced slightly if the heater power (100%) is insufficient for the last calibration point.

17. Press Ref.Value key.

Wait until digits are stable.

18. Enter the stable value from the temperature measurement instrument as reference value.

19. Confirm with Calibration key.

20. Confirm and save the completed calibration procedure with ✓O.K. key.

Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).

21. Reassemble the heater inlet temperature sensor **TSDE** to the original position (see previous page).

Note: Pay attention to correct flow direction of temperature sensor **TSDE**.

4.8.3.9 Calibration Conductivity Sensors Bicarbonate BICLF and END Conductivity ENDLF/ENDLF-S

If the conductivity sensor BICLF or ENDLF/ENDLF-S is exchanged: the temperature sensors TSBIC, TSD/TSD-S must be calibrated prior to the calibration of the conductivity sensors BICLF/ENDLF/ENDLF-S.

Conductivity Measurement Instrument (e.g. HDM 99 or equivalent)

Technical Data:

- Temperature coefficient α = 2.10 %/°C (set)
- Reference temperature T_{Ref} = 25 °C (set)
- Correct cell constant (set)
- Conductivity accuracy: ≤ ±0.1 mS/cm
- Conductivity resolution 0.01 mS/cm
- Use calibrated measurement instrument

Prior to Calibration of BICLF/ENDLF/ENDLF-S

- Perform a chemical disinfection with citric acid 50%
- Wait until Dialog has reached working temperature
- Calibrate temperature sensors TSBIC/TSD/TSD-S

Test and Calibration Solution for BICLF

The applied acid concentrate used as test and calibration solution (if not available use acetate) must be diluted according to the prerequisites with deionised water. The components of the acid concentrate are listed in table 1.

Table 1

Nominal Composition of Ready for Use Dialysate According to Data on Canister (1 l Acid Concentrate + 1.225 BIC + 32.775 l Deionised Water)

Component	Concentration [mmol/l]	Max. Oscillation Range
Sodium	138	0
Potassium	2	2
Calcium	1.5	0.5
Magnesium	0.5	0.5
Chlorine	109	3
Acetate	3	1
Bicarbonate	32	1
Glucose	0 g/l	1 g/l
Osmolarity	292 mOsm/l	5 mOsm/l

The following B. Braun acid concentrates can be used:
e.g. SW376A, SW163A, SW 196A, SW127A, SW93A, SW102A, SW380A, SW95A, SW139A, SW381A, SW178A, SW393A, SW195A
If acid concentrates are not available the following B. Braun acetate concentrates can be used as an alternative:
e.g. SW44 and SW 174
If acid concentrate from B. Braun is not available acid concentrate from a second source can be used. The composition is listed in table 1.

Composition of Calibration Solution for BICLF

Acid concentrate is diluted with deionised water with a ratio of 1:4 (or 1:4.5 with acetate) to calibrate the BICLF sensor, i.e. bicarbonate concentrate is not used.

Composition of Calibration Solution for ENDLF/ENDLF-S

The undiluted acid concentrate (if not available use acetate) is used to calibrate the ENDLF/ENDLF-S sensors (see table 1).

Calibration Points for BICLF and ENDLF/ENDLF-S

The following calibration points are used:

- Calibration points **BICLF**: 0 mS/cm, 3 mS/cm, 5.8 mS/cm
- Calibration points **ENDLF/ENDLF-S**: 0 mS/cm, 14.0 mS/cm
- Conductivity calibration point deviation: 0.2 mS/cm
- Conductivity oscillation range: ± 1 digit/0.1 mS/cm (displayed value of Dialog) over 10 s, i.e. the conductivity should be constant over a time period of 10 s.
- Reference temperature: 38 °C ±2 °C

Calibration Temperature Sensors

The temperature sensors **TSBIC/TSD/TSD-S** must be calibrated prior to the calibration of the conductivity sensors **BICLF/ENDLF/ENDLF-S** (in menu *LL Manual Calibration*, *Calibration 2.5 Dialysis Temperature*).

Measurement of the Temperature and the Conductivity

The measurement sensor for temperature and conductivity of the measurement instrument is connected between **FPE** and the inlet to the balance chamber at **FBK1** (see figure).

Measurement of the Flow

Connect the dialyser couplings to the flow sensor.

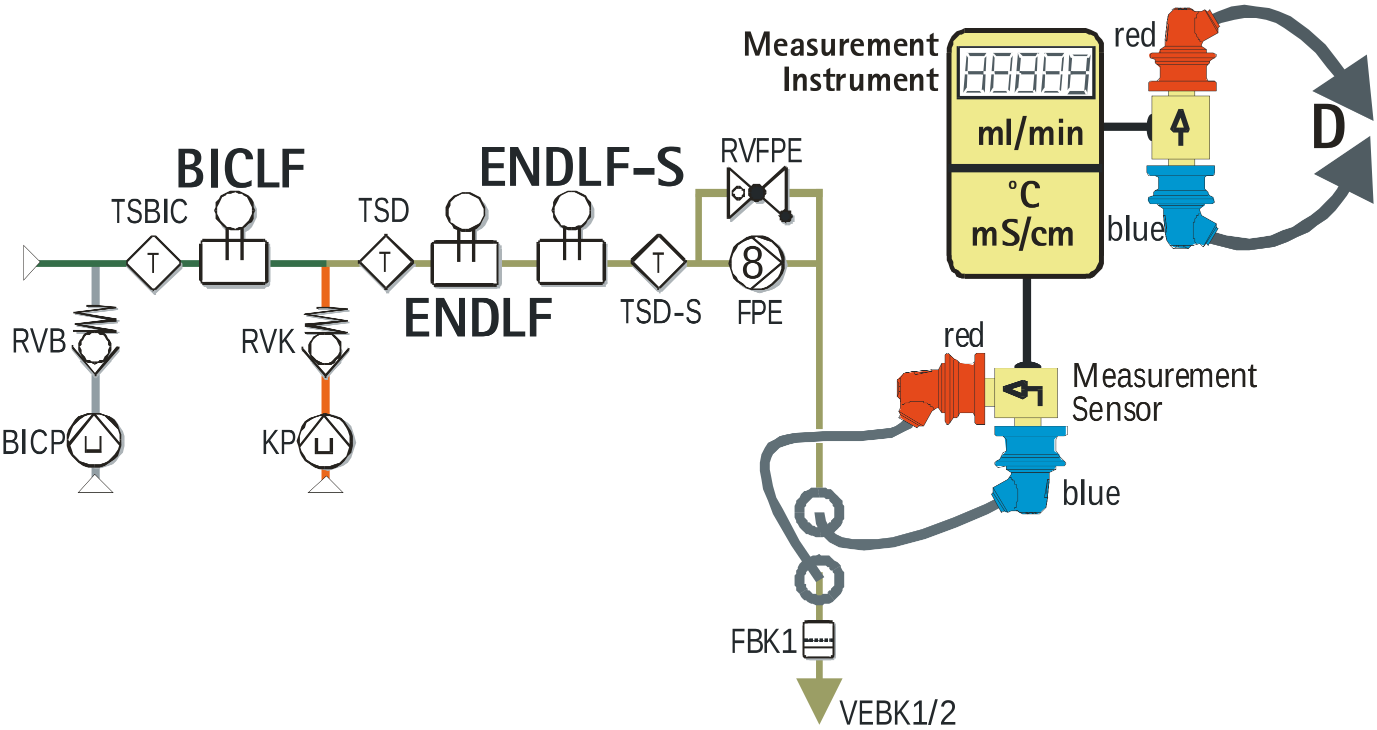


Fig.: Dialysate Preparation

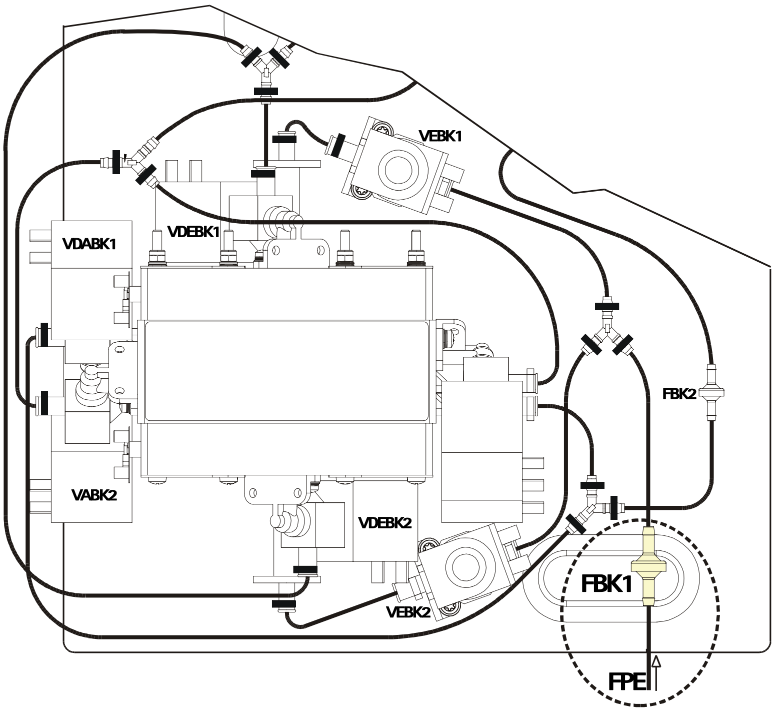


Fig.: Original Tubing UF Sub-Rack with FBK1

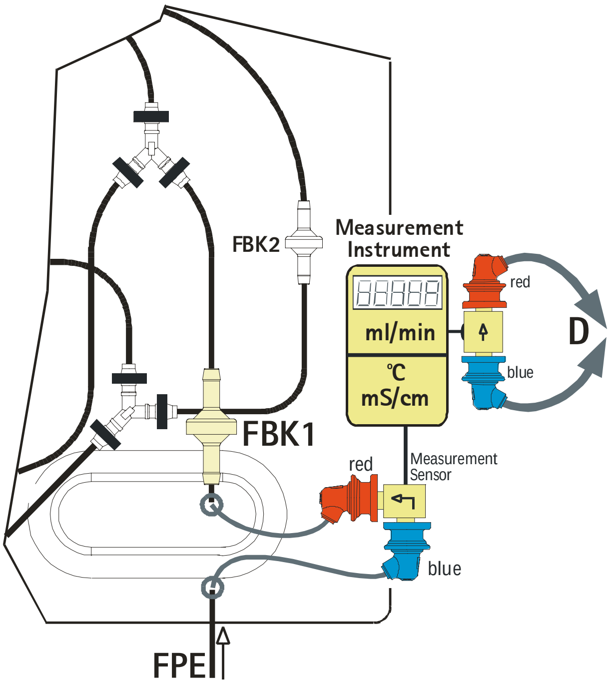
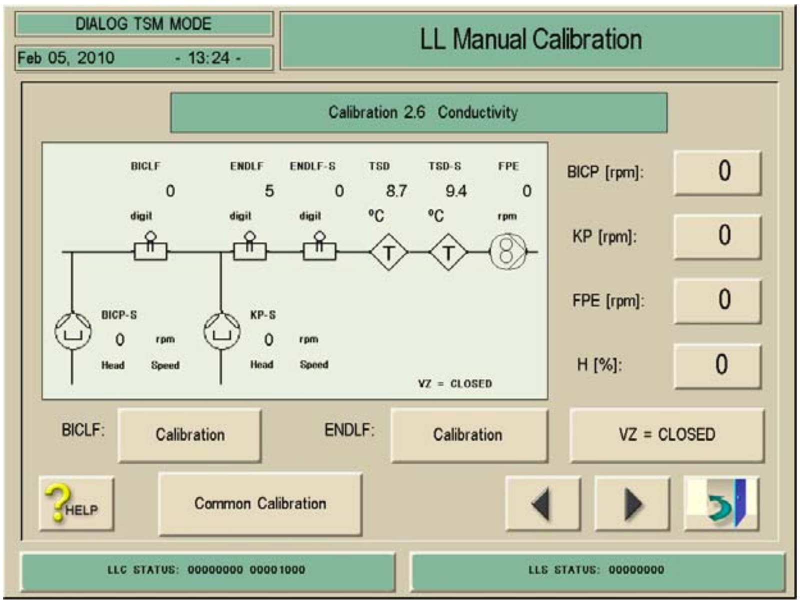


Fig.: UF Sub-Rack with Loop-In Point for BICLF, ENDLF and ENDLF-S Calibration



Feb 05, 2010 - 13:24 -

BICLF 0, ENDLF 5, ENDLF-S 0, TSD 8.7, TSD-S 9.4, FPE 0

BICP-S 0 rpm, KP-S 0 rpm

VZ = CLOSED

BICP [rpm]: 0

KP [rpm]: 0

FPE [rpm]: 0

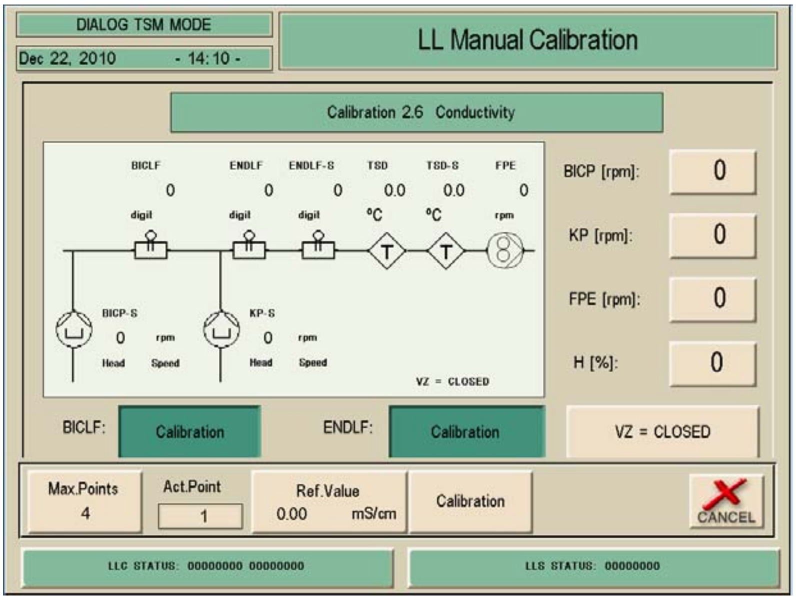
H [%]: 0

VZ = CLOSED

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Calibration Conductivity* menu by pressing on the line *Calibration 2.6 Conductivity*. The following menu is displayed.
3. Press the Common Calibration key to calibrate the conductivity sensors BICLF, ENDLF and ENDLF-S together.



Dec 22, 2010 - 14:10 -

BICLF 0, ENDLF 0, ENDLF-S 0, TSD 0.0, TSD-S 0.0, FPE 0

BICP-S 0 rpm, KP-S 0 rpm

VZ = CLOSED

BICP [rpm]: 0

KP [rpm]: 0

FPE [rpm]: 0

H [%]: 0

VZ = CLOSED

Max.Points 4

Act.Point 1

Ref.Value 0.00 mS/cm

LLC STATUS: 00000000 00000000

LLS STATUS: 00000000

The following menu is displayed.

Composition of the calibration solution for BICLF:
To calibrate the BICLF sensor deionised water is mixed with the respective acid concentrate, i.e. real bicarbonate concentrate is not used (see table 1).

There is no cyclic switching of the balance chambers during the conductivity calibration. Thus a continuous flow is accomplished which is necessary for the calibration. The following valves are opened **VEBK2/VDEBK2** and **VABK1/VDABK1**.
Pay attention that air bubbles do not build up in the reference sensor during calibration.

- Measurement instrument (e.g. HDM 99 or equivalent)
- Calibration solution: diluted and undiluted acid concentrate
- Adapter set (coupling, tubing, dialyser couplings)

4. Connect measurement instrument between **FPE** and balance chamber.
5. Connect dialyser couplings to flow meter.
6. Increase slowly the speed of **FPE**, until a flow of 750 ml/min ±50 ml/min is reached.

BICLF/ENDLF/ENDLF-S Calibration Point 0 mS/cm

7. Change slowly heater power, until a stable temperature value of 38 °C ±2 °C is displayed at the measurement instrument.
Note: Use the heater power value noted during the calibration of **TSBIC/TSD/TSDS/TSDE** at temperature of 38 °C.

8. Speed **BICP**: 0 rpm
Speed **KP**: 0 rpm

9. Press Ref.Value key.

Wait until digits are stable.

10. Enter the stable value from the measurement instrument as reference value.

11. Confirm with Calibration key.
Note: Do not simply confirm the set value as 0.00 mS/cm but by all means enter the actual reference value, e.g. 0.01 mS/cm. Pay attention to the deviation range for the conductivity and the temperature at the measurement instrument.

A calibration solution with a ratio of approx. 1:4 is necessary for the 3 mS/cm and 5.8 mS/cm calibration, i.e. 1 l acid concentrate + 4 l RO (reverse osmosis) water.
If acid concentrate is not available a calibration solution with acetate can be used. The ratio is approx. 1:4.5, i.e. 1 l acetate + 4.5 l RO (reverse osmosis) water.

BICLF Calibration Point 3 mS/cm

12. Connect blue suction rod to the diluted acid concentrate (calibration solution).

Do not change by mistake the suction rods and the pumps **BICP/KP**.

13. Increase slowly the speed (approx. 110 – 120 rpm) of the bicarbonate pump **BICP**, until a stable conductivity value of 3.0 mS/cm ±0.2 mS/cm is displayed at the measurement instrument.

Note: Pay attention to the deviation range for the conductivity and the temperature at the measurement instrument.

14. Press Ref.Value key.

Wait until digits are stable.

15. Enter the stable value from the measurement instrument as reference value.

16. Confirm with Calibration key.

BICLF Calibration Point 5.8 mS/cm

17. Increase slowly the speed (approx. 220 - 230 rpm) of the bicarbonate pump BICP, until a stable conductivity value of 5.8 mS/cm ±0.2 mS/cm is displayed at the measurement instrument.

Note: Pay attention to the deviation range for the conductivity and the temperature at the measurement instrument.

18. Press Ref.Value key.

Wait until digits are stable.

19. Enter the stable value from the measurement instrument as reference value.

20. Confirm with Calibration key.

ENDLF Calibration Point 14.0 mS/cm

21. Connect the blue suction rod to the undiluted acid concentrate.

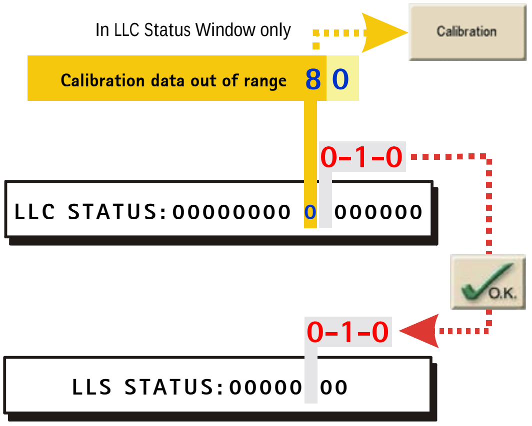
22. Change the speed of the bicarbonate pump **BICP** (approx. 115 - 120 rpm), until a stable conductivity value of 14.0 mS/cm ±0.2 mS/cm is displayed at the measurement instrument.

Note: Pay attention to the deviation range for the conductivity and the temperature at the measurement instrument.

23. Press Ref.Value key.

Wait until digits are stable.

24. Enter the stable value from the measurement instrument as reference value.



25. Confirm with Calibration key.

Note: Pay attention to the *LLC Status* window. The calibration data are only valid if the following digit value is displayed in the *LLC Status* window: **0 X X X X X X X** (see figure).

If the calibration value for **ENDLF** is at the limit range the calibration data could be invalid. Thus the following digit value is displayed in the *LLC Status* window **8 X X X X X X X** (see figure). Repeat calibration procedure.

26. Confirm completed calibration procedure with O.K. key (calibration data are saved).

Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).

27. Stop **FPE** and **BICP** and remove measurement instrument.

4.8.3.10 Calibration Blood Leak Detector

You can check and calibrate the blood leak detector **BL**. The rinsing block must have an even temperature for the calibration. If both dialyser couplings are connected to the rinsing bridge the flow pumps **FPA/FPE** work in main flow. If only one coupling is connected **FPE** is stopped. The reference solution can be drawn in by the red coupling via **FPA**.

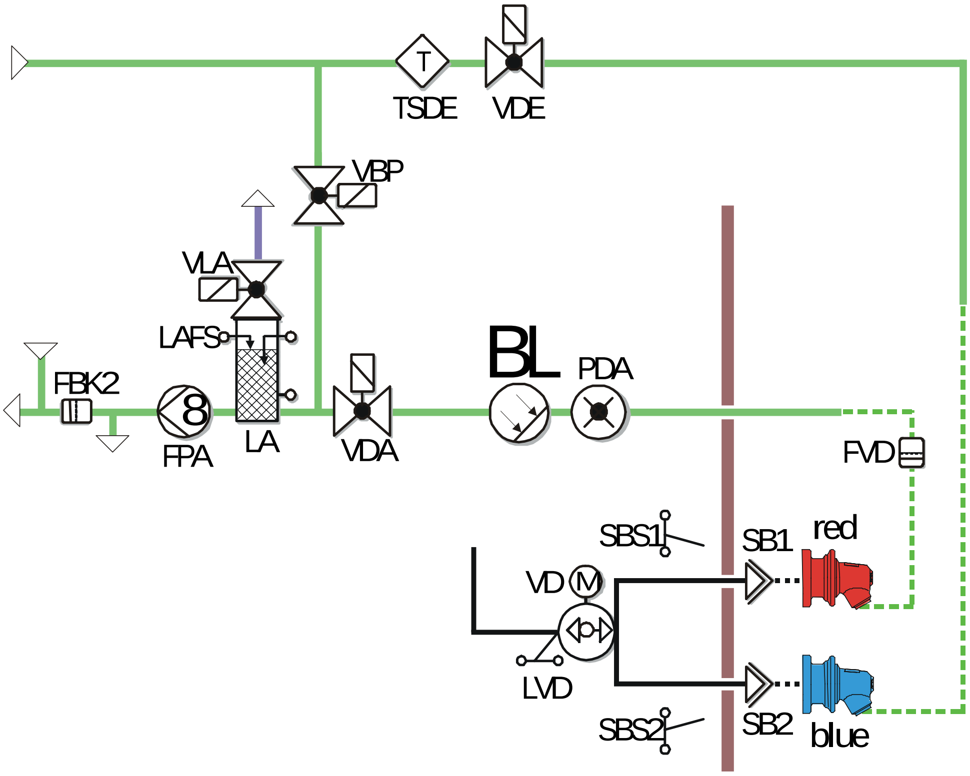


Fig.: Rinsing Bridge with Blood Leak Detector BL

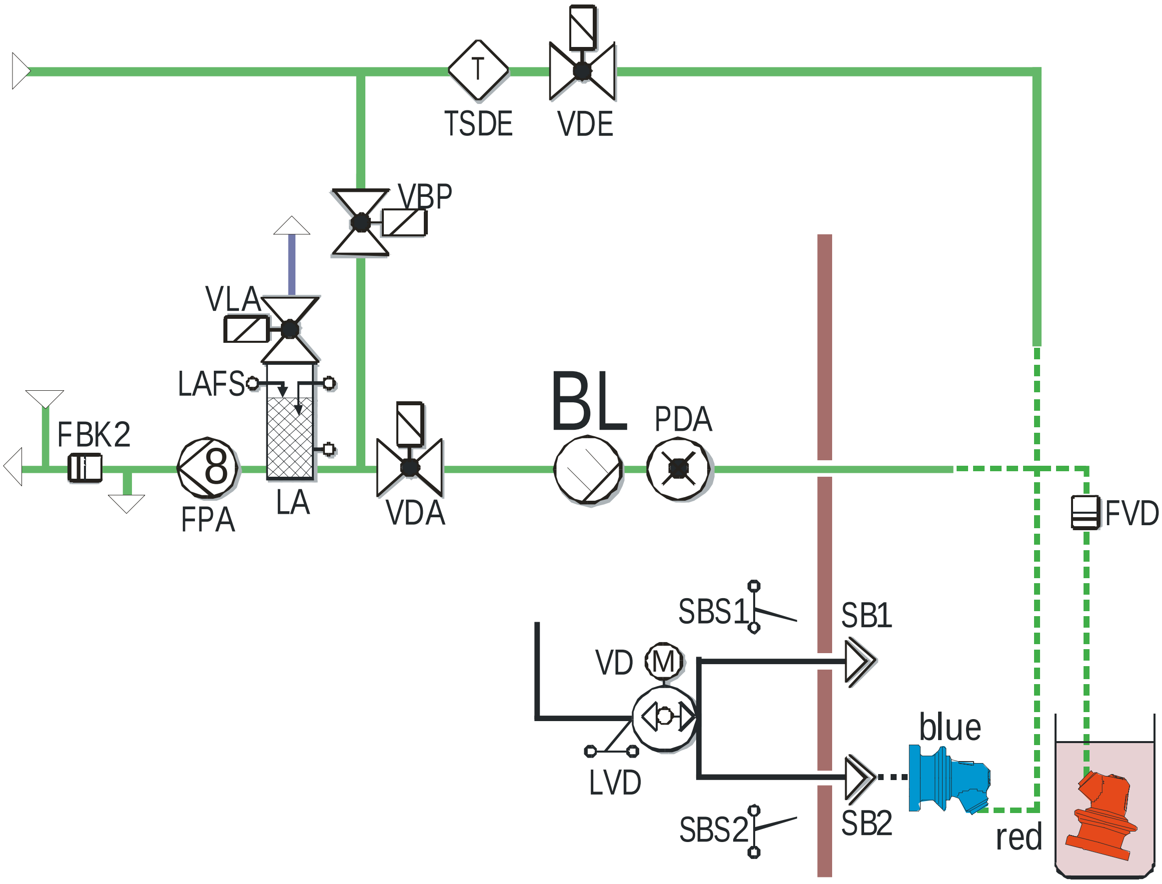


Fig.: Rinsing Bridge with Red Coupling Immerged in Reference Solution for BL Calibration

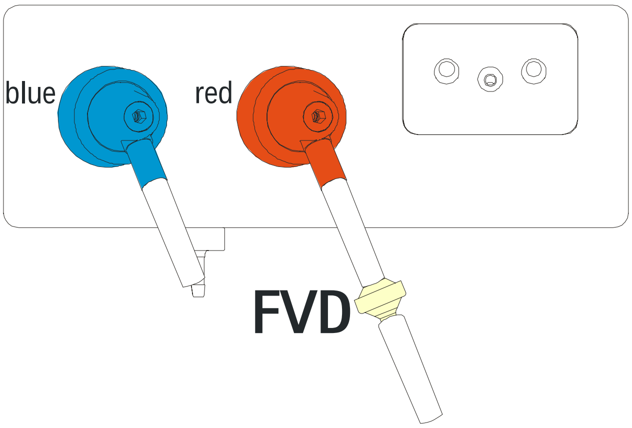


Fig.: Red and Blue Couplings Connected to Rinsing Bridge

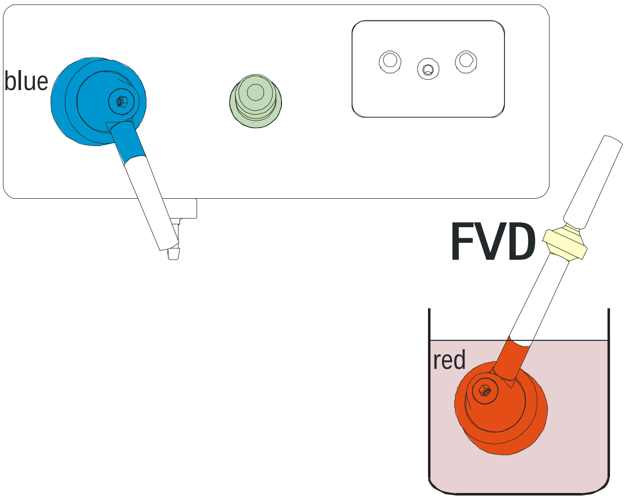
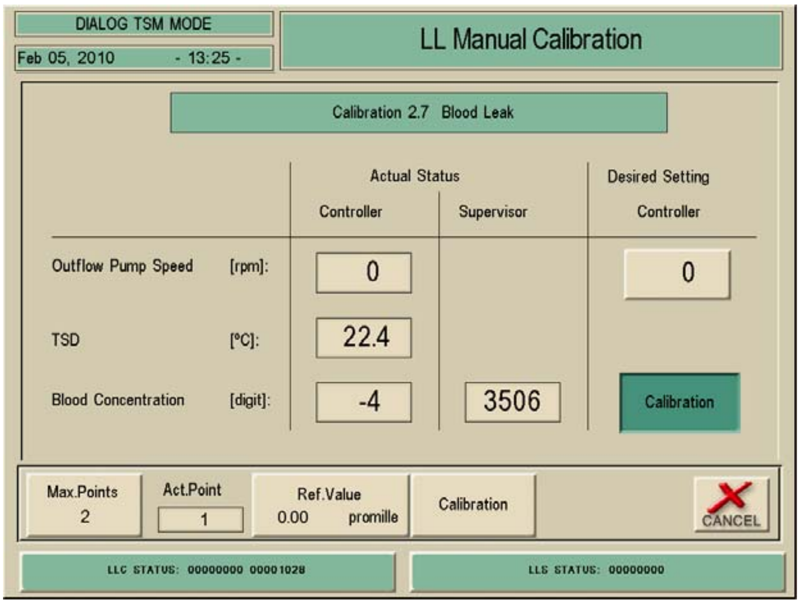


Fig.: Rinsing Bridge with Red Coupling Immerged in Reference Solution for BL Calibration



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		Actual Status		Desired Setting
		Controller	Supervisor	Controller
Outflow Pump Speed	[rpm]:	0		0
TSD	[°C]:	22.4		
Blood Concentration	[digit]:	-4	3506	

Max.Points 2

Act.Point 1

Ref.Value 0.00 promille

LLC STATUS: 00000000 00001028

LLS STATUS: 00000000

1. You can activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Blood Leak* menu by pressing on the line *Calibration 2.7 Blood Leak.* The following menu is displayed.

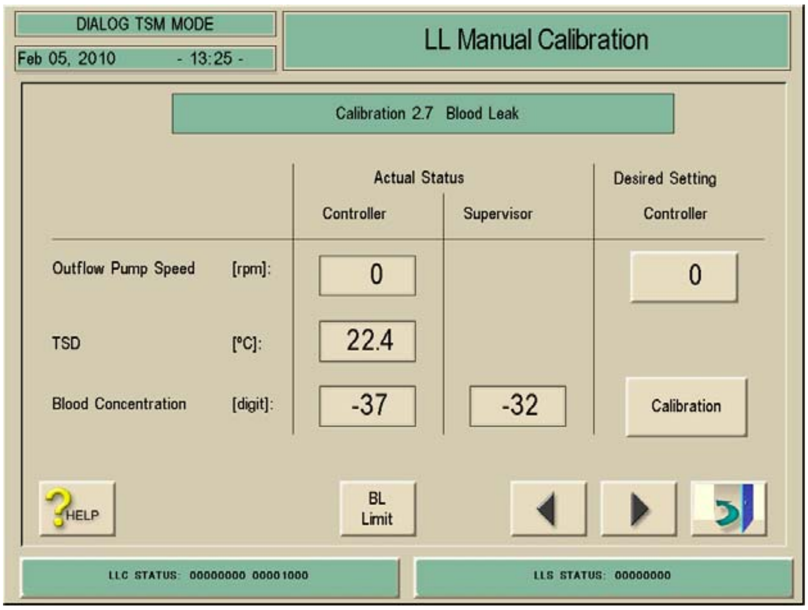
Close front and rear door for the function test and calibration to prevent light irradiation on the sensor.

Leakages
Air and micro-bubbles can lead to incorrect measurement values in the measurement line and can cause fluctuation of the current value.

If air is visible check the complete system for leaks in menu *1.20 Test Water Part*. After the initialisation phase rinse the blood leak detector approx. 1 min and then perform a leakage test of the system in menu *1.19 Leak Test*.

Chemical Disinfection with Citric Acid 50%
A decalcification must be performed before initial calibration.

4.8.3.10.1 Blood Leak Detector Limit



DIALOG TSM MODE

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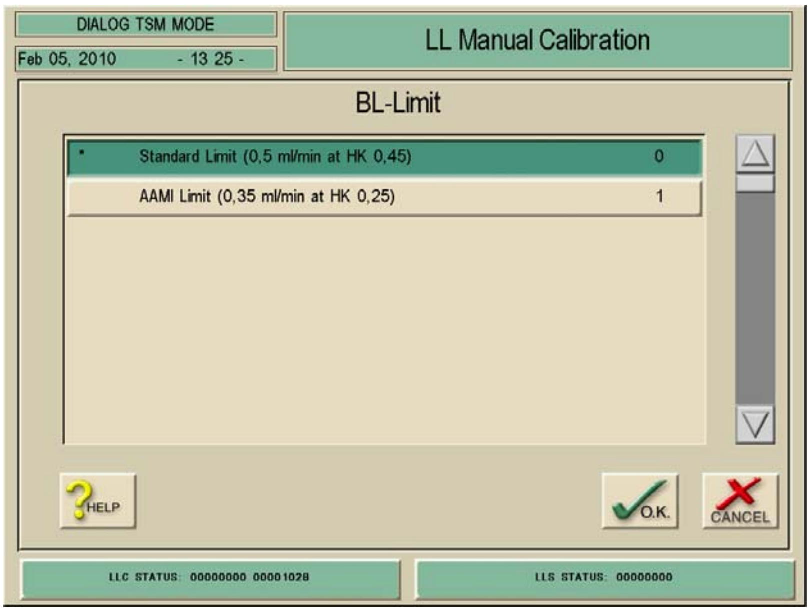
LL Manual Calibration

Calibration 2.7 Blood Leak

		Actual Status		Desired Setting
		Controller	Supervisor	Controller
Outflow Pump Speed	[rpm]:	0		0
TSD	[°C]:	22.4		
Blood Concentration	[digit]:	-37	-32	Calibration

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000



DIALOG TSM MODE

Feb 05, 2010 - 13 25 -

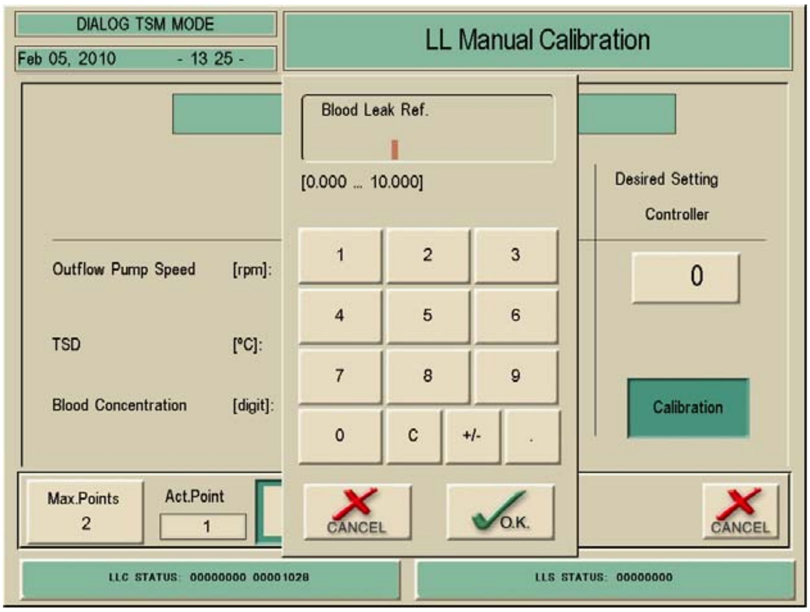
LL Manual Calibration

BL-Limit

*	Standard Limit (0,5 ml/min at HK 0,45)	0
	AAMI Limit (0,35 ml/min at HK 0,25)	1

LLC STATUS: 00000000 00001028

LLS STATUS: 00000000



DIALOG TSM MODE

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LL Manual Calibration

Blood Leak Ref.

[0.000 ... 10.000]

Desired Setting Controller

Outflow Pump Speed [rpm]: 0

TSD [°C]:

Blood Concentration [digit]:

Max.Points 2

Act.Point 1

LLC STATUS: 00000000 00001028

LLS STATUS: 00000000

You can select the limit value for the alarm activation of the blood leak detector in the *Calibration 2.7 Blood Leak Detector*, *BL Limit* menu.

BL Limit

Standard Limit (0.5 ml/min at haematocrite HK 0.45)

The alarm limit is set to 0.5 ml/min at a haematocrite of 0.45, i.e. a blood leak detector alarm is activated if the alarm limit is exceeded.

AAMI Limit (0.35 ml/min at haematocrite HK 0.25)

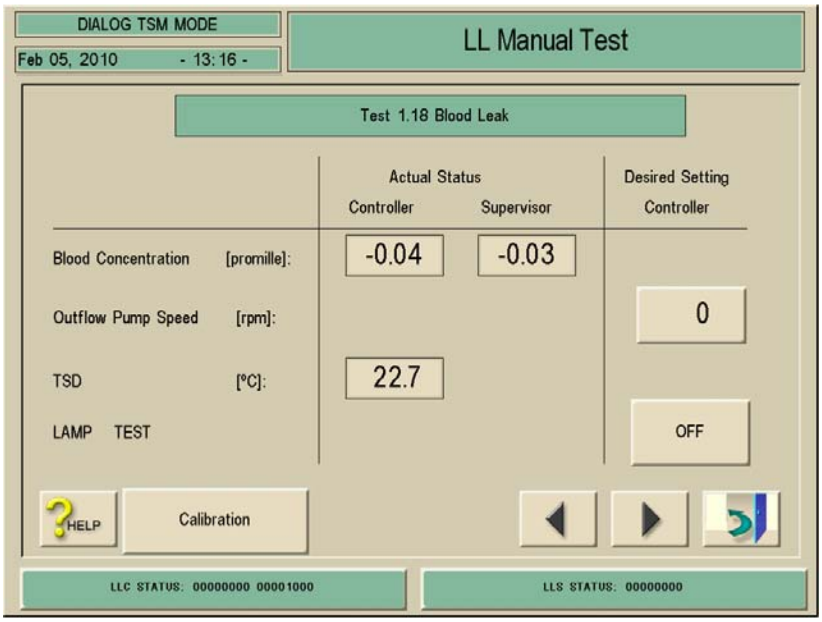
The alarm limit is set to 0.35 ml/min at a haematocrite of 0.25 (AAMI standard), i.e. a blood leak detector alarm is activated if the alarm limit is exceeded.

Please Note

The same blood leak detector is used for both settings:

- The calibration procedure is identical, but with different tolerance ranges
- The test procedure is identical

4.8.3.10.2 Check Blood Leak Detector



DIALOG TSM MODE
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LL Manual Test

Test 1.18 Blood Leak

	Actual Status Controller	Actual Status Supervisor	Desired Setting Controller
Blood Concentration [promille]:	-0.04	-0.03	
Outflow Pump Speed [rpm]:			0
TSD [°C]:	22.7		
LAMP TEST			OFF

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Connect both dialyser couplings to the rinsing bridge.
2. Select menu *Test 1.18 Blood Leak* in TSM to perform a function check of the blood leak detector.
3. Rinse the blood leak detector for approx. 1 min at the beginning of the rinsing time with flow pump outlet **FPA** (approx. 1400 rpm). Thereby possible air bubbles in the system are removed.
4. Rinse blood leak detector for approx. 15 to 30 min with **FPA** (approx. 1000 rpm) to warm up the complete system to a temperature of approx. 40 °C.

Exchange the blood leak detector if one of these three values is out of limits.

5. The *LED test* is activated with the *LAMP TEST OFF* key. The *OFF* key switches to the *RED* key as soon as the key is pressed.

   The *red LED* is tested after 10 s. The controller value for the switched off *red LED* must be as follows (the supervisor value is uncritical):

red LED	Actual Status Controller
Blood Concentration	< 4.00

6. Press the *LAMP TEST RED* key to switch to the *green LED*. The *RED* key switches to the *GREEN* key.

   The *green LED* is tested. The controller value for the switched off *green LED* must be as follows (the supervisor value is uncritical):

green LED	Actual Status Controller
Blood Concentration	> 2.06

7. The actual controller values for the *red LED* and the *green LED* must be divided.

   Note: The calculated value of **red LED** divided by **green LED** is displayed briefly after the key *LAMP TEST* is switched back to OFF.

   The calculated value must be in the following limits (to the first decimal digit/round off):

red LED / green LED
1.15 - 1.44

4.8.3.10.3 Calibration Blood Leak Detector

Close front and rear door for the calibration to prevent light irradiation on the sensor. Air and micro-bubbles must not be present prior or during the calibration of the blood leak detector (if necessary rinse, see information 4.8.3.10).
The blood leak detector must be clean.
FPA must be switched off to prevent a flow during the calibration procedure.
The calibration of the blood leak detector type 2 is performed in two steps:

- Turbidity calibration
- Calibration with reference solution

You can skip directly from the test menu to the calibration menu of the blood leak detector by pressing the Calibration key.
The calibration procedure may take some time and requires stable values. Slight fluctuations due to air bubbles inside the blood leak detector during the calibration process can lead to an abortion of the calibration.

- Reference solution (red dye, art. no. 7700911)
- Graduated cylinder 2 litre

1. Both dialyser couplings are connected to the rinsing bridge.
2. Prepare 1 ‰ reference solution, i.e.:
   Dilute the flask of 2 ml of red dye with 2 litre deionised/RO water. The water should have at least 30 °C for an accurate calibration. Mix the reference solution thoroughly.

4.8.3.10.3.1 Turbidity Calibration with Water

3. Press Calibration key. The calibration window is opened.
4. Set **FPA** slowly to zero.
5. Press the Calibration key to activate the first calibration point of the automatic calibration.

   The values must be in the following limits:

	Actual Status Controller	Actual Status Supervisor
Blood Concentration [‰]	-50 to +50 digits	205 to 230 digits

After the calibration of the first point the second calibration point is automatically displayed.

4.8.3.10.3.2 Calibration with Reference Solution (Red Dye)

6. Carefully pull off the red dialyser coupling from the rinse bridge to prevent any loss of fluid/air-intake and immerge it into the container with reference solution.
7. Set **FPA** slowly to 1000 rpm and draw-in approx. 1 l reference solution.
8. Set the **FPA** slowly to zero. If the displayed actual blood concentration value of the controller is stable, press the Calibration key to confirm.

   The displayed actual blood concentration value must be in the following limit, to ensure a sufficient resolution:

	Actual Status Controller
Blood Concentration [‰]	> 200

9. Confirm and store completed calibration procedure with ✓ O.K. key.

4.8.3.10.4 Actual Value Check Blood Leak Detector

10. Select menu 1.18 in TSM to check the actual value of the blood leak detector.

4.8.3.10.4.1 Check 0 ‰ Blood Concentration

11. Connect red dialyser coupling to rinsing bridge.

12. Set **FPA** slowly to 1000 rpm and rinse.

13. Check blood concentration of the controller and supervisor.

The values for the controller and supervisor must be in the following limits:

	Actual Status Controller	Actual Status Supervisor
Blood Concentration [‰]	-0.1 to 0.1	-0.1 to 0.1

4.8.3.10.4.2 Check 1 ‰ Blood Concentration

14. Set **FPA** slowly to zero.

15. Carefully disconnect red dialyser coupling.

16. Carefully immerge red dialyser coupling into reference solution.

17. Set **FPA** slowly to 1000 rpm and draw-in remaining reference solution.

18. Set **FPA** slowly to zero.

19. Check blood concentration of the controller and supervisor.

The blood concentration values for the controller and supervisor must be in the following limits:

	Actual Status Controller	Actual Status Supervisor
Blood Concentration [‰]	0.90 to 1.1	0.90 to 1.1

4.8.3.11 Calibration of Delivery Rate UFP, BICP and KP

You can calibrate the ultrafiltration pump **UFP**, the bicarbonate pump **BICP** and the concentrate pump **KP**. The **BICP** and **KP** can be calibrated either with a volumetric flask/graduated cylinder or a balance. The calibration with a balance is mandatory for **UFP**. Prior to calibration the balance chamber initialisation must be completed. The respective pump runs for approximately 2 minutes after pressing the START Calibration key and stops after a certain number of revolutions are reached.

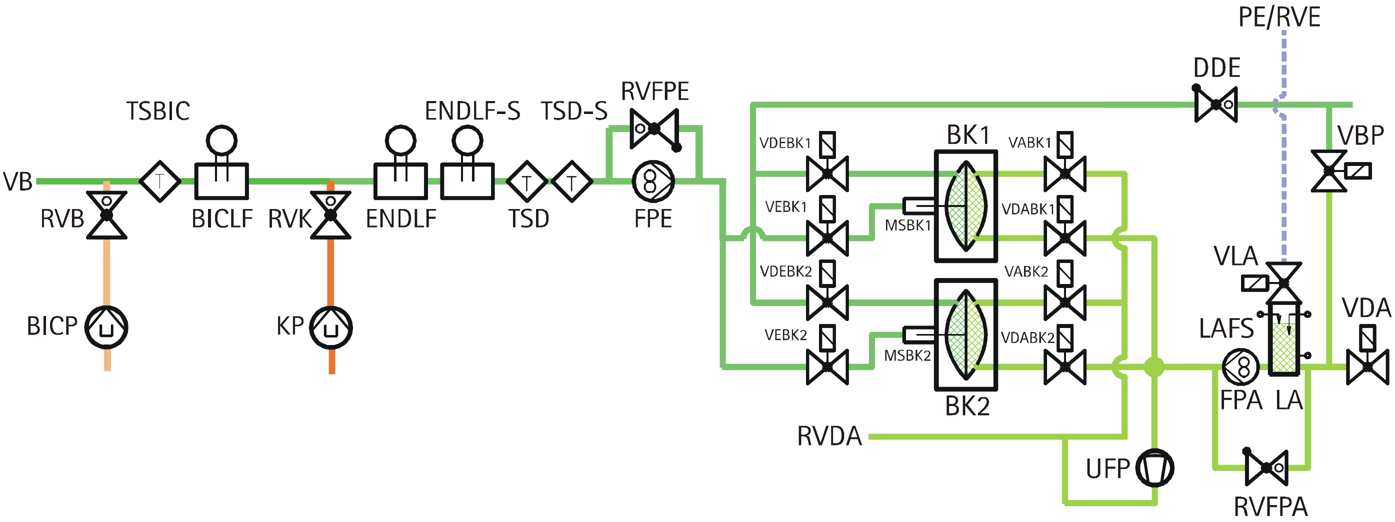
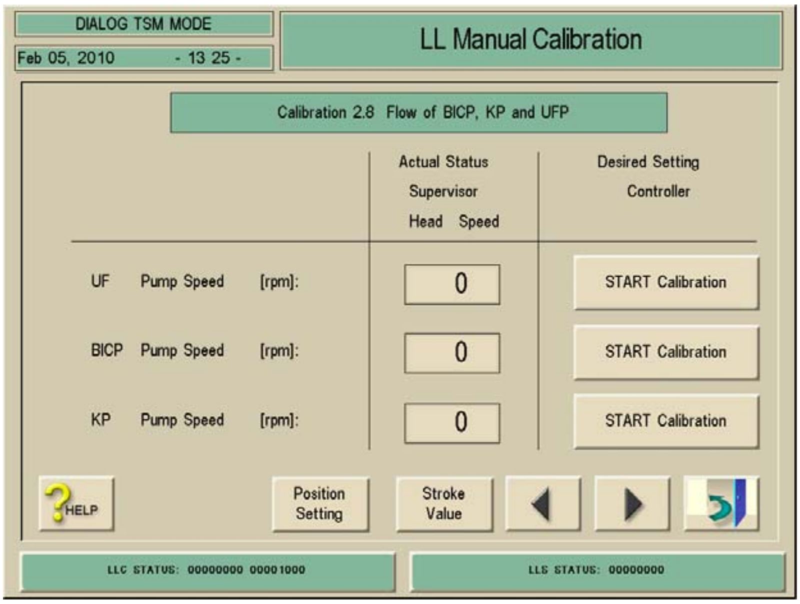


Fig.: Bicarbonate Pump BICP, Concentrate Pump KP and Ultrafiltration Pump UFP


DIALOG TSM MODE

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LL Manual Calibration

Calibration 2.8 Flow of BICP, KP and UFP

	Actual Status Supervisor Head Speed	Desired Setting Controller
UF Pump Speed [rpm]:	0	START Calibration
BICP Pump Speed [rpm]:	0	START Calibration
KP Pump Speed [rpm]:	0	START Calibration

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

During the selection of the menu:

- the balance chamber is initialised and
- the **UFP** is set to a defined initial position (reed sensor/hall sensor position).

Thus the accuracy during the calibration of **UFP** is improved, because **UFP** runs back to the initial position at the end of calibration. Thus complete revolutions are counted.

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Flow of BICP, KP and UF Pump* menu by pressing on the line *Calibration 2.8 Flow of BICP, KP and UF Pump*. The following menu is displayed.

4.8.3.11.1 Calibration BICP and KP Pump

Prior to calibration the initialisation of the balance chamber must be completed. The initialisation is completed, if the *LLC Status* window changes from *000000004* to *000000000*.
The system must be free of air for calibration. Thus an accurate calibration is guaranteed.

- Balance or graduated cylinder
- Tubing clamp

1. Fill graduated cylinder with 200 ml water.
2. Remove respective concentrate suction rod from rinsing chamber and immerge into graduated cylinder.

3. Press the *BICP Pump* or *KP Pump* START Calibration key again to start a pump calibration.
   The piston pump runs two minutes and stops.
4. Press the Ref.Value key, which appears automatically after 2 minutes.
5. Enter the suction delivery volume (200 ml – residual volume = delivery volume) as reference value.
6. Press Calibration key to confirm.
7. Confirm and store completed calibration procedure with O.K. key.

   Note: Generally, follow the instruction for **UFP** calibration if using a balance.

4.8.3.11.2 Calibration UF Pump with Balance

The accuracy of the **UFP** calibration is essential for the precise weight reduction of a patient during dialysis.

- Balance
- Tubing clamp

1. Clamp and remove inlet tubing from **UFP**. Connect another tubing to the **UFP** and immerge tubing into a container with approx. 200 ml demineralised water.
2. Press the *UF Pump* START Calibration key to prime the tubings.

   Wait a few seconds to fully prime the tubings.
3. Press again the *UF Pump* START Calibration key to stop the **UFP**.

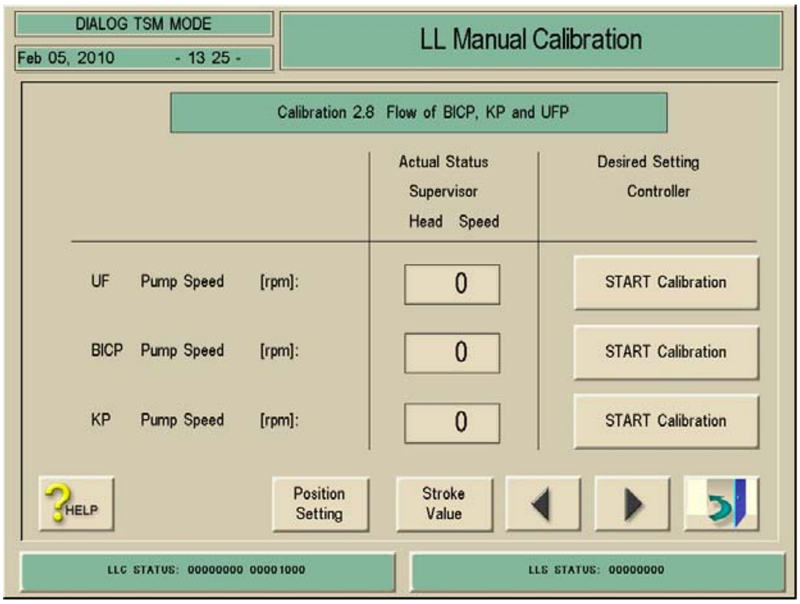
   The **UFP** will rotate back into its initial position.
4. Press CANCEL key.
5. Remove the filled tubing carefully from the measuring cylinder, measure the weight and note value.
6. Replace the tubing carefully in the measuring cylinder.
7. Press the *UF Pump* START Calibration key to start the calibration procedure.

   The **UFP** runs approx. two minutes and stops. It will rotate back into its initial position.
8. After the UF pump has stopped, remove the tubing carefully from the measuring cylinder, measure the weight and note value.
9. Press Ref.Value key.
10. Enter the calculated delivery volume as reference value.

    First measurement – second measurement = delivery volume
11. Press Calibration key to confirm.
12. Confirm and store completed calibration procedure with O.K. key.

    Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).

4.8.3.11.3 Position Setting for BICP, KP and UFP



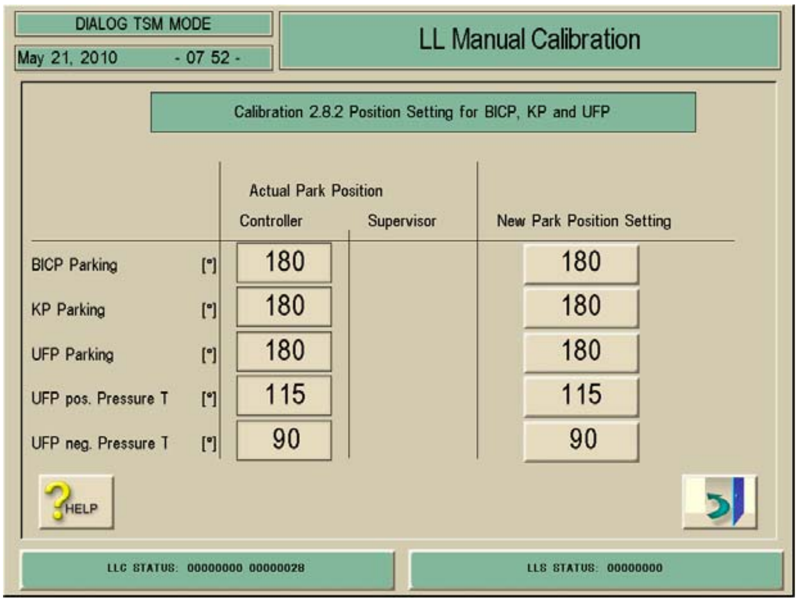
	Actual Status Supervisor Head Speed	Desired Setting Controller
UF Pump Speed [rpm]:	0	START Calibration
BICP Pump Speed [rpm]:	0	START Calibration
KP Pump Speed [rpm]:	0	START Calibration

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

The sub-menu *2.8.2 Position Setting for BICP, KP and UFP* can be selected with the *Position Setting* key.

The sub-menu *2.8.1 Stroke Value of BICP, KP and UFP* can be selected with the *Stroke Value* key.



	Actual Park Position Controller	Supervisor	New Park Position Setting
BICP Parking [°]	180		180
KP Parking [°]	180		180
UFP Parking [°]	180		180
UFP pos. Pressure T [°]	115		115
UFP neg. Pressure T [°]	90		90

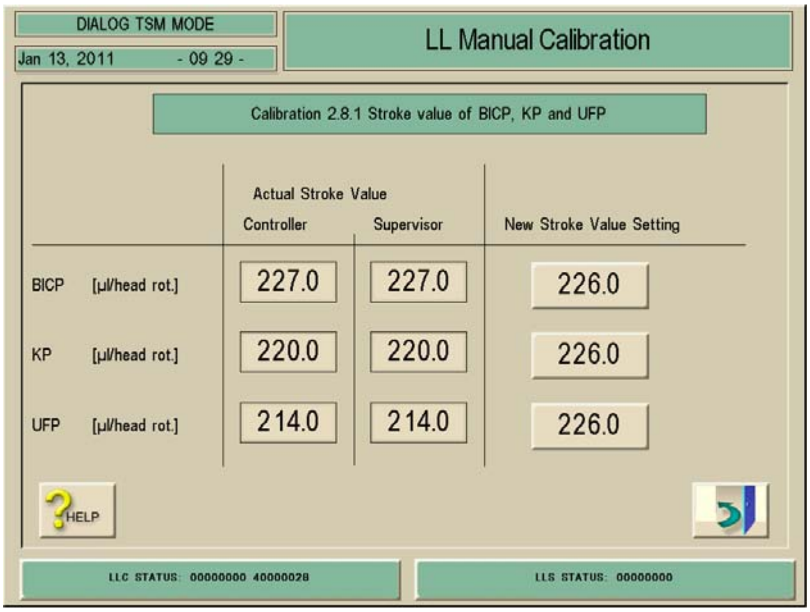
LLC STATUS: 00000000 00000028

LLS STATUS: 00000000

The following settings are required:

BICP Parking:	180 °
KP Parking:	180 °
UFP Parking:	180 °
UFP Positive Pressure Test: (used for DFS pressure test)	115 °
UFP Negative Pressure Test:	90 °

4.8.3.11.4 Stroke Value of BICP, KP and UFP



	Actual Stroke Value Controller	Supervisor	New Stroke Value Setting
BICP [µl/head rot.]	227.0	227.0	226.0
KP [µl/head rot.]	220.0	220.0	226.0
UFP [µl/head rot.]	214.0	214.0	226.0

LLC STATUS: 00000000 40000028

LLS STATUS: 00000000

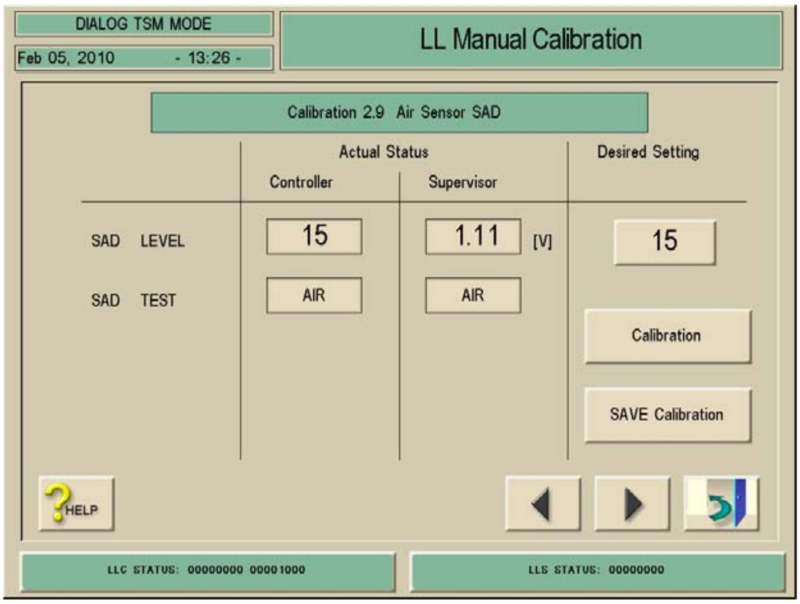
The sub-menu *2.8.1 Stroke Value of BICP, KP and UFP* can be selected from the menus *1.17 UF Pump*, or *2.8 Calibration Flow of BICP, KP and UFP*.

The stroke values (µl/head rotation) can be entered directly if the exact values are known for the bicarbonate pump *BICP* and the concentrate pump. The stroke value for the ultrafiltration pump *UFP* should not be changed, because it is determined by the calibration of the pump with a balance.

It is recommended to calibrate the UFP with the procedure described (with balance) because the accuracy of the stroke value might be insufficient for a proper UF control of the system.

4.8.3.12 Calibration Safety Air Detector SAD

Calibration Level	The value for the calibration level is marked on the SAD (example calibration level KS = 49) and was determined individually for every SAD ex works.
Test Level	The test level is the value used to check the function of the SAD in the cyclic self test. The test level is 5 digits higher than the calibration level: • Test level TS = Calibration Level KS + 5 Digits
Alarm Level	The safety air detector SAD has a fixed alarm level (15 Digits). The alarm level is displayed after the test level is entered.



1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Safety Air Detector SAD* menu by pressing on the line *Calibration 2.9 Safety Air Detector SAD*. The following menu is displayed.

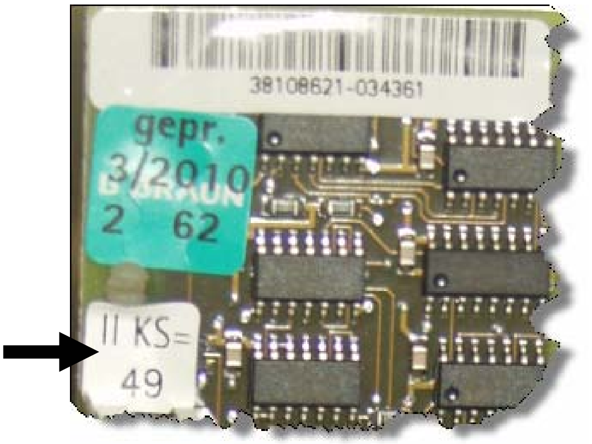
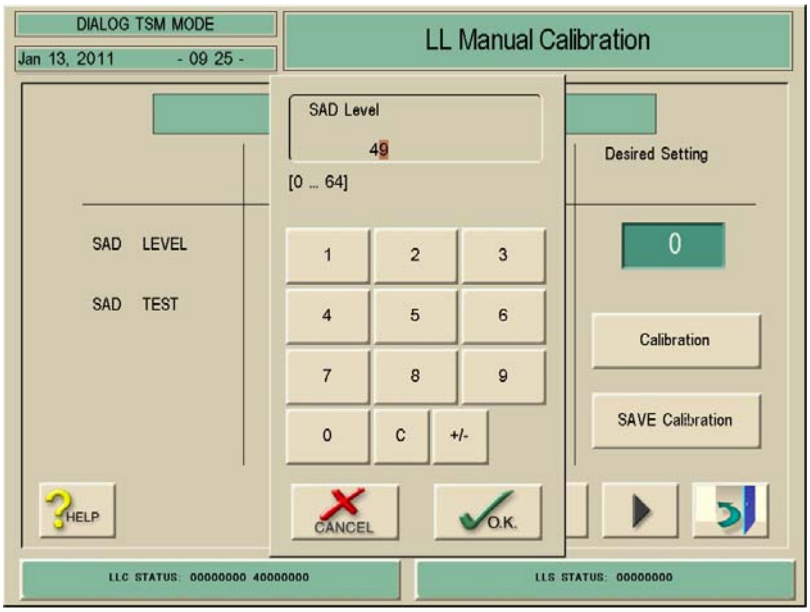


Fig.: Excerpt from SAD Board with KS Label (e.g. KS = 49)

The value for the calibration level is marked on the SAD board (example calibration level KS = 49, see left figure SAD board).



3. Take the value for the calibration level (KS) on the SAD and enter the value in the *Desired Setting* window.
4. Press Calibration key and wait until the Calibration key switches back again. The calibration procedure is completed.
5. Press the SAVE Calibration key to store the calibration.

