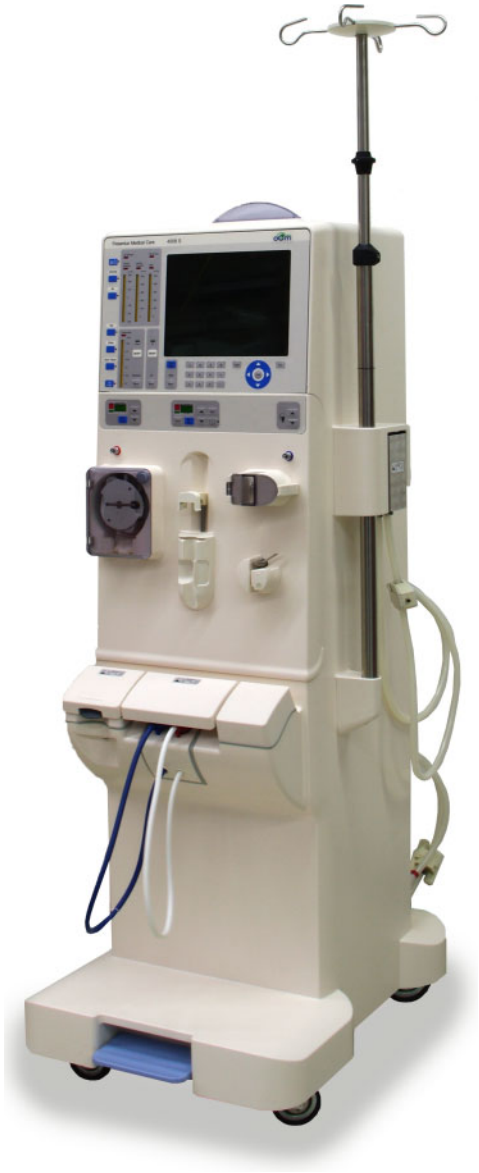
4008 S
Hemodialysis device

Service Manual

Software version: 11.40 and higher
Edition: 7/01.13
Part no.: M49 985 1
CE 0123



FRESENIUS
MEDICAL CARE

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1 Index

The source specifications in the index (e.g., 11-3) refer to the page identification in the footer. In this example, the index entry can be found in chapter 11 on page 3.

2 Important information

2.1 How to use the Service Manual

Purpose

This document 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 document, however, does not replace the training courses offered by the manufacturer.

Identification

The document can be identified by the following information on the title page and on the labels, if any:
– Edition of the document
– Part number of the document

Footer

The footer contains the following information:
– Company name, e.g., Fresenius Medical Care
– Device type
– The English abbreviation for the document type and the international abbreviation for the document language, for example: OP-EN refers to Operating Instructions in English.
– Edition, e.g., 4/03.11 means, 4th edition, March 2011
– The page identification 1-3, for example refers, to chapter 1, page 3.

Organization of the chapters

To facilitate the use of documents from Fresenius Medical Care, the organization of the chapters has been standardized in all manuals. There may therefore be chapters within this document without any content. Chapters without content are identified.

Illustrations

The illustrations used in the documents may differ from the original if this does not have any influence on the function.

Changes

Changes to the document will be released as new editions or supplements. In general: this manual is subject to change without notice.

Reproduction

Reproduction, even in part, is only permitted with written approval.

2.2 Significance of the warning

Warning

Advises the operator that failure to observe this information can result in personal injury.

2.3 Significance of the note

Note

Advises the operator that failure to observe this information can:
– cause damage to the equipment.
– result in a specific function not being executed at all or not being executed correctly.

2.4 Precautions for working on the device

Requirements

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

Authorized persons

Warning

Commissioning steps, extensions, adjustments, calibrations, maintenance measures, 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 document require the availability of the necessary technical measuring equipment and accessories.

Specifications

The technical specifications must be adhered to.

Precautions

Before turning power on, repair any visible damage.

Prior to opening the device and when working on the open device, the following precautions have to be observed:
– Protect the components against ingress of liquids.
– Do not touch live parts.
– Disconnect and connect all jacks, connectors and components only when the device is turned off.

ESD precautions

When repairing the device and when replacing spare parts, observe the applicable ESD precautions.

To be observed after working on the device

A T1 test and a check of the electrical safety must be performed after working on the device.

The current Operating Instructions must be enclosed with the device. If necessary, additional operator training is required.

After work has been completed

Warning

When the device is returned to use, check that the pressure of the water supply meets the prescribed minimum pressure.

Spare parts

Use only original spare parts.
For the identification and for ordering spare parts, test equipment and tools, always use the electronic spare parts catalog.

2.5 Technical documentation

On request, circuit diagrams, descriptions and other documents are made available by the manufacturer. These are intended to support trained personnel of the responsible organization in servicing and repairing the device.

2.6 Warnings

2.6.1 Warnings relating to hygiene

Warning

Risk of infection

To protect the patient from infections, disinfect the device each time you repaired or commissioned the device and each time you carried out TSC or maintenance measures.
Always run a disinfection after having worked on the device in any way!

2.6.2 Warnings relating to electricity

Warning

Risk of injury caused by electrical voltage.

Touching live parts will cause an electric shock.

➢ Disconnect the power plug before opening the device. Actuating the **On / Off** switch stops operation of the device, but does not disconnect the device from the supply voltage!

2.7 Addresses

Manufacturer

Fresenius Medical Care AG & Co. KGaA
61346 Bad Homburg
Germany
Phone: +49 6172 609-0
www.fmc-ag.com

International service

Fresenius Medical Care
Deutschland GmbH
Service Support International
Hafenstrasse 9
97424 Schweinfurt
Germany
Phone: +49 9721 678-333 (hotline)
Fax: +49 9721 678-130

Local service

3 Installation

3.1 Important initial start-up information

For initial start-up only

The following information is intended only for the initial start-up. This information is not applicable for recommissioning devices that have been removed from service or have temporarily been taken out of service.

Environmental conditions

Variations in temperature during transport may cause condensation leading to water developing on live parts. In the event of major variations in temperature, allow sufficient time for the device to adjust to the ambient temperature before start-up. When bringing the hemodialysis device from a cooler into a warmer room, allow approx. 2 hours for the device to adjust to the ambient temperature before switching it on.

Tester's qualification

The checks must only be carried out by persons, who, based on their training, knowledge and on-hand experience, are qualified to carry out such checks in a proper manner. Furthermore, the persons, who carry out the checks, may not be subjected to outside instructions with regards to these checks.

Warning

Commissioning steps, extensions, adjustments, calibrations, maintenance measures, 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 document require the availability of the necessary technical measuring equipment and accessories.

Specifications

The technical specifications must be adhered to.

Precautions

Before turning power on, repair any visible damage.

Prior to opening the device and when working on the open device, the following precautions have to be observed:

– Protect the components against ingress of liquids.
– Do not touch live parts.
– Disconnect and connect all jacks, connectors and components only when the device is turned off.

ESD precautions

When repairing the device and when replacing spare parts, observe the applicable ESD precautions.

TSC/ MA intervals

The TSC/MA procedures on this device are to be performed after 24 months.

3.2 Important information for use in a domestic environment

Operation in a domestic environment (home dialysis) in accordance with IEC 60601-1-11

If the hemodialysis device is to be used in a domestic environment (home dialysis), then special requirements apply to the unit's electrical power connection. Due to regulatory standards, an unambiguous mains power socket must be used for the electrical power connection.

One suitable plug socket, for example, is a 3-pin IEC 60309-2 standard mains power socket. Matching mains power cables for the hemodialysis device are available on request.

Warning

The power supply's protective conductor must comply with the IEC 60364-7-710 standard. The following checks must also be made by suitably-qualified personnel:
– Check the power supply's protective conductor circuit.

The manufacturer points out that local laws take precedence over the normative standards mentioned above.

Fixed location

The location of the hemodialysis device is "fixed" by its connection to the distinctive power socket (i.e. it is only ever connected to this socket). Only one distinctive power socket may be set up on any one domestic premises.

Changing the location in a domestic environment

Where medical care is provided in a domestic environment (home dialysis), the location of the hemodialysis device is fixed. If, following this fixed-location installation, the hemodialysis device needs to be moved to a different location, then the requirements must be met as specified in this chapter.

Moving within a domestic environment

(see **Transportation of hemodialysis unit** page 3-28)

3.3 Initial start-up report

See the following pages.

4008 S (Version V10) **Initial start-up report** FRESENIUS MEDICAL CARE

Technician's name:	**Customer / customer no.:**	
Device type including option(s) / Software version:	**Serial no.:**	**Inventory no.:**
Service report no.:	**Operating hours:**	**Equipment code:**
Device type including option(s):	❑ **SN** ❑ **BPM** ❑ **ZKV**	

No.	Description	Operating condition	Corr.	Meas. value	✓
1	**Preparation**				
1.1	Check and insert the battery fuse.	Off	–	–	❑
1.2	Remove the closing plugs: heater block overflow tube, disinfectant connector, water inlet plate	Off	–	–	❑
2	**Visual inspections**				
2.1	Labels and identifications are present and legible.	Off	–	–	❑
2.2	Mechanical condition permits safe use. No signs of damages or contamination affecting correct function.	Off	–	–	❑
2.3	The power cable shows no signs of damage.	Off	–	–	❑
2.4	Emergency crank for blood pump attached to housing rear.	Off	–	–	❑
2.5	Color coding of the dialyzer couplings and of the shunt cover adapted to customer specifications (counter-current principle).	Off	–	–	
	State upon delivery: Dialysate inlet port (right): Dialyzer coupling and shunt interlock = red Dialysate outlet port (left): Dialyzer coupling and shunt interlock = blue		–	–	❑
	Dialysate inlet port (right): Dialyzer coupling and shunt interlock = blue Dialysate outlet port (left): Dialyzer coupling and shunt interlock = red		–	–	❑
3	**Preparation for operation**				
3.1	Water inlet tube and drain connected.	Off	–	–	❑
3.2	Connect the CDS tubing.	Off	–	–	❑
3.3	Check the DIP switch.	Off	–	–	❑
3.4	V91, V99, V100 are functional and tight: (This test is not applicable if the CDS or the rinse section test is activated.)	Off	–	–	❑
3.5	Rinse to remove any preservatives.	Cleaning / rinsing	–	–	❑
3.6	Connect the DIASAFE® *plus* filter and run the "filter change" program.	Cleaning / filter change	–	–	❑
4	**Check of hydraulics**				
4.1	Water inlet pressure (reduced): 1.2 bar (+0.2 bar / –0.3 bar)	CALIBRATION	❑ Yes ❑ No	_____	❑
4.2	Loading pressure: 1.45 bar (±0.05 bar)	CALIBRATION	❑ Yes ❑ No	_____	❑
4.3	Degassing pump negative pressure: 0.82 bar (±0.01 bar)	CALIBRATION	❑ Yes ❑ No	_____	❑
4.4	Relief pressure of balancing chamber at 800 ml/min: 2.2 bar (±0.05 bar)	CALIBRATION	❑ Yes ❑ No	_____	❑
5	**Check of the zero point of the pressure display (art./ven.)**				
5.1	Arterial zero point: 0 mmHg (±10 mmHg)	CALIBRATION	❑ Yes ❑ No	_____	❑
5.2	Venous zero point: 0 mmHg (±10 mmHg)	CALIBRATION	❑ Yes ❑ No	_____	❑
6	**Check of the blood leak detector**				

No.	Description	Operating condition	Corr.	Meas. value	✓
6.1	Blood leak: Desired = 5 V (±0.2 V)	CALIBRATION	❑ Yes ❑ No	_____	❑
6.2	Dimness: Desired = 5 V (±0.3 V)	CALIBRATION	❑ Yes ❑ No	_____	❑
7	**Check of the dialysate pressure**				
7.1	Zero point checked (flow off).	CALIBRATION	–	–	❑
7.2	Slope checked.	CALIBRATION	–	–	❑
8	**SETUP SETTINGS (PC SERVICE PROGRAM)**				
8.1	Make Setup settings and transfer data to the hemodialysis device.	CALIBRATION	–	–	❑
8.2	Reset the failure record.	CALIBRATION	–	–	❑
8.3	Download setup and calibration data (PC service program)	CALIBRATION	–	–	❑
8.4	Print setup data.	CALIBRATION	–	–	❑
9	**Check of the extracorporeal components**				
9.1	Blood pumps: Check the blood pump rate. (*BP-Rate CHECK*)	CALIBRATION	–	–	❑
9.2	Single-Needle switching pressure checked according to table.	CALIBRATION	–	–	❑
10	**Checking the electrical safety** According to (DIN) EN 62353:2008, IEC 62353:2007				
10.1	Visual inspection performed.	Off	–	–	❑
10.2	Protective earth resistance measured. Max. 0.3 Ω (with power cable)	Off	–	_____ Ω	❑
10.3	Device leakage current measured. ❑ Differential current measurement according to figure 5 ***or*** ❑ Direct measurement according to fig. 4	Preparation	–	–	❑
	Nominal voltage of power supply: _____ V		–	–	
	Device leakage current mains polarity 1: _____ µA		–	–	
	for line voltage: _____ V		–	–	
	Scaled to nominal voltage (maximum 500 µA, see Additional requirements)		–	_____ µA	
	Device leakage current mains polarity 2: _____ µA		–	–	
	for line voltage: _____ V		–	–	
	Scaled to nominal voltage (maximum 500 µA, see Additional requirements)		–	_____ µA	
11	**Functional test**				
11.1	T1 test performed.	T1 Test	–	–	❑
11.2	Blood pump stop alarm checked.	Preparation	–	–	❑
11.3	Venous occlusion clamp closes after blood alarm.	Preparation	–	–	❑
11.4	Pressure of approx. 2 bar in the venous bubble catcher: Pressure may not drop by more than 0.1 bar within 3 minutes.	Preparation	–	–	❑
12	**Check of the conductivity** (Connect the bi*bag*®)				
12.1	Conductivity of reference device (in mS/cm)	Preparation	❑ Yes ❑ No	_____	❑
12.2	Conductivity of hemodialysis device display: desired = reference device conductivity (±0.2 mS/cm)	Preparation	❑ Yes ❑ No	_____	❑
13	**Check of the temperature**				
13.1	Reference device temperature: Desired = 36.5°C (±0.2°C)	Dialysis	❑ Yes ❑ No	_____ °C	❑
14	**Final check**				
14.1	Power failure alarm – continuous sound – text displayed: Power Failure	Preparation	–	–	❑
14.2	Air separation: Activating the air separation pump. Text display with further air separation and blood detected (optical detector dark): Fill program	Preparation	–	–	❑
14.3	Run the disinfection program.	Cleaning / disinfection	–	–	❑
14.4	Operating Instructions and accessories package complete and match the device.	Off	–	–	❑
14.5	Attach TSC inspection label.	Off	–	–	❑

Applied measurement equipment: Temperature, conductivity, pressure (Type, serial number): _____ Protective earth resistance, leakage current (Type, serial number): _____		
Remarks:		
Date:	**Signature:**	**Stamp:**

The device has been released for further use (attach inspection label).	❑ Yes ❑ No
Date of next inspection:	
Remarks:	

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

Warning

On completion of these procedures it is imperative to run a disinfection.

