multiFiltrate

Service Manual

Part no. M28 003 1

Fresenius Medical Care

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1 Important Information

1.1 Organization of the Technical Manual

Page identification

Page number 1-3 is to be interpreted as: Chapter 1, page 3.

Editorial information

The current edition of this Technical Manual is

6/03.07 = 5th edition, September 2006

In case of updates, the chapters concerned will be replaced.

Refer to the table below to verify that the Technical Manual is up-to-date.

Chapter	Current version
1	6/03.07
2	6/03.07
3	6/03.07
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5	6/03.07
6	6/03.07
7	6/03.07

Changes

Manual changes will be released as new editions and supplements. In general - subject to change without notice.

1.2 How to Use the Technical Manual

Purpose

This Technical Manual is intended for service technicians and is to be used for first studies (to acquire a basic knowledge) and for reference purposes (for TSC, maintenance and repair). The Technical Manual, however, does not replace the training courses offered by the manufacturer.

Requirements

Knowledge of the current Operating Instructions for the respective system.
Background experience in mechanics, electrical and medical engineering.

Specifications

For the specifications of the respective system, refer to the current Operating Instructions.

Circuit diagrams and component layouts

The identification on the PCB permits the operator/technician to verify if the circuit diagram/component layout matches the PCB actually installed in the system.

Explanation of the Note and Caution symbols used

Note

Informs the operator that in case of a failure to follow the steps as described, a specific function will be executed incorrectly or will not be executed at all, or will not produce the desired effect.

Caution

Advises the operator against certain procedures or actions that could cause damage to the equipment or may have adverse effects on operators and patients.

1.3 Precautions for Working on the System

Authorized persons

Assembly, extensions, adjustments, modifications or repairs may only be carried out by the manufacturer or persons authorized by him.

Test equipment and accessories

The activities described in the Technical Manual require the availability of the necessary technical test equipment and accessories.

Precautions

When working on the open system, the following precautions must be respected:

– Protect the components against ingress of fluids.
– Do not touch live parts.
– All plugs, connections and components may only be disconnected or connected if de-energized.

ESD precautions

When repairing and when replacing spare parts, observe the applicable ESD precautions (e.g. EN 100 015-1).

1.4 Addresses

Please address any inquiries to:

Manufacturer

Fresenius Medical Care AG & Co. KGaA
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Local service

2 Functional Description

2.1 Extracorporeal Circuit

The elements for maintaining and monitoring the extracorporeal circuit of the multiFiltrate are as follows:

– Pumps
– Heaters
– Pressure transducer
– Air detector
– Venous clamp
– Non-opaque/opaque fluid detector
– Blood leak detector
– Heparin pump

2.1.1 Pumps

Altogether, the multiFiltrate is provided with four pumps:

Pump	Delivery rate
Blood pump	10 – 500 ml/min
Filtrate pump	10 – 180 ml/min
Substituate pump	10 – 170 ml/min
Dialysate pump	10 – 170 ml/min

The pumps are driven by direct-current geared motors. To control the speed, these motors are each provided with a clock pulse generator, which is directly connected to the motor shaft. The pump processors for controlling the individual pumps (P.C.B. LP 123) are fitted on the motor housing.

All pumps are supplied with 24 V. The nominal voltage of the blood pump motor is 20 V. The nominal voltage of the other pumps, however, is 24 V.

A Hall sensor in the pump housing and a permanent magnet in each pump door monitor the state of the pump door.

The line inserting position of the pump rotors for inserting and removing the pump segments is detected by a combination of a reed switch (in the pump housing) and a permanent magnet (in the rotor).

The functional test covers a check of all pumps.

2.1.2 Heaters

To allow heating of replacement fluids, two heaters, which are activated and monitored independently of each other, are installed in the multiFiltrate.

The heater foil is applied to the outside of the heater rod and supplied with approx. 28 V. The temperatures are controlled and monitored by altogether four NTC sensors (two for the operating processor and two for the safety processor). This is implemented on P.C.B. LP 122.

Both heaters are tested during the functional test.

2.1.3 Pressure Transducer

Four pressures are measured at the multiFiltrate:

– Arterial pressure,
  Measuring transducer (P.C.B. LP 343-1) between the patient's arterial access and the blood pump
  Measuring range: –280 – 300 mmHg

– Pre-hemofilter pressure
  Measuring transducer (P.C.B. LP 343-1) between the blood pump and the filter inlet
  Measuring range: 0 – 750 mmHg

– Venous pressure,
  Measuring transducer (P.C.B. LP 450-3) between the filter outlet and the patient's venous access,
  Measuring range: –80 – 500 mmHg.

– Filtrate pressure or dialysate pressure
  Measuring transducer (P.C.B. LP 343-1) between the filter connector and the filtrate pump
  Measuring range: –300 – 300mmHg.

All pressure transducers are subjected to the functional tests.

2.1.4 Air Detector and Venous Clamp

The air detector (P.C.B. LP 450-3) serves for the detection of air in the extracorporeal blood circuit and operates on the ultrasound principle . Both the transmitter and the receiver are integrated in the drip chamber holder. Once the level in the venous drip chamber has fallen below a certain threshold, the venous clamp is closed. This function is executed independently of the operating or safety processor. The additional board AD 28 increases the transmitter voltage during Preparation to ensure that the level of saline solution is reliably detected.

The air detector is subjected to the functional test.

2.1.5 Optical Detector (Non-Opaque/Opaque Fluid Detector)

The optical detector (P.C.B. LP 450-3) detects, according to the infrared principle, whether saline solution or blood is present in the tubing system.

The optical detector is subjected to the functional test.

2.1.6 Blood Leak Detector

The blood leak detector (P.C.B. LP 125) is provided for the detection of a potential blood loss through the membrane. It is operated applying a two-color measuring section. In the course of this, red and green light is alternately transmitted to a reference receiver or, through the filtrate line, to a measuring receiver.

Both the transmitter and the receiver are integrated in the line holder.

The blood leak detector is subjected to the functional test.

2.1.7 Heparin Pump

The heparin pump is used for continuous heparinization of the blood.

A syringe plunger is moved by means of a carriage bar. The carriage bar is connected to a threaded spindle via a slide. A microprocessor-controlled stepper motor causes the spindle to rotate. Depending on the activation, the piston will move up or down.

One Hall sensor each signals when the piston has reached its upper and lower end of travel. The safety system of the pump comprises a speed monitoring device (slotted disc with optical sensor) and a motor current monitoring function. The syringe types are set via a coding switch (HEX switch).

2.2 Weighing Units

The weighing units are used for managing the fluid balance during treatment.

The weighing cells are operated according to the strain gauge principle. Signal conditioning, including analog-to-digital conversion, is achieved per weighing cell on the P.C.B. LP 127. The actual weights are produced by the operating processor.

Scale 1 and scale 2 each have a useful load of approx. 12 kg.

The scales are subjected to the functional test. To test the scales, a test weight (ball) of defined value must be taken off each scale. Proper functioning of the scales can be concluded from the correct difference between the weights before and after lifting.

2.3 Ci-Ca Module (Option)

The Ci-Ca module is intended for regional citrate anticoagulation in the CVVHD treatment therapy.

Turning power on

The Ci-Ca module requires a supply voltage of 24VDC. This voltage is provided by the multiFiltrate system's power supply unit via the connector in the lower IV pole support of the IV pole located on the right of the system.
After the multiFiltrate system was turned on by pressing the power switch on its rear, the supply voltage of the module is connected. The operating processor of the Ci-Ca module switches into the standby mode.
If the multiFiltrate systems is then turned on via the I/O key on the front of the system, the operating processor of the Ci-Ca module will perform an internal processor test. This test is performed simultaneously to the processor test of the multiFiltrate system.

The Ci-Ca module communicates with the multiFiltrate basic system via a serial interface.

Processor test

If a test is not passed successfully, the module will not establish communications with the multiFiltrate system. It is not possible to perform a treatment with citrate anticoagulation. The multiFiltrate system recognizes this problem and displays a message which proposes to use an alternative anticoagulation equipment (e.g. heparin pump) and which has to be confirmed by the operator.

T1 test

The Ci-Ca module performs its own T1 test, independent of the T1 test of the multiFiltrate system. This test will be started automatically and simultaneously to the multiFiltrate T1 test after the prompt whether the starting conditions are met was confirmed with [OK].

This test cannot be skipped or deselected.

System errors

If it is still possible, system errors in the Ci-Ca module are shown on the multiFiltrate display with the indication that citrate anticoagulation is not available.

2.4 Functional Test (T1 Test) and Error Messages

After it has been turned on the rear and the [I/O] key has been pressed, the system automatically starts the processor test. After completion of the processor test, the display test will be performed. In this test, the numerical characters are represented for 2 seconds in all of the three fonts used. After this test, the functional test (T1 test) is started automatically. Depending on the configuration in the SETUP (SETUP automatic), the test is running in the background or (SETUP detailed) the test steps are represented separately on the display.

2.4.1 Battery Test, Part 1

At the beginning of the T1 test, the system assumes the terminal voltage and loads the battery with a defined resistance over the entire test.

2.4.2 Scales Test

In the first step, the temperature compensation and calibration factors are tested. In the second step, the scales are tared. The linearity test follows in step three. The 4 test weights are lifted, and the weight (44.3 g) is tested for a tolerance of ±0.5 g. The offset drift is tested in step four. The test weights are lowered again; the system expects a weight of 0.0 g with a tolerance of ±0.5 g. The time out for each step (2 to 4) is 10 sec. In the event of an error, messages are emitted. Here, the error messages section only relates to scales I. The messages are identical for scales II to IV.

Error message	Causes	Action required
Scale I Cal. factor missing, error. Acknowledge with [START/RESET] key.	Lithium battery on P.C.B. LP 244-OP discharged.	Replace the battery and execute the calibration step in the Service program.
Scale I Temp. coeff. factors missing, error. Acknowledge with [START/RESET] key.	Defect of the EPROM on P.C.B. LP 127 of the scales specified.	Replace the P.C.B. and the weighing bar and execute the calibration step in the Service program.
Scale I Movement detected on Scale I. Acknowledge with [START/RESET] key.	The system is not in a stable position. The scales are subjected to a draft. Bags with tubing system are placed on the scales; this is especially applicable to filtrate scales.	Set up the system in a stable position. Remove the system from the draft, or close the window. Relieve the scales.
	The +12 V and/or –12 V voltage(s) is (are) missing.	Check the fuses on the PSU board LP 128 and replace the P.C.B. LP 128, if necessary. **Caution:** All pressures must be checked and calibrated, if necessary.
	Scales mechanics not smooth.	Check for smoothness and adjust, if necessary. Weight check in the Service program.
	Connector not fitted or defective ribbon cable.	Fit the connector to the motherboard and/or to the P.C.B. LP 127. Replace the ribbon cable.
	P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.

Error message	Causes	Action required
Scale I Test weight outside tolerance. Acknowledge with [START/RESET] key.	The system is not in a stable position. The scales are subjected to a draft. Bags with tubing system are placed on the scales; this is especially applicable to filtrate scales.	Set up the system in a stable position. Remove the system from the draft, or close the window. Relieve the scales.
	Lifting magnet for ball not connected or defective.	Fit the connector to the motherboard. If defective, the lifting magnet must be replaced.
	Ball mechanics not smooth.	Check for smoothness and adjust, if necessary. Weight check in the Service program.
Scale I Zero offset outside tolerance. Acknowledge with [START/RESET] key.	The system is not in a stable position. The scales are subjected to a draft. Bags with tubing system are placed on the scales; this is especially applicable to filtrate scales.	Set up the system in a stable position. Remove the system from the draft, or close the window. Relieve the scales.
	Scales mechanics not smooth.	Check for smoothness and adjust, if necessary. Weight check in the Service program.
	Test weight fails to drop back. Ball mechanics not smooth.	Check for smoothness and adjust, if necessary. Weight check in the Service program (ESC Service).

2.4.3 Pump Test

In the first step, the stop-by-OP function is tested, i.e. the pumps must stop running. In this step, the safety processor releases the pumps, and the operating processor does not activate the pumps. In the second step, all of the four pumps are activated with a rate of 100 ml/min. The safety processor checks whether the pumps are running at the correct rate and whether the reed contact (line inserting position) is actuated. In the third step, the operating processor activates the pumps and the safety processor disables the pump activation, i.e. the pumps may not be running. In the event of an error, messages are emitted. Here, the error messages section only relates to the blood pump. The messages are identical for the other pumps, i.e. the filtrate, substituate and dialysate pumps.

Error message	Causes	Action required
Blood pump Blood pump door open. Acknowledge with [START/RESET] key.	Blood pump door open.	Close the blood pump door.
	Magnet in blood pump door missing.	Replace the blood pump door.
	Hall sensor in pump housing not connected or defective.	Plug the connector onto the appropriate P.C.B. LP 123 or replace the pump housing.
	Control electronics (P.C.B. LP 123) of the specified pump defective.	Replace P.C.B. LP 123.
	P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Blood pump Not stopped by operating processor. Acknowledge with [START/RESET] key.	Control electronics (P.C.B. LP 123) of the specified pump defective.	Replace P.C.B. LP 123.
	P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Blood pump Wrong speed, rate. Acknowledge with [START/RESET] key.	Clock pulse generator of motor on P.C.B. LP 123 not connected.	Connect the clock pulse generator socket.
	Control electronics (P.C.B. LP 123) of the specified pump defective.	Replace P.C.B. LP 123.
	Defect of the clock pulse generator on the geared motor.	Replace the geared motor. **Caution:** Blood pump 20 V/3300 rpm; all other pumps 24 V/3300 rpm.
Blood pump Reed contact – line threading position Acknowledge with [START/RESET] key.	Magnet in rotor missing, defective.	Replace the rotor.
	Reed switch in pump housing not connected or defective.	Plug the connector onto the appropriate P.C.B. LP 123 or replace the pump housing.
	Control electronics (P.C.B. LP 123) of the specified pump defective.	Replace P.C.B. LP 123.
	P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.

Error message	Causes	Action required
Blood pump Stop. Acknowledge with [START/RESET] key.	+24-V supply voltage missing.	Check the fuse on the PSU board LP 128. If necessary, replace P.C.B. LP 128. **Caution:** All pressures must be checked and calibrated, if necessary.
	Control electronics (P.C.B. LP 123) of the specified pump defective.	Replace P.C.B. LP 123.
	P.C.B. LP 244-OP defective. (The pumps are activated serially, i.e. the operating processor is defective only if all pumps fail to be activated.)	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.
Blood pump Not stopped by safety processor. Acknowledge with [START/RESET] key.	Control electronics (P.C.B. LP 123) of the specified pump defective.	Replace P.C.B. LP 123.
	P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.

2.4.4 Pressure Transducer

In the first step, the zero point, amplification and detuning factors are tested. In the second step, the zero points of the pressure transducers are checked with a tolerance of ±20 mmHg. In the third step, Part and Pven are detuned to 300 mmHg. The values are checked with a tolerance of ±20 mmHg. In the fourth step, PPHF and PFil are detuned to 300 mmHg. The values are checked with a tolerance of ±20 mmHg. In the event of an error, messages are emitted. The following table only shows the error messages for "arterial pressure". The messages are identical for the venous, pre-hemofilter and filtrate pressures.

Error message	Causes	Action required
Arterial pressure Factors / Offset lost. Acknowledge with [START/RESET] key.	Lithium battery on P.C.B. LP 244-OP discharged.	Replace the battery and execute the calibration step in the Service program.

Error message	Causes	Action required
Arterial pressure Zero outside tolerance. Acknowledge with [START/RESET] key.	Zero point drifted off.	Check the setting and calibrate the pressure in the Service program.
	P.C.B. LP 343-1 (for venous pressure: P.C.B. LP 450-3) defective.	Replace P.C.B. LP 343-1 (LP 450-3) and calibrate the pressure in the Service program. **Caution:** When replacing the P.C.B. LP 450-3, check / adjust the air detector, optical detector and venous pressure transducer.
	P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.
Arterial pressure Detuning outside tolerance Acknowledge with [START/RESET] key.	Amplification drifted off.	Check the setting and calibrate the pressure in the Service program.
	P.C.B. LP 343-1 (for venous pressure: P.C.B. LP 450-3) defective.	Replace P.C.B. LP 343-1 (LP 450-3) and calibrate the pressure in the Service program. **Caution:** When replacing the P.C.B. LP 450-3, check / adjust the air detector, optical detector and venous pressure transducer.
	P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.

2.4.5 Optical Detector

In the first step, the non-opaque state is checked. In the second step, the optical detector is detuned and the opaque state is checked. In the event of an error, messages are emitted.

Error message	Causes	Action required
Opt. detector Senses opaque fluid. Acknowledge with [START/RESET] key.	Blood present in the system or objects inserted in the OD.	Remove the blood line or the objects from the OD.
	OD adjusted improperly.	Check the setting of the OD.
	P.C.B. LP 450-3 defective.	Replace the P.C.B. LP 450-3. **Caution:** When replacing the P.C.B. LP 450-3, check / adjust the air detector, optical detector and venous pressure transducer.
	Measuring head of OD defective.	Replace and adjust the OD measuring head.
	P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Opt. detector Fails to sense opaque fluid after attenuation. Acknowledge with [START/RESET] key.	OD adjusted improperly.	Check the setting of the OD.
	P.C.B. LP 450-3 defective.	Replace the P.C.B. LP 450-3. **Caution:** When replacing the P.C.B. LP 450-3, check / adjust the air detector, optical detector and venous pressure transducer.
	P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.
	AD 28 defective.	Replace AD 28-1.

2.4.6 Air Detector

In the first step, it is checked whether fluid is present in the drip chamber. if YES, the clamp is activated (opened). In the second step, the air detector is detuned and the alarm state checked. In the event of an error, messages are emitted.

Error message	Causes	Action required
Air detector LDA1 – not in alarm mode. Acknowledge with [START/RESET] key.	LD adjusted improperly.	Check the setting of the LD.
	P.C.B. LP 450-3 defective.	Replace the P.C.B. LP 450-3. **Caution:** When replacing the P.C.B. LP 450-3, check / adjust the air detector, optical detector and venous pressure transducer.
	Ultrasonic detector defective.	Replace and adjust the ultrasonic detector.
	P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Air detector Clamp does not close. Acknowledge with [START/RESET] key.	LD adjusted improperly (LDA2).	Check the setting of the LD.
	P.C.B. LP 450-3 defective.	Replace the P.C.B. LP 450-3. **Caution:** When replacing the P.C.B. LP 450-3, check / adjust the air detector, optical detector and venous pressure transducer.
	P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.

2.4.7 Blood Leak Detector

In the first step, the blood leak detector is checked for being in an acceptable state. In the second step, the blood leak detector is detuned and the alarm state checked. In the event of an error, messages are emitted.

Error message	Causes	Action required
Blood leak detector Calibration values incorrect or missing. Acknowledge with [START/RESET] key.	Lithium battery on P.C.B. LP 244-SP discharged.	Replace the battery and execute the calibration step in the Service program.

Error message	Causes	Action required
Blood leak detector Outside acceptable range. Remove filtrate line. Acknowledge with [START/RESET] key.	Empty filtrate line or objects inserted in the BLD sensor head.	Remove the filtrate line or the objects.
	P.C.B. LP 125 and/or BLD sensor head defective.	Replace P.C.B. LP 125 and the BLD sensor head, and calibrate the BLD.
	P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Blood leak detector Alarm-free after signal attenuation. Acknowledge with [START/RESET] key.	P.C.B. LP 125 and/or BLD sensor head defective.	Replace P.C.B. LP 125 and the BLD sensor head, and calibrate the BLD.
	P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.

2.4.8 Heater

In the first step, the safety relay is checked for being in the open state. In addition, the sensors are checked for interruption and short-circuit. In the second step, the safety relay is activated and checked for being in the closed state. In the third step, the bag and foil sensors of OP and SP are checked for being synchronized. Tolerances are ±1 °C. In the fourth step, the foil sensor is detuned to >120 °C and, thus, the safety shutoff mechanism (fire protection) is checked. In the fifth step, the bag and foil sensors are detuned to >41 °C to check whether the heater is switched off in case of an overtemperature of the solutions. In the sixth step, it is checked whether the heater can be activated. In the event of an error, messages are emitted. Here, the error messages section only relates to the lower heater. The messages are identical for the upper heater.

Error message	Causes	Action required
Lower heater Switch-off path SP defective (Sub. relay not open) Voltage missing. Fuse defective. Acknowledge with [START/RESET] key.	Safety relay on P.C.B. LP 122 defective.	Replace P.C.B. LP 122.
	Activation on P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
	Supply voltage for heater not connected.	Fit the socket on P.C.B. LP 122.
	Fuse on P.C.B. LP 122 defective.	Replace the fuse.

Error message	Causes	Action required
Lower heater Control FET short-circuit Acknowledge with [START/RESET] key.	Control FET defective.	Replace P.C.B. LP 122.
	Activation on P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.
Lower heater Bag sensor broken. Acknowledge with [START/RESET] key.	Socket of sensors not fitted.	Fit the socket on P.C.B. LP 122.
	Sensor interrupted.	Replace the heater.
	P.C.B. LP 122 defective	Replace P.C.B. LP 122.
	Converter on P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Lower heater Foil sensor broken. Acknowledge with [START/RESET] key.	Socket of sensors not fitted.	Fit the socket on P.C.B. LP 122.
	Sensor interrupted.	Replace the heater.
	P.C.B. LP 122 defective	Replace P.C.B. LP 122.
	Converter on P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Lower heater Bag sensor short-circuit. Acknowledge with [START/RESET] key.	Bag sensor short-circuit.	Replace the heater.
	P.C.B. LP 122 defective	Replace P.C.B. LP 122.
	Converter on P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Lower heater Foil sensor short-circuit. Acknowledge with [START/RESET] key.	Bag sensor short-circuit.	Replace the heater.
	P.C.B. LP 122 defective	Replace P.C.B. LP 122.
	Converter on P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
Lower heater Sub. relay not closed, foil defective. Acknowledge with [START/RESET] key.	Supply voltage for heater not connected.	Fit the socket on P.C.B. LP 122.
	Fuse on P.C.B. LP 122 defective.	Replace the fuse.
	Heater foil not connected.	Connect the heater foil to P.C.B. LP 122.
	Heater foil interrupted.	Replace the heater.
	Safety relay defective.	Replace P.C.B. LP 122.
	Activation on P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.

Error message	Causes	Action required
Lower heater Bag sensors, OP-SP not synchronous Acknowledge with [START/RESET] key.	Heater still warm after last treatment or Service program.	Allow the heater to cool down.
	Sensor board (P.C.B. LP 1220) defective.	Replace the heater.
	P.C.B. LP 122 defective	Replace P.C.B. LP 122.
	Converter on P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
	Converter on P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.
Lower heater Foil sensors, OP-SP not synchronous Acknowledge with [START/RESET] key.	Heater still warm after last treatment or Service program.	Allow the heater to cool down.
	Sensor board (P.C.B. LP 1220) defective.	Replace the heater.
	P.C.B. LP 122 defective	Replace P.C.B. LP 122.
	Converter on P.C.B. LP 244-SR defective.	Replace P.C.B. LP 244-SR. **Caution:** The BLD must be calibrated.
	Converter on P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.
Lower heater Foil sensor detuning, no overtemperature cutoff. Acknowledge with [START/RESET] key.	DIL relay on P.C.B. LP 122 defective.	Replace P.C.B. LP 122.
Lower heater Bag sensor detuning, no overtemperature. Acknowledge with [START/RESET] key.	DIL relay on P.C.B. LP 122 defective.	Replace P.C.B. LP 122.
	Activation on P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.

Error message	Causes	Action required
Lower heater Foil sensor detuning, no overtemperature. Acknowledge with [START/RESET] key.	DIL relay on P.C.B. LP 122 defective.	Replace P.C.B. LP 122.
	Activation on P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.
Lower heater FET control defective Acknowledge with [START/RESET] key.	FET on P.C.B. LP 122 defective.	Replace P.C.B. LP 122.
	Activation on P.C.B. LP 44-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.

2.4.9 Battery Test, Part 2

The first step was carried out at the beginning of the functional test, with acceptance of the starting value and loading of the battery. In the second step, the voltage is checked after loading and is compared with the starting value. In the event of an error, messages are emitted.

Error message	Causes	Action required
Battery test Battery not connected, defective. Acknowledge with [START/RESET] key.	Battery not connected.	Connect the rechargeable battery.
	Battery terminal voltage without load <<18 V.	Replace the battery.
	Converter on P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.
Battery test Load test failed. Acknowledge with [START/RESET] key.	Resistor or load relay on the PSU, P.C.B. LP 128, defective.	Replace P.C.B. LP 128. **Caution:** All pressures must be checked and calibrated, if necessary.
	Converter or activation on P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.

Error message	Causes	Action required
Battery test Insufficient capacity. Acknowledge with [START/RESET] key.	System not used for a prolonged period or frequent power failure (preparation). Battery defective.	Load the battery from the mains for a minimum of 10 hours. Replace the battery.
	Charging circuit on the PSU board, P.C.B. LP 128, defective.	Replace P.C.B. LP 128. **Caution:** All pressures must be checked and calibrated, if necessary.
	Converter on P.C.B. LP 244-OP defective.	Replace P.C.B. LP 244-OP. **Caution:** All scales and pressures must be calibrated.

2.4.10 Audible Alarm

In the first step, it is checked whether the audible alarm is silenced. In the second step, the audible alarm is generated and checked for proper functioning by means of a microphone. In the event of an error, messages are emitted.

Error message	Causes	Action required
Audible alarm Not silenced. Acknowledge with [START/RESET] key.	Constant ambient noise.	Repeat the test after the noise has stopped.
	Loud humming noise on the loudspeaker.	Check the route of the loudspeaker cable. Replace the loudspeaker-microphone unit or the motherboard P.C.B. LP 124.
	The microphone line is disturbed.	Check the route of the microphone cable.
	Microphone or amplifier defective.	Replace the loudspeaker-microphone unit or the motherboard P.C.B. LP 124.
Audible alarm Not active. Acknowledge with [START/RESET] key.	Alarm tone not audible.	Loudspeaker cable connected to P.C.B. LP 124? Replace the loudspeaker-microphone unit or the motherboard P.C.B. LP 124.
	Error message despite audible alarm.	Microphone cable connected to P.C.B. LP 124? Replace the loudspeaker-microphone unit or the motherboard P.C.B. LP 124.

2.4.11 Heparin Pump

After turning power on to the multiFiltrate, a self-test of the heparin pump will be performed. Immediately before the multiFiltrate self-test, the operating processor will query the heparin pump status. In the event of an error, messages are emitted. If the heparin pump is not installed, not connected to the power supply or deactivated via Service option, no error message will be displayed.

Error message	Causes	Action required
Heparin pump Heparin pump not ready. No communication.	Heparin pump does not respond.	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump Heparin pump optionally deactivated in Service mode	Heparin pump manually deactivated in the Service mode	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump Heparin pump detects internal error	Internal heparin pump error without definite cause.	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump Wrong / unauthorized syringe type detected	Wrong syringe type set.	Acknowledge with [START/RESET] key. Heparin pump deactivated. Select a valid syringe type. 0 = 50 ml P syringe 1 = 30 ml heparin syringe 2 = 50 ml Injectomat syringe
Heparin pump Unknown hardware error	Heparin pump detects an unknown hardware error.	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump Heparin pump hardware error Gate array error	Heparin pump detects an error in the gate array.	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump Spike on reset line	A reset occurred during operation.	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump Wrong HEX switch position	Wrong HEX switch position set.	Acknowledge with [START/RESET] key. Heparin pump deactivated. Set a valid HEX switch position.
Heparin pump Powerdown	Powerdown without 24 V-cutoff.	Acknowledge with [START/RESET] key. Heparin pump deactivated.

Error message	Causes	Action required
Heparin pump Operating processor internal communication error with heparin pump	Erroneous data transmission. Wrong or missing characters. Check sum error.	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump Watchdog error	The watchdog is not able to interrupt the 24 V control voltage for the stepper motor.	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump NOVRAM error	The CRC protection of the data saved in the E^2PROM is not correct.	Acknowledge with [START/RESET] key. Heparin pump deactivated.
Heparin pump CAMUS transmission error	Not used in the multiFiltrate.	Not used in the multiFiltrate.

2.4.12 multiDataLink

Immediately before the multiFiltrate self-test, the operating processor will query the multiDataLink version identifications. A response given by the mDL is an indicator for its operability. In the event of an error, messages are emitted. If the multiDataLink is not installed, not connected to the power supply or deactivated via Service option, no error message will be displayed.

Error message	Causes	Action required
multiDataLink multiDataLink not standby No communication	multiDataLink does not respond.	Acknowledge with [START/RESET] key. multiDataLink deactivated.
multiDataLink multiDataLink optionally deactivated in Service mode	multiDataLink manually deactivated in the Service program.	Acknowledge with [START/RESET] key. multiDataLink deactivated. Activate multiDataLink in the Service program.

2.4.13 Ci-Ca Module (Option)

The test for the Ci-Ca module can not be enabled if the processor test of the module and the multiFiltrate was not passed successfully. If these processor tests are performed successfully, the T1 test will be started automatically as soon as the operator has confirmed that the starting conditions are met.

The following functions of the Ci-Ca module are tested:

– Stop of the citrate and the calcium pump by the module's operating processor
– Stop of the citrate and the calcium pump by the system's watchdog.
– Function of the citrate pump and the insertion switch
– Function of the calcium pump and the insertion switch

If a test could not be passed successfully, a warning indicating an error number appears on the multiFiltrate display. The test can be repeated any number of times, however, it cannot be skipped.

The T1 test of the multiFiltrate system is performed simultaneously to the T1 test of the Ci-Ca module.

Error number	Description	Possible cause
281	Lacking Ci Hall impulse after test was started (>5 s).	The rotor of the citrate pump is loose, jammed or blocked.
282	Ci Hall impulse too early during pump stop test (<7 s).	Insertion switch pressed --> citrate line already inserted.
283	Ci Hall impulse too late during pump stop test (>9 s).	The rotor of the citrate pump is loose, jammed or blocked.
285	Ci Hall impulse too early during pump stop test (<7 s).	Insertion switch pressed --> citrate line already inserted during the test.
286	Ci Hall impulse too late during pump stop test (>9 s).	The rotor of the citrate pump is loose, jammed or blocked.
288	Ci Hall impulse too early during insertion switch test (<7 s).	Insertion switch pressed --> citrate line already inserted during the test.
289	Ci Hall impulse too late during insertion switch test (>9 s).	The rotor of the citrate pump is loose, jammed or blocked.
291	Lacking Ca Hall impulse after test was started (>5 s).	The rotor of the Ca pump is loose, jammed or blocked.
292	Ca Hall impulse too early during pump stop test (<7 s).	Insertion switch pressed --> calcium line already inserted.
293	Ca Hall impulse too late during pump stop test (>9 s).	The rotor of the Ca pump is loose, jammed or blocked.
295	Ca Hall impulse too early during pump stop test (<7 s).	Insertion switch pressed --> calcium line already inserted during the test.
296	Ca Hall impulse too late during pump stop test (>9 s).	The rotor of the Ca pump is loose, jammed or blocked.
298	Ca Hall impulse too early during insertion switch test (<7 s).	Insertion switch pressed --> calcium line already inserted during the test.
299	Ca Hall impulse too late during insertion switch test (>9 s).	The rotor of the Ca pump is loose, jammed or blocked.