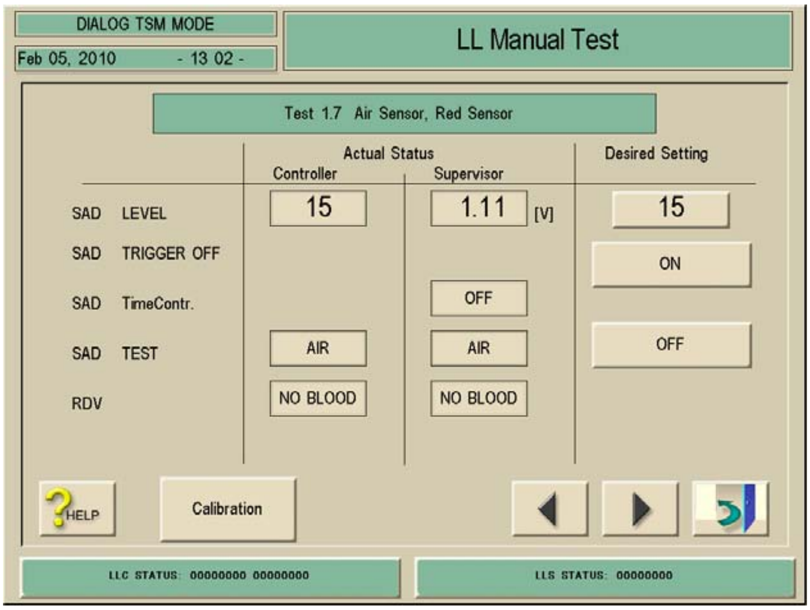
   Note: The calibration data is saved only after the bit sequence 0-1-0 (for detailed information see 4.8.3.1 General Calibration Information).

4.8.3.12.1 SAD Test after Calibration

SAD Test

AIR must be displayed if the *SAD TEST* is activated, even if a tubing filled with fluid is inserted in the SAD.

The displayed result with *SAD TEST OFF* depends on the tubing inserted in the SAD:
AIR: must be detected if a tubing filled with air is inserted.
NO AIR: must be detected if a tubing filled with fluid is inserted.



	Actual Status		Desired Setting
	Controller	Supervisor	
SAD LEVEL	15	1.11 [V]	15
SAD TRIGGER OFF			ON
SAD TimeContr.		OFF	
SAD TEST	AIR	AIR	OFF
RDV	NO BLOOD	NO BLOOD	

1. Activate the menu *Test 1.7 Air Sensor, Red Sensor* in the *LL Manual Test* menu.

2. Insert a tubing filled with water in the SAD and close cover.
   The following settings must be displayed:
   SAD LEVEL: ***15*** *(Desired Setting)*
   SAD TEST: ***NO AIR*** *(Controller/Supervisor)*
   RDV: ***NO BLOOD*** *(Controller/Supervisor)*

3. Press *SAD TEST* ON key (*Desired Setting*).
   The following settings must be displayed:
   SAD LEVEL: ***KS+5*** (*Desired Setting*, see previous page)
   SAD TEST: ***TEST*** *(Desired Setting)*
   SAD TEST: ***AIR*** *(Controller/Supervisor)*

4. Press the SAD TEST TEST key (*Desired Setting*) to terminate the test.
   The following setting must be displayed:
   SAD TEST: ***OFF*** *(Desired Setting)*

5. Press the *SAD TRIGGER OFF* ON key (*Desired Setting*) to activate the *SAD TimeContr.*
   The following settings must be displayed:
   SAD TimeContr.: ***OFF*** *(Supervisor)*
   after approx. 1 second:
   SAD TimeContr.: ***ON*** *(Supervisor)*

6. Remove the tubing from the SAD.

7. Interrupt the light path in the SAD with a piece of paper.
   The following settings must be displayed:
   RDV: ***NO BLOOD*** *(Controller/Supervisor)*
   changes to
   RDV: ***BLOOD*** *(Controller/Supervisor)*

4.8.3.13 Calibration BICLF and ENDLF Ratio

You can set the expected values for the **BICLF** and **ENDLF** ratio. Thus the mixing ratio is monitored to prevent the use of false concentrates.

- **BICLF**: The mixing ratio between H_2O and bicarbonate
- **ENDLF**: The mixing ratio between H_2O and acid

The ratio between bicarbonate, acid/acetate and water is monitored during dialysis. The mixing ratio is monitored and dialysis with false concentrates can be prevented.

All concentrates applied by the user must be checked, during commissioning. If necessary the limit ratio value for bicarbonate and acid/acetate respectively, must be adapted to each machine to meet the customer specific requirements.

ENDLF Ratio for Acid Concentrate with Ratio 1:44

The **ENDLF ratio** should be set to 38 if an acid concentrate is used with a ratio of 1:44.

The acetate dialysis must be disabled, because an acetate dialysis is not possible with this setting: *Treatment Support*, *System Configuration*, *Dialysate Side Parameters, Acetate Mode Disabled (YES)*.

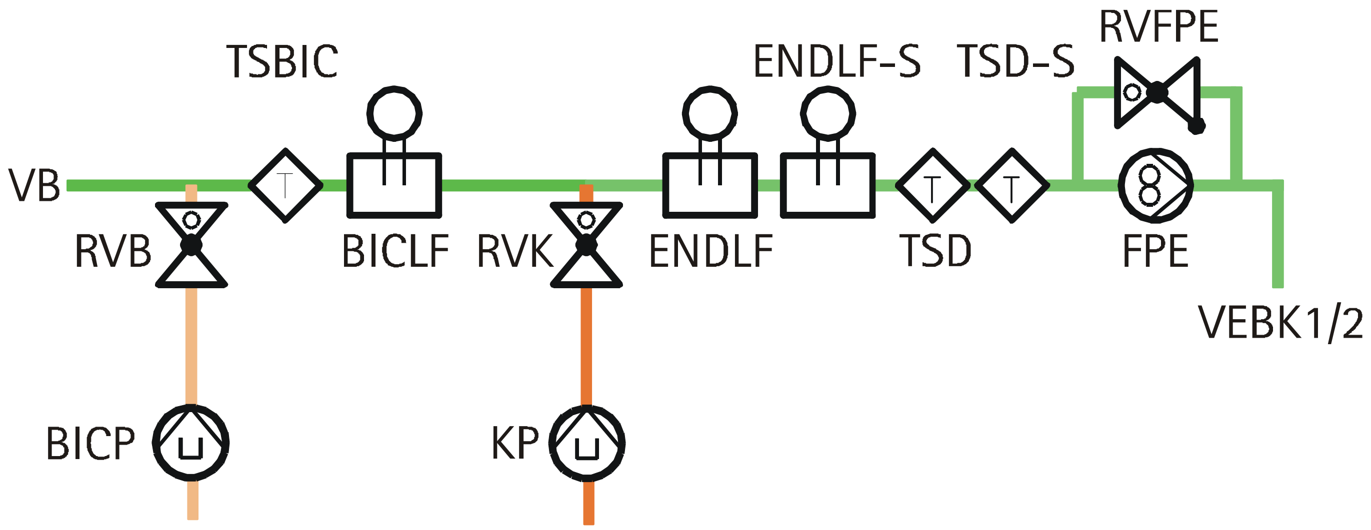
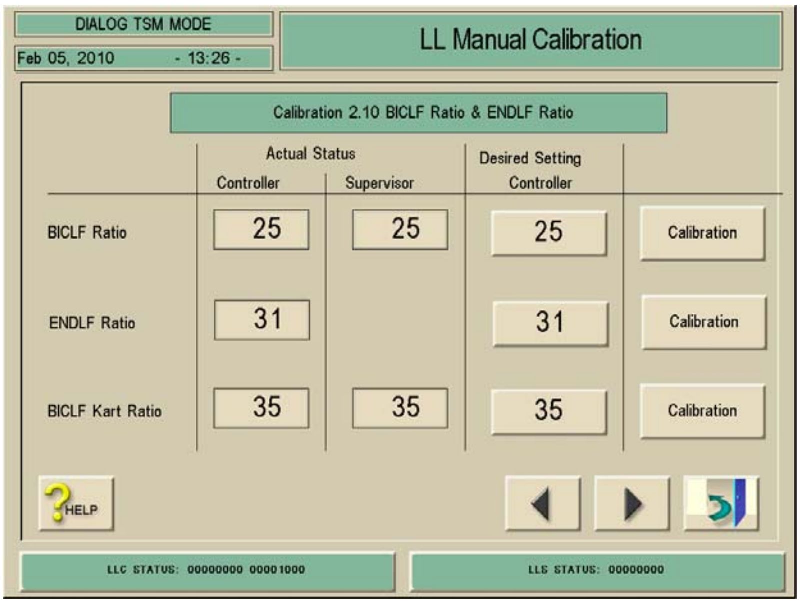


Fig.: BICLF and ENDLF Conductivity Sensors

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *BICLF and ENDLF Ratio* menu by pressing on the line *Calibration 2.10 BICLF and ENDLF Ratio*. The following menu is displayed.



Calibration 2.10 BICLF Ratio & ENDLF Ratio

	Actual Status Controller	Actual Status Supervisor	Desired Setting Controller	
BICLF Ratio	25	25	25	Calibration
ENDLF Ratio	31		31	Calibration
BICLF Kart Ratio	35	35	35	Calibration

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

The *BICLF Cart Ratio* is only displayed if the bicarbonate cartridge holder option is activated in the *Production Report*, *LLC Options*, *Holder for BIC Cartridge*.

You can determine the limit of the **ENDLF ratio** (measured at the end conductivity sensor **ENDLF**).

Ratio Values (Factory Settings)

BICLF Ratio: **25** (ratio water/bicarbonate for canister operation)

ENDLF Ratio: **31** (bicarbonate mode=ratio water/acid)
(acetate mode=ratio water/acetate)

BIC Cart Ratio: **35** (ratio water/bicarbonate for cartridge operation)

Bicarbonate Therapy

The **ENDLF ratio** limit value 31 (factory setting, can be modified) must not be exceeded. An alarm is activated if this **ENDLF ratio** limit is exceeded.

Bicarbonate Mode		
Upper Limit ENDLF Ratio:	<31	
Default Value BICLF Ratio:	25 ± 7 (canister)	
Default Value BICLF Ratio:	35 ± 10 (cartridge)	
	Setting Range (ENDLF Ratio 14 mS/cm)	**Setting Range (BICLF Ratio 3 mS/cm)**
Acid	10 to 50	-
Bicarbonate	-	10 to 50 (canister) 25 to 50 (cartridge)
Concentrate Pump **KP**:	Suction Rod (red)	
Bicarbonate Pump **BICP**:	Suction Rod (blue)	

Acetate Therapy

The **ENDLF ratio** limit value must not fall below 31 (factory setting, can be modified). An alarm is activated if this **ENDLF ratio** limit is lower than 31.

Acetate Mode		
Lower Limit ENDLF RATIO:	>31	
	Setting Range (ENDLF Ratio 14 mS/cm)	**Setting Range (BICLF Ratio 3 mS/cm)**
Acetate	10 to 50	-
Concentrate Pump **KP**:	Suction Rod (red)	
BICP:	is deactivated in acetate mode	

The **BICLF Ratio** and **ENDLF ratio** limits can be modified in the given limits. These limits were determined and set to meet the general requirements. The Dialog is delivered with a standard factory setting. Concentrates, which are individually composed and applied in dialysis centres, can differ from these standard values.

The delivery rates of **KP** and **BICP** must be calibrated correctly prior to determining the actual ratio.

1. Check Bicarbonate

Check the conductivity of all concentrates in the therapy main menu, according to the prerequisites of the customer (setting of **ENDLF ratio** and **BICLF ratio**). If necessary change **END/BICLF ratio**.

1. Select the *Haemodialysis* key in *Therapy Selection*. Machine switches to *Preparation*.
2. Select the *Parameter* key, a parameter window is opened.
3. Select *Bicarbonate* key and activate bicarbonate mode.
4. Connect the respective concentrate (bicarbonate/acid) after the request.
5. Select service overview to display the current RATIO values. Wait till stable ratio values are reached. Use the mean value if there are slight deviations.

6. Connect and check all concentrates in succession and note the **BICLF ratio** and **ENDLF ratio** values.
7. Change the treatment mode to Acetate and connect only acetate concentrates if Acetate mode is performed in that dialysis centre.
8. Wait for the conductivity to be stabilized and read the actual ENDLF ratio from the service overview.
9. Switch off the Dialog and set service switch S1 to *position 2* TSM service program.
10. Switch on Dialog.
11. Select the *Manual Test & Calibration* key.
12. Select *LL Manual Calibration* key and activate *2.10 BICLF Ratio & ENDLF Ratio*.

For bicarbonate therapy with **BICLF ratio** values near the limits or out of the default setting of 25 ±7.

11. If necessary enter the value for **BICLF ratio** (mean value of all bicarbonates) in *BICLF Ratio Desired Setting Controller 25* key (default value 25).
12. Confirm and save the entered value with the *Calibration* key.

ℹ

To prevent alarms during therapy in bicarbonate mode the value of the **ENDLF Ratio** must be less than the set **ENDLF Ratio** e.g. <31.

To prevent alarms during therapy in acetate mode the value of the **ENDLF Ratio** must be more than the set **ENDLF Ratio**, e.g. >31.

13. If necessary select *ENDLF Ratio - Desired Setting Controller - 31* (limit Value 31) and enter the value for the **ENDLF ratio** (between highest value for all acidic concentrates and lowest value for all acetate concentrates).
14. Save the entered limit value.
15. Switch off Dialog and set service switch S1 to *position 0* therapy.

2. Bicarbonate Cartridge Holder Option

The option must be activated, set and checked in the TSM service program. After the activation a ratio value must be set for the *BICLF Cart Ratio*. Check the ratio value in therapy (service overview) and adjust if necessary.

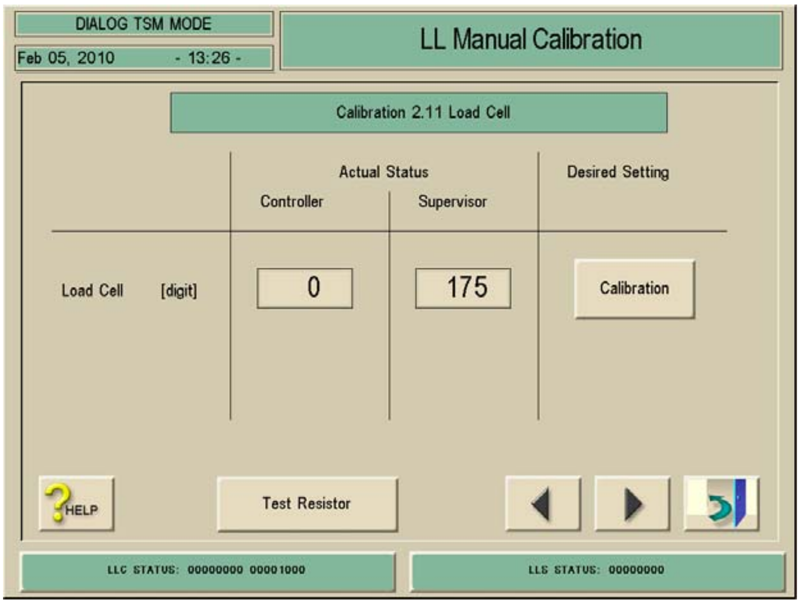
Setting Range: 25 to 50

Limits: Setting ± 10

☞

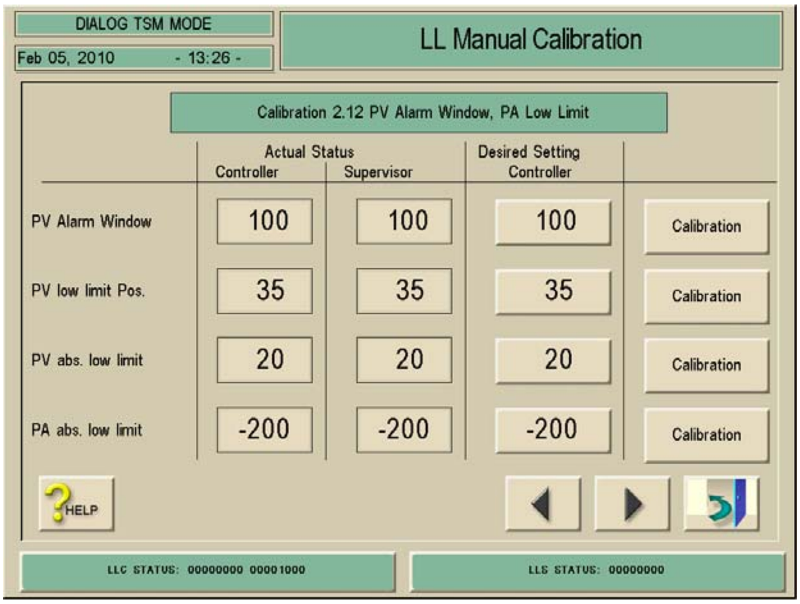
1. Enter 35 in *Desired Setting Controller* for the *BICLF Cart Ratio*.
2. Save the entered value with the *Calibration* key.
3. Check the bicarbonate ratio value in therapy.

4.8.3.14 Calibration Load Cell



Not applicable.

4.8.3.15 Calibration PV Alarm Window, PA Low Limit



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LL Manual Calibration

Calibration 2.12 PV Alarm Window, PA Low Limit

	Actual Status		Desired Setting
	Controller	Supervisor	Controller
PV Alarm Window	100	100	100
PV low limit Pos.	35	35	35
PV abs. low limit	20	20	20
PA abs. low limit	-200	-200	-200

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *PV Alarm Window, PA Low Limit* menu by pressing on the line *Calibration 2.12 PV Alarm Window, PA Low Limit*. The following menu is displayed.

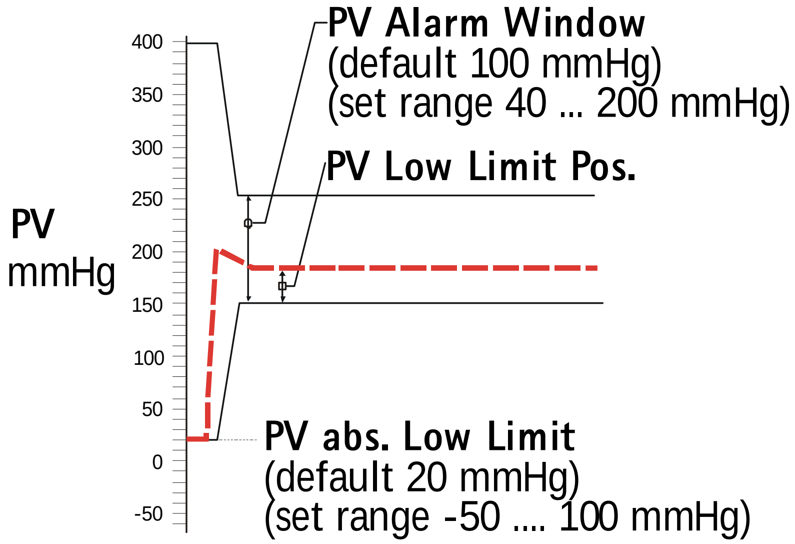


Fig.: PV Settings

PV Alarm Window

You can set the window values for the alarm limits of the **PV** monitoring for therapy.

PV Low Limit Position

You can set the low limit position and window values for the alarm limits of the **PV** monitoring for therapy.

For all Limit Settings (PA and PV)

PV Absolute Low Limit

If any setting values are changed these must be in agreement with the user, because any value can be used as a possible indication for "bleeding" (e.g. if the venous access to the patient is disconnected). Furthermore please note that the LLS limit value is 10 mmHg under the *PV Abs. Low Limit* (protection system).

You can set the absolute low limit for **PV** and the window values for the alarm size and position of the **PV** monitoring for therapy.

The supervisor uses a tolerance of 10 mmHg for monitoring the **PV** limit values to prevent double alarms.

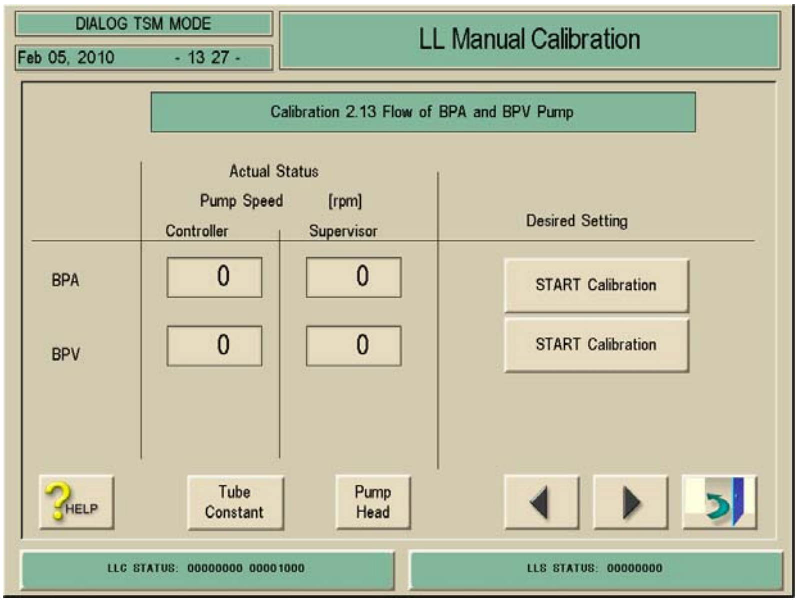
PA Absolute Low Limit

The set *PA Absolute Low Limit* value (-200 mmHg) is used as limit in therapy and TSM service program/system configuration.

4.8.3.16 Calibration Flow Rate of BPA and BPV/OSP

The tube constants can be directly entered or calculated via a comparison measurement. **BPA** and **BPV/OSP** (option HDF online substitution pump) can be activated with the *START Calibration* key. The delivered volume is measured in ml and entered as reference value. The pressure conditions for the tube system during measurement must be identical with the pressure conditions in therapy.

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Flow of BPA and BPV/OSP* menu by pressing on the line *Calibration 2.13 Flow of BPA and BPV/OSP*. The following menu is displayed.

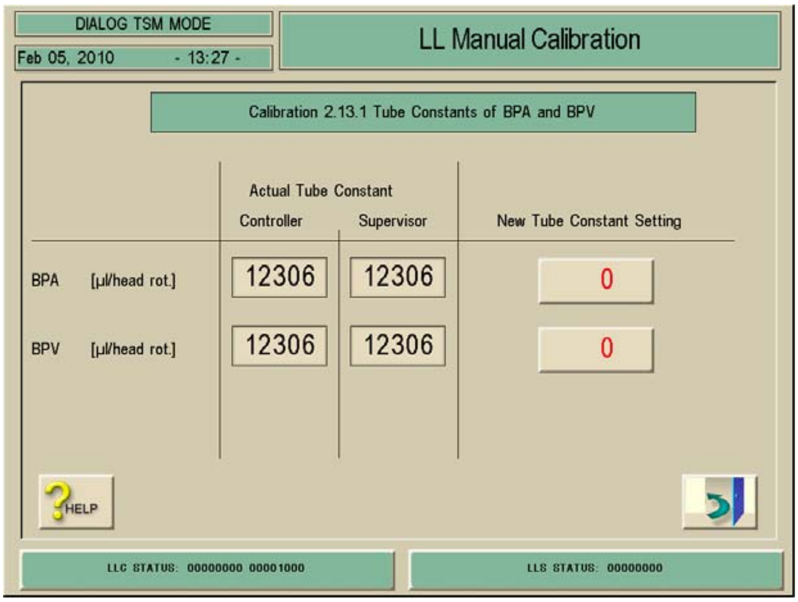


BPA: Controller 0, Supervisor 0
BPV: Controller 0, Supervisor 0

LLC STATUS: 00000000 00001000
LLS STATUS: 00000000

Tube Constant

1. Press the *Tube Constant* key to activate the menu *Calibration 2.13.1 Tube Constants of BPA and BPV*. The following menu is displayed.



BPA [µl/head rot.] 12306 12306 0
BPV [µl/head rot.] 12306 12306 0

LLC STATUS: 00000000 00001000
LLS STATUS: 00000000

The following tube constants must be entered for the applied tubing system.

8 x 12 Tubing System

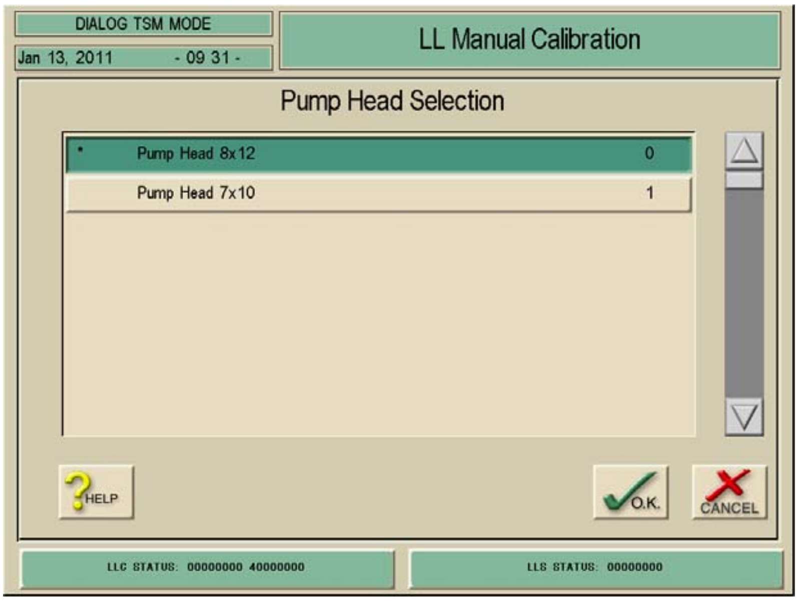
BPA: 12306 µl/head rotation
BPV: 12306 µl/head rotation

7 x 10 Tubing System

BPA: 9293 µl/head rotation
BPV: 9296 µl/head rotation

Pump Head

1. Press the *Pump Head* key to activate the menu *Pump Head Selection*. The following menu is displayed.



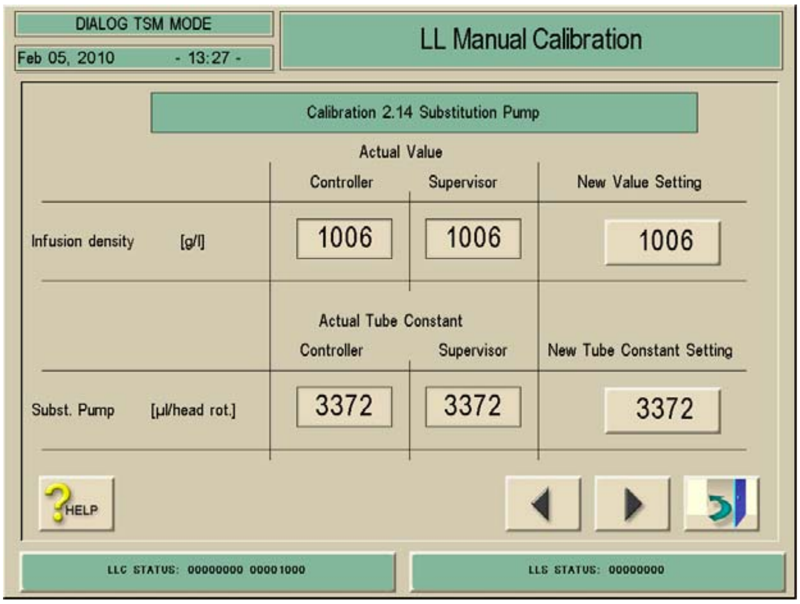
* Pump Head 8x12 0
Pump Head 7x10 1

LLC STATUS: 00000000 40000000
LLS STATUS: 00000000

You can select the pump head roller type used in the blood pumps.

- Pump head 8 x 12
- Pump head 7 x 10 (option)

4.8.3.17 Infusion Density Substitution Pump

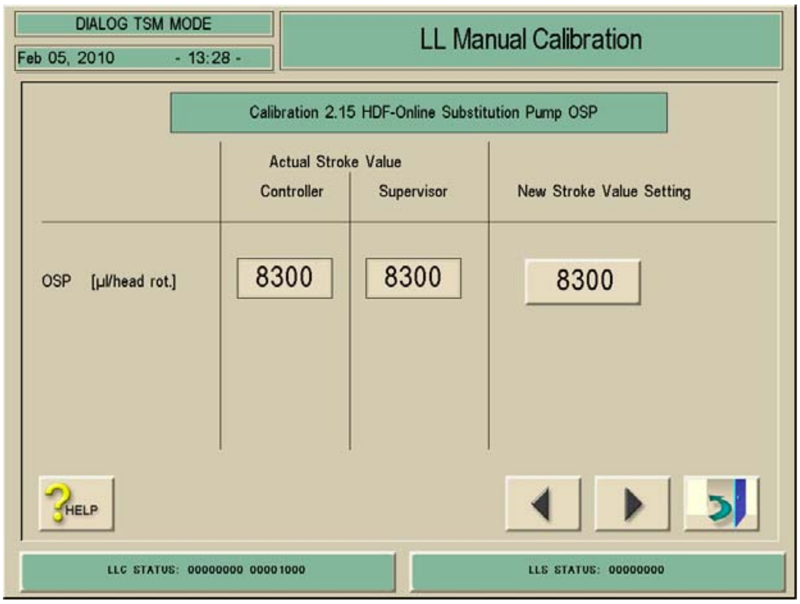


	Actual Value Controller	Actual Value Supervisor	New Value Setting
Infusion density [g/l]	1006	1006	1006

	Actual Tube Constant Controller	Actual Tube Constant Supervisor	New Tube Constant Setting
Subst. Pump [µl/head rot.]	3372	3372	3372

Not applicable.

4.8.3.18 Stroke Value HDF Online Substitution Pump OSP

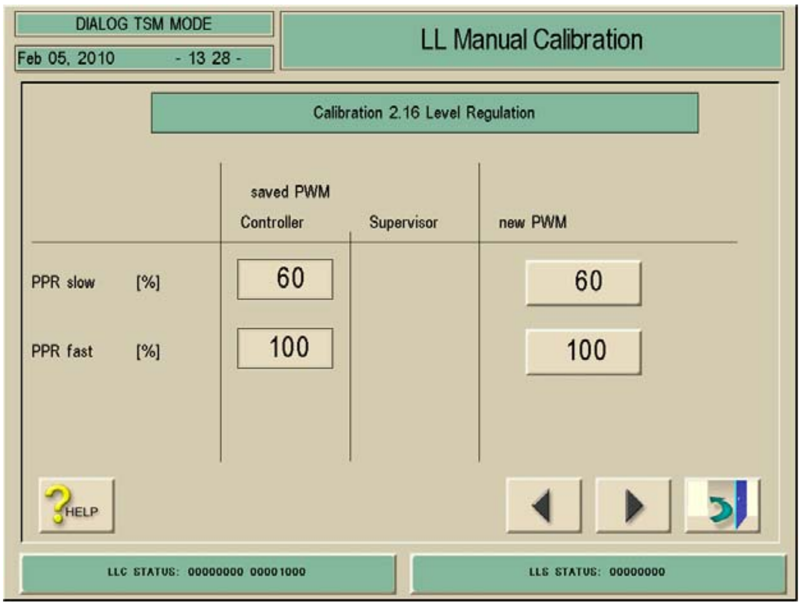


OSP [µl/head rot.] Controller: 8300, Supervisor: 8300, New Stroke Value Setting: 8300

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *HDF Online Substitution Pump OSP* menu by pressing on the line *Calibration 2.15 HDF Online Substitution Pump OSP*. The following menu is displayed.

Stroke Value HDF Online Substitution Pump OSP	The stroke value must be set to 8300 (for pump head 8 x 12).

4.8.3.19 Level Regulation



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LL Manual Calibration

Calibration 2.16 Level Regulation

	saved PWM Controller	Supervisor	new PWM
PPR slow [%]	60		60
PPR fast [%]	100		100

LLC STATUS: 00000000 00001000

LLS STATUS: 00000000

1. Activate the *LL Manual Calibration* menu with the *LL Manual Calibration* key in the *Manual Test and Calibration* menu.
2. Activate the *Level Regulation* menu by pressing on the line *Calibration 2.16 Level regulation*. The following menu is displayed.

Level Regulation

The speed of the level regulation pump (LRP = PPR) can be set for the slow mode and for the fast mode.

The settings are (see default table in chapter 3):

- 60 % for the slow mode
- 100 % for the fast mode

The default settings should not be changed, unless instructed otherwise.

4.8.3.20 Calibration Inlet Flow Pump Nonreturn Valve RVFPE

You can calibrate the inlet flow pump nonreturn valve **RVFPE**.

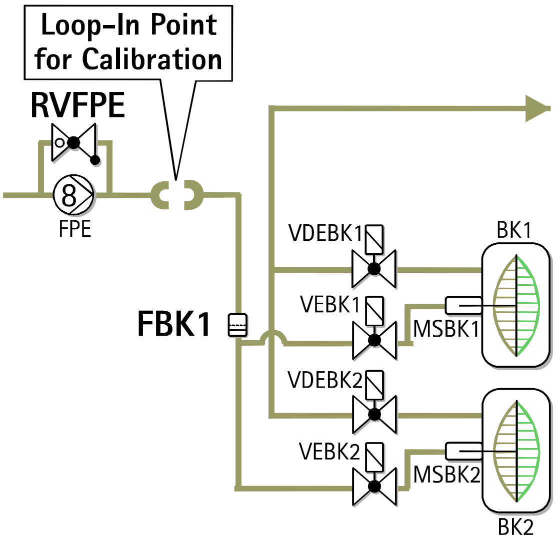


Fig.: Calibration RVFPE/Loop-In Point

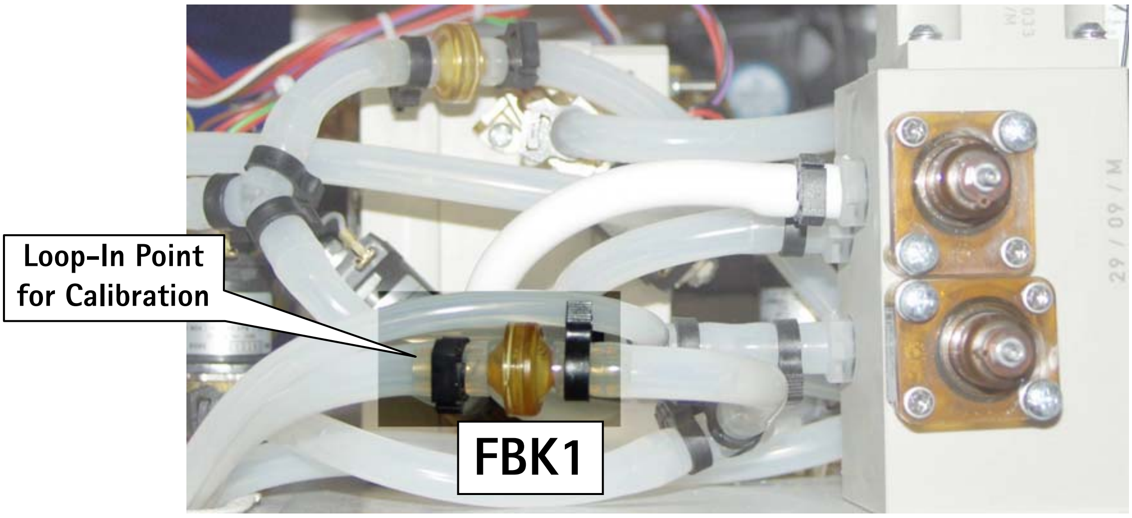


Fig.: UF Sub-Rack with FBK1

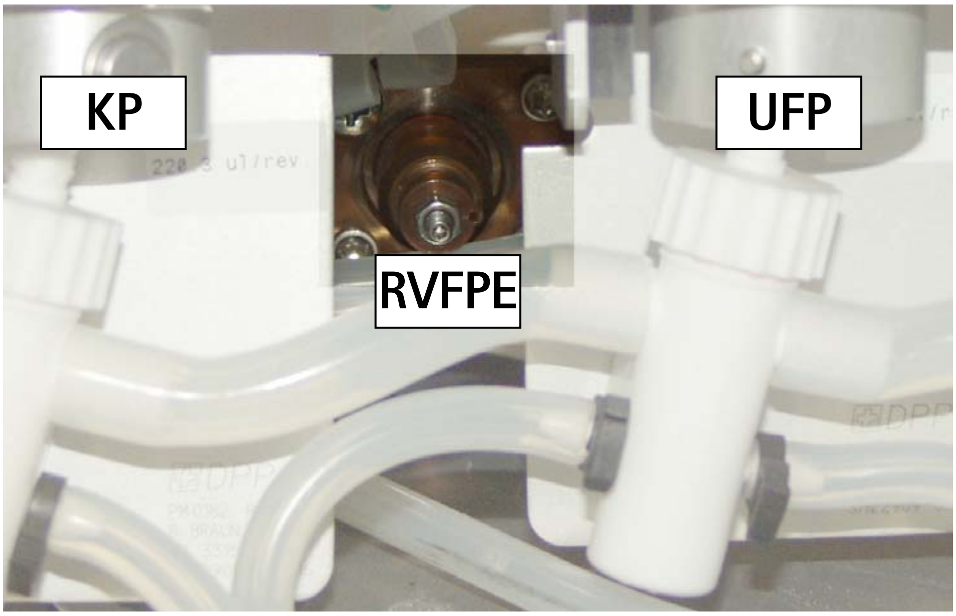


Fig.: DF Sub-Rack with RVFPE

- Manometer 0 to 4 bar (art. no. 7701357 or equivalent)
- Flow meter (art. no. 770085A or equivalent)
- Allen key 3 mm
- Size 7 spanner

Please ensure that the manometer and connection tubing are at the same level as the nonreturn valve during calibration.

1. Connect manometer and flow meter between flow pump **FPE** and **FBK1**.
2. Select *Test 1.20 Water Part (Overview)* in TSM.
3. Increase slowly the speed of **FPA**, until a flow of 500 ml/min is reached.
4. Set temperature **TSD** to 37 °C and wait until temperature is reached.
5. Clamp tubing between manometer and **FBK1**.
6. Loosen lock nut on **RVFPE** adjustment screw.
7. Set a pressure of 975 mmHg (1300 mbar) with the adjustment screw of **RVFPE**.
    - 975 mmHg ±37 mmHg
    - 1300 mbar ±50 mbar
8. Tighten lock nut again.
9. Remove manometer and flow meter.

4.8.3.21 Calibration Dialysate Nonreturn Valve RVDA

You can calibrate the dialysate nonreturn valve **RVDA**.

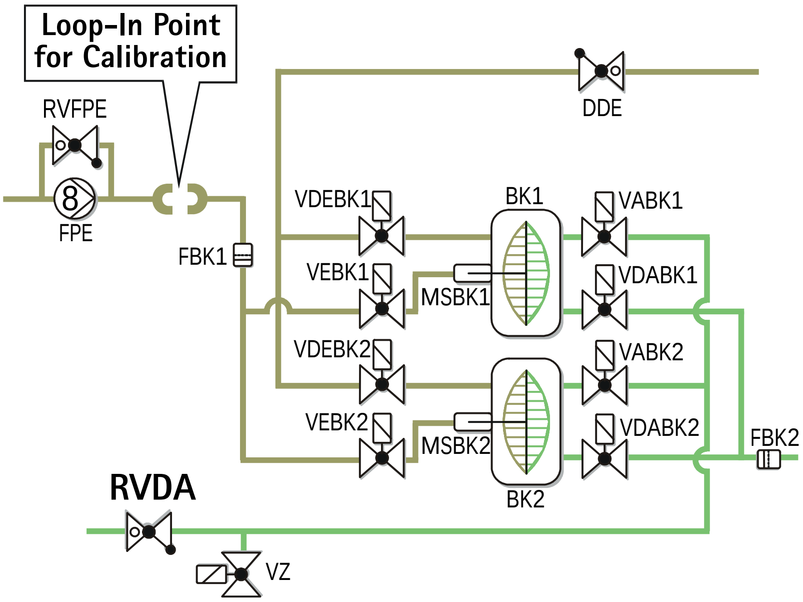


Fig.: Calibration RVDA/Loop-In Point

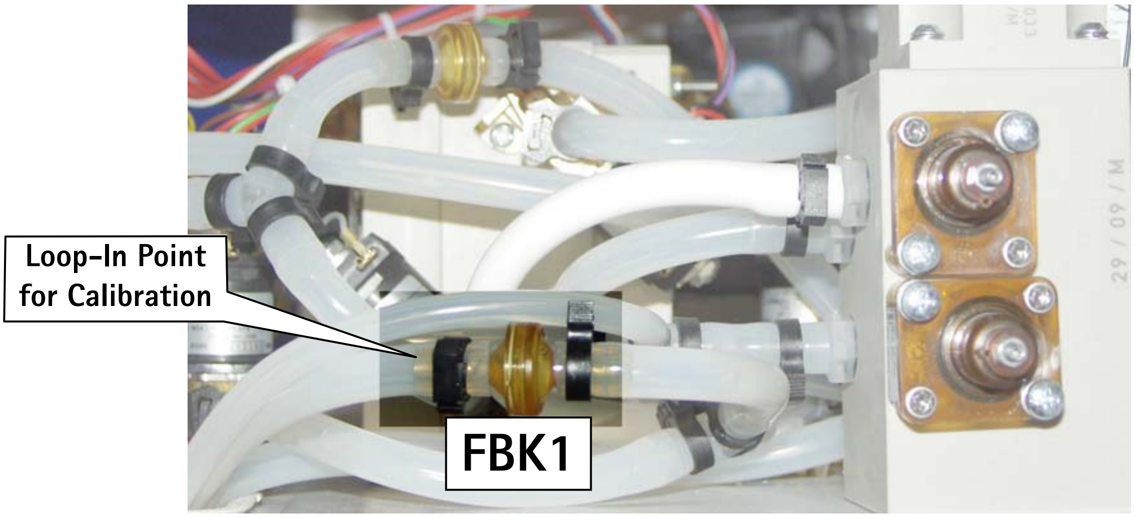


Fig.: UF Sub-Rack with FBK1

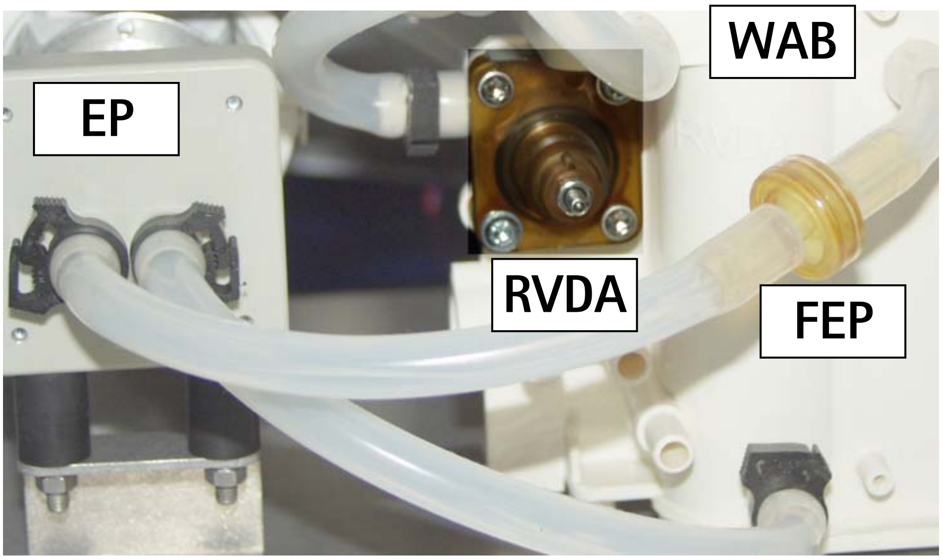


Fig.: Water Sub-Rack with RVDA

- Manometer 0 to 4 bar (art. no. 7701357 or equivalent)
- Flow meter (art. no. 770085A or equivalent)
- Allen key 3 mm

Please ensure that the manometer and connection tubing are at the same level as the balance chamber/rinsing bridge and dialyser during calibration.

1. Remove lower front cover.

2. Connect manometer and flow meter between flow pump **FPE** and **FBK1**.

3. Select *Test 1.20 Water Part (Overview)* in TSM.

4. Increase slowly the speed of **FPA**, until a flow of 500 ml/min is reached.

5. Set temperature **TSD** to 37 °C and wait until temperature is reached.

6. Loosen lock nut on **RVDA** adjustment screw.

7. Set a pressure of 300 mmHg/400 mbar (HDF online 375 mmHg/500 mbar) with the adjustment screw of **RVDA**.

  - 300 mmHg ±37 mmHg
  - 400 mbar ±50 mbar

  HDF Online

  - 375 mmHg ±37 mmHg
  - 500 mbar ±50 mbar

8. Tighten lock nut again.

9. Remove manometer and flow meter.

4.8.3.22 Calibration Outlet Flow Pump Nonreturn Valve RVFPA

You can calibrate the outlet flow pump nonreturn valve **RVFPA**.

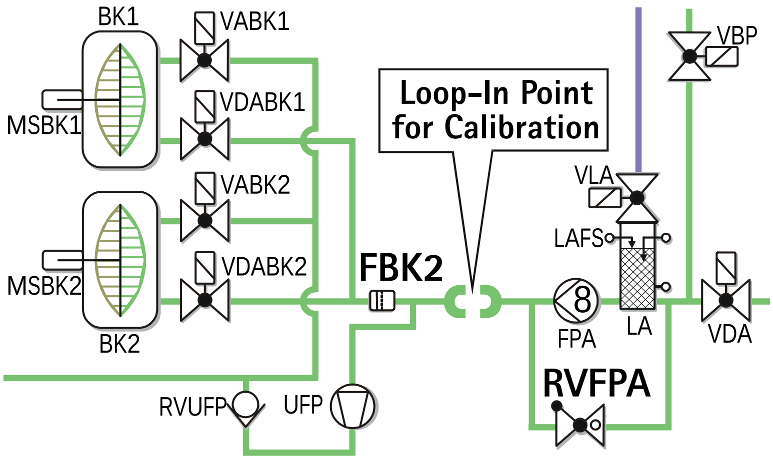


Fig.: Calibration RVFPA/Loop-In Point

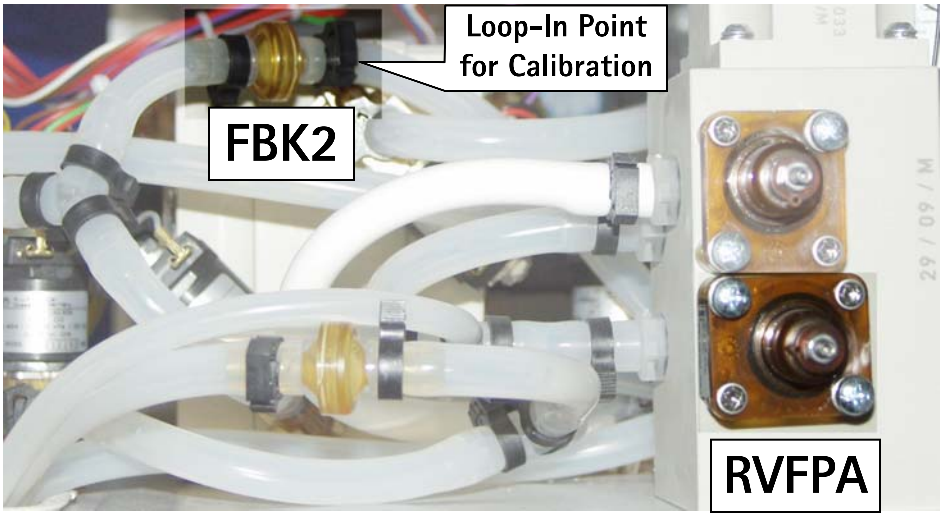


Fig.: UF Sub-Rack with FBK2 and RVFPA

- Manometer 0 to 4 bar (art. no. 7701357)
- Flow meter (art. no. 770085A or equivalent)
- Allen key 3 mm
- Size 7 spanner

Please ensure that the manometer and connection tubing are at the same level as the nonreturn valve during calibration.

1. Connect manometer and flow meter between flow pump **FPA** and **FBK2**.
2. Immerge both dialyser couplings into a vessel filled with warm water (30 to 40 °C). Thus uncontrolled pressure conditions are prevented.
3. Select *Test 1.20 Water Part (Overview)* in TSM.
4. Increase slowly the speed of **FPA**, until a flow of 500 ml/min is reached.
5. Set temperature **TSD** to 37 °C and wait for the temperature reached.
6. Clamp tubing between manometer and **FBK2**.
7. Loosen lock nut on **RVFPA** adjustment screw.
8. Set a pressure of 975 mmHg (1300 mbar) with the adjustment screw of **RVFPA**.
   - 975 mmHg ±37 mmHg
   - 1300 mbar ±50 mbar
9. Tighten lock nut again.
10. Remove manometer and flow meter.

4.8.3.23 Calibration Dialyser Inlet Throttle Valve DDE

You can calibrate the dialyser inlet throttle valve **DDE**.

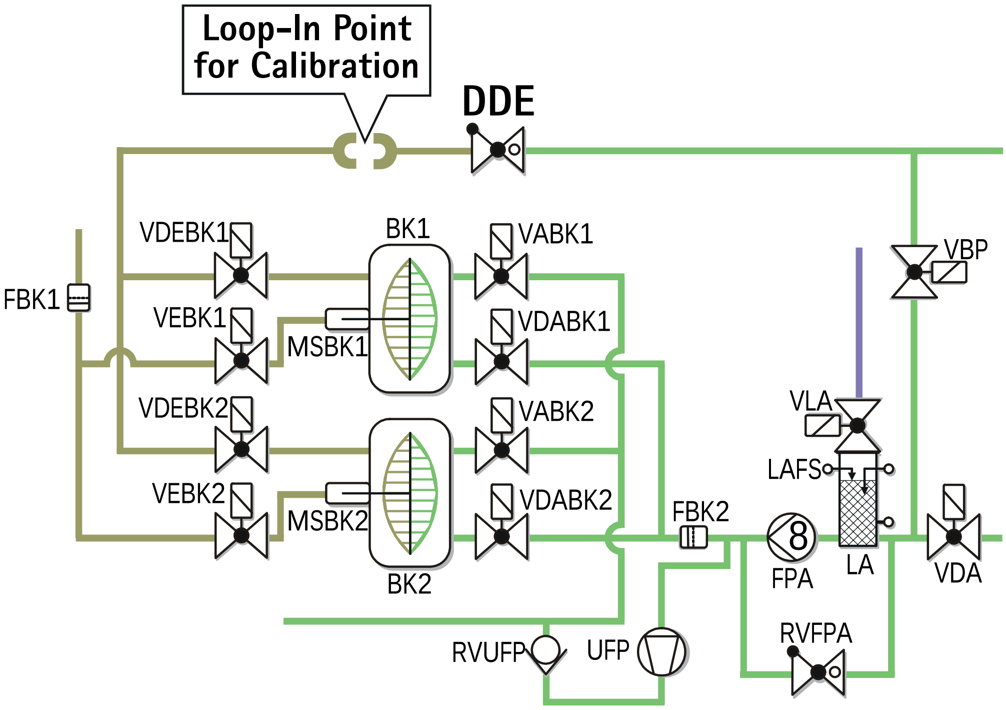


Fig.: Calibration DDE/Loop-In Point

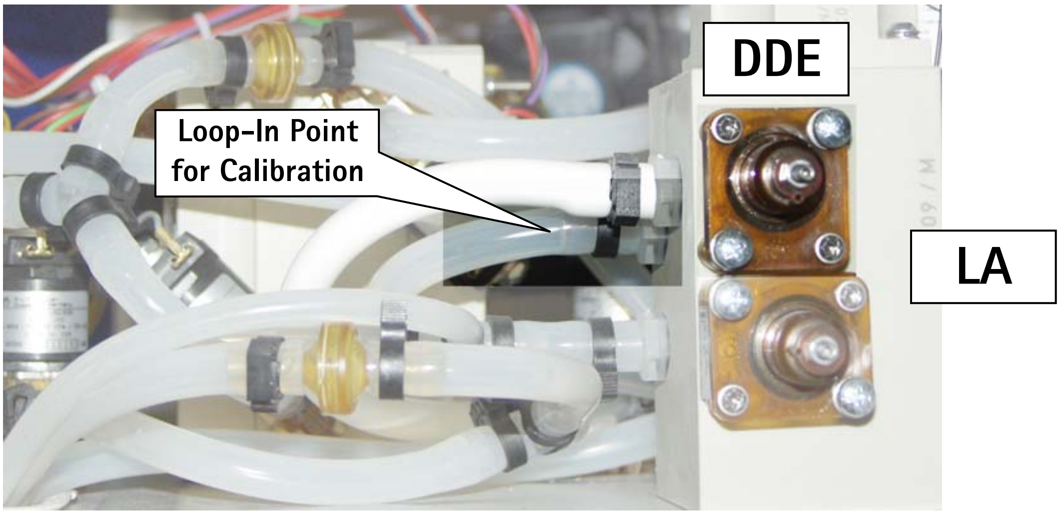


Fig.: UF Sub-Rack with DDE

- Manometer 0 to 4 bar (art. no. 770135A or equivalent)
- Flow meter (art. no. 7700857 or equivalent)
- Allen key3 mm
- Size 7 spanner

Please ensure that the manometer and connection tubing are at the same level as the throttle during calibration.

1. Connect manometer and flow meter between **VDEBK1/2** and dialysate inlet throttle **DDE**.
2. Immerge both dialysate couplings into a vessel filled with water warm water (30 to 40 °C). Thus uncontrolled pressure conditions are prevented.
3. Select *Test 1.20 Water Part (Overview)* in TSM.
4. Increase slowly the speed of **FPA**, until a flow of 500 ml/min is reached.

5. Set temperature **TSD** to 37 °C and wait for the temperature reached.

Note for machines equipped with DF filter:

The **DF** filter and the tubings going to the **DF** filter must be free of air before the **DDE** can be adjusted. Therefore the machine must be switched into Bypass for a few minutes to purge the air. Switch off the bypass for the calibration of **DDE** as it has to be done in mainflow.

6. Loosen lock nut on **DDE** adjustment screw.

7. Set a pressure of 300 mmHg/400 mbar with the adjustment screw of **DDE**.
- 300 mmHg ±37 mmHg
- 400 mbar ±50 mbar

8. Tighten lock nut again.

9. Remove manometer and flow meter.

4.8.3.24 Calibration Pressure Reducer Valve DMV

You can calibrate the pressure reducer valve **DMV**.

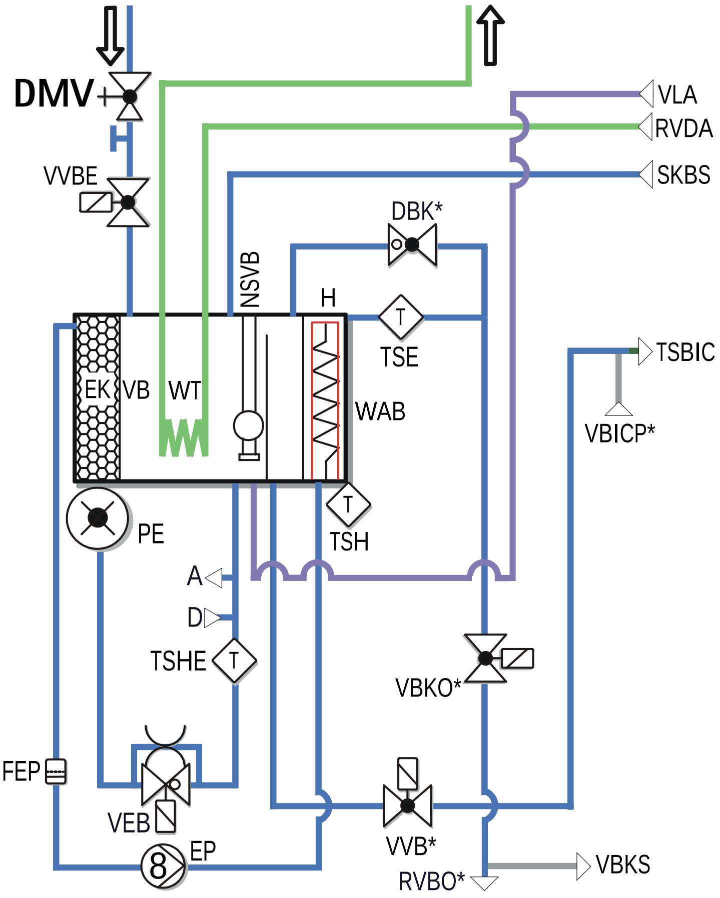


Fig.: Calibration DMV

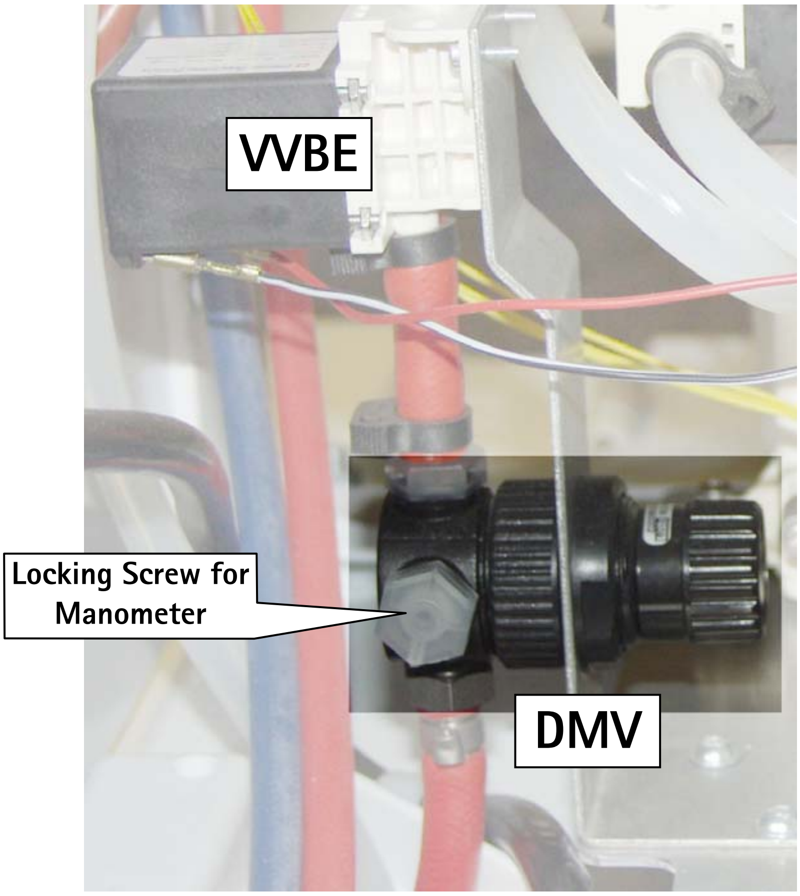


Fig.: Water Sub-Rack with DMV

- Manometer 0 to 2.5 bar (art. no. 34511571 or equivalent)

The calibration of **DMV** is performed in the dynamic operating mode (**FPE** running, level in the upline tank is controlled).

1. Disconnect water inlet hose from wall connection (close water tap if necessary).
2. Start briefly the unit to achieve a pressure free condition in the water inlet part to avoid water spraying.
3. Remove locking screw from **DMV** and screw in the manometer (if necessary use teflon tape to prevent leakages).
4. Connect water tubing and open the water tap.
5. Open the following menus in the TSM service program: *Manual Test and Calibration*, *LL Manual Test* and *1.9 Water Inlet, Upline Tank and Flow Pump FPE*.
6. Set **FPE** to approx. 1400 rpm (approx. 1200 ml/min) and open **VVBE** (the level in the upline tank must be controlled between medium and high level).
7. Pull up the adjustment knob to unlock pressure reducer valve **DMV** and set pressure to approx. 0.9 ±0.1 bar with the adjustment knob.
8. Close water tap.
9. Press down the adjustment knob to lock pressure reducer valve **DMV**.
10. Switch off Dialog.
11. Disassemble manometer.
12. Reassemble locking screw.

4.8.3.25 Gap Arterial Tubing Clamp SAKA/Venous Tubing Clamp Currentless Closed SAKV-SG

You can calibrate the gap for the arterial tubing clamp **SAKA** and the venous tubing clamp currentless closed **SAKV-SG.**

- Calibration template 1.4/1.5 (art. no. 7702493)

1. Remove cap **C** (e.g. use a sharp knife to lift out).
2. Close the respective tubing clamp in *Manual Test and Calibration*, *LL Manual Test*, *Test 1.5 Tubing Clamps*.

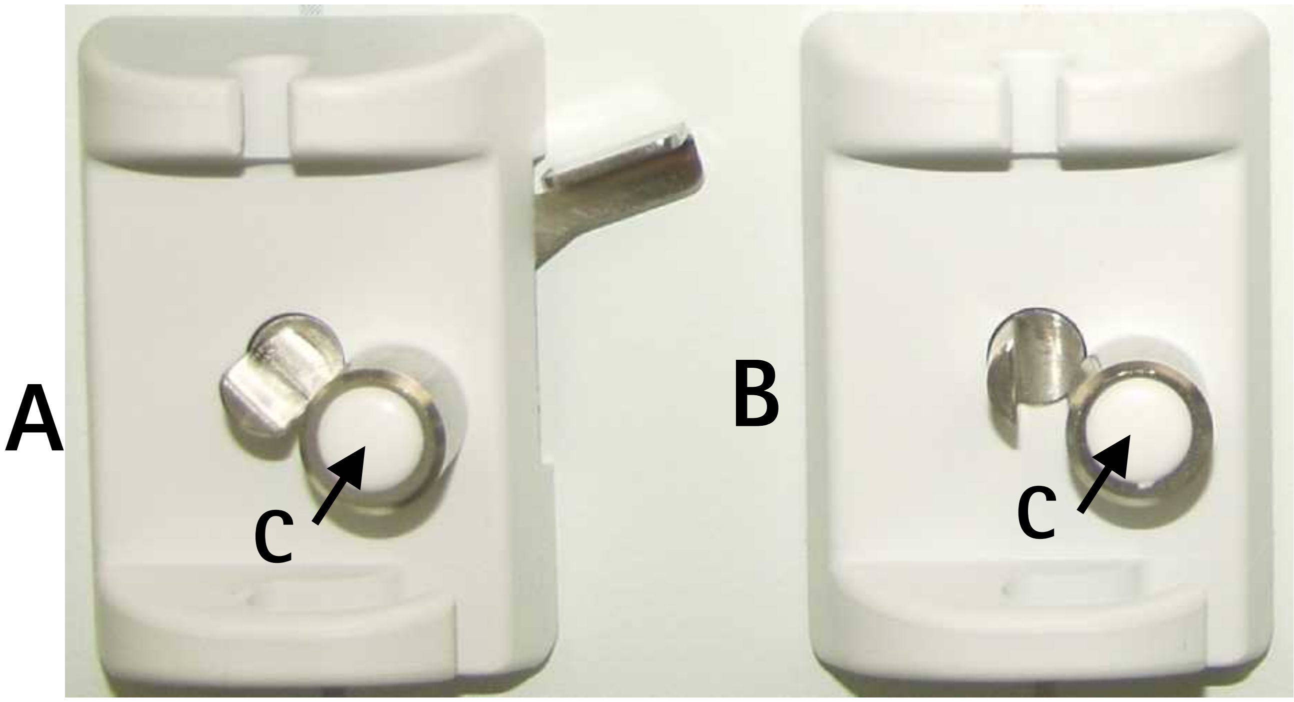
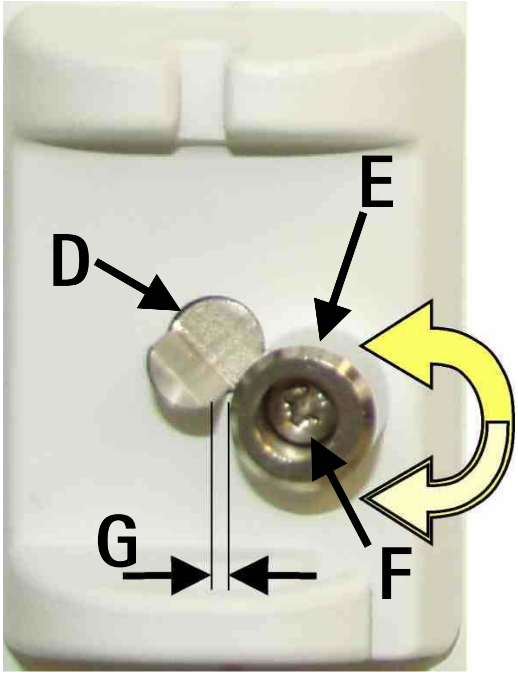


Fig.: Tubing Clamp SAKV-SG

Fig.: Tubing Clamp SAKA



Set gap **G** to 1.4 mm with 1.4 mm template.