3.4 Explanations for the initial start-up report

Identification

Technician's name:
Surname and last name of technician.

Device type including option(s) / software version:
Device name with possible options or extras. Software version, if available.

Service report no.:
Number of the service call.

Customer / customer no.:
Final customer's number.

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

Inventory no.:
Inventory number assigned to the device.

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

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

Re 1

Preparation

Operating condition: Off

Re 1.1

Check and insert the battery fuse.

Install the battery fuse accessible **(1)** (see illustration below) after checking the value.

Attach the seal, if required. Then the battery fuse does not have to be checked when servicing the device the next time.

Re 1.2

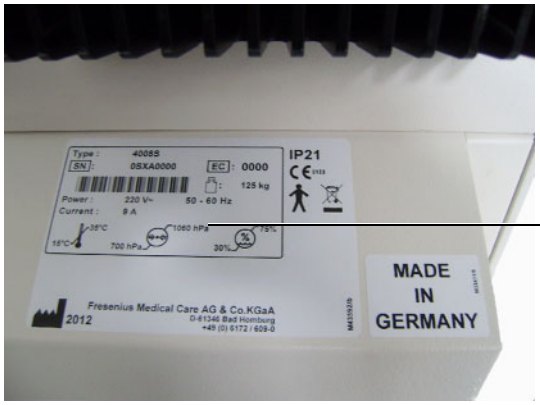
The following closing plugs have to be removed:
– on the overflow tube of the heater block
– on the disinfectant connector
– on the water inlet plate

Re 2 **Visual inspection**

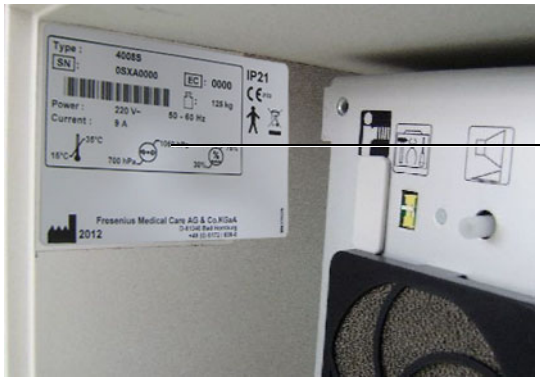
Operating condition: Off

Re 2.1 Labels and identifications are present and legible (with illustrations below).

1 2 x label "Type label complete device“
Check device specification:
Serial number
Equipment code

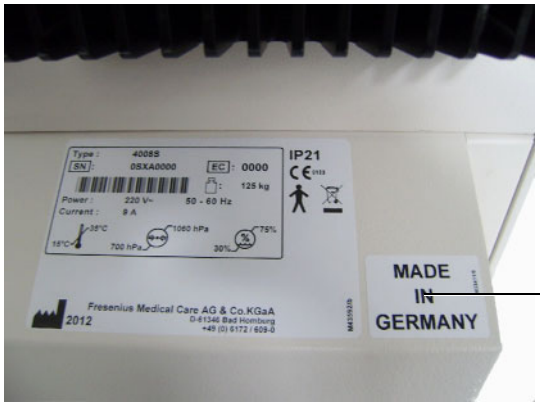


1



1

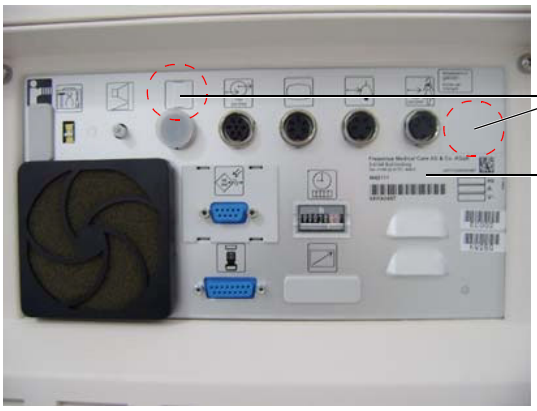
2 1 x label "Made in Germany"



2

3 2 x labels to paste over "traffic light symbol" and "warning symbol" (monitor / chassis unit)

4 1 x label "Type label monitor unit / chassis unit“

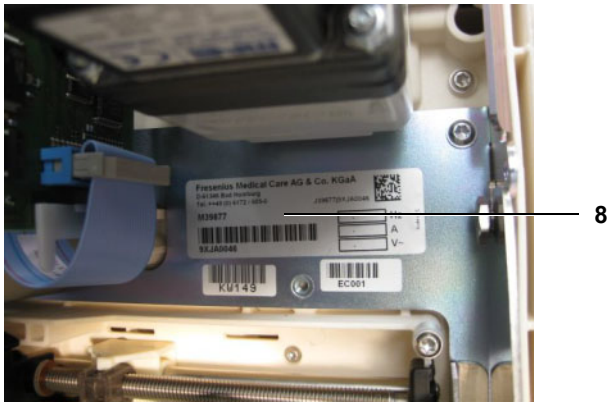


5 1 x label "Hot surface“

6 1 x label "Power supply unit type label“

7 1 x label "Hydraulic unit type label“

8 1 x label "Type label EBM“

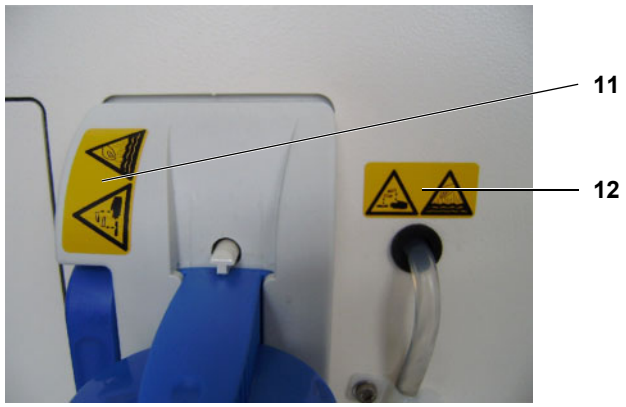


9 1 x label "Insert dialyzer lines here“

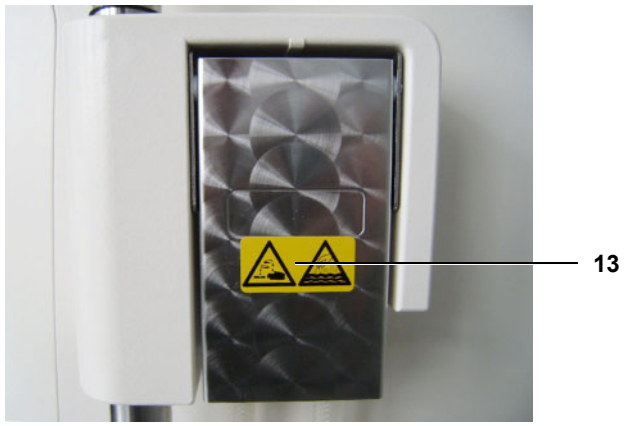
10 1 x label "Refer to instruction manual/booklet“

11 1 x label „Hot rinse“ (DIASAFE® *plus*)

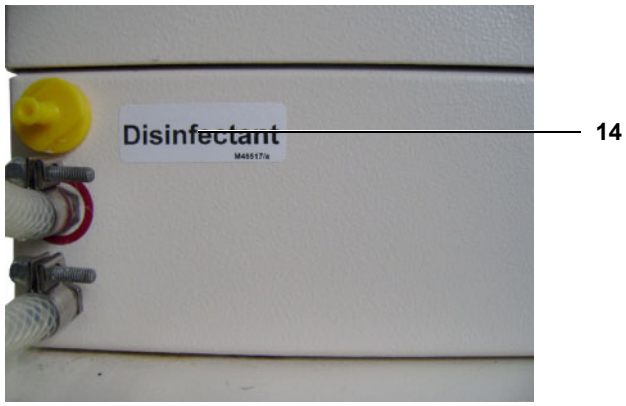
12 1 x label „Hot rinse“ (overflow tube)



13 1 x label „Hot rinse“ (shunt interlock)



14 1 x label „Hot rinse“ (disinfection solution)



15 1 x label „Potential equalization“

16 1 x label "To / from dialyser“

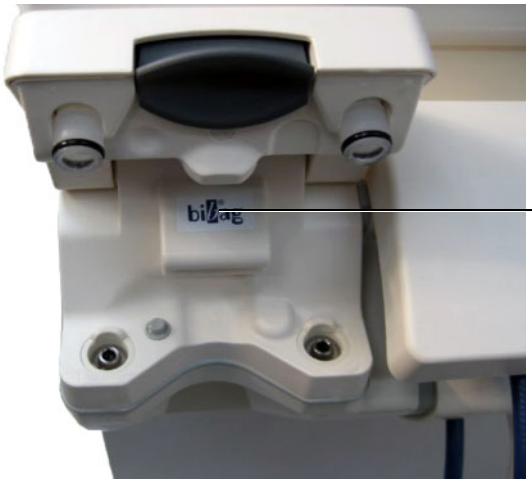
17 1 x label "CDS warning label“ (option)

18 1 x label "Water input / drain, max. 6 bar“

19 1 x label „max. 5 kg“ (IV pole)

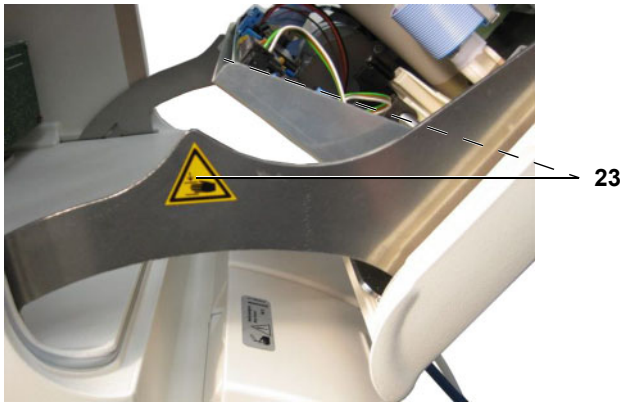
20 1 x label „Hot rinse“ (bi*b*ag® connector, on the outside)

21 1 x label „bi*b*ag®“ (bi*b*ag® connector, on the inside)

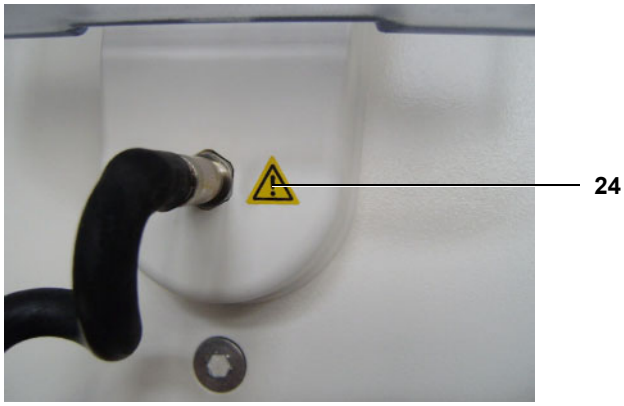


22 1 x label „Hot rinse“ (sealing cap, on the outside)

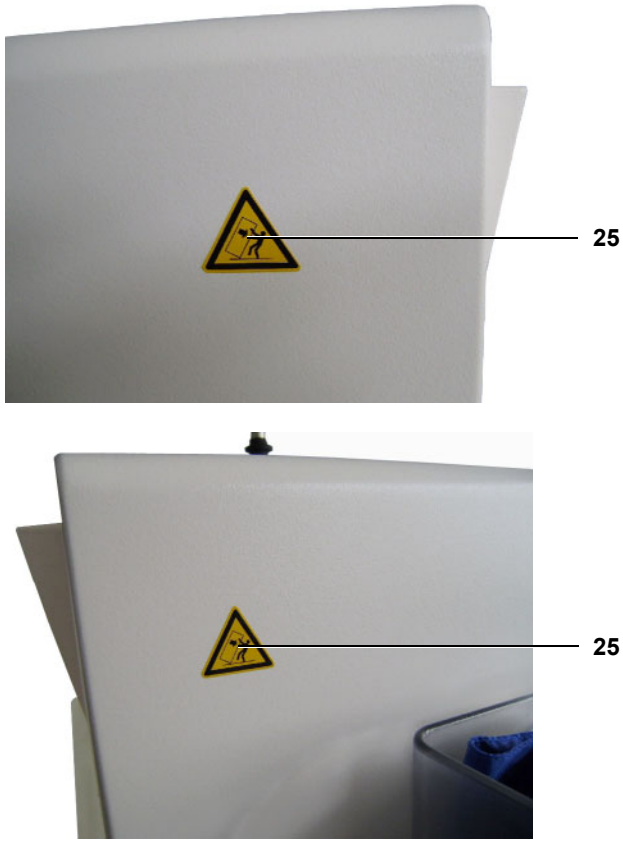
23 2 x Label "Warning label risk of hand injury"
(EBM hinge bracket on the left and on the right)



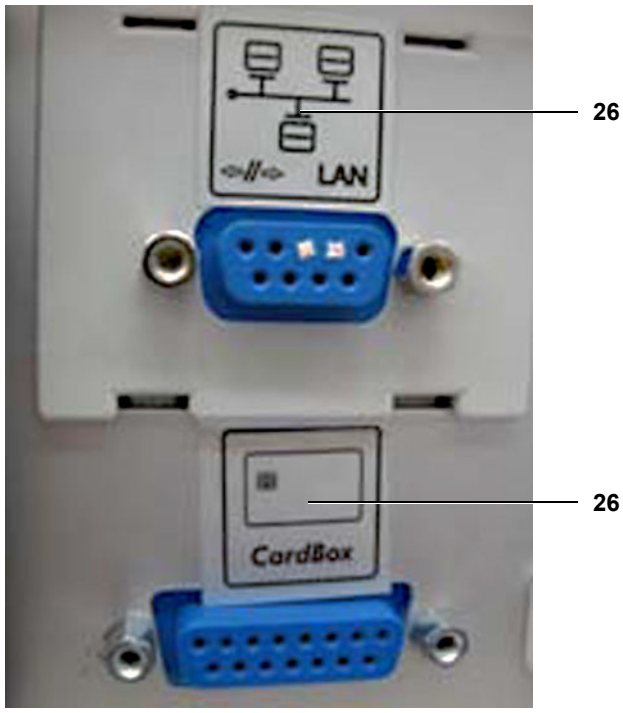
24 1 x label „Warning“ (BPM connection)



25 2 x labels "Tipping hazard" (housing left and housing right)



26 Bed-Side-Link (option):
2 x label: „LAN“ and „CardBox“



27 Country-specific labels:

27.1 Additional label for the People's Republic of China:
1 x label "CCC" (to the right of the "Type label complete device“ on the outside)
1 x label "China RoHS" (to the right of the "Type label complete device“ on the outside)

27.2 Additional label for Russia
1 x label "Service address" (to the left of the "Type label complete device“ on the outside)

Re 2.2 Mechanical condition permits further safe use. There are no signs of damage or contamination affecting proper function of the device.