2.5 Error Messages

2.5.1 Alarm Messages

These messages cause all pumps to stop

Code	Description
E10	Blood pump: Blood pump door open
E11	Blood pump: Stop
E12	Blood pump: Wrong speed, rate
E13	Arterial pressure, arterial pressure too low
E14	Arterial pressure, arterial pressure too high
E15	Venous pressure, venous pressure too low
E16	Venous pressure, venous pressure too high
E17	TMP, TMP too low
E18	TMP, TMP too high
E19	System stopped, Stop key has been pressed
E20	Pre-filter pressure/ Pre-filter pressure too low (for hemoperfusion)
E21	Pre-filter pressure, pre-filter pressure too low
E22	Pre-filter pressure, pre-filter pressure too high
E23	Non-opaque/opaque fluid detector, venous detector senses non-opaque or opaque fluid
E24	Air detector, air and/or microbubbles
E25	Blood leak detector, blood leak, hemolysis, membrane rupture
E26	Blood leak detector, 2 min override active
E27	Power failure, emergency operation available for max. 15 min. Converted by OP from SP code 130.
E28	End of emergency operation, the unit will turn itself off automatically after 5 minutes. Converted by OP from SP code 189.
E29	Pre-filter pressure/ Pre-filter pressure too high (for hemoperfusion)
E30	Blood lines: Blood line jammed / Hydrophobic filter P_pHF wet
E31	Blood lines: Rotor broken

Code	Description
E32	Blood lines: Hydrophobic filter P_{art} wet
E33	Blood lines: Hydrophobic filter P_{ven} wet
E34	Air detector: Transmitting voltage on the air detector too high
E35	Ci-Ca module: Citrate pump turning too slowly (volume monitoring)
E36	Ci-Ca module: Citrate pump turning too fast (volume monitoring)
E37	Ci-Ca module: Calcium pump turning too slowly (volume monitoring)
E38	Ci-Ca module: Calcium pump turning too fast (volume monitoring)
E39	Ci-Ca module: Dialysis is started although the primed Ci/Ca lines are not free from air
E40	Ci-Ca module: Drop counter citrate – insufficient number of drops; check citrate bag, drip chamber and tubing system!
E41	Ci-Ca module: Number of drops counted by citrate drop counter too high; check citrate drip chamber and tubing system!
E42	Ci-Ca module: Drop counter calcium – insufficient number of drops; check calcium bag, drip chamber and tubing system!
E43	Ci-Ca module: Number of drops counted by calcium drop counter too high; check calcium drip chamber and tubing system!
E44	Ci-Ca module: Citrate pump turning too slowly; (motor steps)
E45	Ci-Ca module: Citrate pump turning too fast; (motor steps)
E46	Ci-Ca module: Calcium pump turning too slowly (motor steps)
E47	Ci-Ca module: Calcium pump turning too fast (motor steps)
E48	Ci-Ca module: Citrate insertion switch without contact,Ci pump segment inserted properly?
E49	Ci-Ca module: Calcium insertion switch without contact,Ca pump segment inserted properly?
E50	Ci-Ca module: The citrate bag change takes more than 2 min; finish bag change!

Code	Description
E51	Ci-Ca module: The Ca bag change takes more than 2 min; finish bag change!
E52-54	Not used
E55	Ci-Ca module: MPS treatment is permitted for a maximum of 4 hours!; initiate reinfusion!
E56	Ci-Ca module: HP treatment is permitted for a maximum of 4 hours!; initiate reinfusion!
E57	Ci-Ca module: Balance switched off; Ca supply interrupted!
E58	Ci-Ca module: System error of Ci-Ca module: Anitcoagulation with citrate completed!
E59	Ci-Ca module: Drop counter citrate – insufficient number of drops; Ci bag change required?
E60	Ci-Ca module: Drop counter calcium – insufficient number of drops; Ca bag change required?

2.5.2 Warning Messages

These messages cause the balancing to stop. The blood circuit will be maintained.

For error messages no. 132 through 144 the scales must be recalibrated.

Code	Description
W62	Blood pump: Blood pump door open
W63	Filtrate pump: Cover open
W64	Sub pump: Cover open
W65	Dialysate pump: Cover open
W66	Prime mode: No weight loss on sub-scale-post (HVCVVH)
W67	Prime mode: No weight loss on sub-scale-pre (HVCVVH)
W68	Bag change: Overload on sub-scale-post (HVCVVH)
W69	Bag change: Sub-scale post underload (HVCVVH)
W70	Opt. detector: is opaque
W71	Opt. detector: Fails to sense opaque fluid after attenuation
W72	Scale 1: Temp. coeff. factors missing, incorrect

Code	Description
W73	Scale 2: Temp. coeff. factors missing, incorrect
W74	Scale 3: Temp. coeff. factors missing, incorrect
W75	Scale 4: Temp. coeff. factors missing, incorrect
W76	Scale 1: Calibration factor missing, incorrect
W77	Scale 2: Calibration factor missing, incorrect
W78	Scale 3: Calibration factor missing, incorrect
W79	Scale 4: Calibration factor missing, incorrect
W80	Scale 1: Movement detected on Scale 1
W81	Scale 2: Movement detected on Scale 2
W82	Scale 3: Movement detected on Scale 3
W83	Scale 4: Movement detected on Scale 4
W84	Scale 1: Test weight outside tolerance
W85	Scale 2: Test weight outside tolerance
W86	Scale 3: Test weight outside tolerance
W87	Scale 4: Test weight outside tolerance
W88	Scale 1: Test weight fails to drop back
W89	Scale 2: Test weight fails to drop back
W90	Scale 3: Test weight fails to drop back
W91	Scale 4: Test weight fails to drop back
W92	Air detector: LDA1 – not in alarm mode
W93	Air detector: Clamp fails to close
W94	Lower heater: Switch-off path SP defective (Sub-relay not open)
W95	Upper heater: Switch-off path SP defective (dial. relay not open)
W96	Lower heater: Control FET short-circuit
W97	Upper heater: Control FET short-circuit
W98	Lower heater: Bag sensor broken
W99	Lower heater: Foil sensor broken
W100	Upper heater: Bag sensor broken
W101	Upper heater: Foil sensor broken
W102	Lower heater: Bag sensor short-circuit
W103	Lower heater: Foil sensor short-circuit

Code	Description
W104	Upper heater: Bag sensor short-circuit
W105	Upper heater: Foil sensor short-circuit
W106	Lower heater: Sub. relay not closed, foil defective
W107	Upper heater: Dial. relay not closed, foil defective
W108	Lower heater: Foil sensor detuning, no over-temperature cutoff
W109	Upper heater: Foil sensor detuning, no over-temperature cutoff
W110	Lower heater: Bag sensors, OP-SP not synchronous
W111	Upper heater: Bag sensors, OP-SP not synchronous
W112	Lower heater: Bag sensor detuning, no overtemperature
W113	Lower heater: Foil sensor detuning, no overtemperature
W114	Upper heater: Bag sensor detuning, no overtemperature
W115	Upper heater: Foil sensor detuning, no overtemperature
W116	Lower heater: FET control defective
W117	Upper heater: FET control defective
W118	Battery test: Battery not connected, defective
W119	Battery test: Load test failed
W120	Battery test: Insufficient capacity
W121	Blood leak detector: Outside acceptable range, remove filtrate line
W122	Blood leak detector: Alarm-free after attenuation
W123	Prime mode: No weight loss on SUB scale
W124	Prime mode: No weight loss on DIA scale
W125	Prime mode: No weight loss on SUB scale (CVVHDF)
W126	Prime mode: No weight loss on DIA scale (CVVHDF)
W127	Blood leak detector: Calibration values missing, incorrect
W128	Audible alarm: Not silenced
W129	Audible alarm: not active
W130	Power failure: Emergency operation available for max. 15 minutes (OP generates code 27)

Code	Description
W131	Incorrect allocation of scales, repeat Preparation (very unusual)
W132	Load on scale, incorrect load on scale I (initial weight)
W133	Load on scale, incorrect load on scale II (initial weight)
W134	Load on scale, incorrect load on scale III (initial weight)
W135	Load on scale, incorrect load on scale IV (initial weight)
W136	Balancing, Scale I, leakage from tubing system, objects
W137	Balancing, Scale II, leakage from tubing system, objects
W138	Balancing, upper scales, leakage from tubing system, objects
W139	Balancing, filtrate bag full, replace or empty filtrate bag
W140	Balancing, filtrate scales moved, leakage from tubing system
W141	Scale 1, overload or underload, check load, scale jammed?
W142	Scale 2, overload or underload, check load, scale jammed?
W143	Scale 3, overload or underload, check load, scale jammed?
W144	Scale 4, overload or underload, check load, scale jammed?
W145	Bag change: Overload on SUB scale (CVVHDF)
W146	Bag change: Overload on SUB scale 1 (CVVH, HF)
W147	Bag change: Overload on SUB scale 2 (CVVH, HF)
W148	Bag change: SUB on wrong scale (CVVHDF)
W149	Bag change: Insufficient substituate (CVVH, HF)
W150	Bag change: Insufficient substituate (CVVHDF)
W151	Bag change: Insufficient saline solution on scale 1 (MPS)
W152	Bag change: Overload on plasma scale 1 (MPS)
W153	Bag change: Overload on plasma scale 2 (MPS)
W154	Bag change: Overload on dialysate scale (CVVHDF)
W155	Bag change: Overload on dialysate scale 1 (CVVHD)
W156	Bag change: Overload on dialysate scale 2 (CVVHD)
W157	Dialysate on wrong scale (tubing arrangement test after bag change HDF)

Code	Description
W158	Bag change: Insufficient dialysate (CVVHD)
W159	Bag change: Insufficient dialysate (CVVHDF)
W160	Bag change: Overload on filtrate scale
W161	TMP/MPS TMP >100mmHg
W162	Lower heater: MPS temperature > 37°C
W163	Upper heater: MPS temperature > 37°C
W164	Lower heater: Temperature too high
W165	Upper heater: Temperature too high
W166	Bag change: Overload SUB pre (HVCVVH)
W167	Bag change: Insufficient SUB pre (HVCVVH)
W168	Balancing: Ultrafiltration or substitution rate too high
W169	Lower heater: Foil sensors, OP-SP not synchronous
W170	Upper heater: Foil sensors, OP-SP not synchronous
W171	Balancing: Aborted because maximum allowable deviation of ±500g was exceeded
W172	Lower heater: MPS foil temperature too high, risk of hemolysis
W173	Upper heater: MPS foil temperature too high, risk of hemolysis
W174	Balancing: Balancing stopped, balancing was switched off
W175	Battery capacity: Charging voltage too high, battery deactivated, no power failure
W176	Filtrate scale: Test weight outside tolerance (T0 test)
W177	Filtrate scale: Test weight fails to drop back (T0 test)
W178	Balancing: UF goal reached, ultrafiltration was set to 0
W179	Balancing: Substituate bag empty, replace substituate bag
W180	Balancing: Dialysate bag empty, replace dialysate bag
W181	Balancing: Movement detected on filtrate scales, leakage from tubing system
W182	Filtrate scale: Overload or underload, check load, scale jammed?
W183	Balancing: Plasma bag empty, open outlet line(s) on plasma bags
W184	Balancing: Plasma pump delivers from wrong scale (I)

Code	Description
W185	Balancing: Plasma pump delivers from wrong scale (II)
W186	Balancing: Sub-postdilution bag empty, replace substituate bag
W187	Balancing: Sub-predilution bag empty, replace substituate bag
W188	End of treatment: Plasma infused (MPS only)
W189	End of emergency operation: The unit will turn itself off automatically after 5 minutes
W190	Power failure end
W191	Bag change: Insufficient plasma on scale 2
W192	Prime mode: Overload on dialysate scale (CVVHDF)
W193	Prime mode: Overload on SUB scale (CVVHDF)
W194	Prime mode: Insufficient substituate (CVVHDF)
W195	Prime mode: Insufficient dialysate (CVVHDF)
W196	Prime mode: Overload on sub-scale-pre (HVCVVH)
W197	Prime mode: Overload on sub-scale-post (HVCVVH)
W198	Prime mode: Insufficient SUB pre (HVCVVH)
W199	Prime mode: Insufficient SUB post (HVCVVH)
W200	Blood pump: Not stopped by operating processor
W201	Filtrate pump: Not stopped by operating processor
W202	Sub pump: Not stopped by operating processor
W203	Dialysate pump: Not stopped by operating processor
W204	Blood pump: Wrong speed, rate
W205	Filtrate pump: Wrong speed, rate
W206	Sub pump: Wrong speed, rate
W207	Dialysate pump: Wrong speed, rate
W208	Blood pump: Reed contact – line threading position
W209	Filtrate pump: Reed contact – line threading position
W210	Sub pump: Reed contact – line threading position
W211	Dialysate pump: Reed contact – line threading position
W212	Blood pump: Stop
W213	Filtrate pump: Stop
W214	Sub pump: Stop

Code	Description
W215	Dialysate pump: Stop
W216	Blood pump: Not stopped by safety processor
W217	Filtrate pump: Not stopped by safety processor
W218	Sub pump: Not stopped by safety processor
W219	Dialysate pump: Not stopped by safety processor
W220	Arterial pressure: Factors / offset missing, incorrect
W221	Venous pressure: Factors / offset missing, incorrect
W222	PHF pressure: Factors / offset missing, incorrect
W223	Filtrate pressure: Factors / offset missing, incorrect
W224	Arterial pressure: Zero outside tolerance
W225	Venous pressure: Zero outside tolerance
W226	PHF pressure: Zero outside tolerance
W227	Filtrate pressure: Zero outside tolerance
W228	Arterial pressure: Detuning outside tolerance
W229	Venous pressure: Detuning outside tolerance
W230	PHF pressure: Detuning outside tolerance
W231	Filtrate pressure: Detuning outside tolerance
W232	Heparin pump: does not respond
W233	Heparin pump: manually deactivated in Service program
W234	Heparin pump: detects an internal problem
W235	Heparin pump: Wrong/invalid syringe type
W236	Heparin pump: No anticoagulation
W237	Heparin pump: Anticoagulation stopped
W238	Heparin pump: Anticoagulant Used Up
W239	Heparin pump: Syringe not changed
W240	Heparin pump: Non-registered error code
W241	Heparin pump: Gate-array error
W242	Heparin pump: Restart after spike reset
W243	Heparin pump: Hex switch position error
W244	Heparin pump: Powerdown without 24V cutoff
W245	Heparin pump: Slotted disc error

Code	Description
W246	Heparin pump: Slotted disc not found
W247	Heparin pump: Communication sumcheck error
W248	Heparin pump: No heparin pump STOP
W249	Heparin pump: Communication error with OP
W250	Heparin pump: Watchdog error
W251	Heparin pump: NOVRAM error
W252	CAMUS transmission error
W253	Not used
W254	Not used
W255	mDL not ready/no communication
W256	mDL deactivated via Service option
W257	The BP rate is < 30 ml/min; no rotor breakage monitoring; closure of pressure transducer is not detected.
W259	Lower heater: Switch-off path SP defective (Sub-relay not open), voltage not present, SI defective (for P.C.B. LP122-B)
W260	Upper heater: Switch-off path SP defective (dial. relay not open), voltage not present, SI defective (for P.C.B. LP122-B)
W261	Lower heater: Control FET short circuit (for P.C.B. LP122-B)
W262	Upper heater: Control FET short circuit (for P.C.B. LP122-B)
W263	Air detector: Transmitting voltage for air detector not present / nonconforming (for AD28)
W264	Ci-Ca module: Ci-Ca module does not respond, select alternate anticoagulation if necessary!
W265	Ci-Ca module: Switch-off path "sleep" does not react, select alternate anticoagulation if necessary!
W266	Balancing: HF bag change aborted
W281	Ci-Ca module: Citrate pump - test F1, Rotor slack or stuck?
W282	Ci-Ca module: Citrate pump - OP test F2, rotor slack?
W283	Ci-Ca module: Citrate pump - OP test F3, rotor slack or stuck?
W285	Ci-Ca module: Citrate pump - WD test F5, rotor slack?

Code	Description
W286	Ci-Ca module: Citrate pump - WD test F6, rotor slack or stuck?
W288	Ci-Ca module: Citrate pump - insertion switch test F8, line pump segment inserted too early or rotor slack?
W289	Ci-Ca module: Citrate pump - insertion switch test F9, rotor slack or stuck?
W291	Ci-Ca module: Calcium pump test F11, rotor slack or stuck?
W292	Ci-Ca module: Calcium pump - OP test F12, rotor slack?
W293	Ci-Ca module: Calcium pump - OP test F13, rotor slack or stuck?
W295	Ci-Ca module: Calcium pump - WD test F15, rotor slack?
W296	Ci-Ca module: Calcium pump - WD test F16, rotor slack or stuck?
W298	Ci-Ca module: Calcium pump - insertion switch test F18, line pump segment inserted too early or rotor slack?
W299	Ci-Ca module: Calcium pump - insertion switch test F19, rotor slack or stuck?
W330	Ci-Ca module: Balance switched off!, Ca supply interrupted!
W331	Ci-Ca module: Filtrate rate too low for set Ca dose!, Increase dialysate or substituate or Ca dose if necessary!
W332	Ci-Ca module: Filtrate rate too high for set Ca dose!, Reduce dialysate or substituate or Ca dose if necessary!
W333	Ci-Ca module: Blood flow too low for set citrate dose!, Increase blood flow or citrate dose if necessary!
W334	Ci-Ca module: Blood flow too high for set citrate dose!, Reduce blood flow or citrate dose if necessary!

2.5.3 Fatal Errors

These messages cause the treatment to stop.

Code	Description
E500	Scale 1: (factors missing during treatment)
E501	Scale 2: (factors missing during treatment)
E502	Scale 3: (factors missing during treatment)
E503	Scale 4: (factors missing during treatment)
E504	Memory error: (double values incorrect)
E505	Blood pump: (does not respond)
E506	Substituate pump: (does not respond)
E507	Dialysate pump: (does not respond)
E508	Filtrate pump: (does not respond)
E509	Overvoltage +5V
E510	Overvoltage +12V
E511	Processor test OP: CPU defective,
E512	Processor test OP: Incorrect CRC interrupt vectors
E513	Processor test OP: CRC CRC area defective
E514	Processor test OP: CRC Code area defective
E515	Processor test OP: RAM, bank B defective
E516	Processor test OP: RAM, bank 8 defective
E517	State transition
E518	Program sequence
E519	Self-Test
E520	Balancing
E521	SP does not respond
E522	DP does not respond
E523	Program flow OP: Watchdog
E524	Processor test OP: Watchdog does not respond
E525	Processor test SP: CPU
E526	Processor test SP: Program memory – vectors
E527	Processor test SP: Program memory - CRC area
E528	Processor test SP: Program memory - code area
E529	Processor test SP: RAM - bank B
E530	Processor test SP: RAM - bank B
E531	Processor test SP: Watchdog does not respond

Code	Description
E532	Invalid software combination: OP, DP, SP
E533	Ci-Ca module: Logoff of the option by the MFT
E534	Ci-Ca module: Alarm of the option not followed by MFT alarm
E535	Ci-Ca module: Timeout of the status message of the MFT (>2.5 s)
E536	Ci-Ca module: Too many status messages of the MFT (2x<0.5 s)
E537	Ci-Ca module: Receipt of message not confirmed
E538	Ci-Ca module: unknown identifier
E539	Ci-Ca module: Write buffer full
E540	Ci-Ca module: Read buffer full
E541	Ci-Ca module: Unable to write on TXe
E542	Ci-Ca module: Missing setup values from the MFT (at end of line installation)
E550	Ci-Ca module: Too many extra Hall pulses from the Ca pump
E551	Ci-Ca module: Ca pump could not be stopped
E560	Ci-Ca module: Too many extra Hall pulses from the citrate pump
E561	Ci-Ca module: Citrate pump could not be stopped
E570	Ci-Ca module: Error on checking variable replication (Int)
E571	Ci-Ca module: Error on checking variable replication (Float)
E572	Ci-Ca module: Error on checking variable replication (Long)
E573	Ci-Ca module: Error on checking software diversity

2.5.4 Error Codes of “Scales” Lo-Level Routines

- **Scale no. 1**

Code	Description
E30001	Standstill not possible (timeout after 10 sec)
E30002	Weight value out of range (overload or underload)
E30003	Incorrect calibration weight value
E30004	Negative initial weight
E30005	Wrong initial weight
E30006	ACT_WGT 65535
E30007	Alarm limits permanently violated
E30008	INF_WGT invalid
E30050	Calibration factor missing or incorrect
E30051	Temp. coeff. factors missing or incorrect
E30052	Double fuse defective (zero value)
E30053	Temperature sensor missing / defective

- **Scale no. 2**

Code	Description
E30101	Standstill not possible (timeout after 10 sec)
E30102	Weight value out of range (overload or underload)
E30103	Incorrect calibration weight value
E30104	Negative initial weight
E30105	Wrong initial weight
E30106	ACT_WGT 65535
E30107	Alarm limits permanently violated
E30108	INF_WGT invalid
E30150	Calibration factor missing or incorrect
E30151	Temp. coeff. factors missing or incorrect
E30152	Double fuse defective (zero value)
E30153	Temperature sensor missing / defective

- **Scale no. 3**

Code	Description
E30201	Standstill not possible (timeout after 10 sec)
E30202	Weight value out of range (overload or underload)
E30203	Incorrect calibration weight value
E30204	Negative initial weight
E30205	Wrong initial weight
E30206	ACT_WGT 65535
E30207	Alarm limits permanently violated
E30208	INF_WGT invalid
E30250	Calibration factor missing or incorrect
E30251	Temp. coeff. factors missing or incorrect
E30252	Double fuse defective (zero value)
E30253	Temperature sensor missing / defective

- **Scale no. 4**

Code	Description
E30301	Standstill not possible (timeout after 10 sec)
E30302	Weight value out of range (overload or underload)
E30303	Incorrect calibration weight value
E30304	Negative initial weight
E30305	Wrong initial weight
E30306	ACT_WGT 65535
E30307	Alarm limits permanently violated
E30308	INF_WGT invalid
E30350	Calibration factor missing or incorrect
E30351	Temp. coeff. factors missing or incorrect
E30352	Double fuse defective (zero value)
E30353	Temperature sensor missing / defective

- **Scales nos. 3 and 4 (both)**

Code	Description
E30401	Standstill not possible (timeout after 10 sec)
E30402	Weight value out of range (overload or underload)
E30403	Incorrect calibration weight value
E30404	Negative initial weight
E30405	Wrong initial weight
E30406	ACT_WGT 65535
E30407	Alarm limits permanently violated
E30408	INF_WGT invalid
E30450	Calibration factor missing or incorrect
E30451	Temp. coeff. factors missing or incorrect
E30452	Double fuse defective (zero value)
E30453	Temperature sensor missing / defective

2.5.5 Error Codes of “Pressures” Lo-Level Routines

- **PART**

Code	Description
E30551	Calibration factor missing, incorrect
E30552	Offset factor missing, incorrect
E30553	Offset > measurement value
E30557	DAC setting missing, incorrect

- **PPHF**

Code	Description
E30651	Calibration factor missing, incorrect
E30652	Offset factor missing, incorrect
E30653	Offset > measurement value
E30657	DAC setting missing, incorrect

- **PVEN**

Code	Description
E30751	Calibration factor missing, incorrect
E30752	Offset factor missing, incorrect
E30753	Offset > measurement value
E30757	DAC setting missing, incorrect

- **PFIL**

Code	Description
E30851	Calibration factor missing, incorrect
E30852	Offset factor missing, incorrect
E30853	Offset > measurement value
E30857	DAC setting missing, incorrect

2.5.6 Error Codes of “Heparin Pump” Lo-Level Routines

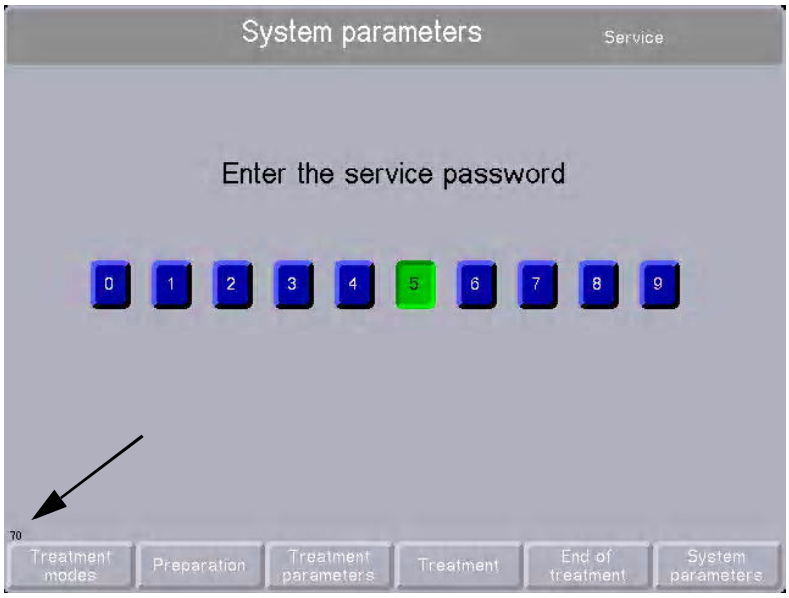
Code	Description
E31000	BCC error
E31001	Handshake error to HP
E31002	Overflow sensitivity: buffer
E31003	Invalid control character
E31004	No end character received
E31005	HP string 3 answered with NAK
E31006	Wrong unknown command from HP
E31008	HP not ready
E31009	HP by option deactivated in Service mode
E31010	HP detects internal error
E31011	Wrong / unauthorized syringe type detected
E31012	HP failed to stop
E31013	Syringe empty
E31014	HP hardware error #1, GA error

Code	Description
E31015	ditto #4, spike on reset line
E31016	ditto #5, wrong HEX switch position
E31017	ditto #8, power down
E31018	ditto #11, slotted disk error
E31019	ditto #55, slotted disk not found
E31020	Unknown hardware error
E31021	Internal HP communication error (group error)

2.5.7 Error Codes of “Pumps” Lo-Level Routines

Code	Hex	Description
E64256	0xFB00	Invalid tubing type
E64767	0xFCFF	No response from blood pump
E65023	0xFDFF	ditto Filtrate pump
E65279	0xFEFF	ditto Substituate pump
E65535	0xFFFF	ditto Dialysate pump

2.6 Overview of Display Identification Numbers



A number is displayed in the lower left corner of the screen. This number is the identification number. When an error occurs, this numbers permits to identify the machine status.

No.	Description
M1	Start-up screen
M2	Self-test window with fonts used
M3	Treatment modes, Selection: Previous/New treatment
M4	Treatment modes, Selection: Delete/Retain balance data
M5	Treatment modes, Selection of treatment modes
M6	Tubing arrangement (self-test already complete)
M7	Tubing arrangement (self-test not yet complete)
M8	Empty self-test window
M9	Preparation for self-test, with confirmation button "All conditions fulfilled? "OK" to confirm!"
M10	Preparation, Rinse, with confirmation button "Enter treatment parameters? "OK" to confirm!"
M11	Preparation, Prime/Rinse tubing system, with confirmation button "Start priming? "OK" to confirm!"
M12	Preparation, Prime tubing system
M13	Preparation, Treatment parameters menu, depending on the type of therapy, the DP enters the allowed parameter fields. With confirmation button ‘All treatment parameters entered? "OK" to confirm!"
M14	Preparation, Waiting for Patient
M15	Preparation, UF volume, with confirmation button ‘Start UF rinse? "OK" to confirm!"
M16	Preparation, with count-down UF volume display
M17	Preparation, ‘Waiting for patient’, with confirmation button ‘Start connection? "OK" to confirm!"
M18	Preparation, "Connect patient"
M19	Preparation, Connect patient, with confirmation button "Start treatment? "OK" to confirm!"
M20	Treatment, Home page, depending on the type of therapy, the DP enters the allowed parameter fields.
M21	Treatment, Treatment data menu, depending on the type of therapy, the DP enters the allowed parameter fields.

No.	Description
M22	Treatment, Treatment menu, depending on the type of therapy, the DP enters the allowed parameter fields. All treatments, except for HP, are identical.
M23	Treatment, Balance data, depending on the type of therapy, the DP enters the allowed balance fields.
M24	Treatment, Alarm limits menu Identical for all treatment modes, for HP, the TMP is renamed into pre-filter pressure (pF)
M25	Heparin pump syringe change
M26-M28	not used
M29	Bag change
M30-M33	not used
M34	Preparation, Prime sub-pre-tubing system (HV-CVVH)
M35	Treatment, Balance data, Confirmation for ‘Delete balance data (Yes/No)’, rest like M23
M36-M39	not used
M40	End of treatment, Reinfusion volume, with confirmation button "Start disconnection? "OK" to confirm!"
M41	End of treatment, Reinfusion volume, with confirmation button "View treatment parameters? "OK" to confirm!". The reinfusion volume counts down to "Zero"
M42	End of treatment, with 2 confirmation buttons "Continue reinfusion / Terminate reinfusion"
M43	End of treatment, Removing tubing system, with confirmation button "View treatment parameters? "OK" to confirm!"
M44	End of treatment, View previous treatment parameters => Final screen.
M45	End of treatment, view previous treatment parameters with confirmation button "Previous screen? "OK" to confirm!"
M46	End of treatment, Reinfusion volume and remaining time
M47	End of treatment (MPS, plasma return not completed)
M48	End of treatment, confirmation for 'Disconnect without blood return'
M49	not used
M50	Preparation, Fill plasma

No.	Description
M51	Preparation, Connect patient, with confirmation button "Start connection? "OK" to confirm!"
M52-M59	not used
M60	System parameters, System parameters menu
M61	System parameters, Default treatment settings, with confirmation button "All parameters entered? "OK" to confirm!"
M62	System parameters, Program treatment modes, with confirmation button "Desired treatment mode selected? "OK" to confirm!"
M63	System parameters, Software versions, with confirmation button "Terminate? "OK" to confirm!"
M64	System parameters, Ci-Ca settings, with confirmation button "All parameters entered? "OK" to confirm!"
M65-M69	not used
M70	Service, Password entry
M71	Service, Calibration main menu
M72	Service, Calibrate/Tare scales
M73	Service, Select pressure
M74	Service, with confirmation button "Pressure sensor open? "OK" to confirm!"
M75	Service, with pressure value and confirmation button "Entered? "OK" to confirm!"
M76	Service, with confirmation button "Tubing inserted? "OK" to confirm!"
M77	System parameters, Event memory, with confirmation button "Terminate? "OK" to confirm!"
M78	Help menu for M72
M79	Service, Pressure, Weights, Temperatures, Voltages
M80	Service, language selection
M81	mDL parameter assignment
M82-M87	not used
M88	Preparation, Starting conditions Ci-Ca with confirmation button "Return to treatment selection" and "Conditions fulfilled"
M89	End of treatment, remove Ci-Ca lines with confirmation button "Patient disconnected? Start removal of Ci/Ca lines"

No.	Description
M90	Preparation, Ci-Ca anticoagulation with confirmation button "On" and "Off"
M91	Preparation, with prompt "Please wait for completion of functional test", after prompt was displayed confirmation button "All conditions fulfilled? "OK" to confirm!"
M92	Preparation, with note H108. After Z3 protocol the confirmation button "Ci-Ca clamps opened? Ci-Ca drip chambers filled? "OK" to confirm!"
M93	Preparation, with note H109. After Z3 protocol confirmation buttons "Refill citrate", "Refill calcium" and "Ci-Ca lines primed and free from air? "OK" to confirm!"
M95	Preparation, Deselect Ci-Ca anticoagulation with confirmation button "No" and "Yes"
M96	Preparation, Deselection Ci-Ca, with note H105 with confirmation button "All conditions fulfilled? "OK" to confirm!"
M97	Treatment, Ci-Ca bag change menu, concentrations and bag volumes displayed, after Z3 protocol 5 confirmation buttons for the Ci-Ca bag exchange appear.
M98	Preparation, Deselection Ci-Ca, with note H107 with confirmation button "All conditions fulfilled? "OK" to confirm!"