3. Loosen screw **F**.
4. Push 1.4 mm template between clamp **D** and eccentric cam **E**.
5. Rotate eccentric cam **E** until 1.4 mm is set.
6. Tighten again screw **F**

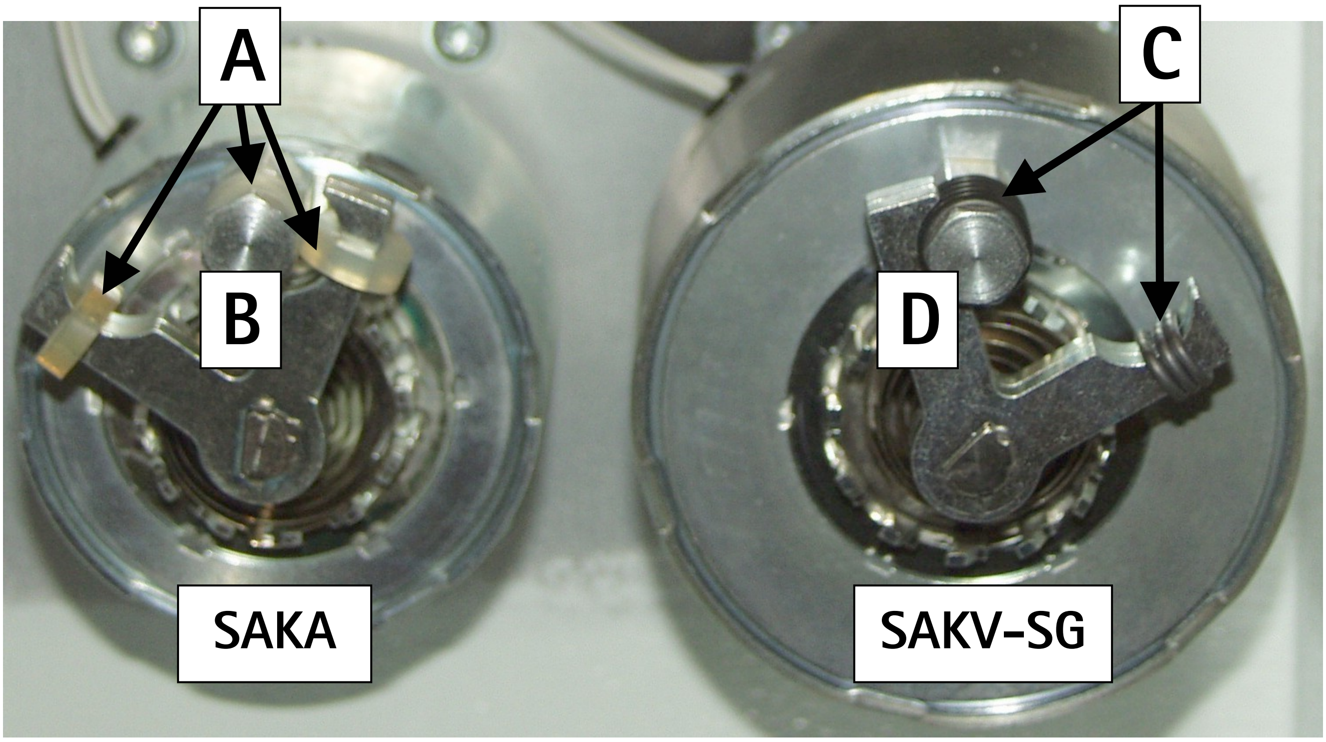
Note
The 1.4 mm template fits through the gap.

7. Check wit the 1.5 mm template.

Note
The 1.5 mm template must not fit through the gap.

8. Reassemble cap **C**.

4.8.3.26 Arterial Tubing Clamp SAKA/Venous Tubing Clamp Currentless Closed SAKV-SG



SAKA

You can check the soft stoppers **A** on the V-stopper/stopper **B** of the arterial tubing clamp **SAKA**.

- Soft stoppers art. no. 34570675

1. Open front door.
2. Check the soft stoppers **A** on the V-stopper/stopper **B**.

   Replace if soft stoppers show any damages (tears/ruptures/ brittleness).

SAKV-SG

You can check the o-rings **C** on the V-stopper/stopper **D** of the venous tubing clamp currentless closed **SAKV-SG**.

- O-ring 7 x 1.5 art. no. 34570624

3. Check the o-rings **C** on the V-stopper/stopper **D**

   Replace if o-rings show any damages (tears/ruptures/ brittleness).
4. Close front door.

4.8.3.27 Setting Servomotor for Disinfection Valve VD

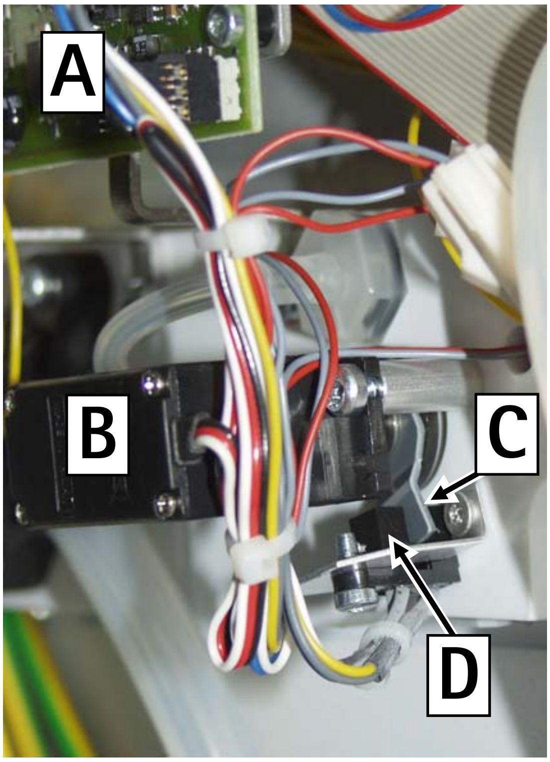


Fig.: Disinfection Valve VD/Rinsing Bridge

Basic Position Disinfection Valve VD

The servomotor and the servomotor board must only be replaced together, because they are a calibrated unit.

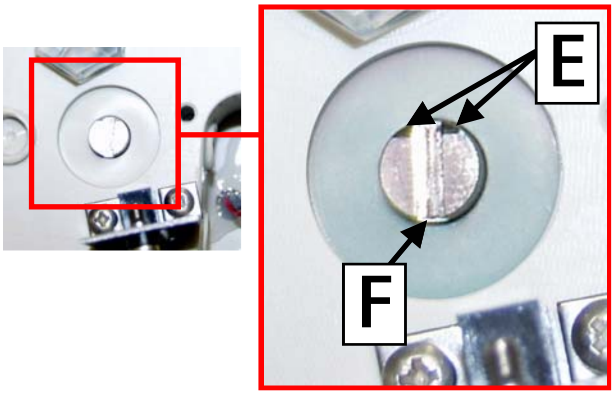
The position tag **C** of the servomotor **B** must be seated in the light barrier **D** when assembled (see figure).

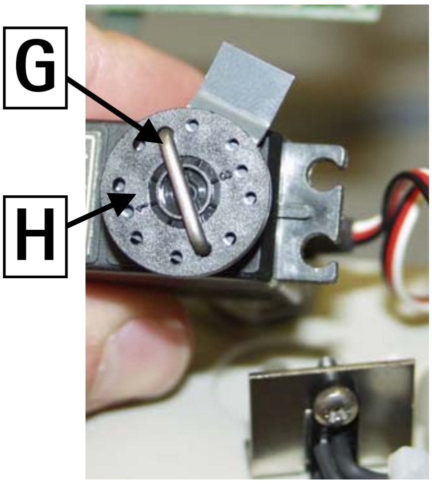
This basic position must be guaranteed if the servomotor is disassembled and assembled again on the disinfection valve (rinsing bridge). Thus the correct operation of **VD** is guaranteed, i.e. switching from the air line to the disinfection line.

In basic position the disinfection valve **VD**:

- is open to the air line, i.e. disinfectants can not be drawn in.

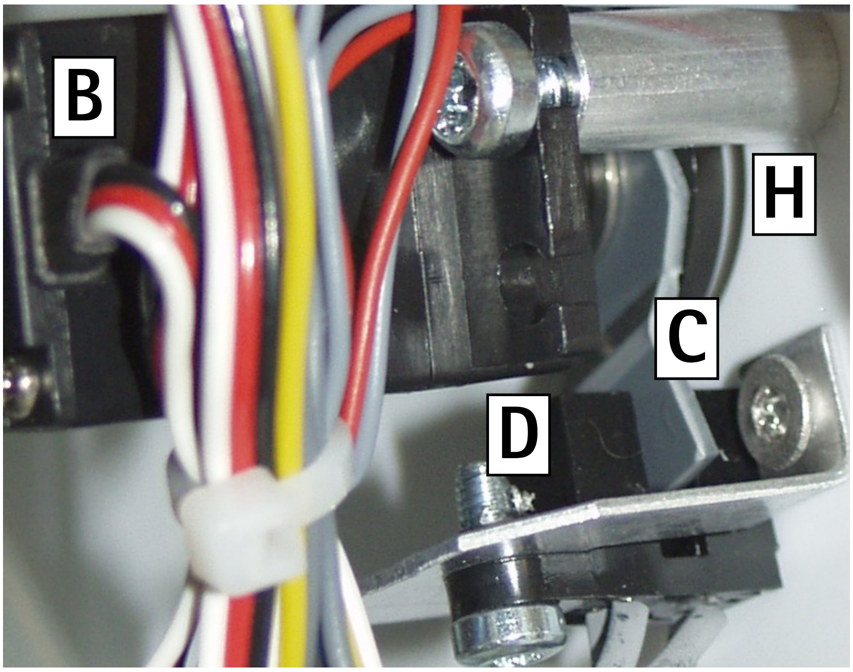
1. Open front door of Dialog.
2. Pull off the connector **A** from the disinfection valve board.
3. Disassemble servomotor **B**.
4. Prior to the assembly of the new servomotor **B:** pay attention to the position of the bevel **E** on the eccentric axle. The bevel **E** must be in upper position (see figure).





Do not pull off the bow G from the control disc H, because its position is set ex works.

5. The bow **G** on the control disc **H** must be seated in the groove **F** of the eccentric axle.

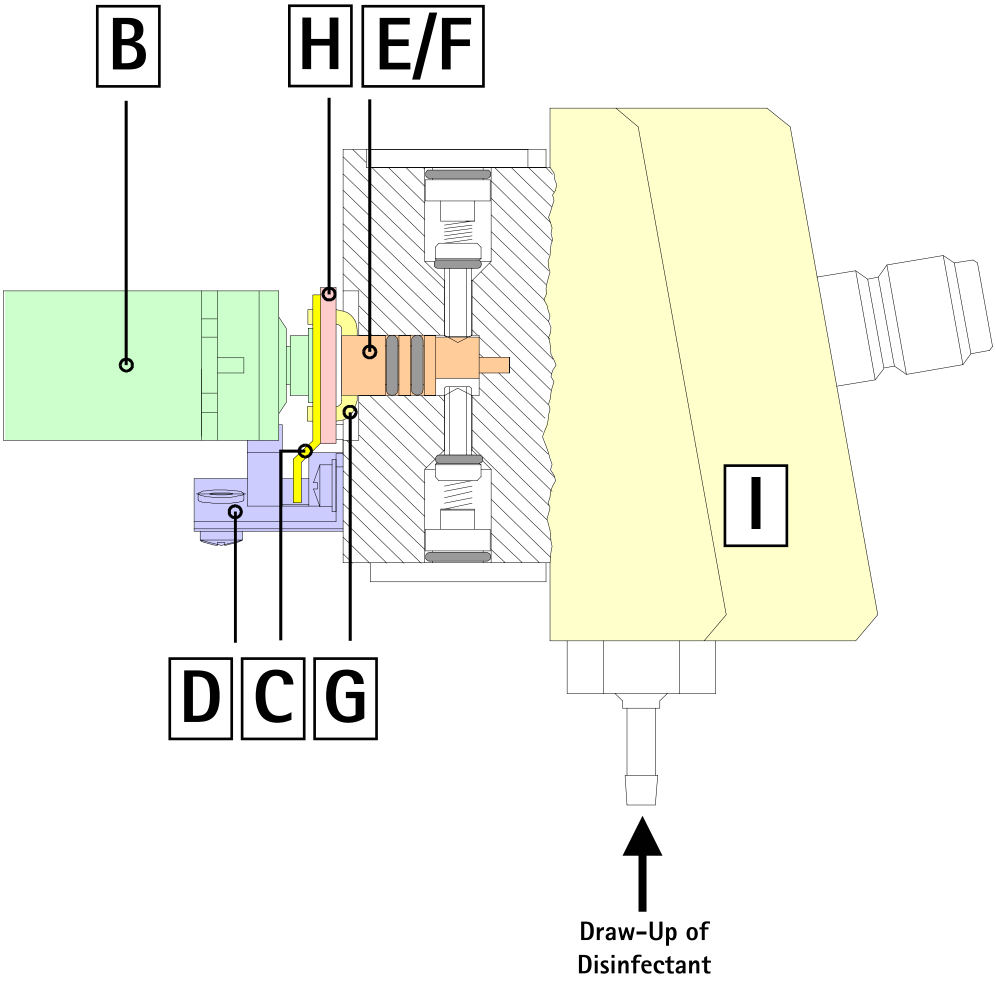


6. **Assemble servomotor B.**

   The position tag **C** of the servomotor **B** is seated in the light barrier **D**. The bow **G** (not visible) is seated in the groove **F** of the eccentric axle.

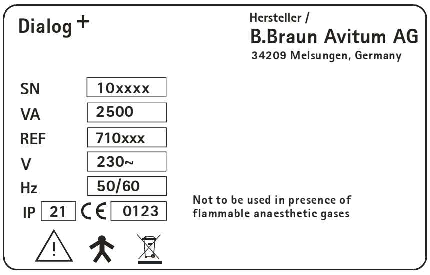
7. Plug in connector to disinfection valve board matching with the motor.

8. Check function of the disinfection valve (position tag **C** in light barrier **D**).



B Servomotor
C Position tag
D Light barrier
E Bevel on eccentric axle
F groove
G Bow (only partly visible, is seated in the eccentric groove)
H Control disc
I Rinsing bridge

4.9 Production Report



Dialog +

Hersteller /
B.Braun Avitum AG
34209 Melsungen, Germany

SN 10xxxx
VA 2500
REF 710xxx
V 230~
Hz 50/60
IP 21 CE 0123

Not to be used in presence of flammable anaesthetic gases

Fig.: Type Plate on Rear Door

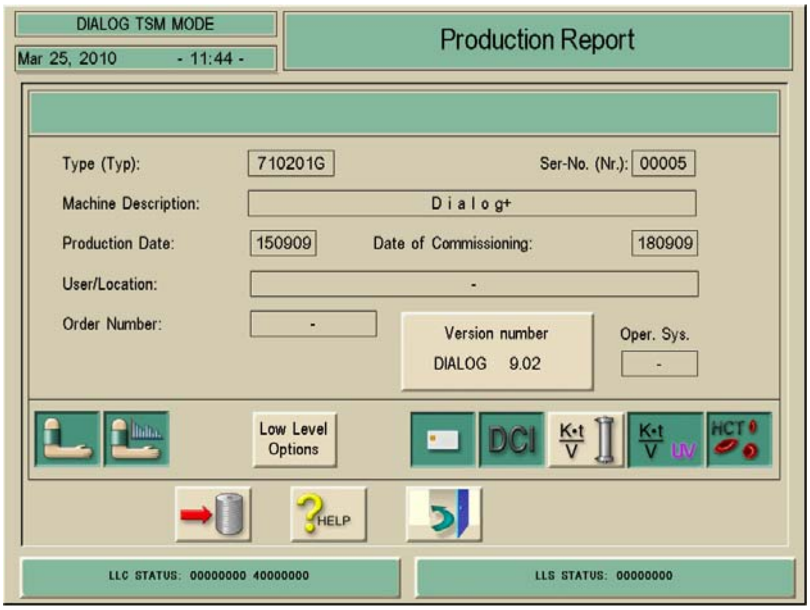
The delivery data of the Dialog are displayed in the menu, i.e. must be entered during the commissioning of the machine, e.g.:

- Type = REF (see type plate)
- Ser-No. = SN (see type plate)

Options can be activated in the following menus:

Icons
For example: bioLogic RR, card reader or K*t/V-UV (Adimea)

Low Level Options (see 4.9.2)
For example: Double pump or BIC cartridge holder



DIALOG TSM MODE
Mar 25, 2010 - 11:44 -

Production Report

Type (Typ): 710201G
Ser-No. (Nr.): 00005
Machine Description: Dialog+
Production Date: 150909
Date of Commissioning: 180909
User/Location: -
Order Number: -
Version number DIALOG 9.02
Oper. Sys. -

LLC STATUS: 00000000 40000000
LLS STATUS: 00000000

Activate the *Production Report* menu with the *Production Report* key in *TSM Main Menu*.

Options assembled in the machine must be activated. Further options present in the Dialog must also be activated in this menu or in the *Low Level Options* menu (see 4.9.2).

The following options can be activated:

- ABPM
- bioLogic RR (icon available if installed)
- Low Level Options
- Card reader
- DCI (Data Communication Interface
- K*t/V
- K*t/V-UV (Adimea)
- HCT (Crit-Line interface)

ABPM Automatic Blood Pressure Measurement

If the ABPM option is assembled in the machine or the option is retrofitted it must be selected and saved to activate the option.

bioLogic RR Automatic Blood Pressure Stabilisation

The bioLogic RR icon is displayed after the installation software was installed for the bioLogic RR option. The bioLogic RR must be selected and saved to activate the option.

Card Reader

If the card reader option is present in the machine, it must be selected and saved to activate the option.

DCI Data Communication Interface

The DCI option communicates with the Dialog machine via an RS 232 interface. The communication is performed via a DIANET protocol.

K*t/V

The *KT/V* option must be selected and saved to activate the option.

Adimea (K*t/V-UV)
(**A**ccurate **di**alysis **mea**surement)

If an Adimea option is present in the machine, it must be selected and saved to activate the option.

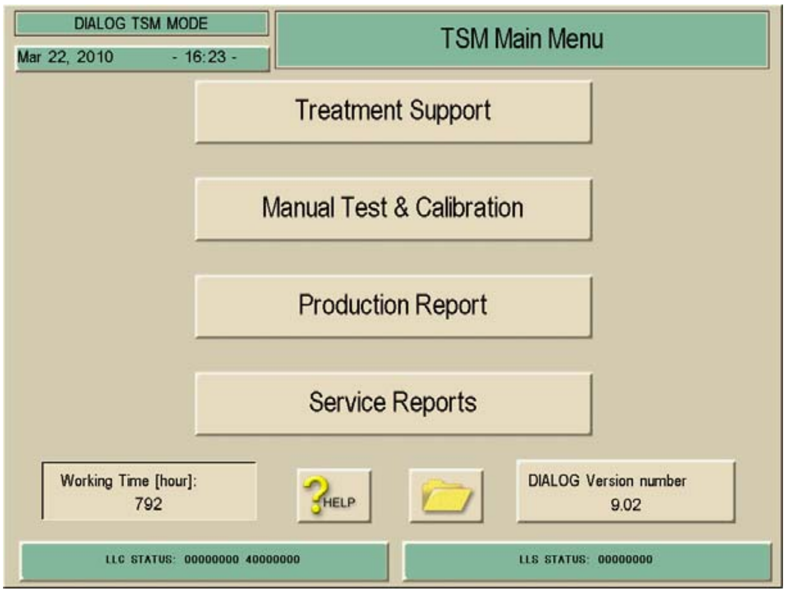
HCT Crit-Line

If a Dialog Serial Interface DSI is present in the machine, it must be selected and saved to activate the option.

Note

- The activation of the HCT Crit-Line option enables a window in therapy. This window allows the data exchange and display of measurement values to a connected HemaMetrics™ Crit-Line device.

4.9.1 Dialog Version Number



DIALOG TSM MODE

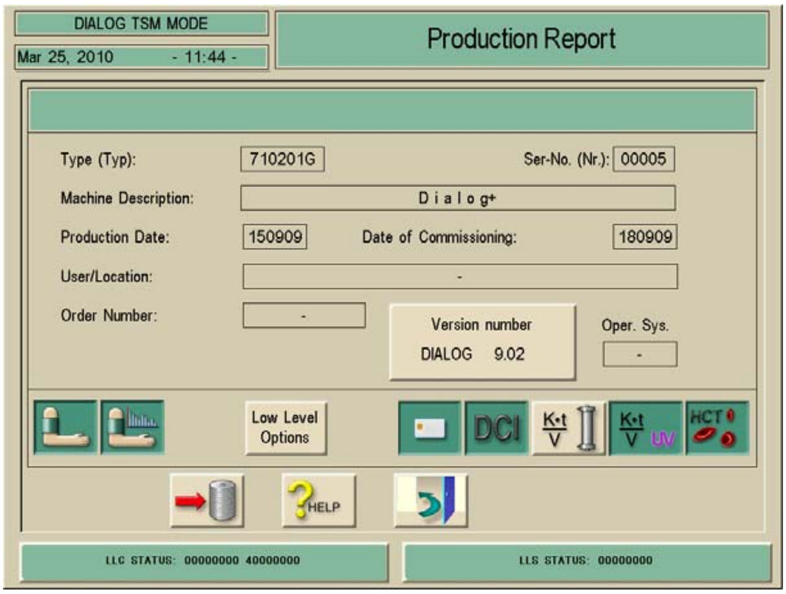
Mar 22, 2010 - 16:23 -

Working Time [hour]: 792

DIALOG Version number 9.02

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000



DIALOG TSM MODE

Mar 25, 2010 - 11:44 -

Type (Typ): 710201G

Ser-No. (Nr.): 00005

Machine Description: D i a l o g+

Production Date: 150909

Date of Commissioning: 180909

User/Location: -

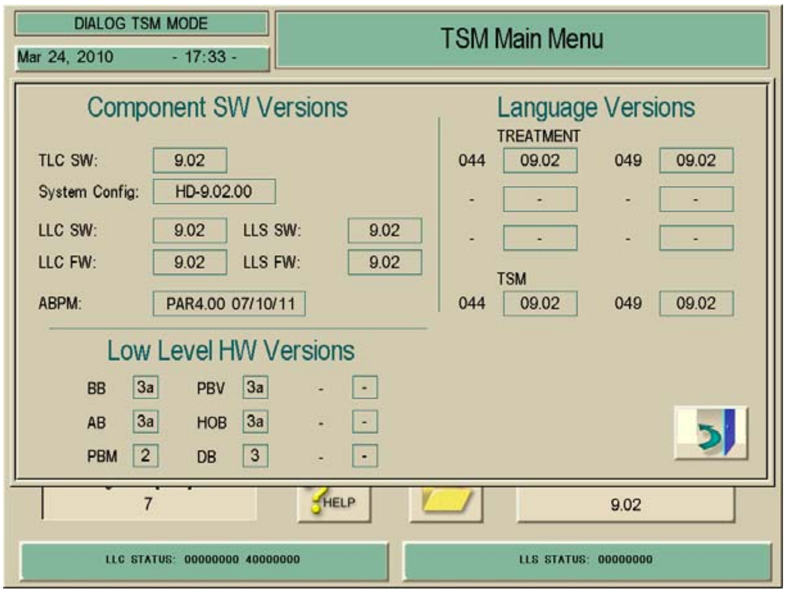
Order Number: -

Version number DIALOG 9.02

Oper. Sys. -

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000



DIALOG TSM MODE

Mar 24, 2010 - 17:33 -

Component SW Versions

TLC SW: 9.02

System Config: HD-9.02.00

LLC SW: 9.02 LLS SW: 9.02

LLC FW: 9.02 LLS FW: 9.02

ABPM: PAR4.00 07/10/11

Language Versions

TREATMENT

044 09.02 049 09.02

- - - -

- - - -

TSM

044 09.02 049 09.02

Low Level HW Versions

BB 3a PBV 3a - -

AB 3a HOB 3a - -

PBM 2 DB 3 - -

7

9.02

LLC STATUS: 00000000 40000000

LLS STATUS: 00000000

The *Dialog Version Number* menu is selected with the *Dialog Version Number* window in *Production Report*. The current software/firmware versions and hardware versions are displayed. This menu can also be selected in the *TSM Main Menu*.

The various software versions for top level, controller, supervisor, etc. are displayed and can be checked. These versions depend on the installed Dialog software version. The following software and hardware statuses can be checked:

Component SW Versions

The versions for the installed software/firmware are displayed.

- Top Level Controller Software TLC SW
- System Configuration (displays the system configuration version number for the haemodialysis machine)
- Low Level Controller Software LLC SW
- Low Level Controller Firmware LLC FW
- Low Level Supervisor Software LLS SW
- Low Level Supervisor Firmware LLS FW
- Automatic Blood Pressure Measurement ABPM (firmware for the ABPM module is displayed)

Language Versions

The installed languages are displayed.

Treatment

- 044 - English
- 049 - German
- or further therapy languages

TSM

- 044 – English
- 049 – German

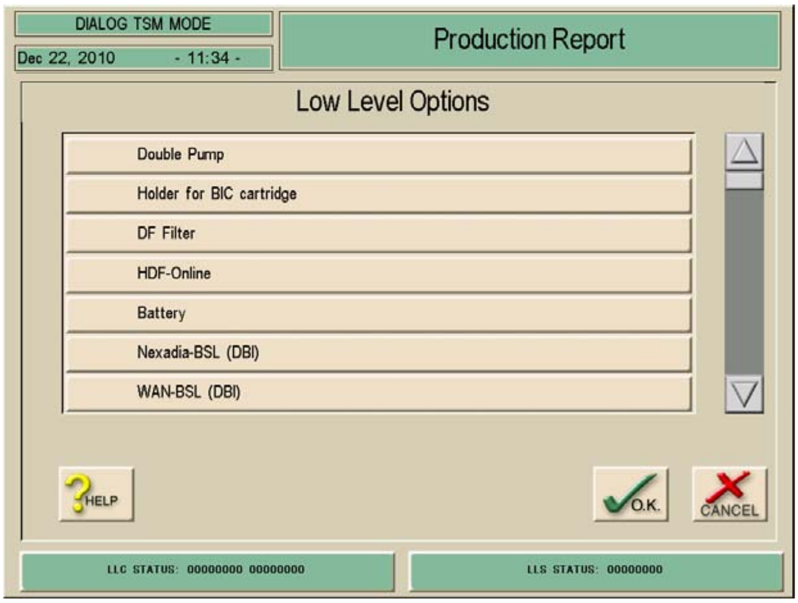
Low Level Hardware Versions

The boards are displayed with the respective hardware versions, e.g. a HDF online machine. The displayed HW versions depend on the assembled boards in the machine.

- Basic Board **BB**
- Analog Board **AB**
- Power Board Motors **BPM**
- Power Board Valves **BPV**
- HDF Online Board **HOB**
- Digital Board **DB**

4.9.2 Low Level Options

Press the *Low Level Options* key in the *Production Report* menu to open the *Low Level Options* menu.


DIALOG TSM MODE
Dec 22, 2010 - 11:34 -
Production Report
Low Level Options
Double Pump
Holder for BIC cartridge
DF Filter
HDF-Online
Battery
Nexadia-BSL (DBI)
WAN-BSL (DBI)

LLC STATUS: 00000000 00000000
LLS STATUS: 00000000

Options assembled in the machine must be activated. Further options present in the Dialog must also be activated in this menu or in the *Production Report* menu (see 4.9).

The following options can be activated:

Low Level Options

- Double Pump
- Holder for BIC Cartridge
- DF Filter
- HDF Online
- Battery (Emergency Supply)
- Nexadia-BSL (DBI)
- WAN-BSL (DBI)

Double Pump

If *Double Pump* is selected and saved, cross-over and the PBS pressure sensor are automatically activated.

Holder for BIC Cartridge

If the option BIC cartridge holder is assembled or the option is retrofitted, it must be selected and saved to activate the option.

DF Filter

If the option *DF Filter* (dialysate fluid filter) is assembled or the option is retrofitted, it must be selected and saved to activate the option.

HDF Online

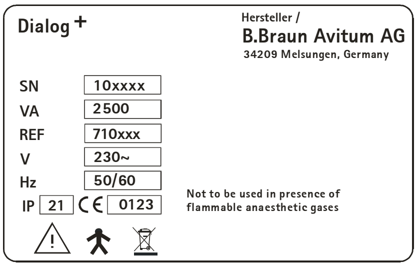
HDF Online must be selected and saved for HDF online machines.

Battery

If the emergency supply (battery) option is assembled or the option is retrofitted, it must be selected and saved to activate the option.

Networking

Note


Dialog +
Hersteller /
B.Braun Avitum AG
34209 Melsungen, Germany
SN 10xxxx
VA 2500
REF 710xxx
V 230~
Hz 50/60
IP 21 CE 0123
Not to be used in presence of flammable anaesthetic gases

Enter the serial number (see SN on type plate) in the menu *Production Report*, if the Dialog is networked. This serial number is required and used (query) as the identification number (ID) of the machine if networked (e.g. Nexadia network).

- Ser-No. = SN (see type plate)

Detailed information for networking (DBI) with Dialog machines are available in the technical information for Nexadia-BSL/WAN-BSL networks.

Nexadia-BSL (DBI)

BSL = Bedside Link
DBI = Dialog Bedside Link Interface

The Dialog can be integrated in a computer network with a Nexadia-BSL module. If the option is assembled or the option is retrofitted, it must be selected and saved to activate the option.

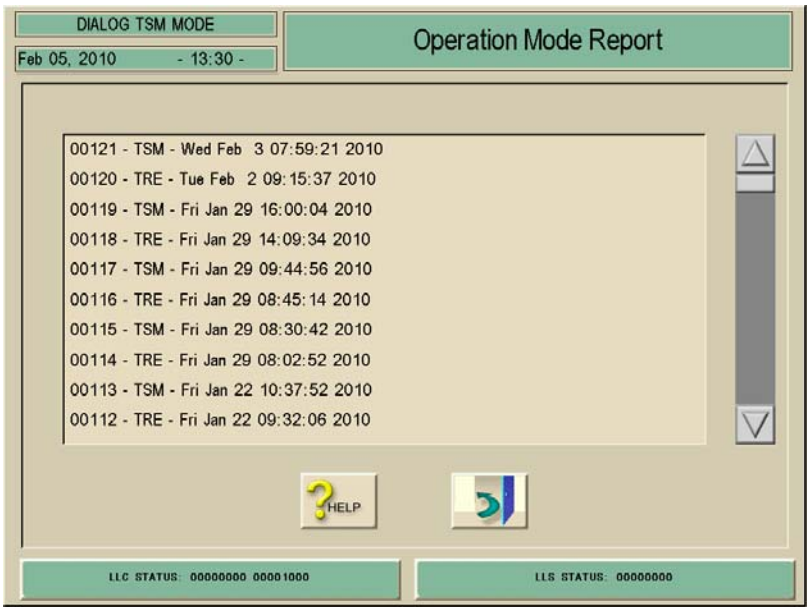
WAN-BSL (DBI)

WAN = Wide Area Network
BSL = Bedside Link
DBI = Dialog Bedside Link Interface

The Dialog can be integrated in a computer network with a WAN-BSL module. If the option is assembled or the option is retrofitted, it must be selected and saved to activate the option.

4.10 Service Reports

The *Operation Mode Report* can be selected in the *Service Reports* menu.



```
00121 - TSM - Wed Feb  3 07:59:21 2010
00120 - TRE - Tue Feb  2 09:15:37 2010
00119 - TSM - Fri Jan 29 16:00:04 2010
00118 - TRE - Fri Jan 29 14:09:34 2010
00117 - TSM - Fri Jan 29 09:44:56 2010
00116 - TRE - Fri Jan 29 08:45:14 2010
00115 - TSM - Fri Jan 29 08:30:42 2010
00114 - TRE - Fri Jan 29 08:02:52 2010
00113 - TSM - Fri Jan 22 10:37:52 2010
00112 - TRE - Fri Jan 22 09:32:06 2010
```

Operation Mode Report

The switching from therapy mode to TSM mode and back to the therapy mode is documented with date and time.

Copyright	This document is the property of B. Braun Avitum AG with all rights reserved.
Service	Only trained personnel must service the Dialog+, i.e. repair, maintenance, software installation, firmware update, retrofitting and commissioning of the Dialog+. Servicing must only be performed with proper tools, calibration equipment and be in accordance with the most recent revision of this service manual/technical information, which must be clearly and thoroughly understood.
Prevent Electrical Shock Hazard	Switch off the Dialog+ and disconnect unit from mains if you have to open the machine for servicing. Do not touch any exposed wiring or conductive surfaces while the Dialog+ is opened. The voltages present when electrical power is connected to the Dialog+ can cause serious injury or death.
ESD Information	Pay attention to ESD information, because electronic components are sensitive to electrostatic discharges.
High Voltage in TFT Monitor	If a battery option is present in the machine: High voltage can be present at the backlight inverter board BIB in the TFT monitor, even if the machine has been disconnected from mains. Pull out the battery compartment in the base platform and switch off the battery voltage (remove fuse) before opening the machine.
Protective Conductor in TFT Housing	If the TFT housing had to be opened during a service job, the tight seat of the protective conductors in the TFT housing must be checked.
TSM Service Program	Only activate the TSM service program for service activities. It is prohibited to connect a patient to the Dialog+ and to run a therapy if the TSM service program is activated in the Dialog+. If the TSM service program is activated the complete alarm system is disabled. The TSM service program is started in the service mode: digital board, service switch S1, position 2.
Software	The software is installed in the software mode: digital board, service switch S1, position 3.
Therapy Mode	After completion of all procedures switch back to the therapy mode: digital board, service switch S1, position 0.
Calibration	Only perform a calibration after the Dialog+ has reached working temperature, and the machine was disinfected and decalcified. You should save the calibration data to the hard disk drive before you exit the TSM service program: *TSM Main Menu*, *File Operations*, *Save Calibration Data*.
Connection and Operation Service Board	The service board must only be operated in the TSM service program. If the service board is connected to the Dialog+ it is prohibited to connect a patient to the Dialog+ and to run a therapy.
Prevent 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.
Contaminated Machines	Protective gear should be worn in case of servicing of assumed contaminated machines.
Cover in Rear Door	Servicing of mechanical assembly groups (components in contact with fluid): the cover in the rear door must be assembled during servicing because it serves as a spray protection for the assembled SMPS-MC.
Tubing	Tubing must be replaced only by the same tubing type/length and identical installation manner. Make sure that the tubings in the machine are not kinked or twisted after servicing (e.g. if sub-racks are pulled out and inserted again). The tubing must not touch moving/rotating components (e.g. motors of gear pumps).
Wiring	Wiring must be replaced only by the same cable type/length and identical installation manner. The cables must not touch moving/rotating components (e.g. motors of gear pumps).
Fuses	If fuses are replaced they must exactly match the type and rating specified by the manufacturer in the spare parts list/technical information. Where applicable: fuses must be approved by UL/CSA.
Spare Parts	Only use original spare parts manufactured and sold by B. Braun Avitum AG.
Ambient Temperature	Before the Dialog+ is switched on the machine must have room temperature (see operating manual, chapter 15).

Table of Contents

5.1 Check List for Technical Safety Inspection and Preventive Maintenance

For **Dialog+ SW 9.xx**

The technical safety inspection shall be performed and documented every 12 months, according to the specified check list and with reference to the service manual and instructions for use.
The preventive maintenance is recommended every 12 months, according to the specified check list and with reference to the service manual and instructions for use and shall be documented.

REF {Type/Typ}: .... **SN {Serien-No./Nr.}: ....**

Year of Purchase: .... **Responsible Organisation (User): ....**

....

Operating Hours: .... h **Inventory No.: ....**

SW Version: ....

Manufacturer:

B. Braun Avitum AG
34209 Melsungen, Germany

S	M		**Check List (S = Technical Safety Inspection Points; M = Preventive Maintenance Points)** **Note:** Text in { } brackets is information for the execution of the check list!	NO	YES	OK
			Technical Safety Inspection			☐
			Technical Safety Inspection with Preventive Maintenance			☐
	M	**1.**	**Disinfection/decalcification was performed**	☐	☐	☐
		2.	**Visual Inspection with Maintenance Procedures**			
S		2.1	Visual Inspection {Machine: clean/complete; no damages/moisture influences (protection covers) or loose assemblies; no moveable parts touching tubings or wires; casters are moveable; type plate legible}	☐	☐	☐
	M	2.2	Clean interior space and exterior surfaces	☐	☐	☐
	M	2.3	Suction tubing for disinfection and concentrate exchanged ❶	☐	☐	☐
	M	2.4	O-rings at suction rod exchanged ❶	☐	☐	☐
	M	2.5	Balance chamber – no visible leakages	☐	☐	☐
S		2.6	Check tight seat and damages of mains supply (power supply cord, strain relief), potential equalisation cable, staff call/data lines (if present) and connectors	☐	☐	☐
	M	2.7	Tubing connectors , clamps and couplings (internal/external) are assembled correctly	☐	☐	☐
	M	2.8	Membranes, o-rings and tubings at the dialyser couplings exchanged ❶	☐	☐	☐
	M	2.9	HDF Online Option present	☐	☐	☐
		2.9.1	O-rings {12.37 x 2.62} and membranes {for HDF filter with couplings} exchanged ❷	☐	☐	☐
		2.9.2	Hydrophobic filter HFB exchanged ❷	☐	☐	☐
		2.9.3	Filter FSU {between PSABF and VSAA} exchanged ❷	☐	☐	☐
	M	2.10	DF Filter Option present	☐	☐	☐
		2.10.1	Membranes exchanged ❶	☐	☐	☐
	M	2.11	Tight seat of boards and connectors (incl. mains connection in switch mode power supply)	☐	☐	☐
		2.12	Exchange dust filter of fan (rear door) ❶	☐	☐	☐
	M	2.13	Filter (FVD, FB, FK, FBK1/2, FBIC, FEP) exchanged ❶	☐	☐	☐
	M	2.14	Filter level regulation module (HFA, HFV, HFE (HFS if present)) exchanged ❶	☐	☐	☐
	M	2.15	BIC Cartridge Holder Option present	☐	☐	☐
		2.15.1	O-rings exchanged ❶	☐	☐	☐
	M	2.16	Battery on PC motherboard exchanged (after operating period of 4 years) {Battery is not included in the maintenance kit, if necessary order separately.}	☐	☐	☐
	M	2.17	Monitor: no restriction of motion of rotation; touch membrane/keyboard membrane not damaged	☐	☐	☐
	M	2.18	Check non-return valve RVDA (400 mbar ±50 mbar or 300 mmHg ±37 mmHg) and set if necessary (for HDF Online: 500 mbar ±50 mbar or 375 mmHg ±37 mmHg)	☐	☐	☐
	M	2.19	Check non-return valve DDE (400 mbar ±50 mbar or 300 mmHg ±37 mmHg) and set if necessary	☐	☐	☐
	M	2.20	Check non-return valve RVFPE (1,300 mbar ±50 mbar or 975 mmHg ±37 mmHg) and set if necessary	☐	☐	☐
	M	2.21	Check non-return valve RVFPA (1,300 mbar ±50 mbar or 975 mmHg ±37 mmHg) and set if necessary	☐	☐	☐

S	M		**Check List (S = Technical Safety Inspection Points; M = Preventive Maintenance Points)** **Note:** Text in { } brackets is information for the execution of the check list!	NO	YES	OK
	M	2.22	Conductivity Sensors			
		2.22.1	ENDLF sensor: Visual inspection	☐	☐	☐
		2.22.2	BICLF sensor: Visual inspection	☐	☐	☐
	M	2.23	Piston Pumps			
		2.23.1	BIC piston pump: Visual inspection	☐	☐	☐
		2.23.2	KP piston pump: Visual inspection	☐	☐	☐
	M	2.23.3	UF piston pump: Visual inspection	☐	☐	☐
	M	2.24	Blood leak detector (BLD) test passed	☐	☐	☐
		2.24.1	Check blood leak detector and calibrate if necessary ❶	☐	☐	☐
	M	2.25	**Degassing Pressure Sensor PE** (permissible tolerance ±13 [mbar])			
			- Comparison measurement (at approx. -530): Measurement instrument: .... Display on machine: .... **[mbar]**			☐
			- Comparison measurement (at approx. -130): Measurement instrument: .... Display on machine: .... **[mbar]**			☐
	M	2.26	**Dialysate Outlet Pressure Sensor PDA** (permissible tolerance ±13 [mbar])			
			- Comparison measurement (at approx. -530): Measurement instrument: .... Display on machine: .... **[mbar]**			☐
			- Comparison measurement (at approx. 0): Measurement instrument: .... Display on machine: .... **[mbar]**			☐
			- Comparison measurement (at approx. +530): Measurement instrument: .... Display on machine: .... **[mbar]**			☐
	M	2.27	**Heparin Pump**			
		2.27.1	Position (80 mm ± 15 mm) {Drive fast forward to end position with 30 ml syringe. Check display position in mm.} .... **[mm]**			☐
	M	2.28	Set summer/winter time {TSM, Treatment Support, System Configuration, if applicable in this country}	☐	☐	☐
		3.	**Function Inspection (Document Measurement Values)**			
S		3.1	**Blood Pump:** - Check function, moveability, noise rating			☐
		3.1.1	- Check roller/one-way bearing; clean and lubricate shaft slightly if necessary			☐
		3.1.2	- Alarm cover switch			☐
S		3.2	**Single-Needle Pump:** Option present	☐	☐	☐
		3.2.1	- Check function, moveability, noise rating			☐
		3.2.2	- Check roller/one-way bearing; clean and lubricate shaft slightly if necessary			☐
		3.2.3	- Alarm cover switch			☐
S		3.3	**Venous Tubing Clamp SAKV:** - Function/gap checked, set gap 1.4 (+0.1 mm) if necessary			☐
S		3.4	**Arterial Tubing Clamp SAKA:** Option present	☐	☐	☐
		3.4.1	- Function/gap checked, set gap 1.4 (+0.1 mm) if necessary			☐
S		3.5	**Arterial Pressure PA:** (permissible. tolerance ±10 [mmHg])			
			Comparison measurement (at approx. -400): Measurement instrument: .... Display on machine: .... **[mmHg]**			☐
			Comparison measurement (at approx. 0): Measurement instrument: .... Display on machine: .... **[mmHg]**			☐
S		3.6	**Inlet Pressure PBE:** (permissible. tolerance ±10 [mmHg])			
			Comparison measurement (at approx. 0): Measurement instrument: .... Display on machine: .... **[mmHg]**			☐
			Comparison measurement (at approx. +400): Measurement instrument: .... Display on machine: .... **[mmHg]**			☐
S		3.7	**Venous Pressure PV:** (permissible. tolerance ±10 [mmHg])			
			- Comparison measurement (at approx. 0): Measurement instrument: .... Display on machine: .... **[mmHg]**			☐
			Comparison measurement (at approx. +400): Measurement instrument: .... Display on machine: .... **[mmHg]**			☐
S		3.8	**Single-Needle Pressure PBS:** (permissible. tolerance ±10 [mmHg]) Option present	☐	☐	☐
			- Comparison measurement (at approx. 0): Measurement instrument: .... Display on machine: .... **[mmHg]**			☐
			- Comparison measurement (at approx. +400): Measurement instrument: .... Display on machine: .... **[mmHg]**			☐

S	M	Check List (S = Technical Safety Inspection Points; M = Preventive Maintenance Points) **Note:** Text in { } brackets is information for the execution of the check list!		NO	YES	OK
S		3.9	**Staff Call:** Option present	☐	☐	☐
		3.9.1	- Function or contact continuity passed	☐	☐	☐
S		3.10	**Automatic Blood Pressure Measurement ABPM:** Option present	☐	☐	☐
		3.10.1	- ABPM inspection protocol performed {see separate ABPM inspection protocol, paragraph 5.2}	☐	☐	☐
		4.	**Electrical Safety Check According to EN 62353/EN 60601-1**			
S		4.1	**Protective Earth Resistance:** < 0.3 [Ω] {note highest value}: .... **[Ω]** {(Machine incl. power supply cord. Move the power supply cord during the check. Thus possible loose connections can be detected. Data lines and potential equalisation cable must not be connected during the check of the protective earth resistance (see figure 1)} {Measurement points:} {Exterior: Potential equalisation bolt, rinsing bridge (dialyser inlet and outlet)} {Interior: Heater body (top), rear door (top left corner), frame (rear), housing cover (top left), front door (top left)} {Monitor: Monitor (one of the screws in the front panel/housing}			☐
S		4.2	**Equipment Leakage Current:** {All water connections and data lines must be connected during the check (see figure 2) of the equipment leakage current.} ≤ 0.5 [mA]: - During heat-up phase {change mains polarity and note highest value}: .... **[mA]**			☐
S		4.3	**Patient Leakage Current:** {All water connections and data lines must be connected during the check (see figure 3) of the patient leakage current.} ≤ 10 [µA] DC: - Under normal conditions {at dialyser coupling}, conductivity at 13 - 15 mS/cm: .... **[µA]**			☐
			≤ 10 [µA] AC: - Under normal conditions {at dialyser coupling}, conductivity at 13 - 15 mS/cm: .... **[µA]**			☐
		5.	**Setting into Service According to Instructions for Use**			
S		5.1	**Applied Accessories/Disposables:** Applied line system: Name:			
S		5.2	**Switch on machine:** - Self-test passed			☐
S		5.3	**Power Fail Function:** {Activate buzzer in power supply, i.e. switch on machine for approx. 5 minutes and then disconnect mains plug.} - Check function, duration of a constant audible alarm > 1 minute			☐
S		5.4	**Temperature:** - Comparison measurement {at dialyser coupling}, at 37 °C (-1.5; +0.5): .... **[°C]**			☐
S		5.5	**Conductivity:** - Comparison measurement {at dialyser coupling, e.g. 14.3 mS/cm (±0.2)}: .... **[mS/cm]**			☐
S		5.6	**Safety Air Detector (SAD):** - Test alarm function (visual/audible) passed			☐
S		5.7	**Monitor**			
		5.7.1	Function of the keys, display illumination, OSDs (for Dialog+) and touch screen OK			☐
		5.7.2	Image display OK			☐
S		5.8	**Ultrafiltration:** {see chapter 3 Measures after Repair, paragraph 3.8.2.5 Test Run UF Comparison Measurement} - Comparison measurement at 15 min with UF rate 500 ml/h (125 ml UF volume ±15 ml) : Display on machine: .... Meas. instrument: .... **[ml]**			☐
S		5.9	**Battery Option:** Option present	☐	☐	☐
		5.9.1	- Activate audible alarm {The machine must be in therapy mode. Disconnect mains plug: The buzzer from the SMPS-MC gives three signalling tones as an indication that the machine is running in battery mode.}	☐	☐	☐
	M	5.10	**Disinfection:** - Perform by responsible organisation {user} {inform responsible organisation}	☐	☐	☐
			- Performed by service technician	☐	☐	☐

S	M	**Check List (S = Technical Safety Inspection Points; M = Preventive Maintenance Points)** **Note:** Text in { } brackets is information for the execution of the check list!	NO	YES	OK

Applied Measurement Equipment:

Electrical Safety: .... * ID/Serial No.: ....

Conductivity: .... * ID/Serial No.: ....

Temperature: .... * ID/Serial No.: ....

Pressure: .... * ID/Serial No.: ....

Flow: .... * ID/Serial No.: ....

Balance: .... * ID/Serial No.: ....

Pressure Manometer: .... * ID/Serial No.: ....

Template 1.4/1.5: .... * ID/Serial No.: ....

Other Measurement Device: .... * ID/Serial No.: ....

.... * ID/Serial No.: ....

* If applicable, please enter the type and identification number of the equipment used

CHECK RESULTS:				
Customer specific parts or information on the machine (e.g. stickers/labels) were removed during the technical safety inspection/preventive maintenance or repair:		☐	☐	☐
New labelling must be performed by responsible organisation (user):		☐	☐	☐
Results of Test and Evaluation: 0 = no deficiencies; 1 = minor deficiencies; 2 = deficiencies requiring repair	2☐	1☐	0☐	☐

Comments:

....

....

....

The technical safety inspection/technical safety inspection with preventive maintenance was passed: ☐ ☐ ☐

Next Inspection Date: ....

The technical safety inspection/technical safety inspection with preventive maintenance was performed correctly.

Name Service Technician/Company:

....

....

Date / Signature

{❶ **Maintenance Kit**}

{A maintenance kit can be ordered for the technical safety inspection with preventive maintenance of a Dialog machine. All parts are included which are recommended for exchange during a preventive maintenance.}

{**Art. No.**	**Description**}
{3451893D	Maintenance Kit}

{❷ **Maintenance Kit/Supplement HDF Online**}

{A second maintenance kit can be ordered for the technical safety inspection with preventive maintenance. As a supplement this kit includes all parts recommended for exchange during a preventive maintenance of a HDF online machine.}

{**Art. No.**	**Description**}
{34560686	Maintenance Kit/Supplement HDF Online}

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

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

Table 1: Legend of Abbreviations and Symbols

Protective Earth Resistance

Test current: ≥ 200 mA

The test current must be measured in both directions.

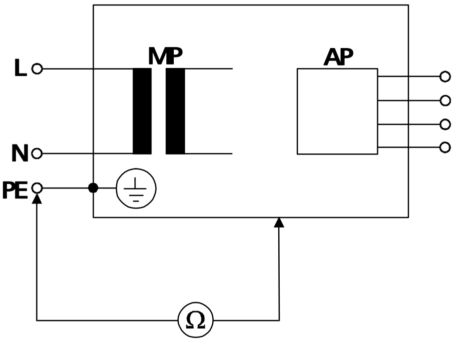


Fig. 1: Protective Earth Resistance

Equipment Leakage Current:

- Differential Measurement

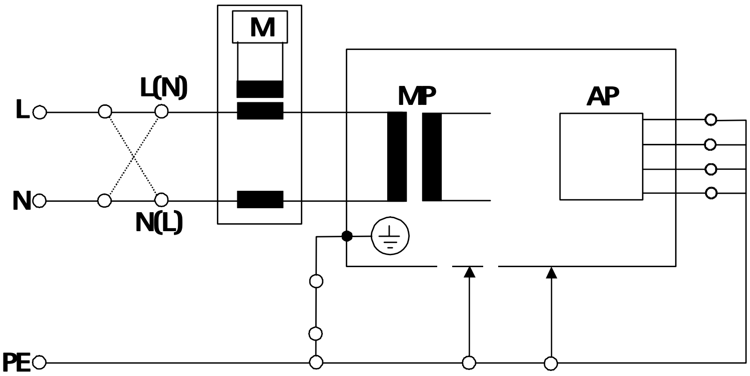


Fig. 2: Equipment Leakage Current

Patient Leakage Current

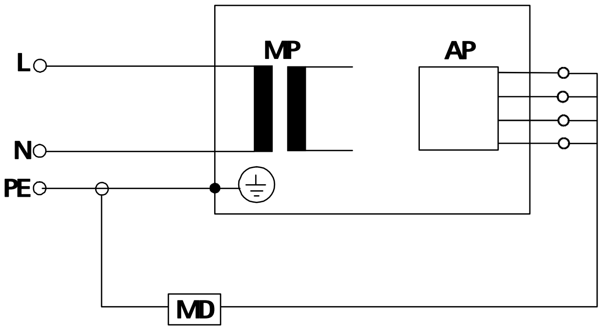


Fig. 3: Patient Leakage Current

5.2 Inspection Protocol for Automatic Blood Pressure Measurement ABPM

Measurement Inspection The measurement inspection is recommended every **12 months** and should be documented. The measuring methods are described in the execution procedures.

Dialysis Machine Dialog **REF {Type/Typ}:** .... **SN {Serien-No./Nr.}** ....

Automatic Blood Pressure Measurement ABPM ABPM Module M2009/2010

Manufacturer B. Braun Avitum AG, 34209 Melsungen, Germany

Responsible Organisation (User) Address: ....

....

....

1. Visual Inspection

- Tight seat of all connectors : -- **OK ☐**
- No damages which could affect the function or the safety (incl. tubing and cuff): --**OK ☐**

2. Limits of Error of the Pressure Indication

Admit a static pressure to the machine.

Pressure [mmHg]	Measurement Values Dialog	 Reference	Deviation [mmHg]
290			
200			
100			
50			
0			

The permissible tolerance for each measurement is:
ABPM Module: -- ± 3 mmHg: **OK ☐**

3. Air Leakage

Initial Pressure [mmHg]	Final Pressure [mmHg]	Air Leakage [mmHg]

Pressure drop ABPM Module: ------------------------ ≤ 18 mmHg in 3 min: **OK ☐**

4. Rapid Exhaust

- Time for pressure reduction from >260 mmHg to <15 mmHg max. 10 s: .... **s** **OK ☐**
- Trigger of rapid exhaust between 300 mmHg and 330 mmHg: --------------- **OK ☐**

5. Function Inspection The results of a measurement on a test person are plausible ------------------ **OK ☐**

6. Result of Inspection The blood pressure measurement module has passed the measurement inspection: -- **No ☐ Yes ☐**

Comments: ....

....

The measurement inspection was performed correctly.

Name Service Technician:

....

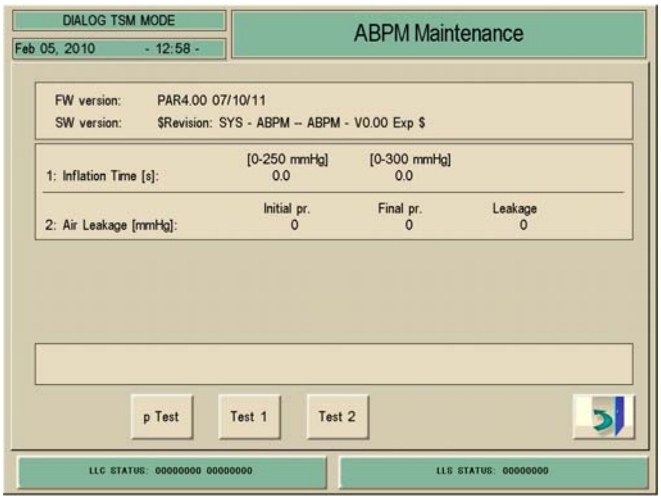
....
Date / Signature

5.2.1 Execution Procedure for Measurement Inspection ABPM

- Reference pressure instrument (accuracy ≤ 0.8 mmHg)
- Measurement chamber with 500 ml volume (rigid metal vessel, e.g. art. no. 7703090)
- Syringe 50 ml (for pressure build-up)
- Stopcock system incl. tubing (e.g. art. no. 770203A)
- Pressure tubing

Activate the *ABPM Maintenance* menu with the *ABPM Maintenance* key in *TSM Service Program*, *TL Manual Test and Calibration*.

The *ABPM Maintenance* menu is used for the function test of the Dialog automatic blood pressure measurement ABPM option.



DIALOG TSM MODE
Feb 05, 2010 - 12:58 -

ABPM Maintenance

FW version: PAR4.00 07/10/11
SW version: $Revision: SYS - ABPM – ABPM - V0.00 Exp $

	[0-250 mmHg]	[0-300 mmHg]	
1: Inflation Time [s]:	0.0	0.0	
	Initial pr.	Final pr.	Leakage
2: Air Leakage [mmHg]:	0	0	0

LLC STATUS: 00000000 00000000
LLS STATUS: 00000000

To Point 2: Limits of Error of the Pressure Indication

Measurement according to EN 1060-1:1995 and EN 1060-3:1997.

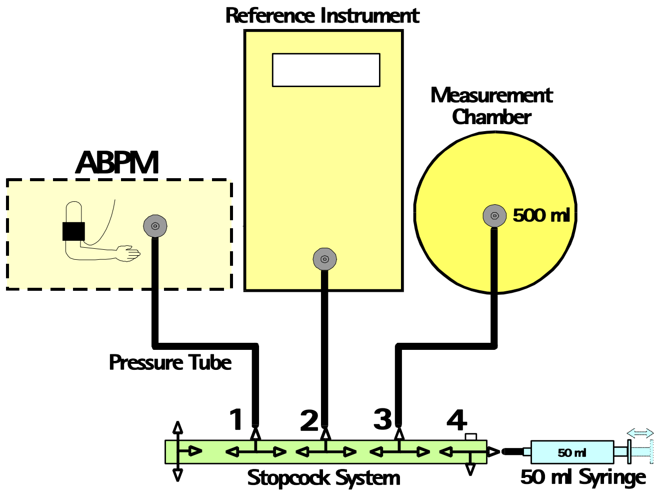


Fig.: Inspection Set-up for Compliance of Error Limits of the Measurement Display

1. Connect all components according to figure (set stopcock system according to figure).
2. Switch on Dialog in TSM service program.
3. Select in TSM *Manual Test and Calibration*, *TTL Manual Test and Calibration* and then *ABPM Maintenance*.
4. Press p Test button.

   Wait until a pressure build-up of approx. 170 mmHg (start of pressure retention phase).
5. Increase the test pressure to 290 mmHg (± 10 mmHg) with the syringe. Read the value displayed on the Dialog and close stopcock 4 immediately. Now read the value on the reference instrument and enter in table.
6. Decrease pressure according to test points and enter values in table.
7. Enter deviations in table.

To Point 3: Air Leakage

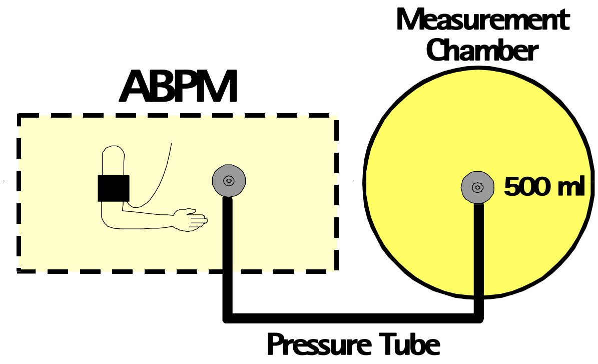


Fig.: Inspection Set-Up for Inspection of Air Leakage

1. Set-up and connect ABPM according to figure.
2. Press Test 2 button.
   A test pressure of approx. 200 mmHg is automatically built up (test duration 4 minutes).
3. Enter values in table after test is expired.
   The values are displayed after the time has elapsed:
   The *Initial Pressure*, *Final Pressure* and *Leakage* are displayed in the *ABPM Maintenance* menu point 4.

Pressure drop ABPM module:----------------------- ≤ 18 mmHg

To Point 4: Rapid Exhaust

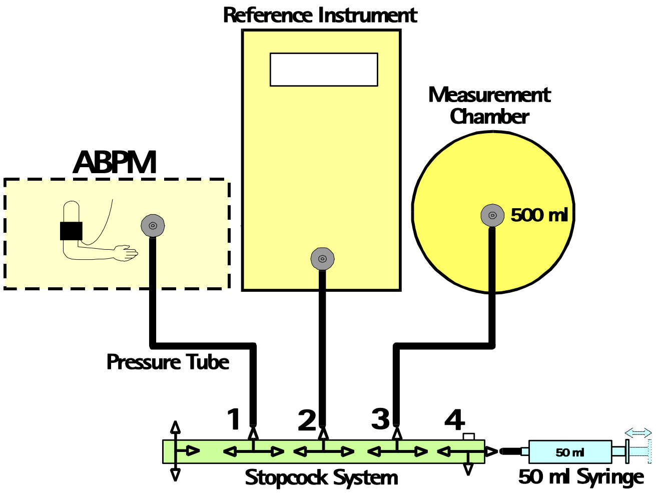


Fig.: Inspection Set-up for Rapid Exhaust

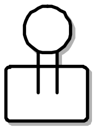
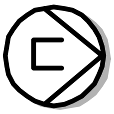
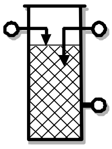
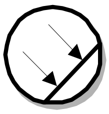
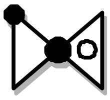
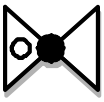
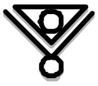
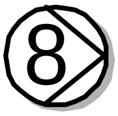
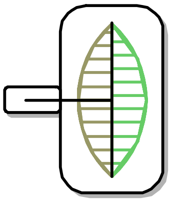
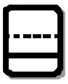
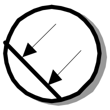
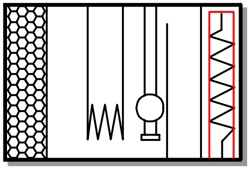
1. Press Test 2 button.
   Wait until a pressure build-up of approx. 290 mmHg (start of pressure retention phase).
2. Increase slowly pressure to > 300 mmHg with the syringe until valve opens for rapid exhaust.
3. The valve for rapid exhaust must open between 300 and 330 mmHg. The indicated time for the pressure drop must not be exceeded.