To be checked:
– Tubings and cuff of BPM (option)

Re 2.3 The power cable shows no signs of damage.

Re 2.4 Blood pump emergency crank attached to housing rear.

Re 2.5

Color coding of the dialyzer couplings and of the shunt cover adapted to customer specifications (counter-current principle).

– Adapt coding of the dialyzer couplings and of the shunt cover as desired by the customer. Ensure counter-current principle by correct color coding.
– Document the change in the Medical Device Register.

State upon delivery:

Dialysate inlet port (right): Dialyzer coupling and shunt interlock = red
Dialysate outlet port (left): Dialyzer coupling and shunt interlock = blue

Re 3 **Preparation for operation**

Re 3.1

Water inlet tube and drain connected.
Maximum water inlet tube length: 3 m
Maximum drain tube length: 3 m

Operating condition: Off

Re 3.2

Connect the CDS tubings.

Operating condition: Off

Re 3.3

Check the DIP switch.
The basic settings of the DIP switches are marked red in the illustrations below.
A detailed overview can be found in chapter 5
(see chapter 5.2 page 5-64).

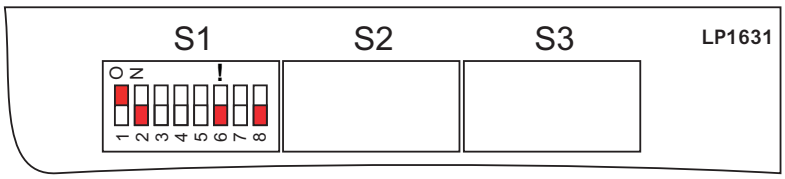
Operating condition: Off

Check of the DIP switches P.C.B. LP 1631 (CPU 1):

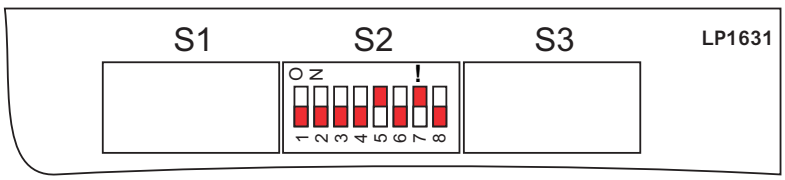
Note

DIP switch 6 (array 1) is provided for service purposes / trouble-shooting only and must be set to position OFF for dialysis mode.

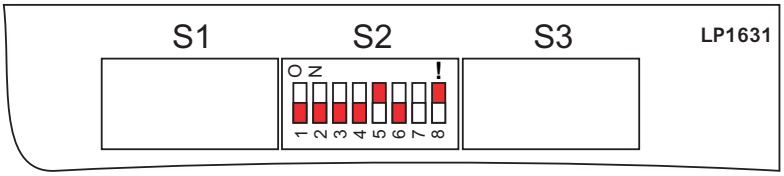
– P.C.B. LP 1631: Array 1
(switch 3, 4, 5 to OFF and switch 7 depending on the heater rod)



– Without Central Delivery System:
P.C.B. LP 1631: Array 2, switch 7 on ON



– With Central Delivery System:
  P.C.B. LP 1631: Array 2, switch 8 is on ON
  (switch 7 is no longer relevant!)

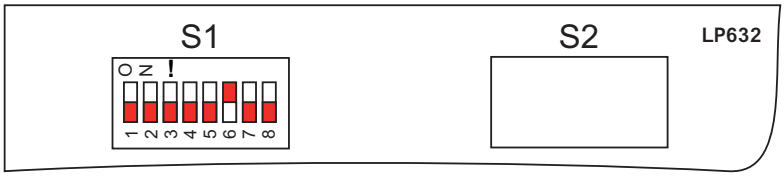


Check of the DIP switches P.C.B. LP 632 (CPU 2):

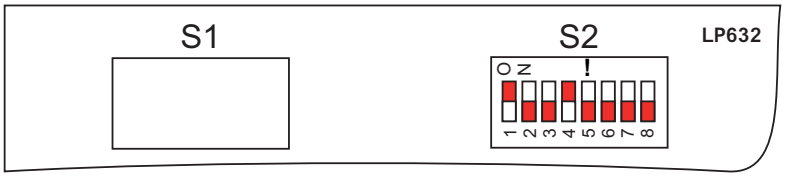
Warning

DIP switch 3 (array 1) allows skipping test runs that are requested by the device.
If the switch is set such that a test run can be skipped, then it must be noted that the operator has the possibility of evading the automatic test of the safety systems.
The person requesting such a setting is responsible for this procedure.

– P.C.B. LP 632: Array 1, switch 3 is on OFF



– P.C.B. LP 632: Array 2, switch 5 is on OFF



Re 3.4

V91, V99, V100 are functional and tight (test not applicable with activated CDS or with activated rinse section test).

Operating condition: Off

Re 3.5

Rinse to remove any preservatives.

Operating condition: Cleaning / rinsing

– Turn the hemodialysis device on
– Wait until the device is completely booted up. Then set the service switch **(1)** to ON (top).

– (heater rod not active!) Press the **Cleaning** key. Rinse and reset the Service switch to OFF (down) after having completed the rinse program.

Re 3.6 Connect the DIASAFE® *plus* filter and run the "filter change" program.

Operating condition: Cleaning / filter change

– Use the "filter change" program item in the cleaning menu and start the disinfection program requested by the device.

Re 4 Check of hydraulics

Re 4.1 Water inlet pressure (reduced): 1.2 bar (+0.2 bar / –0.3 bar)

Operating condition: Service mode / CALIBRATION

Re 4.2 Loading pressure: 1.45 bar (±0.05 bar)

Operating condition: Service mode / CALIBRATION

Re 4.3 Degassing pump negative pressure: 0.82 bar (±0.01 bar)

Operating condition: Service mode / CALIBRATION

Re 4.4 Relief pressure of balancing chamber at 800 ml/min: 2.2 bar (±0.05 bar)

Operating condition: Service mode / CALIBRATION

Re 5 Check of the zero point of the pressure display (art./ven.)

Re 5.1 Arterial zero point: 0 mmHg (±10 mmHg)

Operating condition: Service mode / CALIBRATION

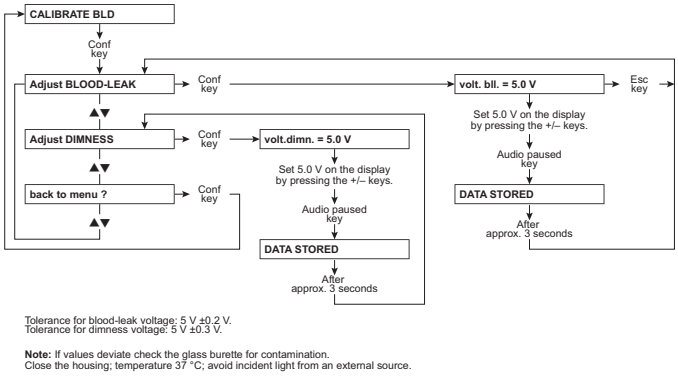
Re 5.2 Venous zero point: 0 mmHg (±10 mmHg)

Operating condition: Service mode / CALIBRATION

Re 6 **Check of the blood leak detector**

(see chapter 9.1.42 page 9-37)

Ensure that the operating temperature of the device has reached approx. 37 °C. Then check the values. The rear of the device must be closed to protect it from any incident ambient light.



Tolerance for blood-leak voltage: 5 V ±0.2 V.
Tolerance for dimness voltage: 5 V ±0.3 V.

Note: If values deviate check the glass burette for contamination.
Close the housing; temperature 37 °C; avoid incident light from an external source.

Re 6.1 Blood leak: Desired = 5 V (±0.2 V)

Operating condition: Service mode / CALIBRATION

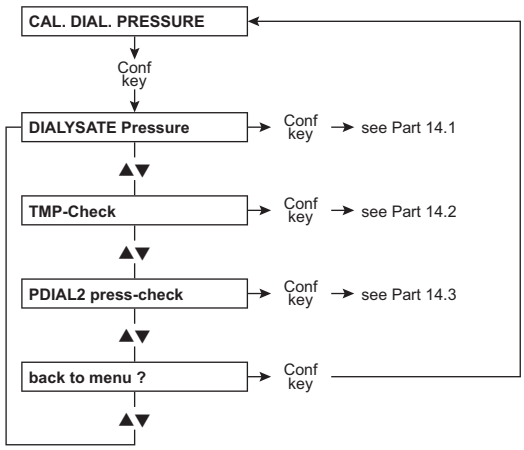
Re 6.2 Dimness: Desired = 5 V (±0.3 V)

Operating condition: Service mode / CALIBRATION

Re 7 **Check of the dialysate pressure**

(see chapter 9.1.38 page 9-34)

Check zero point. With the dialysate circuit open, the water level must be approx. 10 cm above the shunt interlock.



Note

The accuracy of the pressure gauge used must correspond to that of the UMED or HMED.

The accuracy of the pressure gauge used must at least correspond to the following values:

-1 to 2 bar ±5 mbar
2 to 8 bar ±20 mbar

Re 7.1 Check zero point

Operating condition: Service mode / CALIBRATION

– Venous pressure inlet is open against atmosphere.
– Flow off.

Re 7.2 Slope checked

Operating condition: Service mode / CALIBRATION

Re 8 Setup settings (PC Service program)

Re 8.1 Make setup settings in the service program and transfer data to the hemodialysis device.

Operating condition: Service mode / CALIBRATION

Re 8.2 Reset the failure record

Operating condition: Service mode / CALIBRATION

Re 8.3 Download setup and calibration data

Operating condition: Service mode / CALIBRATION

Re 8.4 Print setup data.

Operating condition: Service mode / CALIBRATION

Re 9 Check of the extracorporeal components

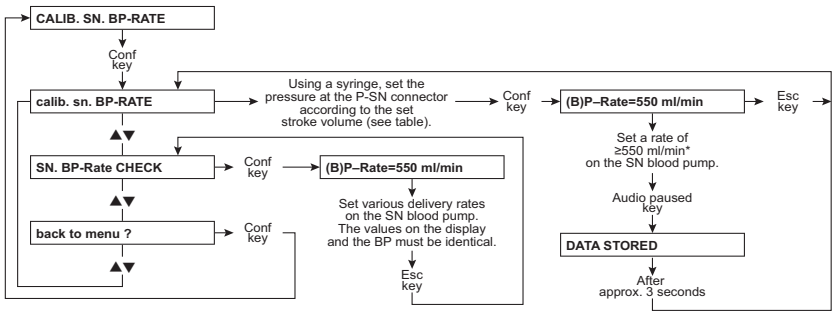
Re 9.1 Blood pumps: Check the blood pump rate.
(see chapter 9.1.8 page 9-9).

Operating condition: Service mode / CALIBRATION

Re 9.2

Check Single-Needle switching pressure according to table.

Operating condition: Service mode / CALIBRATION



Note: Set the line diameter to 8 mm before starting the calibration procedure and press Start/Stop on the blood pump.

* The BP rate of 550 ml/min represents a default value. It can be changed using the ▲▼ (+/–) keys.

Check the upper switching points according to the table below. The upper switching point depends on the stroke volume.

The lower switching point is fixed (75 mmHg).

Stroke volume (ml)	10	15	20	25	30	35	40	45	50
Switching point (mmHg) ± 7 mmHg	110	130	150	172	195	219	244	270	299

Re 10 **Checking the electrical safety**

According to (DIN) EN 62353:2008, IEC 62353:2007

Re 10.1

Perform visual inspection.

Operating condition: Off

– Fuses accessible from the outside comply with the indicated values.
– Labels and identifications are present and legible.
– Mechanical condition permits further safe use.
– No damage or contaminations detectable.
– Power cable not damaged.

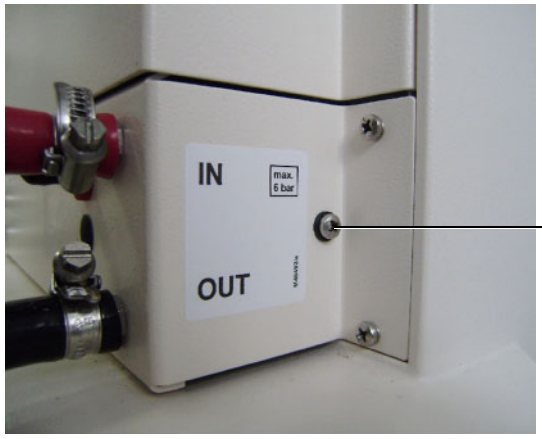
Re 10.2

Protective earth resistance measured.
Max. 0.3 Ω (with power cable).

Operating condition: Off

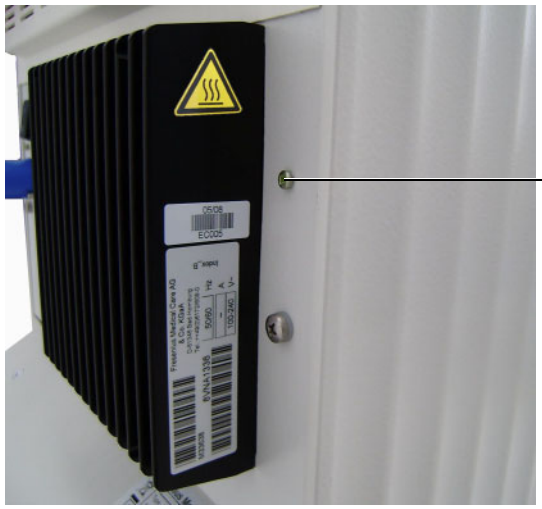
The protective earth resistance must be checked on the following measurement points. The exact measuring points are indicated in the figures.