3 Installation

3.1 Preface

Instructions for all technicians who are authorized to commission our systems.

We, as manufacturers, permanently aim at delivering systems of highest quality.
To reach this aim, we need your support.
Please commission our systems uniformly using the enclosed "initial start-up report" and enter the values determined in the columns provided.

The following is applicable:
Corrections are necessary only if the measured values are outside of the specified tolerances!

We will then evaluate the initial start-up reports, which will enable us to monitor the quality of our systems on their delivery.
After initial start-up, please asap send – by mail or by fax – the completed form (Initial Start-Up Report) back to the following address:
Thank you very much for your help!

Service Central Europe

Fresenius Medical Care
Deutschland GmbH
Geschäftsbereich Zentraleuropa
Kundendienst / Servicecenter
Steinmühlstraße 24
61352 Bad Homburg
Germany
Phone: +49 6172 609-7100
Fax: +49 6172 609-7102
E-mail: ServicecenterD@fmc-ag.com

International service

Responsible Regional Organization
(Technical Service)

3.2 Important Information on Initial Start-Up

For initial start-up only

This technical document is intended for initial start-up only. It is not intended for restarting systems that have been shut down or have been put out of service temporarily.

Tester's qualification

The initial start-up must be performed by the Technical Service of Fresenius Medical Care or a person authorized by them.

The initial start-up procedure may only be performed by persons who are qualified to properly perform the specified checks owing to their educational background and training, their knowledge and experience gained in practice. Furthermore, the persons performing the tests must not be bound by any directives when performing this activity.

Test equipment and accessories

The activities described in this technical document require the availability of the necessary technical test equipment and accessories.

Any information on the specifications must be observed.

Environmental conditions

Variations in temperature during transport may lead to condensation water developing on live parts. In the event of major variations in temperature, allow sufficient time for the system to adjust to the ambient temperature before start-up.

TSC/TMC/MA intervals

The TSC/TMC/MA procedures for this system are to be performed after 12 months.

3.3 Initial Start-Up Report multiFiltrate

Technician's name:	System type including option(s) / software version:	
Customer/customer no.:	System no.:	Inventory no.:
Service report number:	Operating hours:	Equipment code:

No.	Description	Meas. value	✓
1	**Unpacking**		
1.1	Unpack the system.		❑
1.2	Check that all parts of the system have been accounted for.		❑
1.3	System without visible shipping damage.		❑
2	**Preparing for operation**		
2.1	Place the scales trays on the scales plates.		❑
2.2	Install the IV pole.		❑
2.3	Connect the power cable and secure it to prevent improper replacement.		❑
3	**Visual inspections**		
3.1	Fuses accessible from the outside comply with the indicated values.		❑
3.2	Labels and labeling are present and legible.		❑
3.3	The mechanical condition permits further safe use.		❑
3.4	There are no signs of damage or dirt.		❑
3.5	The power cable shows no signs of damage.		❑
4	**Functional check**		
4.1	Pump checked for stopping with open door.		
	Blood pump		❑
	Filtrate pump		❑
	Substituate pump		❑
	Dialysate pump		❑
4.2	The venous occlusion clamp closes after an air detector alarm.		❑

No.	Description	Meas. value	✓
4.3	The pressure of 2 bar applied in the venous bubble catcher may not drop by more than 0.1 bar within 3 minutes.		❑
4.4	Air detector operation/calibration checked.		
	Jumper J1-P.C.B. LP 450 set to the operation position. Place the checking block into the air detector. LEDs DI 5 and DI 10 are light. Jumper J1-P.C.B. LP 450 set to the operation position. Place the adjusting block into the air detector. LEDs DI 5 and DI 10 are dark.		❑ ❑
4.5	Pressure transducers: Zero and gain checked		
	Arterial pressure (red) Zero point: Display within the range of ± 5mmHg Amplification: 300Apply 300 mmHg, tolerance ±5 mmHg	_____ _____	❑
	Venous pressure (blue) Zero point: Display within the range of ± 5mmHg Amplification: 300Apply 300 mmHg, tolerance ±5 mmHg	_____ _____	❑
	PHF pressure (white) Zero point: Display within the range of ± 5mmHg Amplification: 300Apply 300 mmHg, tolerance ±5 mmHg	_____ _____	❑
	Filtrate pressure (yellow) Zero point: Display within the range of ± 5mmHg Amplification: 300Apply 300 mmHg, tolerance ±5 mmHg	_____ _____	❑
4.6	Scales: calibration with 5000 g test weight		
	Scale I Calibration: Test load on scales: display 5000 g ±1 g	_____g	❑
	Scales II Calibration: Test load on scales: display 5000 g ±1 g	_____g	❑
	Scales III Calibration: Test load on scales: display 5000 g ±1 g	_____g	❑
	Scales IV Calibration: Test load on scales: display 5000 g ±1 g	_____g	❑

No.	Description	Meas. value	✓
5	**Ci-Ca module option: visual inspections**		
5.1	Colored markings of drop counters must be present.		❑
5.2	Adhesive labels of citrate and calcium pumps are present and legible.		❑
5.3	The mechanical condition permits further safe use.		❑
5.4	There are no signs of damage or dirt.		❑
5.5	Line holders must be present and undamaged.		❑
6	**Ci-Ca module option: extracorporeal components**		
6.1	Citrate drop counter checked for proper function		❑
6.2	Calcium drop counter checked for proper function		❑
6.3	Line occlusion of the pumps checked.		
	Citrate pump (pressure loss max. 10 mmHg/min)	_____	❑
	Calcium pump (pressure loss max. 10 mmHg/min)	_____	❑

No.	Description	Meas. value	✓
7	**Check of the electrical safety** In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!		
7.1	Visual inspections performed as specified under 3 and 5.		❑
7.2	Protective earth resistance max. 0.3 Ω (with power cable)	_____ Ω	❑
7.3	Leakage current measurement (device leakage current) ❑ Differential current measurement according to figure C.6 ***or*** ❑ Direct measurement according to figure C.5		❑
	Nominal voltage of power supply: _____ V		
	Device leakage current mains polarity 1: _____ µA		
	With line voltage: _____ V		
	Scaled to nominal voltage (maximum 500 µA, see Additional conditions)	_____ µA	
	Device leakage current mains polarity 2: _____ µA		
	With line voltage: _____ V		
	Scaled to nominal voltage (maximum 500 µA, see Additional conditions)	_____ µA	
7.4	Patient leakage current measurement		
7.4.1	For degree of protection type "BF" according to fig. C.8		❑
	Nominal voltage of power supply: _____ V		
	Patient leakage current _____ µA		
	for line voltage _____ V		
	scaled to nominal voltage (maximum 480 µA, see Additional conditions):	_____ µA	
7.4.2	For degree of protection type "CF" according to fig. C.8		❑
	Nominal voltage of power supply: _____ V		
	Patient leakage current _____ µA		
	for line voltage _____ V		
	scaled to nominal voltage (maximum 34 µA, see Additional conditions):	_____ µA	

No.	Description	Meas. value	✓
8	**Functional test**		
8.1	Functional test (T1 test) checked for proper performance.		❑
8.2	Ci-Ca option: After successful completion of the test, screen M86 'Starting conditions' is displayed.		❑
8.3	Power failure alarm executed.		❑
9	**Final check**		
9.1	Entries made in the Medical Device Register.		❑
9.2	Operating Instructions and accessories package complete and match the system.		❑

Test equipment used:

Temperature, pressure
(type, serial number):

_____

Protective earth resistance, leakage current
(type, serial number):

_____

Comments:

Date:	**Signature:**	**Stamp:**

The system has been released for its intended use. **(Attach inspection sticker.)**	❑ Yes ❑ No
Next inspection date:	
Comments:	

Date:	**Signature:**	**Stamp:**

3.4 Explanations on the Initial Start-Up Report

- **Identification**

  Technician's name:
  Technician's first name and surname.

  Customer/customer no.:
  Number of the final customer.

  Service report number:
  Number of the service call.

  System type including option(s):
  System name with possible options and extras.

  System no.:
  Serial number indicated on the type label.

  Inventory no.:
  Inventory number assigned to the system.

  Operating hours:
  Operating hours, if a time meter is installed.

  Equipment code:
  Equipment code indicated on the system.
  (e.g. EC xxx, E-code xxx)

- **Re: 1.1**

  Remove the system from its transport packaging and save the packaging for possible future return shipments.

- **Re: 1.2**

  Check that all parts of the system have been accounted for. Inform your contact at Fresenius immediately of any missing parts.

- **Re: 4 - Functional check**

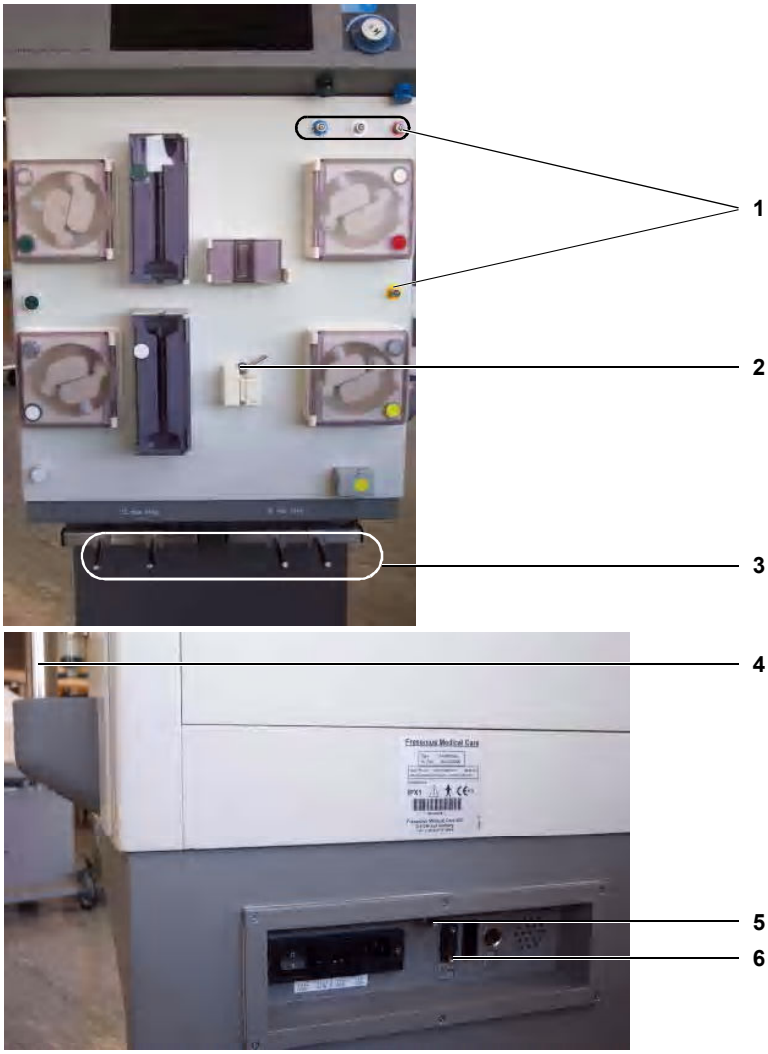
  For detailed information refer to chapter 5 "Adjustment Instructions and Tests"

- **Re: 5 - Check of the electrical safety**

  In Germany according to DIN VDE 0751-1, edition 10/2001.
  In other countries, observe the local regulations!

  (Use DIN VDE 0751-1, edition 10/2001, for medical products. Use DIN VDE 0701-1 for electrical production equipment.)

● **Re: 5.2 Protective earth resistance measurement points**



Legend

1 Luer locks
2 Venous clamp
3 Filtrate bag hook
4 IV pole and second IV pole (Ci-Ca module option)
5 Potential equalization
6 RS232 screwed connection

● **Re: 5.3 Leakage current measurement (device leakage current)**

Fig.: Differential current measurement according to fig. C.6

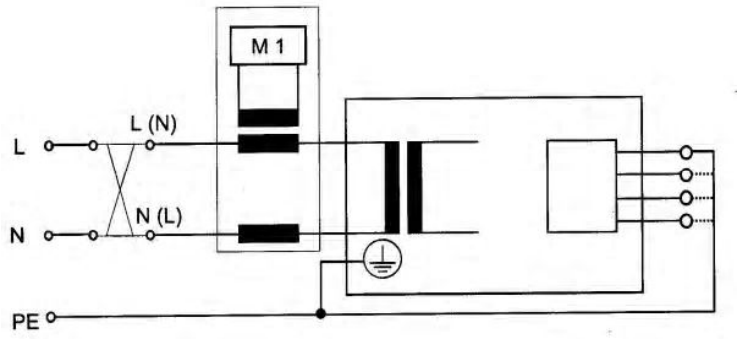
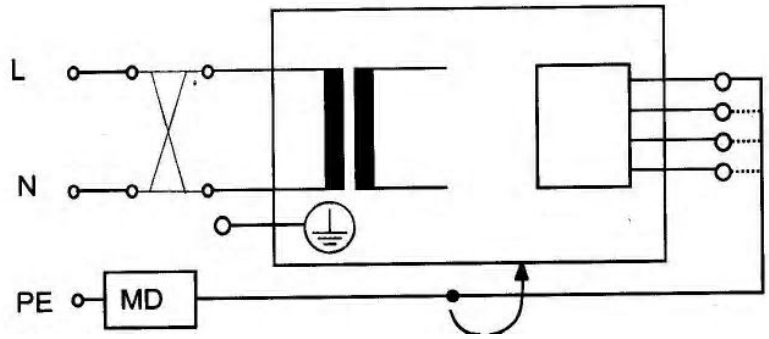


Fig.: Direct measurement according to fig. C.5



Basic requirements:

– Measurement of the protective earth resistance performed.
– The system is in standby operating mode (system connected to the mains).
– The same measurement kit (M28 060 1) as for the patient leakage current measurement is used for the measurement. Place the measuring plates on both bag trays and insert the heater bags filled with NaCl. Measurement setup, see appendix.
– When performing a direct measurement, the following precautions also must be observed:
  The system must be insulated when installed. All external connections and the potential equalization must have been removed from the system.

Documentation covers the nominal voltage during the measurement and the device leakage current at line voltage, scaled to the nominal line voltage.

Example:
Line voltage during measurement: 225 V
Device leakage current
for mains polarity 1: 38 µA
for mains polarity 2: 57 µA
Maximum value of both mains polarities: 57 µA
Nominal voltage of the power supply: 230 V
Scaled to nominal voltage: 58 µA
(58 µA: 225 V • 230 V = 58 µA)
Device leakage current < 500 µA: OK

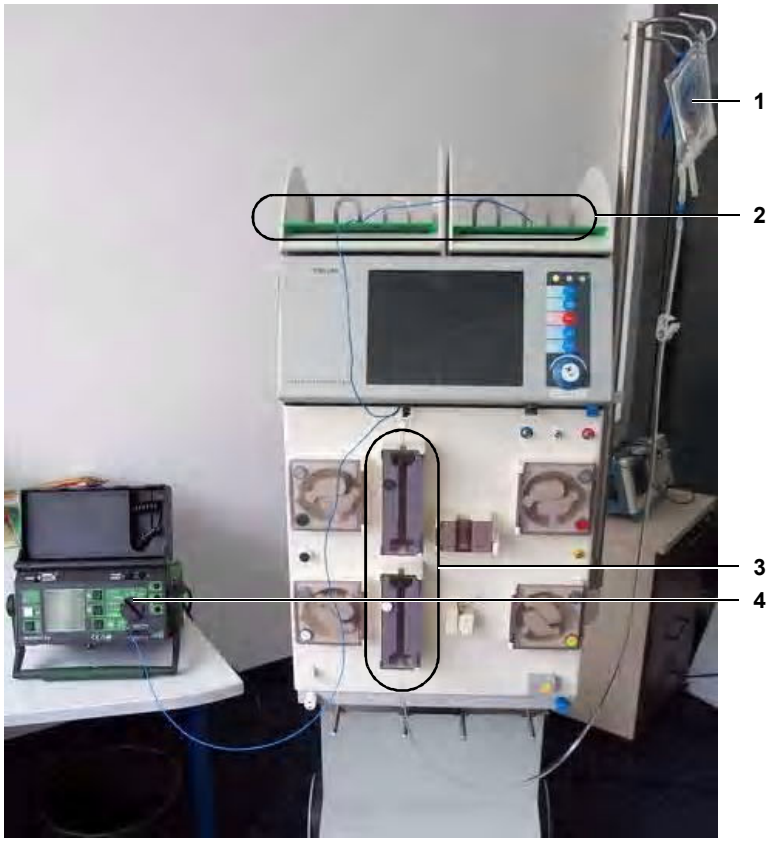
Additional conditions:
If the device leakage current is higher than 90 % of the admissible alarm limit (450 µA), the last measured value or the first measured value must additionally be considered for the rating.
If the device leakage current considerably increased since the last measurement or continuously increased since the first measurement (creeping deterioration of the insulation), or if the sum composed of the current value plus the difference since the last measurement is > 500 µA, the measurement has not been passed.

Example 1:
Leakage current: 470 µA
Last measured value: 450 A
470 + (470 – 450) = 470 + 20 = 490
OK

Example 2:
Leakage current: 470 µA
Last measured value: 390 µA
470 + (470 – 390) = 470 + 80 = 550
Not passed

- **Re: 5.3 and 5.4 Patient and device leakage current measurement**

Fig.: Setup of the measurement kit for measuring the patient leakage current and the device leakage current



Legend

1 Saline bag with 0.9 % NaCl solution for heater

2 Measuring plates for bag trays, left and right

3 Heater bag with measuring probe

4 Patient leakage current measurement: "AWT A" connector
Device leakage current measurement: Protective earth terminal
Symbol: ⏚

Note on item 3 concerning device leakage measurement

The upper heater bag must be completely filled with NaCl solution so that the electrode of the measuring probe is situated inside the solution.

Note on item 4 concerning device leakage measurement

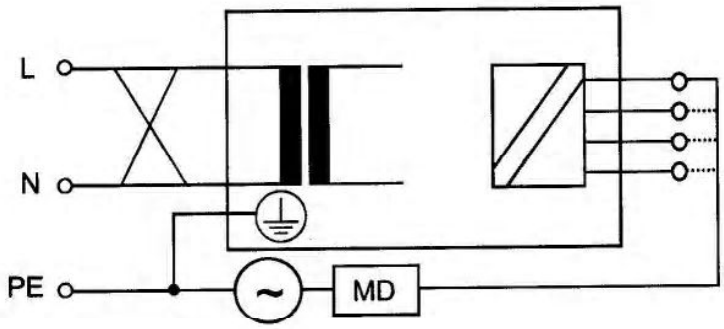
The connection line to the measurement kit must be inserted in the protective earth socket of the SECUTEST unit. If the measuring instrument fails to provide this arrangement, the connection line must be connected to a part of the multiFiltrate that is connected to the protective earth, e.g. the venous clamp.

If the steps are not followed as described, a specific function will be executed incorrectly or will not be executed at all, or will not produce the desired effect.

- **Re: 5.4.1 Patient leakage current measurement for degree of protection (BF)**

Degree of protection type BF is applying to systems with ceramic heater, operated at a line voltage of 220 V to 240 V and at a line frequency of 60 Hz.

Fig.: Patient leakage current measurement according to figure C.8



Basic requirements:
- Measurement of the protective earth resistance performed.
- The system is in standby operating mode (system connected to the mains).
- Neither the system nor the test equipment must be touched during the measurement nor must a cable be connected to the serial interface.
- The patient leakage current measurement kit (M28 060 1) is used for the measurement. Place the measuring plates on both bag trays and insert the heater bags filled with NaCl. Measurement setup, see appendix.

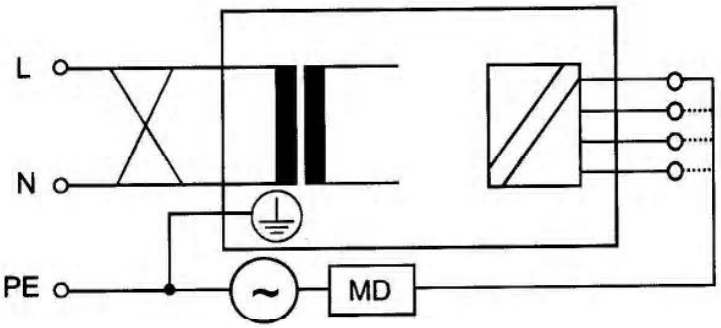
Documentation covers the nominal voltage during the measurement and the patient leakage current at line voltage, scaled to the nominal line voltage.

Example:
Measurement value: 48 µA, measured at 225 V
Nominal voltage: 230 V
Scaled to nominal voltage: 49 µA
(48 µA: 225 V x 230 V = 49 µA)

- **Re: 5.4.2 Patient leakage current measurement for degree of protection (CF)**

Degree of protection type CF is applying to systems with ceramic heater, operated at a line voltage of 100 V to 240 V and at a line frequency of 50 Hz or at a line voltage of 100 V to 127 V and at a line frequency of 60 Hz.

Fig.: Patient leakage current measurement according to figure C.8



Basic requirements:
- Measurement of the protective earth resistance performed.
- The system is in standby operating mode (system connected to the mains).
- Neither the system nor the test equipment must be touched during the measurement nor must a cable be connected to the serial interface.
- The patient leakage current measurement kit (M28 060 1) is used for the measurement. Place the measuring plates on both bag trays and insert the heater bags filled with NaCl. Measurement setup, see appendix.

Documentation covers the nominal voltage during the measurement and the patient leakage current at line voltage, scaled to the nominal line voltage.

Example:
Measurement value: 28 µA, measured at 244 V
Nominal voltage: 230 V
Scaled to nominal voltage: 26 µA
(28 µA: 244 V x 230 V = 26 µA)

- **Confirming the test**

Test equipment used:
Type and serial number of the test equipment used.

Comments:
Irregularities encountered during the test will be recorded in this section.

Date, signature, stamp
Performance of the test has to be confirmed by indicating date, tester's signature and stamp.

- **Assessing the test**

The system has been released for its intended use.
(Attach inspection sticker.)

During the intended use of the system it must be ensured that the system does not present a hazard to patients, employees or other third parties.

Within the scope of the overall assessment, the tester must make a definite decision whether the system may be used or not. The responsible organization must immediately be informed of any defects detected.

Next inspection date:
The next inspection date has to be entered in the report.
The intervals specified by the manufacturer have to be respected!

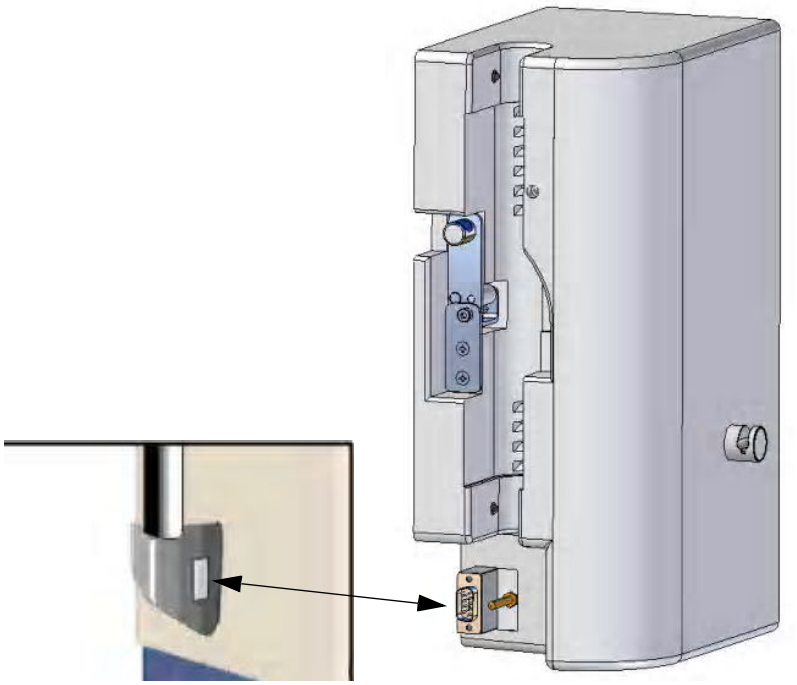
Comments:
Irregularities encountered during the assessment will be recorded in this section.

Date, signature, stamp:
Assessment of the initial start-up has to be confirmed by indicating date, tester's signature and stamp.

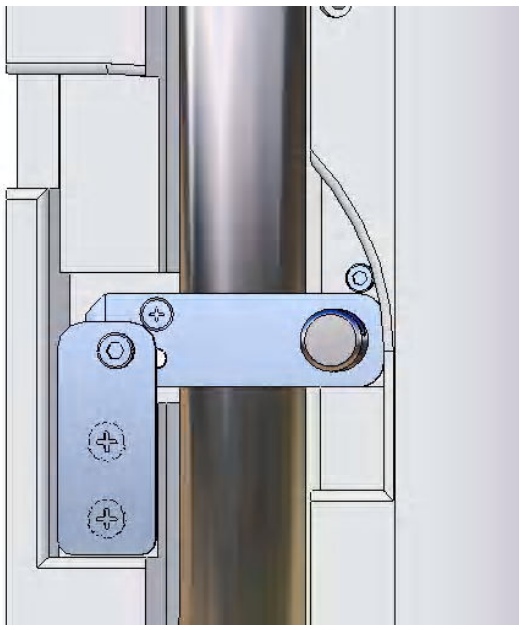
3.5 Installing the Ci-Ca Module (Option)

Caution

Before the Ci-Ca module is installed, the power plug of the system must be disconnected.



The Ci-Ca module is provided with spring pressure pieces, which make the module click into place at the IV pole on the left side of the multiFiltrate system. If the securing lever on the rear of the module has not been unlocked yet, it has to be done before installing the module by removing the locking screw. The securing lever has to point up when the module is connected. Place the module onto the lower IV pole bearing and slide it along the multiFiltrate housing panel, over the action point of the pressure pieces and onto the IV pole, until the pressure pieces click into place. Make sure that the electrical connectors easily slide into each other.



When the module is locked in place at the IV pole, the securing lever with pressure roll has to be thrown and then secured with the locking screw so that it cannot be opened. In this case, another action point must be overcome.

4 TSC / TMC / Maintenance

4.1 Important Information Regarding the Procedure

Tester's qualification

The initial start-up must be performed by the Technical Service of Fresenius Medical Care or a person authorized by them!

The tests may only be performed by persons who are qualified to properly perform the specified checks owing to their educational background and training, their knowledge and experience gained in practice. Furthermore, the persons performing the tests must not be bound by any directives when performing this activity.

Test equipment and accessories

The activities described in this technical document require the availability of the necessary technical test equipment and accessories.

Any information on the specifications must be observed.

TSC/TMC/MA intervals

The TSC/TMC/MA procedures for this system are to be performed after 12 months.