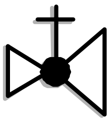
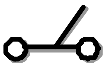
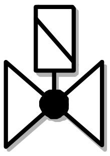
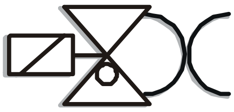
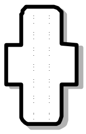
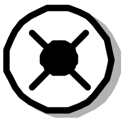
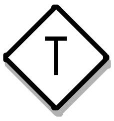
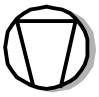
Pressure reduction from >260 mmHg to <15 mmHg: ---- max. 10 s

Table of Contents Page

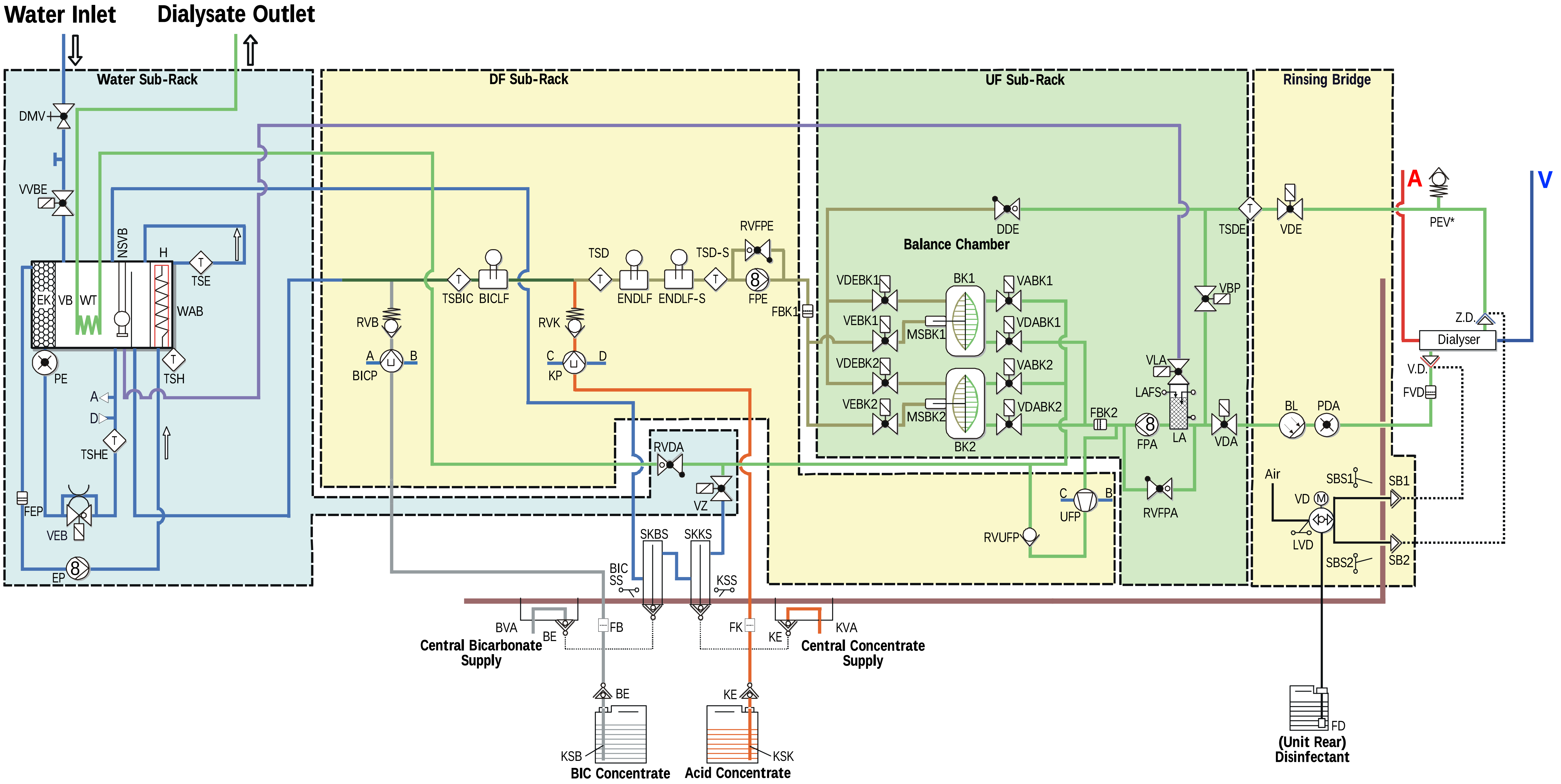
6.1 Flow Diagrams

6.1.1 Legend Flow Diagrams

Symbol	Abbreviation	Description
	BICLF ENDLF ENDLF-S	Bicarbonate conductivity sensor End conductivity sensor End conductivity sensor supervisor
	BICP KP UFP BPA BPV	Bicarbonate pump Concentrate pump Ultrafiltration pump Arterial blood pump Venous blood pump
	LA LAFS	Air separator Air separator level sensors
	BL	Blood leak detector
	DDE RVDA RVFPA RVFPE	Dialyser Inlet throttle Dialysate nonreturn valve Flow pump outlet nonreturn valve Flow pump inlet nonreturn valve
	RVB RVK DBK	Bicarbonate nonreturn valve Concentrate nonreturn valve Throttle BIC cartridge
	BVA KVA	Bicarbonate supply connection Concentrate supply connection
	EP FPA FPE	Degassing pump Outlet flow pump Inlet flow pump
	BK1 BK2 MSBK1 MSBK2	Balance chamber 1 Balance chamber 2 Membrane position sensor balance chamber 1 Membrane position sensor balance chamber 2
	FBK1 FBK2 FVD FB FK	Filter balance chamber (inlet) Filter balance chamber (outlet) Filter from dialysate Filter bicarbonate Filter concentrate
	KtV-UV	KtV-UV sensor (option Adimea)
	WAB	Water block with degassing chamber, upline tank, heat exchanger, level sensor, double-stage heater

	DMV	Pressure reducer valve
	VD ZD	Dialyser coupling (from dialysate) Dialyser coupling (to dialysate)
	BICSS KSS LVD SBS1 SBS2	Bicarbonate rinsing connection sensor Concentrate rinsing connection sensor Light barrier valve disinfection Rinsing connection sensor 1 Rinsing connection sensor 2
	VABK1 VABK2 VBP VD VDA VDABK1 VDABK2 VDE VDEBK1 VDEBK2 VEBK1 VEBK2 VLA VVBE VZ	Outlet balance chamber valve 1 Outlet balance chamber valve 2 Bypass valve Disinfection valve Dialyser outlet valve Dialyser outlet balance chamber valve 1 Dialyser outlet balance chamber valve 2 Dialyser inlet valve Dialyser inlet balance chamber valve 1 Dialyser inlet balance chamber valve 2 Inlet balance chamber valve 1 Inlet balance chamber valve 2 Air separator valve Upline tank inlet valve Circulation valve
	VEB	Degassing bypass valve
	SPA	Rinsing adapter
	RVB RVBO RVBU PEV	BIC nonreturn valve Top BIC nonreturn valve Bottom BIC nonreturn valve Sample valve
	PA PBE PBS PDA PE PV	Arterial pressure sensor Blood inlet pressure sensor Blood control pressure sensor Dialysate outlet pressure sensor Degassing pressure sensor Venous pressure sensor
	TSBIC TSD TSD-S TSE TSH TSHE TSDE	Bicarbonate temperature sensor Dialysate temperature sensor Dialysate temperature sensor supervisor Degassing temperature sensor Heater temperature sensor Heater inlet temperature sensor Dialyser inlet temperature sensor
	UFP	Ultrafiltration pump
	RVUFP	Ultrafiltration pump nonreturn valve

6.1.2 Flow Diagram Dialog+



Water 🟦

Bicarbonate ⬜

Concentrate 🟧

Dialysate Flow 1 🟩

Dialysate Flow 2 🟫

Dialysate 🟩

Air 🟪

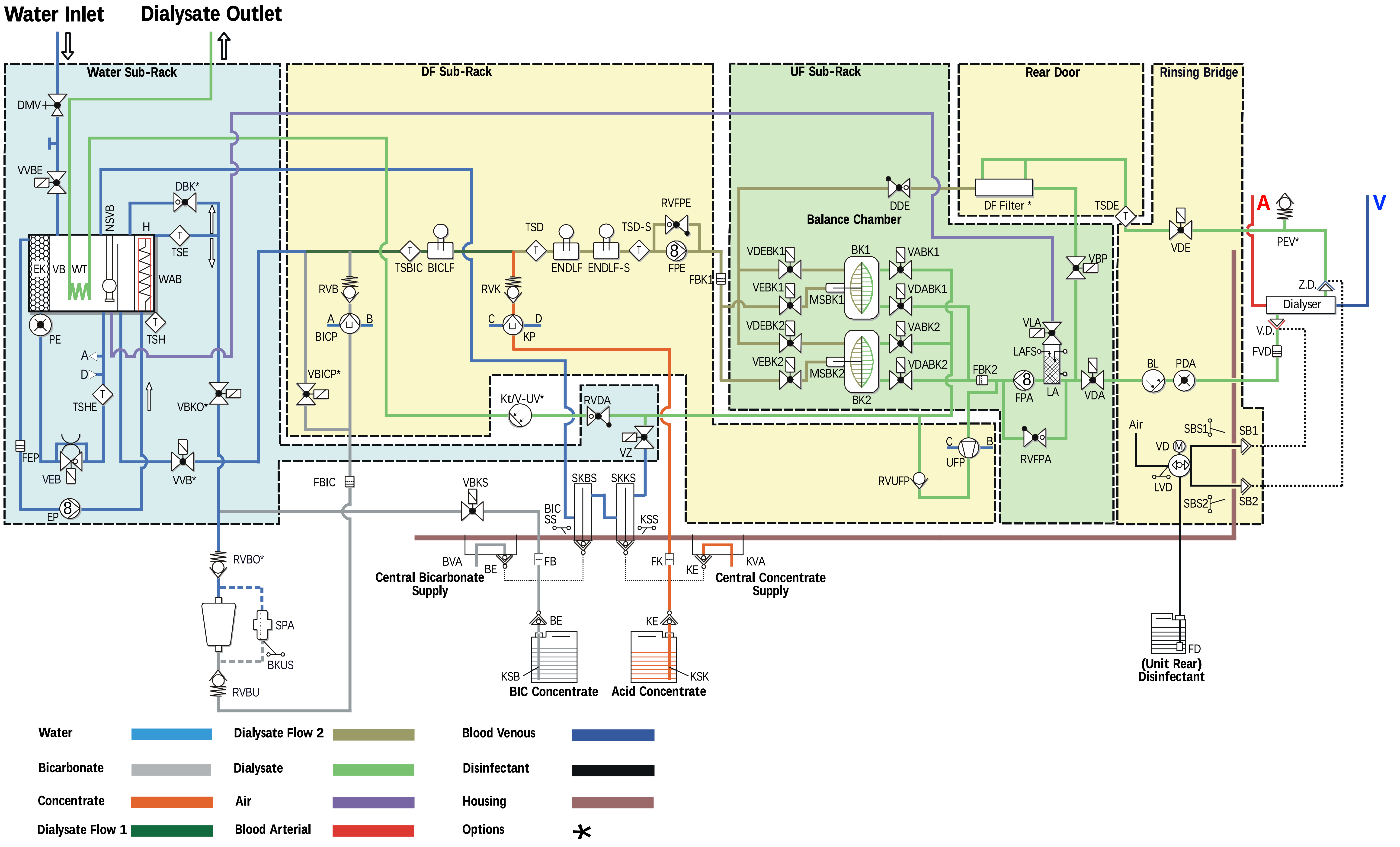
Blood Arterial 🟥

Blood Venous 🟦

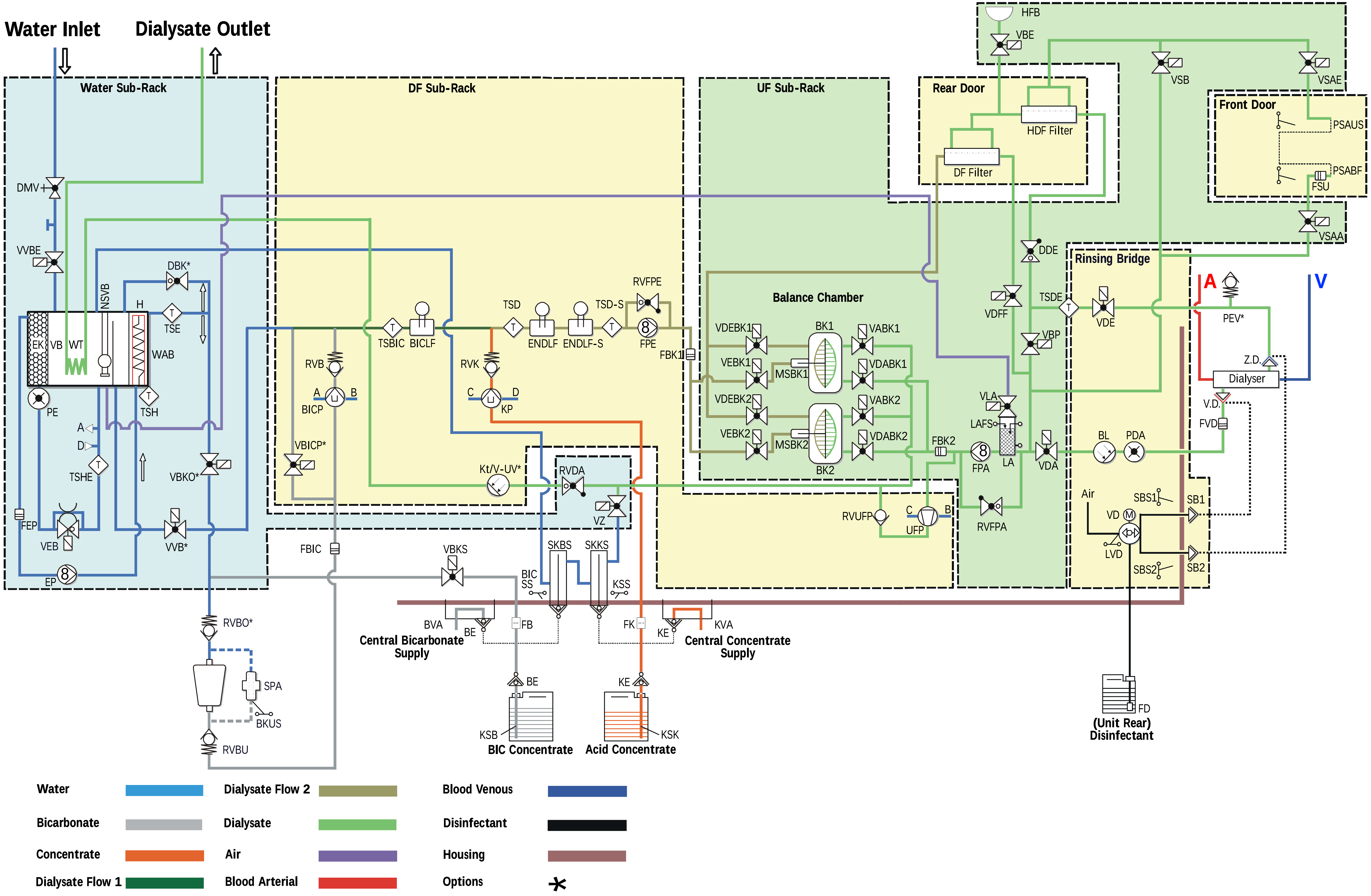
Disinfectant ⬛

Housing 🟫

6.1.3 Flow Diagram Dialog+ BIC/DF Option



6.1.4 Flow Diagram Dialog+ HDF-Online

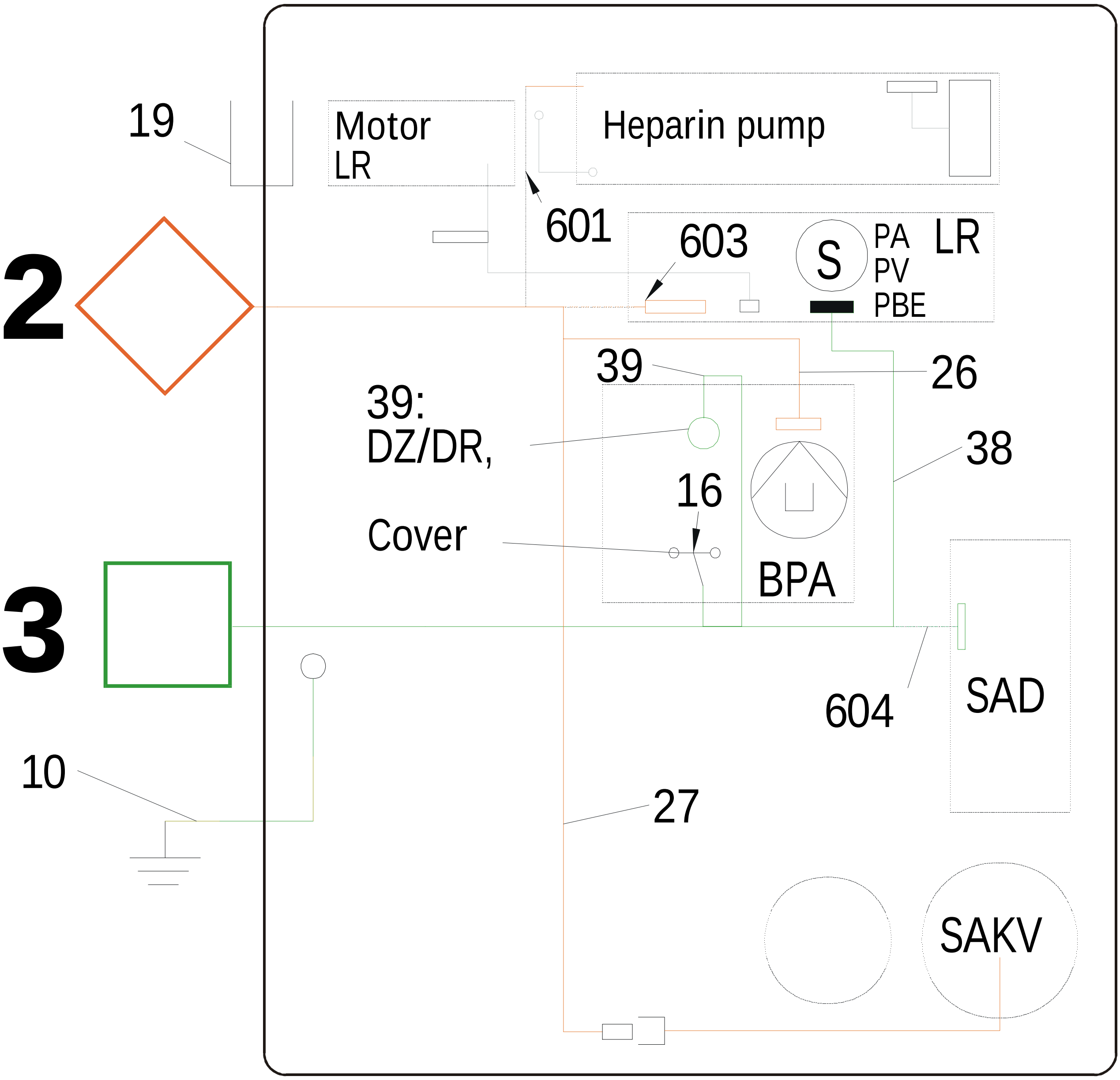


6.2 Wiring Diagrams Dialog+

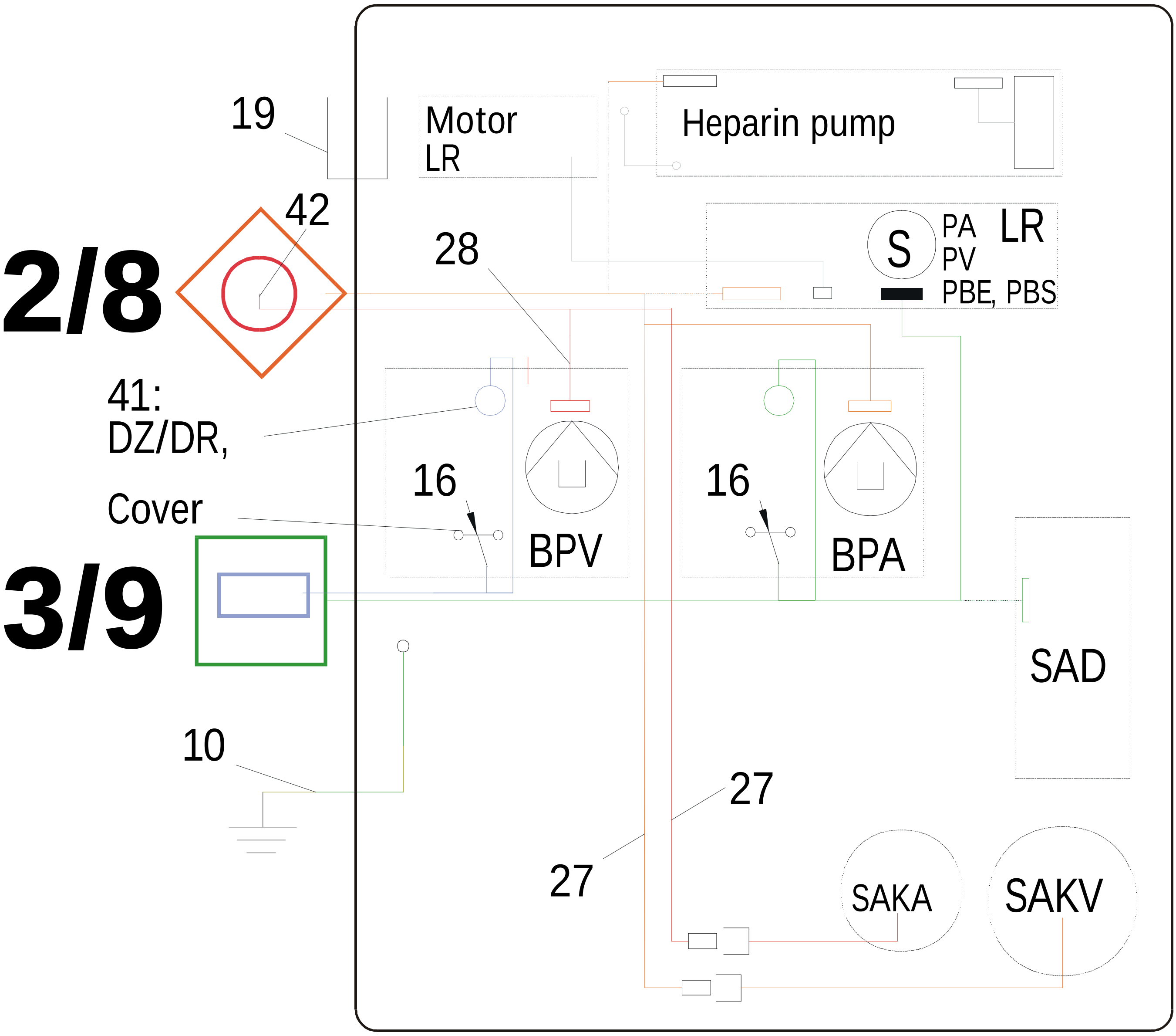
6.2.1 Legend Wiring Diagram

Symbol	Description
2 ◇	Cable connection from basic board to front door: - Single pump - Double pump - HDF online
3 □	Cable connection from basic board to front door: - Single pump - Double pump - HDF online
8 ○	Cable connection from basic board to front door: - Double pump - HDF online
9 ▭	Cable connection from basic board to front door: - Double pump - HDF online

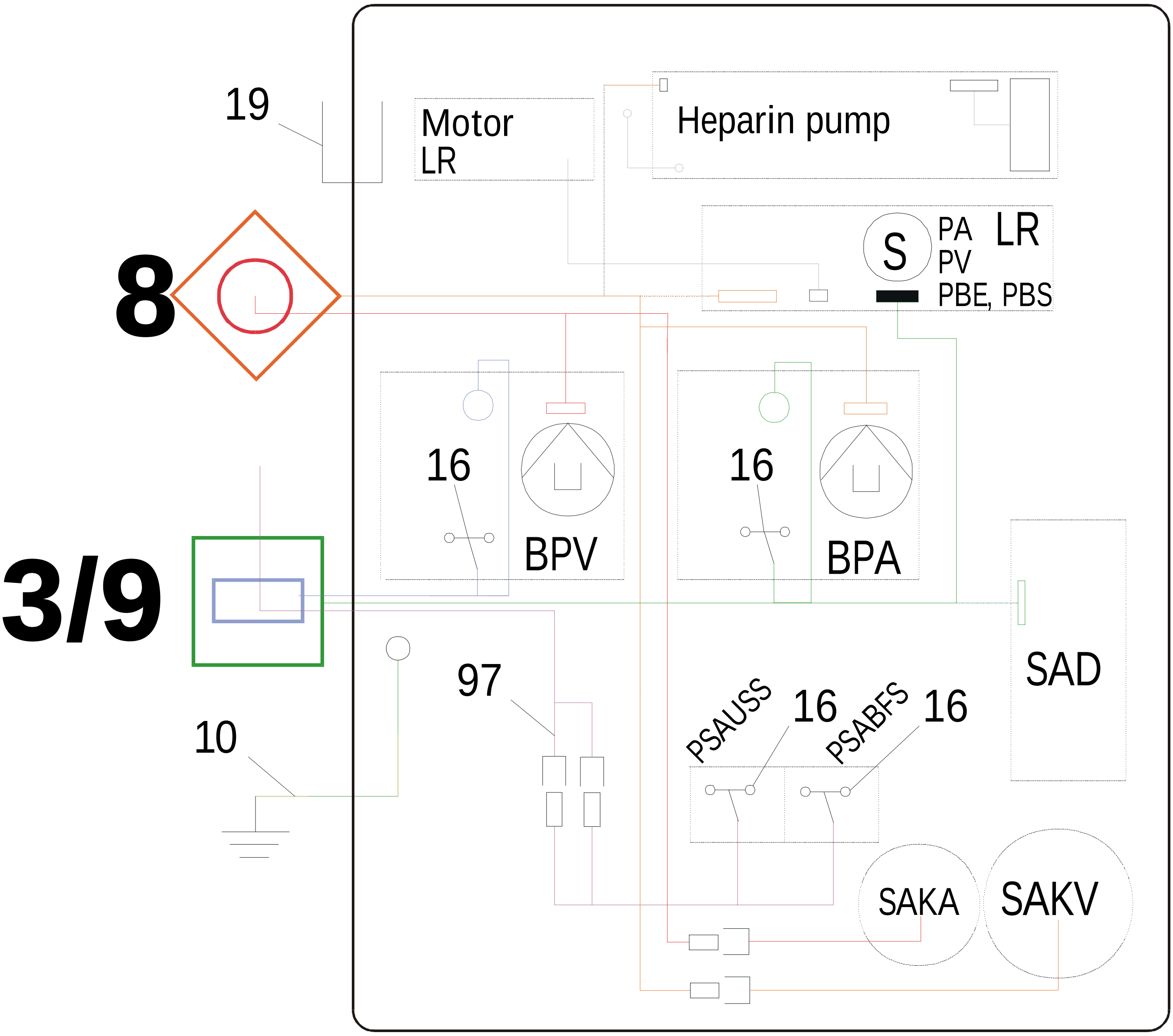
6.2.2 Wiring Diagram Front Door Single Pump



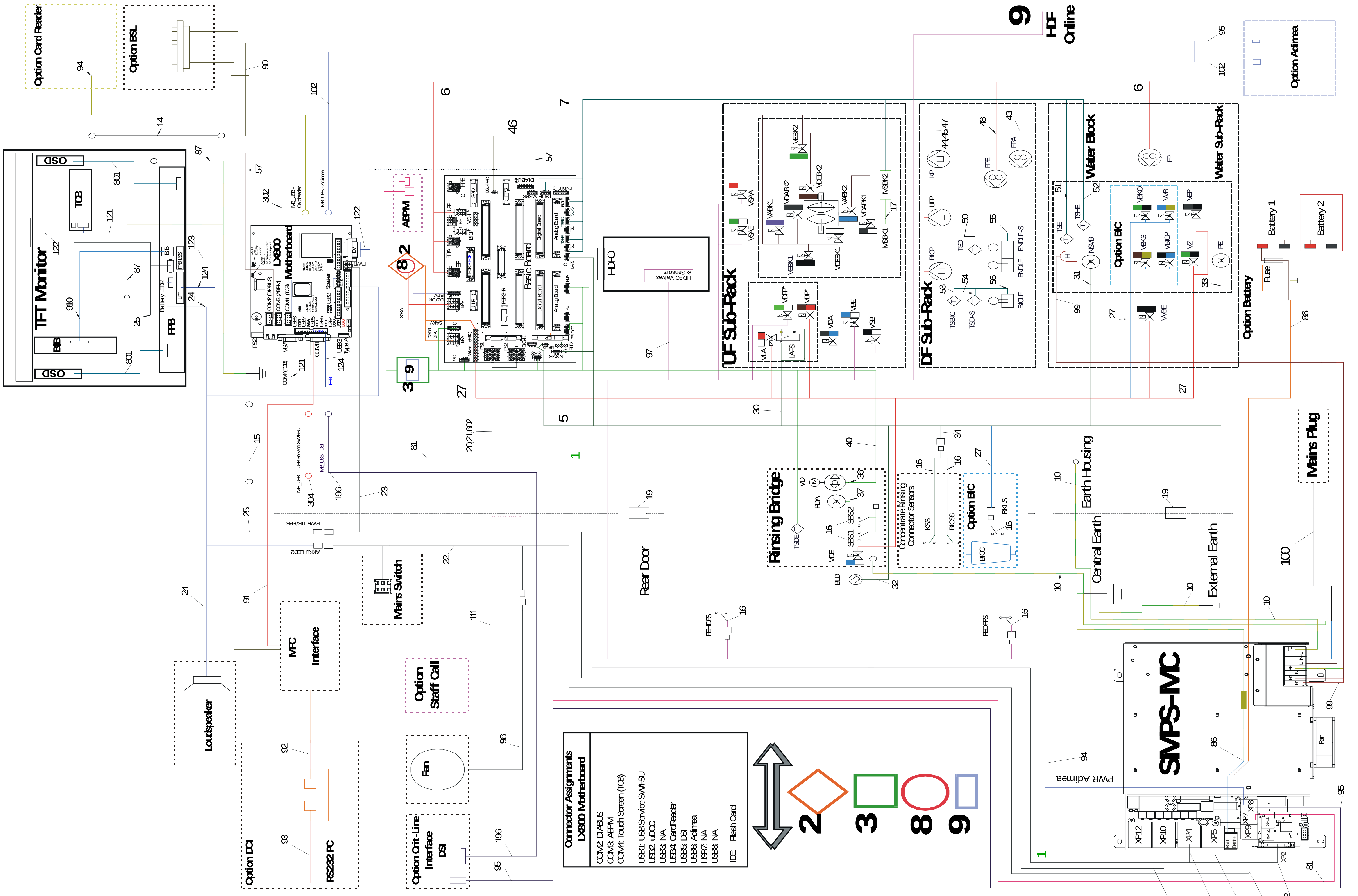
6.2.3 Wiring Diagram Front Door Double Pump



6.2.4 Wiring Diagram Front Door HDF Online

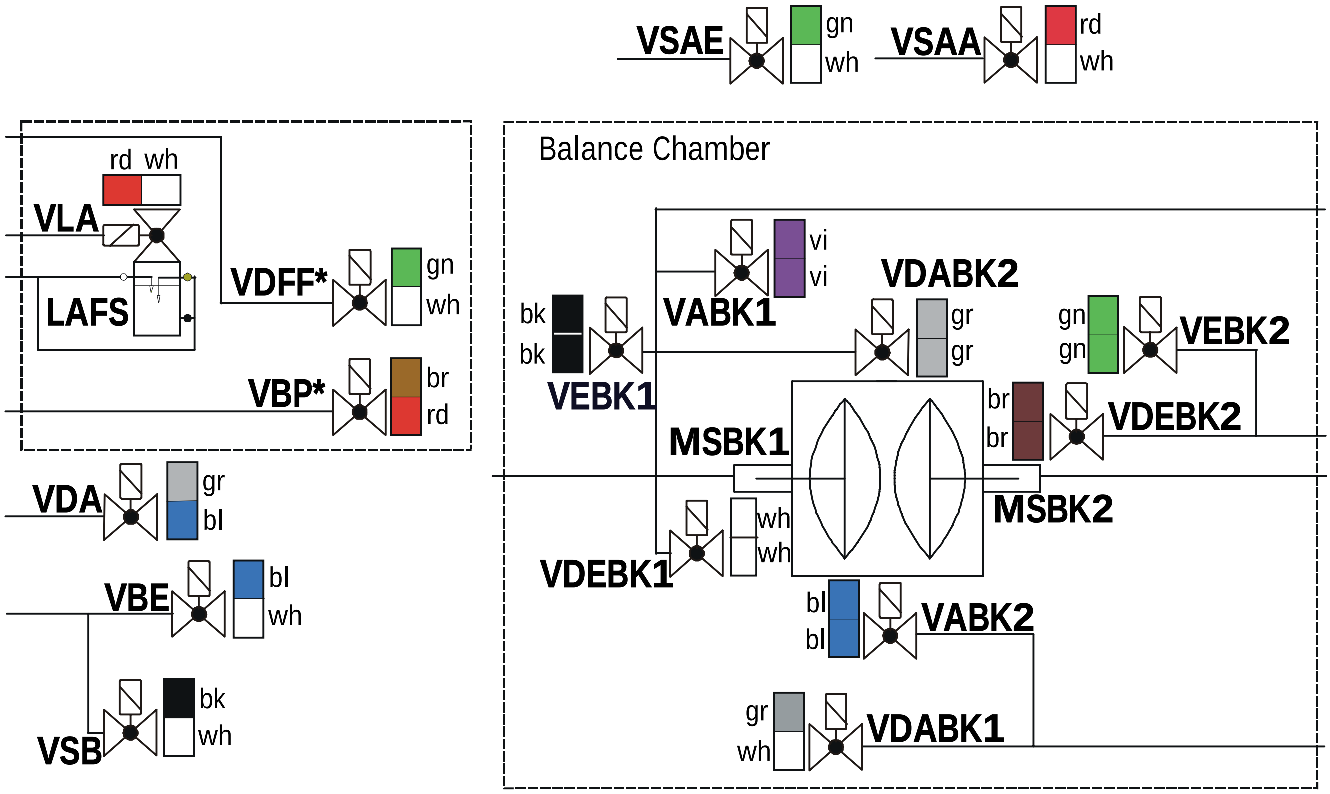


6.2.5 Wiring Diagram Housing

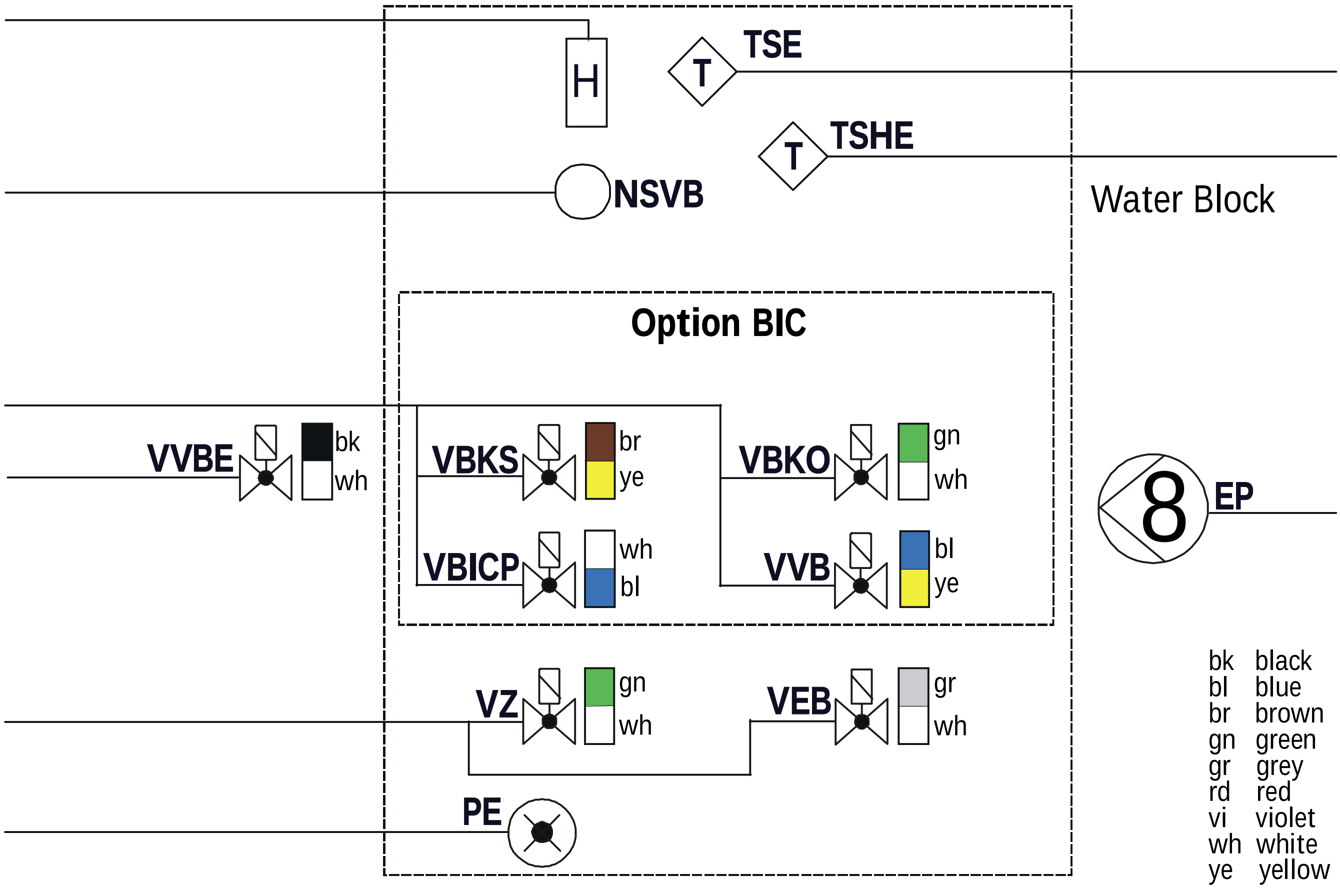


6.2.3 Colour Coding Solenoid Valves

6.2.3.1 Solenoid Valves UF Sub-Rack



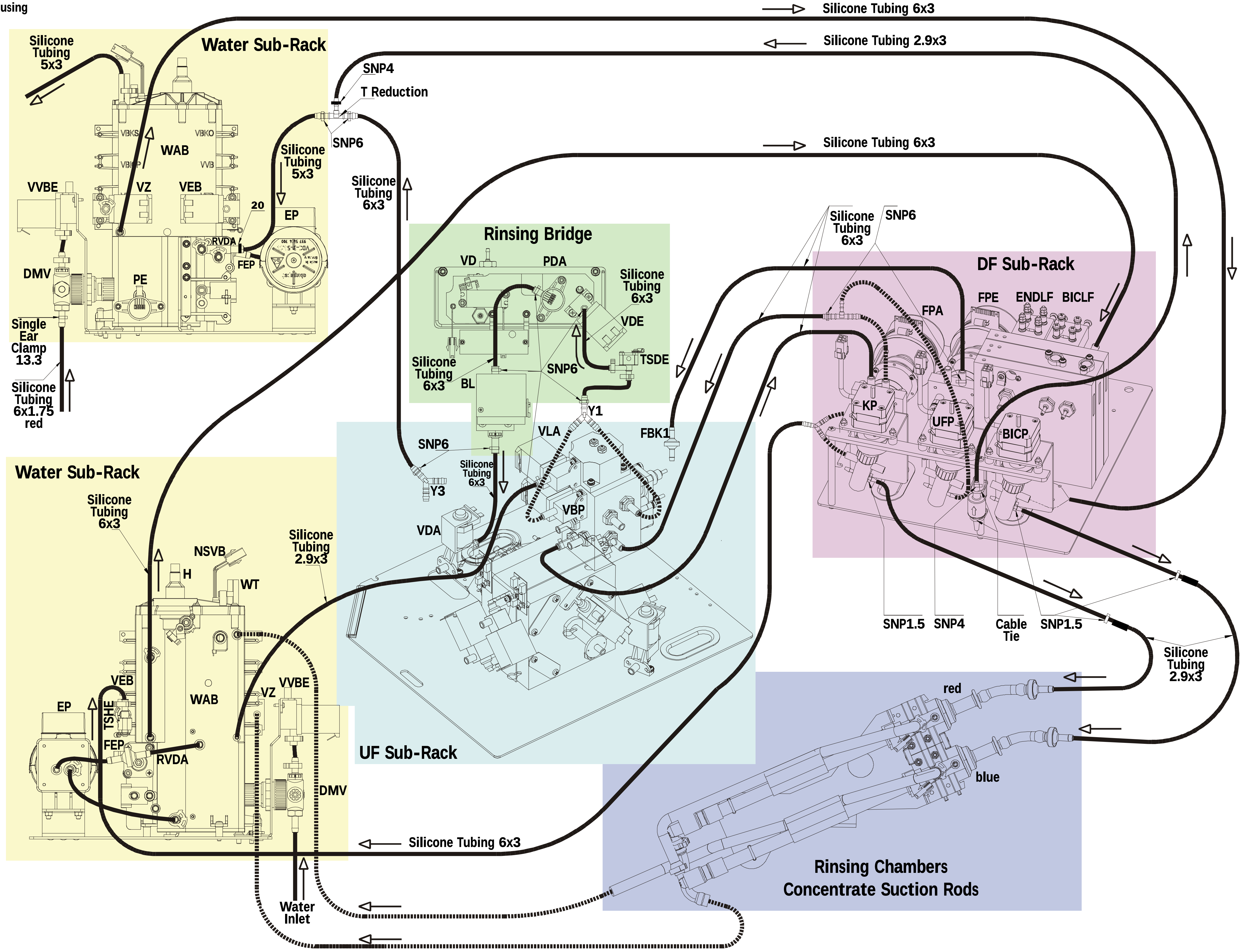
6.2.3.2 Solenoid Valves Water Sub-Rack



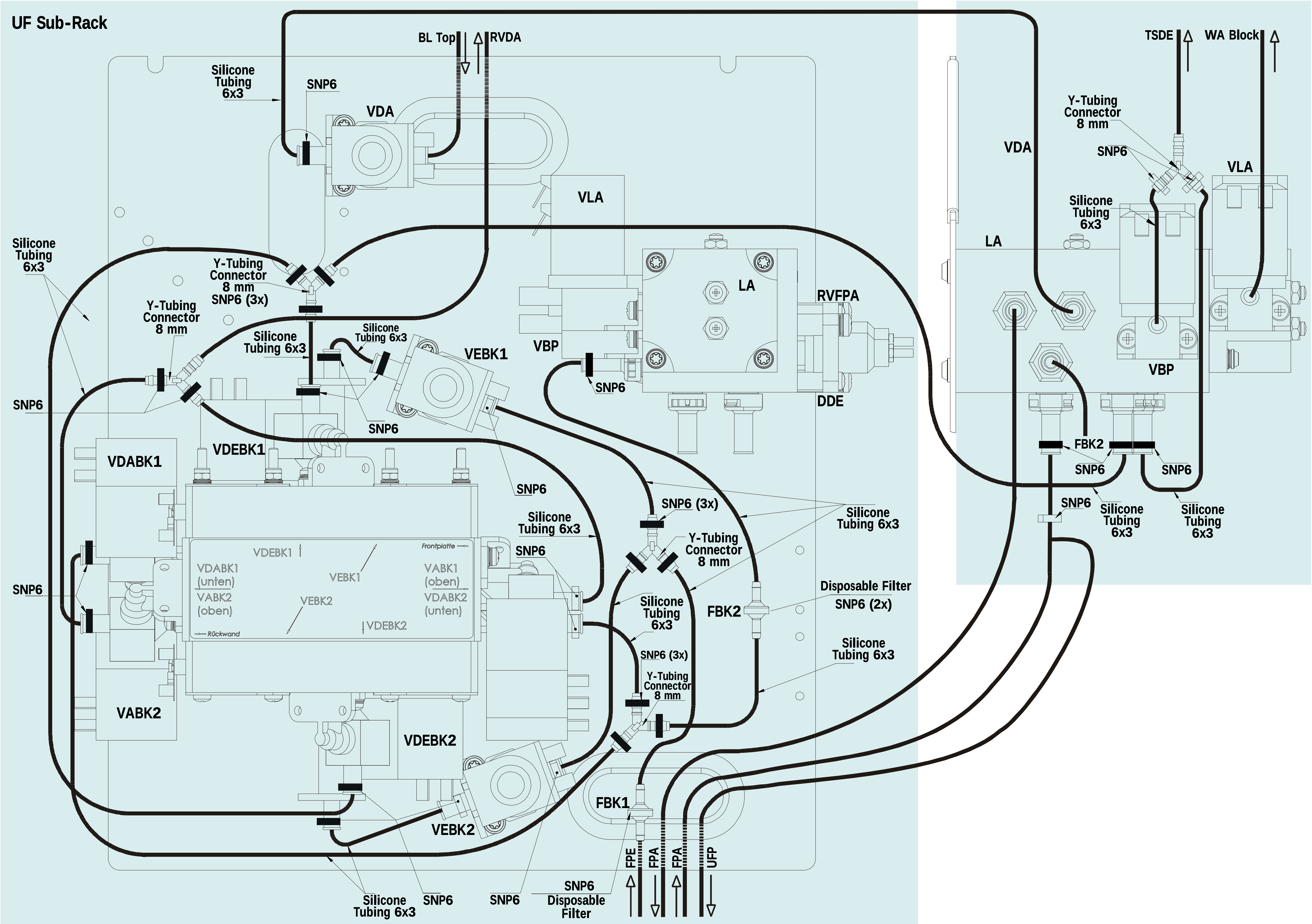
bk	black
bl	blue
br	brown
gn	green
gr	grey
rd	red
vi	violet
wh	white
ye	yellow

6.3 Tubing Diagrams

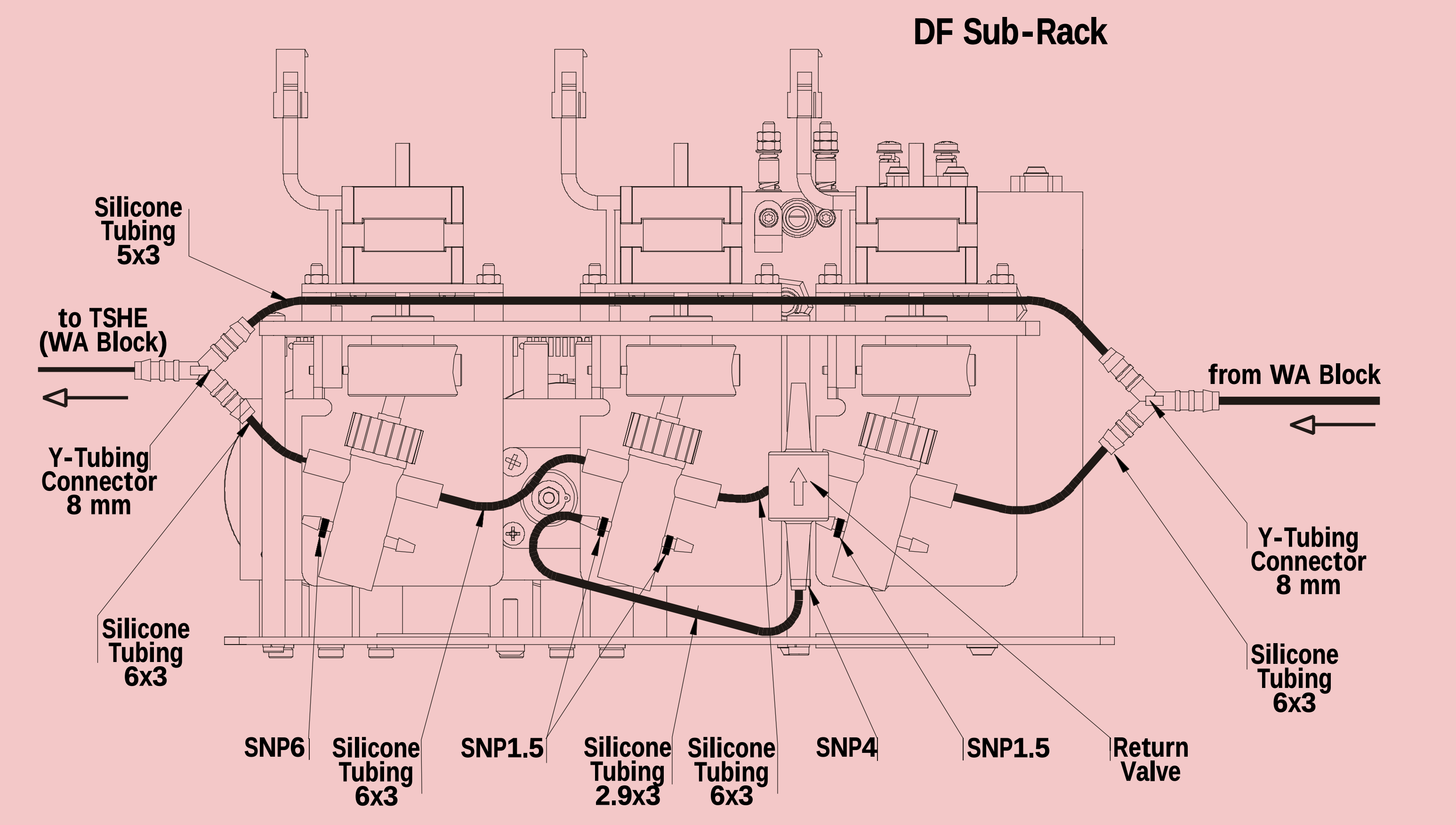
6.3.1 Tubing Diagram Housing

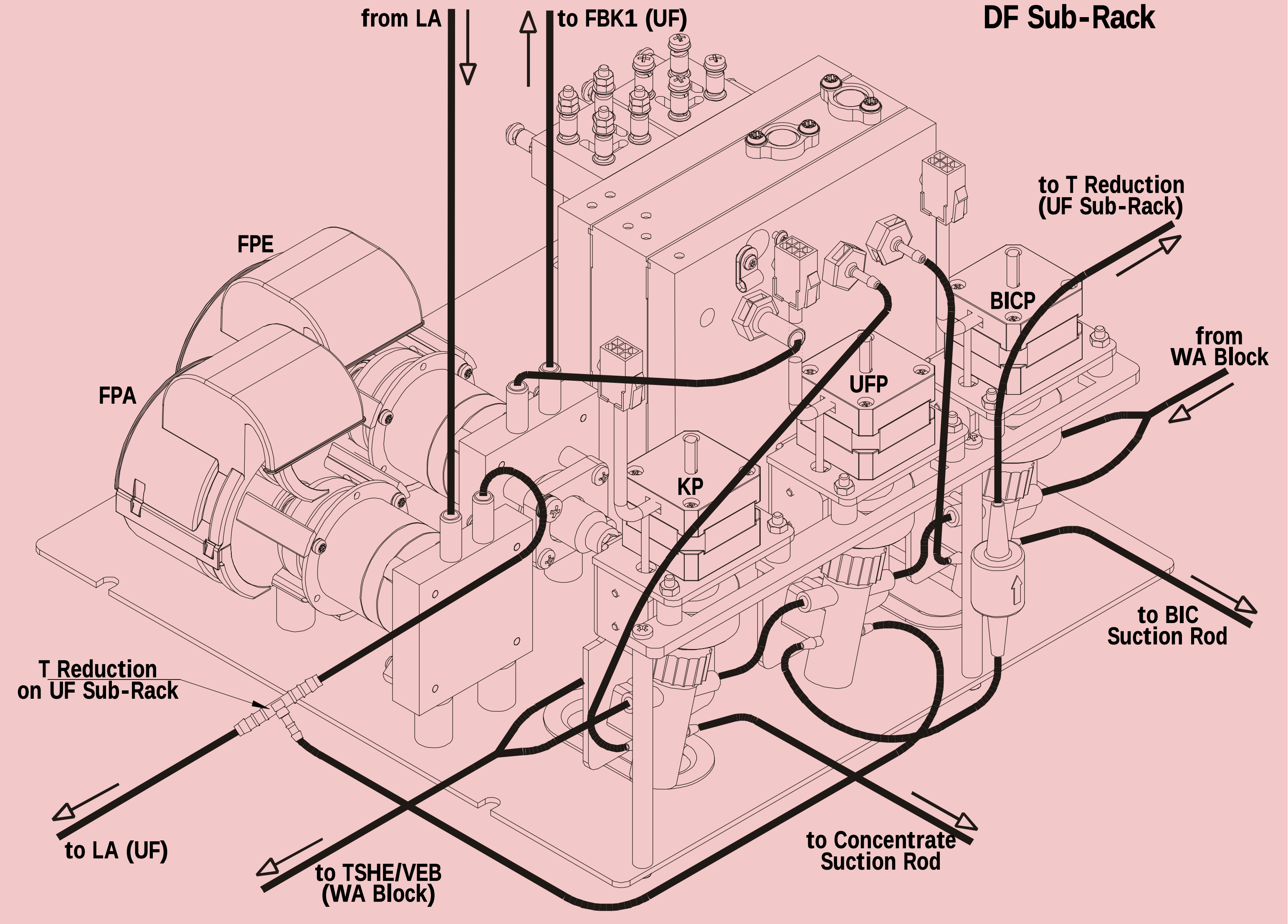


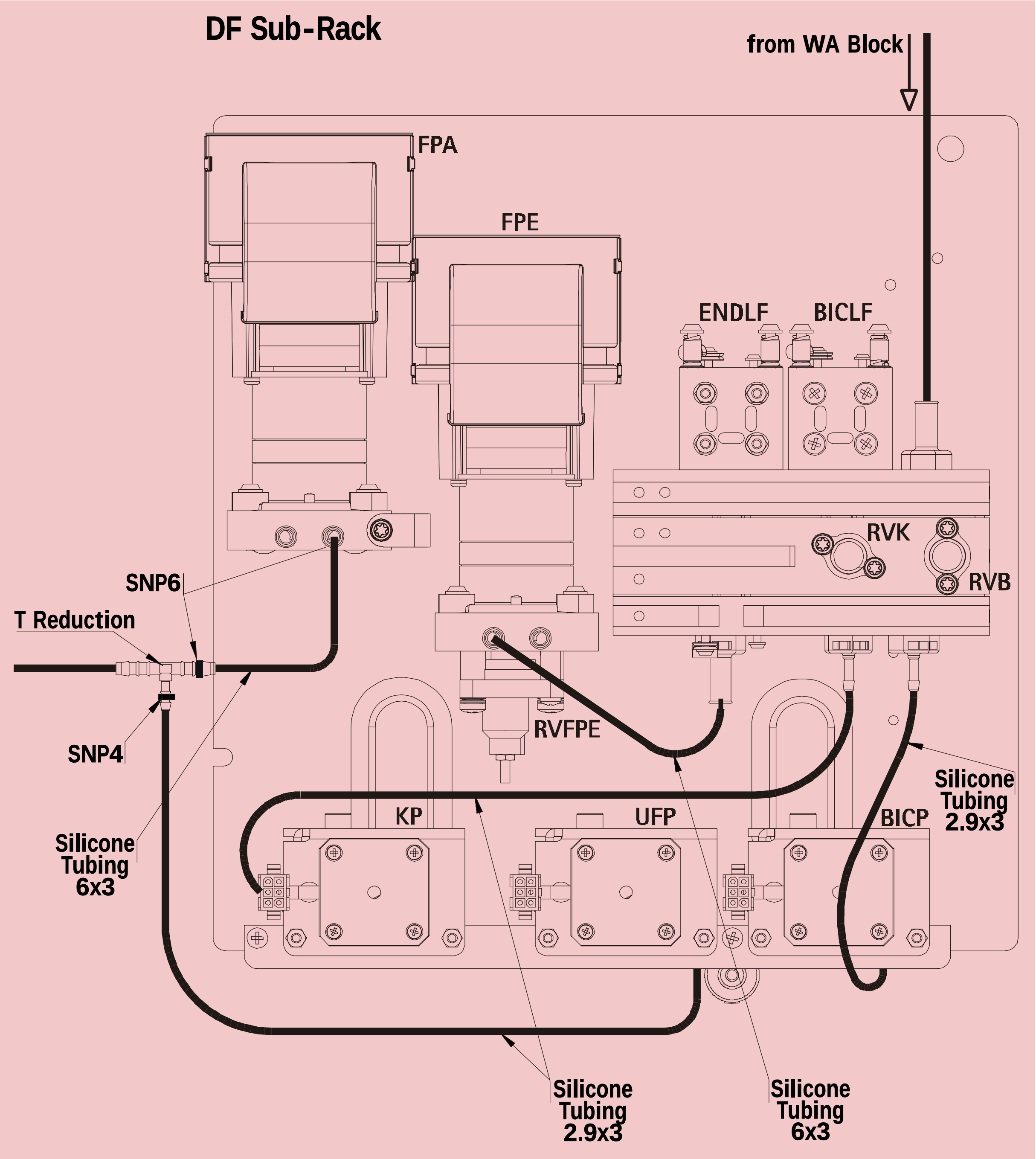
6.3.2 Tubing Diagram UF Sub-Rack



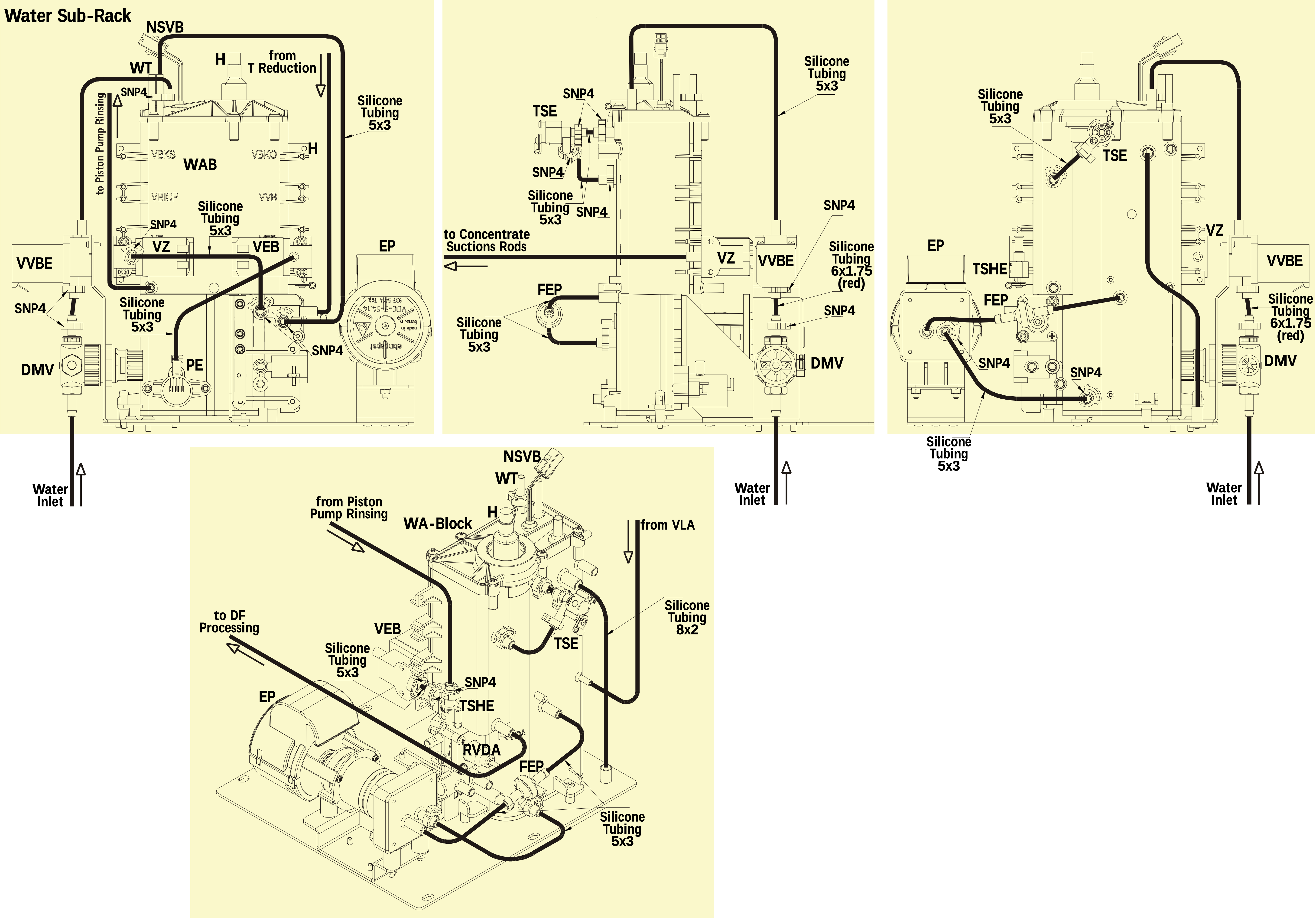
6.3.3 Tubing Diagram DF Sub-Rack



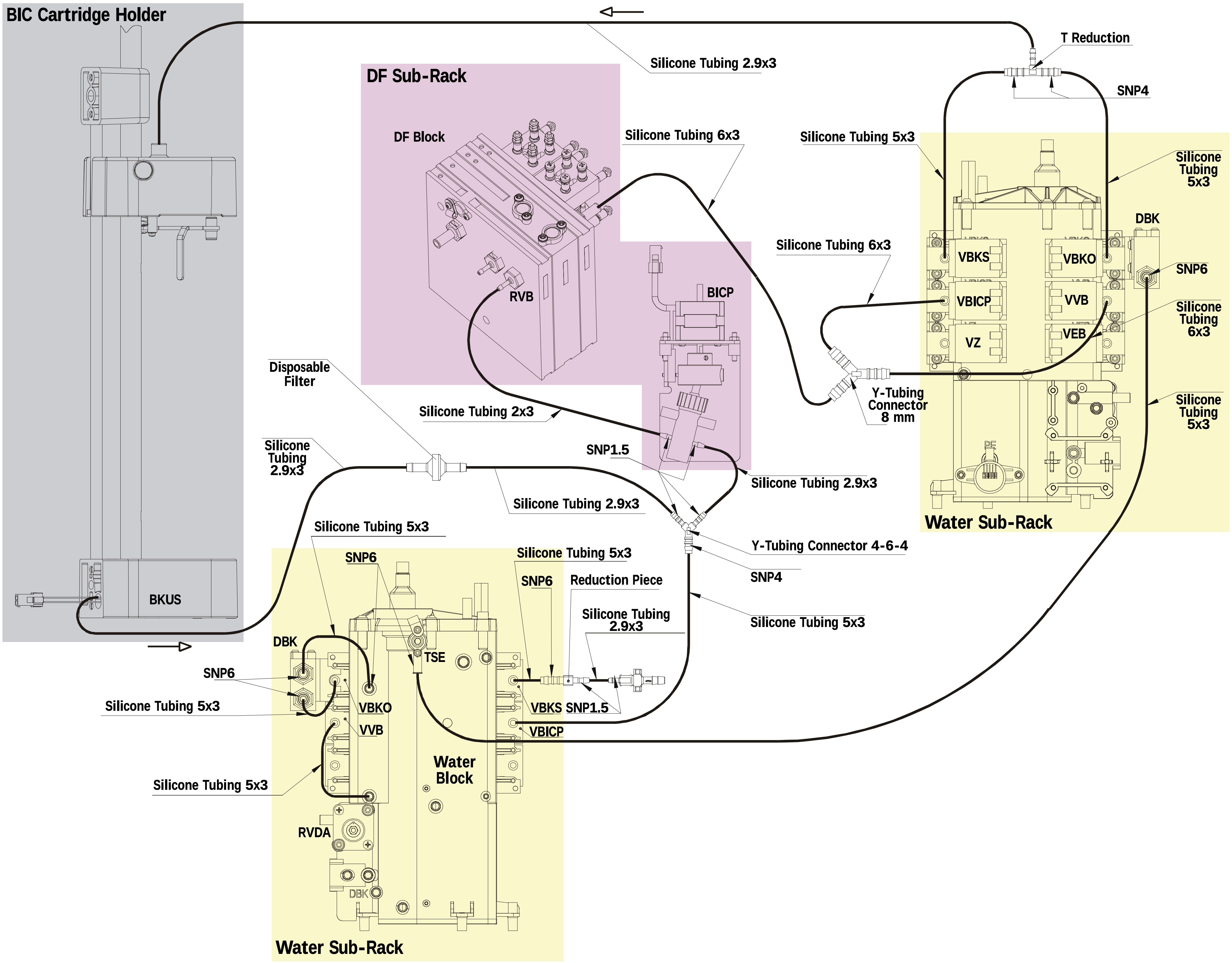




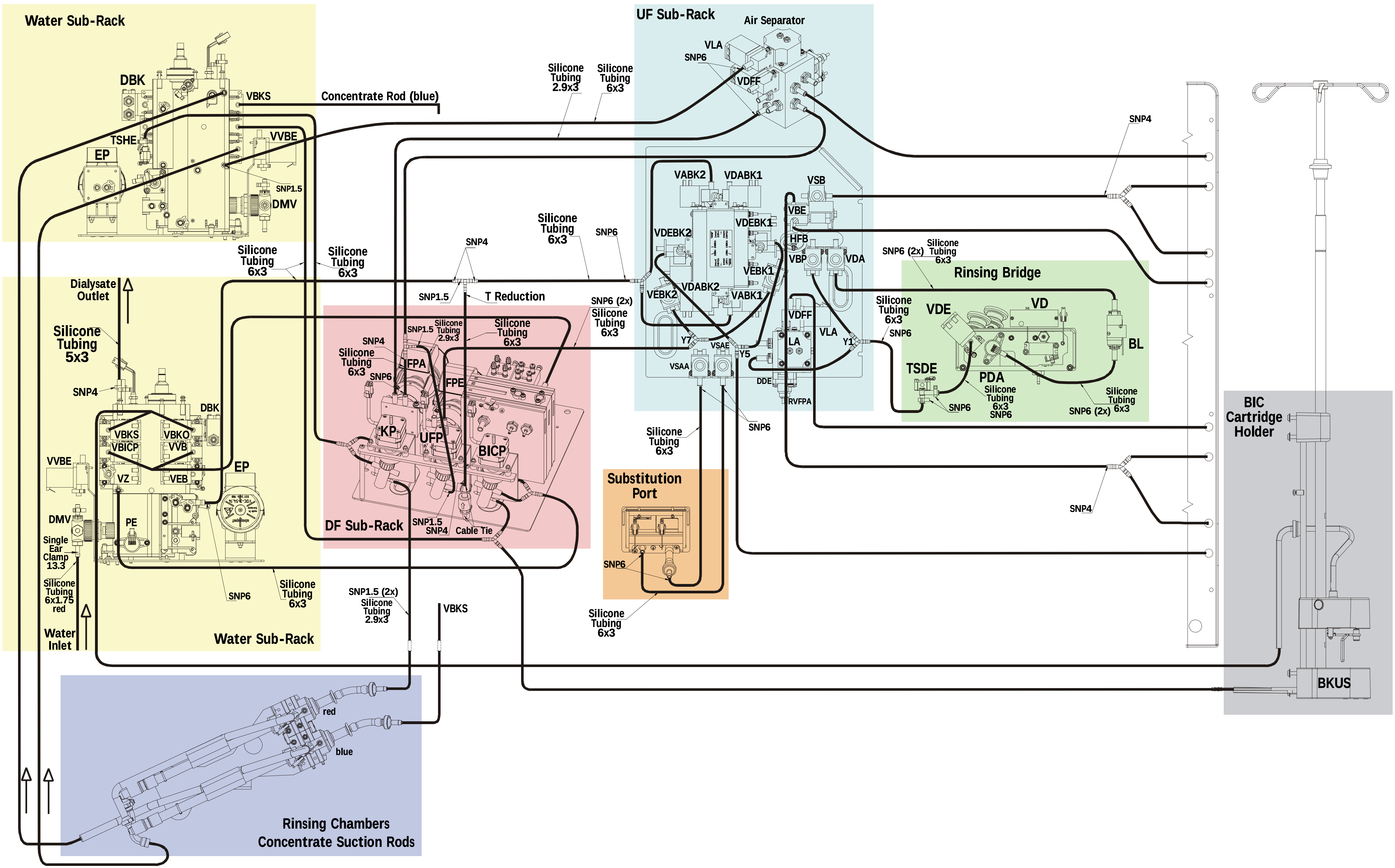
6.3.4 Tubing Diagram Water Sub-Rack



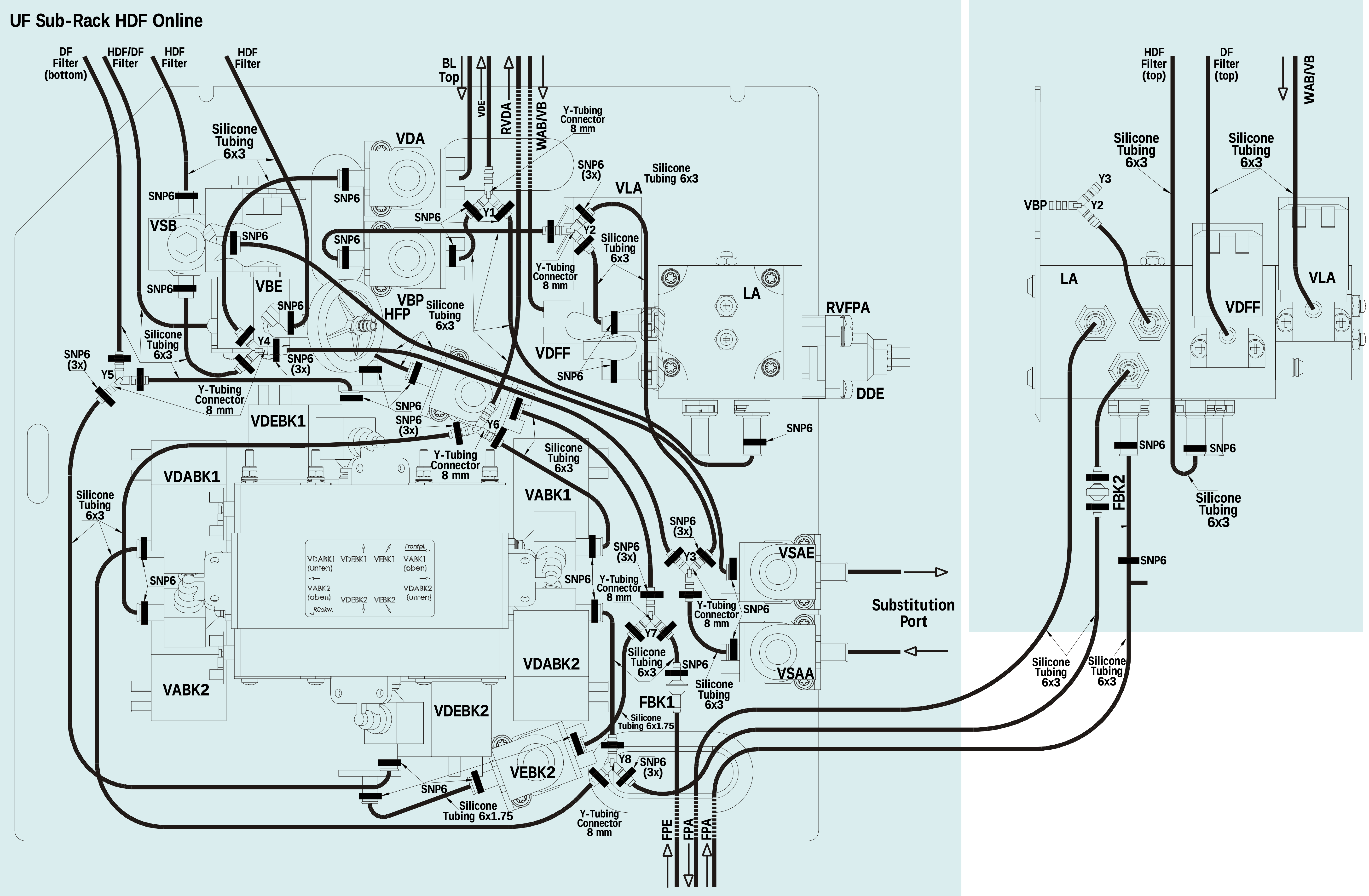
6.3.5 Tubing Diagram BIC Cartridge Holder



6.3.6 Tubing Diagram Housing HDF Online



6.3.7 Tubing Diagram UF Sub-Rack HDF Online



Contact your Local B. Braun Representative for Service Support

Spare Parts List

The spare parts list (edition 1-2010, edition date March 2010) is valid with immediate effect.