– Heater rod - outward measurement point (screw head) **(1)** on the bottom right on the rear side of the device

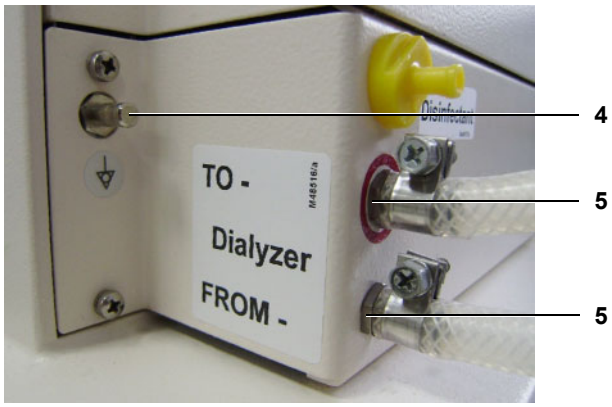


– Screw head **(2)** / monitor rear

– Screw head **(3)** / power supply unit



– Potential equalization bolts **(4)** / back of device, lower left
– Dialyzer tube connectors (adapters) (**5**) / lower left of device rear

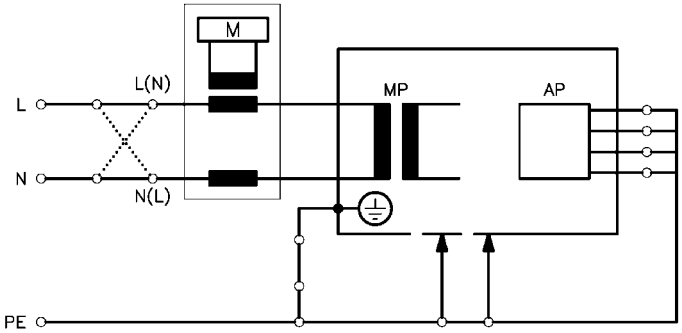


Re 10.3

Measure the device leakage current.
Complete the VDE measurement report, remains with the device.

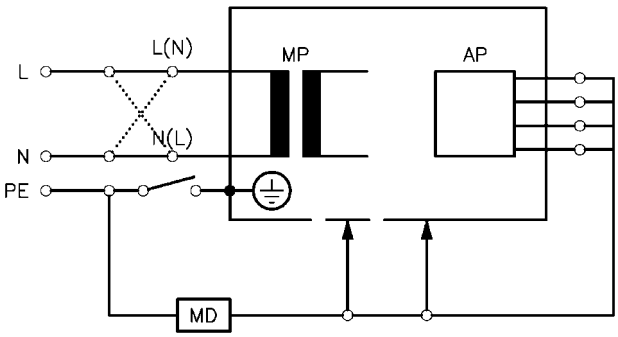
Operating condition: Preparation

Differential current measurement according to figure 5:



or

Direct measurement according to fig. 4



The unit under test must be insulated when installed.

All earth connections (e.g. potential equalization, ...) have to be removed.

Basic conditions:

– Measurement of the protective earth resistance performed.
– Perform the measurement with the hemodialysis device being at operating temperature.
– Dialysate:
  Dialysis temperature: ≥ 36.5 °C
  Dialysate flow: ≥ 300 ml/min
  Conductivity: ≥ 13 mS/cm
– When performing a direct measurement, the following precautions also must be observed:
  The device must be insulated when installed.
  All external connections must have been removed from the device.

The line voltage during the measurement will be recorded, as well as the maximum device leakage current, scaled to the nominal voltage of the power supply. Maximum device leakage current: 500 µA.

Example:

Line voltage during measurement: 225 V
Device leakage current:
mains polarity 1: 180 µA
mains polarity 2: 120 µA
Maximum value of both mains polarities: 180 µA
Nominal voltage of power supply: 230 V
Scaled to nominal voltage 184 µA
(180 µA: 225 V x 230 V = 184 µA
Device leakage current < 500 µA: OK

Additional requirements:

– If the value scaled to the nominal voltage 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 has considerably increased since the last measurement or has continuously increased since the first measurement (slow 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:

Device leakage current: 470 µA
Last measured value: 450 µA
470 + (470 – 450) = 470 + 20 = 490 (-> successfully passed!)

Example 2:

Device leakage current: 470 µA
Last measured value: 390 µA
470 + (470 – 390) = 470 + 80 = 550 (-> not passed!)

Re 11 **Functional test**

Re 11.1 T1 test performed.

Operating condition: T1 Test

Perform additional checks only after completion of the T1 test. The T1 test must be passed without errors.

Re 11.2

Blood pump stop alarm checked.

Operating condition: Preparation

– Set blood pump delivery rate > 0 ml/min (blood pump must rotate).
– Open blood pump door and check immediate stoppage of rotor.
– Check triggering of blood pump stoppage alarm after max. 30 seconds (setup settings: 15 / 30 seconds).
  Red status indicator (LED) on blood pump is lit,
  operation status indicator (traffic light) is lit or flashing red,
  message on the screen: *Alarm – Bloodpump-stop*.

Re 11.3

Venous occlusion clamp closes after blood alarm.

Operating condition: Preparation

– The venous occlusion clamp must close in the event of a blood alarm.

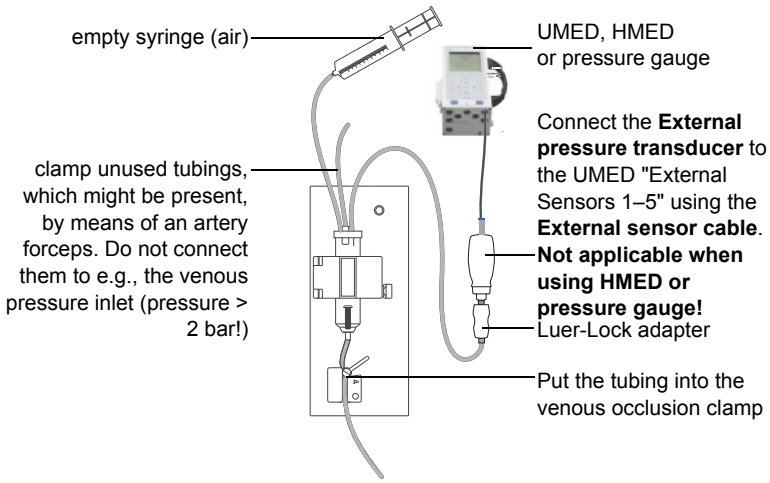
Re 11.4

Pressure of approx. 2 bar in the venous bubble catcher.
Pressure may not drop by more than 0.1 bar within 3 minutes.

Operating condition: Preparation

The venous occlusion clamp is closed (blood alarm).

– Insert the venous bubble catcher into the air detector (ultrasonic detector). For the moment, do not place the line in the venous occlusion clamp.
– Manually open the venous occlusion clamp, hold it and insert the tubing.
– Release the venous occlusion clamp. The venous occlusion clamp closes.
– Use the syringe to generate a pressure of approx. 2 bar
  (see **Checking the venous occlusion clamp** page 9-51).
– The pressure may not drop by more than 0.1 bar within 3 minutes.



Re 12 **Check of the conductivity**

(Connect the bi*ba*g®)

Re 12.1 Conductivity of reference device

Operating condition: Preparation

The device must be entirely closed during this check!

– Measure the conductivity using a reference measuring instrument connected between the dialyzer couplings.

Re 12.2 Conductivity of hemodialysis device display:
The desired value is the value of reference instrument (± 0.2 mS/cm)

Operating condition: Preparation

The device must be entirely closed during this check!

Compare the conductivity displayed on the display with the specifications on the acid / concentrate container.

– The display of the hemodialysis device may deviate from the value of the reference instrument by no more than ±0.2 mS/cm.

Re 13 **Check of the temperature**

Re 13.1 Reference device temperature: Desired = 36.5 °C (±0.2 °C)

Operating condition: Dialysis

The device must be entirely closed during this check!
Check the desired temperature of 36.5 °C (±0.2 °C) using a reference measuring instrument connected between the dialyzer couplings.
– Optical detector = dark (NTC 109 is active)
– Flow = 500 ml/min

Re 14	**Final check**
Re 14.1	Power failure alarm – continuous sound – text displayed: Power Failure Operating condition: Preparation
Re 14.2	Air separation: Activating the air separation pump. Operating condition: Preparation Text display with further air separation and blood detected (optical detector dark): Fill program
Re 14.3	Run the disinfection program. Operating condition: Cleaning / disinfection
Re 14.4	Operating Instructions and accessories package complete and match the device. Operating condition: Off
Re 14.5	Attach TSC inspection label. Operating condition: Off
Confirming the test	**Applied measurement equipment:** Type and serial number of the test equipment used. **Remarks:** Any irregularities which occurred during the test are documented in this section. **Date, signature, stamp** The person performing the test must confirm with his signature, date and stamp that the test has been performed.
Assessing the test	**The device has been released for further use (attach inspection label).** It must be ensured that the intended use of the device will not present a hazard to patients, operators and other third parties. Within the scope of the overall assessment, the tester must make a definite decision whether the device may be used or not. The responsible organization must immediately be informed of any defects detected. **Date of next inspection:** The next inspection date has to be entered in the report. The intervals prescribed by the manufacturer must be observed.

Remarks:
Any irregularities which occurred during the assessment are documented in this section.

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

3.5 Transportation of hemodialysis unit

Warning

– Risk of caustic burning

Warning; Corrosive substance

– Risk of scalding

Warning; Hot surface; Hot fluids or vapors

Before transporting the device, ensure that there are no corrosive or hot liquids in the device. Programs, such as disinfection or hot disinfection (incl. cool down rinse), must have been run through completely.

Warning

Risk of tilting when pushing the device or leaning against it

If lateral force is exerted it may result in tilting or slipping of the device. Check transportation conditions are as stated.

Transportation preparation

- Check transportation/storage temperature (see chapter 4.11 page 4-13). It may be necessary to fill the hemodialysis device with an antifreeze solution. If so, use the 4008 Removal from Service Set.
- Turn the device off.
- Disconnect the power plug.
- Attach the power cable to the device.
- Pull out the water inlet and water drain lines.
- Attach the water inlet tube and water drain tube to the device.
- Pull out the Central Delivery System (if fitted).
- Attach the Central Delivery System tube to the device (if fitted).
- Remove the concentrate canister and disinfectant canister.
- Close the vent tubing.
- Remove any objects from the IV pole.
- Retract the IV pole completely.
- Remove the blood pressure cuff holder and the pressure tubing (optional).

During transportation

- Lift the hemodialysis device over uneven surfaces (e.g. cobblestones).
- For vehicular transportation, cushion the hemodialysis device appropriately and keep it upright if possible. If the hemodialysis device has to be transported on its side, then lower it gently and transport it with adequate cushioning on all sides.

After transportation

- After moving the device, bring the hemodialysis device back into service (see Restarting after removing 4008 from Service).

4 Specifications

4.1 Dimensions and weight

Dimensions

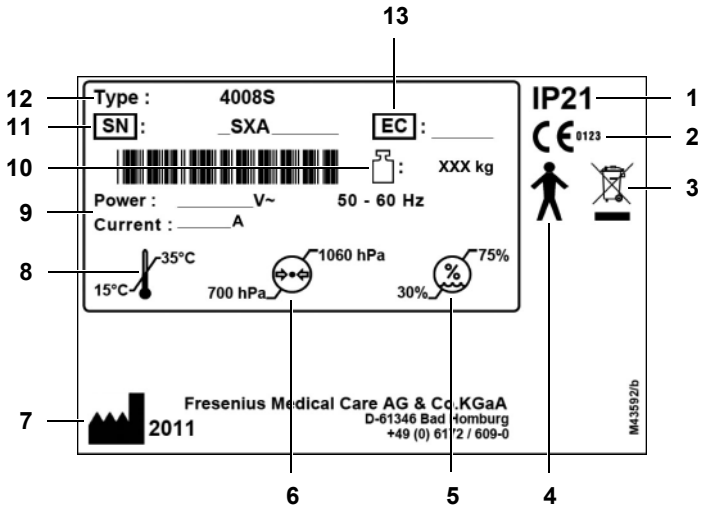
Height: approx. 137 cm (approx. 164 cm incl. IV pole)
Width: approx. 50 cm (incl. shunt interlock)
Depth: approx. 65 cm (approx. 83 cm with extended concentrate rack)

Weight

Empty weight incl. all options: approx. 86 kg
Safe working load: approx. 39 kg
Maximum total weight: approx. 125 kg
(Empty weight incl. all options + safe working load = maximum total weight)

4.2 Type label (identification of the device)

The type label shown is only an example. The decisive criterion is the data specified on the type label of the device.



1 IP type of protection 21
2: Protection against touch and foreign bodies with a diameter of at least 12.5 mm
1: Protection against ingress of liquids: drip-proof

2 CE mark

3 Identification of electric and electronic devices

4 Degree of protection against electric shock: type B

5 Relative humidity (Operating conditions)

6 Atmospheric pressure (Operating conditions)

7 Manufacturer with date of manufacture as year digit

8 Operating temperature range

9 Power requirements (voltage / power consumption)

10 Maximum total weight (empty weight + safe working load)

11 Serial number

12 Type identification

13 Equipment code (EC)

4.3 Operating environment

The device has been specified by the manufacturer for operation in rooms suitable for dialysis treatments, inside of professional health care facilities, or for medical care in a domestic environment.

Due to the permissible voltage tolerances, medical care in a domestic environment with a line voltage of 100 V is not permitted.

Normative and local regulations must be observed.