4.2 TSC / MA Report multiFiltrate

Technician's name:	System type including option(s) / software version:	
Customer/customer no.:	System no.:	Inventory no.:
Service report number:	Operating hours:	Equipment code:

Type	No.	Description	Meas. value	✓
	1	**Visual inspections**		
TSC	1.1	Fuses accessible from the outside comply with the indicated values.		❑
TSC	1.2	Labels and labeling are present and legible.		❑
TSC	1.3	The mechanical condition permits further safe use.		❑
TSC	1.4	There are no signs of damage or dirt.		❑
TSC	1.5	The power cable shows no signs of damage.		❑
MA	1.6	Replace the lithium battery of operating and safety processors (P.C.B. LP 244) every 4 years.	_____	
	2	**Extracorporeal components**		
TSC	2.1	Pump checked for stopping with open door.		
		Blood pump		❑
		Filtrate pump		❑
		Substituate pump		❑
		Dialysate pump		❑
TSC	2.2	Pump rotors checked for damage and rolls for smooth running.		
		Blood pump		❑
		Filtrate pump		❑
		Substituate pump		❑
		Dialysate pump		❑
TSC	2.3	The venous occlusion clamp closes after an air detector alarm.		❑
TSC	2.4	The pressure of 2 bar applied in the venous bubble catcher may not drop by more than 0.1 bar within 3 minutes.		❑

Type	No.	Description	Meas. value	✓
MA	2.5	Air detector operation/calibration checked.		
		Jumper J1-P.C.B. LP 450 set to the operation position. Place the checking block into the air detector. LEDs DI 5 and DI 10 are light.		❑
		Jumper J1-P.C.B. LP 450 set to the operation position. Place the adjusting block into the air detector. LEDs DI 5 and DI 10 are dark.		❑
MA	2.6	Pressure transducers: zero point and amplification as well as tightness checked.		
		Arterial pressure (red) Zero point: Display within the range of ± 5mmHg Amplification: 300Apply 300 mmHg, tolerance ±5 mmHg Tightness: 600 mmHg, drop max. 10 mmHg within 1 min	 _____ _____ _____	❑
		Venous pressure (blue) Zero point: Display within the range of ± 5mmHg Amplification: 300Apply 300 mmHg, tolerance ±5 mmHg Tightness: 600 mmHg, drop max. 10 mmHg within 1 min	 _____ _____ _____	❑
		PHF pressure (white) Zero point: Display within the range of ± 5mmHg Amplification: 300Apply 300 mmHg, tolerance ±5 mmHg Tightness: 600 mmHg, drop max. 10 mmHg within 1 min	 _____ _____ _____	❑
		Filtrate pressure (yellow) Zero point: Display within the range of ± 5mmHg Amplification: 300Apply 300 mmHg, tolerance ±5 mmHg Tightness: 600 mmHg, drop max. 10 mmHg within 1 min	 _____ _____ _____	❑
MA	2.7	Blood leak detector values checked for red coloration and dimness.		❑

Type	No.	Description	Meas. value	✓
	3	**Mechanical components**		
MA	3.1	Mechanical parts of scales checked for tight seat, parallelism and smoothness.		❑
		Scale I Scales II Scales III Scales IV		❑ ❑ ❑ ❑
MA	3.2	Zero load, calibration and ball weight of scales checked.		
		Scale I Zero load: display within a range from 60 g to 4500 g Calibration: Test load on scales: display 5000 g ±1 g Ball weight: display within a range from 43.8 g to 44.8 g	 _____g _____g _____g	❑
		Scales II Zero load: display within a range from 60 g to 4500 g Calibration: Test load on scales: display 5000 g ±1 g Ball weight: display within a range from 43.8 g to 44.8 g	 _____g _____g _____g	❑
		Scales III Zero load: display within a range from 60 g to 4500 g Calibration: Test load on scales: display 5000 g ±1 g Ball weight: display within a range from 43.8 g to 44.8 g	 _____g _____g _____g	❑
		Scales IV Zero load: display within a range from 60 g to 4500 g Calibration: Test load on scales: display 5000 g ±1 g Ball weight: display within a range from 43.8 g to 44.8 g	 _____g _____g _____g	❑
MA	3.3	Rotary selector checked for easy movement and tight fit		❑
MA	3.4	Brakes of wheel assy. checked		❑

Type	No.	Description	Meas. value	✓
	4	**Ci-Ca module option: visual inspections**		
TSC	4.1	Colored markings of drop counters must be present.		❑
TSC	4.2	Adhesive labels of citrate and calcium pumps are present and legible.		❑
TSC	4.3	The mechanical condition permits further safe use.		❑
TSC	4.4	There are no signs of damage or dirt.		❑
TSC	4.5	Line holders must be present and undamaged.		❑
	5	**Ci-Ca module option: extracorporeal components**		
TSC	5.1	Citrate drop counter checked for proper function		❑
TSC	5.2	Calcium drop counter checked for proper function		❑
TSC	5.3	Line occlusion of the pumps checked.		
		Citrate pump (pressure loss max. 10 mmHg/min)	_____	❑
		Calcium pump (pressure loss max. 10 mmHg/min)	_____	❑

Type	No.	Description	Meas. value	✓
	6	**Check of the electrical safety** In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!		
TSC	6.1	Visual inspections performed according to item 1.		❑
TSC	6.2	Protective earth resistance max. 0.3 Ω (with power cable)	_____ Ω	❑
TSC	6.3	Leakage current measurement (device leakage current) ❑ Differential current measurement according to figure C.6 ***or*** ❑ Direct measurement according to figure C.5		❑
		Nominal voltage of power supply: _____ V		
		Device leakage current mains polarity 1: _____ µA		
		With line voltage: _____ V		
		Scaled to nominal voltage (maximum 500 µA, see Additional conditions)	_____ µA	
		Device leakage current mains polarity 2: _____ µA		
		With line voltage: _____ V		
		Scaled to nominal voltage (maximum 500 µA, see Additional conditions)	_____ µA	
TSC	6.4	Patient leakage current measurement		
TSC	6.4.1	For degree of protection type "BF" according to fig. C.8		❑
		Nominal voltage of power supply: _____ V		
		Patient leakage current _____ µA		
		With line voltage: _____ V		
		scaled to nominal voltage (maximum 480 µA, see Additional conditions):	_____ µA	
TSC	6.4.2	For degree of protection type "CF" according to fig. C.8		❑
		Nominal voltage of power supply: _____ V		
		Patient leakage current _____ µA		
		With line voltage: _____ V		
		scaled to nominal voltage (maximum 34 µA, see Additional conditions):	_____ µA	

Type	No.	Description	Meas. value	✓
	7	**Functional test**		
TSC	7.1	Functional test (T1 test) checked for proper performance.		❑
TSC	7.2	Ci-Ca module option After successful completion of the test, screen M86 'Starting conditions' is displayed.		❑
TSC	7.3	Power failure alarm executed.		❑
	8	**Final check**		
TSC	8.1	Entries made in the Medical Device Register.		❑

Test equipment used:

Pressure
(type, serial number):

_____

Protective earth resistance, leakage current
(type, serial number):

_____

Comments:

Date:	**Signature:**	**Stamp:**

The system has been released for its intended use. **(Attach inspection sticker.)**	❑ Yes ❑ No
Next inspection date:	
Comments:	

Date:	**Signature:**	**Stamp:**

4.3 multiFiltrate TSC Report

Technician's name:	System type including option(s) / software version:	
Customer/customer no.:	System no.:	Inventory no.:
Service report number:	Operating hours:	Equipment code:

Type	No.	Description	Meas. value	✓
	1	**Visual inspections**		
TSC	1.1	Fuses accessible from the outside comply with the indicated values.		❑
TSC	1.2	Labels and labeling are present and legible.		❑
TSC	1.3	The mechanical condition permits further safe use.		❑
TSC	1.4	There are no signs of damage or dirt.		❑
TSC	1.5	The power cable shows no signs of damage.		❑
	2	**Extracorporeal components**		
TSC	2.1	Pump checked for stopping with open door.		
		Blood pump		❑
		Filtrate pump		❑
		Substituate pump		❑
		Dialysate pump		❑
TSC	2.2	Pump rotors checked for damage and rolls for smooth running.		
		Blood pump		❑
		Filtrate pump		❑
		Substituate pump		❑
		Dialysate pump		❑
TSC	2.3	The venous occlusion clamp closes after an air detector alarm.		❑
TSC	2.4	The pressure of 2 bar applied in the venous bubble catcher may not drop by more than 0.1 bar within 3 minutes.		❑

Type	No.	Description	Meas. value	✓
	3	**Ci-Ca module option: visual inspections**		
TSC	3.1	Colored markings of drop counters must be present.		❑
TSC	3.2	Adhesive labels of citrate and calcium pumps are present and legible.		❑
TSC	3.3	The mechanical condition permits further safe use.		❑
TSC	3.4	There are no signs of damage or dirt.		❑
TSC	3.5	Line holders must be present and undamaged.		❑
	4	**Ci-Ca module option: extracorporeal components**		
TSC	4.1	Citrate drop counter checked for proper function		❑
TSC	4.2	Calcium drop counter checked for proper function		❑
TSC	4.3	Line occlusion of the pumps checked.		
		Citrate pump (pressure loss max. 10 mmHg/min)	_____	❑
		Calcium pump (pressure loss max. 10 mmHg/min)	_____	❑

Type	No.	Description	Meas. value	✓
	5	**Check of the electrical safety** In Germany according to DIN VDE 0751-1, edition 10/2001. In other countries, observe the local regulations!		
TSC	5.1	Visual inspections performed according to item 1.		❑
TSC	5.2	Protective earth resistance max. 0.3 Ω (with power cable)	_____ Ω	❑
TSC	5.3	Leakage current measurement (device leakage current) ❑ Differential current measurement according to figure C.6 ***or*** ❑ Direct measurement according to figure C.5		❑
		Nominal voltage of power supply: _____ V		
		Device leakage current mains polarity 1: _____ µA		
		With line voltage: _____ V		
		Scaled to nominal voltage (maximum 500 µA, see Additional conditions)	_____ µA	
		Device leakage current mains polarity 2: _____ µA		
		With line voltage: _____ V		
		Scaled to nominal voltage (maximum 500 µA, see Additional conditions)	_____ µA	
TSC	5.4	Patient leakage current measurement		
TSC	5.4.1	For degree of protection type "BF" according to fig. C.8		❑
		Nominal voltage of power supply: _____ V		
		Patient leakage current _____ µA		
		With line voltage: _____ V		
		scaled to nominal voltage (maximum 480 µA, see Additional conditions):	_____ µA	
TSC	5.4.2	For degree of protection type "CF" according to fig. C.8		❑
		Nominal voltage of power supply: _____ V		
		Patient leakage current _____ µA		
		With line voltage: _____ V		
		scaled to nominal voltage (maximum 34 µA, see Additional conditions):	_____ µA	

Type	No.	Description	Meas. value	✓
	6	**Functional test**		
TSC	6.1	Functional test (T1 test) checked for proper performance.		❑
TSC	6.2	Ci-Ca module option After successful completion of the test, screen M86 'Starting conditions' is displayed.		❑
TSC	6.3	Power failure alarm executed.		❑
	7	**Final check**		
TSC	7.1	Entries made in the Medical Device Register.		❑

Test equipment used:

Pressure
(type, serial number):

_____

Protective earth resistance, leakage current
(type, serial number):

_____

Comments:

Date:	**Signature:**	**Stamp:**

The system has been released for its intended use. **(Attach inspection sticker.)**	❑ Yes ❑ No
Next inspection date:	
Comments:	

Date:	**Signature:**	**Stamp:**

4.4 Explanations on the TSC / MA Report

- **Identification**

  Technician's name:
  Technician's first name and surname.

  Customer/customer no.:
  Number of the final customer.

  Service report number:
  Number of the service call.

  System type including option(s):
  System name with possible options and extras.

  System no.:
  Serial number indicated on the type label.

  Inventory no.:
  Inventory number assigned to the system.

  Operating hours:
  Operating hours, if a time meter is installed.

  Equipment code:
  Equipment code indicated on the system.
  (e.g. EC xxx, E-code xxx)

- **Re: 2 - Extracorporeal components**

  For detailed information refer to chapter 5 "Adjustment Instructions and Tests"

- **Re: 3 - Mechanical components**

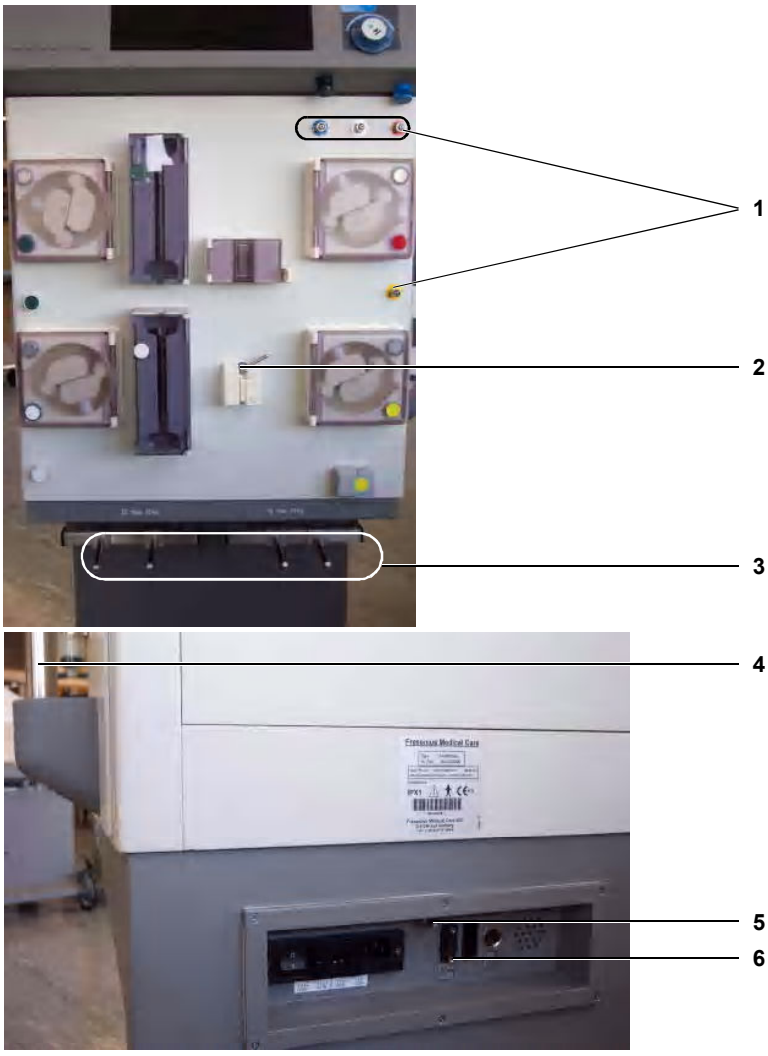
  For more detailed information on item 3.2, please refer to the Quick Guide on the PC Service Software MFT.

- **Re: 4 - Check of the electrical safety**

  In Germany according to DIN VDE 0751-1, edition 10/2001.
  In other countries, observe the local regulations!

  (Use DIN VDE 0751-1, edition 10/2001, for medical products. Use DIN VDE 0701-1 for electrical production equipment.)

- **Re: 4.2 Protective earth resistance measurement points**



Legend

1 Luer locks
2 Venous clamp
3 Filtrate bag hook
4 IV pole and second IV pole (Ci-Ca module option)
5 Potential equalization
6 RS232 screwed connection

● **Re: 4.3 Leakage current measurement (device leakage current)**

Fig.: Differential current measurement according to fig. C.6

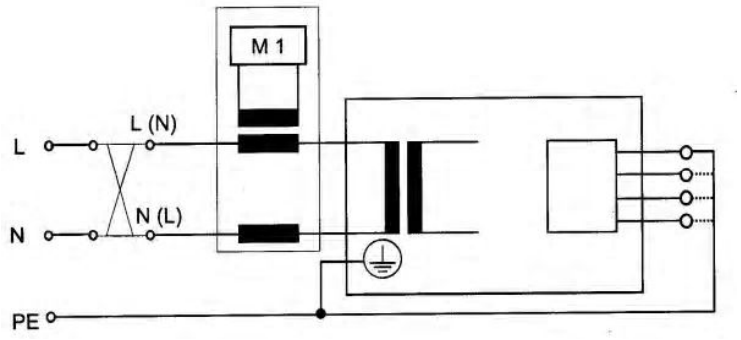
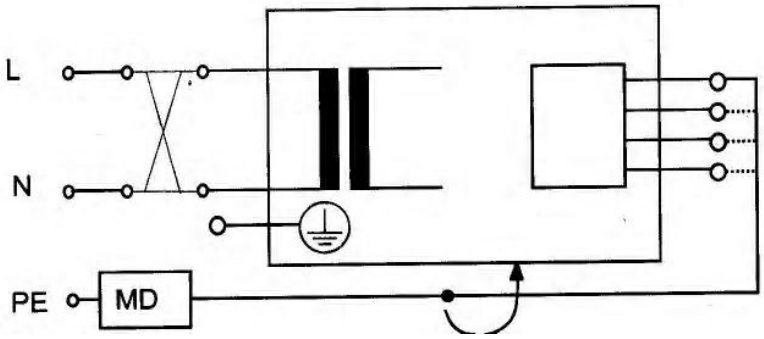


Fig.: Direct measurement according to fig. C.5



Basic requirements:

– Measurement of the protective earth resistance performed.
– The system is in standby operating mode (system connected to the mains).
– The same measurement kit (M28 060 1) as for the patient leakage current measurement is used for the measurement. Place the measuring plates on both bag trays and insert the heater bags filled with NaCl. Measurement setup, see appendix.
– When performing a direct measurement, the following precautions also must be observed:
  The system must be insulated when installed. All external connections and the potential equalization must have been removed from the system.

Documentation covers the nominal voltage during the measurement and the device leakage current at line voltage, scaled to the nominal line voltage.

Example:
Line voltage during measurement: 225 V
Device leakage current
for mains polarity 1: 38 µA
for mains polarity 2: 57 µA
Maximum value of both mains polarities: 57 µA
Nominal voltage of the power supply: 230 V
Scaled to nominal voltage: 58 µA
(58 µA: 225 V • 230 V = 58 µA)
Device leakage current < 500 µA: OK

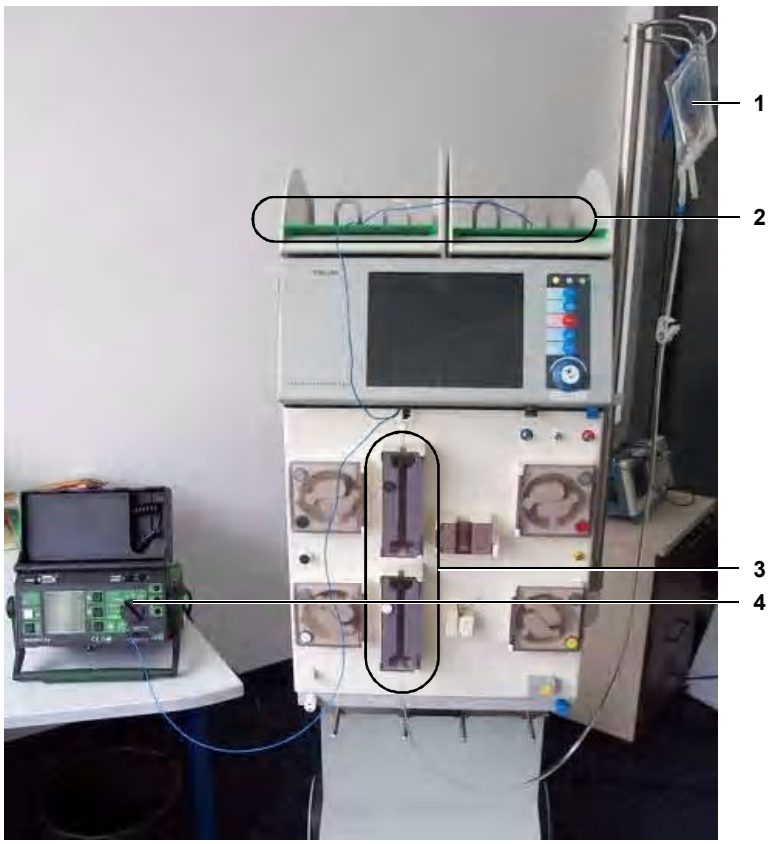
Additional conditions:
If the device leakage current is higher than 90 % of the admissible alarm limit (450 µA), the last measured value or the first measured value must additionally be considered for the rating.
If the device leakage current considerably increased since the last measurement or continuously increased since the first measurement (creeping deterioration of the insulation), or if the sum composed of the current value plus the difference since the last measurement is > 500 µA, the measurement has not been passed.

Example 1:
Leakage current: 470 µA
Last measured value: 450 A
470 + (470 – 450) = 470 + 20 = 490
OK

Example 2:
Leakage current: 470 µA
Last measured value: 390 µA
470 + (470 – 390) = 470 + 80 = 550
Not passed

● **Re: 4.3 and 4.4 Patient and device leakage current measurement**

Fig.: Setup of the measurement kit for measuring the patient leakage current and the device leakage current



Legend

1 Saline bag with 0.9 % NaCl solution for heater
2 Measuring plates for bag trays, left and right
3 Heater bag with measuring probe
4 Patient leakage current measurement: "AWT A" connector
Device leakage current measurement: Protective earth terminal
Symbol: ⏚

Note on item 3 concerning device leakage measurement

The upper heater bag must be completely filled with NaCl solution so that the electrode of the measuring probe is situated inside the solution.

Note on item 4 concerning device leakage measurement

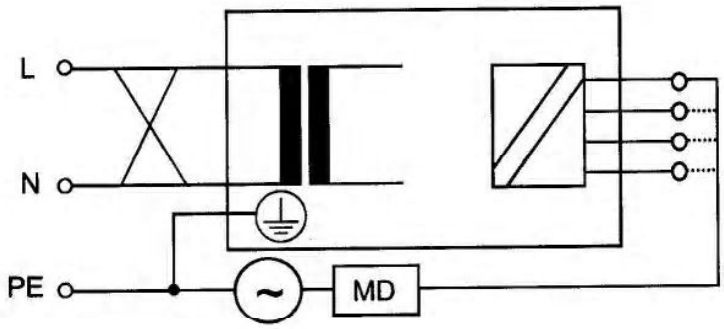
The connection line to the measurement kit must be inserted in the protective earth socket of the SECUTEST unit. If the measuring instrument fails to provide this arrangement, the connection line must be connected to a part of the multiFiltrate that is connected to the protective earth, e.g. the venous clamp.

If the steps are not followed as described, a specific function will be executed incorrectly or will not be executed at all, or will not produce the desired effect.

- **Re: 4.4.1 - Patient leakage current measurement for degree of protection (BF)**

Degree of protection type BF is applying to systems with ceramic heater, operated at a line voltage of 220 V to 240 V and at a line frequency of 60 Hz.

Fig.: Patient leakage current measurement according to figure C.8



Basic requirements:
- Measurement of the protective earth resistance performed.
- The system is in standby operating mode (system connected to the mains).
- Neither the system nor the test equipment must be touched during the measurement nor must a cable be connected to the serial interface.
- The patient leakage current measurement kit (M28 060 1) is used for the measurement. Place the measuring plates on both bag trays and insert the heater bags filled with NaCl. Measurement setup, see appendix.

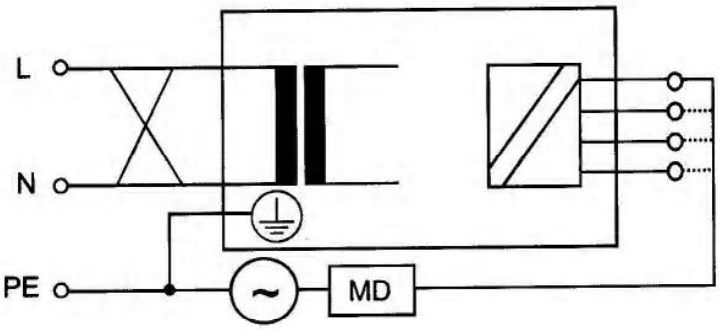
Documentation covers the nominal voltage during the measurement and the patient leakage current at line voltage, scaled to the nominal line voltage.

Example:
Measurement value: 48 µA, measured at 225 V
Nominal voltage: 230 V
Scaled to nominal voltage: 49 µA
(48 µA: 225 V x 230 V = 49 µA)

- **Re: 4.4.2 Patient leakage current measurement for degree of protection (CF)**

Degree of protection type CF is applying to systems with ceramic heater, operated at a line voltage of 100 V to 240 V and at a line frequency of 50 Hz or at a line voltage of 100 V to 127 V and at a line frequency of 60 Hz.

Fig.: Patient leakage current measurement according to figure C.8



Basic requirements:
– Measurement of the protective earth resistance performed.
– The system is in standby operating mode (system connected to the mains).
– Neither the system nor the test equipment must be touched during the measurement nor must a cable be connected to the serial interface.
– The patient leakage current measurement kit (M28 060 1) is used for the measurement. Place the measuring plates on both bag trays and insert the heater bags filled with NaCl. Measurement setup, see appendix.

Documentation covers the nominal voltage during the measurement and the patient leakage current at line voltage, scaled to the nominal line voltage.

Example:
Measurement value: 28 µA, measured at 244 V
Nominal voltage: 230 V
Scaled to nominal voltage: 26 µA
(28 µA: 244 V x 230 V = 26 µA)

- **Confirming the test**

Test equipment used:
Type and serial number of the test equipment used.

Comments:
Irregularities encountered during the test will be recorded in this section.

Date, signature, stamp
Performance of the test has to be confirmed by indicating date, tester's signature and stamp.

- **Assessing the test**

The system has been released for its intended use.
(Attach inspection sticker.)

During the intended use of the system it must be ensured that the system does not present a hazard to patients, employees or other third parties.

Within the scope of the overall assessment, the tester must make a definite decision whether the system may be used or not. The responsible organization must immediately be informed of any defects detected.

Next inspection date:
The next inspection date has to be entered in the report.
The intervals specified by the manufacturer have to be respected!

Comments:
Irregularities encountered during the assessment will be recorded in this section.

Date, signature, stamp:
Assessment of the initial start-up has to be confirmed by indicating date, tester's signature and stamp.

5 Adjustment Instructions and Tests

5.1 Service Tools

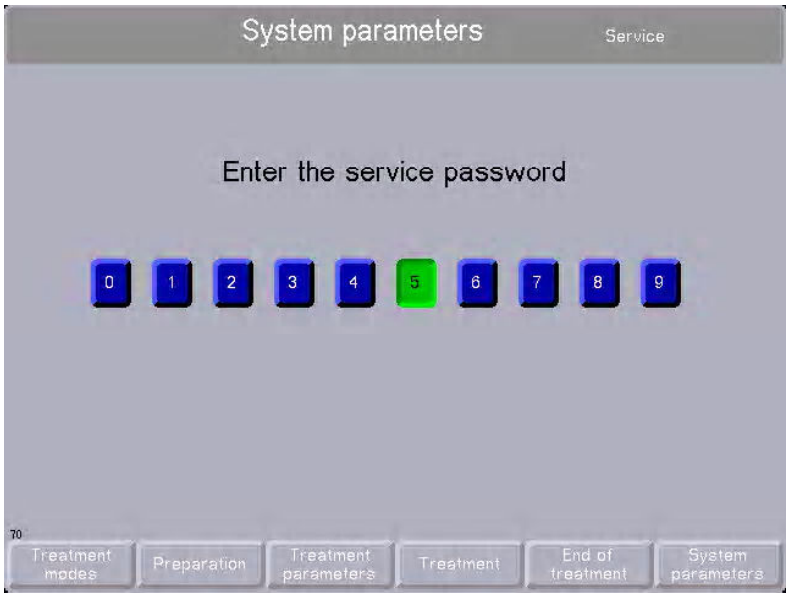
Part no.	Description
M28 489 1	Dongle ICD cable for programming the OP and SP
M28 060 1	Measuring kit for measuring the patient leakage current
M28 098 1	Crosstalk Reduction Adapter
510 130 1	ESC tester with measuring adapter for patient leakage current
M30 770 1	HMED pressure measuring instrument with case (set)
631 064 1	Secutest VDE test device (without printer module)
630 652 1	Printer module for secutest
630 648 1	Carrying bag for secutest
630 387 1	ESD Service Kit
670 004 1	Multimeter Fluke 75
M28 486 1	RS232 null-modem cable, 9-pin D-SUB
M28 487 1	Gender Changer connector – connector, 9-pin D-SUB
M28 488 1	Connector–socket extension, 1.5 m, 25-pin D-SUB
M28 497 1	CD-ROM with programming software for ICD dongle for programming the OP and SP
M36 234 1	Service Software, complete set (incl. card reader, null-modem cable, Gender Changer)
M36 235 1	Service Software, software set without hardware
M28 498 1	Square wrench, housing door
675 845 1	Hook test weight 5 kg / M1
630 360 1	Equipotential bonding cable
M36 067 1	Calibration kit for air detector
640 560 1	Neutral filter for calibrating the optical detector

5.2 Service Program

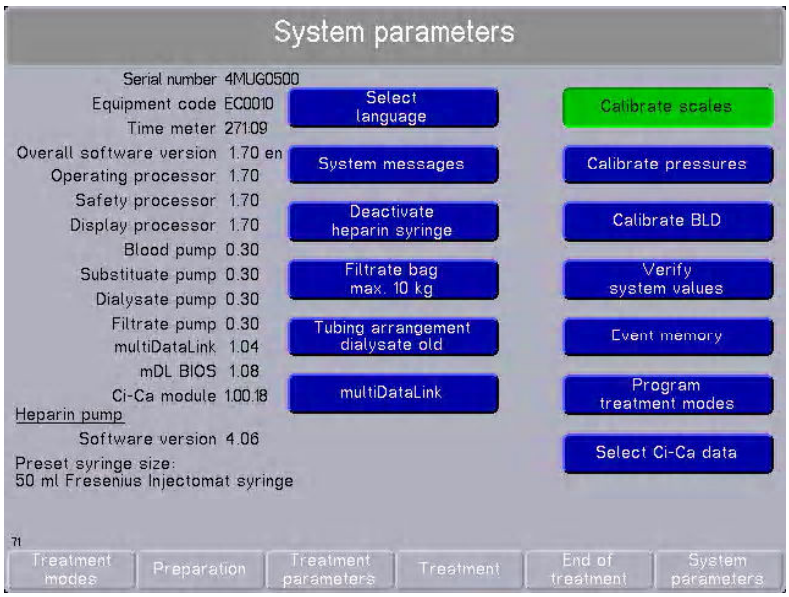
5.2.1 Start

The system must be turned off via **I/O**. The power switch on the rear of the system must be turned on.

– Press and hold the **Start/Reset** key. Simultaneously press the **I/O** until the **yellow** status indicator lights up.



– Using the rotary selector, select the numerical code and confirm each number by pressing the **OK** key.



After the password has been checked positively, all revisions are displayed to the left of the screen. The menu fields of the Service program are displayed to the right of the screen.

– Use the rotary selector to select the desired menu field and press **OK**.

5.2.2 Selecting the Language

– Use the rotary selector to select the desired language and press **OK**.

– Turn off the system via the **I/O** key immediately thereafter.

– Once again turn on the system via the **I/O** key and restart the Service program.

5.2.3 System Messages

Only the error messages (E XX) and warnings (W XX) of the previous treatments are filtered out of the events memory (see below) and displayed on the screen.

5.2.4 Deactivating and Activating the Heparin Pump

Permits activation and deactivation of the optional heparin syringe.

Screen display	Machine status
Deactivate heparin syringe	The heparin syringe is currently active.
Activate heparin syringe	The heparin syringe is currently not active.

Note

If the system does not contain any installed heparin syringe, the machine status should be set to ***Heparin syringe currently not active***. If the setting fails to reflect the proper machine status, a warning is displayed during the T1 test.

5.2.5 Filtrate Bag Monitoring Limit

Permits to set the monitoring limit to a value between 10 kg and 20 kg on the filtrate scales.

Screen display	Machine status
Filtrate bag max. 5 kg	Currently, the monitoring limit is set to 5 kg.
Filtrate bag max. 10 kg	Currently, the monitoring limit is set to 10 kg.
Filtrate bag max. 20 kg	Currently, the monitoring limit is set to 20 kg.