Refurbished Spare Parts

Conditions for Delivery of Refurbished Spare Parts (depending on availability):
Defective spare parts must be sent back with the accompanying documents (Material Return Form) to B. Braun Avitum AG via the representative of the respective country for the ability to supply refurbished spare parts. The condition and the version of the defective spare parts must allow a qualified refurbishment.

Backward Compatibility of Spare Parts

New spare parts always have article numbers with numeric characters and are backward compatible unless otherwise specified in the spare parts list. If a spare part is modified the last digit of the article number changes to an alphabetic character with the initial index A. These spare parts are in principle backward compatible to the previous article number (numeric or alphanumeric - with or without an index).

B. Braun Avitum AG
34209 Melsungen
Germany

Tel. No.: +49 5661 713662
E-Mail: Heike.Sinning@bbraun.com

Material Return Form

B. Braun Avitum AG
Wareneingang - Service
Schwarzenberger Weg 73-79

D-34212 Melsungen
Germany

Reason for returning the part (please tick ☑):
- Warranty return (replacement to be ordered separately) ---------------- ☐
- Defective part for refurbishment -- ☐
- Wrong shipment --- ☐
- Complaint sample (use complaint form for details) --------------------- ☐
- Spare part returned for investigation ----------------------------------- ☐
- Spare part returned for disposal by B. Braun Avitum AG---------------- ☐

Sender: Name of Company: ....

....

.... City: ....

Country: .... Name of responsible person: ....

Customer number: .... Telephone/e-mail: ....

Returned part: Article number: .... Part serial number: ....

Part description: ....

Description of the defect: ....

....

From machine type: .... Serial number: .... Working hours: ....

Software Version: .... Description of the problem on the machine: ....

....

....

The described defect appears: Intermittently ☐ Permanently ☐ (please tick ☑)

Cleaned/disinfected: Cleaned ☐ yes Disinfected ☐ yes (please tick ☑)

Disinfectant: ....

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 Dialog Machines

All spare parts sent by the customer to the B. Braun 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.

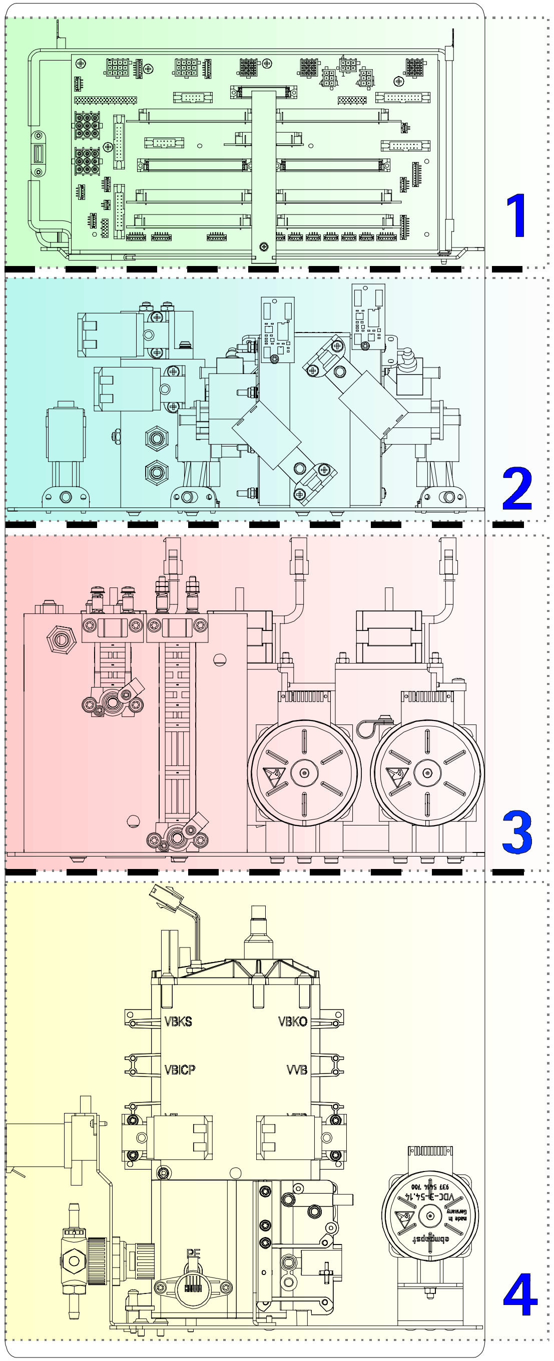
Returned parts containing electronic components (electrostatic sensitive devices) must be packed in special ESD packaging material. Only shielded bags or antistatic bags may be used. Unprotected electronic parts (e.g. wrapped in normal plastic bags or parts padded with Styrofoam) are assumed to be damaged 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

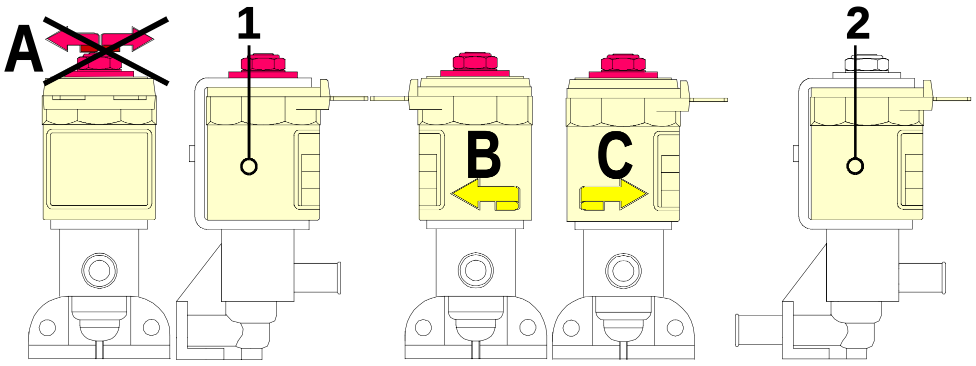
7.1 Sub-Racks

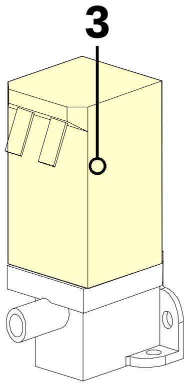


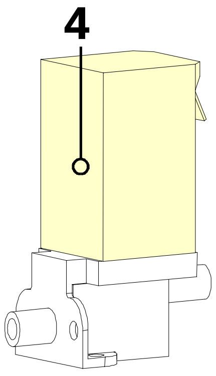
Pos.	Art. No.	Qty.	Description	Comments
1	-		Top level sub-rack	**see paragraph 7.6 for single parts**
2	-		UF sub-rack	**see paragraph 7.5 for single parts**
3	-		DF sub-rack	**see paragraph 7.4 for single parts**
4	-		Water sub-rack	**see paragraph 7.3 for single parts**

7.2 Solenoid Valves

Pos.	Art. No.	Qty.	Description	Comments
1	3451902C	1	Solenoid valve 2/2 way	**connector/flange (AKM)** **(pay attention to bottom notes)**
2	3451906C	1	Solenoid valve 2/2 way	**connector/connector (AKM)**
3	34560270	1	Solenoid valve 2/2 way	**connector/flange (DPP)**
4	34560289	1	Solenoid valve 2/2 way	**connector/connector (DPP)**



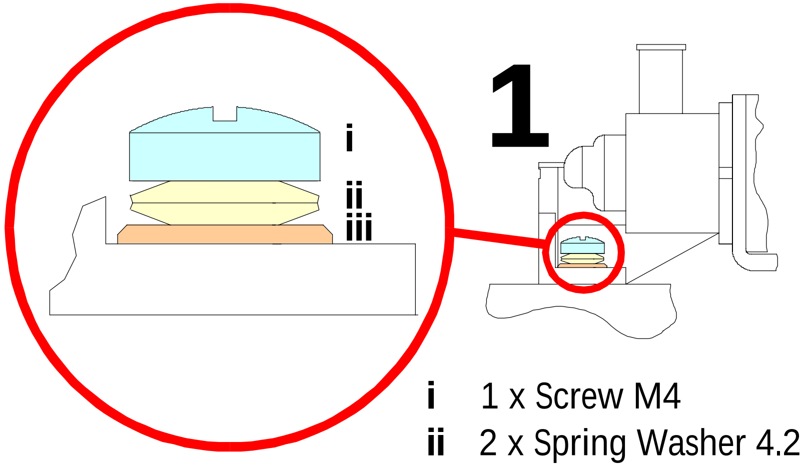




Notes for Solenoid Valve 3451902C

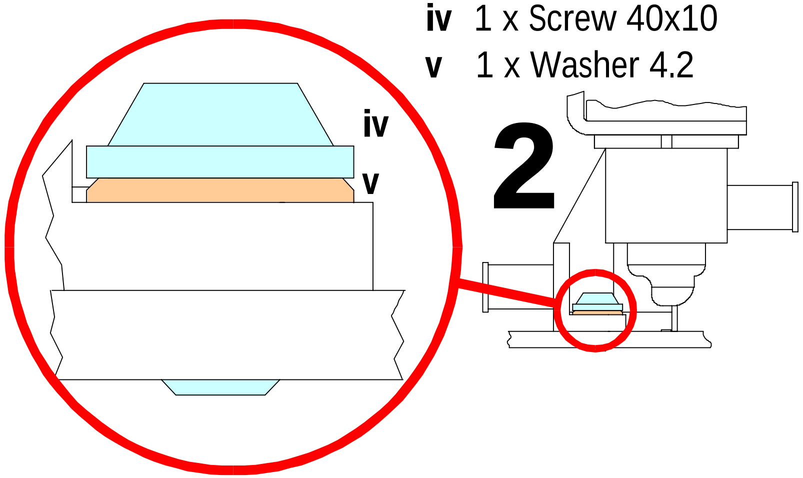
Self-Locking Nut A
Do not readjust the self-locking nut A, because the nut is assembled with a defined torque (1.3 Nm ± 10 %).

The position of the magnet coil can be adapted to the assembly location, i.e. the coil can be carefully turned (**B** or **C**) without loosening the self-locking nut **A**. The procedure is only permissible if the coil can be turned without much effort.

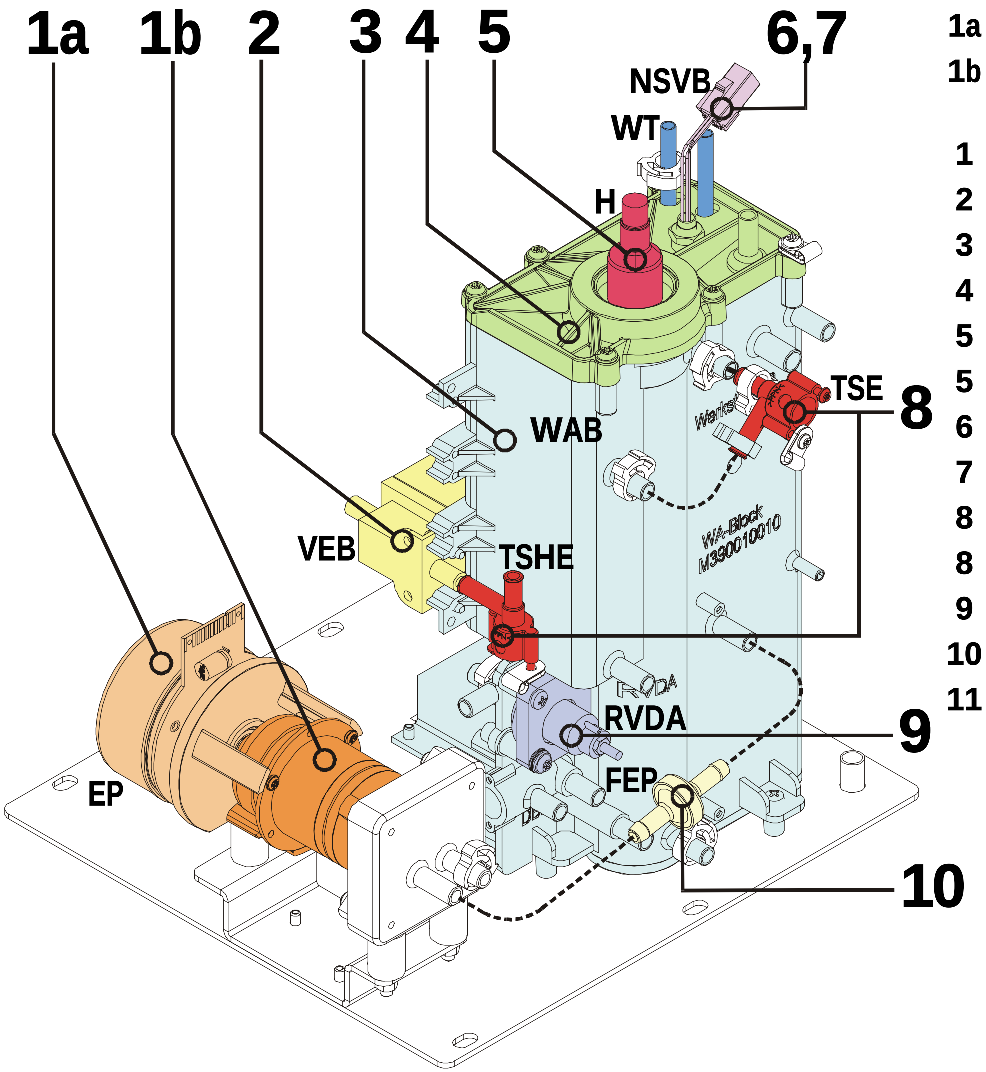


- **i** 1 x Screw M4
- **ii** 2 x Spring Washer 4.2
- **iii** 1 x Washer 4.2

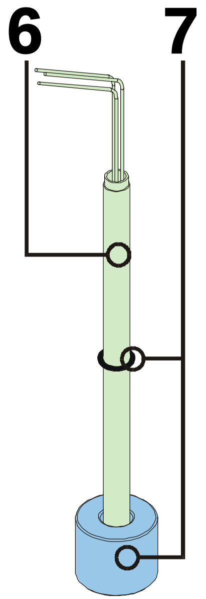
- **iv** 1 x Screw 40x10
- **v** 1 x Washer 4.2



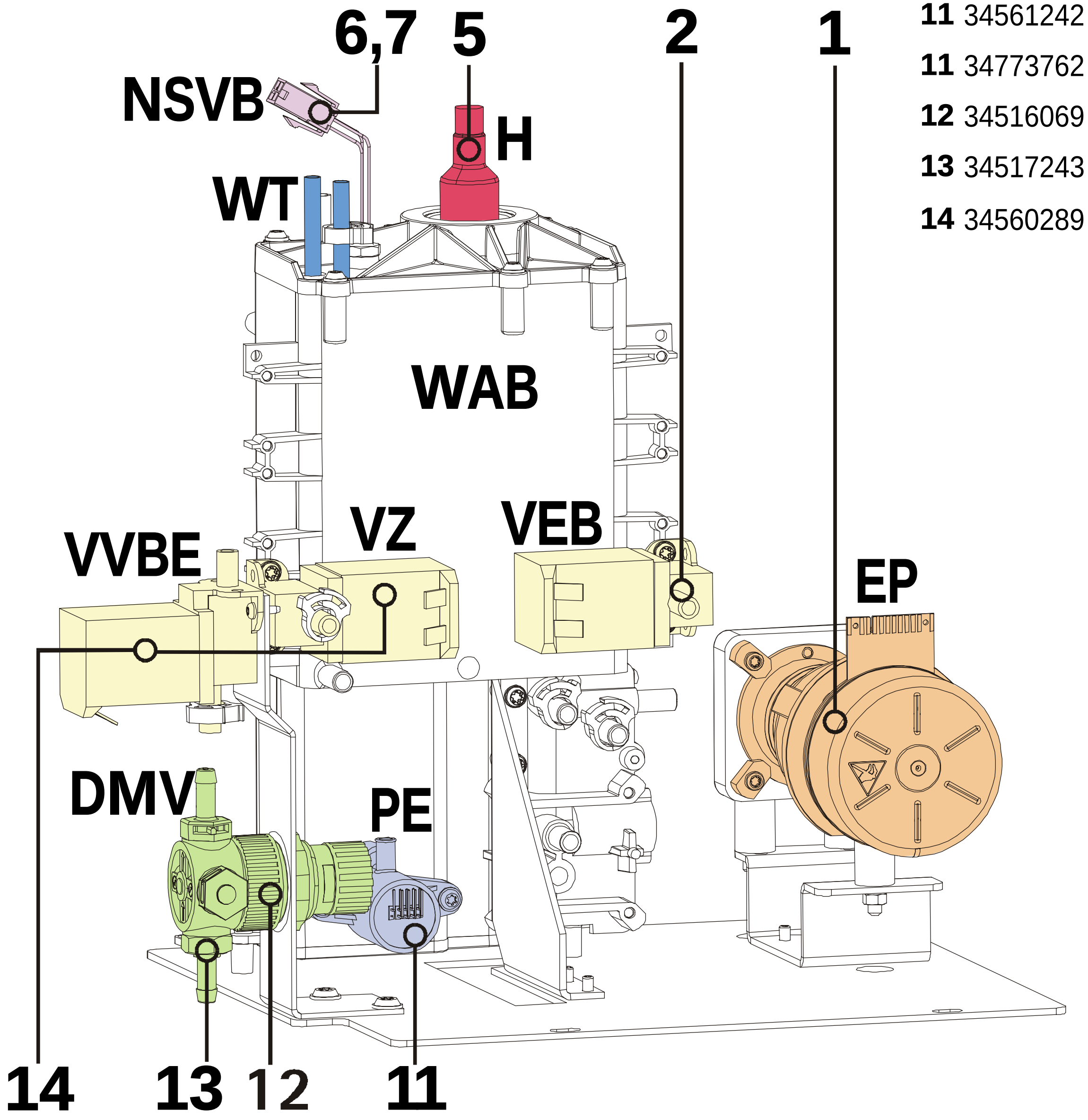
7.3 Water Sub-Rack



Pos.	Art. No.	Qty.	Description	Comments
1a	34560718	1	Motor for gear pump (SW 1.7.4)	see separate figure
1b	34560319	1	Gear pump (Micropump version 2) with magnet, without motor	version 2 for EP only is shown without motor cover
1	34770950	20	O-ring 8.0 x 1.6	
2	34560386	1	Solenoid valve 2/2 way with bypass	
3	34561315	1	Water block without lid	
4	34561323	1	Lid for waterblock	
5	3456021A	1	Heater element 120 V/2x900 W	incl. two seals
5	3456020A	1	Heater element 240 V/2x900 W	incl. two seals
6	34560459	1	Level sensor complete	with float ball
7	34560246	1	Float ball incl. o-ring	
8	3451614B	1	Temperature sensor	without connector
8	34570730	1	Housing complete for temperature sensor	
9	3451727B	1	Throttle 0.4 bar	
10	3451664B	1	Throttle 1.3 bar	für HDF-Online
11	34517782	5	Disposable filter	



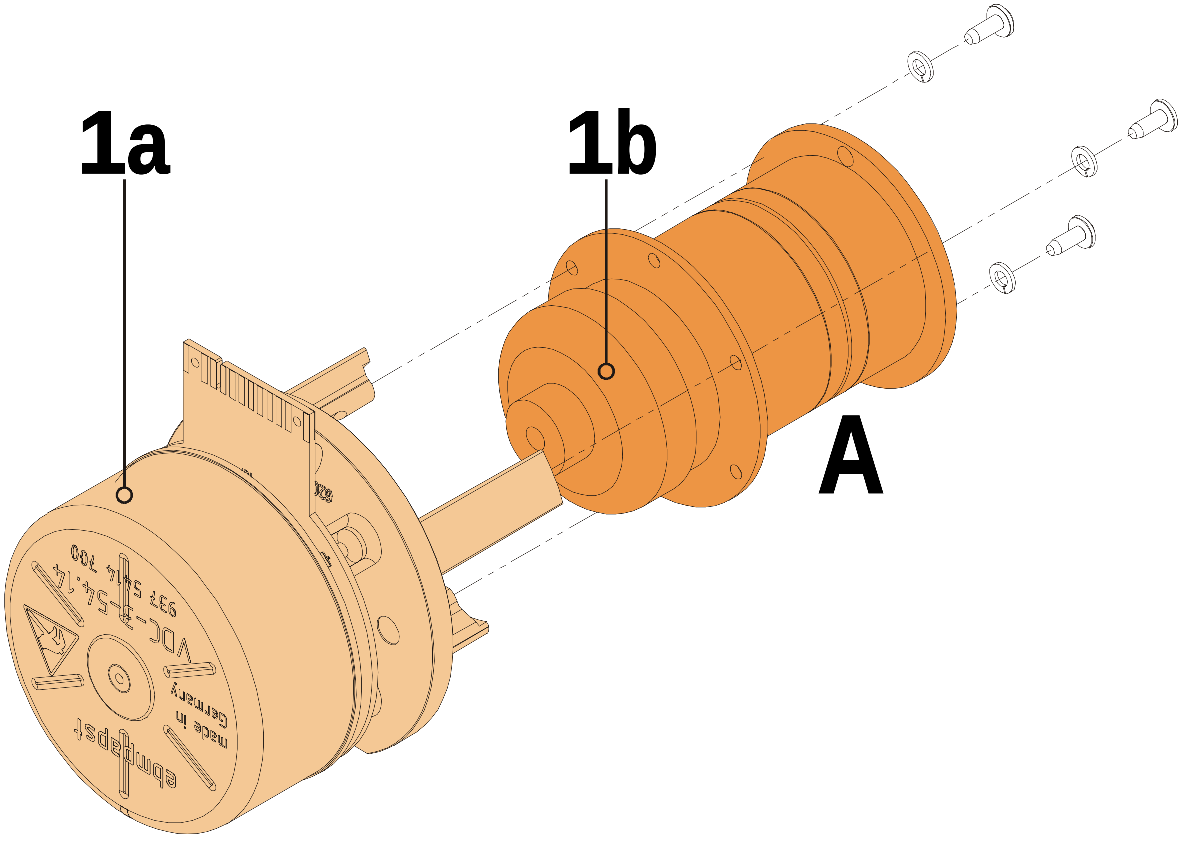
Water Sub-Rack



Pos.	Art. No.	Qty.	Description	Comments
11	34561242	1	Pressure sensor	
11	34773762	10	O-ring 9.25 x 1.78	
12	34516069	1	Throttle 0 - 4 bar	
13	34517243	1	Tubing connector ∅ 7 x 1/8"	stainless steel
14	34560289	1	Solenoid valve 2/2 way	connector/connector (DPP)

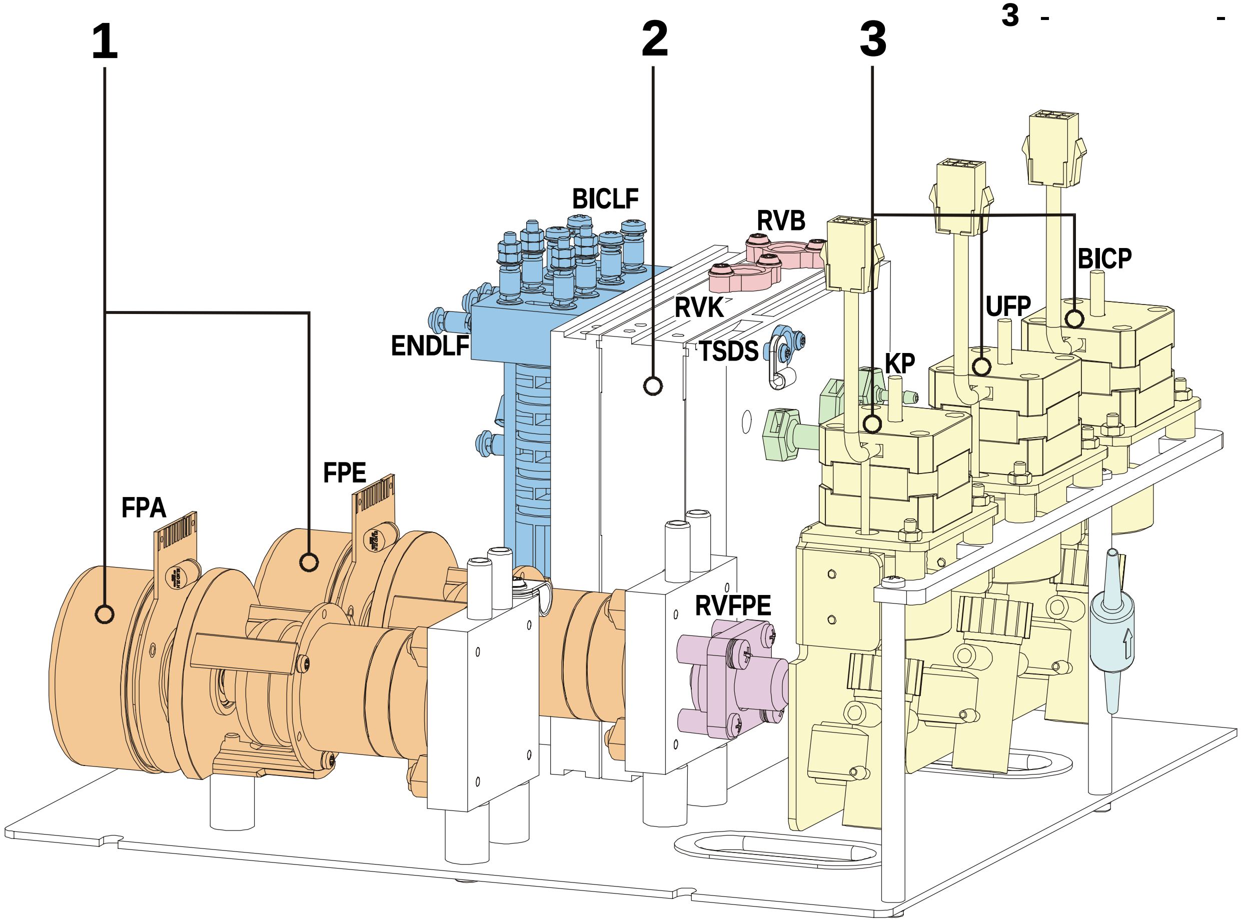
7.3.1 Gear Pump for EP

Pos.	Art. No.	Qty.	Description	Comments
1a	34560718	1	Motor for gear pump (SW 1.7.4)	
1b	34560319	1	Gear pump (Micropump version 2) with magnet, without motor	**Micropump Version 2 for EP only (see A in figure)**

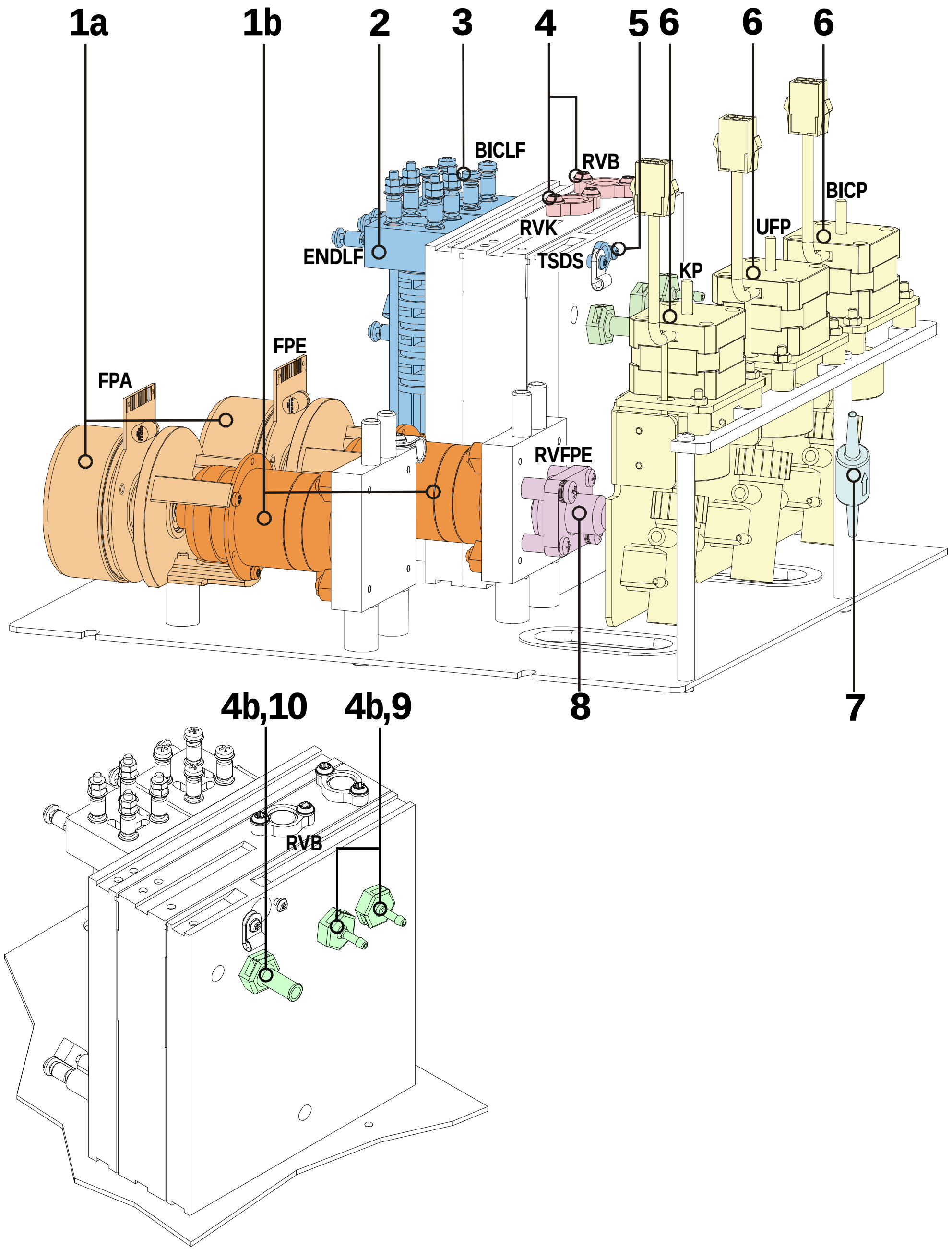


7.4 DF Sub-Rack

Pos.	Art. No.	Qty.	Description	Comments
1	-	-	Gear pumps	see separate figure for single parts, paragraph 7.4.1
2	-	-	DF block	see separate figure for single parts, paragraph 7.4.1
3	-	-	Piston pumps	see separate figure for single parts, paragraph 7.4.2

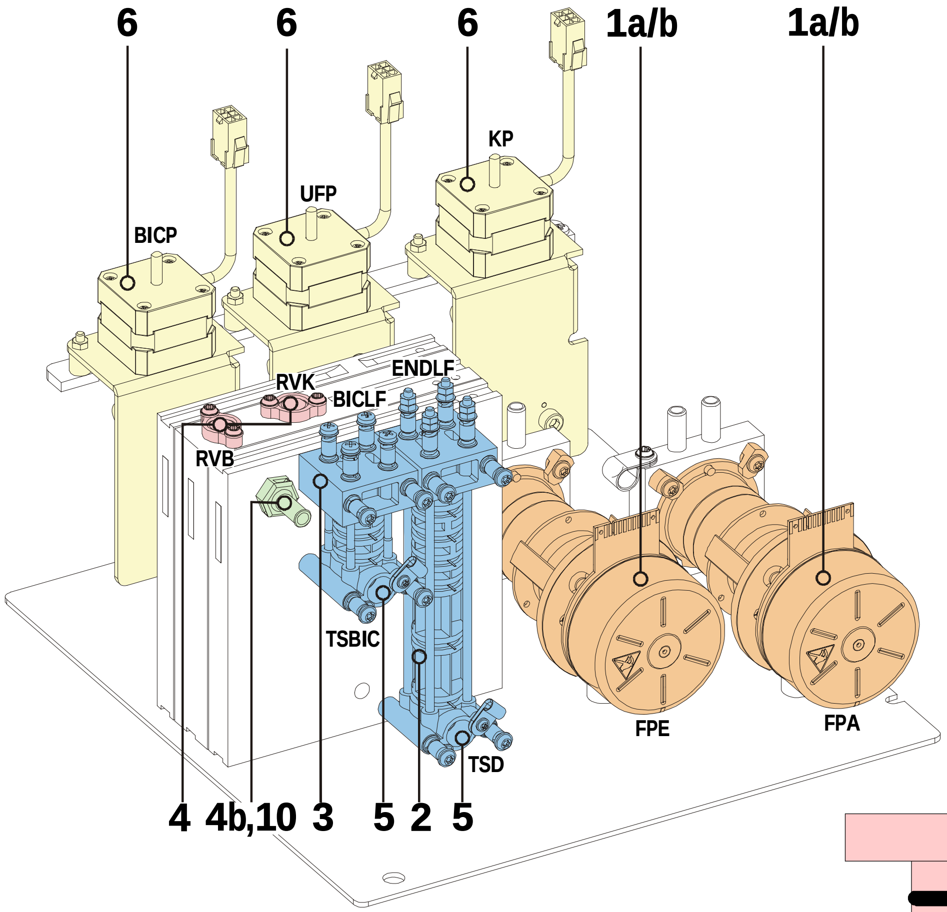


7.4.1 DF Block

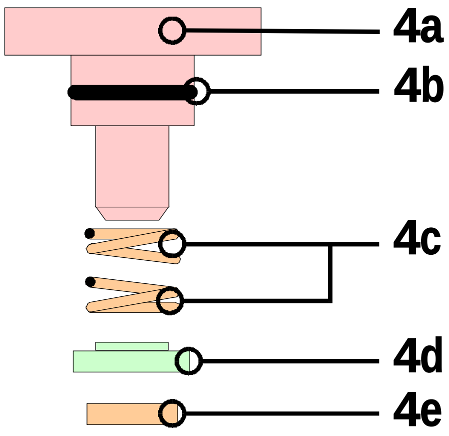


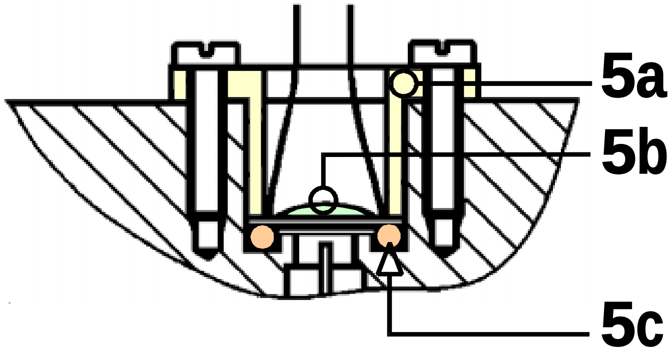
Pos.	Art. No.	Qty.	Description	Comments
1a	34560718	1	Motor for gear pump (SW 1.7.4)	**see separate figue**
1b	34515330	1	Gear pump (Micropump version 1) with magnet, without motor	**version 1 for FPA/FPE only is shown without motor cover**
1	34770950	20	O-ring 8.0 x 1.6	
1	34771140	20	O-ring 3.1 x 1.6	
2	34561030	1	END conductivity sensor version 2	**with temperature sensor**
3	34561021	1	Bicarbonate conductivity sensor version 2	**with temperature sensor**
4a	34770925	5	Plug	
4b	34770852	5	O-ring 11.1 x 1.6	
4c	34771050	10	Pressure spring 500 mmHg	
4d	34772928	3	Centre disc	
4e	34771085	5	Seal	
5a	34570373	10	Plug (long)	
5b	3451614B	1	Temperature sensor	**without connector**
5c	3477104A	10	O-ring 8.3 x 2.4	
6	-	-	Piston pumps	**see paragraph 7.4.2**
7	34514988	1	Return valve, incl. 2 x tubing clamps, 2 x cable ties	**return valve RV necessary for standard UFP**
8	3451664B	1	Druckregler 1,3 bar	
8	34570683	10	O-Ring 4,47 x 1,78	
9	3477103A	2	Tubing connector ∅ 3.5 x 1/8"	**plastic**
10	3451916A	5	Tubing connector ∅ 8 x 1/8"	**plastic**

DF Block



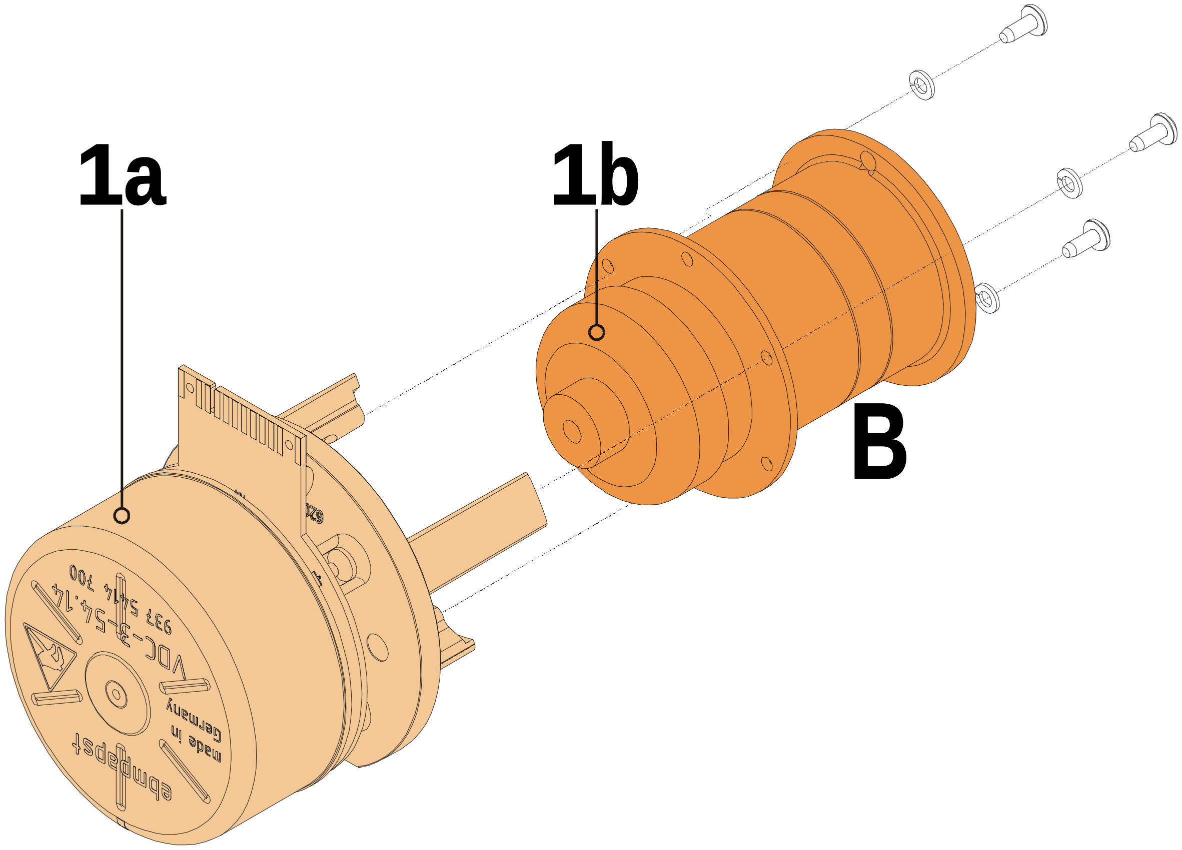
Pos.	Art. No.	Qty.	Description	Comments
4a	34770925	5	Plug	
4b	34770852	5	O-ring 11.1 x 1.6	
4c	34771050	10	Pressure spring 500 mmHg	
4d	34772928	3	Centre disc	
4e	34771085	5	Seal	
5a	34570373	10	Plug (long)	
5b	3451614B	1	Temperature sensor	without connector
5c	3477104A	10	O-ring 8.3 x 2.4	





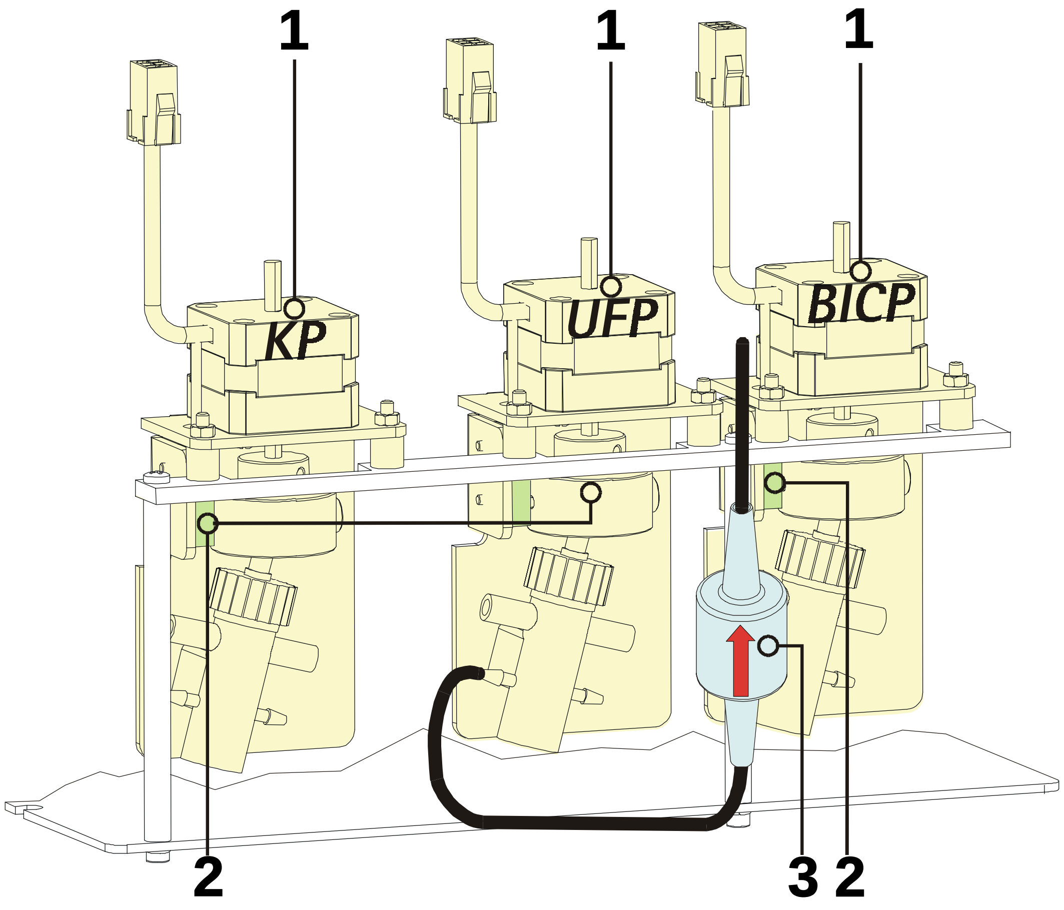
7.4.1.1 Gear Pump for FPE/FPA

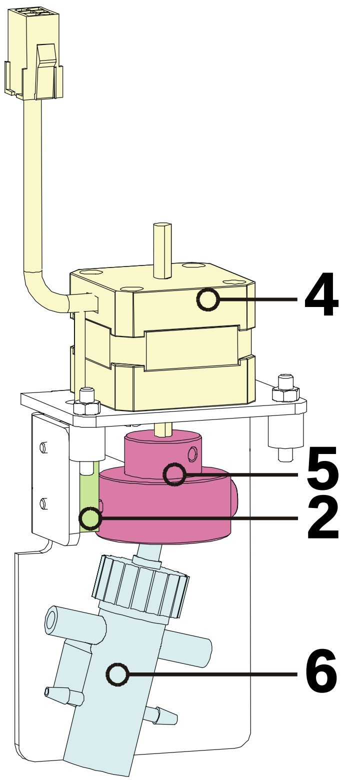
Pos.	Art. No.	Qty.	Description	Comments
1a	34560718	1	Motor for gear pump (SW 1.7.4)	
1b	34515330	1	Gear pump (Micropump version 1) with magnet, without motor	**Micropump Version 2 for FPA/FPE only (see B in figure)**



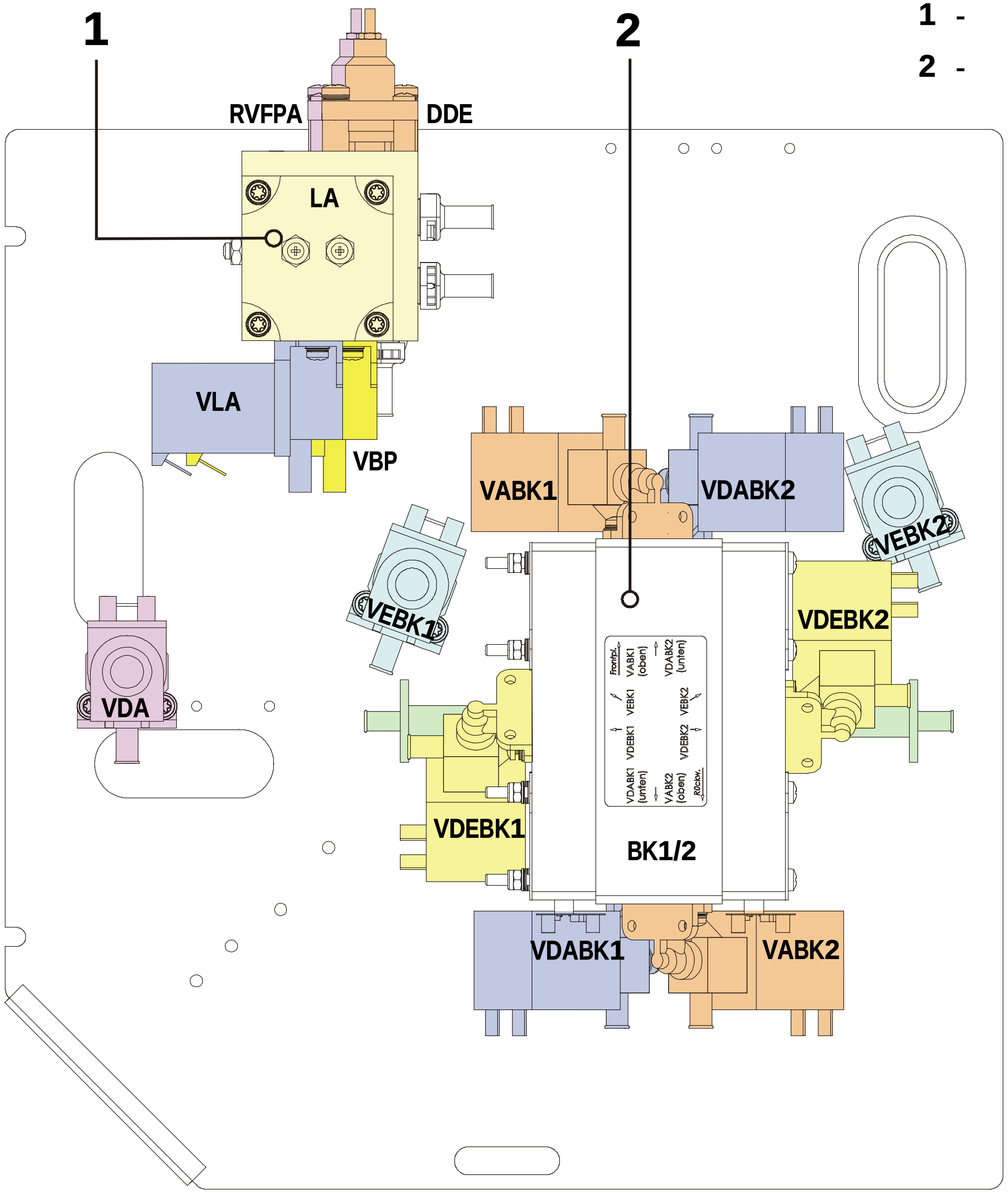
7.4.2 Piston Pumps

Pos.	Art. No.	Qty.	Description	Comments
1	3451749E	1	Piston pump	**for UF/BICP/KP piston pump. Return valve additionally necessary for standard UF piston pump.**
2	34519246	1	Reed sensor complete	
3	34514988	1	Return valve, incl. 2 x tubing clamps, 2 x cable ties	**return valve RV necessary for standard UFP**
4	34560556	1	Motor for piston pump	
5	34560572	1	Bell joint for piston pump	
6	34560602	1	Pump body for piston pump	
-	7703848	1	Assembly jig (motor piston pump)	**required for motor assembly**



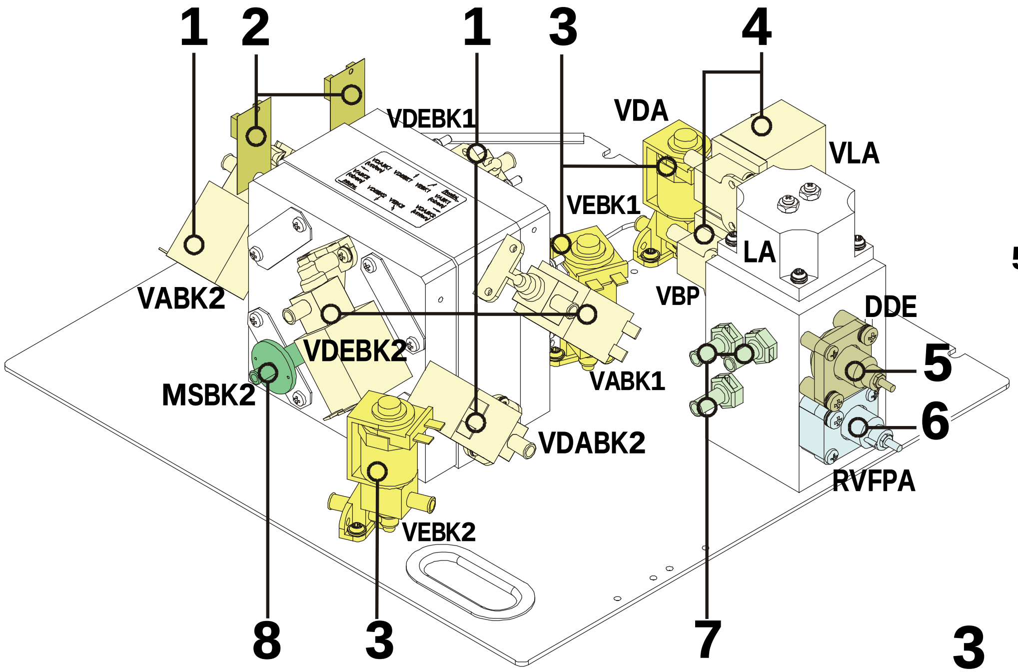


7.5 UF Sub-Rack

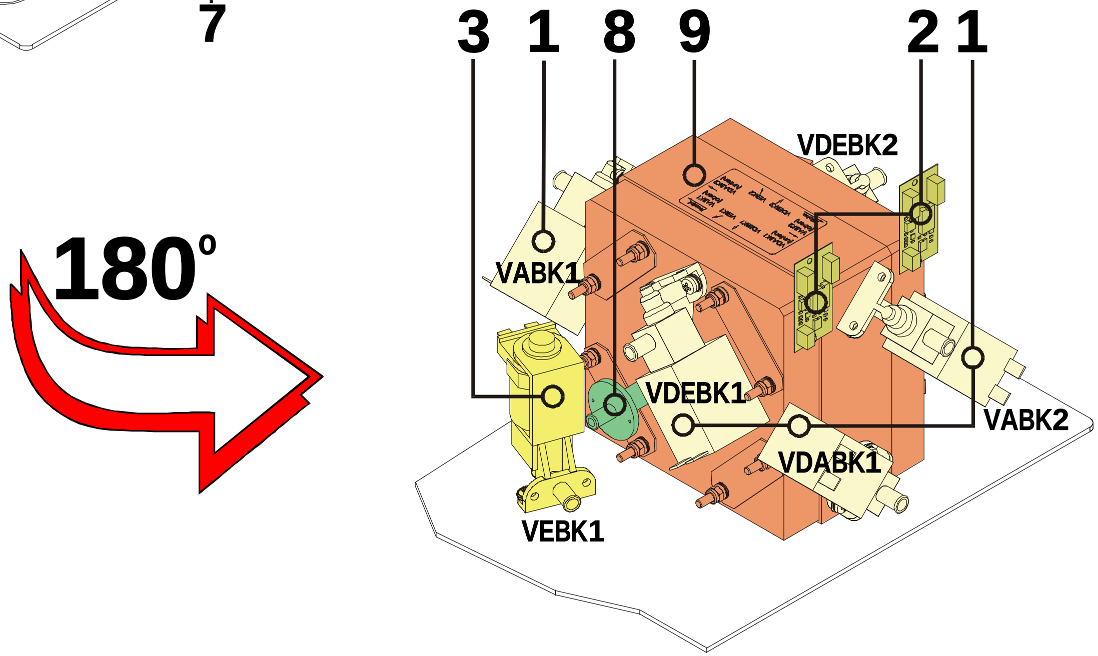


Pos.	Art. No.	Qty.	Description	Comments
1	-	-	Air separator complete	see separate figure
2	-	-	Balance chamber 2	see separate figure

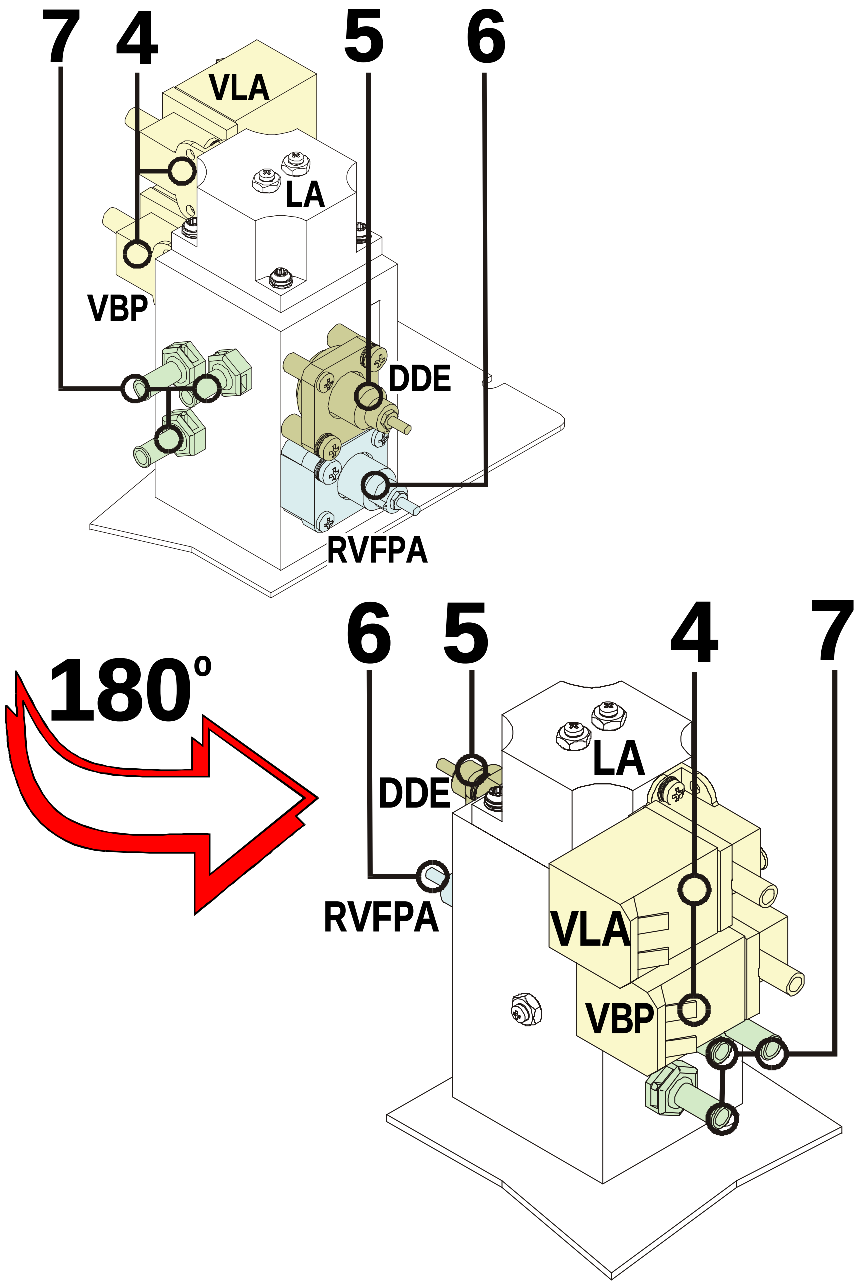
7.5.1 Balance Chamber 2



Pos.	Art. No.	Qty.	Description	Comments
1	3451902C	1	Solenoid valve 2/2 way	**manuf. AKM only, connector/flange**
1	34770852	5	O-ring 11.1 x 1.6	
2	3451665A	2	Membrane position sensor board	**exchange as pair only**
3	3451906C	1	Solenoid valve 2/2 way	**manuf. AKM only, connector/connector**
4	34560270	1	Solenoid valve 2/2 way	**connector/flange (DPP)**
5/6/7	-	-	-	**see next page**
8	3451909A	1	Coil	
8	34770976	10	O-ring 15.6 x 1.78	
9	3451897A	1	Repair kit balance chamber	**for complete replacement of both membranes, incl. all o-rings/assembly parts (self-locking nuts, screws, springs etc.)**
9	3451615A	2	Membrane for balance chamber	
-	34570195	20	Tubing clamp SNP-1.5 ∅ 7-8 mm	**plastic**
-	34570209	20	Tubing clamp SNP-4 ∅ 10-11 mm	**plastic**