The dialysis room must meet the following minimum requirements:
- No explosure to splash water
- Ceiling, wall, floor surfaces: smooth, impermeable to liquids, scuff-resistant, suitable for wet disinfection
- Ensure the floor is properly load-bearing
- Heat dissipation, per device
- Minimum window ventilation
- Space needed
- Staff call / nurse call per dialysis bed
- Safety lighting
- Safe distance from e.g. MRI scanners / MRT areas

4.4 Electrical safety

Classification according to IEC 60601-1

Type of protection against electrical shock	Safety class I
Degree of protection against electric shock	Type B
Degree of protection against electric shock (blood pressure cuff)	Defibrillator-protected applied part of type CF
Degree of protection against ingress of liquids	drip-proof
Leakage currents	according to IEC 60601-1

4.5 Electrical supply

Line voltage	100 V AC, 50 – 60 Hz, 16 A (Medical care cannot be provided in domestic environments with line/mains voltage of 100 V). 110 V AC, 50 – 60 Hz, 15 A 120 V AC, 50 – 60 Hz, 14 A 127 V AC, 50 – 60 Hz, 14 A 220 V AC, 50 – 60 Hz, 9 A 230 V AC, 50 – 60 Hz, 9 A 240 V AC, 50 – 60 Hz, 9 A (The decisive criterion is the line voltage, the operating current and the frequency specified on the type label of the device.)
Power supply (internal)	+5 V, +0.3 V, short-circuit-proof +12 V, +0.4 V, short-circuit-proof +24 V, 0.7 V, short-circuit-proof
Battery	Lead-acid battery (maintenance-free) 18 V (= 1 x 12 V + 1 x 6 V) / 3.4 Ah Supply voltage for audible alarm if power fails for at least one minute.
Battery LP 632	Snap-hat battery (2.8 V / 48 mAh)
Battery LP 1631	Battery CR 1225, Lithium (3 V / 42 mAh)
Power switch	Main power switch, all-pole, simultaneous disconnection

4.6 Fuses

Battery	1 x T 3.15 A; power supply unit, fuse in housing foot (rear) / SI5
Power board	T 3.15 A Safety fuse Axial FF 10 A Safety fuse
Heater board	T 2.5 A Safety fuse T 6.3 A Safety fuse T 16 A Safety fuse

4.7 Supply mains

The standards specified by IEC 60364-7-710 must be met.

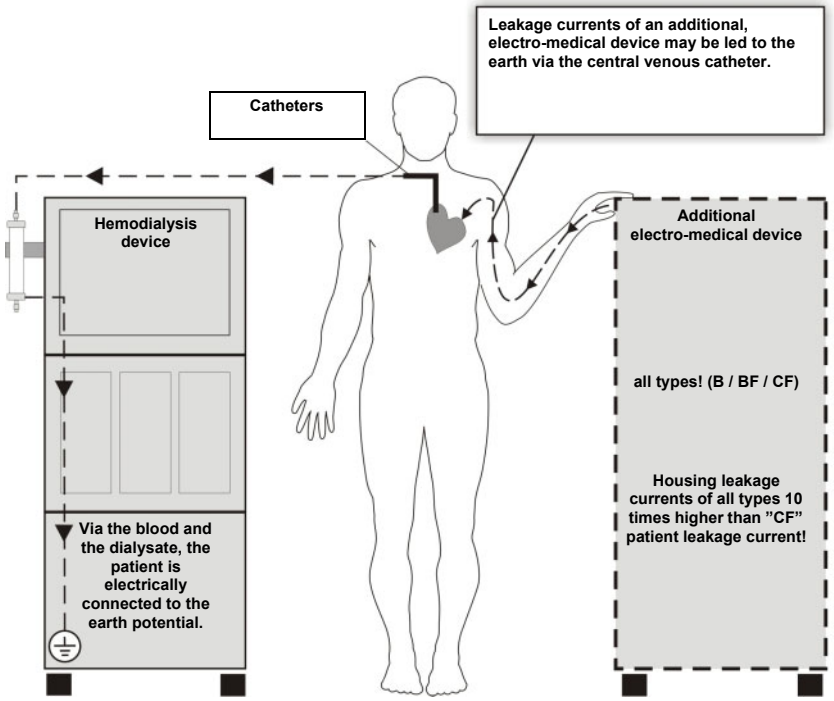
The national standards and regulations must be observed when connecting the device to the power supply system.

– Mains power interruption < 20 ms
– An appropriate grounding system must be installed.
– Power socket with protective conductor terminal required.
– The cable cross-section and the cable lengths to the wall outlet must be dimensioned so that the voltage tolerance and protective equipment functionality is maintained at all times. Recommended cable cross-section to wall outlet: at least 3 x 1.5 mm^2 Cu for 220–240 V and at least 3 x 2.5 mm^2 Cu for voltages lower than 220 V).
– Individual protection for each electric circuit with protective elements that will automatically and quickly enough switch off if an error occurs (recommendation: 16 A for 220–240 V and 20 A for voltages lower than 220 V).
– Maximum 1 device per socket and power circuit.
– The use of multiway sockets and extension cables is prohibited.
– Residual-current devices (RCD), which protect against dangerous shock currents in case of an error. Recommendation: one residual-current device for each device (or outlet) (RCD less than or equal to 30 mA).
– Overvoltage / lightning protection in the main and emergency power supply.

Warning

When using central venous catheters, the following precautions must be observed:

1. The hemodialysis device must be connected to a potential equalization.
2. If additional electro-medical devices are connected to the patient or they are positioned within close proximity of the patient, it must be ensured that all leakage currents of these devices (device leakage currents, housing leakage currents, earth leakage currents and patient leakage currents) are below the respective limit for CF applied parts.
   This means:
   10 µA maximum in normal conditions, and 50 µA in "single fault conditions".
   This also applies to patient positioning devices (e.g. patient chairs).
   Devices with leakage currents within these limits, but with an application current exceeding the specified leakage currents (e.g., on electro stimulators) may not be used. This also applies to defibrillators, which have no applied part of the CF type.
   If all requirements have been fulfilled, these devices may be operated on the patient or within the reachable area of the patient, provided they are, like the hemodialysis device, integrated into the potential equalization.
   If these conditions are not fulfilled, no other electro-medical devices must be connected to the patient or positioned within the reachable area of the patient.
   In case of doubt, contact the local technician.



3. When determining the room design, a group 1 room is sufficient, i.e., the power may be turned off in case of a single fault condition, and the treatment may be stopped or repeated.
   Additionally, the room must comprise a potential equalization. For further information see IEC 60364-7-710.

4.8 Guidance and manufacturer's declaration for EMC (IEC 60601-1-2)

The information refers to the requirements of IEC 60601-1-2:2007.

4.8.1 Electromagnetic emissions

Guidance and manufacturer's declaration - Electromagnetic emissions		
The hemodialysis device is ready for use in an environment as described below. The customer or the user of the hemodialysis device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guideline**
RF emissions CISPR 11	Group 1	The hemodialysis device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The hemodialysis device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

4.8.2 Electromagnetic immunity

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The hemodialysis device is intended for use in the electromagnetic environment specified below. The customer or the user of the hemodialysis device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guideline**
Discharge of static electricity (DSE) according to IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial and / or hospital environment.
Surge according to IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and / or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 seconds	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 seconds	After power supply interruptions, the battery of the hemodialysis device takes over the supply without delay.
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{rms} 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V_{rms} 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the hemodialysis device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = 1.17 \sqrt{P}$ for 150 kHz to < 80 MHz $d = 1.17 \sqrt{P}$ for 80 MHz to < 800 MHz $d = 2.34 \sqrt{P}$ for 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol. 

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the hemodialysis device is used exceeds the applicable RF compliance level above, the hemodialysis device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the hemodialysis device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

4.8.3 Recommended separation distances between portable and mobile RF telecommunication devices and the device

- **Safety distances by output power rating of the transmitter**

Recommended separation distances between portable and mobile RF telecommunication devices and the hemodialysis device

The hemodialysis device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the hemodialysis device can contribute to avoiding electromagnetic errors, by adhering to the minimum distance between portable and mobile HF telecommunications devices (transmitters) and the hemodialysis device – dependent on the exit performance of the communication device, as indicated below.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to < 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to < 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.34 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- **Safety distances by radiation sources**

Radiation sources	Minimum distance from medical electrical equipment, including all connecting cables
Mobile phone (cell phone)	3.3 m
DECT phone (cordless phone)	1.2 m
Bluetooth devices (notebook, mobile phone)	0.2 m
Radio remote controls	0.1 m
WLAN devices (e.g.: notebook, repeater, access point, print server)	0.7 m

4.9 Operating conditions

Water inflow pressure 1.5 bar to 6.0 bar

Water inflow temperature 5 °C to 30 °C
for „integrated hot rinse“: 85 °C to 95 °C

Water inflow rate 1.3 l/min; with an inlet pressure of 1.5 bar

Water inflow line The length of the water inflow line to a fixed permeate connection (e.g. MSC 08) must not be more than 3 m.

Water quality Only water, which is suitable for hemodialysis, should be used for operating the hemodialysis device. The quality of the water should comply with the local regulations (e.g., ISO 13959:2009).

Maximum permitted values for total viable count and endotoxin concentration in dialysis water (permeate):

Standard specification	Alarm limits	
	Total microbial counts [CFU/ml]	Endotoxin concentration [EU/ml]
ISO 13959:2009	< 100 (AL* : 50)	< 0.25 (AL* : 0.125)

*AL = Action Level. ISO 13959:2009: Concentration from which on steps should be taken to interrupt the trend towards higher, unacceptable values. The value usually is about 50% of the alarm limit.

Water drain	The height of the water drain outlet must be 0 to 100 cm over ground level. The drain outlet must be lower than the dialyzer. An air gap of at least 2 cm must be maintained at the end of the drain. A dedicated, separate, unused drain outlet must be provided for each hemodialysis device. Never combine drain outlets from multiple devices before the air gap is reached. The length of the drain outlet to the air gap must not exceed 3 m. Observe any specific national provisions on the drain outlet air gaps design and backflow prevention measures.
Temperature at water drain	Maximum temperature at water drain: 95 °C
Concentrate supply	0 to –100 mbar; max. suction height 1 m, max. height of fall 0 m
Central Delivery System	Pressure: 0 to 500 mbar Temperature: 15–35 °C Flow: Max. 30 ml/min
Operating temperature range	15 °C to 35 °C
Atmospheric pressure	700 hPa to 1060 hPa
Relative humidity	30 % to 75 %, temporarily 95 %
IV pole pressure	Max. 5 kg
Temporary downtime	Prior to the downtime, it is recommended to carry out a hot rinse program without a cooling rinse (PGM 2) and a disinfection prior to commencing operations.

4.10 Consumption data / energy data

The consumption data / energy data are examples of average values for typical operation.

Environmental conditions: Water inlet temperature 15 °C, Ambient temperature 22 °C.

For the dialysis, a treatment with a blood pump rate of 350 ml/min and a dialysate flow of 500 ml/min is assumed.

Insofar as not noted otherwise, the following consumption values are established for every operating hour.

The data for the cleaning programs is based on the default settings and apply to each program run.

Other data is available from the manufacturer on request.

Average water consumption	Dialysis: approx. 30 liters Disinfection: approx. 14.5 liters Heat disinfection: approx. 10.5 liters
Mean acid concentrate consumption	Dialysis (mixing ratio 1+44 ACF): approx. 0.7 liters

Mean bicarbonate consumption	approx. 650 g bicarbonate (bi*b*ag®) every 6 hours
Mean energy consumption	Dialysis: approx. 0.67 kWh Heat disinfection: approx. 0.79 kWh
Average energy emission to drain	Dialysis: approx. 0.50 kWh Heat disinfection: approx. 0.46 kWh
Average energy emission to environment	Dialysis: approx. 0.17 kWh Heat disinfection: approx. 0.33 kWh

4.11 Storage conditions

The hemodialysis device must be stored upright in a well-ventilated room with little variations in temperature.

Storage temperature

Storage temperature:

without antifreeze	+5 °C to +60 °C
with antifreeze	-20 °C to +60 °C

Atmospheric pressure

500 hPa to 1060 hPa

Relative humidity

30 % to 75 %, temporarily 95 %

Antifreeze solution

When storing the hemodialysis device with antifreeze, make sure to use antifreeze of the following composition:
- 49.875 % water
- 49.875 % glycerin
- 0.25% ClearSurf

Frost resistance

Up to –20 °C

Charging the integrated battery

If the device is not used the batteries have to be charged every six months as follows:
- Connect the device to the external power supply by means of the power cable.
- Then turn the device on for approx. 10 hours.

4.12 External connection options

Other, additional equipment connected to this device must comply with the applicable IEC or ISO standards (e.g., IEC 60950-1 for information technology equipment).

Furthermore, all device configurations shall comply with the requirements for medical electrical systems (see Chapter 16 and Appendix I to EN 60601-1:2006).

Connecting the device to an IT network that contains components not installed and validated by the manufacturer can introduce unknown risks for patients, operators or third parties. These risks must be identified, analyzed, evaluated and monitored by the responsible organization. For assistance, consult IEC 80001-1:2010 and annexes H5 and H6 to EN 60601-1:2006.

Any modification to an IT network that has been installed and validated by the device manufacturer can introduce new risks and therefore require a repeat analysis. Especially problematic activities include:
– changing the IT network configuration
– connection of additional components and devices to the IT network
– removal of components and devices from the IT network
– updating or upgrading components and devices in the IT network

Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult the local service.

Warning

The operator may not touch the patient and the plug connectors or socket contacts of the device at the same time. Otherwise, there is the risk of patient leakage current.

Network	Socket for Fresenius card reader (option UniDataLink)
Input / output	Used to connect external equipment (UniDataLink option or service gage equipment. Service gage equipment must not be used during a treatment session.)
Alarm in (alarm input)	Used to connect an external Fresenius patient button or an AquaUNO / AquaC UNO H. These devices can be used to trigger a device stop.
Alarm out (alarm output)	For the connection of an external alarm indicator (staff call). (Potential-free alarm output. Alternating contact maximum 24 V / 24 W). Connector: 5-pin diode plug via a shielded line; shield grounded on either side.
Service PC	Used exclusively to connect a service PC (must not be used during a treatment session).

4.13 Override conditions

Audio paused	Mute alarm time: adjustable in the SETUP MENU from 1 minute to 2 minutes (factory setting: 1 minute) Any new alarm reactivates the silenced audible alarm.
Blood leak override	Override time: 2 minutes

Alarm override

The key **Start/Reset** overrides:
– an arterial and venous pressure alarm for approx. 8 seconds
– a blood leak alarm for approx. 8 seconds
– a TMP alarm for approx. 2 minutes (time determined by the UF coefficient).

When overriding a safety system, the responsibility for the patient's safety rests with the operator of the device.