5.2.6 Dialysate Tubing Arrangement

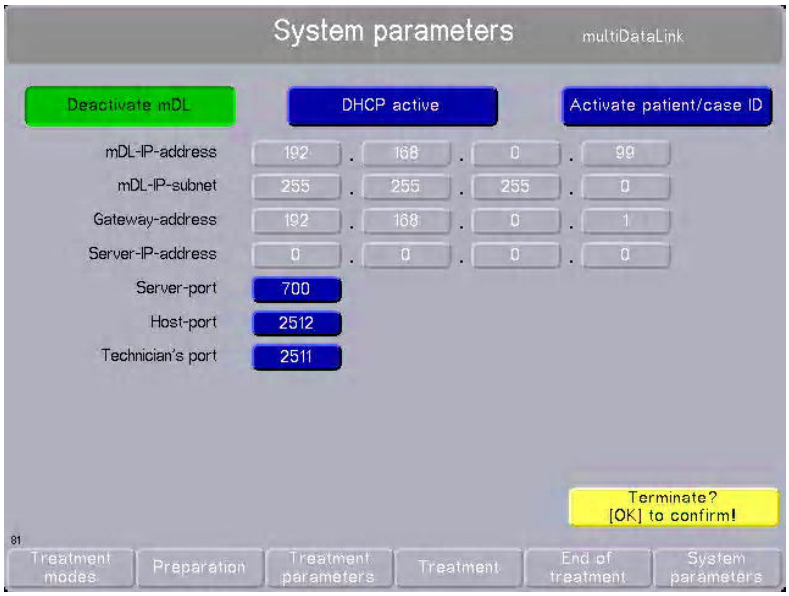
Permits to switch from **old** to **"Fin"** dialysate tubing arrangement and vice versa in the preparation mode.

old Tubing system with heater bag **downstream** of the pump segment

"Fin" Tubing system with heater bag **upstream** of the pump segment

Screen display	Machine status
Tubing arrangement dialysate old	Display of the old tubing arrangement. Heater bag for dialysate downstream of the dialysate pump.
Tubing arrangement dialysate "Fin"	Display of the new tubing arrangement. Heater bag for dialysate upstream of the dialysate pump.

5.2.7 Option MultiDataLink (mDL)



This screen permits to set the multiDataLink parameters.

Activating and deactivating mDL

This soft key permits activation and deactivation of the optional mDL.

Screen display	Machine status
Deactivate mDL	mDL is currently active.
Activate mDL	mDL is currently not active.

Note

If the system does not contain any installed mDL, the machine status should be set to ***mDL currently not active***. If the setting fails to reflect the proper machine status, a warning is displayed during the T1 test.

DHCP active / inactive

This soft key informs the mDL of whether a DHCP server is active in the connected network. If this is the case, the mDL receives its IP addresses from this server. If no, the IP addresses must be set manually.

	DHCP active	DHCP inactive
mDL-IP-address	Automatic	0...255 adjustable
mDL-IP-subnet	Automatic	0...255 adjustable
Gateway-address	Automatic	0...255 adjustable
Server-IP-address	Automatic	0...255 adjustable

	DHCP active	DHCP inactive
Server-port	0...65535 adjustable Default value: 700	0...65535 adjustable Default value: 700
Host-port	0...65535 adjustable Default value: 2512	0...65535 adjustable Default value: 2512
Technician's port	0...65535 adjustable Default value: 2511	0...65535 adjustable Default value: 2511

Note

Before setting the mDL parameters, please clarify with the responsible hospital network administrator whether a DHCP server is available for automatically assigning the IP addresses. If no, the administrator has to specify defined addresses which will then have to be entered manually.

The port numbers depend on the application which further processes the multiFiltrate data. The administrator of this software will have to specify the appropriate values if these are different from default values.

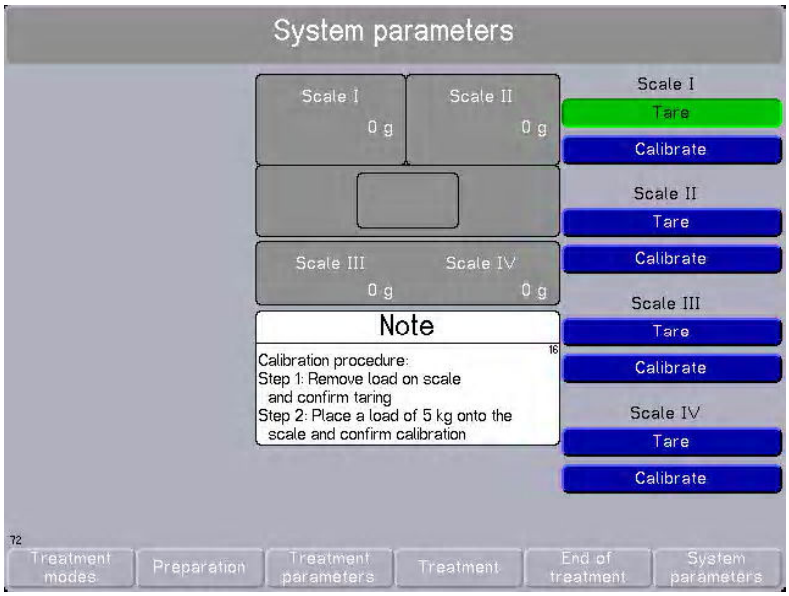
– Use the rotary selector to select the **Terminate? [OK] to confirm!** field and press **OK**.

Activating/deactivating the Patient/Case ID

This soft key permits activation and deactivation of the optional patient/case ID.

Screen display	Machine status
Deactivate patient/case ID	The patient/case ID is currently active
Activate patient/case ID	The patient/case ID is currently not active

5.2.8 Taring and Calibrating the Scales



The screen displays the zero load weights of the scales 1 to 4. Upon start of the Service program, the scales are not tared. Hence, a display value within a range from 2500 g to 3500 g is expected for scales 1 and 2. A display value within a range from 250 g to 350 g is expected for scales 3 and 4. Each of the scales (1 to 4) is provided with its own menu field for taring and calibrating purposes. The tare and calibrate procedures are described by the example of scale 1. The same procedures apply to scales 2 to 4.

- **Taring the scales**

Requirement

The system must be turned on via **I/O** for at least 5 minutes to bring the scales to operating temperature.

– Using the rotary selector, select the **Tare** field under **Scale I** and press **OK**.

While taring is in progress, the field selected is represented light-green. After a time out of approx. 10 seconds, the weight of the scale is indicated to be 0 g.

- **Calibrates the scales**

Test equipment

Test weight of 5000 g of accuracy class M1 or better.

Requirement

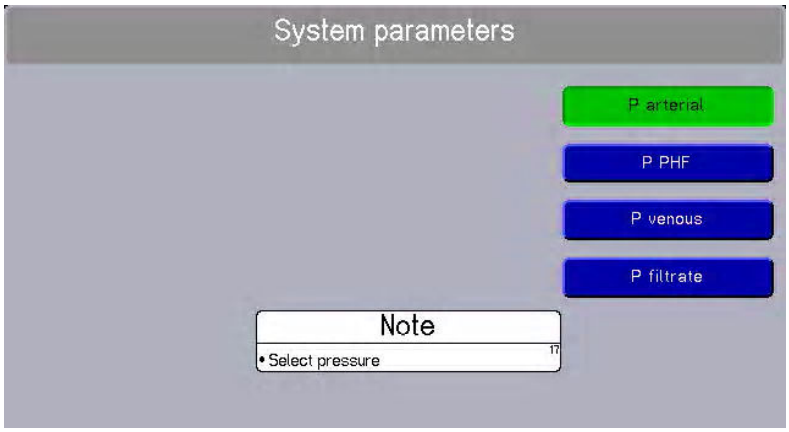
The scales must be unloaded!
Tubing sets may not be inserted.
The scales must have been tared beforehand.

Each scale must be tared separately!

– To calibrate the scales 1 and 2, place the test weight centrally on the rear part of the scale pan.
– To calibrate the scales 3 and 4, suspend the test weight from a hook.
– Use the rotary selector to select the **Calibrate** field of the loaded scale and press **OK**.

While calibration is in progress, the field selected is represented light-green. The time out is approx. 10 seconds.

5.2.9 Calibrating the Pressures



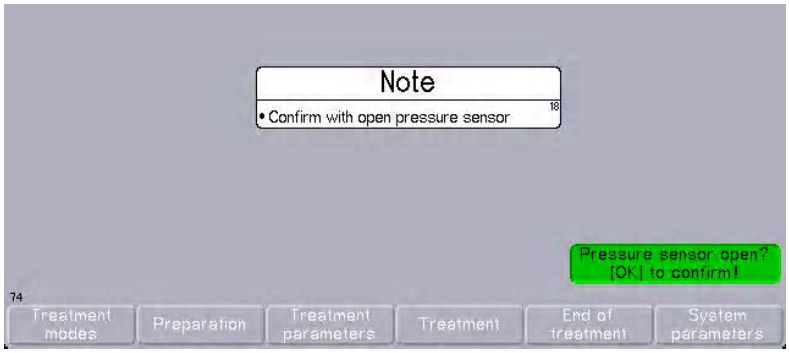
The menu fields for calibration of the pressures (arterial, venous, prehemofilter and filtrate) are displayed to the right of the screen. Performance of the calibration procedure of the pressure transducers is described by example of the arterial pressure. The three other pressures are calibrated in the same manner.

● **Zero offset of pressure transducers**

Requirement

The pressure transducers must have ambient pressure (pressure transducers open).

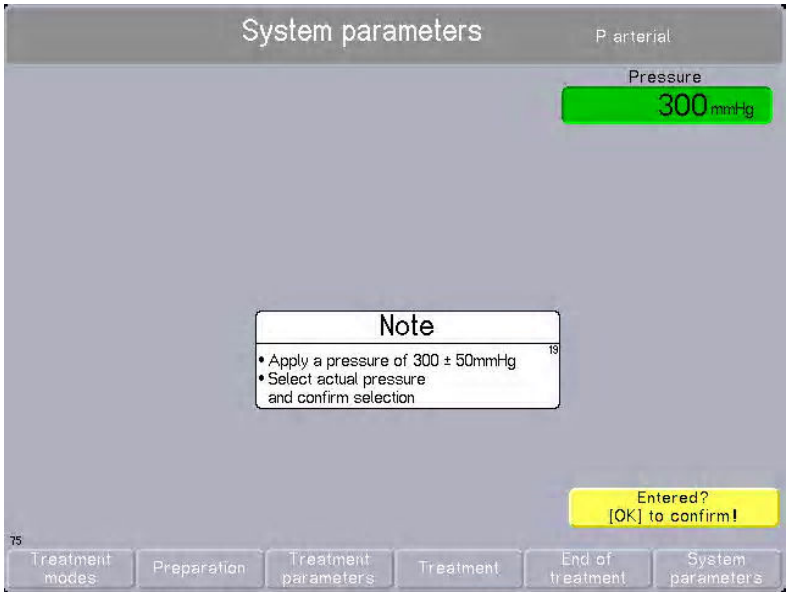
– Use the rotary selector to select the **P arterial** field and press **OK**.



– Use the rotary selector to select the **Pressure sensor open? ”OK” to confirm!** field and press **OK**.

The zero offset is made automatically. It is completed when the next screen is displayed.

- **Calibrating the pressure transducers**



Test equipment

Pressure gauge with a measurement range from 0–350 mmHg (0–500 mbar), disposable syringe, artery forceps

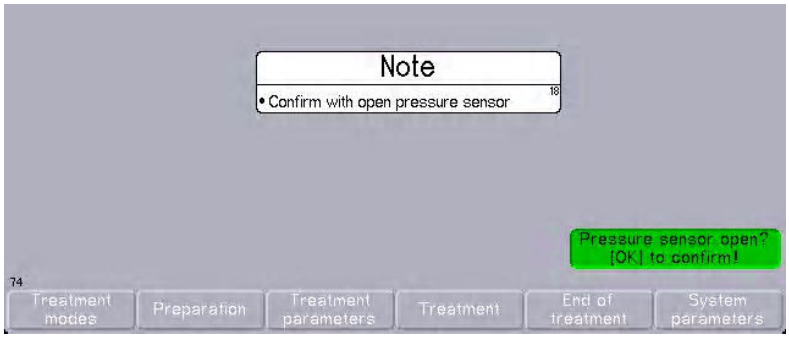
Measuring instrument

– Connect the measuring instrument to the pressure transducer.
– Using the syringe, build up a pressure of 300 mmHg. (tolerance ±50 mmHg) Then, using the artery forceps, occlude to the direction of the syringe so that the pressure transducer and the pressure gauge are still under load.
– Using the rotary selector, set the value indicated by the pressure gauge on the screen, i.e. in the **Parterial** field.
– Use the rotary selector to select the **Entered? ”OK” to confirm!** field and press **OK**.

After calibration is completed, the system returns to the previous screen.

● **Determining the setting of the DAC for detuning in the self-test**

Requirement The pressure transducers must have ambient pressure.



– Use the rotary selector to select the **Pressure sensor open? ”OK” to confirm!** field and press **OK**.

While the self-test is in progress, the field selected is represented light-green. The time out is approx. 10 seconds.

Note

If an error occurs during calibration, check and, if necessary, calibrate the corresponding evaluation board (P.C.B. LP 450-3 or P.C.B. LP 343-1).

5.2.10 Calibrating the Blood Leak Detector

Test equipment

Filtrate line filled with water.

– Insert the water-filled filtrate line into the BLD measuring head.
– Use the rotary selector to select the **Tubing inserted? "OK" to confirm!** field and press **OK**.

After completion of the calibration procedure, the message **"Calibration complete. Press ESC to continue."** is displayed.

– Press the **ESC** key.

5.2.11 Verifying the System Values

– Use the rotary selector to select **Verify system values** and press **OK**.

Using this service step, all relevant parameters as well as the function of the pumps, pressure transducers and scales can be verified.

Press the **Start/Reset** key to activate the heater.

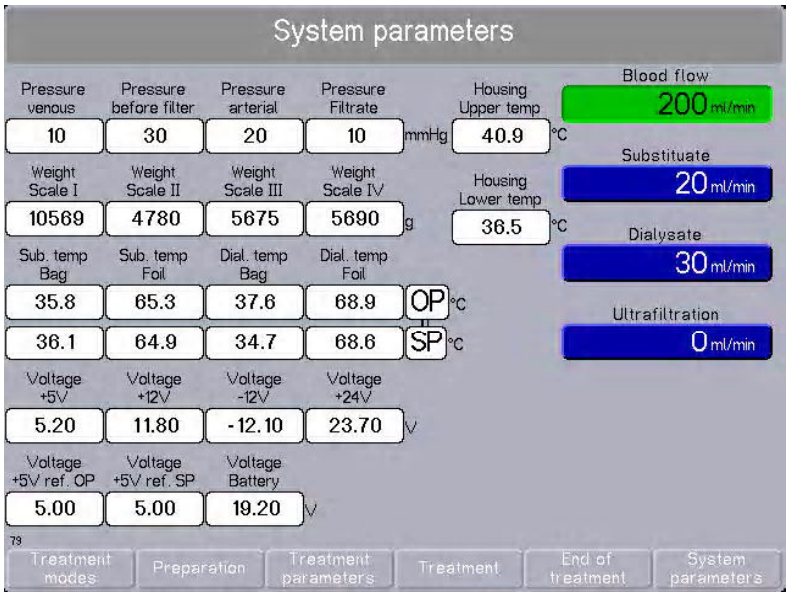
Caution

If heater bags are not inserted and if there is no fluid in the system, the heater will become very hot.

Ci-Ca module (option)

Citrate and calcium pump can be limitedly be activated in this menu.

– Press the **STOP** key.
  The pumps stop
– Press the **START/RESET** key
  The pumps start running at a delivery rate of 500ml/h if the insertion switch is pressed (tubing inserted)



Display of pressure values (venous, PHF, arterial, and filtrate); resolution 1 mmHg. With open pressure transducers, the display must show values within a range from – 5 mmHg to 5 mmHg.

Display of weights (scale 1, scale 2, scale 3, and scale 4); resolution 1 g.

Display of the temperatures of the heaters for the sensors of the operating processor (OP) and the safety processor (SP).

Screen	Heater location
Sub. temp. Bag	Lower heater, bag sensor
Sub. temp. Foil	Lower heater, foil sensor
Dial. temp. Bag	Upper heater, bag sensor
Dial. temp. Foil	Upper heater, foil sensor

Display of system voltages. This display is only intended for a rough check of the system voltages. Owing to the hardware and software conversions, the accuracy is within a range of ±5% only. Use a calibrated multimeter to perform a check for the indicated range directly on P.C.B. LP 124 or LP 244 SR/BR (SP/OP).

Screen	Desired value	Voltage
Voltage +5 V	5.0 - 5.3 V	Logic voltage
Voltage +12 V	11.5 - 12.3 V	Supply voltage
Voltage - 12 V	-(11.2 - 12.3 V)	Supply voltage
Voltage +24 V	23.0 - 24.0 V	Supply voltage
Voltage +5 V ref. OS	5.05 - 4.95 V	Supply voltage of the operating processor for the A-D converter
Voltage +5 V ref. SS	5.05 - 4.95 V	Supply voltage of the safety processor for the A-D converter
Battery voltage	18.0 - 22.5 V	Battery terminal voltage

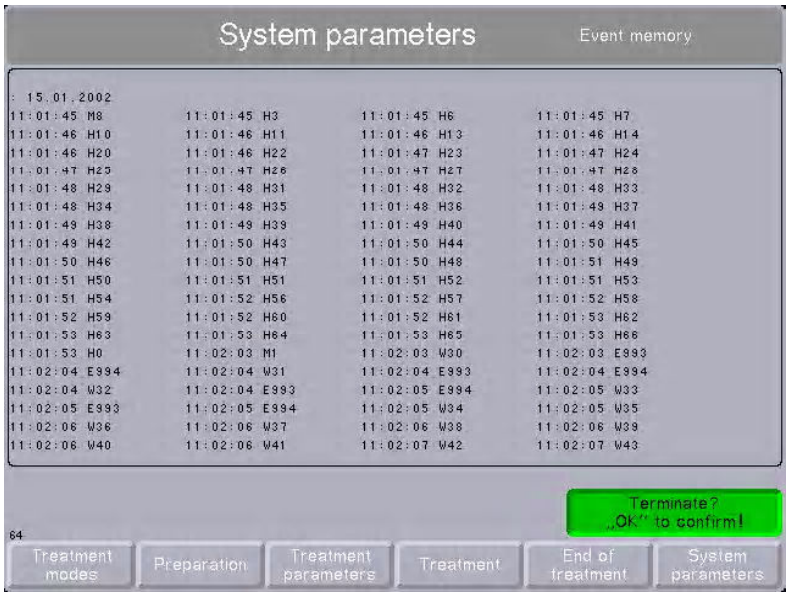
The housing temperatures are determined by means of the sensors of the scales. These sensors transmit their values to the safety processor.

Screen	Temperature
Housing Upper temp.	Mean value of the sensors of the two upper scales
Housing Lower temp.	Mean value of the sensors of the two lower scales

Specified pump rates. Opposed to the entries made during the treatment, all specified values must be entered in ml/min. With the exception of the door-open state, the pumps are not monitored during the Service program.

Screen	Delivery rate
Blood pump	10 – 500 ml/min
Filtrate pump	10 – 200 ml/min
Substituate pump	10 – 200 ml/min
Dialysate pump	10 – 200 ml/min

5.2.12 Events Memory



To permit analysis and reproducibility of objected states occurring once in the display processor, the events of the previous treatments (from the view of the display processor) are recorded together with the moment of occurrence and are stored in a file when the system is turned off with I/O. At the beginning of the treatment, the date is additionally stored.

– Turn the rotary selector to the right to scroll down and to the left to scroll up screen by screen.

Screen	Delivery rate
Mxx	Menu no. xx
>Fx	Move to the x^{th} foot bar key
Fx>	Selection of the x^{th} foot bar key with OK
YYYYY	Treatment mode

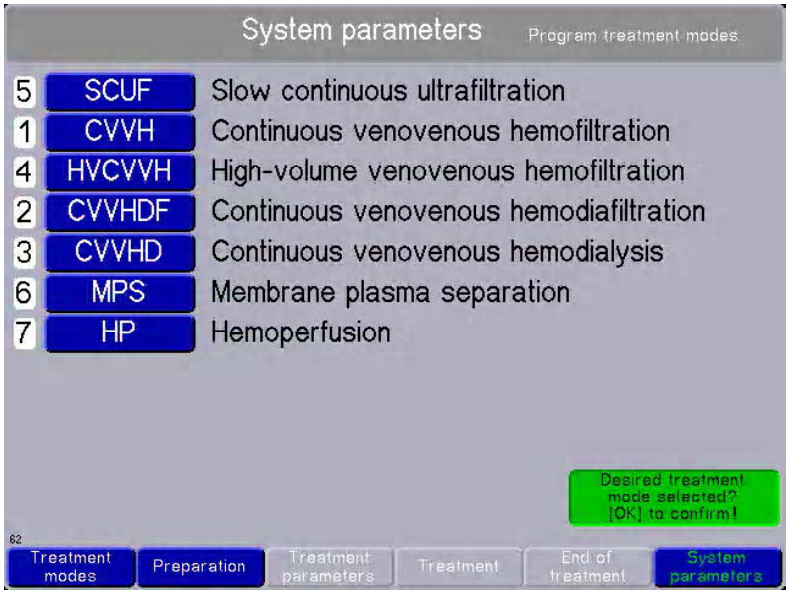
Screen	Delivery rate
y	Internal operating mode
Hxx	Display of note no. xx
Wxxx	Display of warning no. xxx
Exxx	Display of error no. xxx
H0	Hiding of the respective display
->x	Turn right by x steps before function key
<-4	Turn left by x steps before function key
.->x	Turn by x steps took place before a preceding H, W or F entry (in M61 only).
Oxx	Internal options command
BRxx	Blood flow in ml/min
ARxxxx	Substituate rate in ml/h; plasma rate in ml/min
DRxxxx	Dialysate rate in ml/h
SVxxxx	Plasma volume in ml
EExxxx	Ultrafiltration in ml/h
UZxxxx	UF goal in ml/h
TSxx	Temperature in 0.1 °C
ABxx	Bolus anticoagulation in 0.1 ml
KA	Continuous anticoagulation in 0.1 ml/h
SPVxxxx	Rinse volume in ml
UFVxxxx	UF volume in ml
RIVxxxx	Reinfusion volume in ml
DHxxx	Display brightness in %
LSxxx	Volume of audible alarm in %
SCxxx	Pressure in mmHg
AHxxx	Upper arterial pressure limit in mmHg
ALxxx	Lower arterial pressure limit in mmHg
VHxxx	Upper venous pressure limit in mmHg
VLxxx	Lower venous pressure limit in mmHg
THxxx	Upper TMP/pF pressure limit in mmHg

Screen	Delivery rate
TLxxx	Lower TMP/pF pressure limit in mmHg
DCx	Pressure limit alteration code Art. size = 1; art. position = 4 Ven. size =2; ven. position =5 TMP/UF size = 3; TMP/UF position = 6
!!....Z.xx:x	Internal program run observations

Legend

x Numerical character
y Lower-case letter
Y Upper-case character

5.2.13 Program Treatment Modes



Using this menu, the treatment types can be programmed in the order as they are used most frequently, while those treatment types that are not desired can be hidden.

– Use the rotary selector to select the desired treatment modes and press **[OK]**.

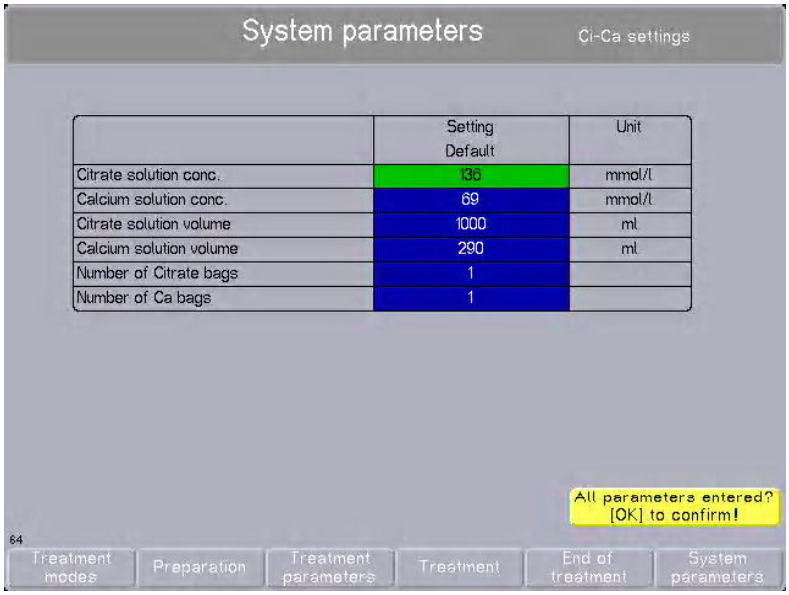
– Turn off the system via the **I/O** key immediately thereafter.

– Once again turn on the system via the **I/O** key and restart the Service program.

Note

The selected treatment modes remain active only if you turn the system off and back on again immediately after terminating the selection.

5.2.14 Programming the Ci-Ca Data (Option)



All settings relevant for the Ci-Ca treatment are performed in this menu.

– Use the rotary selector to select the desired field and press **[OK]**.
– Use the rotary selector to enter the desired value and press **[OK]**.

Note

To reduce the risk of using the wrong citrate or calcium containers, only one type of container (container size and concentration) should be used throughout the hospital or a comparable organization institution. Save the same settings for citrate and calcium containers in the setup of all multiFiltrate systems of this organization institution.

Ci-Ca settings	min.	max.	Resolution	Unit
Citrate solution conc.	50	500	1	mmol/l
Calcium solution conc.	50	500	1	mmol/l
Citrate solution volume	100	2000	10	ml
Calcium solution volume	100	2000	10	ml
Number of Citrate bags	1	1	1	pc.
Number of Ca bags	1	1	1	pc.

5.3 Extracorporeal Components

Note

Carry out all steps described below in the Service program.

5.3.1 Tightness of the Venous Occlusion Clamp

Measurement setup

Test equipment

Pressure gauge, disposable syringe, venous tubing system with occlusion clamp or artery forceps or test tubing, stop watch

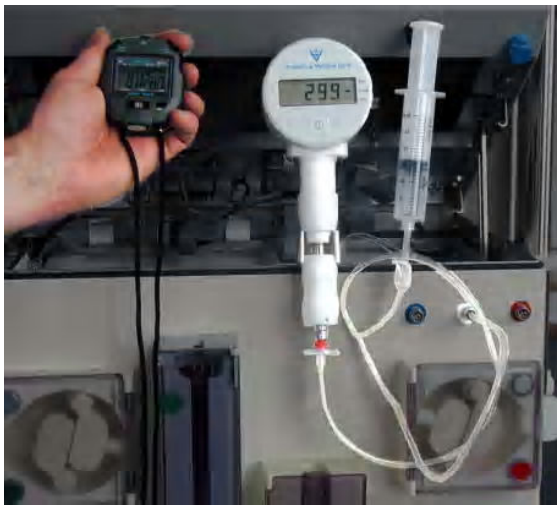
- With the open line end in front, insert the measuring instrument into the venous occlusion clamp.
- Using the syringe, build up a pressure of 2 bar. Then, using the artery forceps, occlude to the direction of the syringe so that the pressure gauge is still under load.
- Start the stop watch. After 3 minutes have elapsed, the pressure applied may not drop by more than 0.1 bar.

5.3.2 Checking the Pressure Transducers

Zero point

Check the pressure transducers in the Service program in the **Check system values** menu item. With open pressure transducers, the pressures displayed must be within a range from –5 mmHg to +5 mmHg.

Measurement setup



Amplification

- Connect the measuring instrument to the pressure transducer.
- Using the syringe, build up a pressure of 300 mmHg ±20 mmHg. Then, using the artery forceps, occlude to the direction of the syringe so that the pressure transducer and the pressure gauge are still under load.
- The value displayed on the screen must be identical with the value indicated by the pressure gauge. Tolerances: ±5 mmHg.

Leakage

- Connect the measuring instrument to the pressure transducer.
- Using the syringe, build up a pressure of 600 mmHg. Then, using the artery forceps, occlude to the direction of the syringe so that the pressure transducer and the pressure gauge are still under load.
- Start the stop watch. After one minute has elapsed, the pressure applied may not drop by more than 10 mmHg.

5.3.3 Venous Pressure Transducer (P.C.B. LP 450-3)

Usually, the pressure board LP 450-3 has been precalibrated. Whenever the printed circuit board is replaced, the zero point must be set. The amplification must be checked and readjusted, if necessary.

Fig.: P.C. B. LP 450-3, no SMT

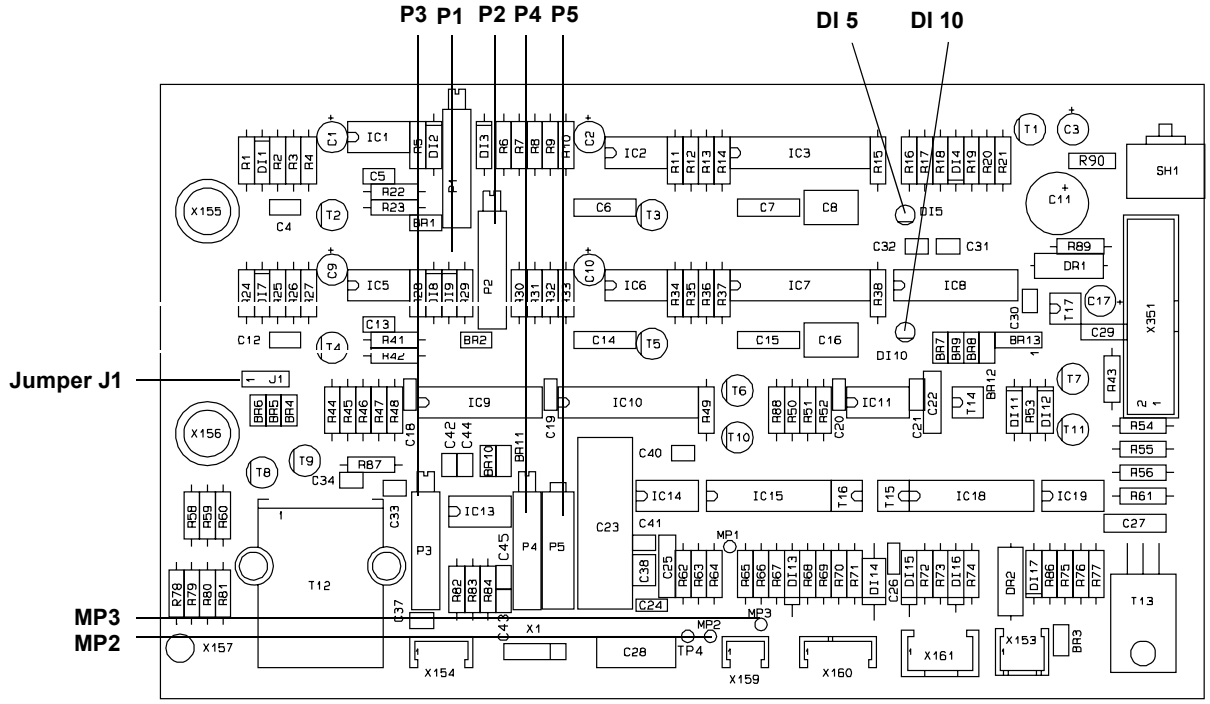
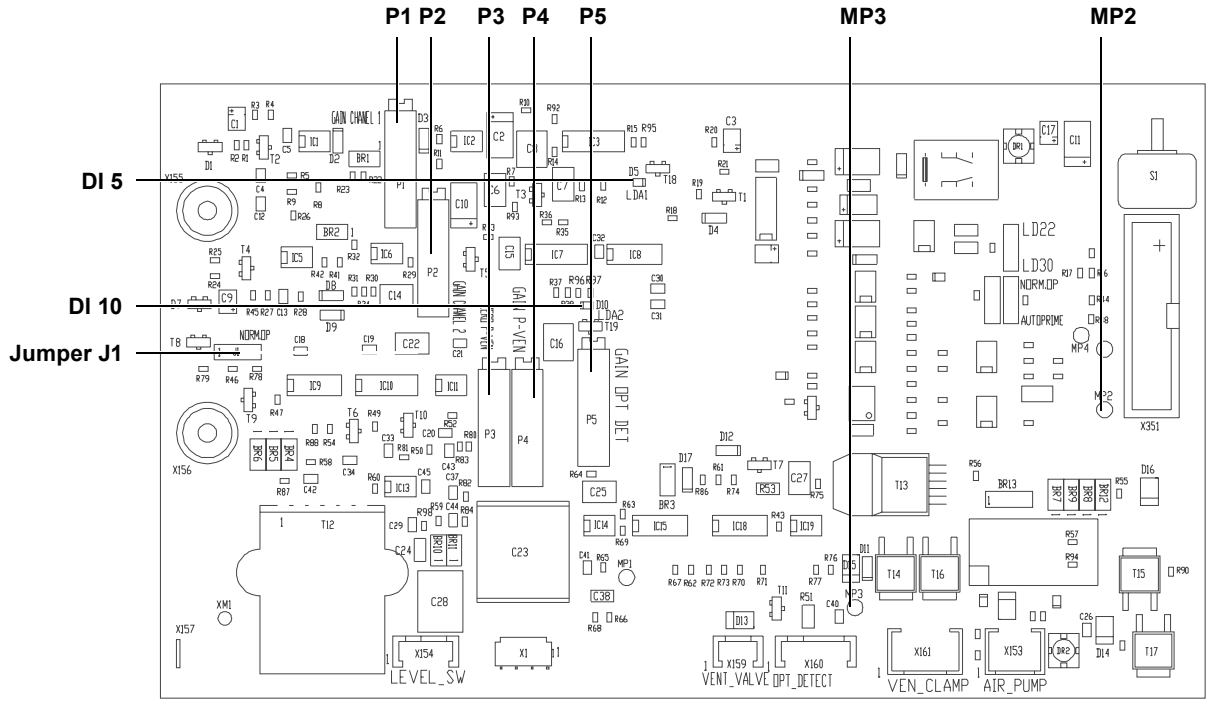


Fig.: P.C.B. LP450-3, SMT



Setting the zero point

Setting the zero point with open pressure transducers.
– Connect the negative pole of the multimeter to MP3 (0 V).
– Connect the positive pole of the multimeter to MP2.
– Use the potentiometer P3 to set the following voltage.