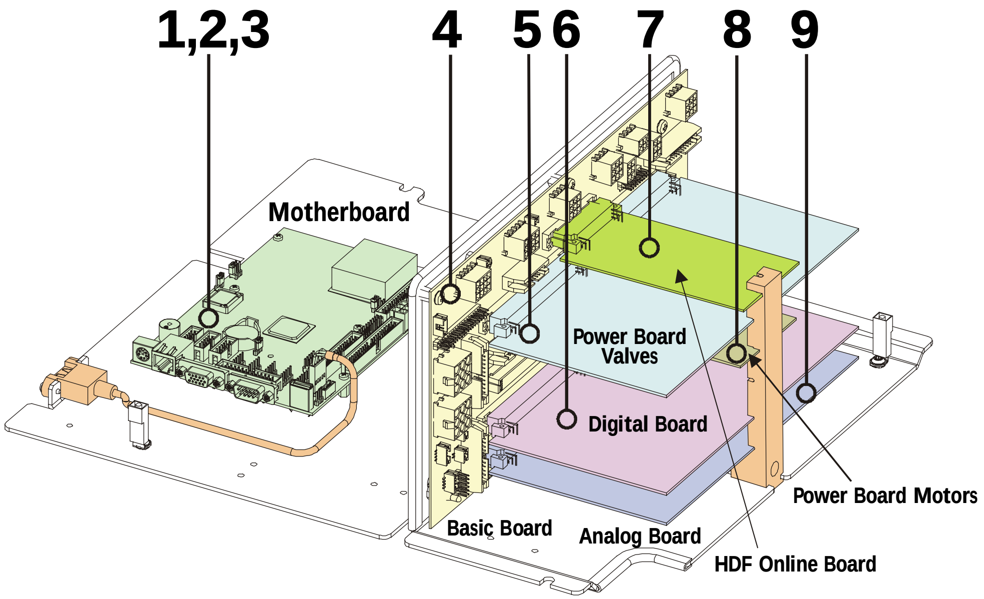


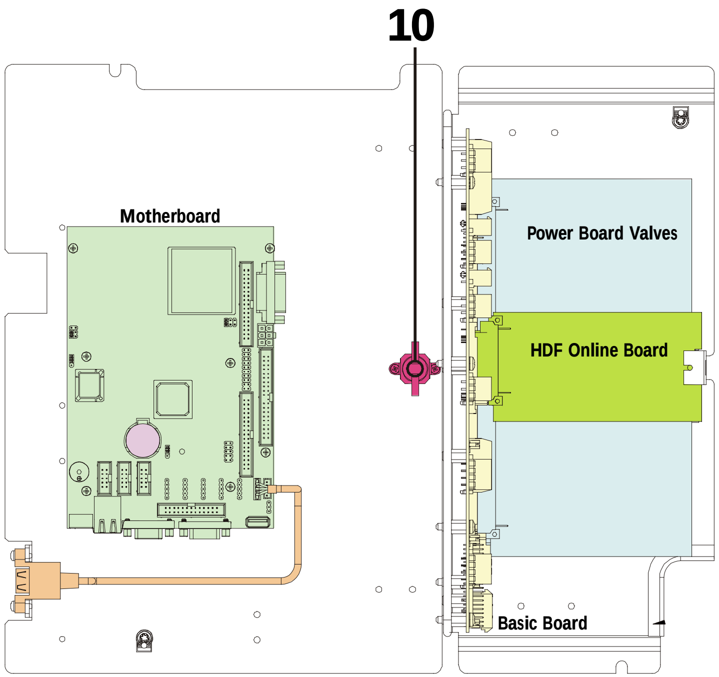
7.5.2 Air Separator Assembly Group



Pos.	Art. No.	Qty.	Description	Comments
4	34560270	1	Solenoid valve 2/2 way	**connector/flange (DPP)**
4/7	34770852	5	O-ring 11.1 x 1.6	
5	3451727B	1	Throttle 0.4 bar	
5/6	34570683	10	O-ring 4.47 x 1.78	
6	3451664B	1	Throttle 1.3 bar	
7	3451916A	5	Tubing connector ∅ 8 x 1/8"	**plastic**

7.6 Top Level Sub-Rack

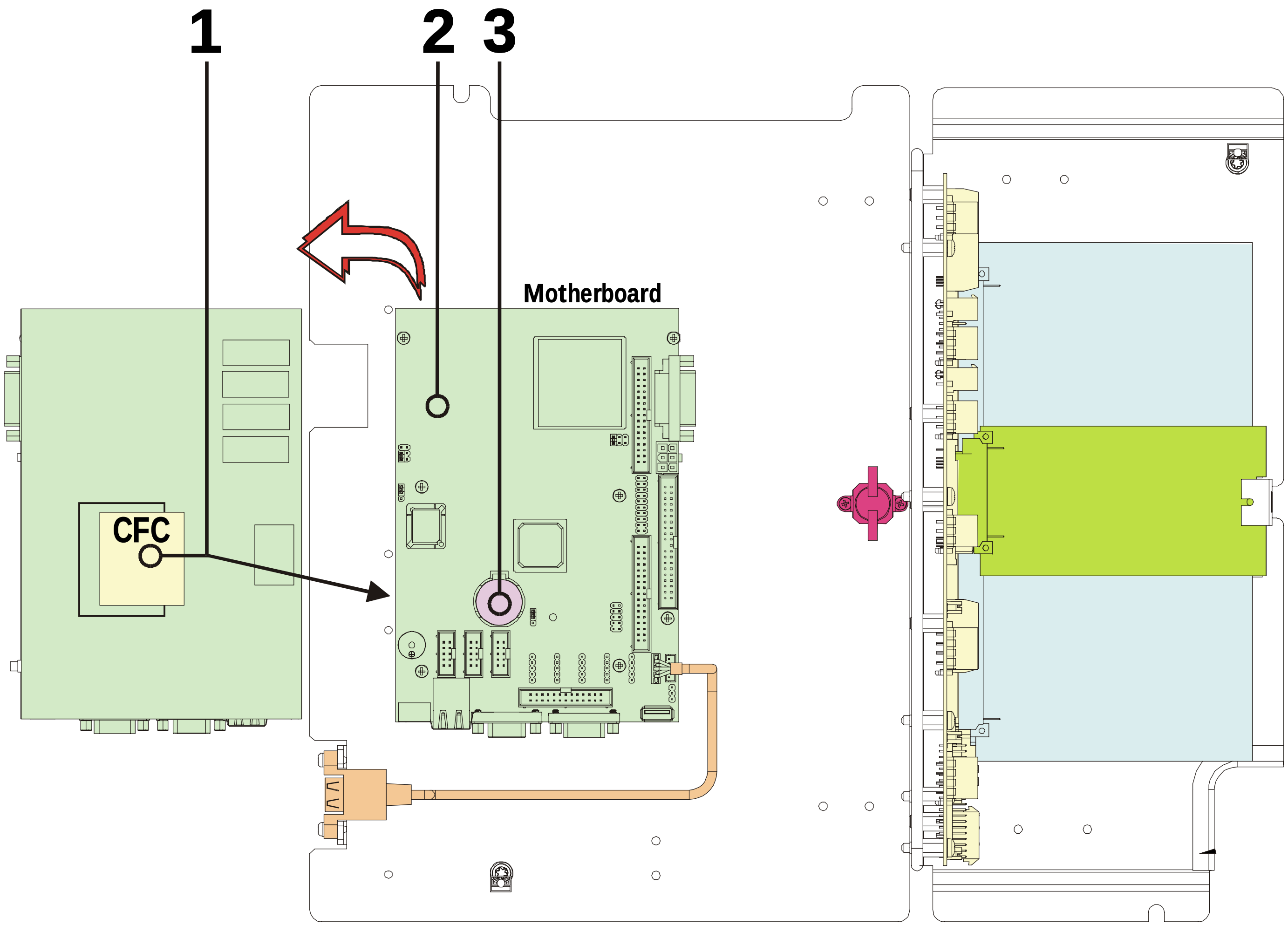




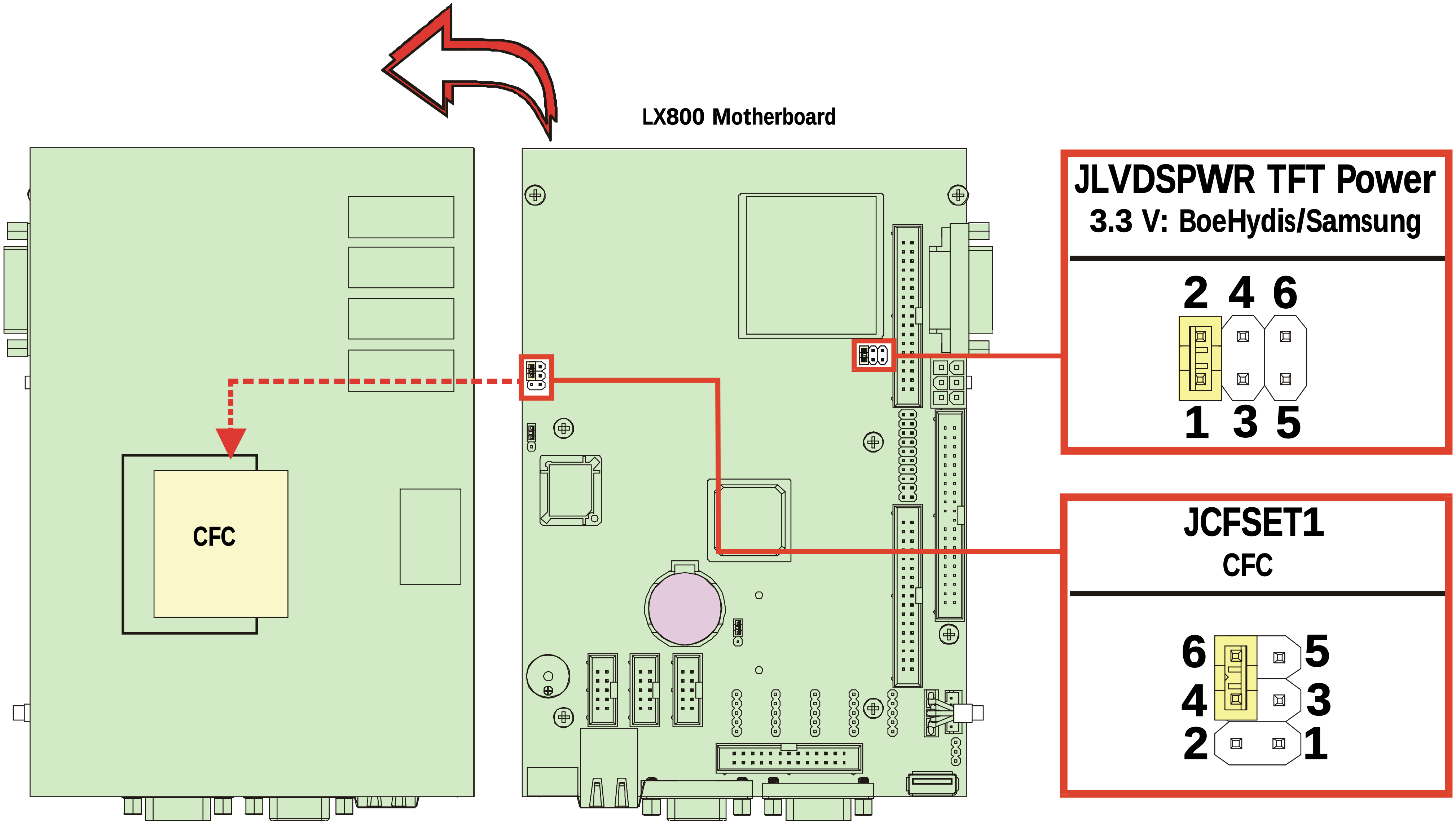
Pos.	Art. No.	Qty.	Description	Comments
1	34560610	1	LX800 motherboard	**see 7.6.1**
2	34519327	1	Battery BR2032, 3V	**see 7.6.1**
3	34560882	1	Compact flash card 1 GB	**see 7.6.1**
4	34560726	1	Basic board	
5	34560769	1	Power board (valves)	
6	34560740	1	Digital board	
7	34560866	1	HDF online board	
8	34560750	1	Power board (Motors)	
9	34560734	1	Analog board	
10	34561277	1	Temperature switch	**assemble temperature switch on TL sub-rack with heat sink paste**

7.6.1 LX800 Motherboard

Pos.	Art. No.	Qty.	Description	Comments
1	34560882	1	Compact flash card 1 GB	**The SW for the machine has to be installed again after replacing the CFC.**
2	34560610	1	LX800 Motherboard	
3	34519327	1	Battery BR2032, 3V	

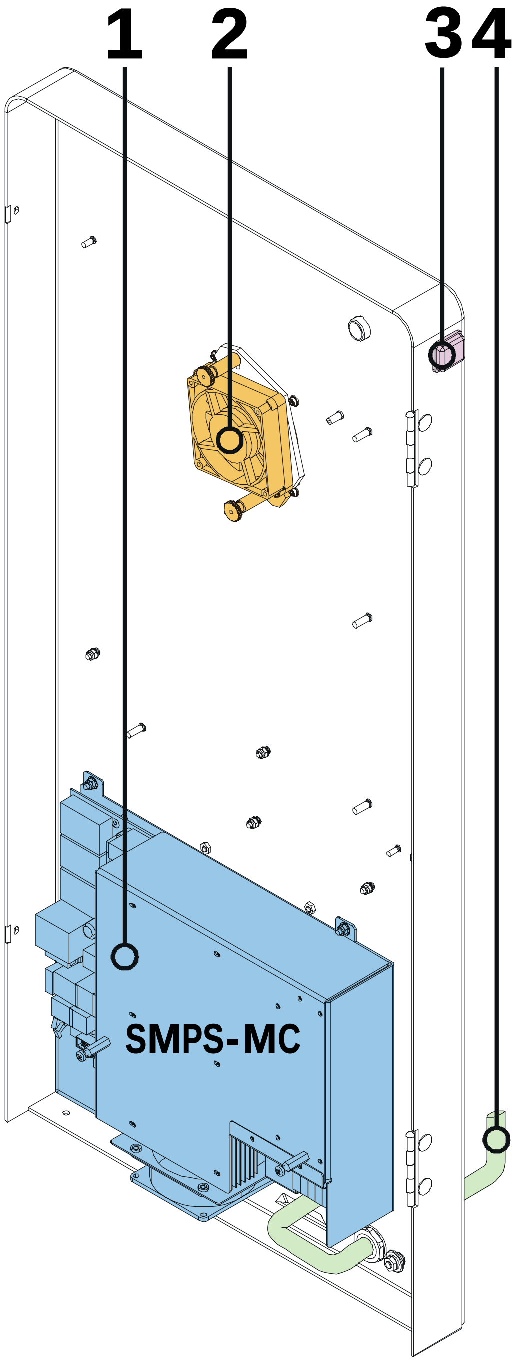


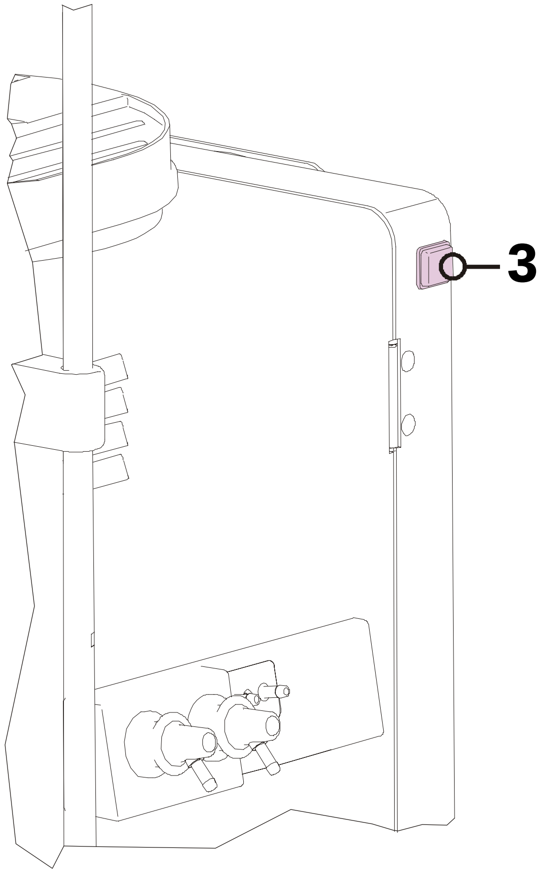
7.6.2 Settings for TFT Display/CFC



7.7 Rear Door

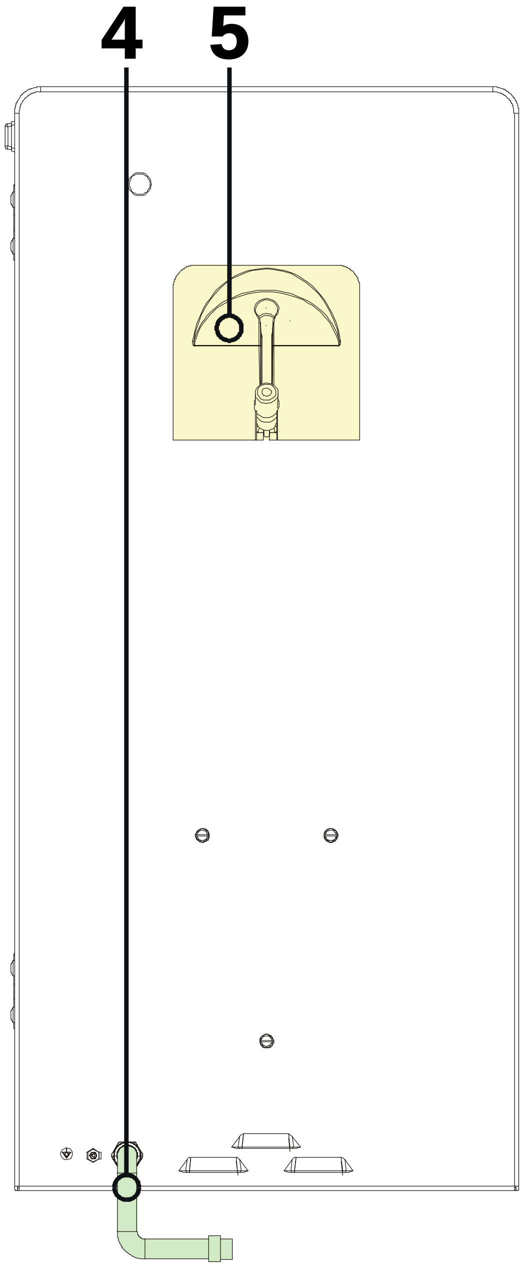
Pos.	Art. No.	Qty.	Description	Comments
1	34560220	1	Switch mode power supply microcontroller SMPS-MC, 110/240V, version 5	
2	34561307	1	Fan 92 x 92 mm with connector	
2	34570284	5	Dust filter	
3	3451059A	1	Mains switch	
3	34770003	5	Protection cap for mains switch	
4	-	-	Mains cord	**see separate figure (paragraph 7.7.1)**

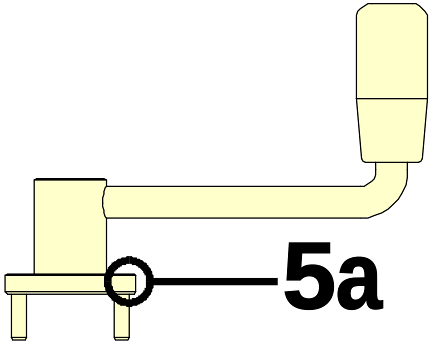


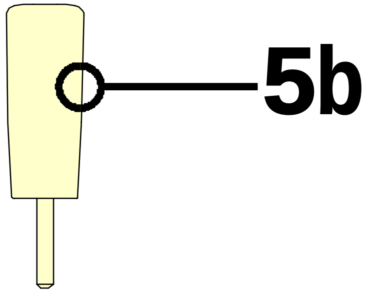


Rear Door

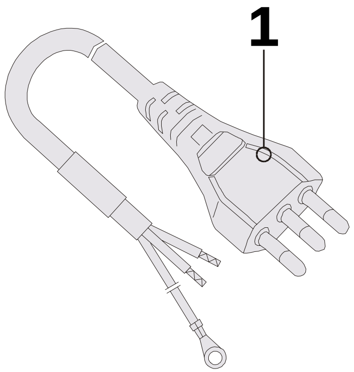
Pos.	Art. No.	Qty.	Description	Comments
4	34518029	1	Strain relief	
5	3451441A	1	Tubing holder/fan cover	**compatible to crank 5a/5b**
5a	34518355	1	Crank for blood pump	
5b	34560157	1	Crank for blood pump	

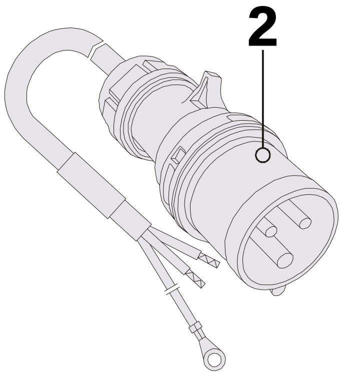


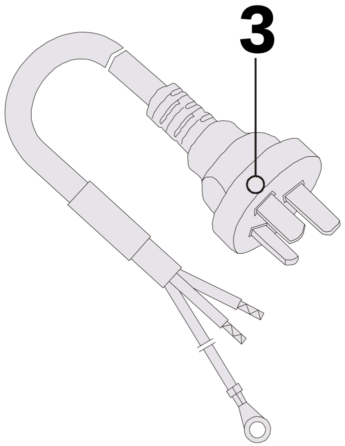




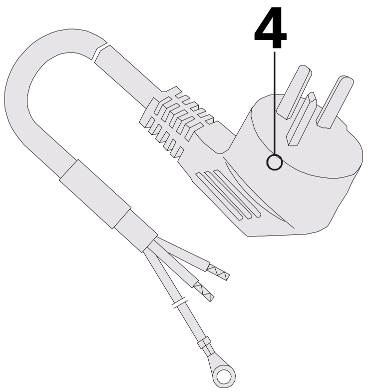
7.7.1 Mains Cord

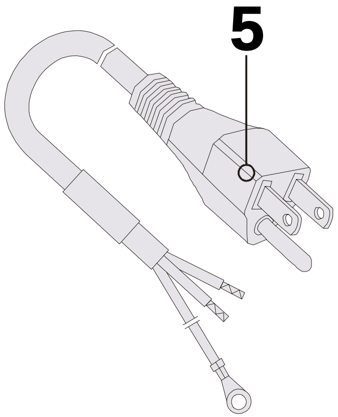


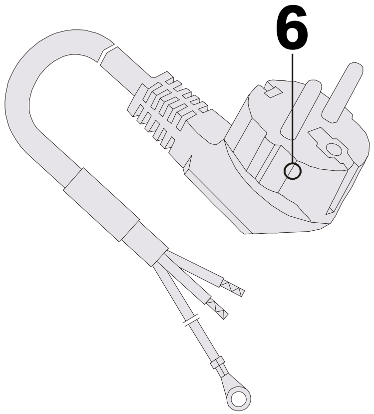




Pos.	Art. No.	Qty.	Description	Comments
1	34561218	1	Mains cord (Brazil)	**mains cord with mains plug**
2	34561145	1	Mains cord (Cekon)	**mains cord with mains plug**
3	34561226	1	Mains cord (China)	**mains cord with mains plug**

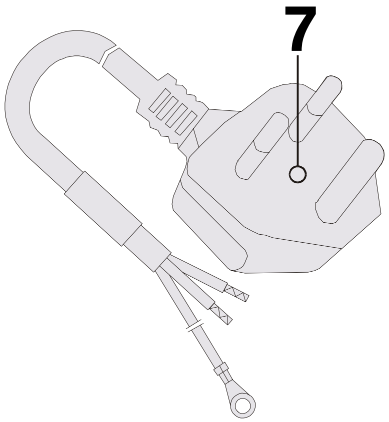


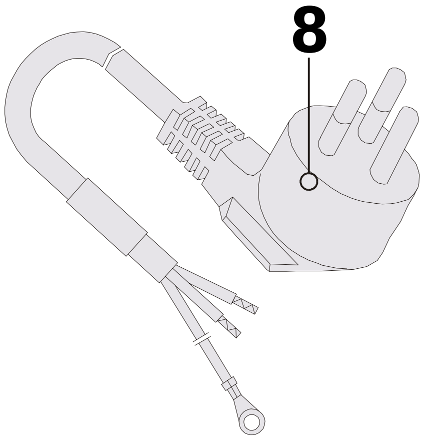


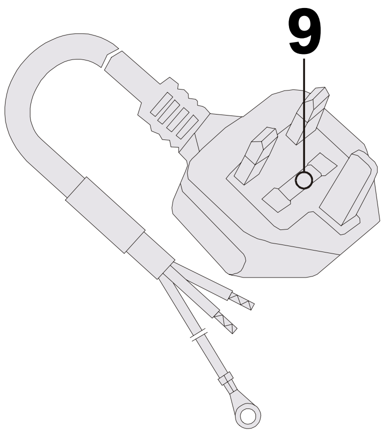


Pos.	Art. No.	Qty.	Description	Comments
4	34561200	1	Mains cord (Israel)	**mains cord with mains plug**
5	34561170	1	Mains cord (Philipines)	**mains cord with mains plug**
6	34561153	1	Mains cord (Schuko)	**mains cord with mains plug**

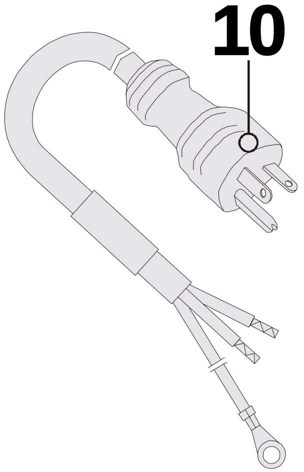
Pos.	Art. No.	Qty.	Description	Comments
7	34561196	1	Mains cord (South Africa/India)	**mains cord with mains plug**
8	34561234	1	Mains cord (Thailand)	**mains cord with mains plug**
9	34561188	1	Mains cord (UK)	**mains cord with mains plug**



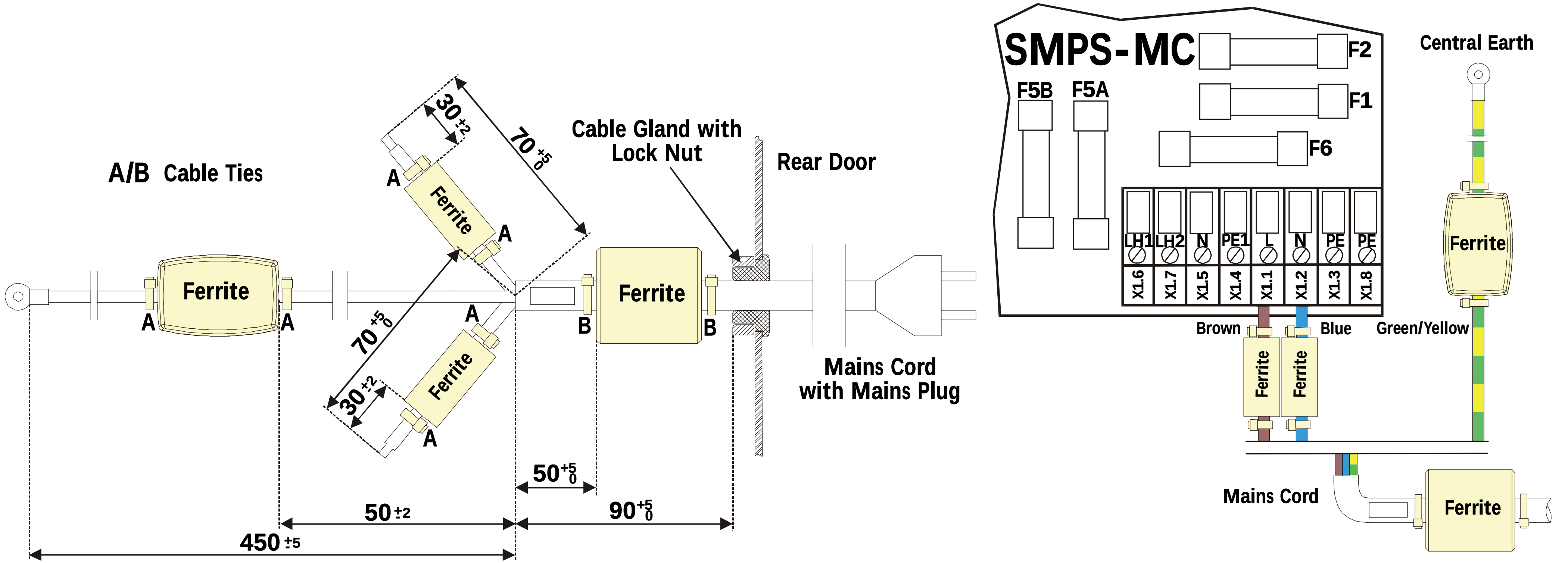




Pos.	Art. No.	Qty.	Description	Comments
10	34561161	1	Mains cord (USA)	mains cord with mains plug



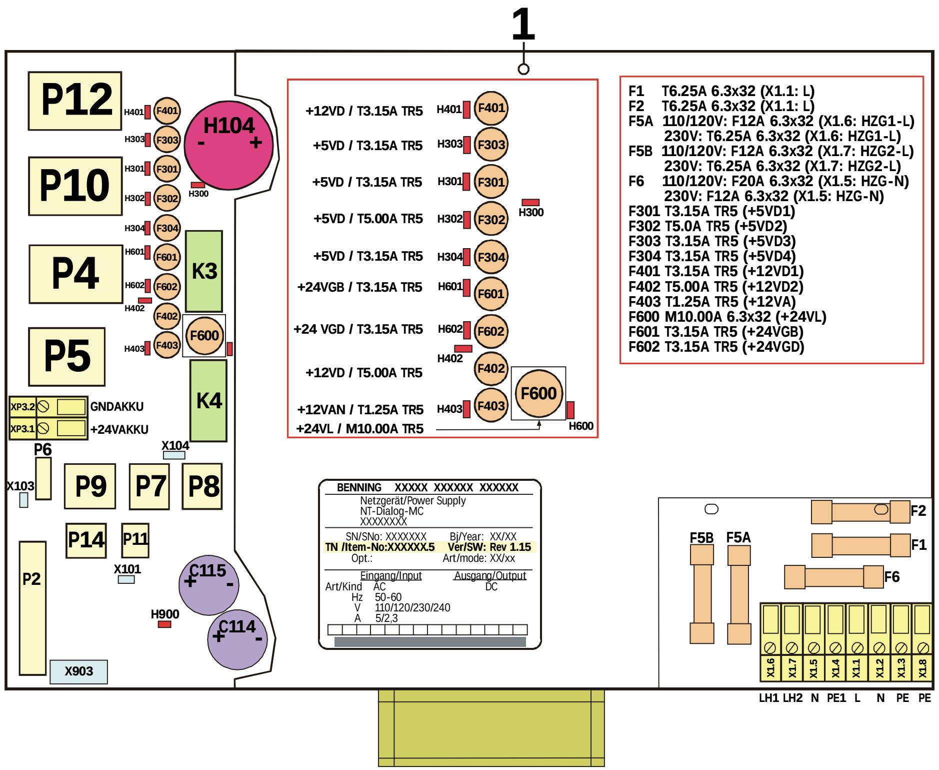
7.7.1.1 Connection Mains Cord to SMPS-MC



7.7.2 Compatibility Table for Boards

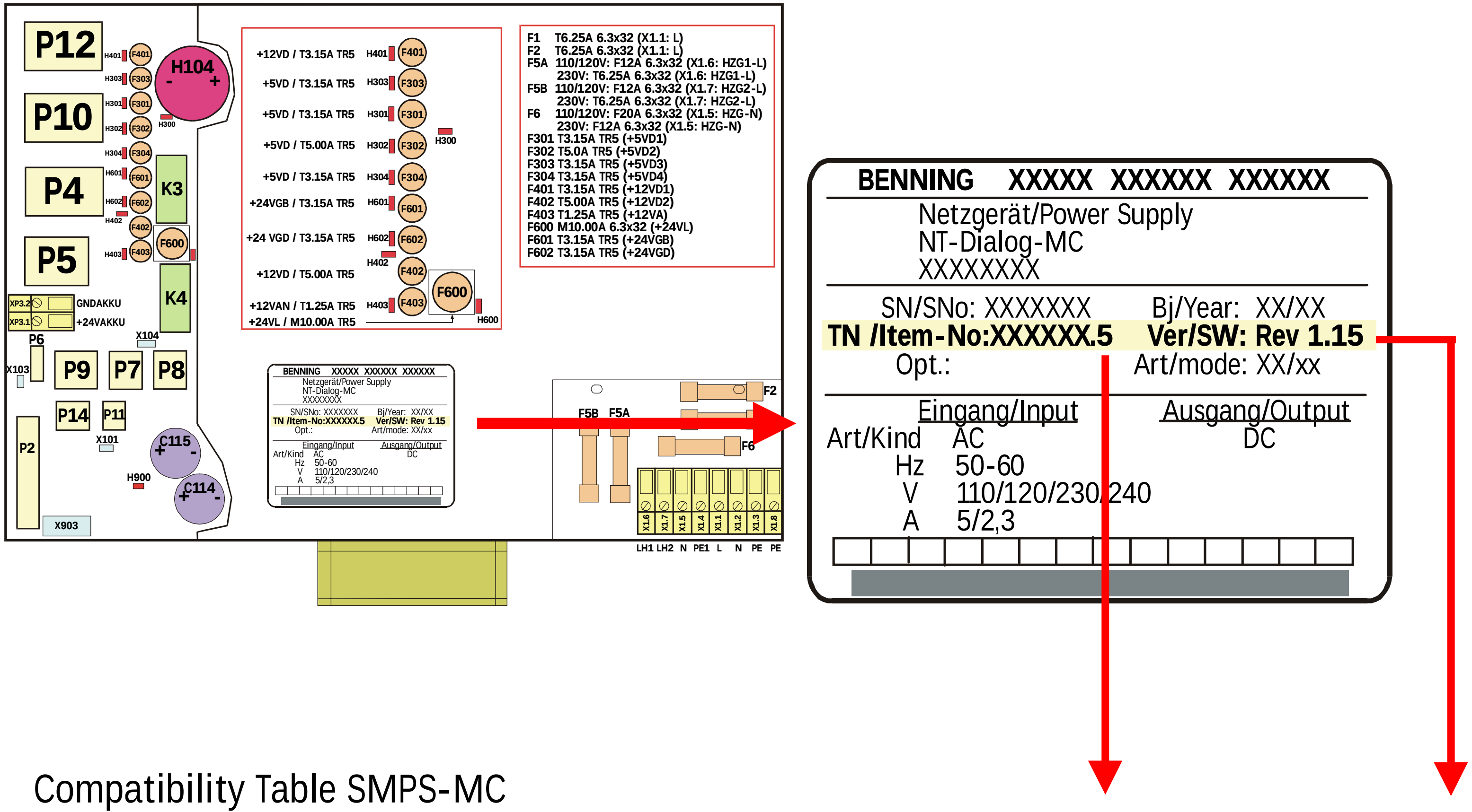
	Art. No.	Dialog+ SW 9.xx SMPS-MC	Dialog+ SW 9.xx SMPS-MC HDF Online
Power Board Valves BPV	34560769 (38108644)	X	X
Power Board Motors BPM	34560750 (38108643)	X	X
Basic Board BB	34560726 (38108640)	X	X
Digital Board DB After the replacement of a digital board: the LLS and LLC software must be reinstalled if the LLS or LLC software does not match with the software version in the machine. The digital board is always delivered with the latest LLS/LLC software versions!	34560740 (38108642)	X	X
Analog Board AB	34560734 (38108641)	X	X
HDF Online Board HOB	34560866 (38108647)	-	X
MSBK Board	3451665A (3810671X)	X	X

7.7.3 Switch Mode Power Supply Microcontroller SMPS-MC



Pos.	Art. No.	Qty.	Description	Comments
1	34560220	1	Switch mode power supply microcontroller SMPS-MC, 110/240V, version 5	see table 7.7.3.1
F1/F2	34570462	10	Fuse T6.25 A (6.3 x 32 mm)	
F5/F6	34771328	10	Fuse F12 A (6.3 x 32 mm)	for 230 V
F5/F6	34570187	10	Fuse M20 A (6.3 x 32 mm)	for 110/120 V
F301	34570160	10	Fuse T3.15 A (TR5)	
F302	34570470	10	Fuse T5 A (TR5)	
F303	34570160	10	Fuse T3.15 A (TR5)	
F304	34570160	10	Fuse T3.15 A (TR5)	
F401	34570160	10	Fuse T3.15 A (TR5)	
F402	34570470	10	Fuse T5 A (TR5)	
F403	34518819	10	Fuse T1.25 A (TR5)	
F600	34570179	10	Fuse M10 A (6.3 x 32 mm)	
F601	34570160	10	Fuse T3.15 A (TR5)	
F602	34570160	10	Fuse T3.15 A (TR5)	
K3/K4	34514775	2	Relay (12 V)	for 24 V
C114/C115	34519912	2	Capacitor 1F	
H104	34560580	1	Buzzer	
-	34560416	10	Plug for buzzer	

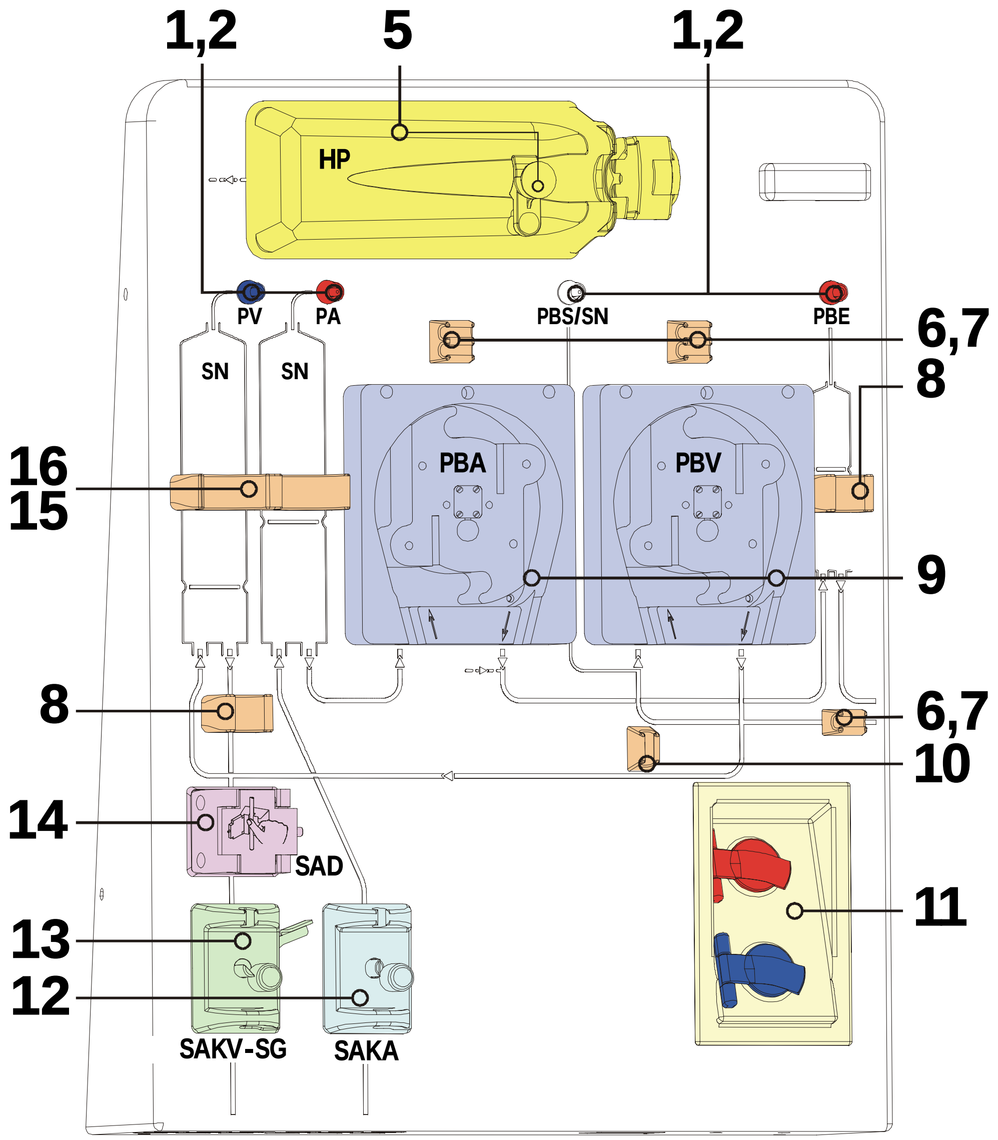
Switch Mode Power Supply Microcontroller SMPS-MC



7.7.3.1 Compatibility Table SMPS-MC

SMPS-MC Type Plate	Version Number SMPS-MC (TN/Item-No)	SW Version (Ver/SW)	Dialog+ SW 9.xx
34560220 (version 5)	XXXXXX.5	Rev. 1.15	X ex works

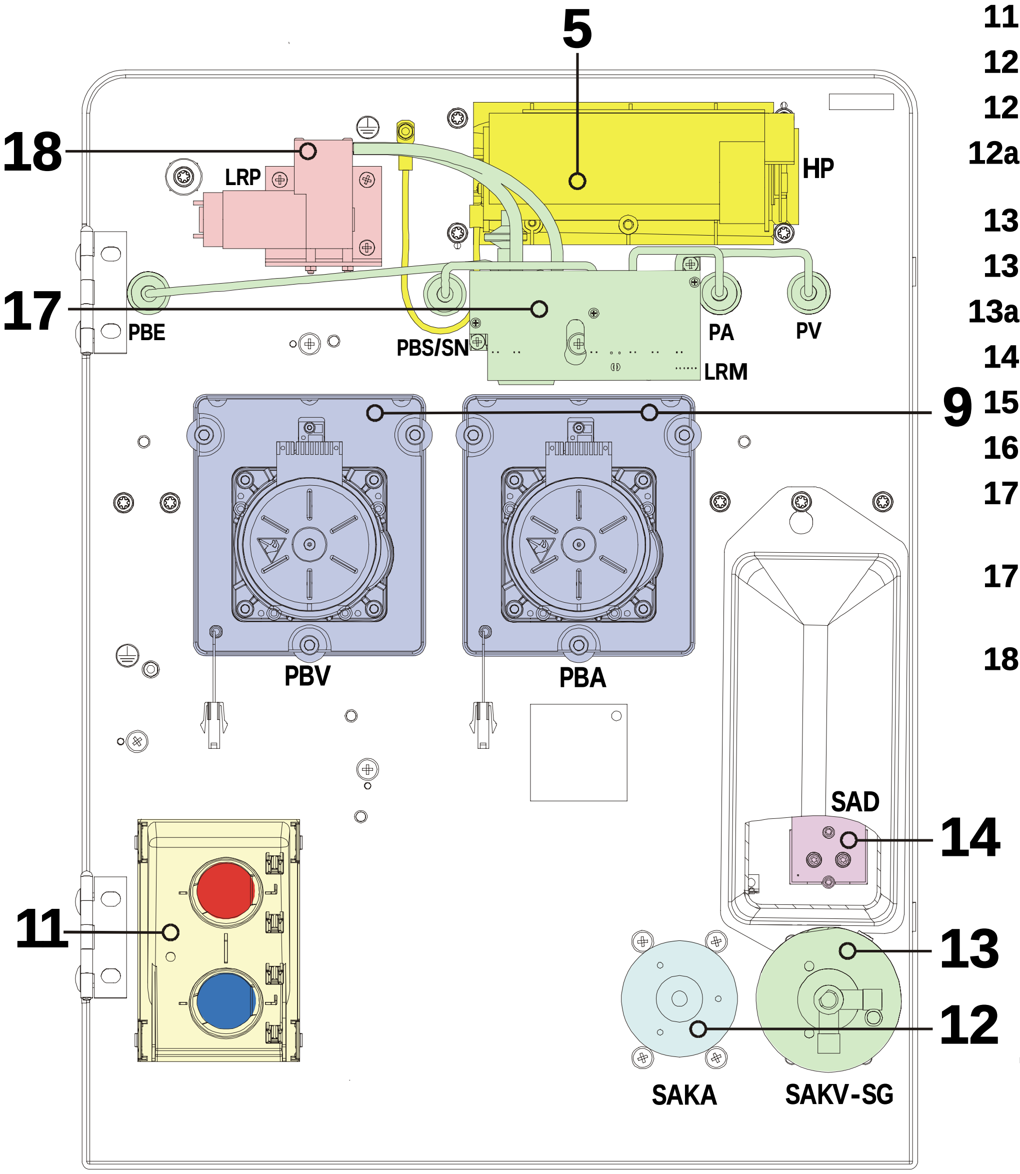
7.8 Front Door

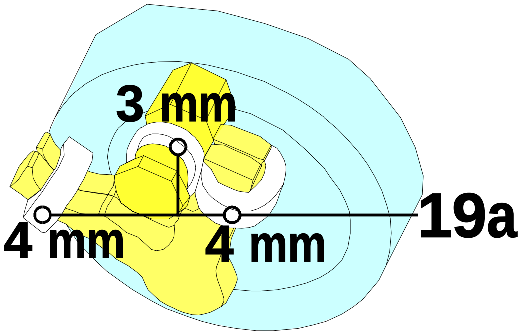


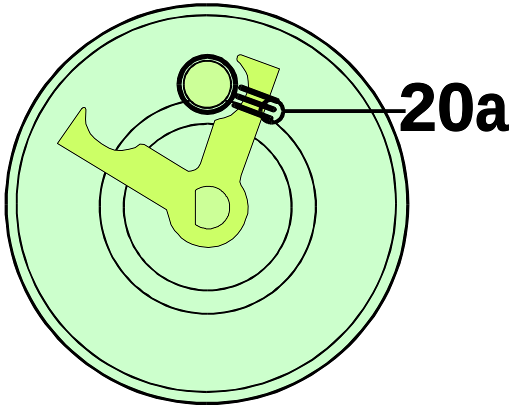
Pos.	Art. No.	Qty.	Description	Comments
1	34516352	1	Pressure sensor	see also position 24
2	3457058A	5	Manometer connection (white), for PBS/SN	with plastic nut A and safety disc B (pay attention to correct assembly, see left figure)
2	3451833A	5	Manometer connection (red), for PA/PBE	
2	3451884A	5	Manometer connection (blue), for PV	
5	3451432B	1	Heparin pump Compact	
5	34560785	1	Housing with seal	
5	34514732	1	Syringe holder	
5	34570640	5	Dummy plug	
5	34570667	1	Clamp	
5	34570659	1	Unlocking lever set	
6	34570535	1	Single tubing holder	∅ 6.8 mm
7	34570543	1	Double tubing holder	∅ 6.8 mm
8	34570527	1	Single holder, small	
9	34560793	1	Blood pump without roller	see separate figure
9	34561331	1	Pump head with cover	
9	34560947	1	Drive unit for blood pump (SW 1.7.4)	
9	34560807	1	Roller 8x12 for blood pump	
9	34570616	5	Latch	
9	3451669E	1	Cover for blood pump	without hinge pin (see separate figure)
9	34560025	1	Magnet ∅ 5 mm	for cover
9	34560033	1	Metal disc ∅ 10 mm	for cover
9	34519823	1	Hinge pin with interior thread	hinge pin
9	34516670	1	Seal for blood pump	

Front Door

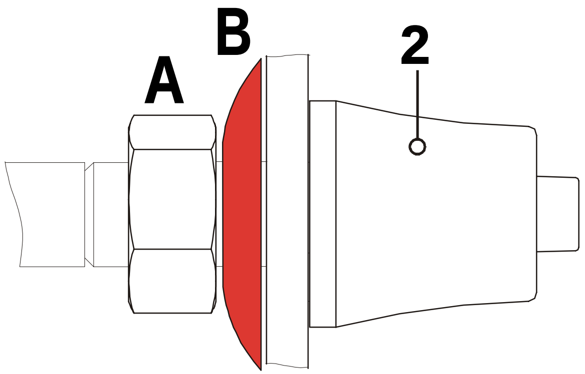
Pos.	Art. No.	Qty.	Description	Comments
10	34570560	1	Single tubing holder	**∅ 6 mm**
11	3451415A	1	Cover complete	
12	3456000A	1	Rotary magnet	**for SAKA**
12	34570578	1	Cover with tubing holder	**for SAKA**
12a	34570675	10	Soft stopper	**for SAKA, set for 10 rotary magnets, with 20 x 4 mm, 10 x 3 mm**
13	34514107	1	Rotary magnet (currentless closed)	**for SAKV-SG**
13	34514317	1	Cover with tubing holder	**for SAKV-SG**
13a	34570624	9	O-ring 7.0 x 1.5	**for SAKV-SG**
14	3456005C	1	SAD version 3 with red detector	**see separate figure (paragraph 7.8.4)**
15	34570551	1	Double holder, big	
16	34570519	1	Single holder, big	
17	34560815	1	Valve block level regulation (single pump)	**see separate figure (paragraph 7.8.5)**
17	34560831	1	Valve block level regulation (double pump)	**see separate figure (paragraph 7.8.5)**
18	34560823	1	Diaphragm pump	**with assembly elbow**







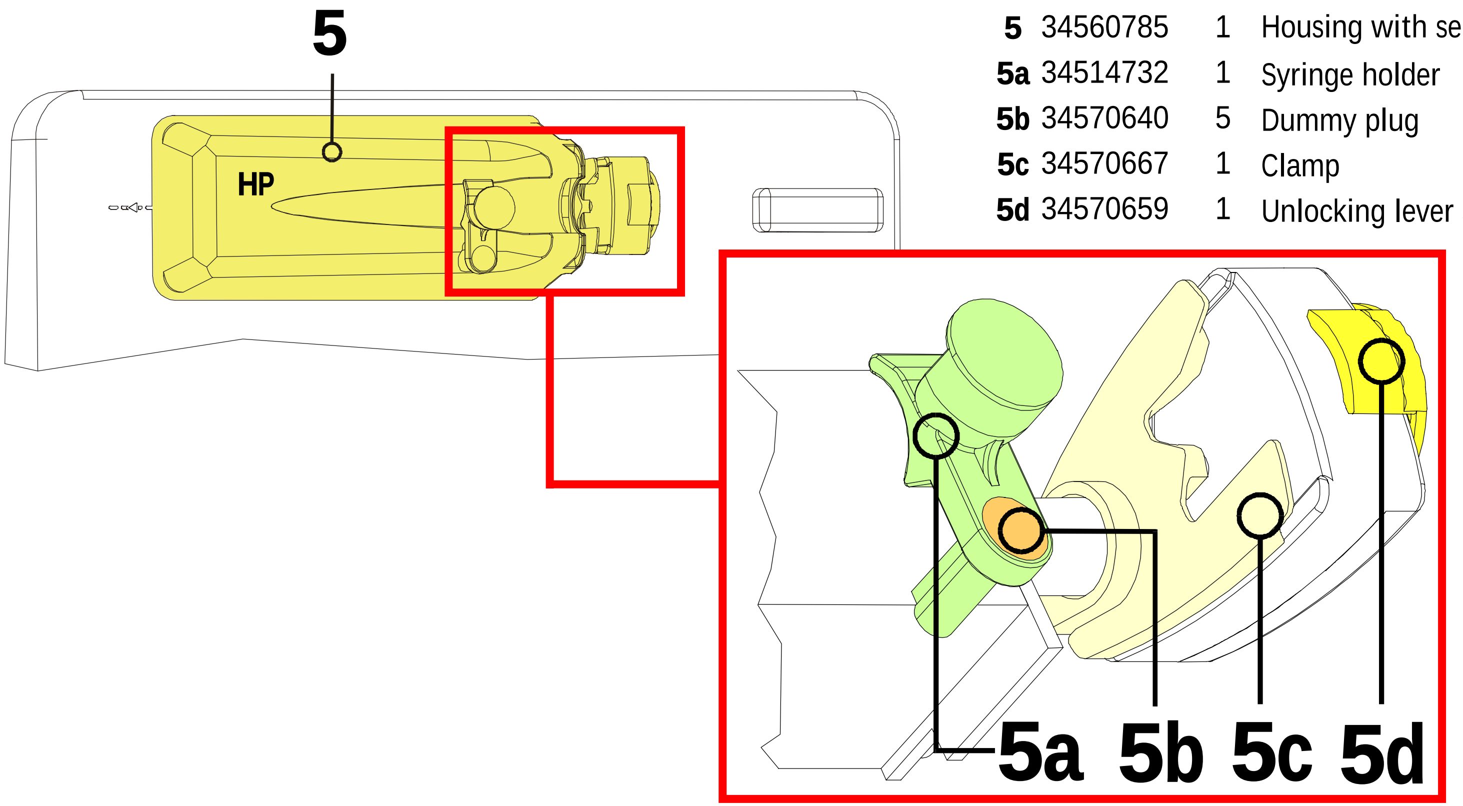
7.8.1 Manometer Connection



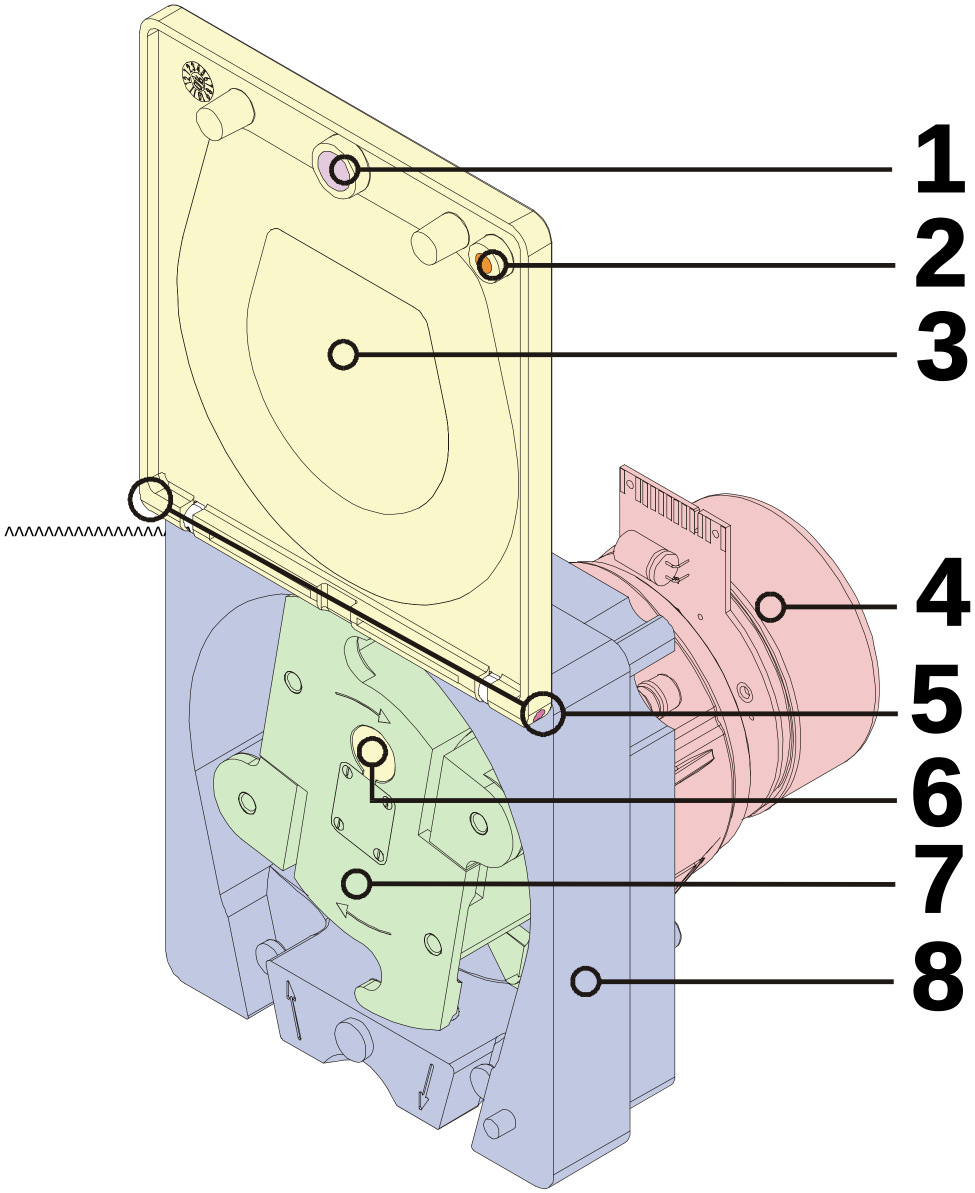
Pos.	Art. No.	Qty.	Description	Comments
2	3457058A	5	Manometer connection (white), for PBS/SN	**with plastic nut A and safety disc B (pay attention to correct assembly, see left figure)**
2	3451833A	5	Manometer connection (red), for PA/PBE	
2	3451884A	5	Manometer connection (blue), for PV	

7.8.2 Heparin Pump

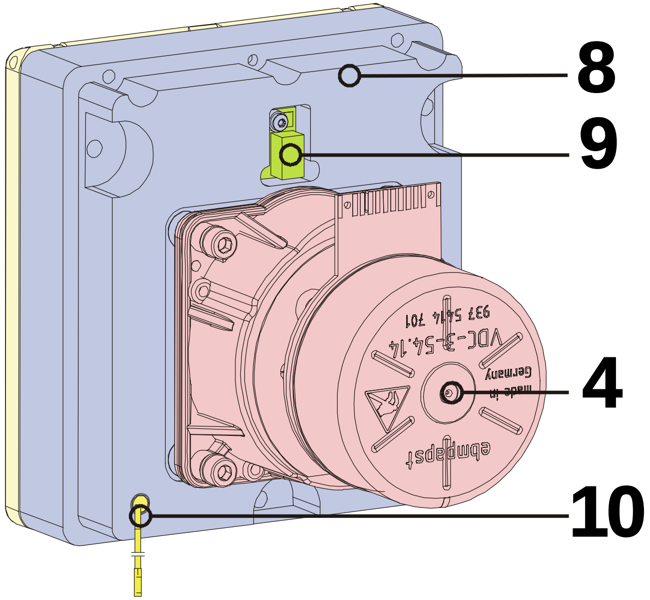
Pos.	Art. No.	Qty.	Description	Comments
5	3451432B	1	Heparin pump Compact	
5	34560785	1	Housing with seal	
5a	34514732	1	Syringe holder	
5b	34570640	5	Dummy plug	
5c	34570667	1	Clamp	
5d	34570659	1	Unlocking lever set	



7.8.3 Blood Pump

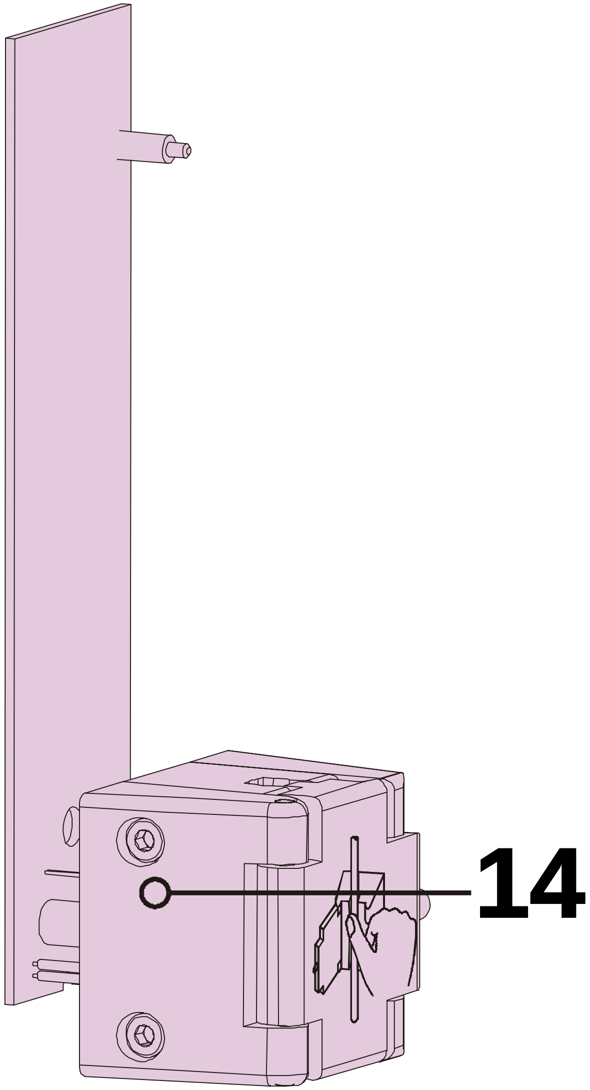


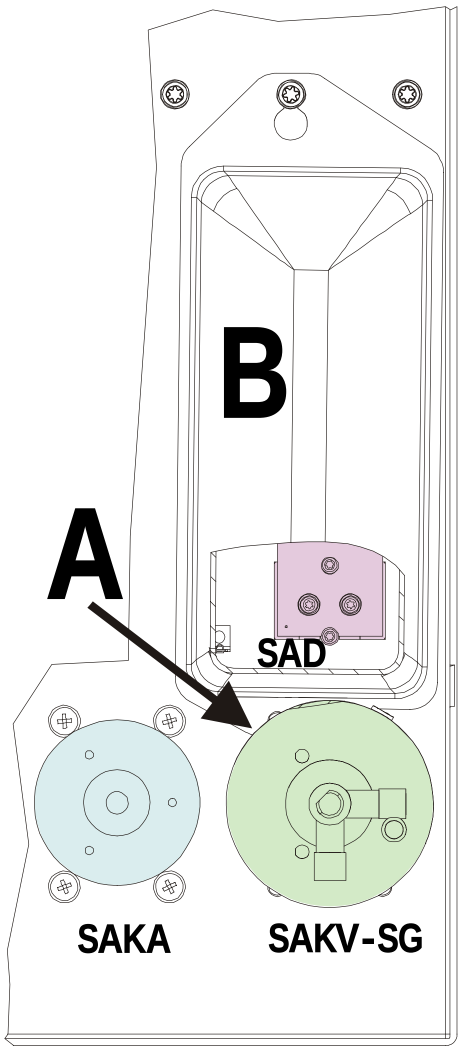
Pos.	Art. No.	Qty.	Description	Comments
1	34560033	1	Metal disc ∅ 10 mm	**for cover, use Loctite 406**
2	34560025	1	Magnet ∅ 5 mm	**for cover, use Loctite 406**
3	3451669E	1	Cover for blood pump	**without hinge pin (see separate figure)**
4	34560947	1	Drive unit for blood pump (SW 1.7.4)	
5	34519823	1	Hinge pin with interior thread	**hinge pin**
6	34570616	5	Latch	
7	34560807	1	Roller 8x12 for blood pump	
8	34561331	1	Pump head with cover	**without drive unit**
8	34560793	1	Blood pump without roller	**complete with drive unit and cover**
9	34561358	1	Direction of rotation board for blood pump	
10	34517138	1	Reed sensor with contacts and o-ring 3.68 x 1.78	
-	34516670	1	Seal for blood pump	
-	7703708	1	Grease SKD 4002	**100 g tube (to lubricate the shaft of the blood pump)**