4.14 Materials used

● **Plastics**

Description	Use in the dialysis circuit
ABS	
EPDM	X
NBR	
PA (PA 6.6)	
PBT	
PBT	X
PBT / ABS GF 20	
PC	X
PC+ABS	
PE	
PE (soft)	
PEEK	X
PES	X
Polyester	
POM	
PP	X
PP-H	X
PP(E)	
PPO	X
PPS	X
PPSU	X

Description	Use in the dialysis circuit
PS	
PSU	
PTFE	X
PUR	
PVC	
PVDF	X
Silicone SIK	X
Silicon tubing	X
TPE	
VMQ SI (Q)	
Silicone	X
TEEE	
CM/ EPDM-L	
EPDM	

- **Metals / glass**

Description	Use in the dialysis circuit
Graphite	X
Glass	X
Aluminum	
Sheet copper	
Steel sheet	
Aluminum sheet	
St37K	
1.4300	
1.4301	
1.4305	
1.4401	X
1.4404 / 1.4435	X

Description	Use in the dialysis circuit
Spring steel 1.4568	
Titanium	X
Spring steel 1.4310	

- **Miscellaneous – various materials**

Description	Use in the dialysis circuit
Radox	
Lexan (plexiglass)	
Oxit 100	
Steel 1.1121	
Steel, cadmium-plated and chrome-plated	
MS 58	
MS 63	
Leather (bag)	
Nylon 6/6 UL 94 V-2	
Paper	
Perlon D536/20 (roller blind strap)	
Silpad 400	
Thermally conducting paste	
Synchroflex (toothed belt)	
Sirex PU foam (insulating boards), open-pored, adhesive on one side	
Ceramics	X

- **Miscellaneous – adhesives**

Description	Use in the dialysis circuit
Loctite	
Scotch-Weld DP 460	
Scotch-Weld V 23	

Description	Use in the dialysis circuit
Cyanolit	
Elastosil	
3 M Scotch Weld EPXDPU60	

- **Miscellaneous – lacquers**

Description	Use in the dialysis circuit
Enamel: Pehapol	
Base: Epoxy resin	
Prime coat: P 81.914 (base)	
Hardener: P 85.033 (PUR)	
Insulating lacquer: Type FS 190	
Dilution: Type FS 225	
Screening lacquer: Elektro DAG 438/ Fa. Acheson	
Screwlock Loctite 243	

- **Miscellaneous – packaging**

Description	Use in the dialysis circuit
Ethafoam (polystyrene)	
Corrugated cardboard	
Cellular rubber	
Wooden pallet	

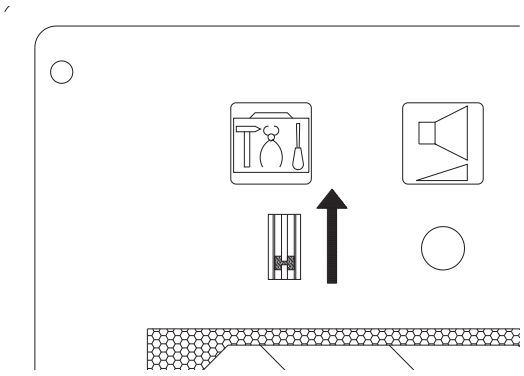
- **Electrical equipment**

Description	Assembly type	Use in the dialysis circuit
Copper, cast steel, cast zinc	Motors	
Copper, polyester / polyurethane Potting compound PU 151/20, UP resin, Iron core	Transformers	
Copper + tin, glassfiber enforced thermoplast	Plug connectors	
P.C.B. base material, epoxy fiberglass Ferrite cores, lithium batteries, lead-acid battery	Electronic components	
Copper, PVC, Teflon	Cables	

5 Setup / service program

5.1 Service mode

The Service menus CALIBRATION, DIAGNOSTICS, MISCELLANEOUS, and SETUP MENU can only be called in service mode.



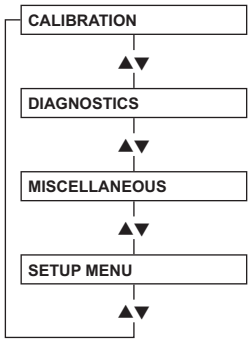
To enter the service mode, proceed as follows:

1. The device must be switched off.
2. Set the Service switch to ON (up).
3. Turn the device on.

Warning

Setting the service switch to ON while the treatment or the cleaning program is in progress will turn off the heater relay.

5.1.1 Service mode overview



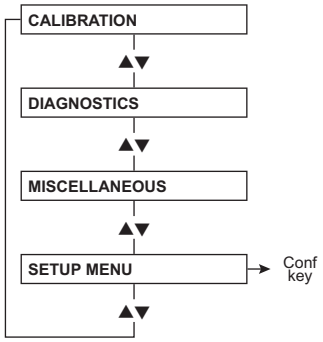
5.1.2 Service mode key functions

CALIBRATION, DIAGNOSTICS, MISCELLANEOUS and SETUP MENU are controlled with the following keys.

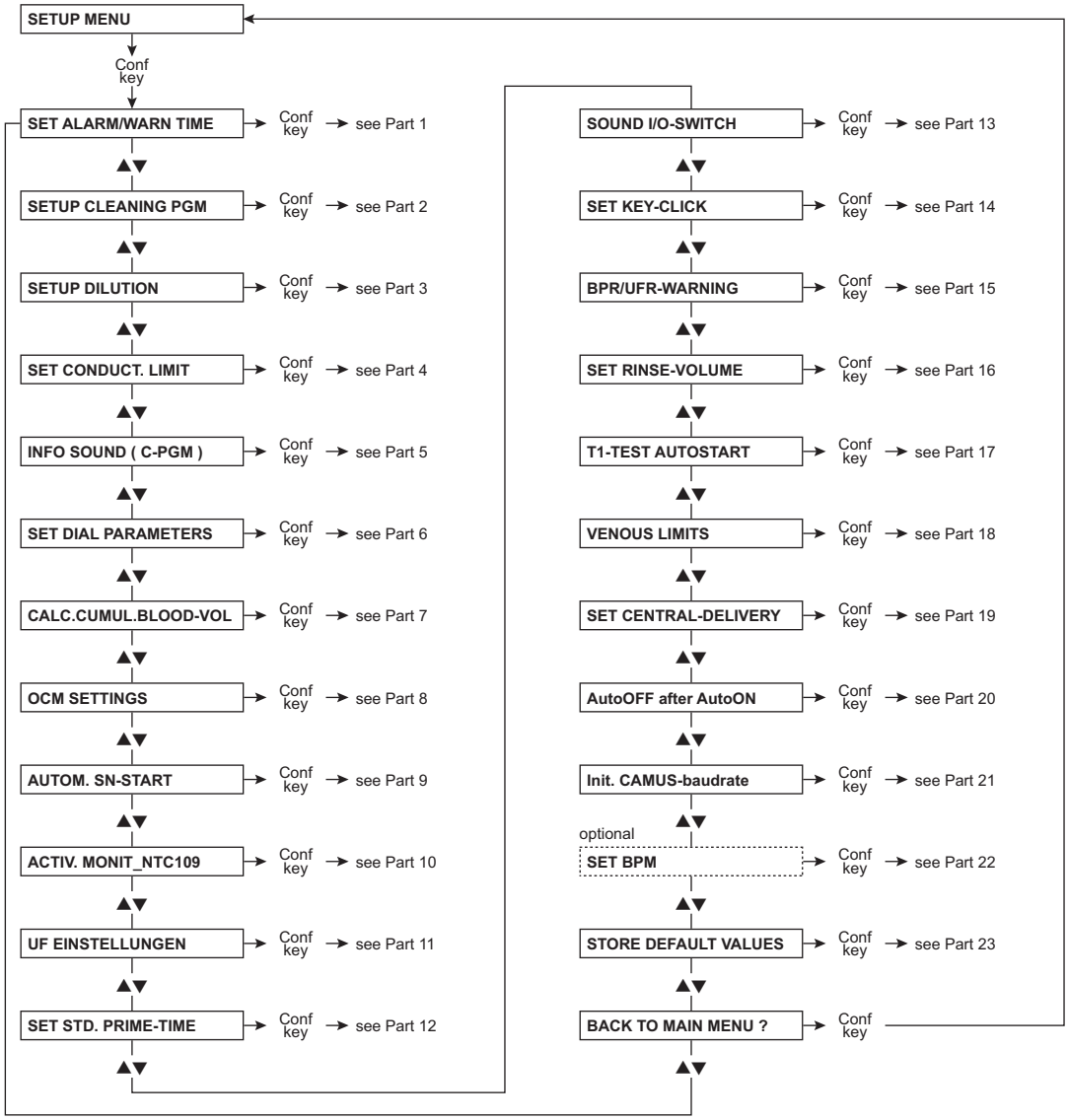
Function	Key
Scrolling through menu items	▲ / ▼
Selecting a menu item	**Conf**
Changing values and functions in the menus	**+ / –**
Storing the modified values	**(Audio paused)**
Exiting a menu without saving the data	**Esc**

5.1.3 SETUP MENU

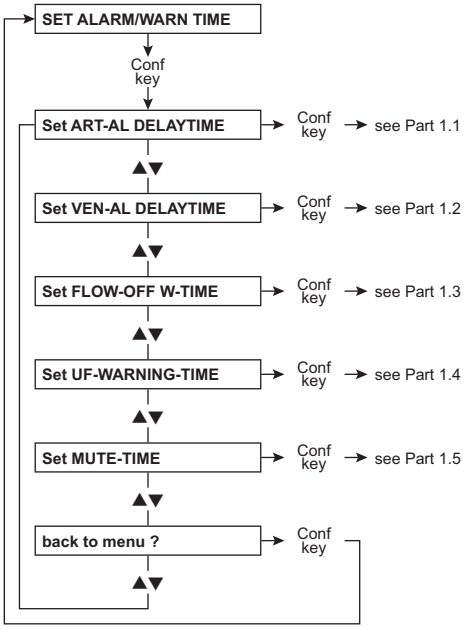
The **SETUP MENU** can only be called in service mode.



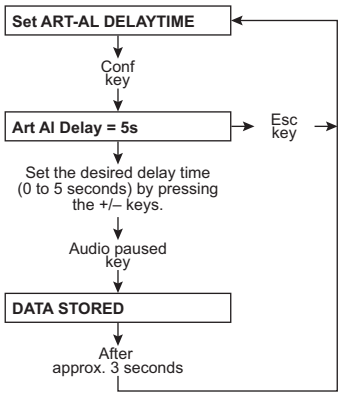
5.1.3.1 SETUP MENU - menu structure



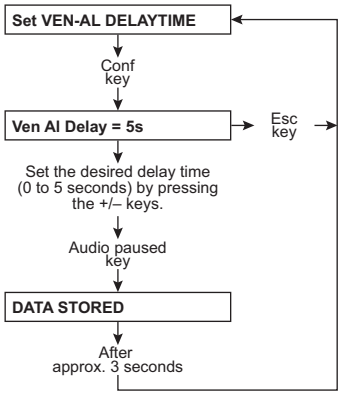
5.1.3.2 Part 1: Setting alarm and warning times



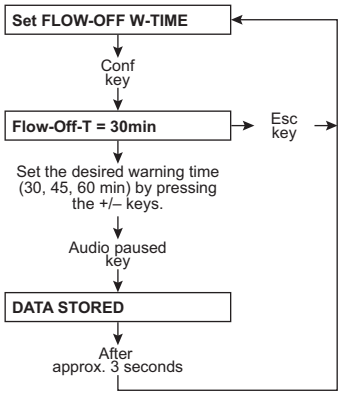
- **Part 1.1: Setting the arterial alarm delay**



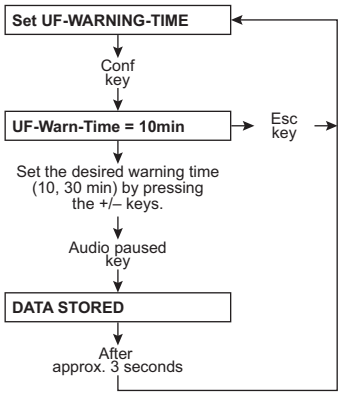
Part 1.2: Setting the venous alarm delay



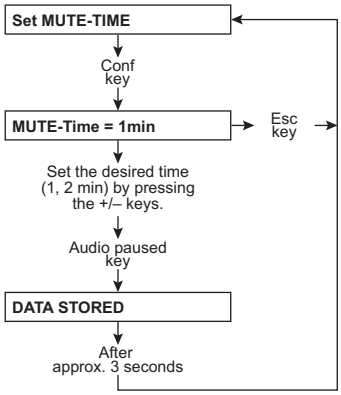
Part 1.3: Setting the flow-off warning time



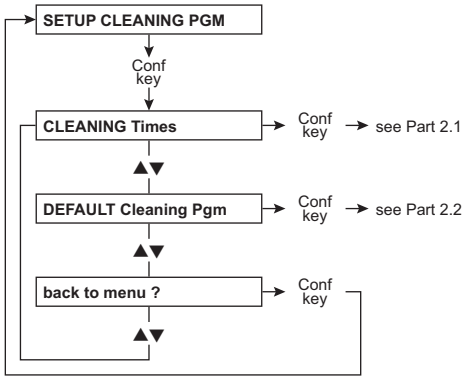
Part 1.4: Setting the UF warning time



- **Part 1.5: Setting the mute time**



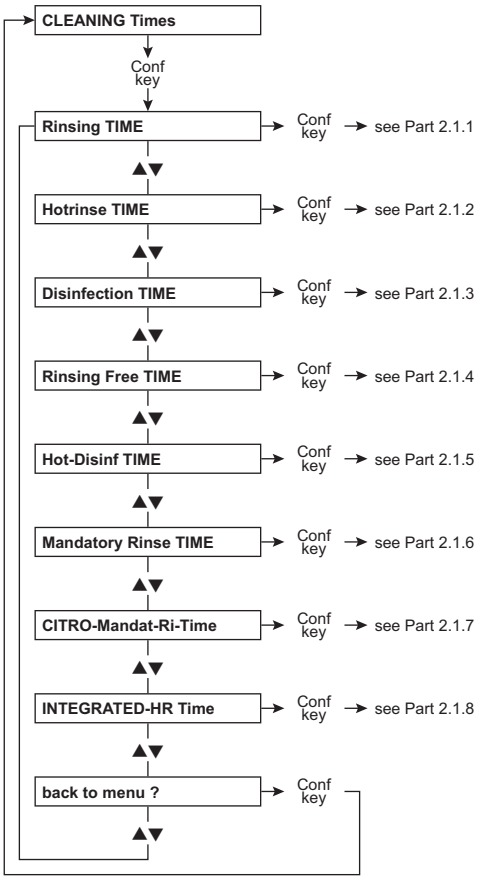
5.1.3.3 Part 2: Setting the cleaning program



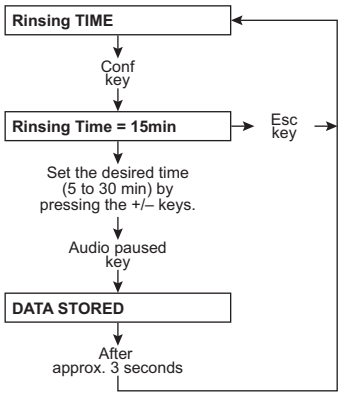
Part 2.1: Cleaning times

Note

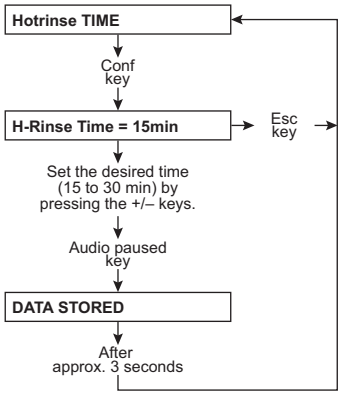
When indicating the cleaning times, the default values and the adjustable range are not indicated, as they depend on the particular device options.