Pressure transducer	Voltage
Venous	3 V ±0.2 V

Setting the amplification

For verification and setting purposes, apply a pressure of 300 mmHg ±20 mmHg to the pressure transducers.

– Use the potentiometer P4 to set the following voltage.

Pressure transducer	Voltage
Venous	5.9 V ±0.2 V

Note

Whenever the P.C.B. LP 450-3 is replaced, the air detector must be recalibrated.

5.3.4 Air Detector (P.C.B. LP 450-3)

Test equipment

Adjusting block and checking (reference) block M36 067 1

Check using the checking block (red)

– Set the jumper J1 / P.C.B. LP 450-3 to the ”operation” position (NORM OP).
– Fill the spherical recesses of the checking block with grease and remove any excess grease so that only the recesses themselves will be struck with grease.
– Place the greased checking block into the drip chamber holder. It must be ensured that the ultrasonic sensors must correctly click into place into the spherical recesses of the adjusting block. The block must not touch the holder wall, but must hang freely between the sensors.

Desired function: The LEDs DI 5 and DI 10 on the P.C.B. LP 450-3 are light.

If the desired function fails to be fulfilled, the ultrasonic detector must be set.

Check using the adjusting block (grey)

– Set the jumper J1 / P.C.B. LP 450-3 to the ”operation” position (NORM OP).
– Fill the spherical recesses of the adjusting block with grease and remove any excess grease so that only the recesses themselves will be struck with grease.
– Place the greased adjusting block into the drip chamber holder. It must be ensured that the ultrasonic sensors must correctly click into place into the spherical recesses of the adjusting block. The block must not touch the holder wall, but must hang freely between the sensors.

Desired function: The LEDs DI 5 and DI 10 on the P.C.B. LP 450-3 are dark.

If the desired function fails to be fulfilled, the ultrasonic detector must be set.

– Take the adjusting block out of the drip chamber holder and completely remove the grease from the drip chamber holder, only using non-pilling fabric and disinfectants authorized for this purpose.

Calibration

– Set the jumper J1 / P.C.B. LP 450-3 to the ”calibration” position (CALIB).
– Fill the spherical recesses of the adjusting block with grease and remove any excess grease so that only the recesses themselves will be struck with grease.
– Place the greased adjusting block into the drip chamber holder. It must be ensured that the ultrasonic sensors must correctly click into place into the spherical recesses of the adjusting block. The block must not touch the holder wall, but must hang freely between the sensors.
– Turn potentiometer 1 and then potentiometer 2 on P.C.B. LP 450-3 until the LEDs DI 5 and DI 10 on P.C.B. LP 450-3 are dark.
– Slowly (caution: time constant) turn potentiometer 1 / P.C.B. LP 450-3 back until the LED DI 5 on P.C.B. LP 450-3 lights.
– Slowly (caution: time constant) turn potentiometer 2 / P.C.B. LP 450-3 back until the LED DI 10 on P.C.B. LP 450-3 lights.
– Set the jumper J1 / P.C.B. LP 450-3 to the ”operation” position (NORM OP).

Desired function: The LEDs DI 5 and DI 10 on the P.C.B. LP 450-3 are dark.

– Take the adjusting block out of the drip chamber holder and completely remove the grease from the drip chamber holder, only using non-pilling fabric and disinfectants authorized for this purpose.

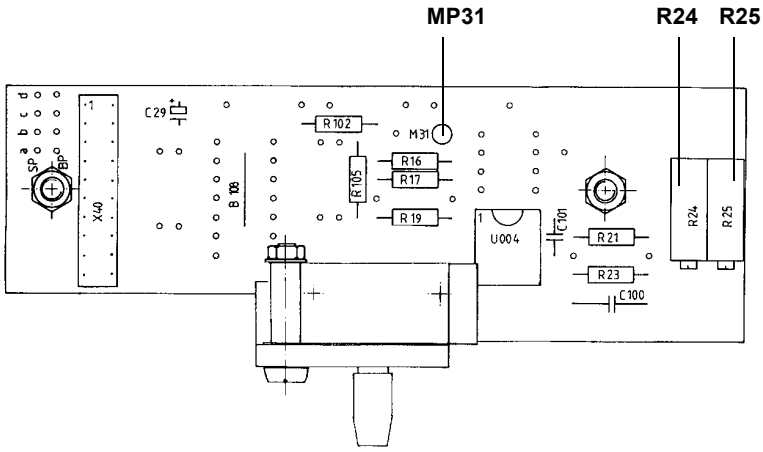
5.3.5 Optical Detector Sensing Opaque / Non-Opaque Fluid (P.C.B. LP 450-3)

Calibration

– Start the Service program and select **"Verify system values"**.
– Hold the neutral filter (640 560 1) (to be used in 2 layers) into the optical detector. Close the flap to minimize external light.
– Slowly turn the potentiometer P5 on P.C.B. LP 450-3 until the audible signal turns silent.
– Slowly turn potentiometer P5 until the audible signal is sounded. Then turn it for another half-revolution.

5.3.6 Arterial / Filtrate / PHF Pressure Transducers (P.C.B. LP 343-1)

Usually, the pressure boards LP 343-1 have been precalibrated. Whenever the printed circuit boards are replaced, the zero point must be set. The amplification must be checked and readjusted, if necessary.



Setting the zero point

Setting the zero point with open pressure transducers.

– Connect the negative pole of the multimeter to the shield connection of a jack connector.
– Connect the positive pole of the multimeter to MP31.
– Use the potentiometer R24 to set the following voltage.

Pressure transducer	Voltage
Arterial, filtrate	5 V ±0.2 V
PHF	2 V ±0.2 V

Setting the amplification

For verification and setting purposes, apply a pressure of 300 mmHg ±20 mmHg to the pressure transducers (see **Measuring instrument**, chapter 5.1.9, Calibrating the Pressures).

– Use the potentiometer R25 to set the following voltage.

Pressure transducer	Voltage
Arterial, filtrate	7.9 V ±0.2 V
PHF	4.9 V ±0.2 V

5.3.7 Blood Leak Detector

System requirements

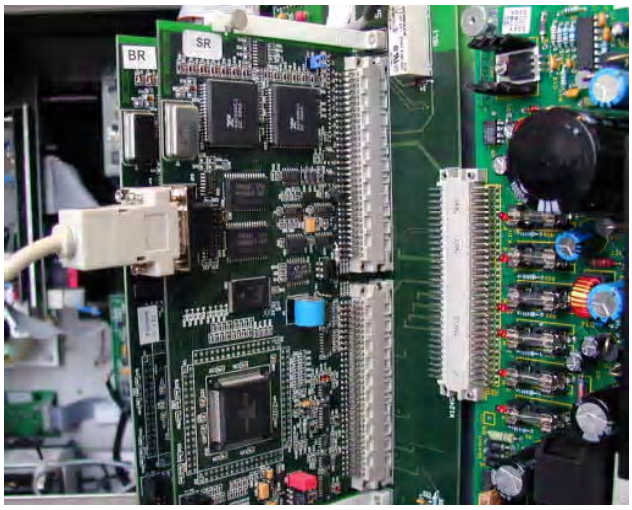
PC with Service Software MFT M36 235 1
with null-modem cable M36 234 1

Checking red coloration and dimness

– Via PC with Service Software MFT

Calibrate

– A filtrate tubing set filled with water must be inserted in the BLD measuring head.
– Via PC with Service Software MFT



5.3.8 Setting the Heparin Pump

In case of a data loss, the heparin pump must be reinitialized to redefine the end points.

- **Initialization**

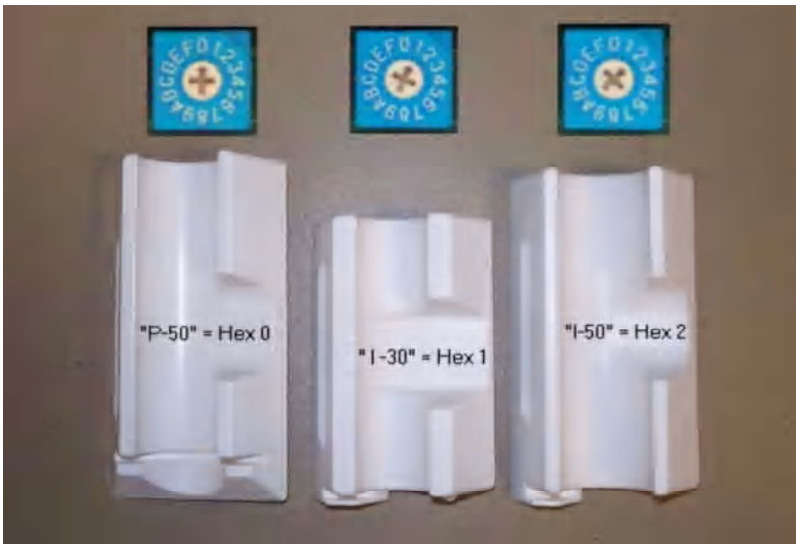
After turning the system on, the heparin pump will be initialized by moving the slide carriage up and down once, using the two control keys.

Press and hold the corresponding key during the up and down movement. The end points are defined after completion of the initialization.

- **Hex coding switch**

Hex coding	Syringe type
0	Type: 50 ml Fresenius P syringe
1	Type: 30 ml Fresenius Medical Care heparin syringe
2	Type: 50 ml Fresenius Injectomat syringe

The Hex codings 3 … F are not used.
A wrong Hex coding will result in an error message.


"P-50" = Hex 0
"I -30" = Hex 1
"I-50" = Hex 2

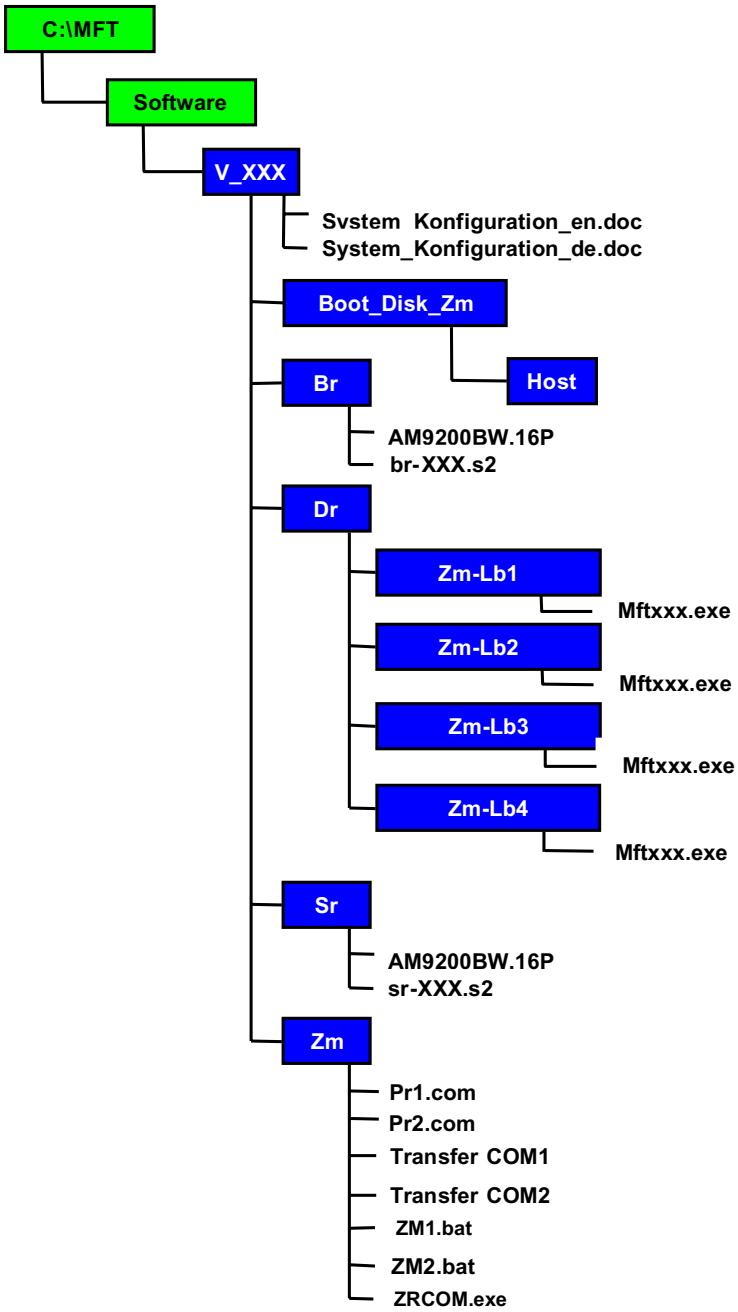
5.4 Programming the Processors

Directory tree

Path C:\MFT\Software must be created. The subordinate paths are created automatically.

The Word file "System_Configuration_**.doc“ contains information on the modifications of the respective software version.

Light (green) paths must be created
Dark (blue) paths are created automatically



5.4.1 Display Processor (DP)

Note

In case of an update of the display processor the preset system parameters will be lost. The have to be saved via the Service Software and then reinstalled on the display processor of the multiFiltrate.

After an update, the mDL parameters, the parameters for language, filtrate bag monitoring and heparin pump activation and the settings for Ci-Ca treatments must be checked and, if necessary, readjusted.

System requirements

PC with Service Software MFT M36 235 1

Procedure

– Via PC with Service Software MFT

5.4.2 Operating and Safety Processors (OP and SP)

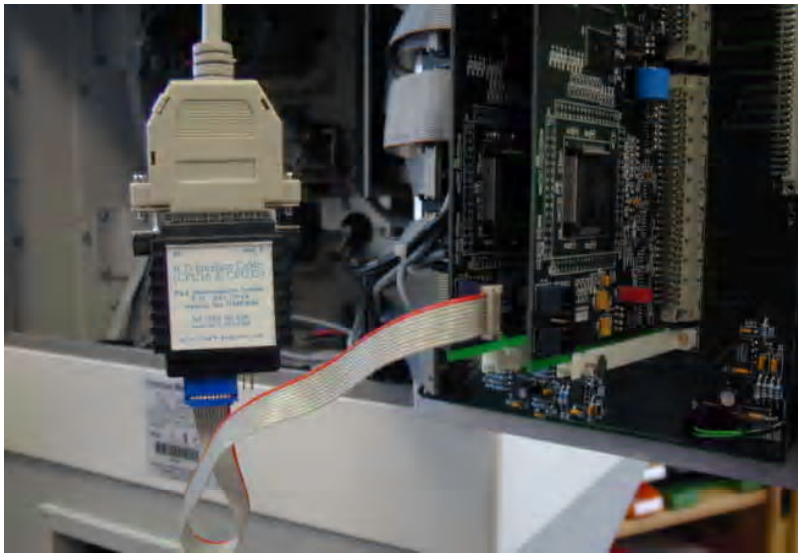
System requirements

PC/laptop with flash software **PROG16-68HC16 program**,
25-pin D-SUB interface cable (M28 488),
Use a dongle ICD cable (M28 489), if necessary a cross protection adapter; software for OP / SP is saved under the folder structure on the PC.

● **Preparation**

The system is disconnected from external power supply (on the rear).

– Open the rear wall of the system housing.



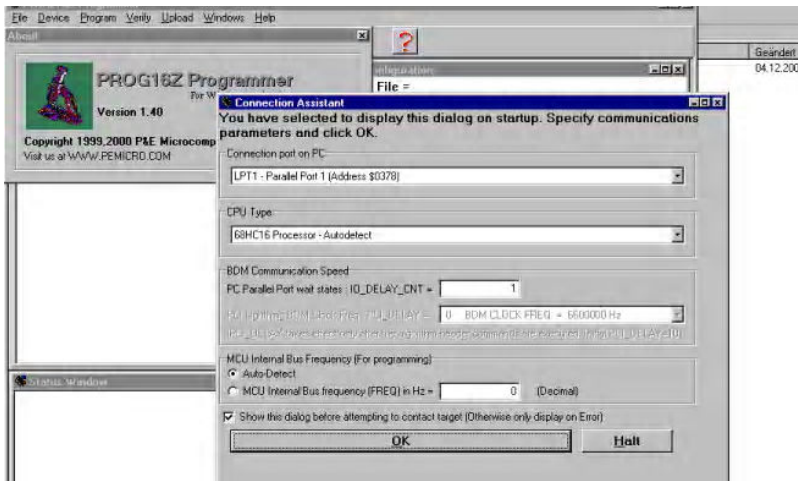
– Connect the interface cable to the parallel port (LPT1) of the PC and the other end to the dongle ICD cable. If necessary, use the cross protection adapter.
– Fit the 10-pin ribbon cable socket of the dongle onto the processor board to be programmed.

● **Procedure (identical for both OP and SP)**

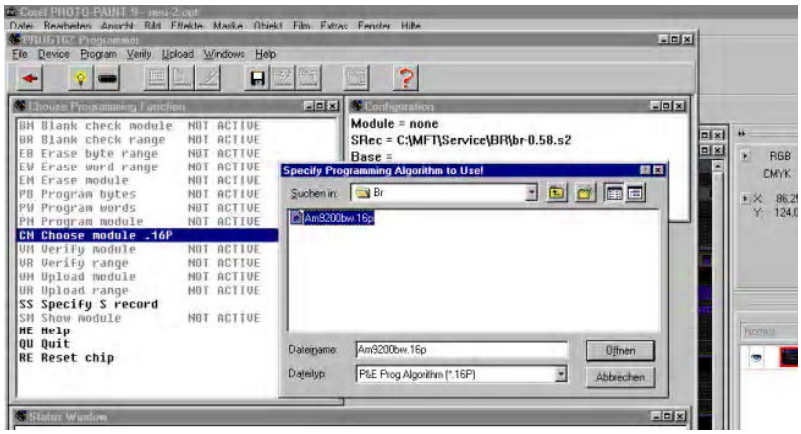
– Turn on the system using the power switch (on the rear).
– Start the **PROG16-68HC16 program** on the PC.

Note

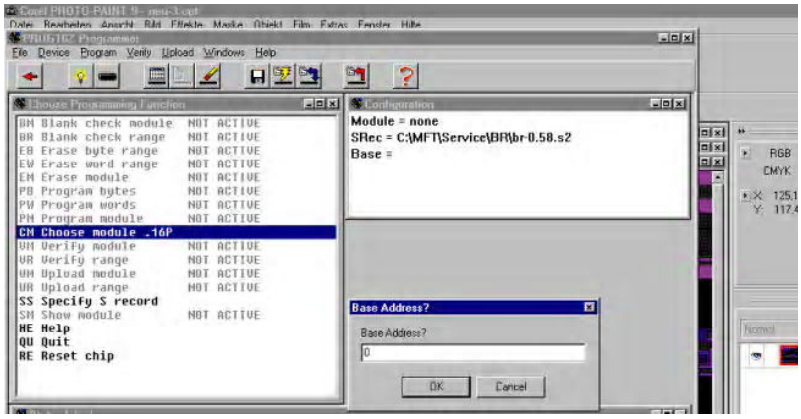
After having turned the multiFiltrate on, avoid waiting too long until starting the program because, otherwise, the battery will be loaded for an unnecessarily long period.



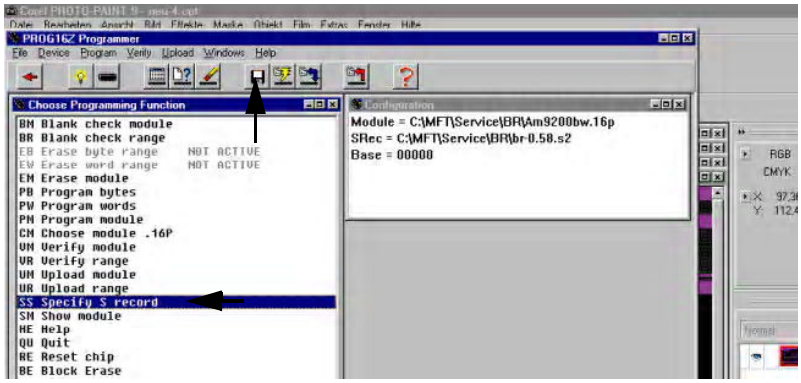
– Confirm the Connection Assistant with **OK**.



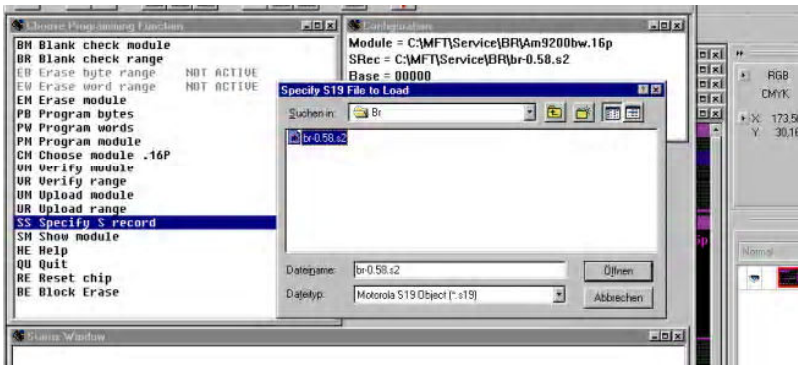
– Select the directory of the connected processor board (BR (OP) or SR (SP)), select the file **AM9200bw.16p** and click **Öffnen (Open)**.



– Enter **0** in the "Base Address?" window and click **OK**.



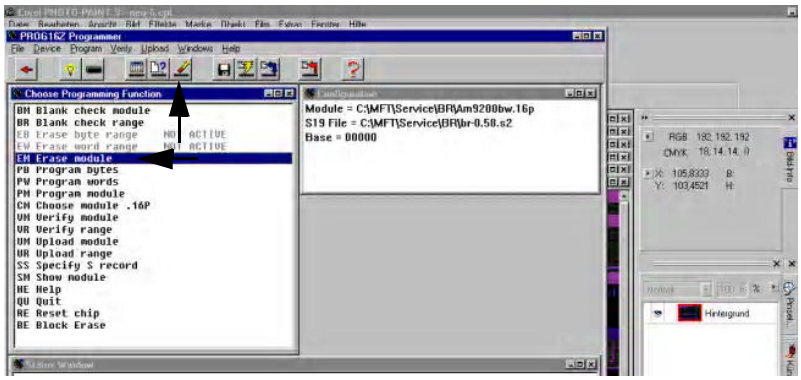
– Click the diskette symbol in the function bar or call up **SS Specify S record** by double-clicking the pertinent line in the left-hand window.



– Select the file name (e.g. sr-x.xx.s2) of the new software in the BR (OP) / SR (SP) directory, and confirm by pressing the **ENTER** key or clicking the **Öffnen (Open)** button.

Note

Enter the **"*.*"** file name and display the files by clicking the **Öffnen (Open)** button. Select the desired file using the cursor and apply it by pressing the **Enter** key or clicking the **Öffnen (Open)** button.



Erasing the Flash

– Click the **eraser symbol** in the function bar, or call up **EM Erase module** by double-clicking the pertinent line in the left-hand window.

The status window displays the process. Once the process is completed, the message **Module has been erased** is emitted.

Programming the Flash

– Click the **lightning symbol** in the function bar, or call up **PM Program module** by double-clicking the pertinent line in the left-hand window.

This process is displayed in the status window. The addresses are incremented **$xxxxx**. At the end of the program, **Programmed** is displayed.

– To exit the menu, click the **closing symbol (X)**, or select **FILE** and **Exit (ALT-X)** from the menu bar.

- **Completion**

  – Turn off the system using the power switch on the rear.
  – Remove the 10-pin ribbon cable socket of the dongle of the printed circuit board.

5.4.3 Interchangeability of Safety and Operating Processor

Safety and operating processor are electrically identical.

Although their software versions are having the same number (e. g. 1.51), they differ by the stored program code and by the saved data.

At the factory, the processors with the respective programming are identified by the labels "SR" (SP) and "BR" (OP).

Note

In exceptional cases an operating processor may be used as safety processor (or vice versa). The following must be observed:

- **Using an operating processor (OP) as a safety processor (SP)**

  – Erase the flash as described above and then program it using the "SR-x.xx.S2" software (SR = SP).
  – Check: Jumper J7 **must** be connected.
  – Turn off the system using the power switch.
  – Turn on the system using the power switch.
  – Press ESC and I/O to turn the system on (initialization).
  – Turn the system off after several seconds.
  – Turn the system on in the Service mode (I/O and Start).
  – Calibration of the blood leak detector.
  – Turn the system off after several seconds.

- **Using a safety processor (SP) as an operating processor (OP)**

  – Erase the flash as described above and then program it using the "BR-x.xx.S2" software (BR = OP).
  – Check: Jumper J7 must **not** be connected.
  – Turn off the system using the power switch.
  – Turn on the system using the power switch.
  – Press ESC and I/O to turn the system on (initialization).
  – Turn the system off after several seconds.
  – Turn the system on in the Service mode (I/O and Start).
  – Calibration of all pressures (TM 5.1.9)
  – Calibration and taring of all scales (TM 5.1.8)
    The correct weight will be displayed only after having saved "5 kg".
  – Enter date, time, serial number and EC-code.

- **As a rule, the following steps then have to be performed:**

  – T1 test
  – selection of a new treatment mode (once).
  – correct identification on the printed circuit board (BR (OP) or SR (SP)).

5.5 Ci-Ca Module (Option)

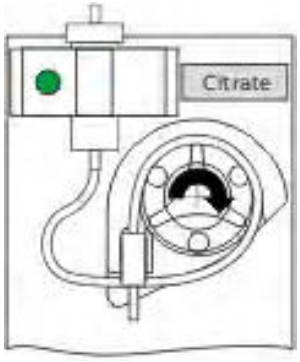
Note

In case of a failure of the Ci-Ca module, the entire module is replaced. The module is not directly repaired on site.

5.5.1 Preparing the Functional Test

The functional test of the components of the Ci-Ca module is performed in the treatment mode of the basic system.

– Turn the system on in the treatment mode.
– Start the functional test.
– Turn on the Ci-Ca anticoagulation.
– Select the CVVHD treatment mode.
– Put a 5 kg weight on the scale 1 or 2.
– Insert a filled dummy in the air detector.

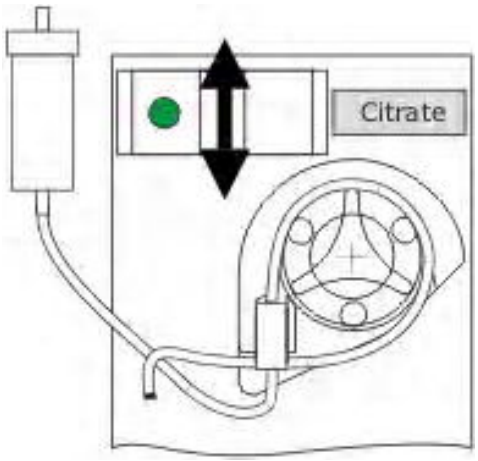


– Insert a shunted pump tube segment with drip chamber into the citrate and calcium pump.

– Use the rotary selector to select **Set up? [OK] to confirm!** and press **[OK]**.
– Use the rotary selector to select all messages during preparation (status line is blue) up to the message **Start connection? [OK] to confirm!** and confirm them by pressing **[OK]**.
– Establish an alarm-free condition of the venous pressure transducer and have the optical detector sense opaque.
– Use the rotary selector to select **Start treatment? [OK] to confirm!** and press **[OK]**.

5.5.2 Functional Test of the Drip Counter

The functional tests of the citrate and the calcium drip counter are performed analogously.



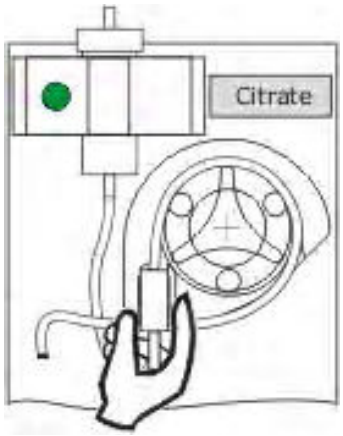
- Remove the drip chamber from the respective drip counter.
- Move one finger or a pen quickly to and fro through the optical sensor of the drip counter.
- Check the result.
- Confirm the drip counter alarm.
- Repeat the test.
- Record the result.

5.5.3 Functional Test of the Hall Sensor

The functional test of the citrate and the calcium pump is successfully passed if the simulated treatment is completed without any alarm. If both pumps perform several revolutions without alarm it can be assumed that both pumps and their Hall sensors are in full working order.