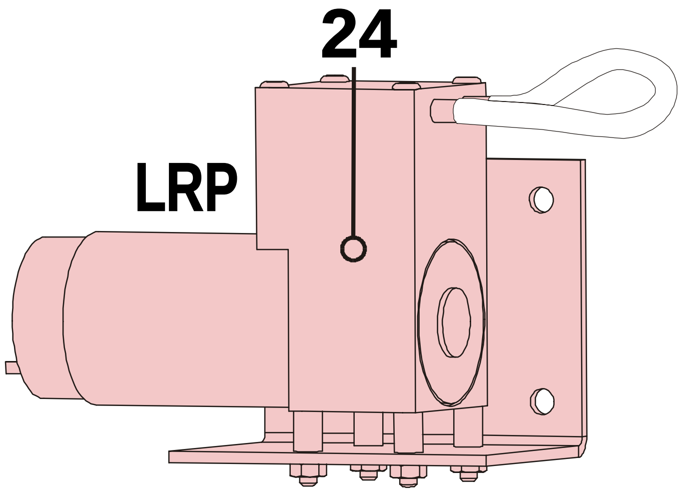
Pos.	Art. No.	Qty.	Description	Comments
14	3456005C	1	SAD version 3 with red detector	**SAD with board; do not tamper, exchange only complete** **If cover for SAD is present: a ball head allen key 2.5/3 is required for bottom screw behind rotary magnet.**

7.8.4 Safety Air Detector SAD

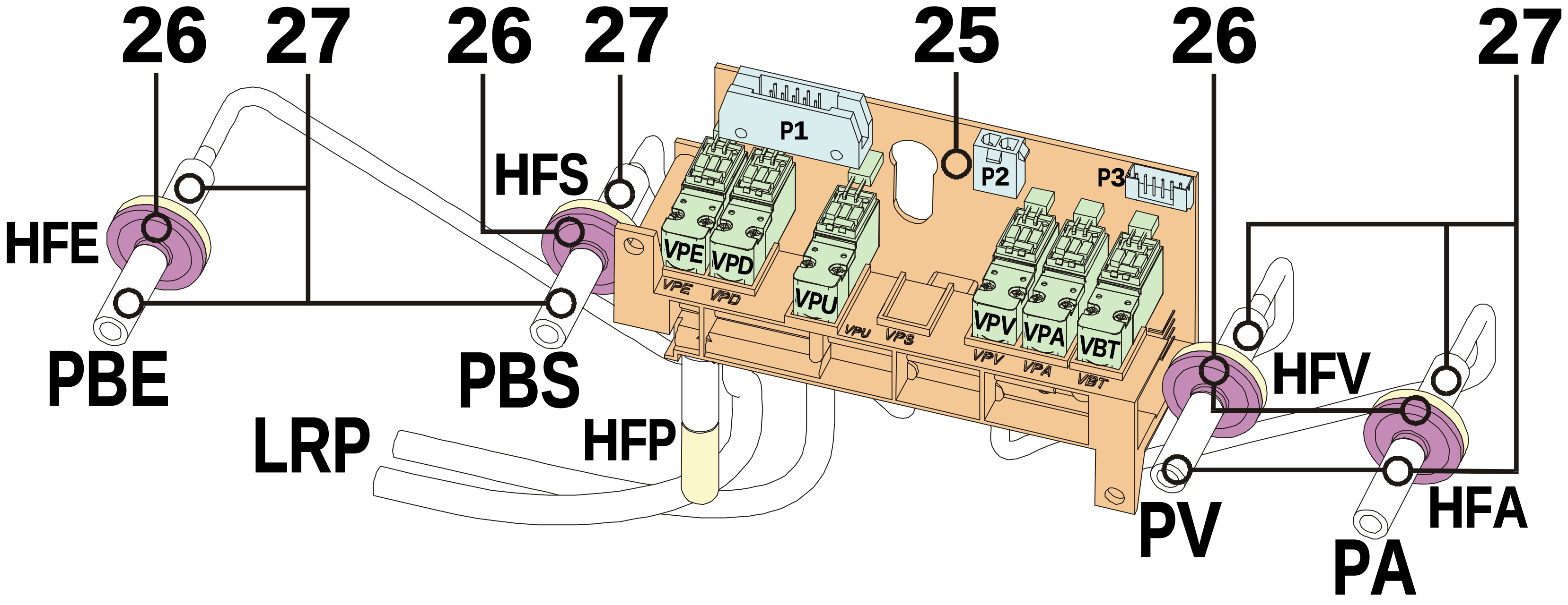




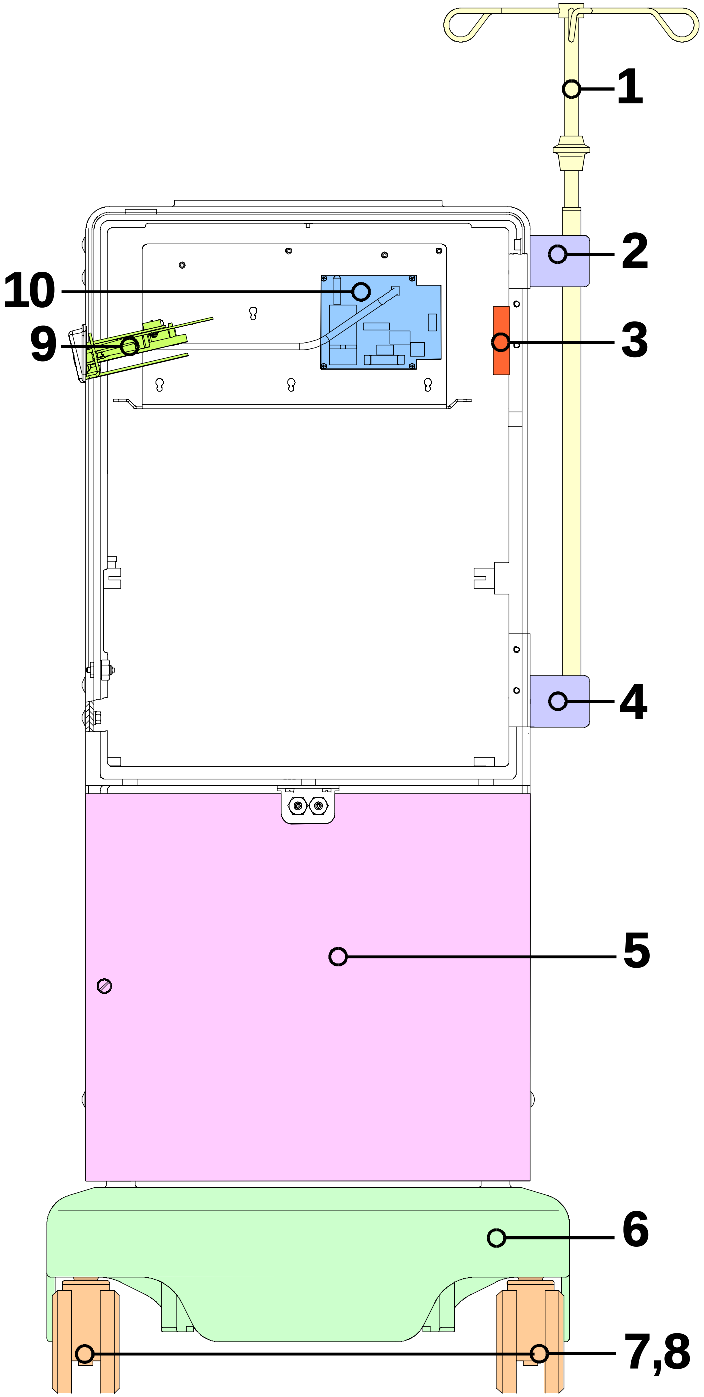
7.8.5 Level Regulation Module



Pos.	Art. No.	Qty.	Description	Comments
24	34560823	1	Diaphragm pump	**LRP with assembly elbow**
25	34560815	1	Valve block level regulation (single pump)	**complete with 3 pressure sensors (for PA, PV, PBE), 6 valves, incl. filter and tubing**
25	34560831	1	Valve block level regulation (double pump)	**complete with 4 pressure sensors (for PA, PV, PBE, PBS), 6 valves, incl. filter and tubing**
26	34516409	1	Filter	**pay attention to the assembly position of the filter: transparent side towards the block**
27	34565205	5m	PUR tubing 3.6 x 1.1 (5 m)	**for manometer connection (filter)**



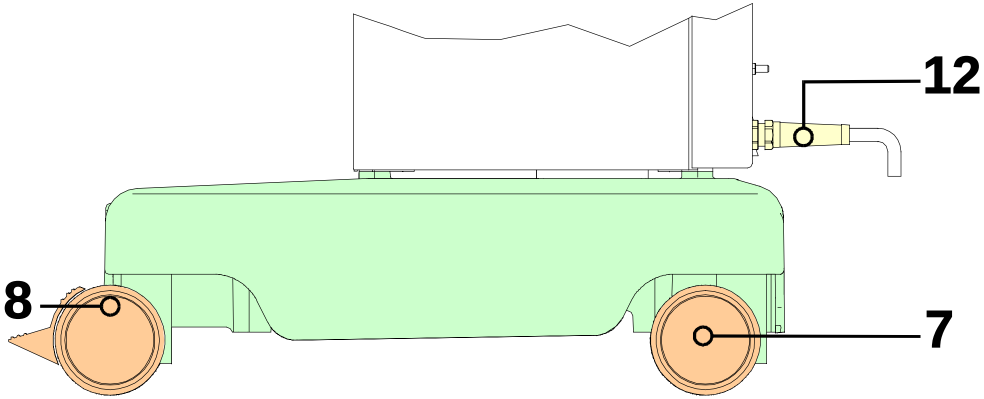
7.9 Basic Housing

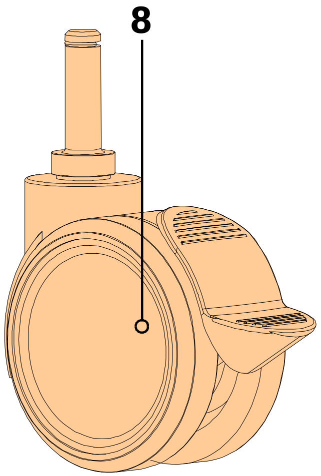


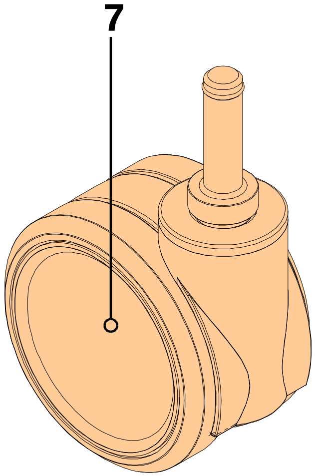
Pos.	Art. No.	Qty.	Description	Comments
1	3451962A	1	IV pole version 2	**height adjustable**
2	3451439A	1	Holder, top	
3	34514929	1	Loudspeaker	
4	3451438A	1	Holder, bottom	
5	34517804	1	Front panel, bottom	
6	34561269	1	Base platform	
6	34519564	1	Silicone profile	
7	3451489A	1	Swivel caster	
8	3451490A	1	Swivel caster with brake	
9	34560548	1	Card-Reader-Board	**see 7.22 for details**
10	3451487C	1	ABPM module M2009 with filter	**see 7.19 for details**

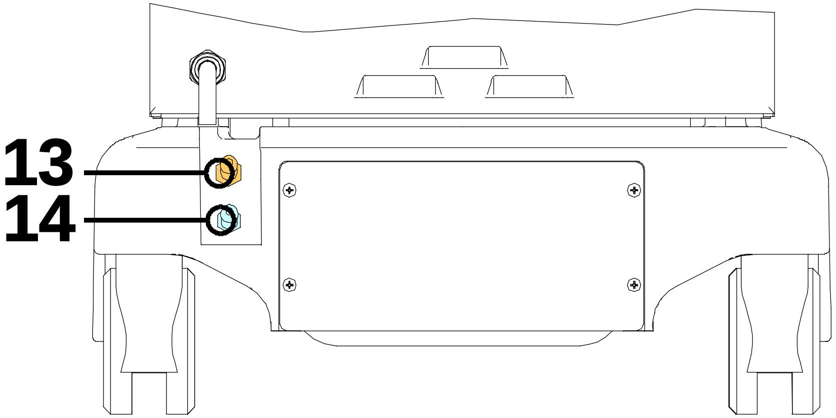
Basic Housing

Pos.	Art. No.	Qty.	Description	Comments
7	3451489A	1	Swivel caster	
8	3451490A	1	Swivel caster with brake	
12	34518029	1	Strain relief	
13	34560122	1	Double tubing connector 11xM12	**stainless steel, for water inlet**
14	34560130	1	Double tubing connector 11xM12	**plastic, for dialysate outlet**
-	34770852	5	O-ring 11.1 x 1.6	
-	34771271	10	Tubing clamp 15/9	
-	39234126	1	Tubing clamp 12-20 mm	
-	34565140	50m	PVC tubing 10 x 3, red	**for water inlet**
-	3456517A	1	PVC tubing 10 x 3 / red (3 m), with two single ear clamps 19.5	**for water inlet**
-	34565159	50m	PVC tubing 10 x 3, black	**for dialysate outlet**
-	3456518A	1	PVC tubing 10 x 3 / black (3 m), with a single ear clamps 19.5 and a tubing clamp 12-20 mm	**for dialysate outlet**
-	34565167	3m	Silicone tubing 8 x 3.2 / red (3 m), with two single ear clamps 17.5	**external high temperature tubing**
-	39224538	1	Single ear clamp 17.5	**for external high temperature tubing**

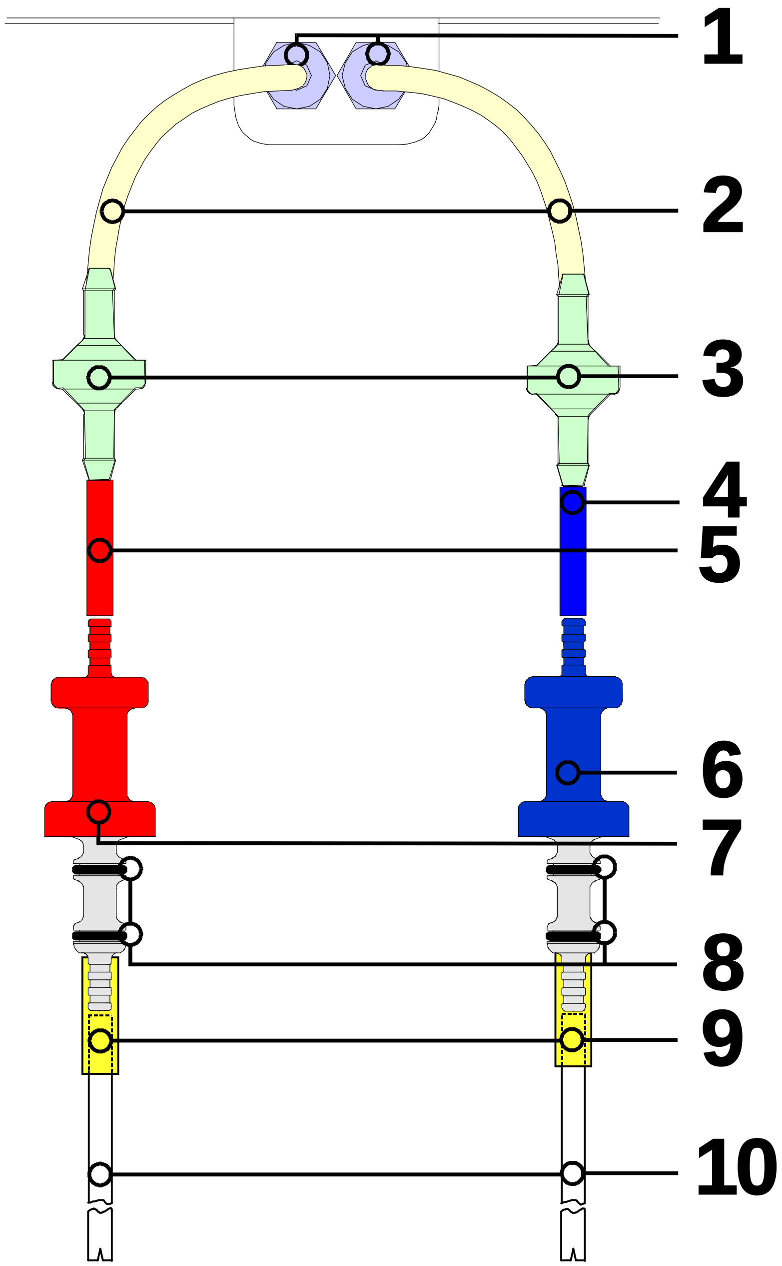








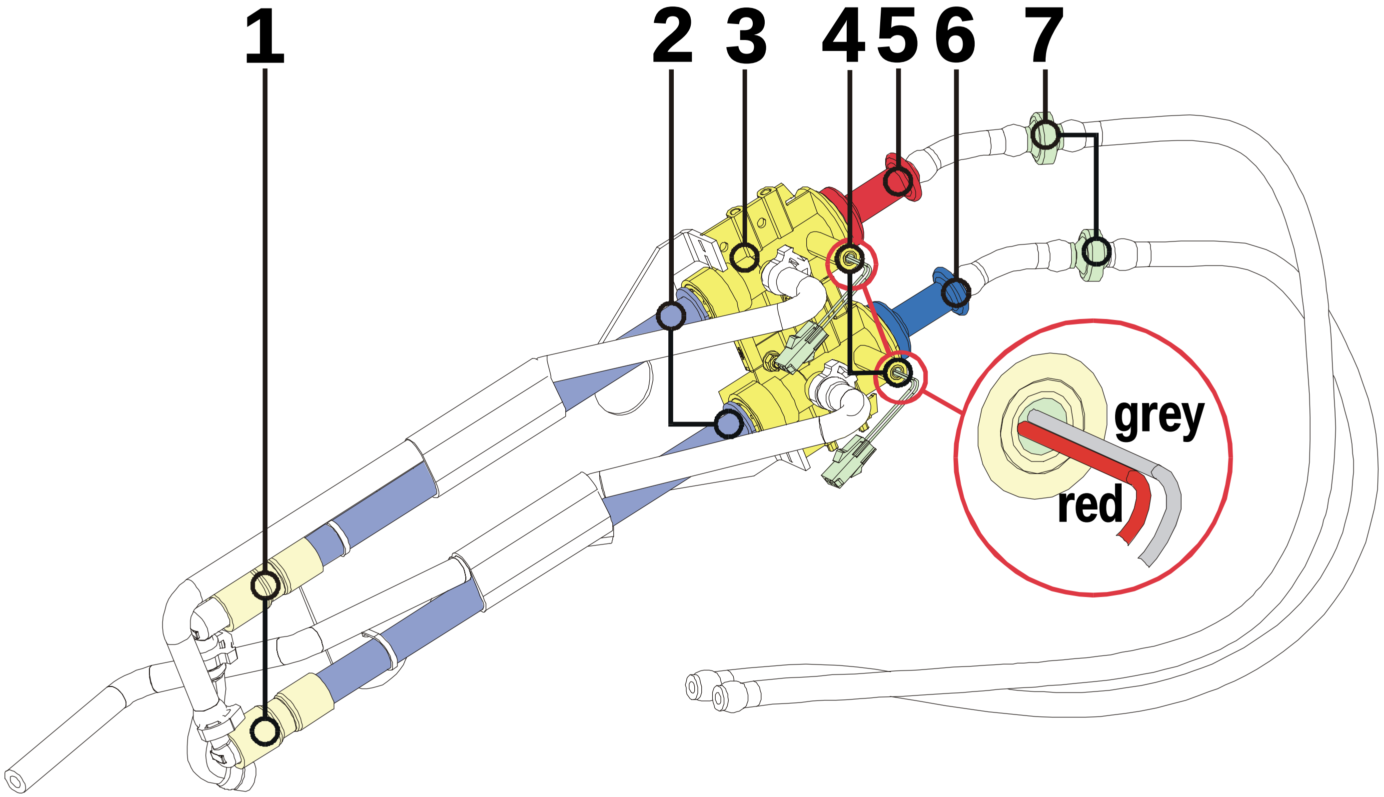
7.9.1 Concentrate Suction Rods



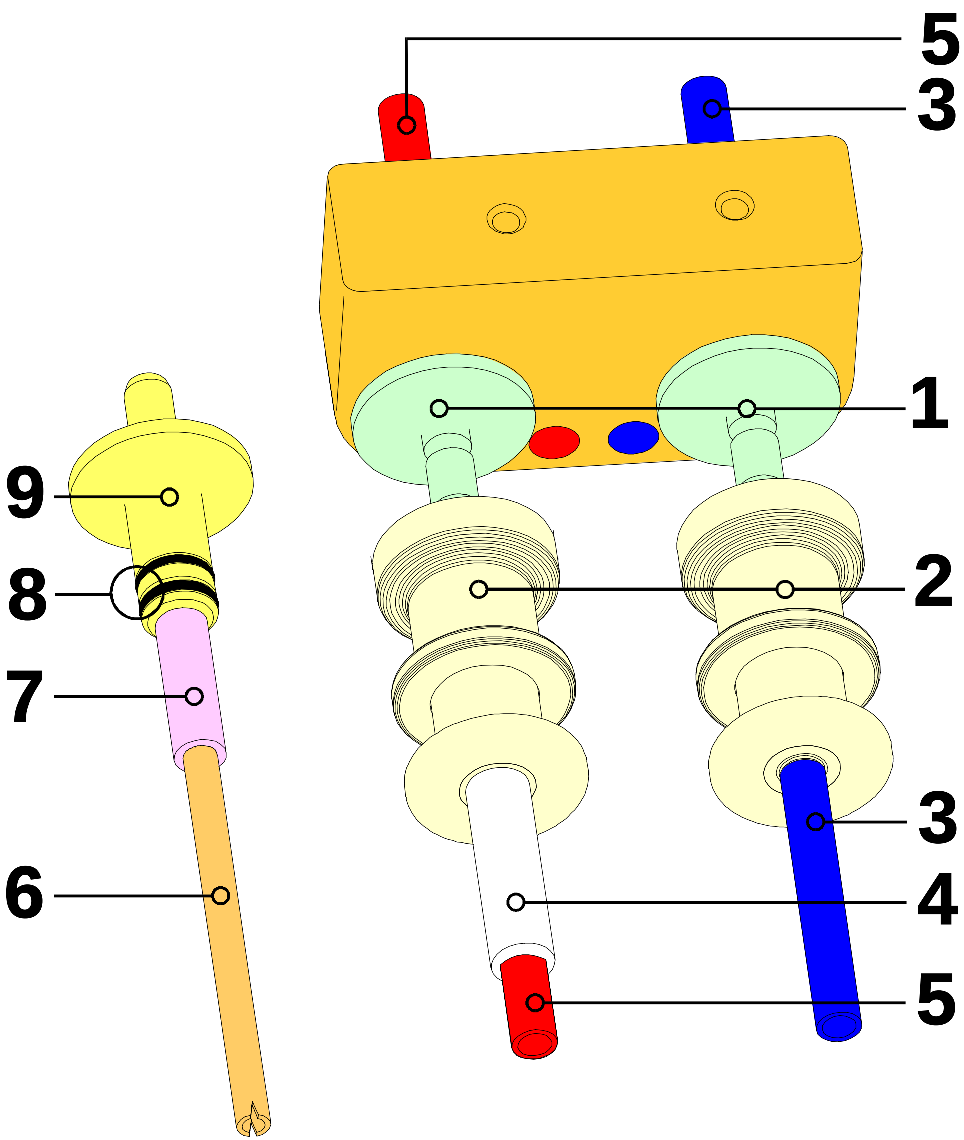
Pos.	Art. No.	Qty.	Description	Comments
1	3451726A	1	Feed-through connector	
2	34565213	10m	Silicone tubing 2.9 x 3 (10 m)	
3	34517782	5	Disposable filter	
4	34565248	10m	Silicone tubing 5 x 1.5 / blue (10 m)	
5	34565230	10m	Silicone tubing 5 x 1.5 / red (10 m)	
6	3451475A	1	Male connector (blue) with o-rings	
7	3451476A	1	Male connector (red) with o-rings	
8	34570004	5	O-ring 9.3 x 2.4	
9	34565280	3m	Silicone tubing 3.2 x 1.6 (3 m)	
10	3451728A	1	PE tube 4 x 1	**with silicone tubing**

7.9.2 Rinsing Chambers for Concentrate Suction Rods

Pos.	Art. No.	Qty.	Description	Comments
1	34565345	1m	Silicone tubing 12 x 2.5 (1 m)	
2	34560777	1	Retainer tubes (blue) for suction rods	**1 x 260 mm and 1 x 280 mm**
3	34514120	1	Retainer for suction rods	
4	34517138	1	Reed sensor with contacts and o-ring 3.68 x 1.78	**Pay attention to the assembly position of the reed sensors (red left/grey right)**
5	3451476A	1	Male connector (red) with o-rings	
6	3451475A	1	Male connector (blue) with o-rings	
7	34517782	5	Disposable filter	



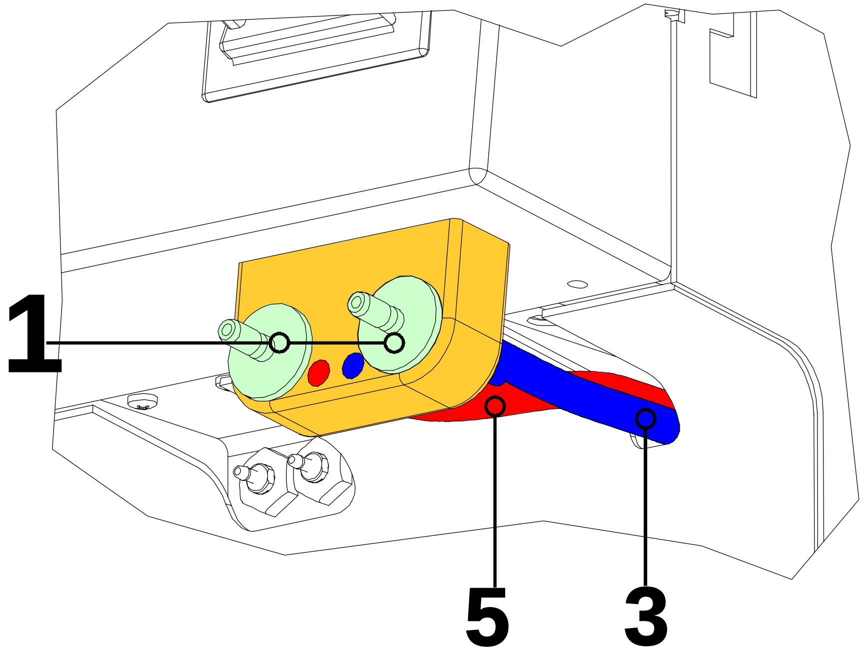
7.9.3 Central Concentrate Supply (Option)

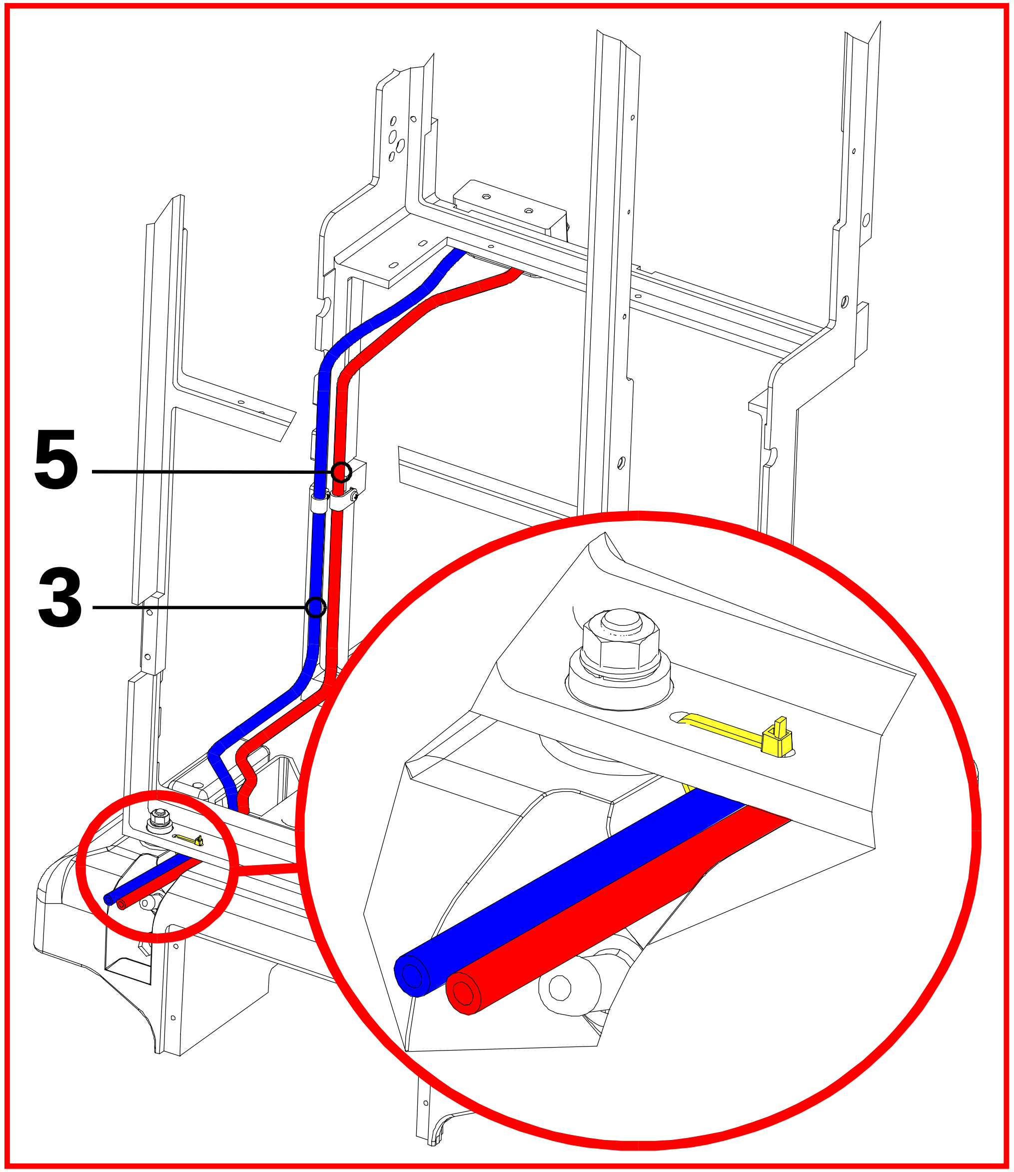


Pos.	Art. No.	Qty.	Description	Comments
1	3451467A	1	Connection nipple	
2	3451459A	1	Suction coupling	
2	34570438	5	O-ring 8.0 x 1.25	
3	34565248	10m	Silicone tubing 5 x 1.5 / blue (10 m)	
4	39239829	m	Tubing, white	**per meter**
5	34565230	10m	Silicone tubing 5 x 1.5 / red (10 m)	
6	3451728A	1	PE tube 4 x 1	**with silicone tubing**
7	34565280	3m	Silicone tubing 3.2 x 1.6 (3 m)	
8	34570004	5	O-ring 9.3 x 2.4	
9	3451465A	2	Suction nipple with o-rings 9.3 x 2.4	

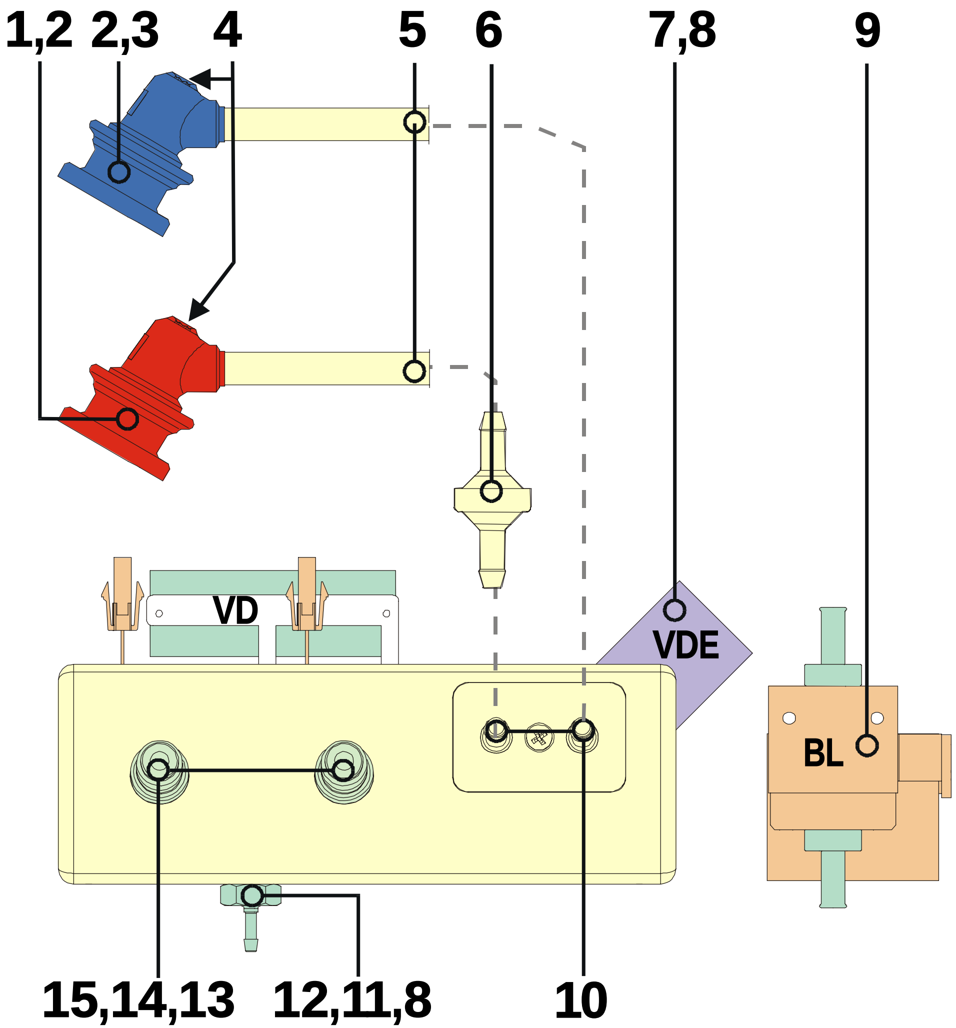
Central Concentrate Supply (Option)

Pos.	Art. No.	Qty.	Description	Comments
3	34565248	10m	Silicone tubing 5 x 1.5 / blue (10 m)	
5	34565230	10m	Silicone tubing 5 x 1.5 / red (10 m)	



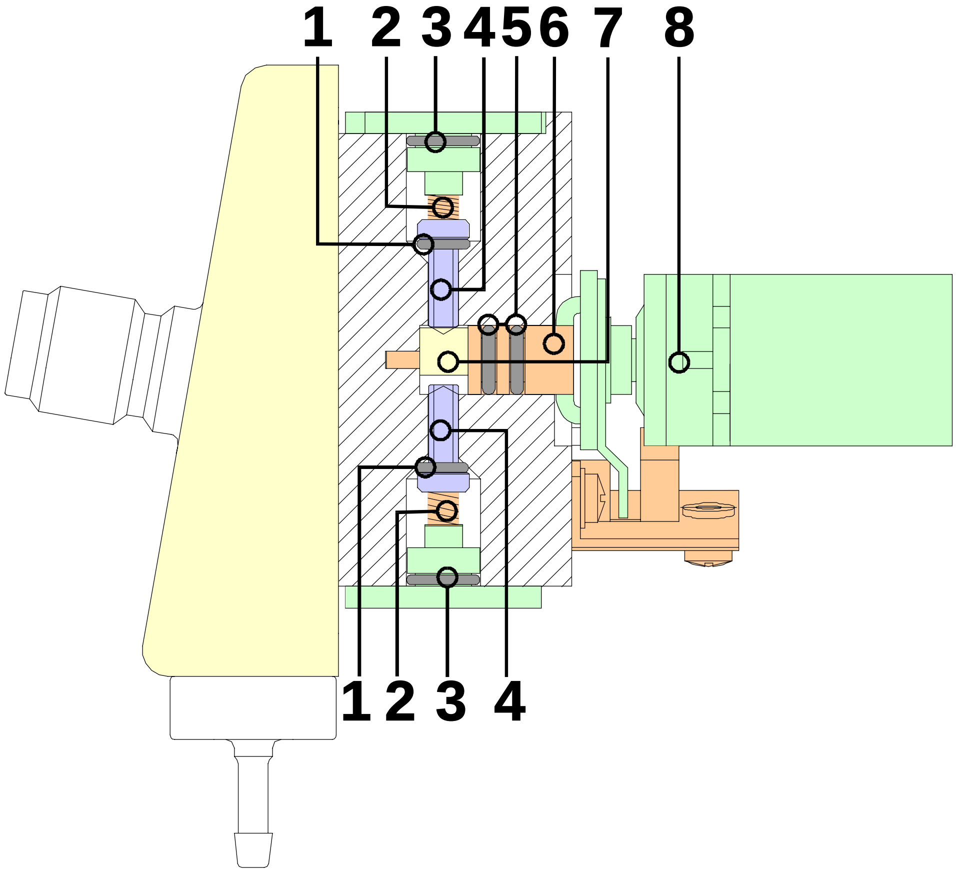


7.9.4 Rinsing Bridge 4



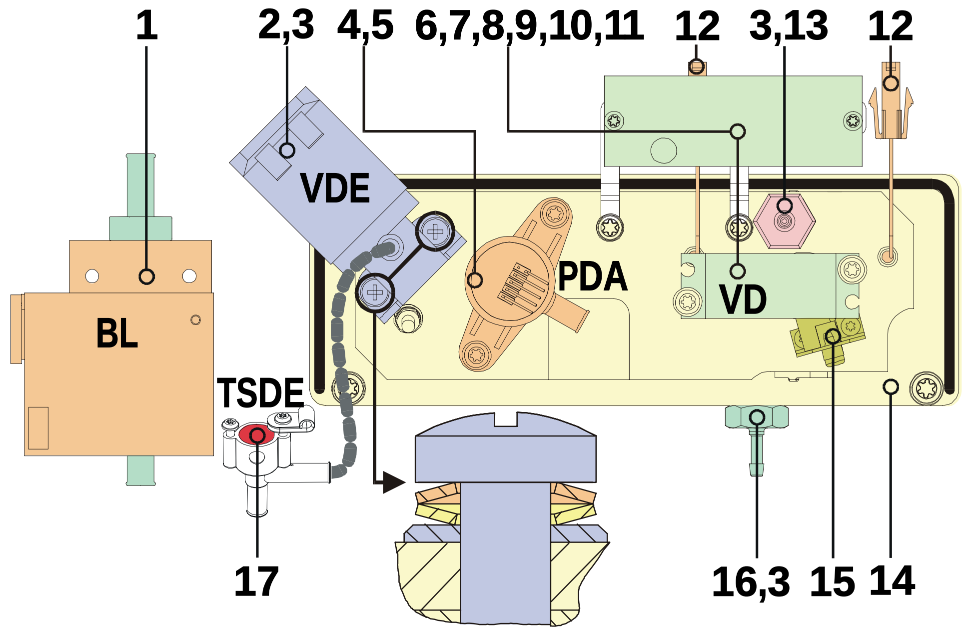
Pos.	Art. No.	Qty.	Description	Comments
1	3451445A	1	Dialyser coupling, red	
2	34990445	5	O-ring 12.37 x 2.62	**for dialyser coupling**
3	3451446A	1	Dialyser coupling, blue	
4	34773550	20	Membrane for dialyser coupling	
5	34565191	10m	Silicone tubing 5 x 3 (10 m)	
6	34517782	5	Disposable filter	
7	34560270	1	Solenoid valve 2/2 way	**connector/flange (DPP)**
8	34770852	5	O-ring 11.1 x 1.6	
9	3451908C	1	Blood leak detector 3	**replaces version 2**
10	34773762	10	O-ring 9.25 x 1.78	
11	34517251	1	Tubing connector ∅ 3.5 x 1/8"	**stainless steel**
12	34517294	1	Suction set with tubing, suction port and black lid	**for disinfection**
12	34514562	1	Suction set with tubing, suction port and yellow lid	**for disinfection**
12	34565272	10m	PVC tubing 3.5 x 1 (10 m)	**for disinfection**
12	34512675	1	Suction port	**for suction tubing**
13	34511792	1	Tubing coupling	
14	34517138	1	Reed sensor with contacts and o-ring 3.68 x 1.78	
15	34771255	20	O-ring 14 x 1.5	

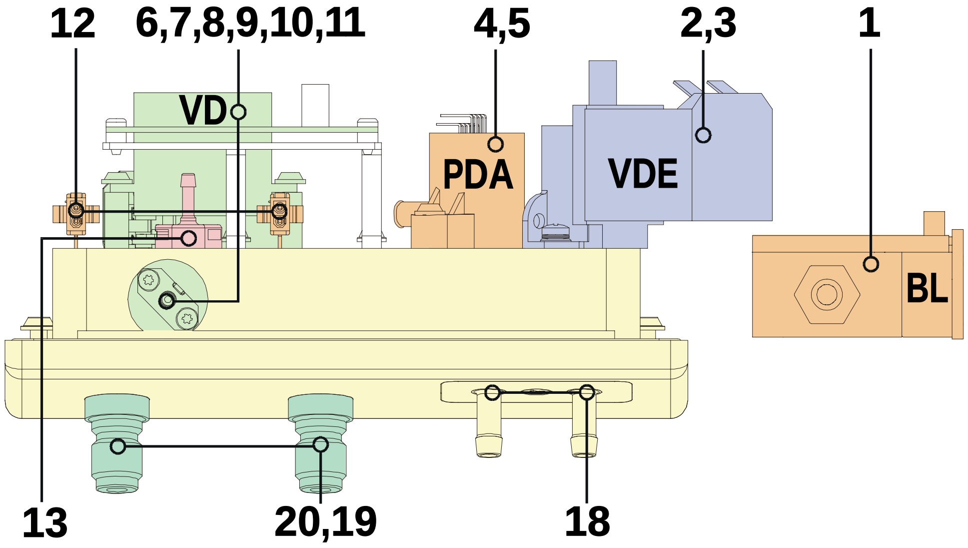
Rinsing Bridge 4



Pos.	Art. No.	Qty.	Description	Comments
-	3451898B	1	Repair kit disinfection valve consisting of: 2 x O-ring 2.7 x 1.5 2 x O-ring 5 x 1.6 3 x O-ring 6.4 x 1.3 2 x Cover 4 x Countersunk screw M3x8 2 x Valve tappet 2 x Pressure spring 1 x Eccecntric roller 1 x Eccecntric shaft	**for the complete replacement of all small parts in the disinfection valve**
1	34570012	10	O-ring 2.7 x 1.5	**for valve tappet**
2	34517332	2	Pressure spring	**for valve tappet**
3	3477106A	5	O-ring 6.4 x 1.3	**for cover valve tappet**
4	34517324	2	Valve tappet	**for VD**
5	34570457	10	O-ring 5.0 x 1.6	**for eccecntric shaft**
6	34560858	1	Eccecntric roller	
7	34560840	1	Eccecntric shaft	
8	3451659D	1	Servomotor with board	**for VD, servomotor and board must be exchanged together**

Rinsing Bridge 4

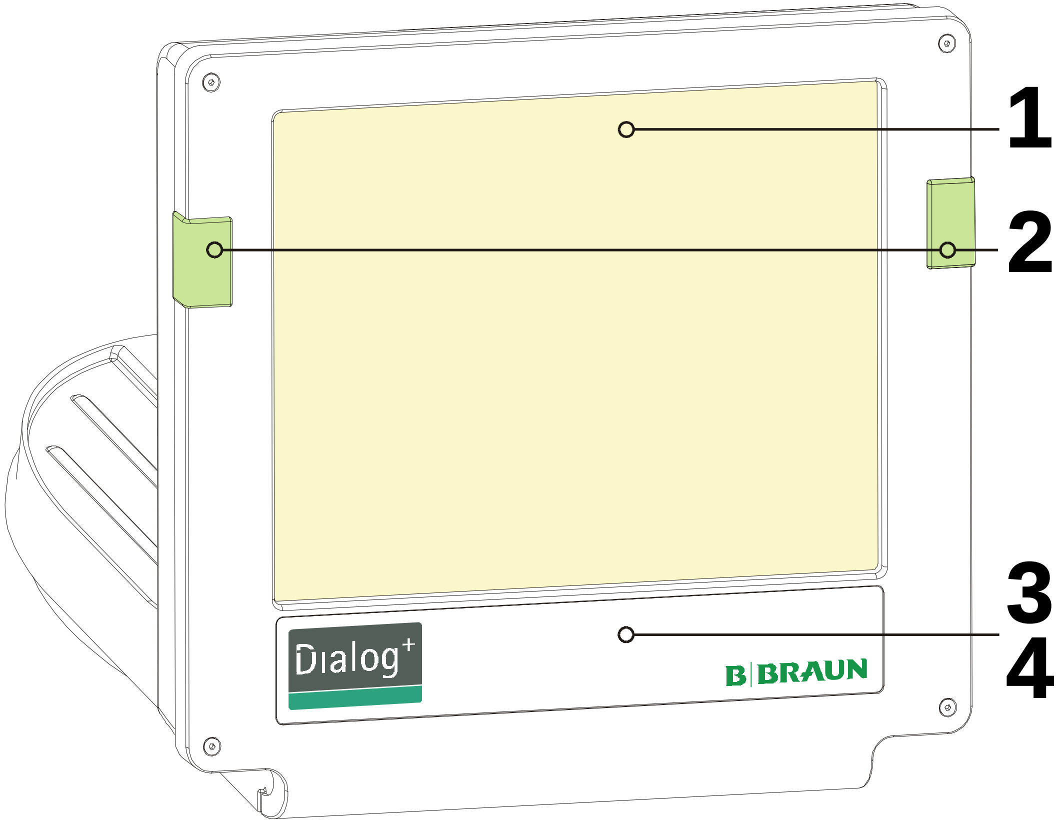


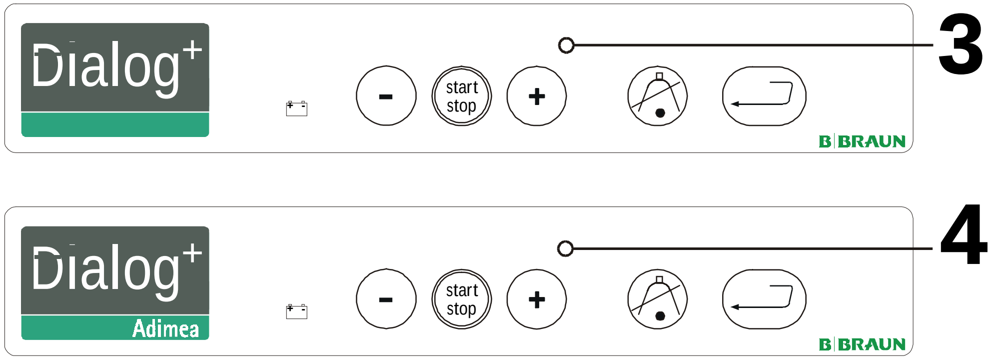


Pos.	Art. No.	Qty.	Description	Comments
1	3451908C	1	Blood leak detector 3	replaces version 2
2	34560270	1	Solenoid valve 2/2 way	connector/flange (DPP)
3	34770852	5	O-ring 11.1 x 1.6	
4	34561242	1	Pressure sensor	
5	34773762	10	O-ring 9.25 x 1.78	
6	34570012	10	O-ring 2.7 x 1.5	for valve tappet
7	34517332	2	Pressure spring	for valve tappet
8	3477106A	5	O-ring 6.4 x 1.3	for cover valve tappet
9	34517324	2	Valve tappet	for VD
10	34570457	10	O-ring 5.0 x 1.6	for ececntric shaft
11	3451659D	1	Servomotor with board	for VD
12	34517138	1	Reed sensor with contacts and o-ring 3.68 x 1.78	without housing
13	3477103A	2	Tubing connector ∅ 3.5 x 1/8"	
14	34514627	1	Rinsing bridge housing, version 4	
15	34516603	1	Fork light barrier for servomotor	
16	34517251	1	Tubing connector ∅ 3.5 x 1/8"	
17	3451614B	1	Temperature sensor	with shrinking tube, without connector/housing
17	34570730	1	Housing complete for temperature sensor	
18	34773762	10	O-ring 9.25 x 1.78	
19	34511792	1	Tubing coupling	
20	34771255	20	O-ring 14 x 1.5	

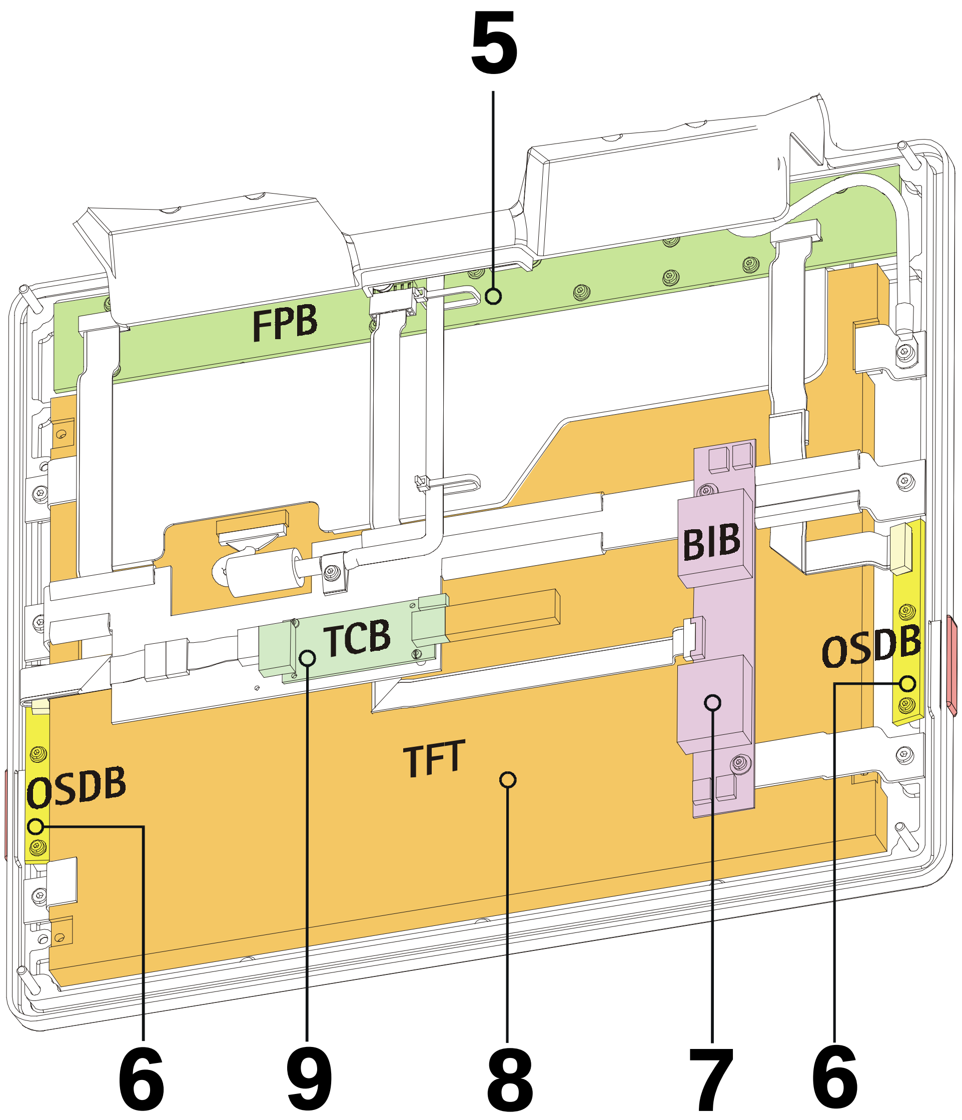
7.10 TFT Monitor

Pos.	Art. No.	Qty.	Description	Comments
1	34514260	1	Touch screen for TFT	
2	34570691	2	OSD cover	**complete with seal and screws**
3	34561285	1	Membrane	
4	34561366	1	Membrane for Adimea option	





TFT Monitor



Pos.	Art. No.	Qty.	Description	Comments
5	3451428A	1	Front panel board FPB	
6	3451429A	1	Optical status display board OSD	
7	34514686	1	Backlight inverter board BIB for Boe Hydis TFT	
8	3451463B	1	TFT display 15“ (Boe Hydis or Samsung)	
9	3451460A	1	Touch controller board TCB version 3	
-	34560912	1	Ribbon cable 12 pin FPB - OSD	
-	34560971	1	Ribbon cable FPB - BIB	

7.11 Test and Calibration Equipment and Tools

Inspection for Calibration Equipment

 # Calibration equipment is subject to inspection and must be checked and calibrated in regular intervals.

Pos.	Art. No.	Qty.	Description	Comments
#	7701357	1	Manometer 0-4 bar	
#	34511571	1	Manometer 2.5 bar	
-	770085A	1	Flow meter 1.1 l/min	
-	7700911	1	Reference solution (red)	**for calibration blood leak detector**
#	7702493	1	Template 1.4/1.5	**for tubing clamp**
#	-	*	Dialysis measurement instrument HDM 99XP For example manufacturer: IBP Instruments GmbH Internet: www:ibpmt.com	**for temperature, conductivity, flow and pressure measurement** **for details contact manufacturer directly**
-	-	-	Crossover cable RS 232	**for HDM 99 RS 232 interface** **for details contact IBP directly**
#	-	*	SecuLife ST For example manufacturer: GMC Instruments Group Internet: www:gossenmetrawatt.com	**for electrical safety check according to IEC 62353/EN 60601-1/IEC 601-1** **for details contact manufacturer directly**
-	-	*	Balance (e.g. Pocket Balance) For example manufacturer: Kern & Sohn GmbH Internet: www:kern-sohn.com	**for calibration of UFP, BICP and KP** **for details contact manufacturer directly**

* not in the product range of B. Braun Avitum AG

Test and Calibration Equipment and Tools

Pos.	Art. No.	Qty.	Description	Comments
-	7701756	1	Extraction tool set (AMP)	
-	770203A	1	Stopcock system with five stopcocks, incl. lines	**for the combined calibration of the pressure sensors (5 x original Perfusor lines 50 cm**
-	7703090	1	Measurement chamber 500 ml	**for function test ABPM module and LRP**
-	7701497	1	Special socket spanner ∅ 18 mm	**for assembly of MFC socket**
-	7703589	1	Crossover cable RJ45	**for network**
-	7703597	1	Coupling (female/female) RJ45	**for network**
-	7703635	1	Extension cable D-sub 9 pin (male/female)	**for network**
-	7703643	1	Chip card for BSL-Nexadia	**for network**
-	7703473	1	Test plug RS 232	**for network**
-	7703856	1	Chip card for card reader	
-	7703805	1	Male to male connector	**Adapter to connect both dialyser couplings for the measurement of the patient leakage current**
-	770284A	1	DCI cable, external	
-	7703848	1	Assembly jig (motor for piston pump)	**required for motor assembly**

7.12 Service Kits

Pos.	Art. No.	Qty.	Description	Comments
-	3451897A	1	Repair kit balance chamber	**for the complete replacement of both membranes, incl. all o-rings and assembly parts (self-locking nuts, screws, springs etc.)**

7.13 Software

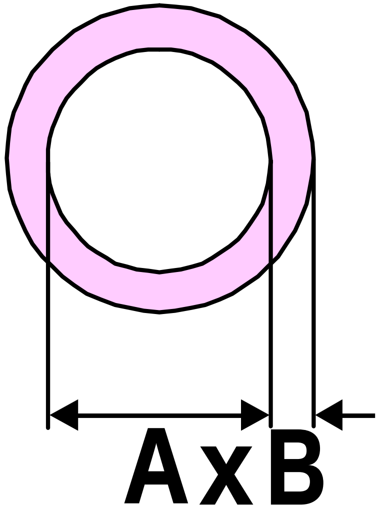
Pos.	Art. No.	Qty.	Description	Comments
-	770902	1	Software 9.02	**USB-Stick with TLC/LLS/LLC**
-	7703554	1	CD Remote Bedside Link List ReBeLL, version 1.5.13	**for network**
-	7703562	1	CD WAN-BSL, firmware version 1.0.4.8	**for WAN-BSL only**
-	7703864	1	Field service utility FSU, version 2.00	

7.13.1 Software Compatibility Table

Software (ex Works)	BIOS	Dialog		Dialog Advanced		Dialog Advanced GX1LCD (ex Works)	Dialog+ ≤SW 8.XX *GX1LCD # LX800	Dialog+ SW 9.XX LX800
		POS-460	GX1LCD	POS-460	GX1LCD			
Software 3.46 (QNX2)	-	X	-	-	-	-	-	-
Software 3.48 (QNX2)	1.8	-	X	-	-	-	-	-
Software 5.35 (QNX2)	-	-	-	X	-	-	-	-
Software 5.36 (QNX2)	1.8	-	-	-	X	-	-	-
Software 6.XX (QNX4)	1.8	-	-	-	-	X	-	-
Software 7.21 bis 7.53 (QNX4)	*1.8/1.9 #1.01/ 1.04	-	-	-	-	-	X	-
Software-Update 7.53 (Linux) Diskettes with TLC/LLS SW only if SW 7.52 is present		-	-	-	-	-	X	-
Software 7.58 (Linux)		-	-	-	-	-	X	-
Software 7.59 (Linux)	*1.9 #1.01/ 1.04	-	-	-	-	-	X	-
Software-Update 7.59 (Linux) USB Stick with TLC/LLS SW only if SW 7.52 is present		-	-	-	-	-	X	-
Software ≥ 8.20 (Linux)		-	-	-	-	-	X	-
Software 9.02 (Linux)	1.04	-	-	-	-	-	-	X

7.14 Miscellaneous

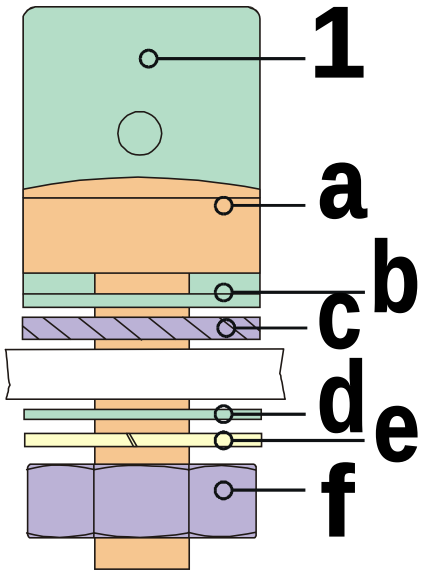
Note: See also chapter 6 (Tubing Diagrams)



A x B Tubing

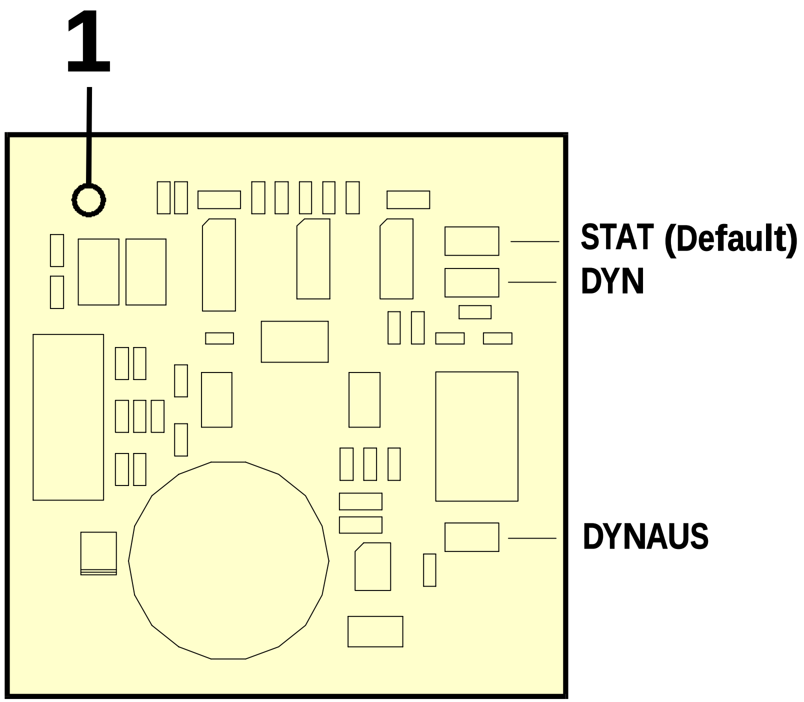
Pos.	Art. No.	Qty.	Description	Comments
-	34565329	1m	Tubing 12 x 2 / RAL 9001 (1 m)	
-	34565337	2m	Silicone tubing 8 x 2 (2 m)	
-	34565221	10m	Silicone tubing 6 x 3 (10 m)	
-	34565256	2m	Silicone tubing 6 x 1.75 / red (2m)	**internal high temperature tubing**
-	39238032	1	Single ear clamp 13.3	**for internal high temperature tubing**
-	34565167	1	Silicone tubing 8 x 3,2 / red (3 m), with two single ear clamps 17.5	**external high temperature tubing**
-	39224538	1	Single ear clamp 17.5	**for external high temperature tubing**
-	34565264	2m	Silicone tubing 6 x 1.75 (2 m)	
-	34565191	10m	Silicone tubing 5 x 3 (10 m)	
-	34565248	10m	Silicone tubing 5 x 1.5 / blue (10 m)	
-	34565230	10m	Silicone tubing 5 x 1.5 / red (10 m)	
-	34565205	5m	PUR tubing 3.6 x 1.1 (5 m)	
-	34565272	10m	PVC tubing 3.5 x 1 (10 m)	
-	34565213	10m	Silicone tubing 2.9 x 3 (10 m)	
-	34565280	3m	Silicone tubing 3.2 1.6 (3 m)	
-	34565299	3m	Silicone tubing 2 x 3 (3 m)	**transparent**
-	34565302	5m	Silicone tubing 2 x 1.5 (5 m)	
-	34565140	50m	PVC tubing 10 x 3 / red (50 m)	**for water inlet**
-	3456517A	1	PVC tubing 10 x 3 / red (3 m), with two single ear clamps 19.5	**for water inlet**
-	34565159	50m	PVC tubing 10 x 3 / black (50 m)	**for dialysate outlet**
-	3456518A	1	PVC tubing 10 x 3 / black, (3 m), with a single ear clamp 19.5 and a tubing clamp 12-20 mm	**for dialysate outlet**
-	39234126	1	Tubing clamp 12-20 mm	
-	34565345	1m	Silicone tubing 12 x 2.5 (1 m)	