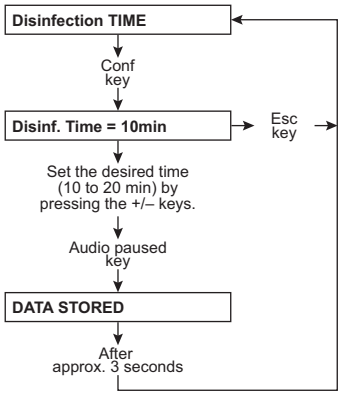
Part 2.1.1: Rinsing time



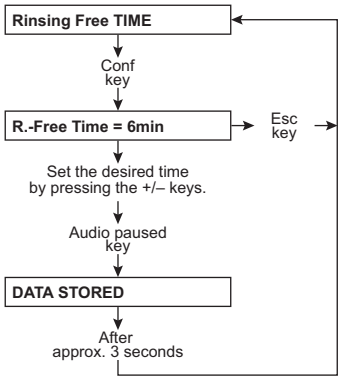
● Part 2.1.2: Hotrinse time



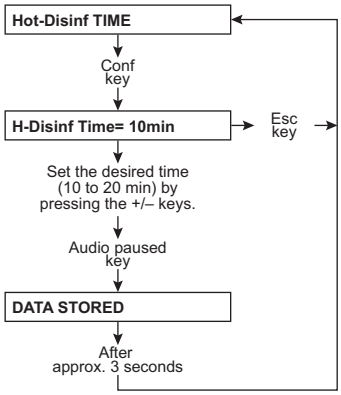
● Part 2.1.3: Disinfection time



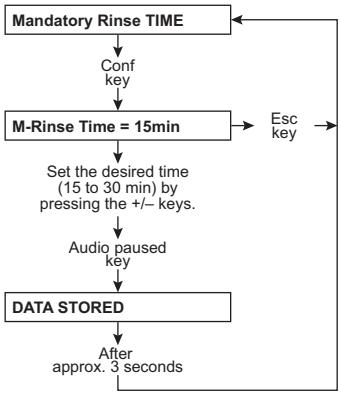
● Part 2.1.4: Rinsing free time



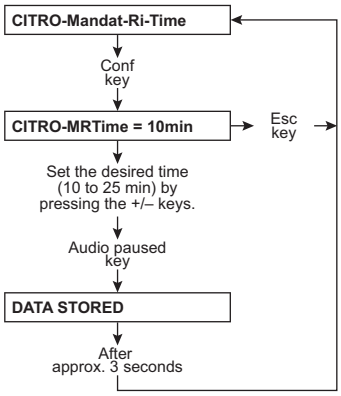
Part 2.1.5: Hot disinfection time



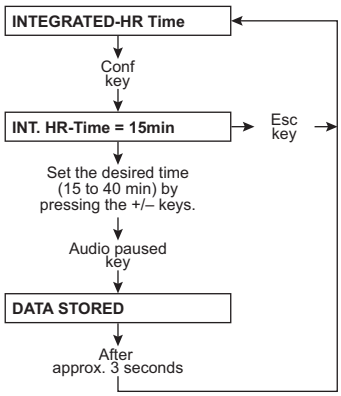
Part 2.1.6: Mandatory rinse time



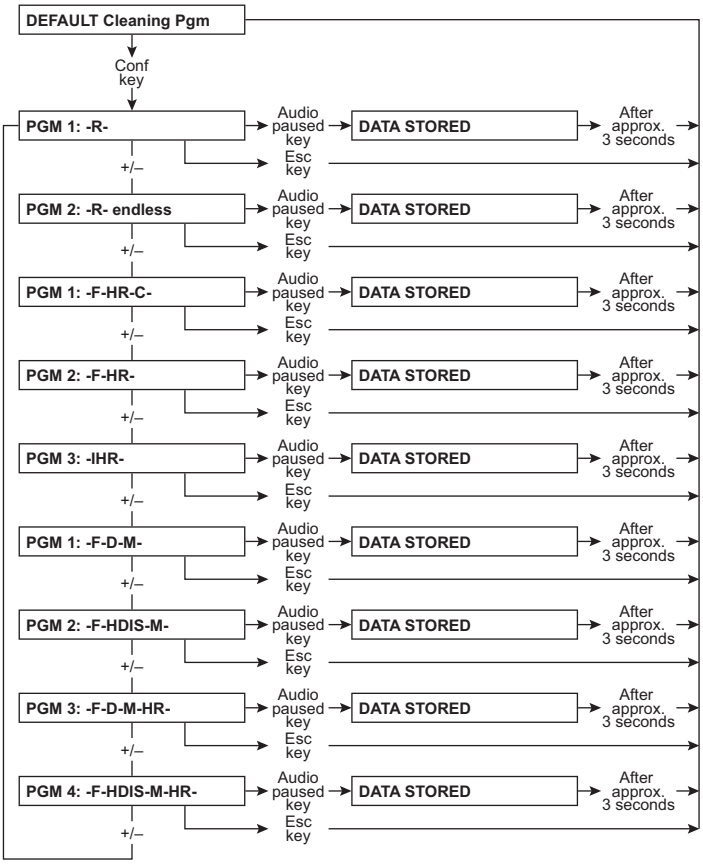
Part 2.1.7: Citro mandatory rinsing time



● Part 2.1.8: Integrated hot rinse time

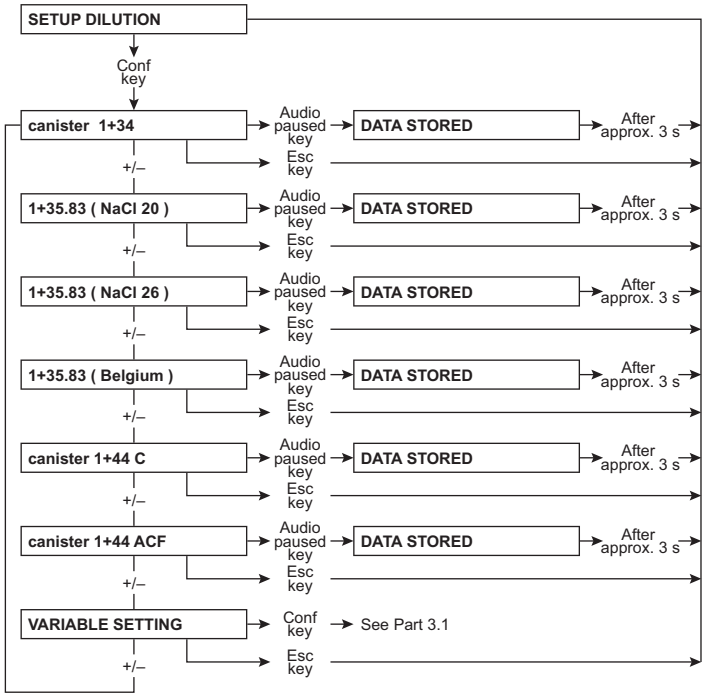


● Part 2.2: Default cleaning programs

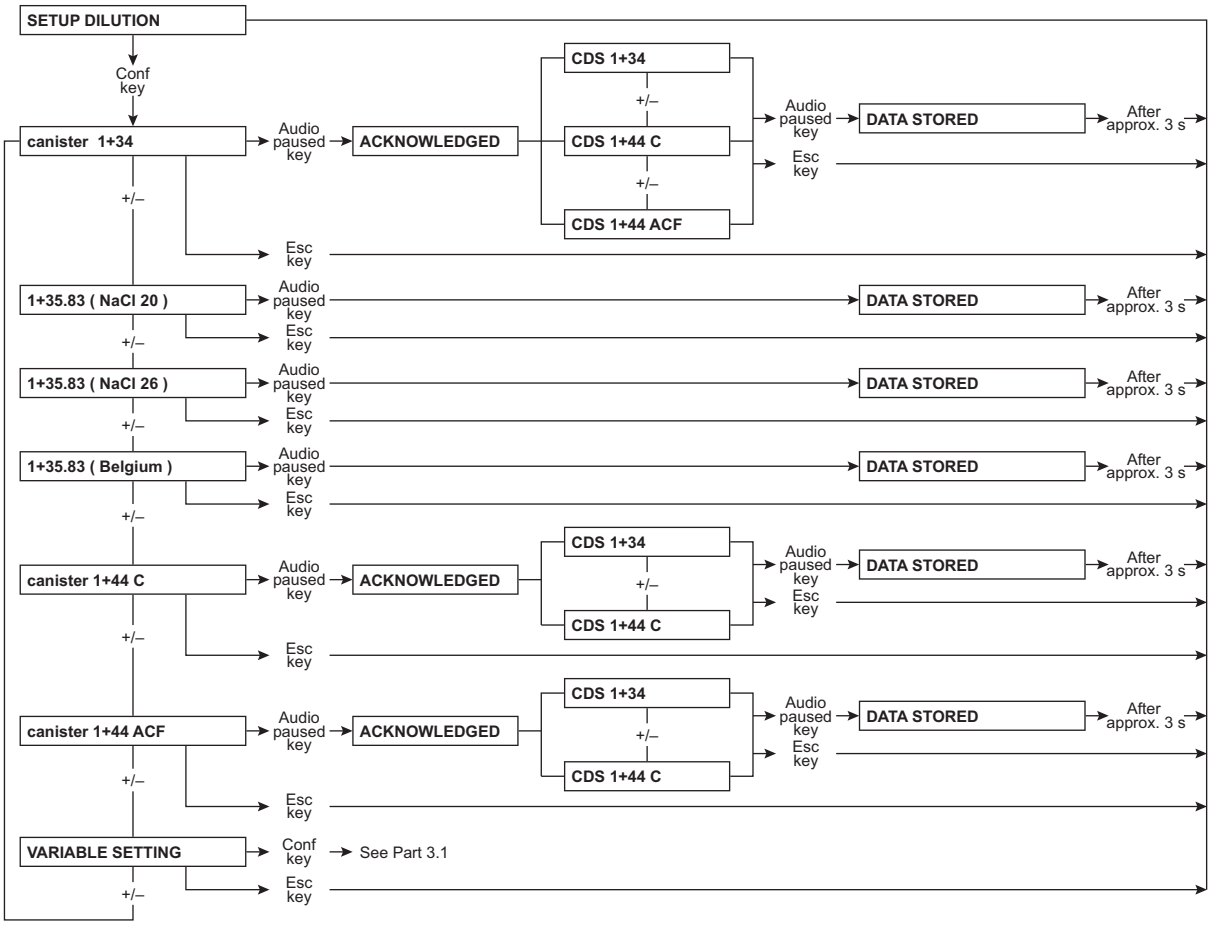


5.1.3.4 Part 3: Mixing ratio

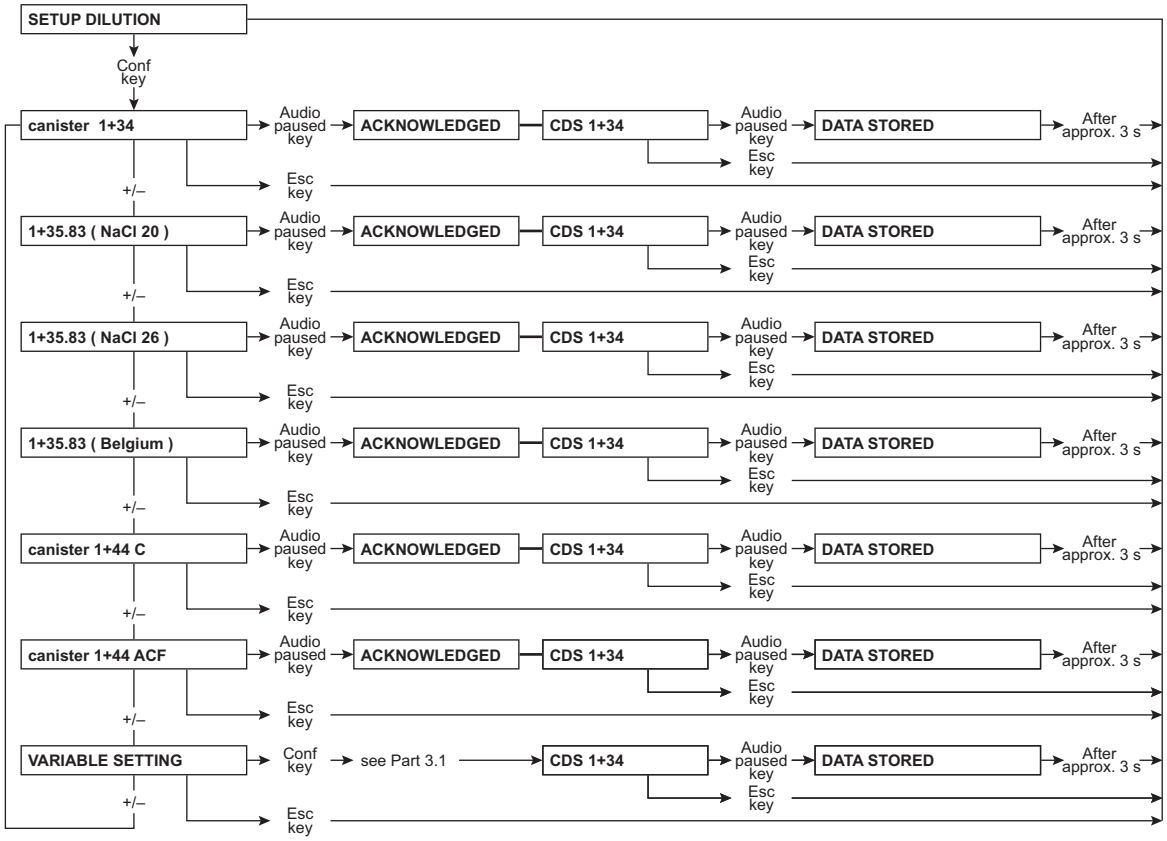
If "**NO central-delivery**"
is set: (see **Part 19: Setting central delivery** page 5-24)