5.5.4 Functional Test of the Insertion Switch

The functional tests of the insertion switches of the citrate and the calcium pump are performed analogously.



Remove the tubing segment from the pump which is to be tested so that the insertion switch is released.

Check the result:

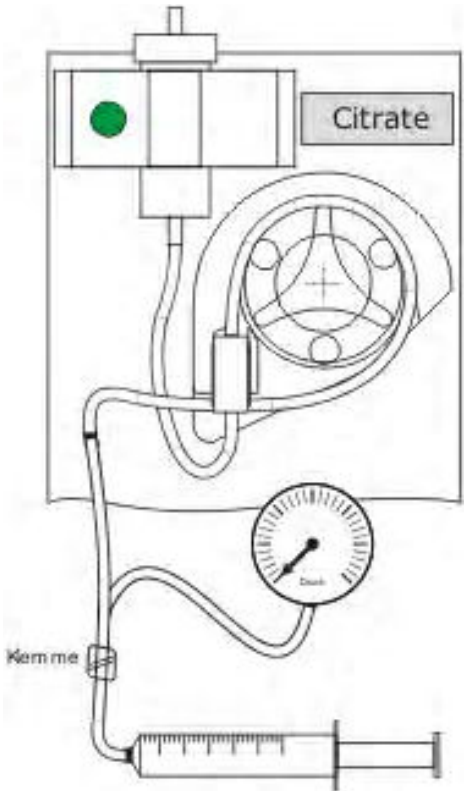
- the respective pump stops immediately
- an appropriate alarm appears on the display of the multiFiltrate

Repeat the test

Record the result

5.5.5 Functional Test of the Line Occlusion

The functional tests of the line occlusion of the citrate and the calcium pump are performed analogously. The test is performed while the system is turned off.



Fully insert the test line segment and manually turn the pump so that one roll entirely occludes the line segment.

Connect the outlet of the line segment via a Y-piece to the pressure measuring device and the syringe.

Apply a pressure of 520 ± 10 mmHg to the outlet and close the clamp.

Pressure loss within 1 min: max. 10 mmHg

Relieve the pressure and turn the rotor so that the next roll of the rotor fully occludes the line segment (approx. 1/3 revolution) and repeat the steps 3 and 4.

Relieve the pressure and turn the rotor so that the last roll of the rotor fully occludes the line segment (approx. 1/3 revolution) and repeat the steps 3 and 4.

Relieve the pressure and record the result.

6 PC Service Software MFT

6.1 Organization of the Quick Guide

Editorial information

The Quick Guide is available as a separate document. It is subject to an own updating cycle and is revised independently from the Technical Manual. It may be enclosed to chapter 6.

6.2 General Information

Caution

After each transmission of data from the service program to the dialysis system, the operator of the service program must check the data at the dialysis system for plausibility. The operator himself or herself is responsible for the correctness of the data.

Caution

After each transmission of data from the service program to the dialysis system, the dialysis system must be switched off and on again before a patient treatment is started.

Caution

This service program is only intended for service purposes. Ensure that the interface cable to the PC is not connected during patient treatment.

6.3 Preparation

6.3.1 System Requirements

- PC with at least 10 MByte of free hard disk space
- Microsoft Windows 98, ME, 2000 or XP
- 32 MByte RAM
- 1 CD-ROM drive
- 1 free USB port (for SmartCardReader)
- 1 free RS232 interface (for communication with the Multifiltrate)

6.3.2 Software Installation

Caution Install the SmartCardReader drivers before connecting the SmartCardReader to the PC!
These will be installed when the PC Service Software Multifiltrate is installed.

Caution

When installing the software an older PC Service Software 4008 version already installed will automatically be uninstalled.

To retain an existing version of the service software, start the installation with "setup.exe /noremove". In this case, select an installation path differing from the path of the previous installation to avoid overwriting.

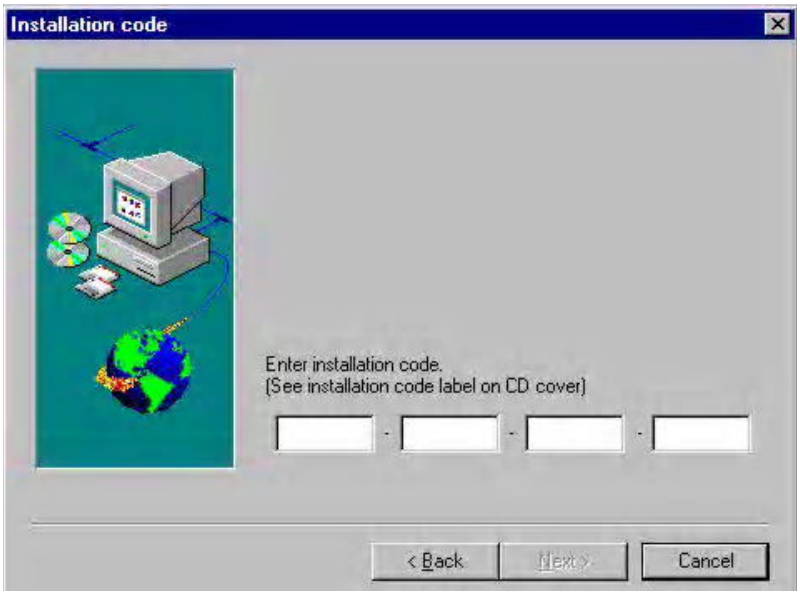
Caution

For Windows NT, 2000, or XP, you must have administrator's rights to install the PC Service Software MFT.

Procedure

– Start Windows on the computer.
– Insert the installation CD into the CD-ROM drive.

If the setup does not start automatically:
– start the Windows Explorer.
– start Setup.exe from the CD-ROM drive.



– In the Setup dialog Installation Code screen, enter the installation code printed on the CD cover.

When installing the SmartCard Reader driver under Windows XP a message may be displayed informing you that the drivers failed to pass the Windows Logo test.

– The software will be installed after clicking the "Continue Anyway" button and then the "Finish" button.

The software installation is complete.

6.3.3 Hardware Installation

Connect the PC and the Multifiltrate via the supplied interface cable.

Caution

This is not a standard cable. It is therefore imperative to use the enclosed interface cable.

Caution

Install the SmartCardReader drivers before connecting the SmartCardReader to the PC!

These will be installed when the PC Service Software Multifiltrate is installed.

Connect the SmartCard Reader to a vacant USB port.

6.3.4 ServiceCard Description

The use of the PC Service Software Multifiltrate requires an appropriate authorization. The PC Service Software Multifiltrate and the respective ServiceCard will check your authorization.

The ServiceCard is read out via the SmartCard Reader.
– Connect the SmartCard Reader to a vacant USB port.
– Insert the ServiceCard into the SmartCard Reader.

The ServiceCard will be checked when starting the application and while working with the software. If the card is not inserted or if it is removed, an error message will be displayed.

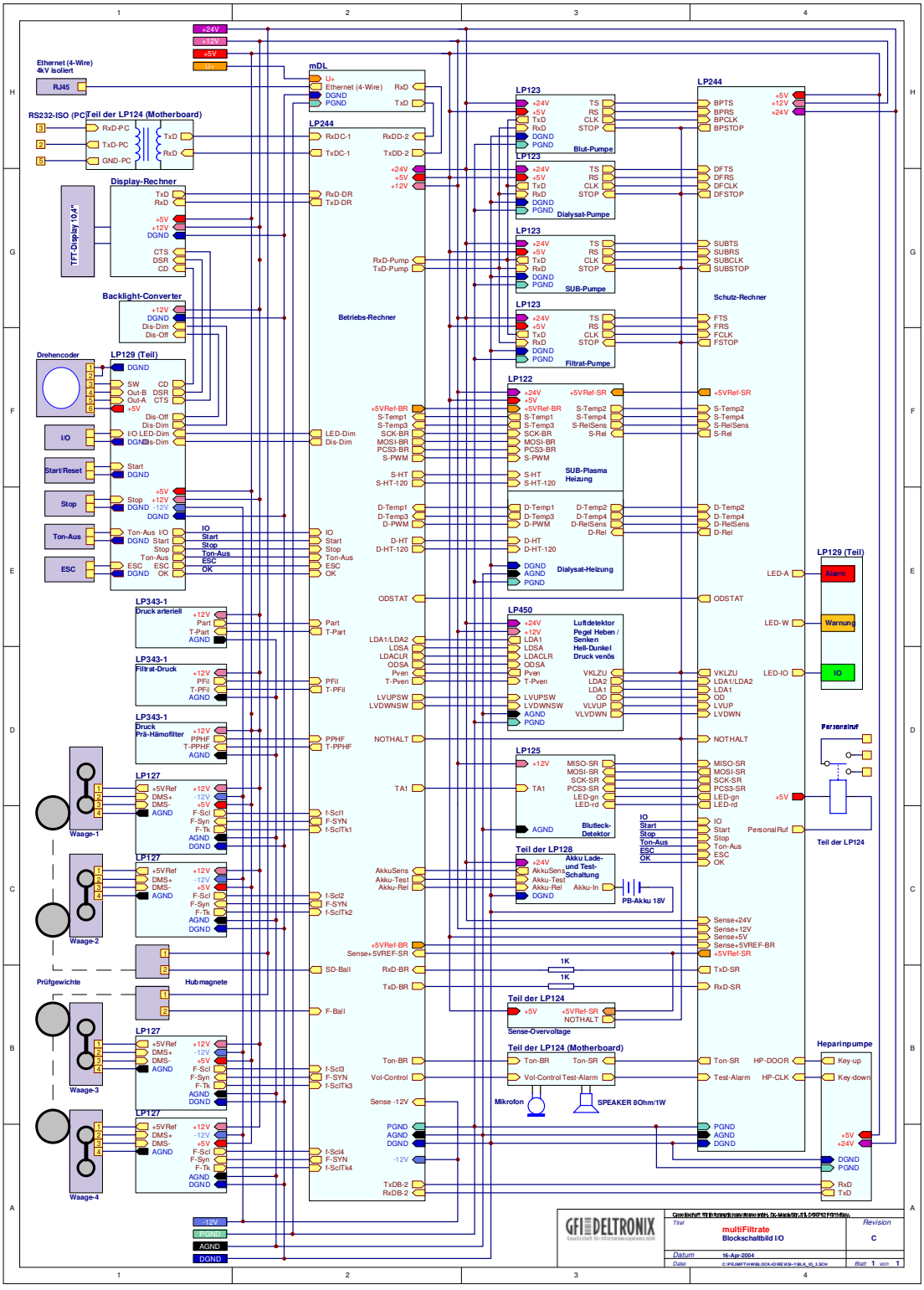
Since the authorization is limited to a specific period of time, the expiration date of the ServiceCard is checked by an operating time monitoring function. Once this date is exceeded, the PC Service Software Multifiltrate can no longer be accessed. In this case, the expiration date must be adapted by an authorized body.

6.3.5 Starting the Software

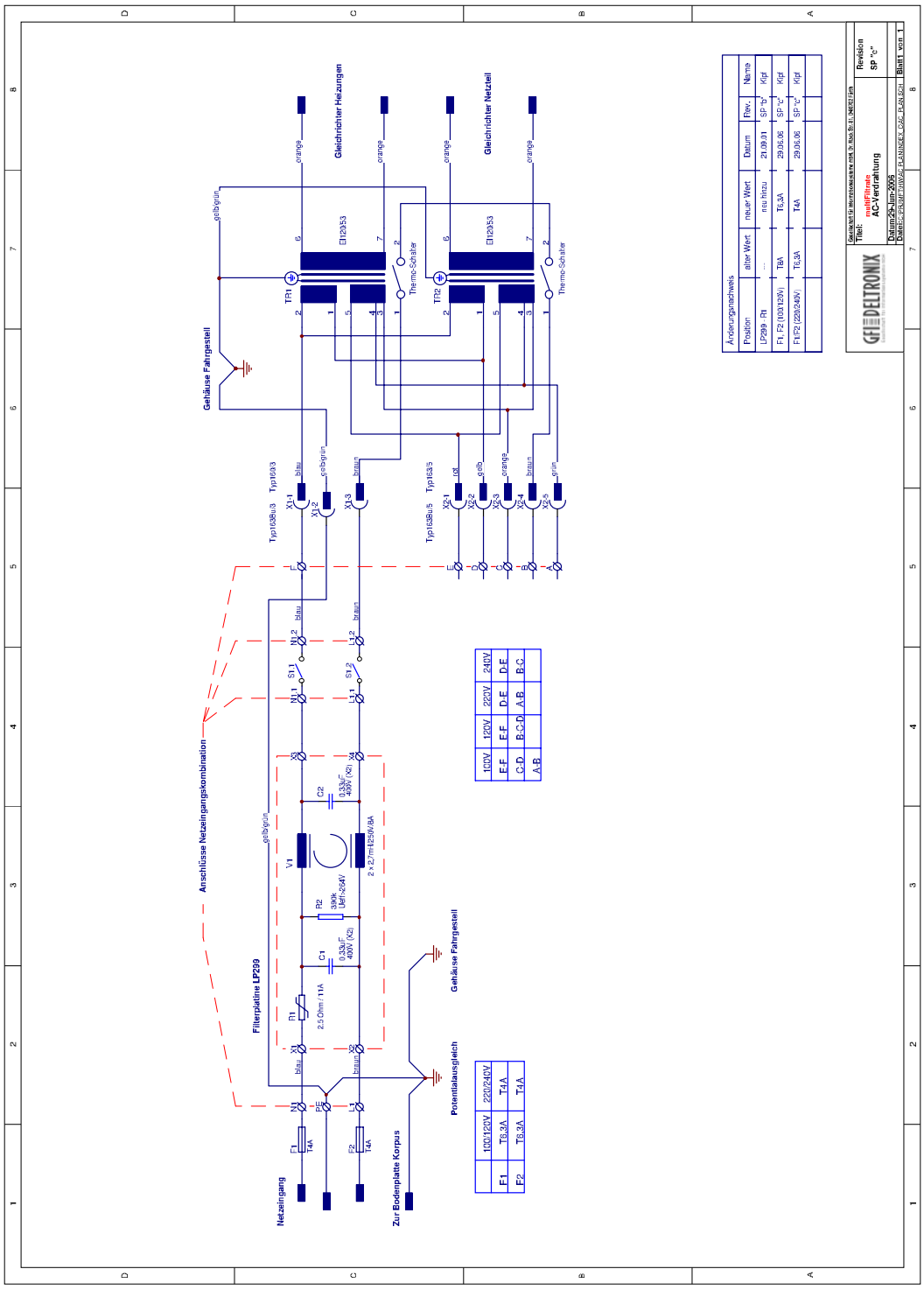
The software can be started by selecting Start->All Programs->Fresenius->Service MFT->Service MFT.

7 Block Diagrams and Component Layouts

7.1 Block Diagram

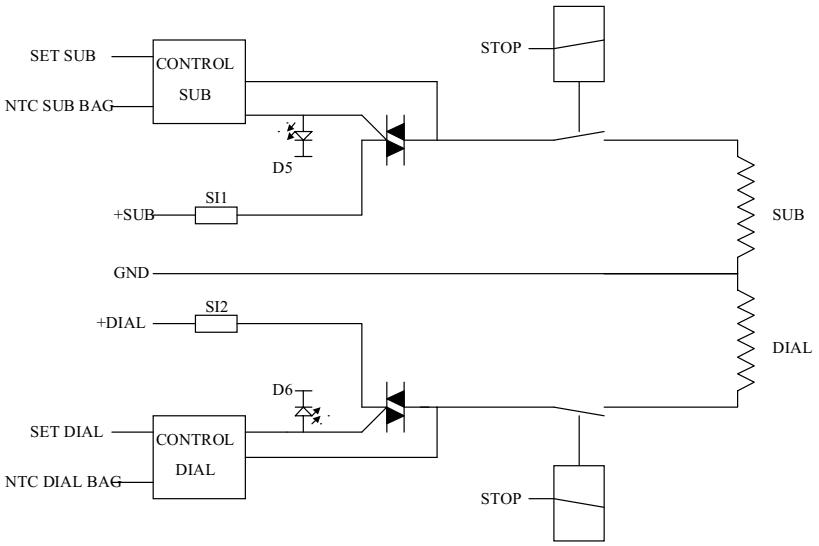


7.2 AC Wiring


Gleichrichter Heizungen
Gleichrichter Netzteil
Gehäuse Fahrgestell
Anschlüsse Netzeingangskombination
Filterplatine LP239
Netzeingang
Potentialausgleich
Zur Bodenplatte Korpus
Thermo-Schalter
Änderungsnachweis
Position
alter Wert
neuer Wert
Datum
Rev.
Name
multiFiltrate
AC-Verdrahtung
Revision
SP "c"
Datum 29-Jun-2006
Blatt 1 von 1

7.3 P.C.B. LP 122 Heater Control

7.3.1 Block Diagram

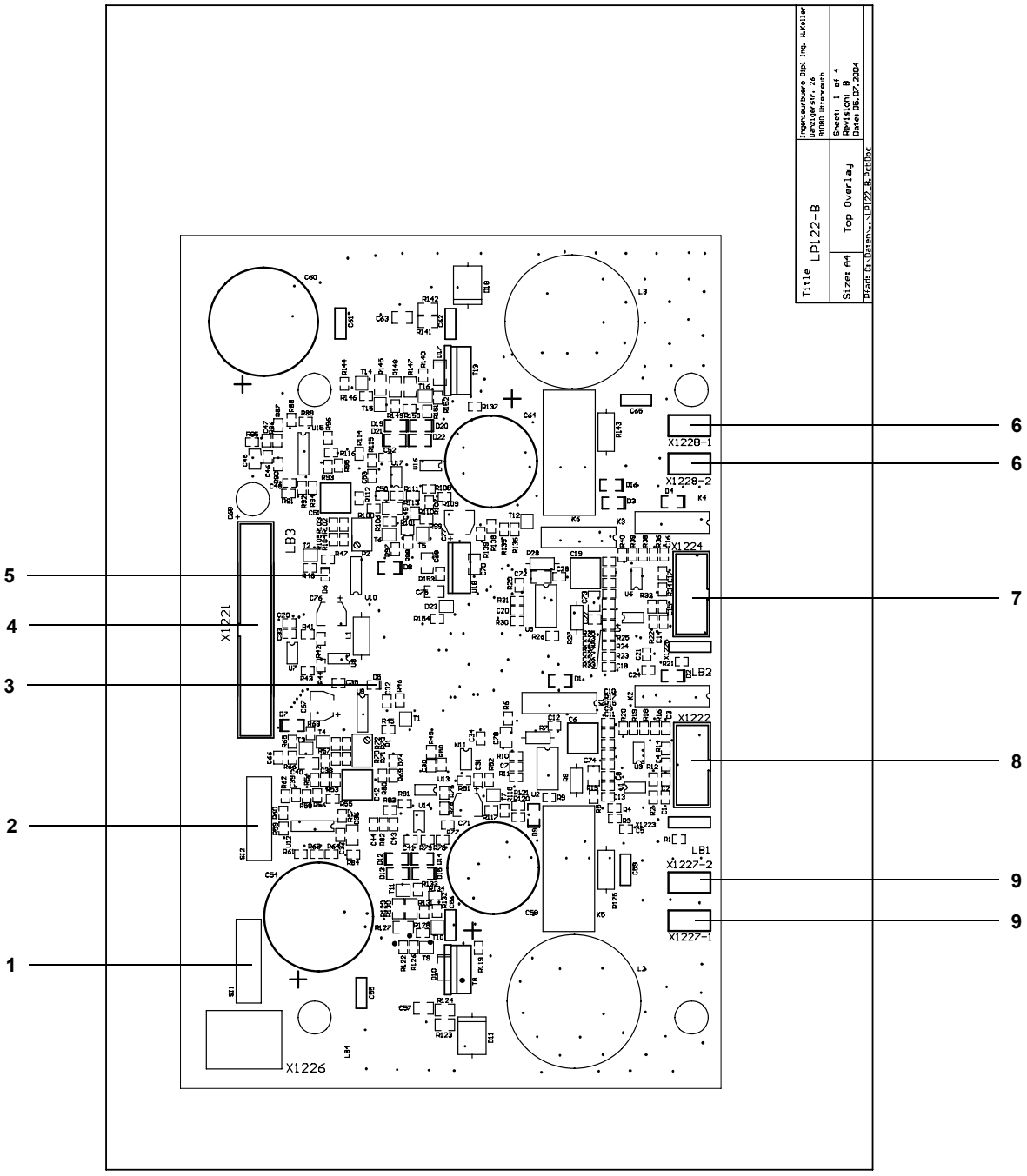


7.3.2 Description

- **Assignment of position numbers**

Pos. No.	Description	Pos. No.	Description
1	SI 1 Substituate heater 10 A	6	To dialysate heater
2	SI 2 Dialysate heater 10 A	7	From dialysate temperature sensors
3	LED D5 control pulse of substituate heater	8	From substituate temperature sensors
4	To motherboard P.C.B. LP 124	9	To substituate heater
5	LED D6 control signal of dialysate heater		

7.3.3 Component Layout



7.4 P.C.B. LP 123 Pump Control

7.4.1 Description

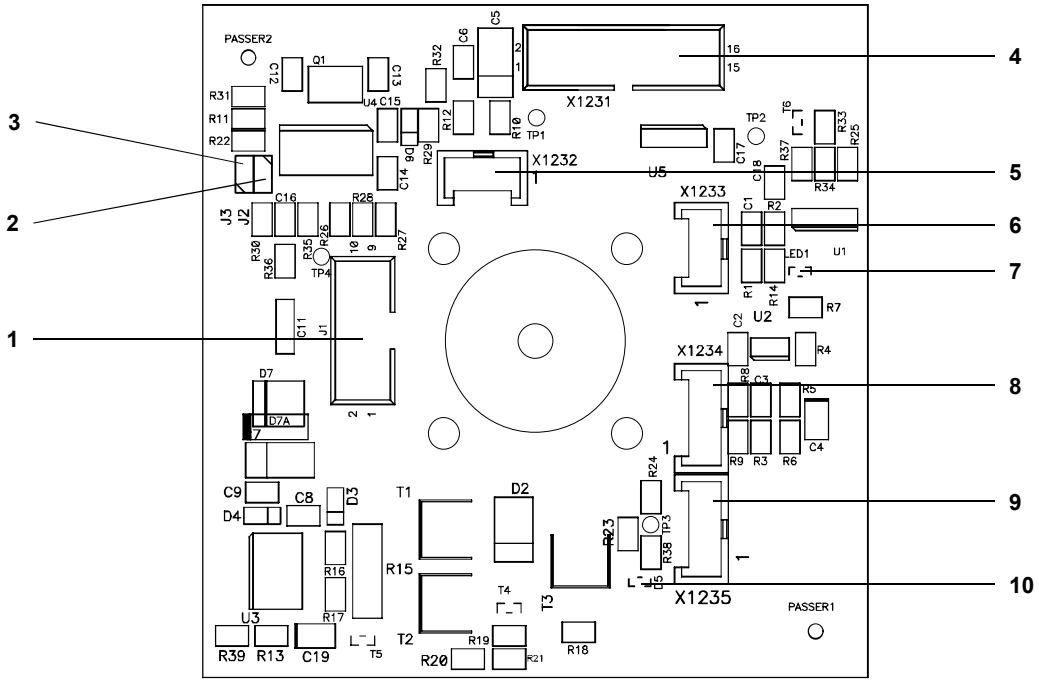
- **Pump coding**

J2 (ADR-H)	J3 (ADR-L)	Address	Pump coding
Closed	Closed	0	Blood pump
Closed	open	1	Filtrate pump
open	Closed	2	Substituate pump
open	open	3	Dialysate pump

- **Assignment of position numbers**

Pos. No.	Description	Pos. No.	Description
1	Not assigned	6	Reed contact rotor
2	Jumper J2	7	LED1 threading position
3	Jumper J3	8	Motor speed
4	To motherboard P.C.B. LP 124	9	+/- Motor
5	Door switch (Hall sensor)	10	LED5 operating voltage

7.4.2 Component Layout



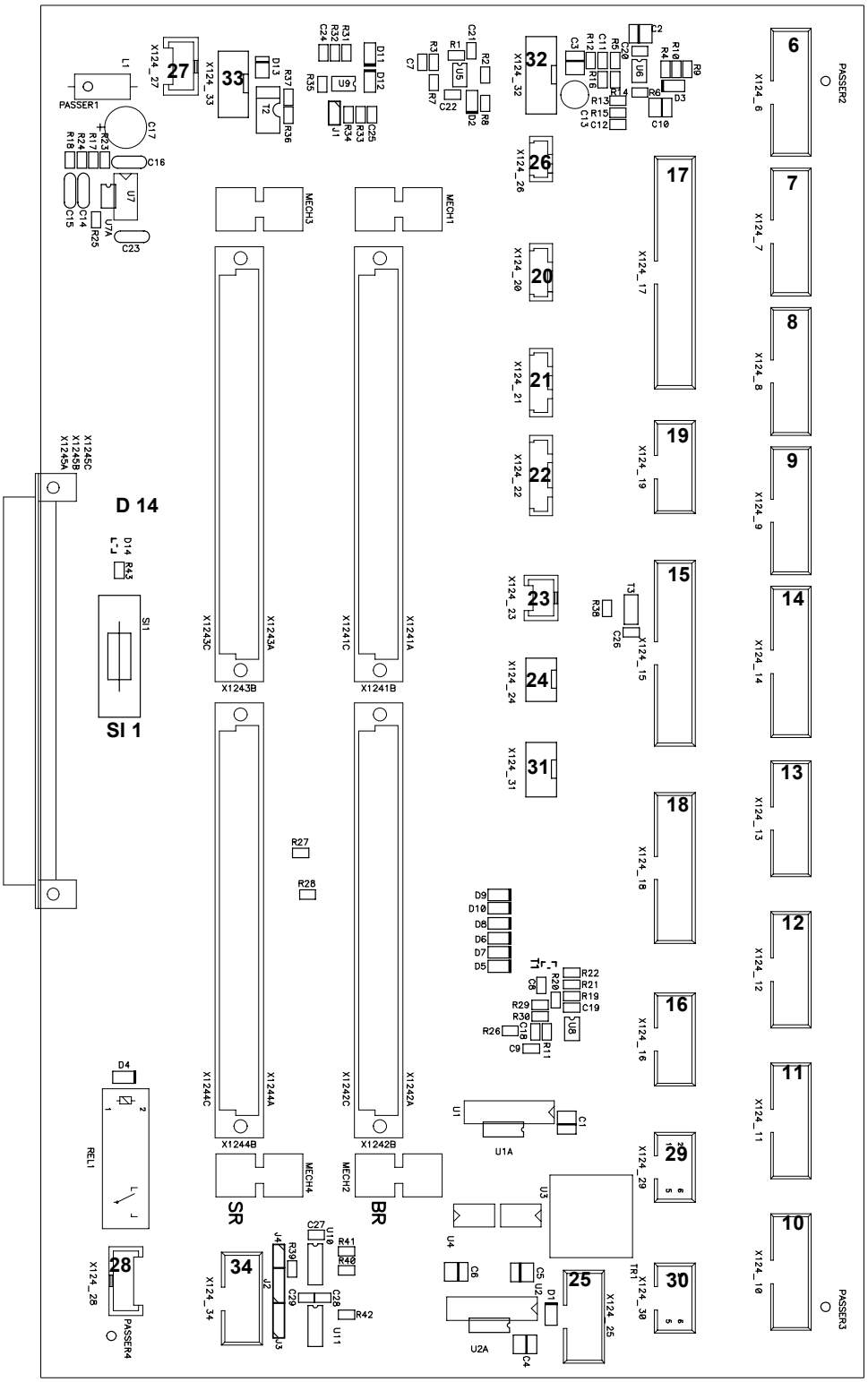
7.5 P.C.B. LP 124 Motherboard

7.5.1 Description

- **Assignment of position numbers**

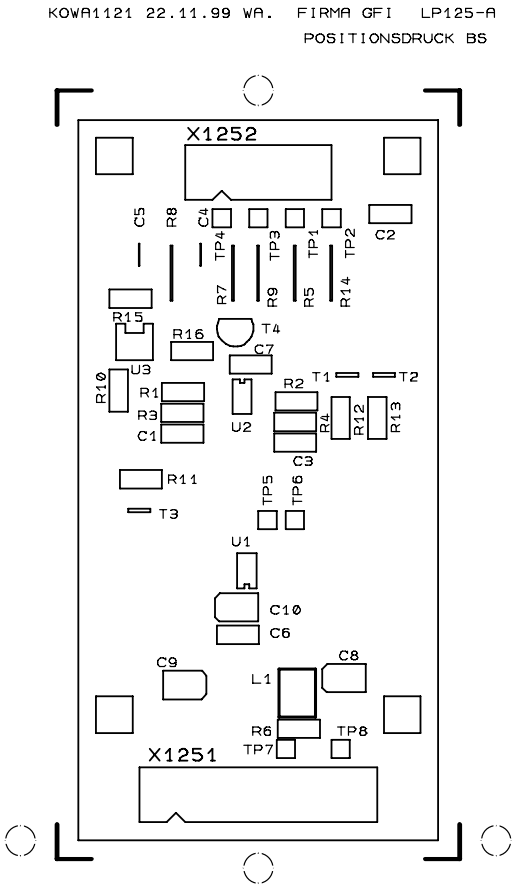
Pos. No.	Description	Pos. No.	Description
6	Blood pump	21	Filtrate pressure
7	Filtrate pump	22	PHF pressure
8	Substituate pump	23	Lifting magnets I/II
9	Dialysate pump	24	Lifting magnets III/IV
10	Scale I	29	mDI
11	Scales II	30	mDI
12	Scales III	31	Fan
13	Scales IV	32	n.c.
14	User interface	33	n.c.
15	Air detector	34	CiCa module
16	Display processor		
17	Heater P.C.B. LP 122B		
18	Blood leak detector		
19	Heparin pump	SI 1	1 A fuse, CiCa module supply voltage
20	Arterial pressure	D 14	CiCa module supply voltage LED

7.5.2 Component Layout



7.6 P.C.B. LP 125 Blood Leak Detector

7.6.1 Component Layout



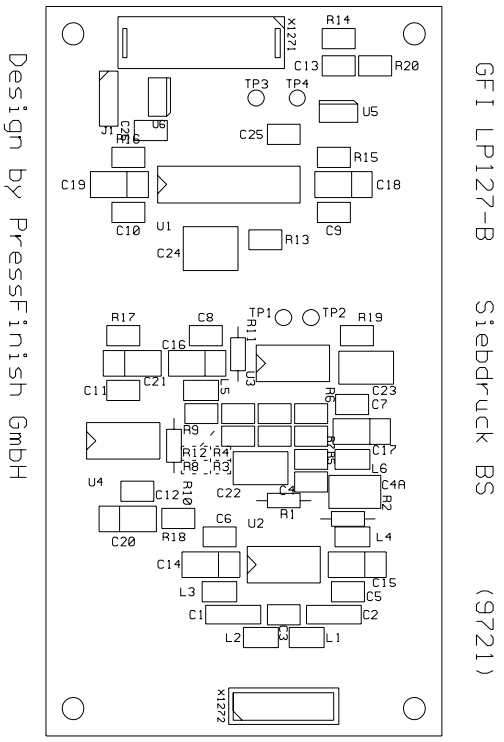
7.7 P.C.B. LP 127 Scales Board

7.7.1 Description

The EEPROM used for storage is provided with a synchronous serial interface (SPI interface). By means of the jumper J1 in position 1-2, the EEPROM can be protected from being overwritten inadvertently.