Pos.	Art. No.	Qty.	Description	Comments
-	34570195	20	Tubing clamp SNP-1.5 ∅ 7-8 mm	**plastic**
-	34570209	20	Tubing clamp SNP-4 ∅ 10-11 mm	**plastic**
-	34570365	20	Tubing clamp SNP-6 ∅ 11.4-13 mm	**plastic**
-	34517766	10	Canister lid, red	**with retainer for suction rod**
-	34517774	10	Canister lid, blue	**with retainer for suction rod**
-	3399 0492	m	Spiral band	**per meter**
-	34773770	5	Y-Tubing connector 6 mm	
-	34570705	5	Y-Tubing connector 8 mm	
-	7703619	1	Touch-up pen pale green	
-	7703627	1	Touch-up pen light grey	
-	7702345	1	Silicone grease 410	**(Renolit) 100 g tube**
-	7702353	1	Silicone rubber adhesive (white) RTV 162	
-	7702388	1	Silicone rubber adhesive (transparent) RTV 118	**must no be used for electronic components**
1	34570322	10	Grounding for sub-racks consisting of: screw **a**, terminal **b**, tooth lock washer **c**, washer **d**, spring washer **e**, nut **f**	**pay attention to correct assembly sequence!**
-	7703708	1	Grease SKD 4002	**100 g tube** **(to lubricate the shaft of the blood pump)**



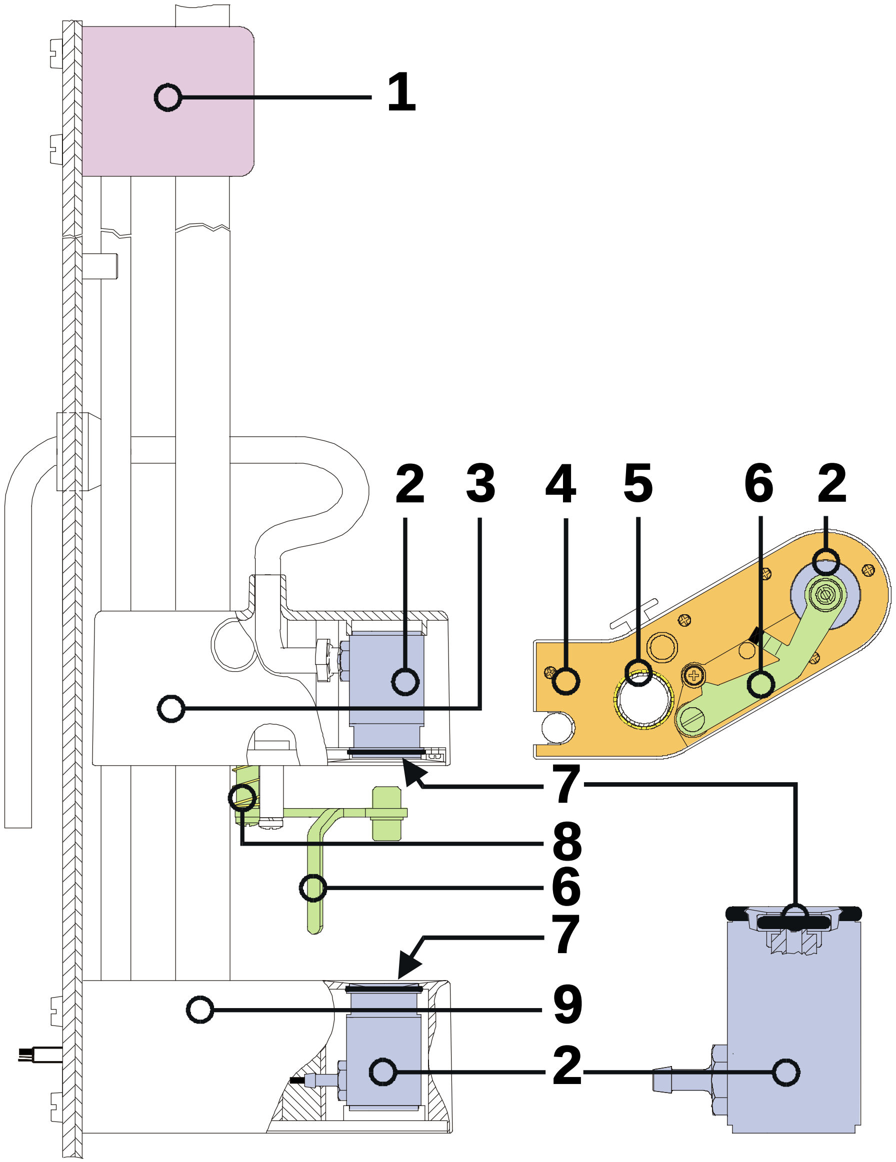
7.16 Staff Call (Option)

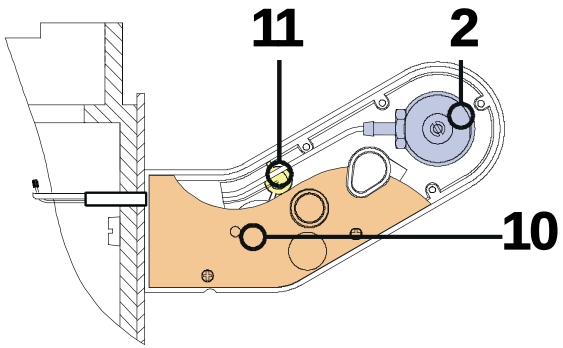
Pos.	Art. No.	Qty.	Description	Comments
1	34517685	1	Staff call board	



7.17 Bicarbonate Cartridge Holder (Option)

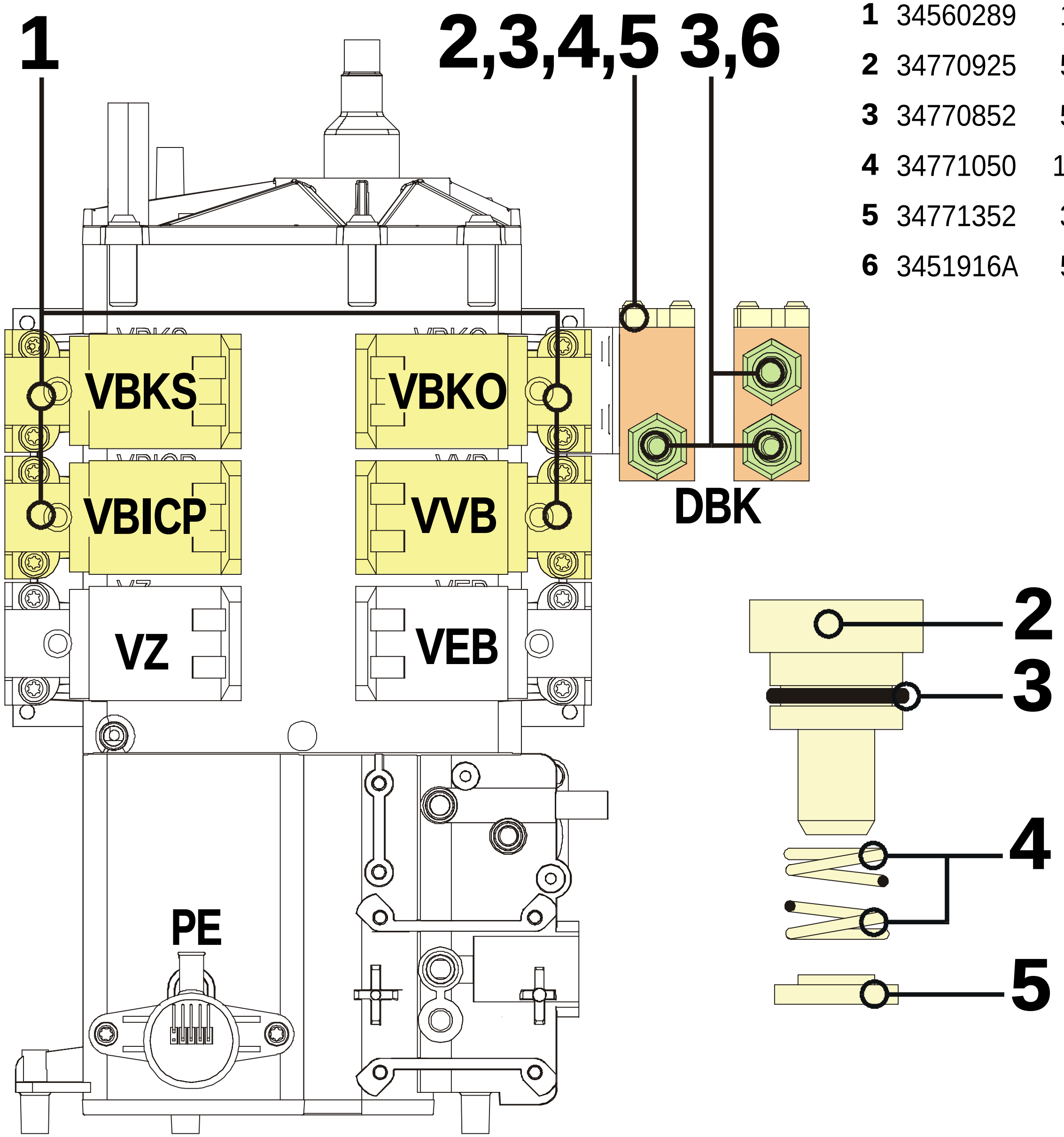
7.17.1 Bicarbonate Cartridge Holder





Pos.	Art. No.	Qty.	Description	Comments
1	3451439A	1	Holder, top	
2	3456008A	1	Valve with piercing spike version 2 complete with o-ring	
3	3451437A	1	Housing, top	**incl. thread forming screws 22 x 12**
4	34514422	1	Cover for top housing	**incl. thread forming screws 22 x 12**
5	34519866	1	Slide ring	
6	34560092	1	Swivel arm version 2	
7	34570594	10	O-ring 9.2 x 2.7	
7	34570241	5	O-ring 9.19 x 2.62	**alternative**
8	34570420	5	Rotary spring	
9	34514430	1	Housing, bottom	**incl. thread forming screws 22 x 12**
10	34514449	1	Cover for bottom housing	**incl. thread forming screws 22 x 12**
11	34517138	1	Reed sensor with contacts and o-ring 3.68 x 1.78	**bottom BIC cartridge holder**
-	34517782	5	Disposable filter	**filter FBIC**

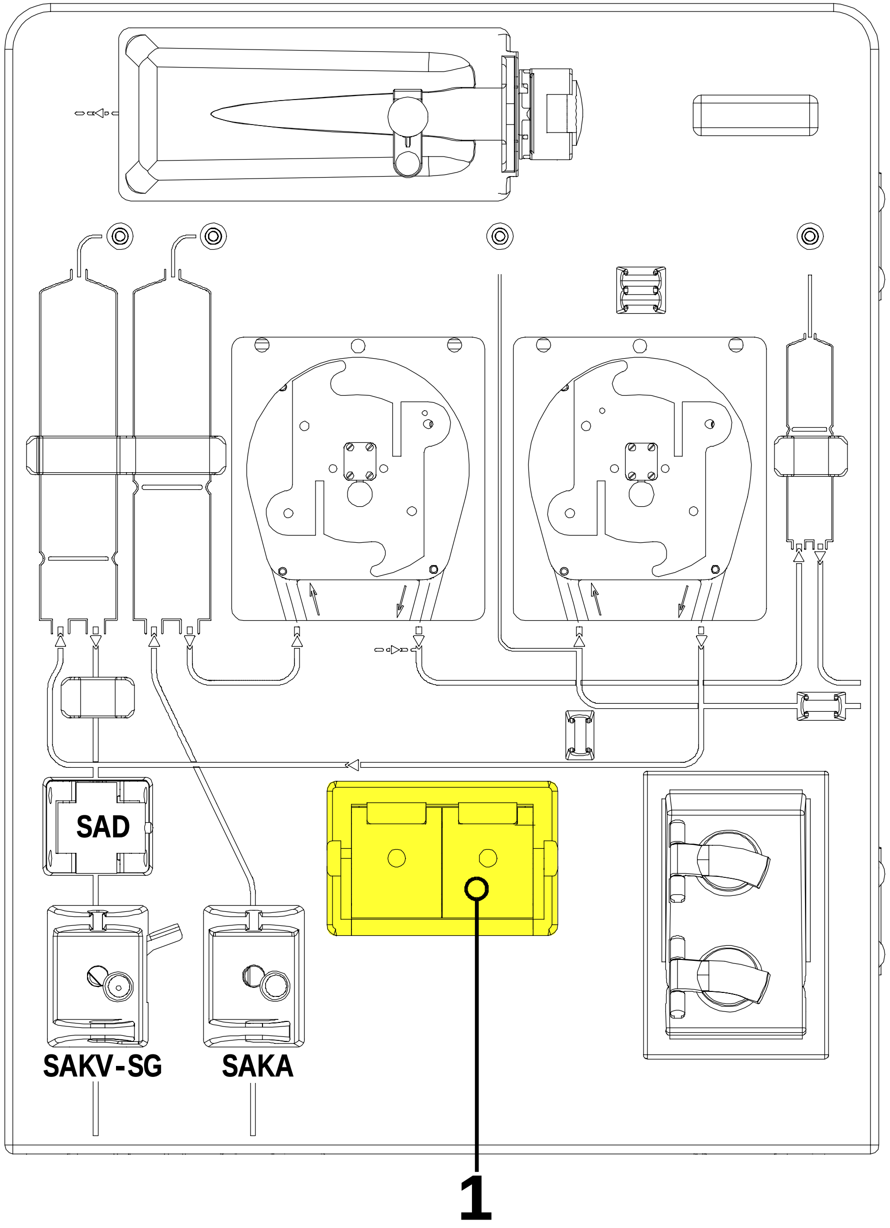
7.17.2 Solenoid Valves and Throttle



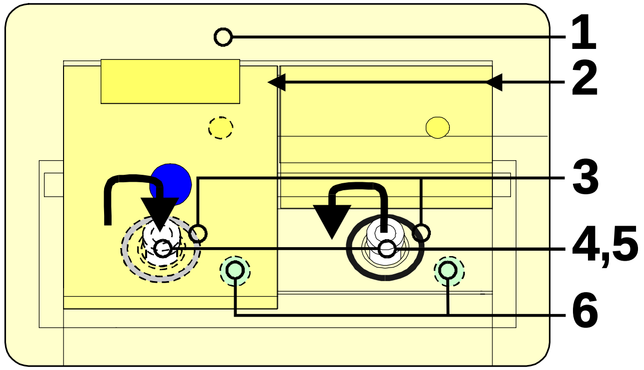
Pos.	Art. No.	Qty.	Description	Comments
1	34560289	1	Solenoid valve 2/2 way	**connector/connector (DPP)**
2	34770925	5	Plug	
3	34770852	5	O-ring 11.1 x 1.6	
4	34771050	10	Pressure spring 500 mmHg	
5	34771352	3	Centre disc	
6	3451916A	5	Tubing connector ∅ 8 x 1/8"	**plastic**

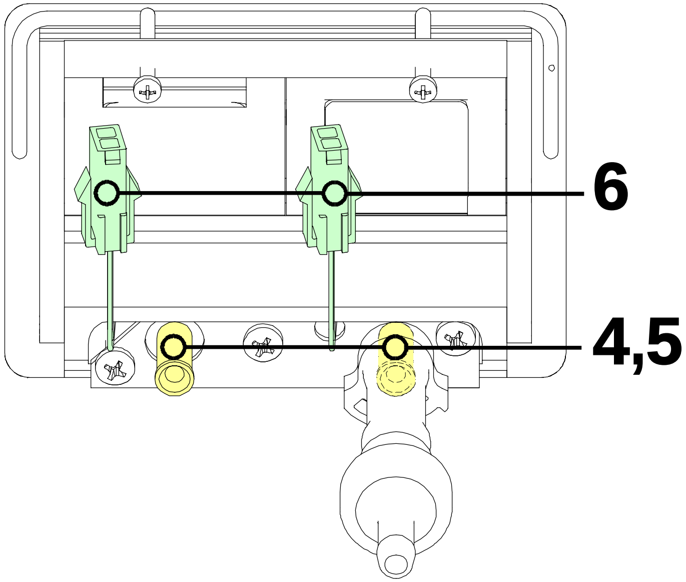
7.18 HDF Online (Option)

Pos.	Art. No.	Qty.	Description	Comments
1	-	-	Substitution port	**see separate figure**
-	-	-	UF sub-rack	**see separate figure**

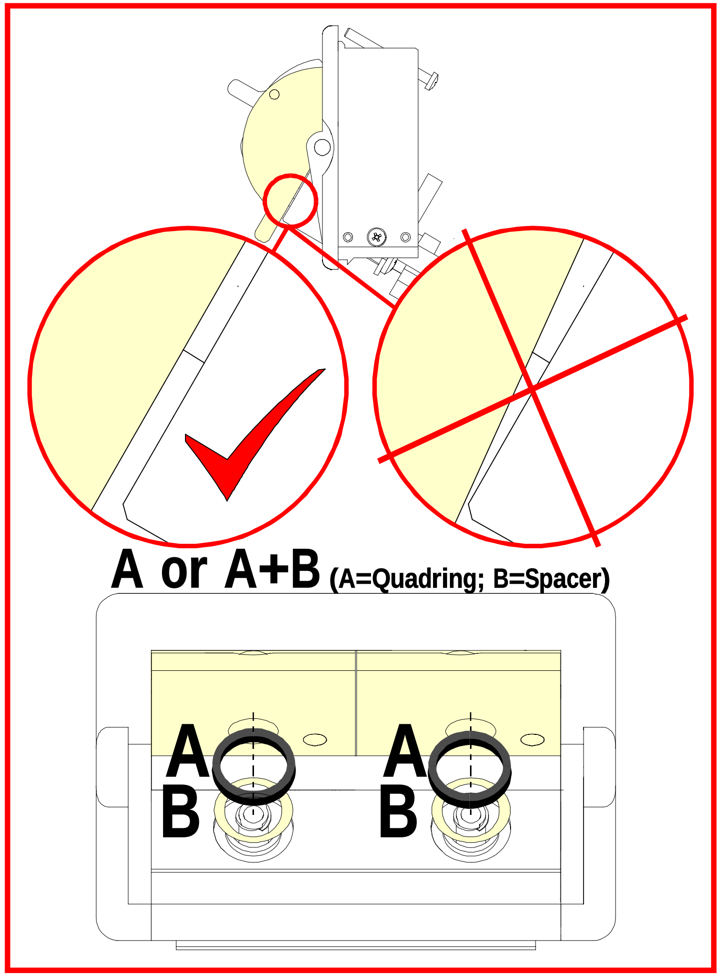


7.18.1 Substitution Port

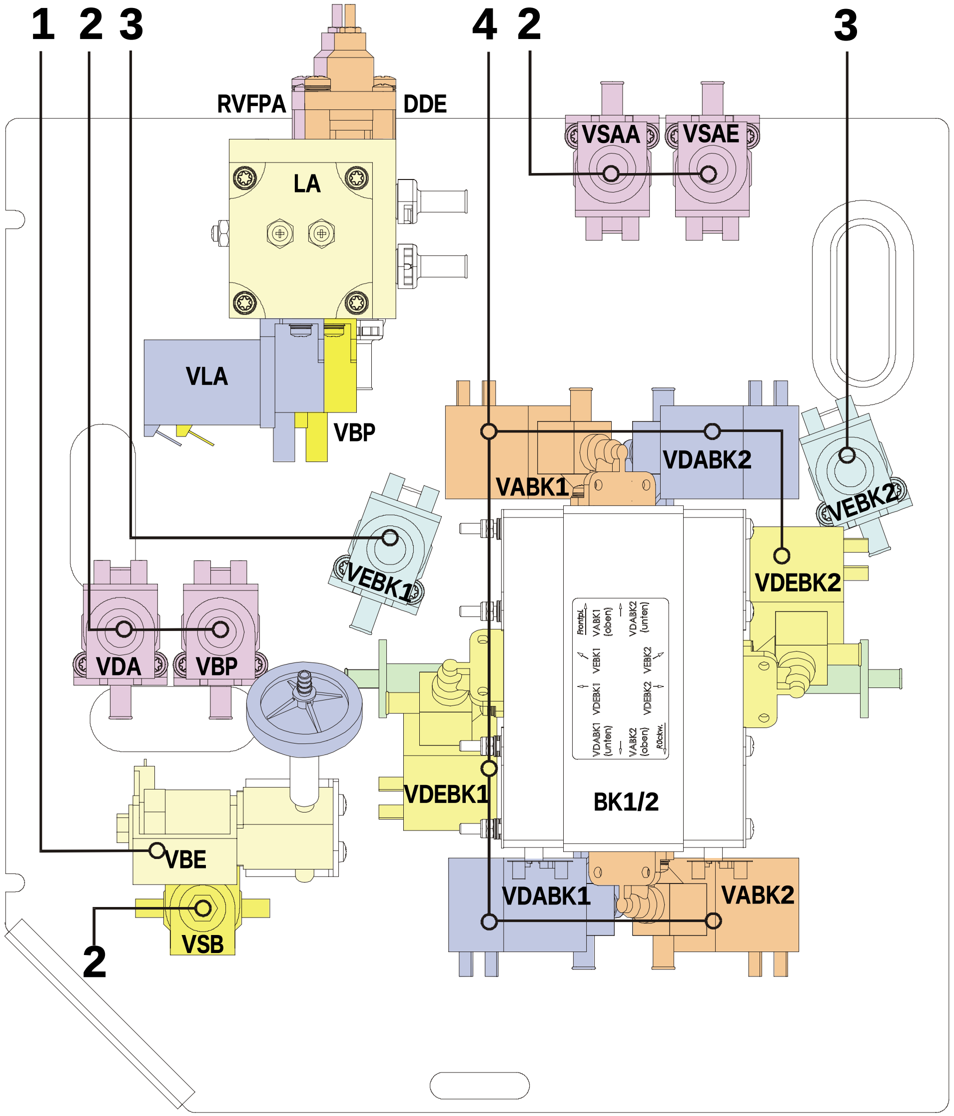




Pos.	Art. No.	Qty.	Description	Comments
1	3451448A	1	Substitution port complete	
2	34570349	5	Pressure spring ∅ 4.6 x 14 mm	
3	3457035A	2	Quadring 12.37 x 2.62 incl. spacer	
4	34560017	1	Substitution connector	**stainless steel, without o-ring**
5	3477106A	5	O-ring 6.4 x 1.3	
6	34517138	1	Reed sensor with contacts and o-ring 3.68 x 1.78	

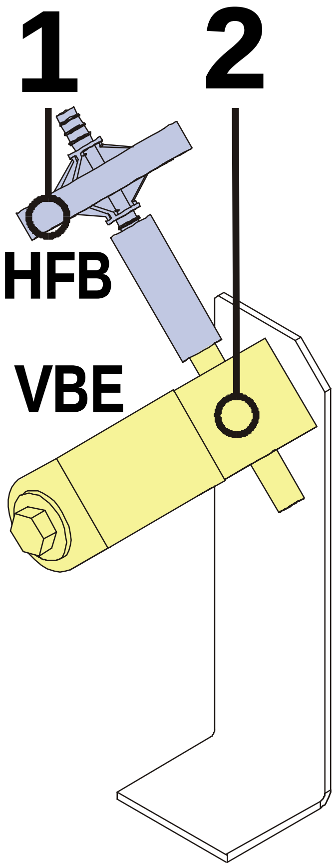


7.18.2 UF Sub-Rack HDF Online



Pos.	Art. No.	Qty.	Description	Comments
1	-	-	Valve block	**see separate figure**
2	34560289	1	Solenoid valve 2/2 way	**connector/connector (DPP)**
3	3451906C	1	Solenoid valve 2/2 way	**manuf. AKM only, connector/connector**
4	3451902C	1	Solenoid valve 2/2 way	**manuf. AKM only, connector/flange**
4	34770852	5	O-ring 11.1 x 1.6	

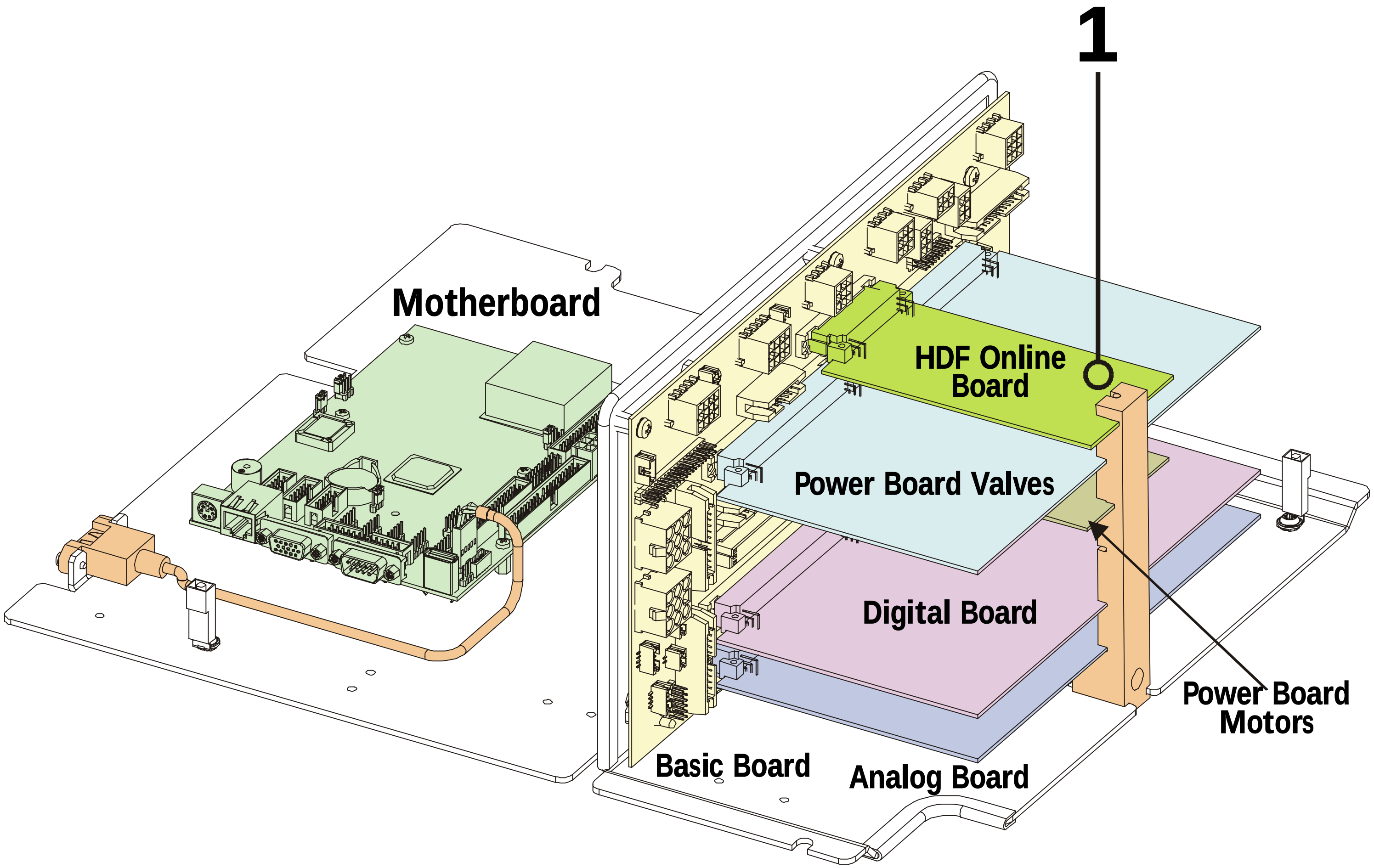
7.18.3 Valve Block HDF Online



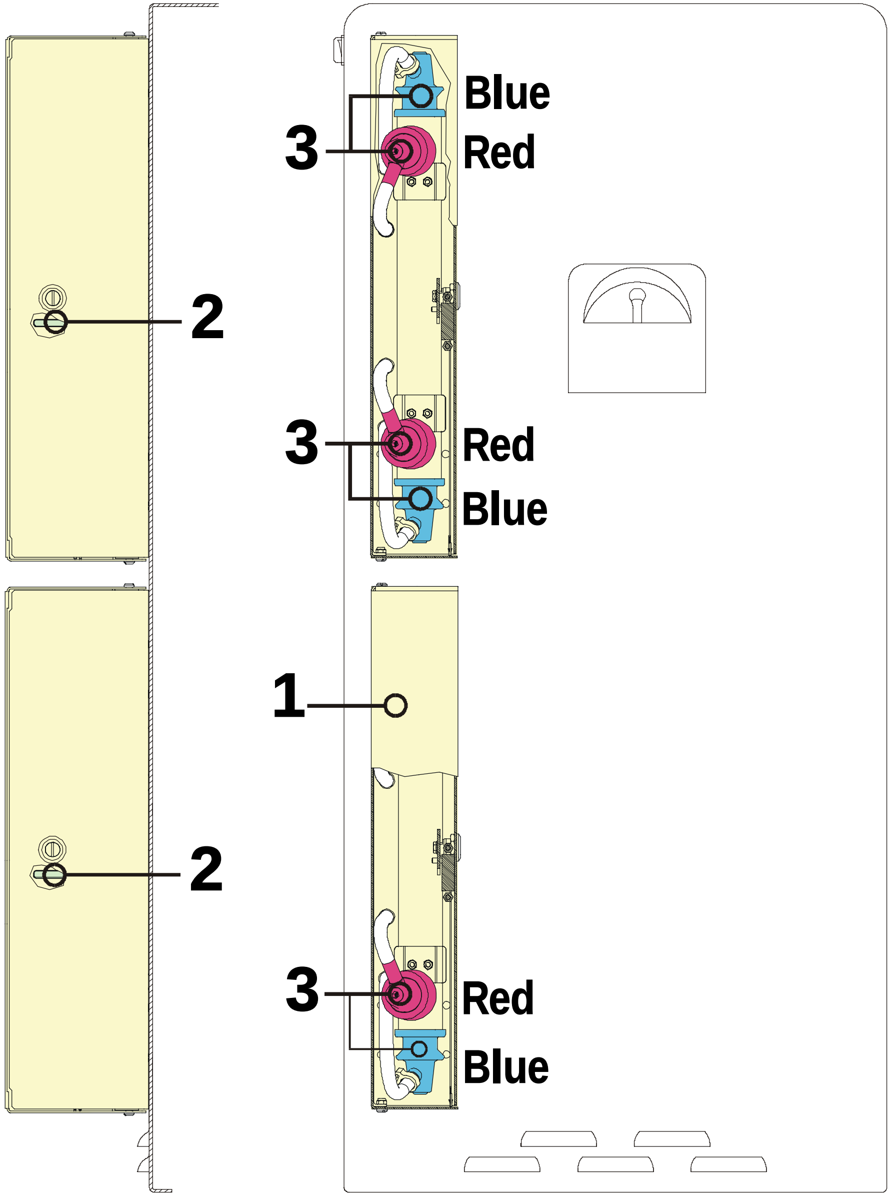
Pos.	Art. No.	Qty.	Description	Comments
1	34560661	1	Hydrophobic filter	**with tubing adapter**
2	3451900A	1	Solenoid valve 3/2 way	

Pos.	Art. No.	Qty.	Description	Comments
1	34560866	1	HDF online board	

7.18.4 Board HDF Online



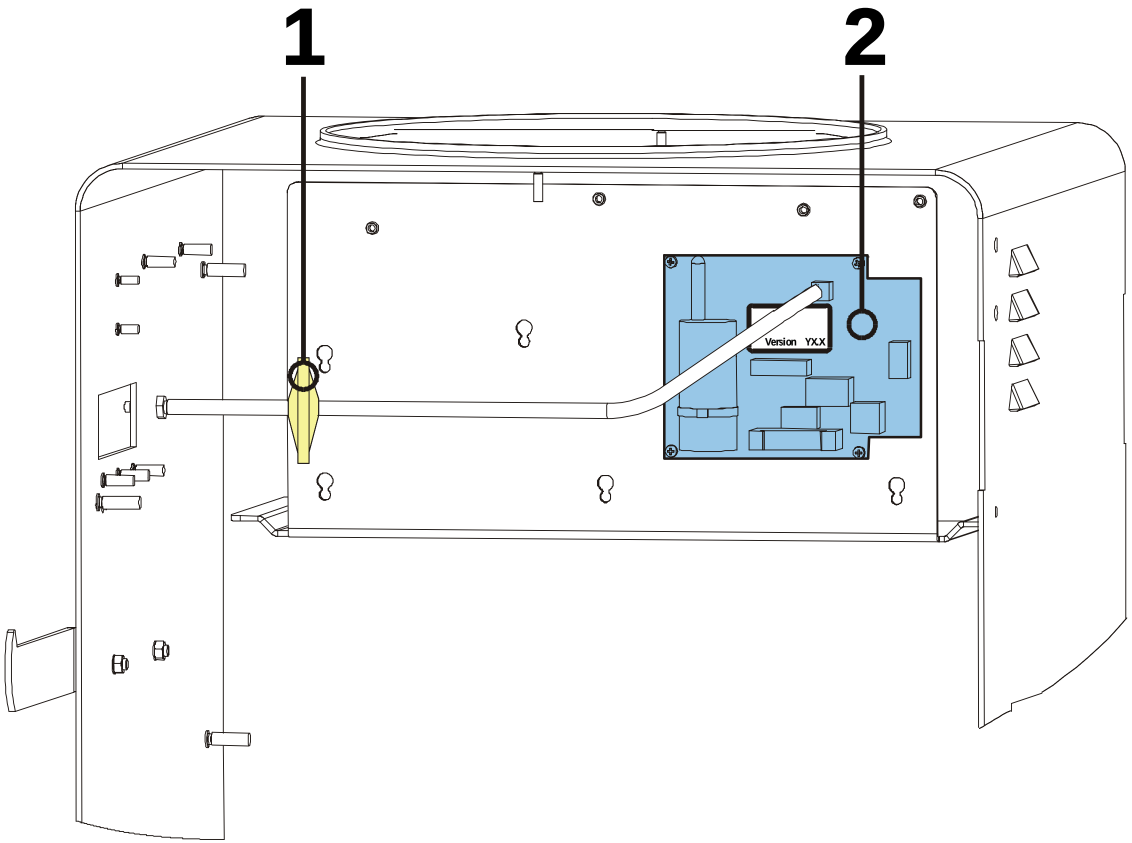
7.18.5 DF/HDF Filter Holder HDF Online

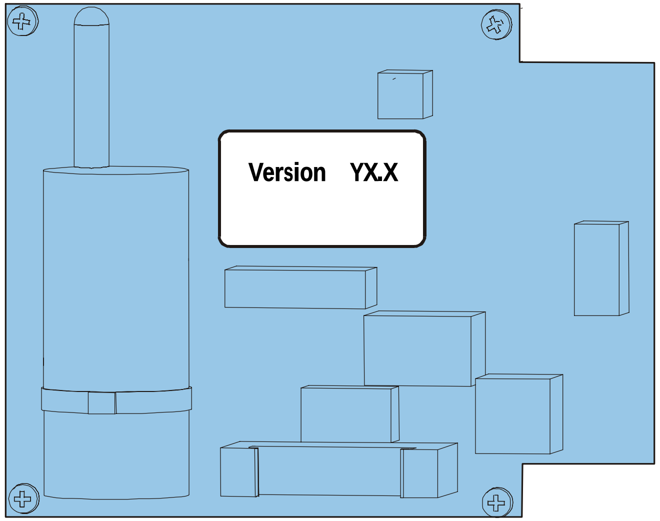


Pos.	Art. No.	Qty.	Description	Comments
1	3456004A	1	Filter holder complete version 2	
2	34517138	1	Reed sensor with contacts and o-ring 3.68 x 1.78	
3	3451445A	1	Dialyser coupling (red)	
3	3451446A	1	Dialyser coupling (blue)	
3	34990445	5	O-ring 12.37 x 2.62	
3	34773550	20	Membrane for dialyser coupling	

7.19 Automatic Blood Pressure Measurement ABPM Module M2009

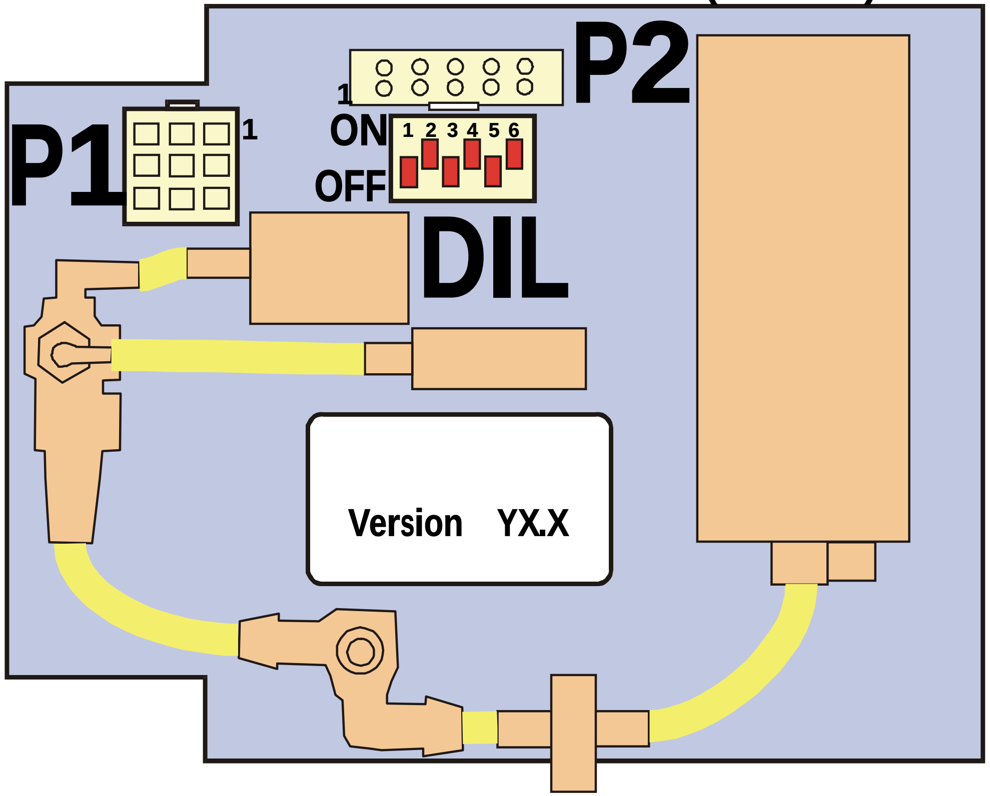
Pos.	Art. No.	Qty.	Description	Comments
1	34560955	1	Filter (ABPM module M2009)	
2	3451487C	1	ABPM module M2009 with filter	**firmware version of ABPM module on sticker: Version Y (FW):X.X**





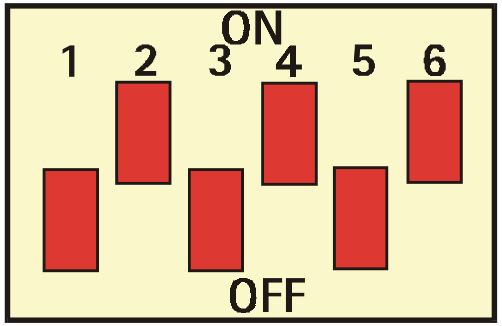
7.19.1 Compatibility Table ABPM Module M2009

DIL Switch: Default LX800 (ex Works)



Position of DIL Switch for LX800 Motherboard

DIL Switch



	DIL Switch					
	1	2	3	4	5	6
LX800 (default)	OFF	ON	OFF	ON	OFF	ON

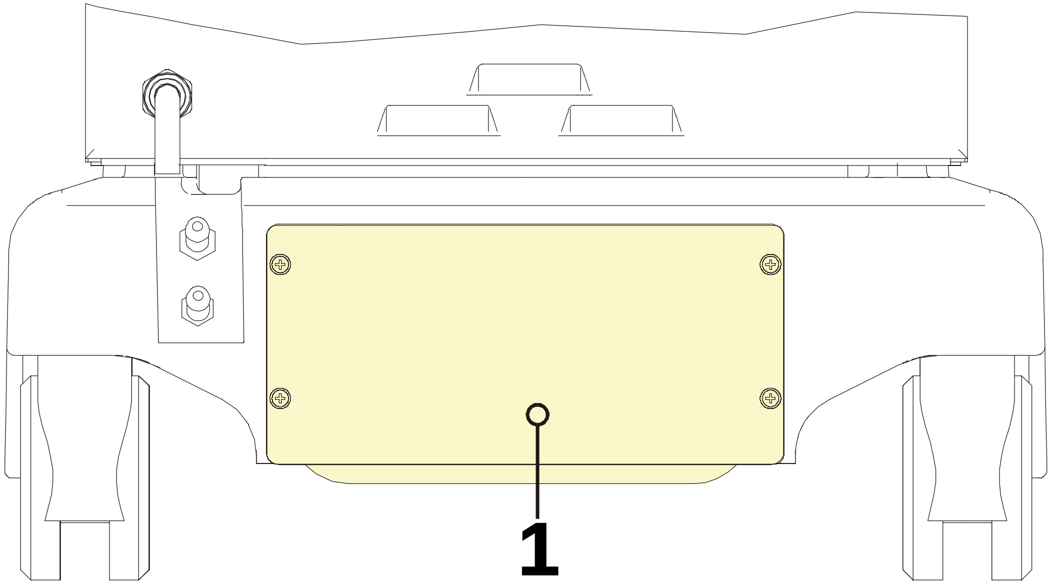
Pos.	Art. No.	Qty.	Description	Comments
1	-	-	Battery sub-rack	**see separate figure**

7.20 Emergency Power Supply (Option)

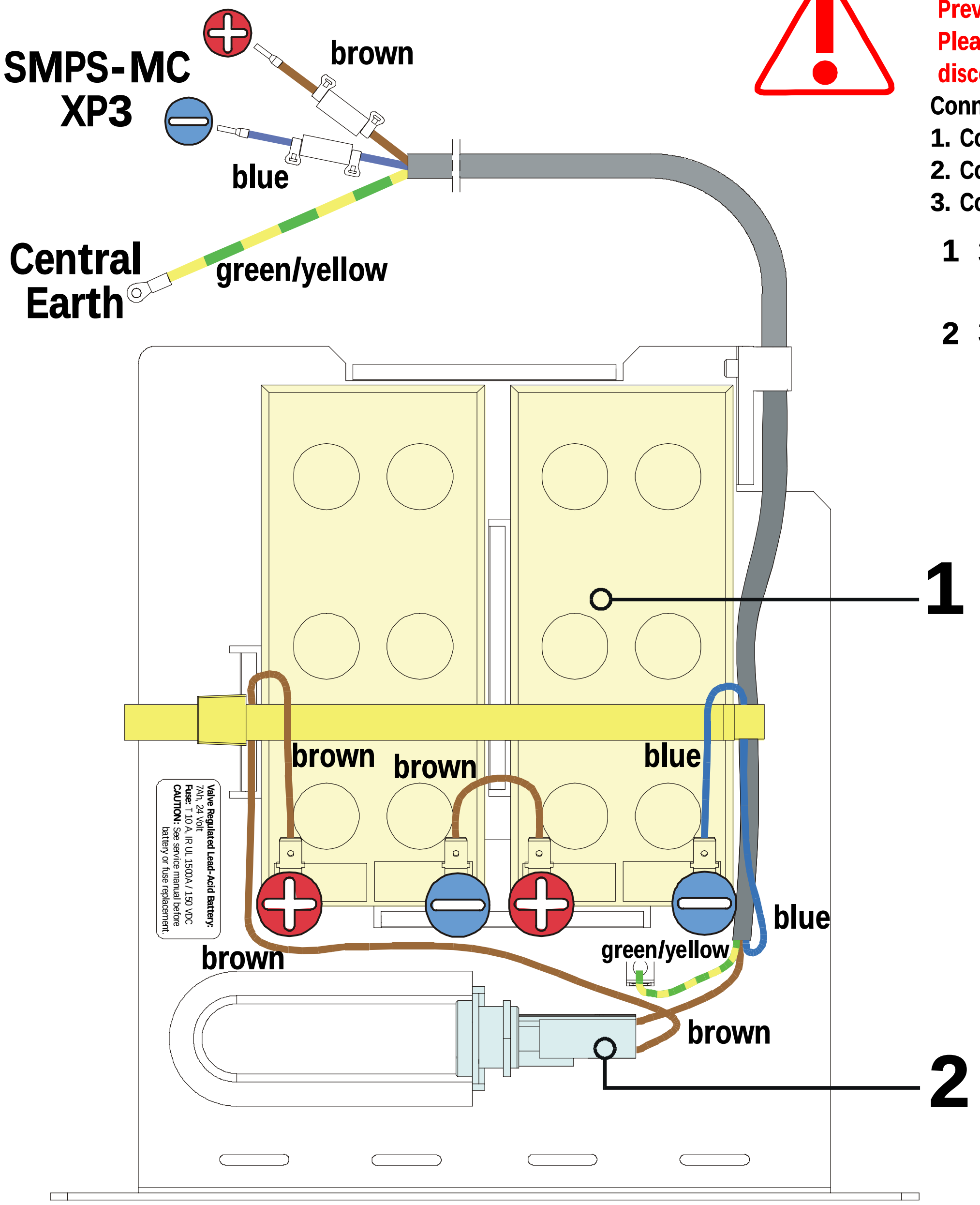
The battery (rechargeable) contains diluted sulfric acid, a very toxic substance. If the battery leaks and the liquid inside spills on the skin or clothing, immediately wash it off with plenty of clean water.

If the liquid splashes into the eyes, immediately flush the eyes with plenty of clean water and consult a doctor. Sulfric acid in the eyes may cause loss of eyesight and acid on the skin will cause burns.

Pay attention to the included documentation of the battery supplier!



7.20.1 Battery Sub-Rack



If a battery must be replaced exchange the complete battery set!
Prevent shorts in the battery compartment during disassembly and assembly:
Please pay attention to the correct disassembly/assembly sequence during the connection and disconnection of the batteries.

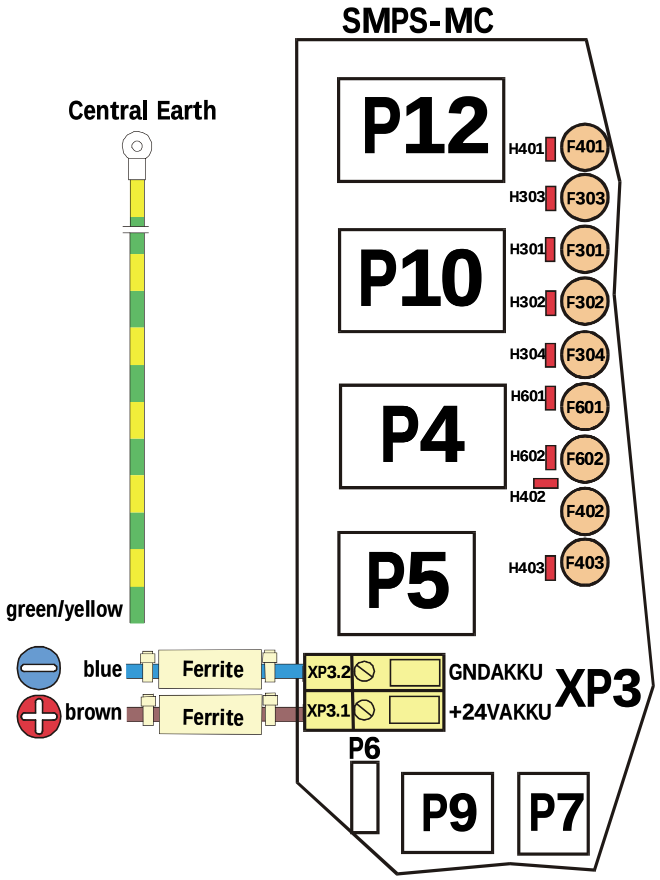
Connection

1. Connect (+) terminal (brown).
2. Connect (-) terminal (blau).
3. Connect ground terminal (green/yellow).

Disconnection

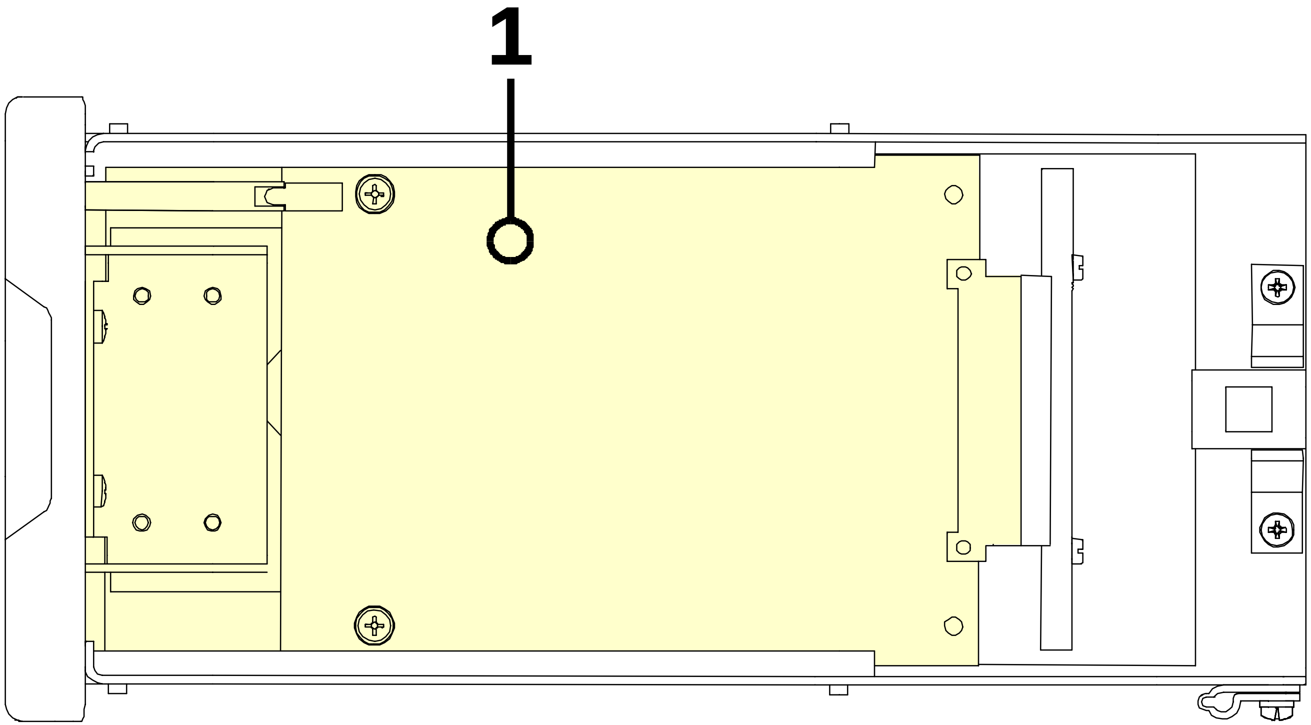
1. Disconnect (-) terminal (blue) abziehen.
2. Disconnect ground terminal (green/yellow).
3. Disconnect (+) terminal (brown).

Pos.	Art. No.	Qty.	Description	Comments
1	34561250	1	Battery (rechargeable) set 12 V/7 Ah, incl. cable ties	**2 x battery (rechargeable) 12 V/7 Ah**
2	34570721	10	Fuse T10 A (5 x 20 mm)	



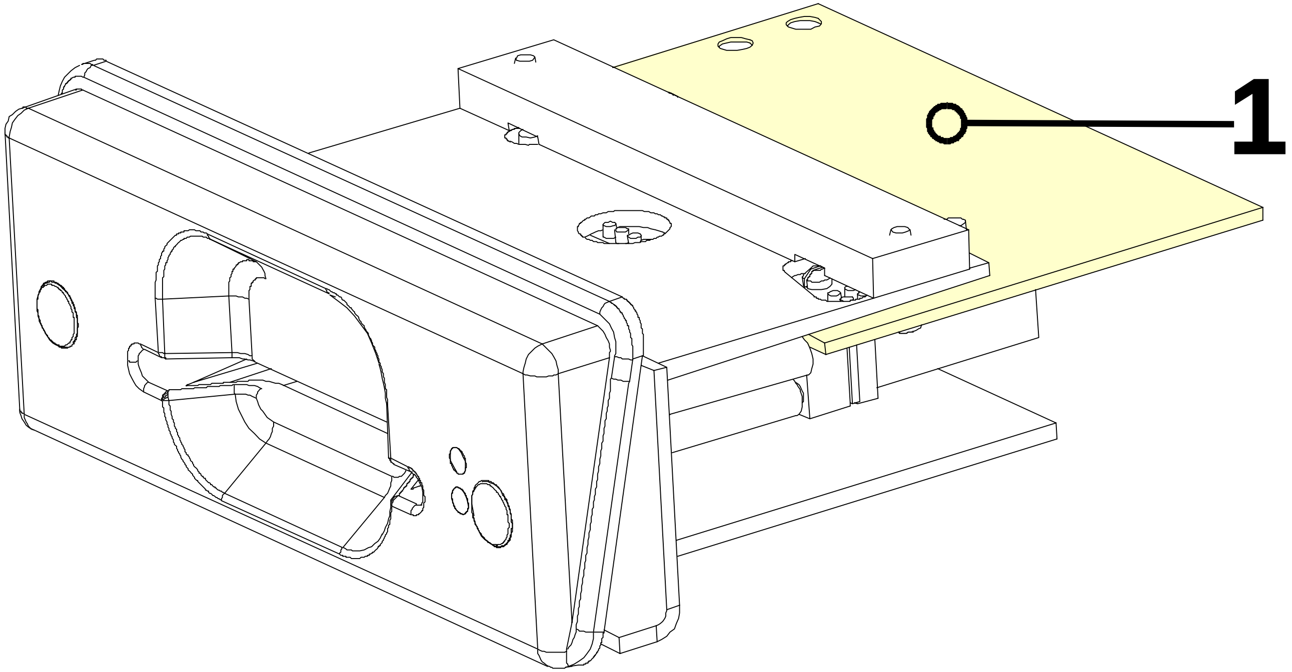
Pos.	Art. No.	Qty.	Description	Comments
1	34514554	1	Bedside link board (BSL board)	**without firmware**

7.21 Nexadia®-BSL/WAN-BSL (Option)



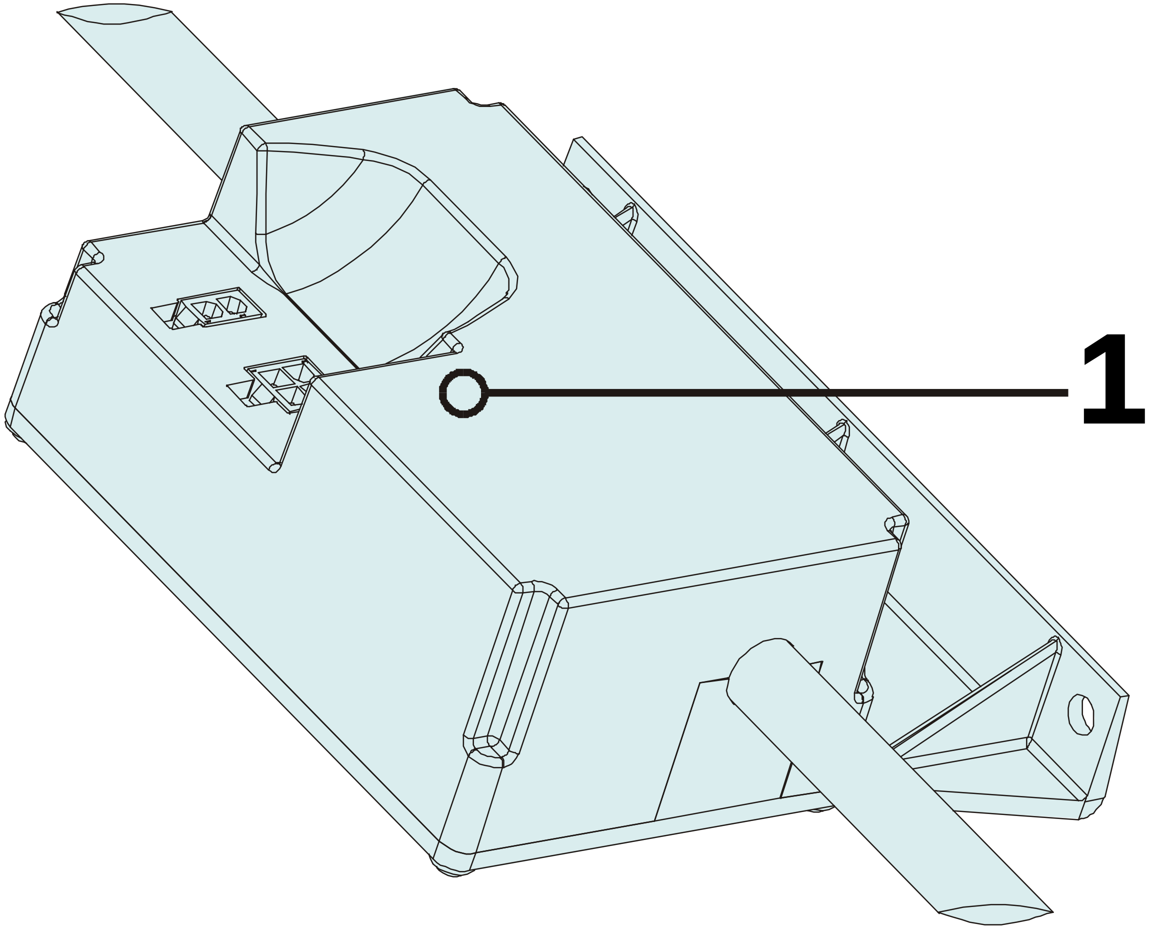
7.22 Card Reader (Option)

	Art. No.	Qty.	Description
1	34560548	1	Card reader board



	Art. No.	Qty.	Description	
1	3456063A	1	Kt/V-UV board	**with housing and tubing**

7.23 Adimea Option



8.1 ESD/EMC Information

8.1.1 Electrostatic Discharge ESD

Prevent a direct contact of body parts with ground potential!
Electrical shock hazard - do not touch any live components!

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 Ket

Fig. : 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.

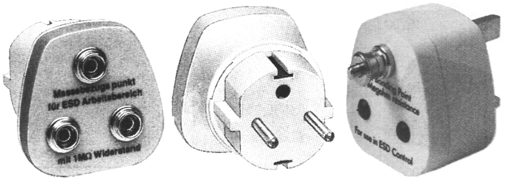


Fig. : Mains Plugs with Earth Bonding Point

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

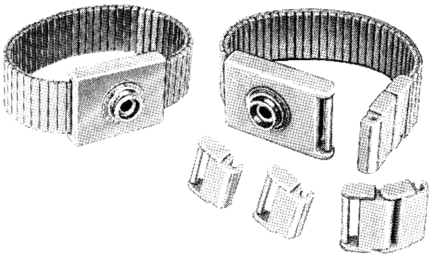


Abb. : Handgelenkband

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).

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 and Assembly Groups

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, i.e. 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 pcb's

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.

8.1.2 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 201, 202 and 204 are guidelines from the IEC 60601-1-2 and must be observed.

Electromagnetic Emissions, Table 201

Guidance and manufacturer's declaration – electromagnetic emissions		
The Dialog+ machine is intended for use in the electromagnetic environment specified below. The customer or the user of the Dialog+ machine should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions acc. to CISPR 11	Group 1	The Dialog+ machine 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.
RF emissions acc. to CISPR 11	Class B	The Dialog+ machine is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions acc. to IEC 61000-3-2	Class A	The Dialog+ machine is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions acc. to IEC 61000-3-11 and DIN EN 60601-1-2:1993	Complies	The Dialog+ machine is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. If the network impedance of the supply network has a max. impedance of $Z = (0.250 + j\ 0.150)\ \Omega$ or the machine is connected to a public low-voltage power supply network with a rated power supply of 230 V, measured between life L and neutral N, connected to a one or three phase public power supply with a constant current load of the power supply ≥ 100 A per phase, then it is also valid for the Dialog+ machine with the switch mode power supply microcontroller SMPS-MC.

Electromagnetic Immunity, Table 202

Guidance and manufacturer's declaration – electromagnetic immunity			
The Dialog+ machine is intended for use in the electromagnetic environment specified below. The customer or the user of the Dialog+ machine should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) acc. to 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 acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output for lines	± 2 kV for power supply lines ± 1 kV for input/output for lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge acc. to IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential 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 acc. to 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 Dialog+ machine requires continued operation during power mains interruptions, it is recommended that the Dialog+ machine be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	3 A/m	3 A/m	The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity, Table 204

Guidance and manufacturer's declaration – electromagnetic immunity

The Dialog$^+$ machine is intended for use in the electromagnetic environment specified below. The customer or the user of the Dialog$^+$ machine should assure that it is used in such an electromagnetic 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 Dialog$^+$ machine, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.1.2 **Recommended separation distance:**	
Conducted RF acc. to IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d=1.2\sqrt{P}$	**Note:** **The recommended distances are specified in the operating instructions (for software ≥ 9.xx), chapter 15.**
Radiated RF acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz 3 V/m 80 MHz to 2.5 GHz	3 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 in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 	

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 land mobile 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 Dialog$^+$ machine is used exceeds the applicable RF compliance level above, the Dialog$^+$ machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Dialog$^+$ machine.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

8.2 Technical Information TI

8.3 Assembly Instructions AI

8.4 Field Service Information FSI

8.5 Instruction Leaflets IL

Edition Number	Updates Edition/Chapter/Paragraph	Page	Date (yyyy-mm-dd)
0.1/2009	FAT Edition Dialog+ SW 9.xx Service Manual (English)		2009-09-09
1/2010	First Edition for Series, Dialog+ SW 9.xx Service Manual (English)		2010-03-29
1-1_1/2010	Revision Chapter 1 Commissioning		2011-03-01
4-1-1_1/2010 4-2-1_1/2010 4-3-1_1/2010	Revision Chapter 4 TSM Service Program		2011-03-01
5-1_1/2010	Revision Chapter 5 Technical Safety Inpsection and Preventive Maintenance		2011-03-01
9-1_1/2010	Revision Chapter 9 Edition/Updates		2011-03-01