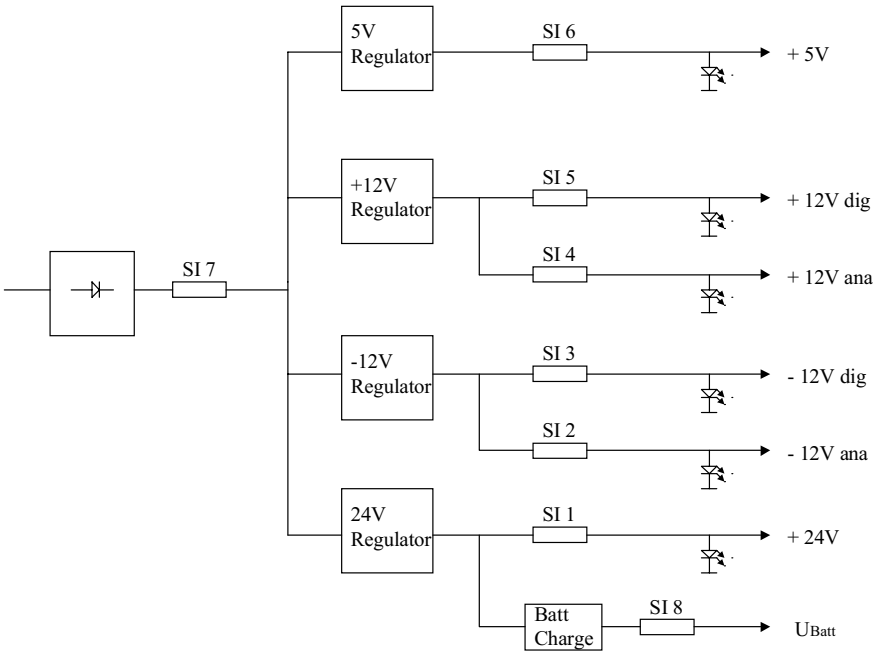
Jumper	Position	Function
J1	1-2	EEPROM write protection
	2-3	EEPROM write enable

7.7.2 Component Layout



7.8 P.C.B. LP 128, Power Supply Unit

7.8.1 Block Diagram

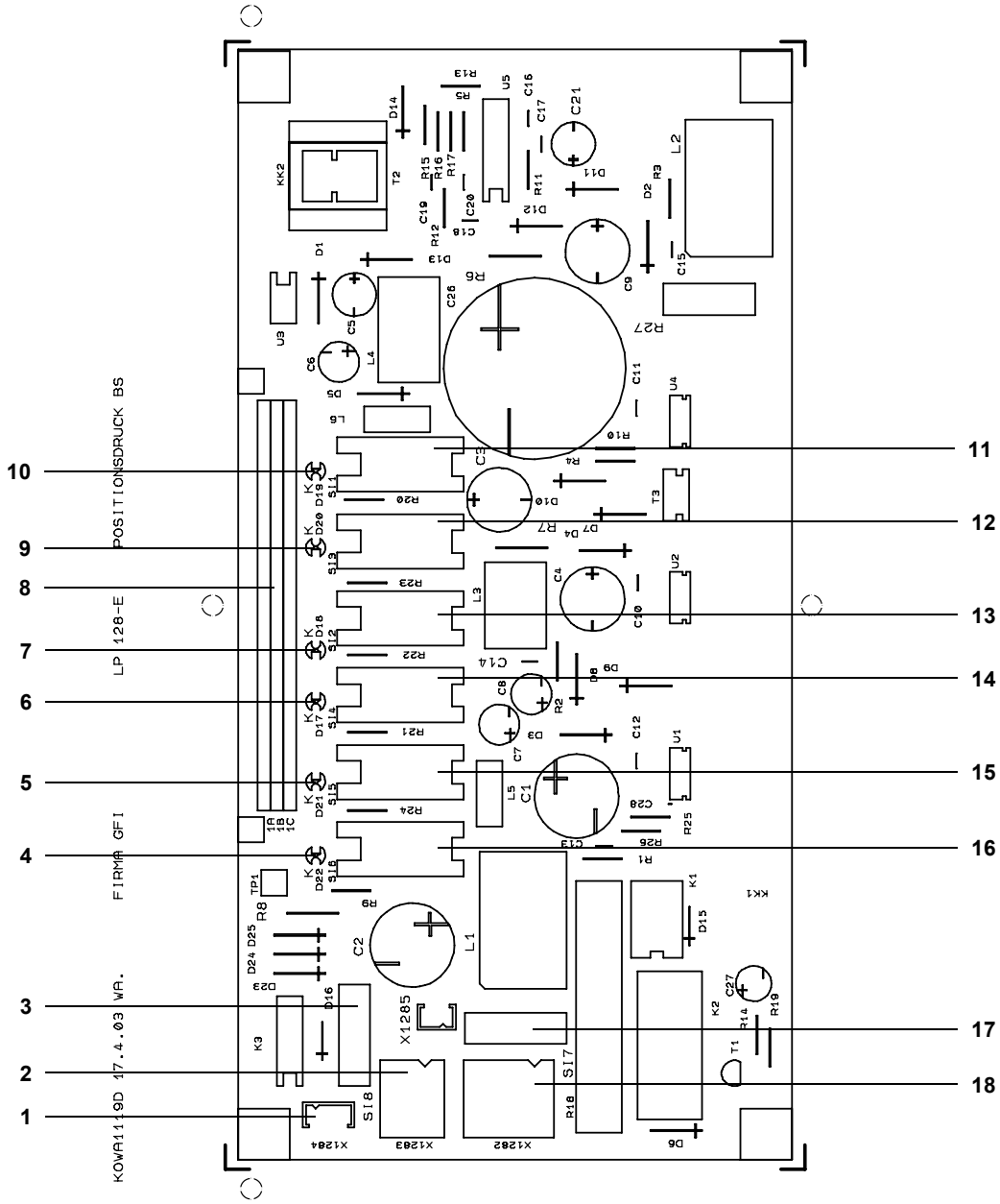


7.8.2 Description

- **Fuse arrangement**

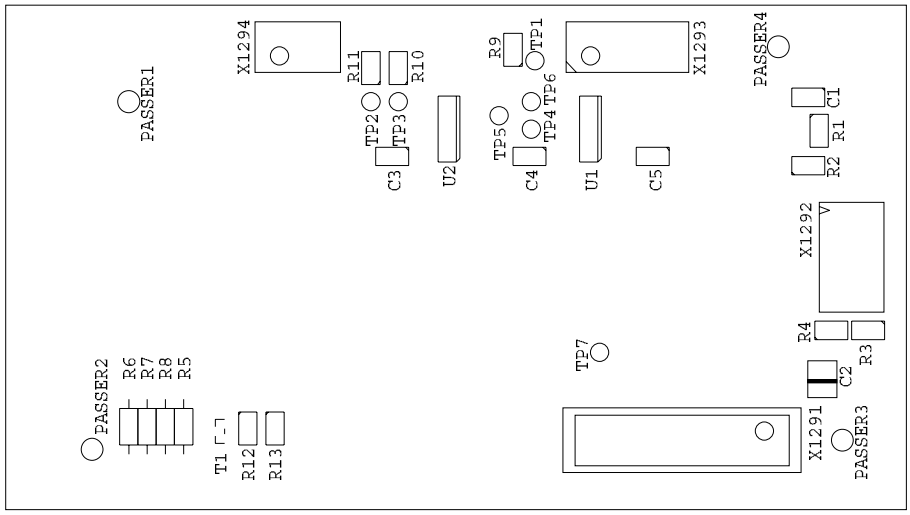
Pos. No.	Description	Pos. No.	Description
1	P Fail	10	LED D19 (SI 1)
2	Battery	11	SI 1 (3.15 A / +24 V)
3	SI 8 (5 A)	12	SI 3 (100 mA / -12 V)
4	LED D22 (SI 6)	13	SI 2 (100 mA / -12 V)
5	LED D21 (SI 5)	14	SI 4 (315 mA / +12 V)
6	LED D17 (SI 4)	15	SI 5 (1.6 A / +12 V)
7	LED D18 (SI 2)	16	SI 16 (1.6 A / +5 V)
8	P.C.B. LP 124	17	SI 7 (10 A)
9	LED D20 (SI 3)	18	32 V DC

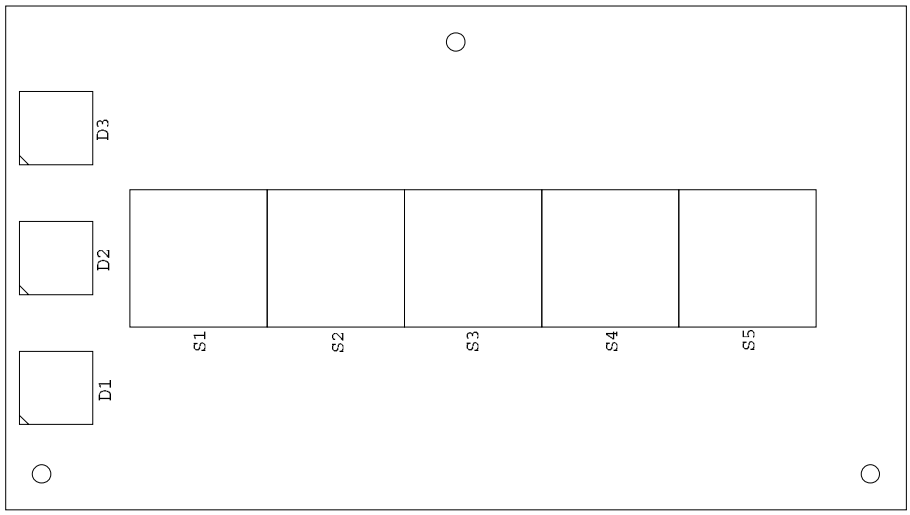
7.8.3 Component Layout



7.9 P.C.B. LP 129 User Interface

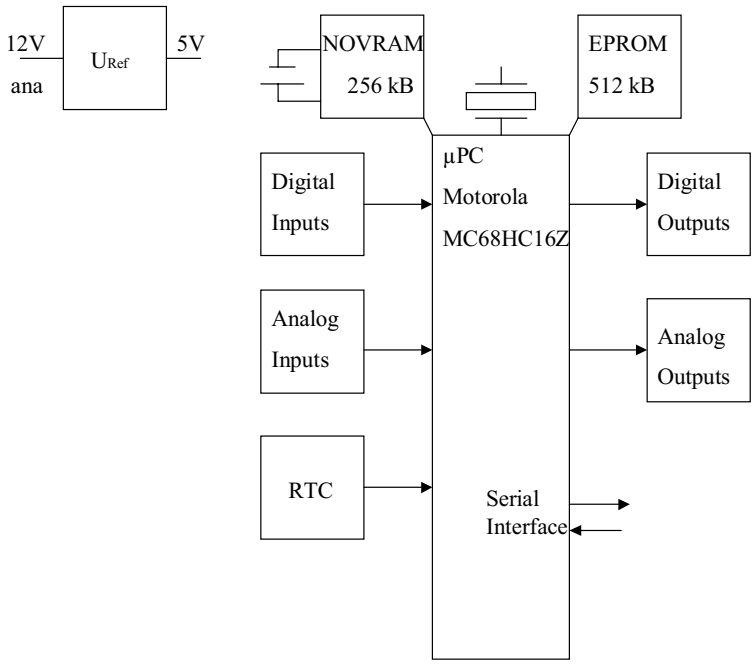
7.9.1 Component Layout





7.10 P.C.B. LP 244 Operating and Safety Processors

7.10.1 Block Diagram



7.10.2 Jumper Description

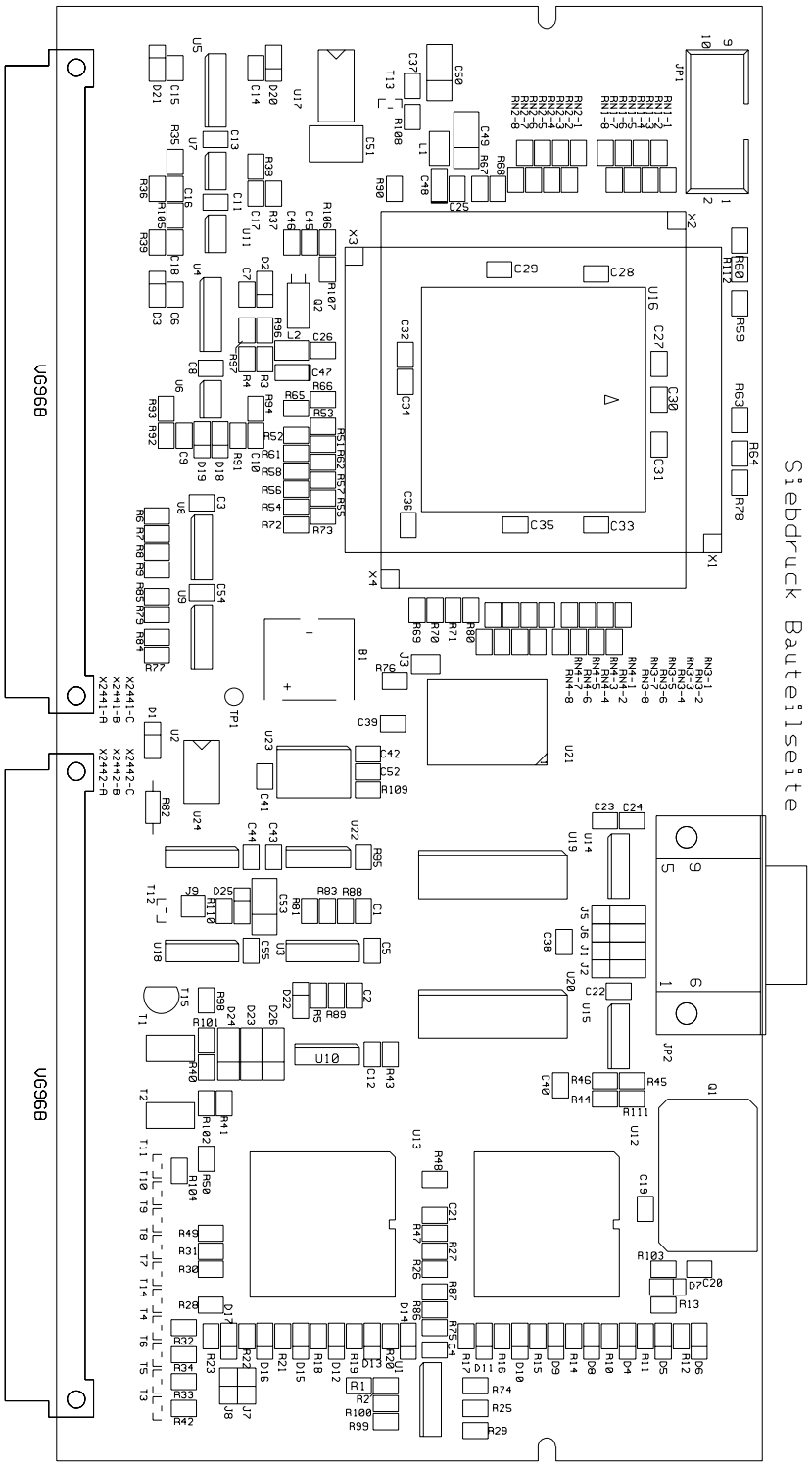
Note

Jumpers are intended for developing purposes only. Do not make any changes!

Jumper	Position	Function
J1	1-2	Listening to U12, Rx channel B (1)
	2-3	Listening to U12, Rx channel A (2)
J2	1-2	Listening to U12, Tx channel B (1)
	2-3	Listening to U12, Tx channel A (2)
		(1)If the P.C.B. LP 244 acts as operating processor, the communication with the corresponding safety processor can be listened to, with the jumpers in this position. (2)If the P.C.B. LP 244 acts as operating processor, the communication with the pump processor can be listened to, with the jumpers in this position.

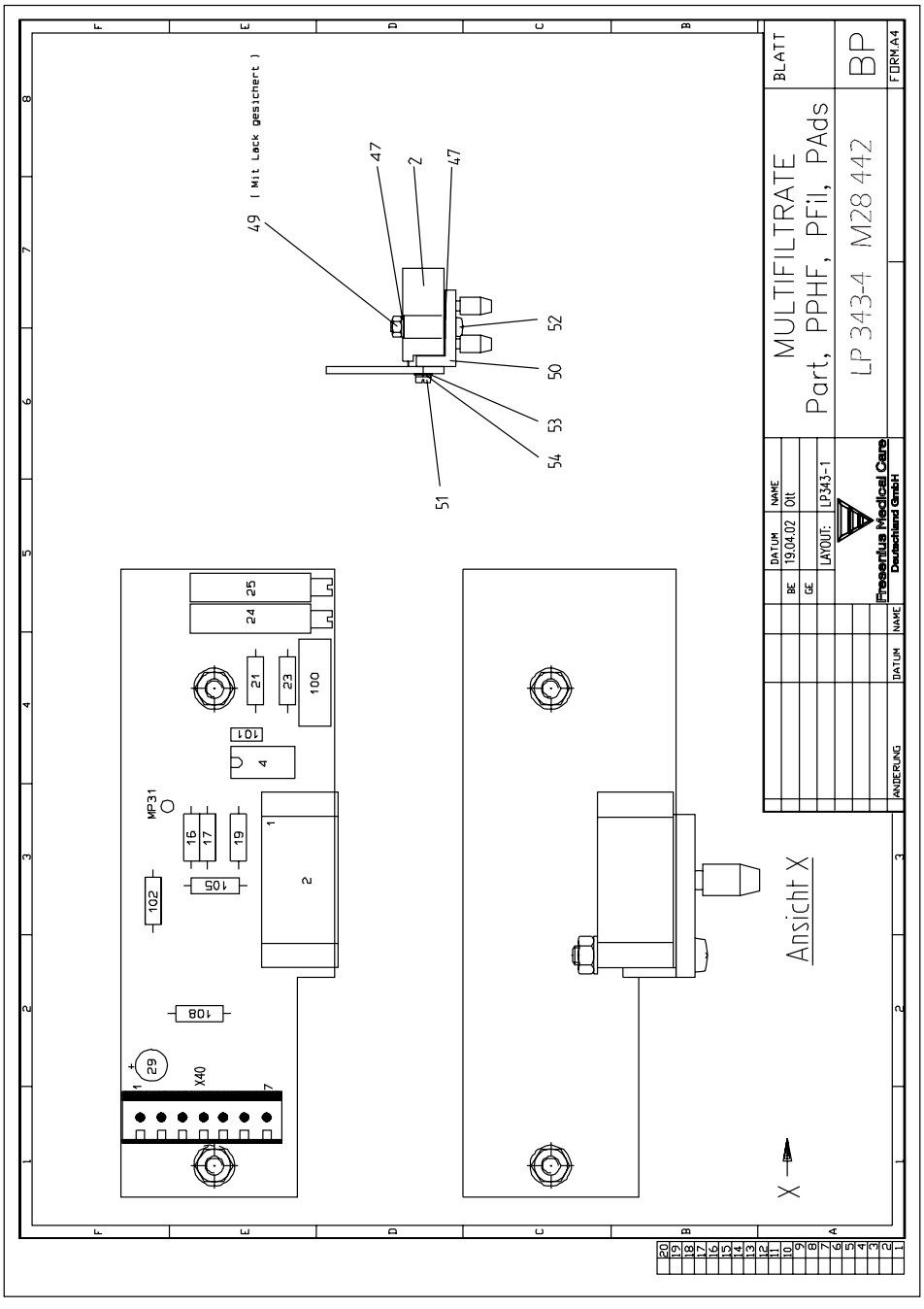
Jumper	Position	Function
J3-4	open	Flash EPROM deactivated
	Closed	Flash EPROM activated (default)
J5	1	Listening to U12, Tx channel A/B, see J2, V.24 level
	2	GND
	3	Listening to U12, Rx channel A/B, see J1, V.24 level
J6	1	Listening to display processor, see (2), V.24 level
	2	GND
	3	Listening to display processor, see (2), V.24 level
J7	1-2	Jumper connected at SP
J8	1-2	Jumper, not used at present
J9-10	open	Watchdog NMI deactivated
	Closed	Watchdog NMI activated

7.10.3 Component Layout



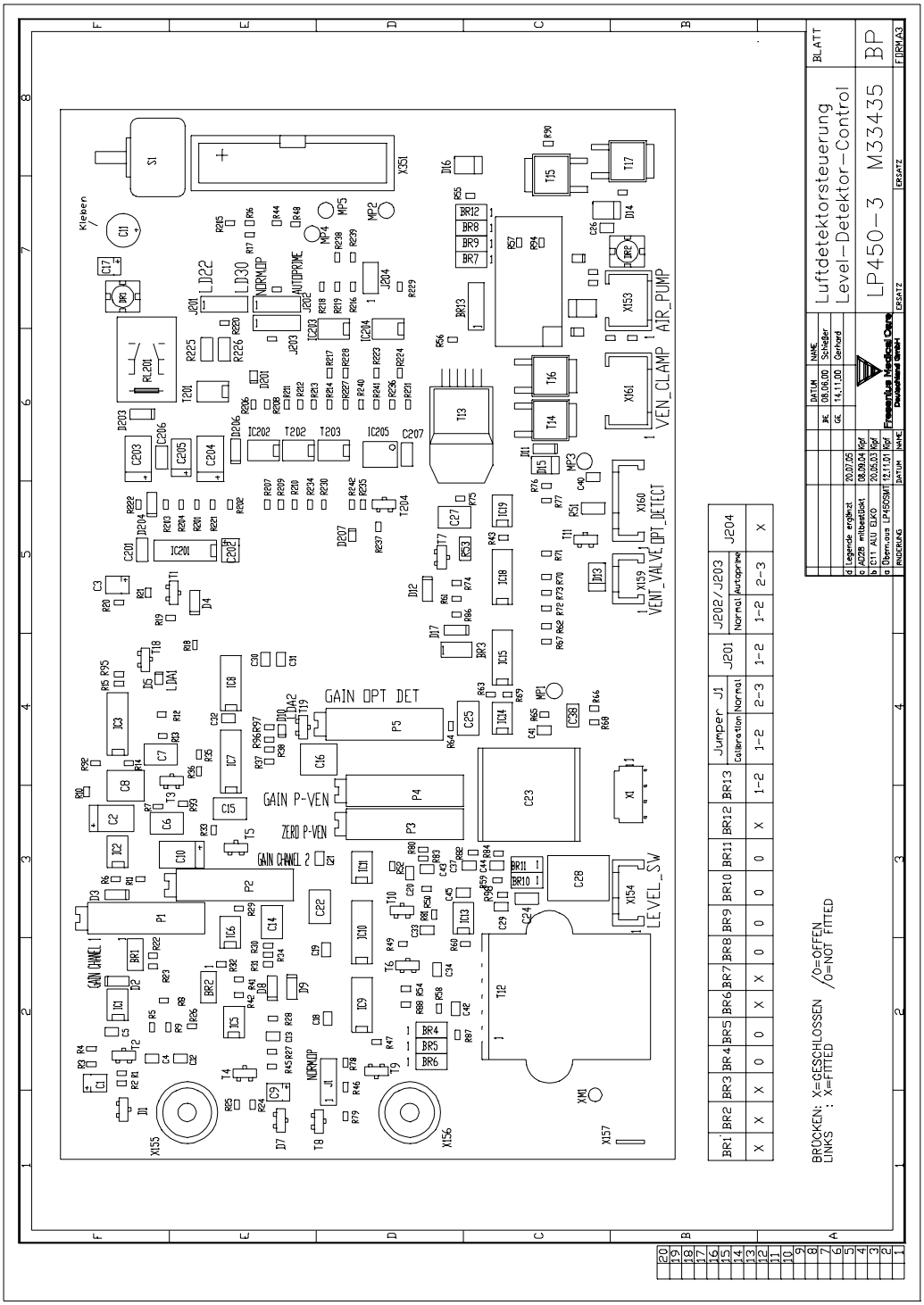
7.11 P.C.B LP 343-4 Pressure Transducer

7.11.1 Component Layout



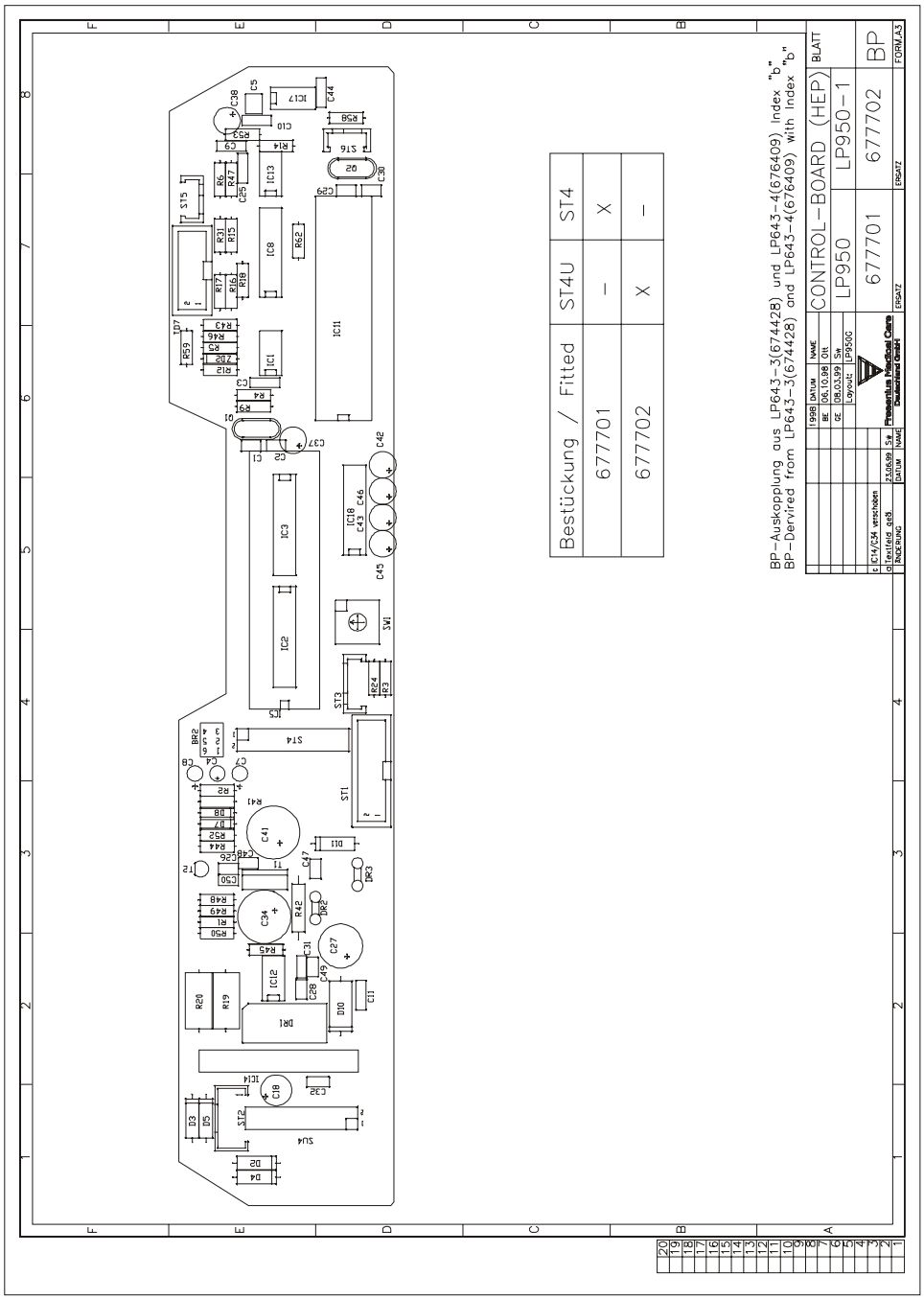
7.12 P.C.B. LP 450-3 multiFiltrate Air Detector Control

7.12.1 Component Layout



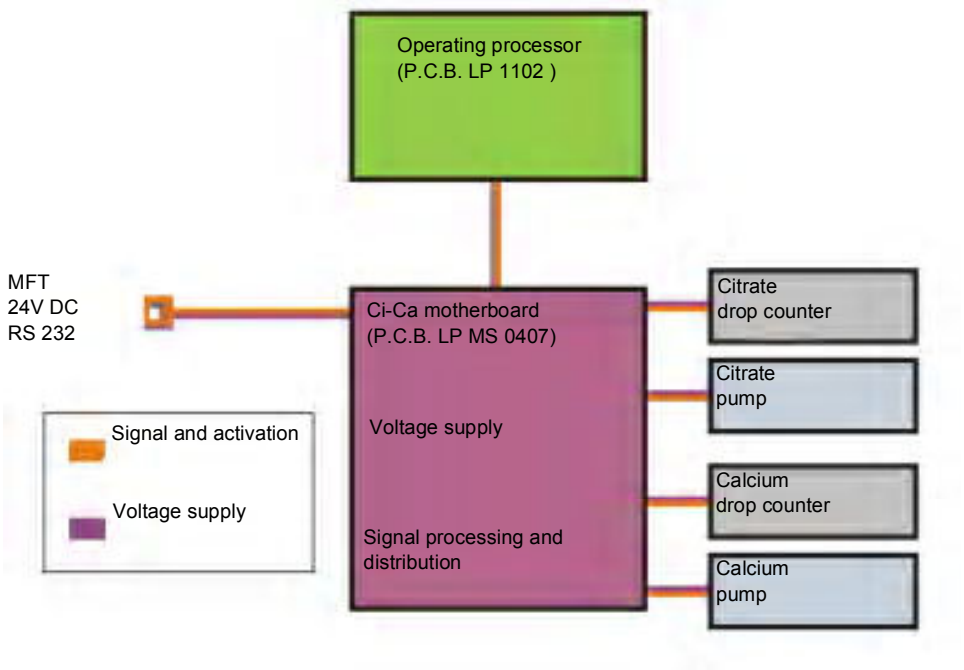
7.13 P.C.B. LP 950, Control Board (Heparin Pump)

7.13.1 Component Layout



7.14 Ci-Ca Module

7.14.1 Block Diagram



7.14.2 Component Layout (P.C.B. LP MS 0407)