If "**central Acid**"
is set: (see **Part 19: Setting central delivery** page 5-24)



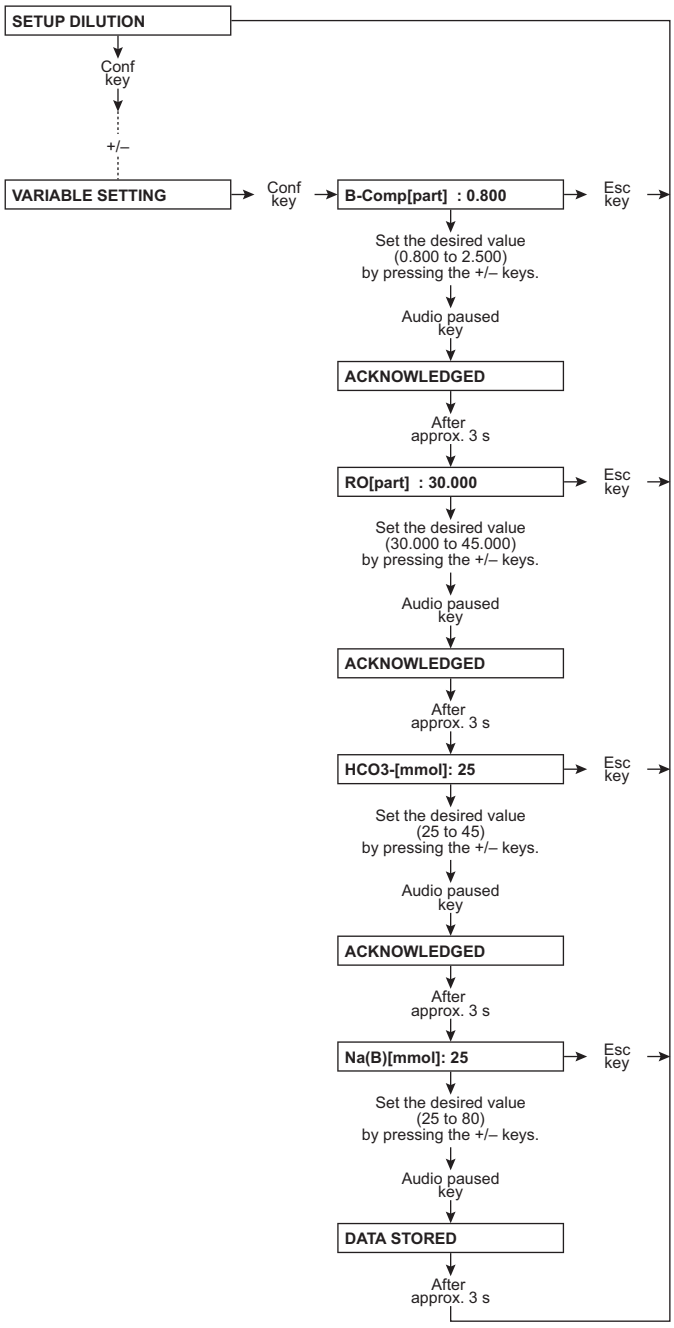
If "**centr acetate-supply**"
is set: (see **Part 19: Setting central delivery** page 5-24)



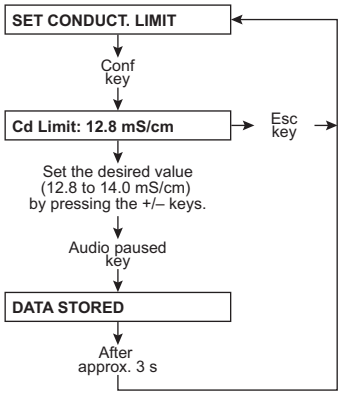
● Part 3.1 User adjustable mixing ratio

Warning

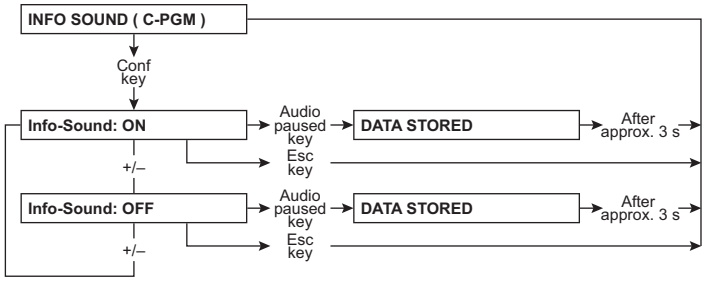
The operator or technician is informed about his duty of care to enter the component parameters and settings correctly or to check them and to set the CD alarm window to the expected conductivity value.
When using the user adjustable mixing ratio, make sure to use the right concentrate.
Using a bi*b*ag® in combination with the user adjustable mixing ratio is not allowed.
Only enter approved user adjustable mixing ratios.



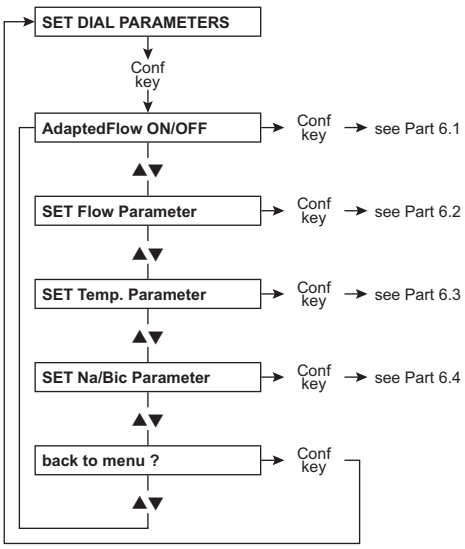
5.1.3.5 Part 4: Setting the conductivity limit



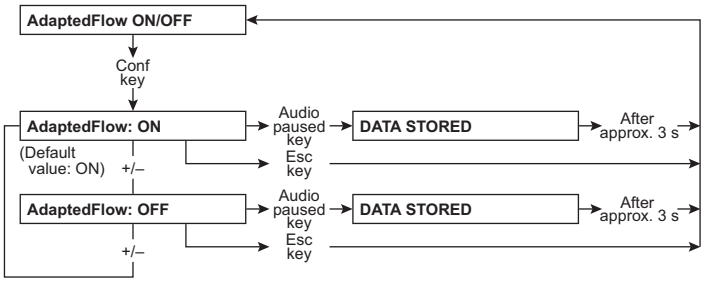
5.1.3.6 Part 5: Cleaning program info sound



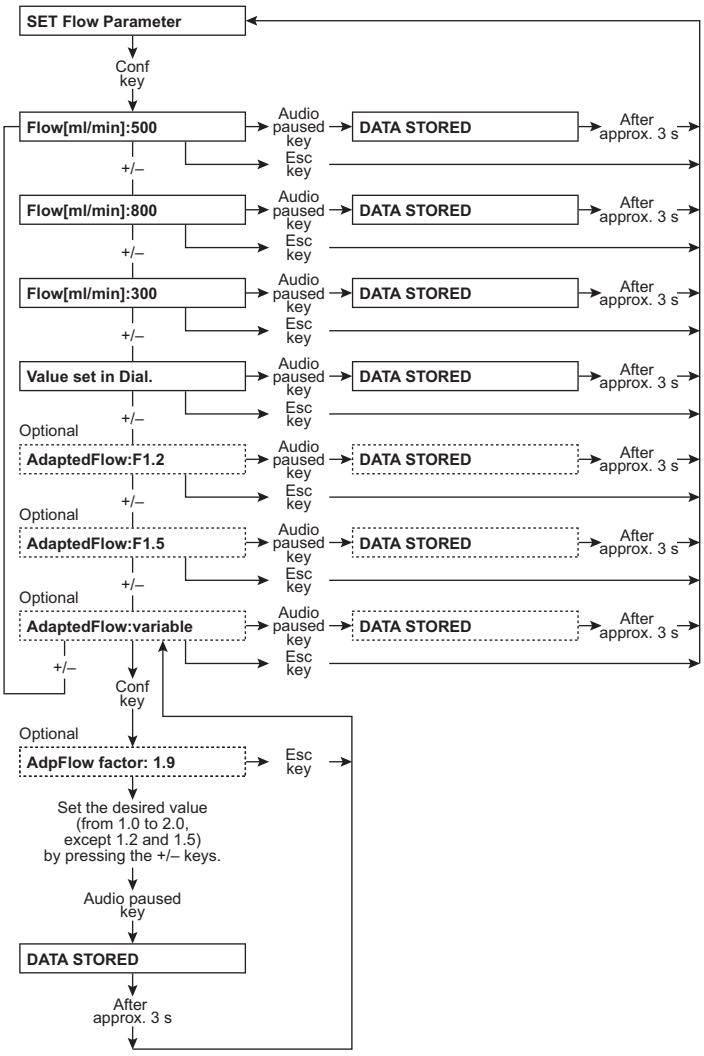
5.1.3.7 Part 6: Setting dialysis parameters



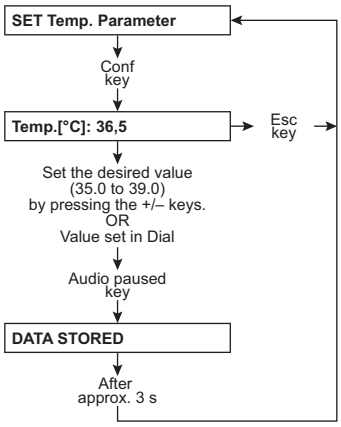
Part 6.1: Adapted Flow ON/OFF (optional)



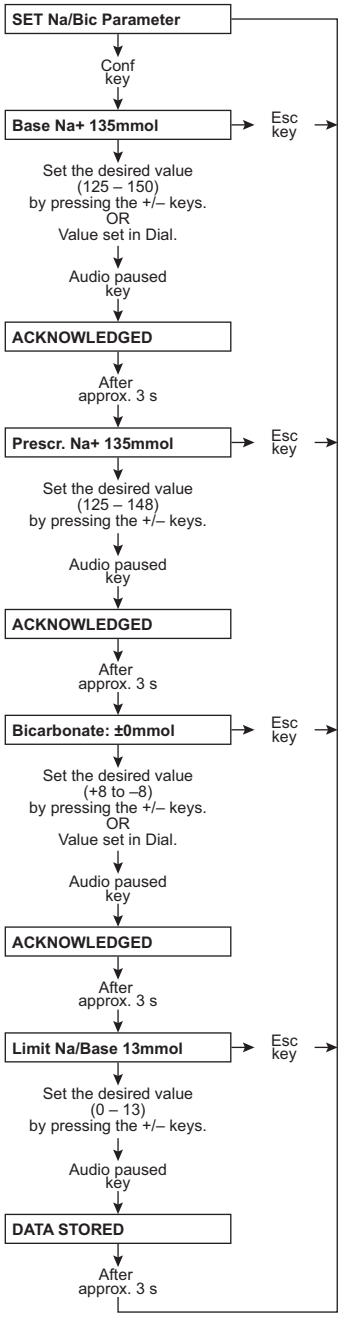
Part 6.2: Setting the dialysate flow



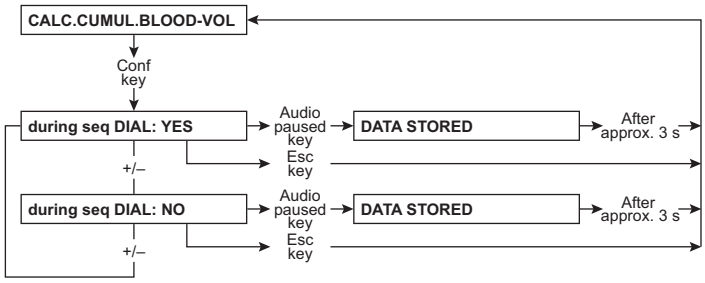
● Part 6.3: Setting the dialysate temperature



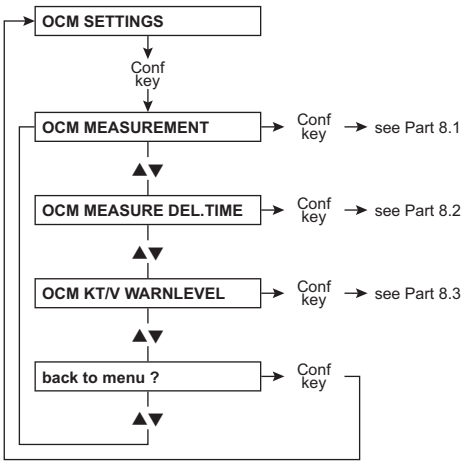
● Part 6.4: Setting Na/Bic



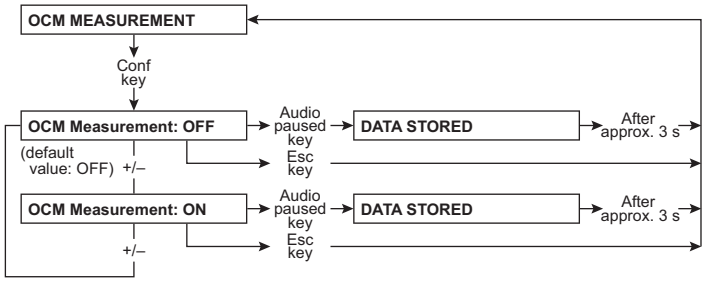
5.1.3.8 Part 7: Cumulated blood volume



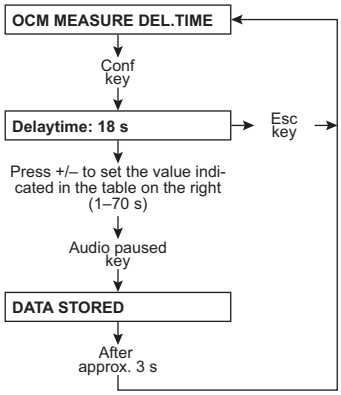
5.1.3.9 Part 8: OCM settings



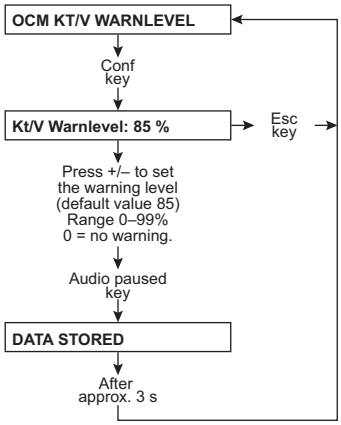
- **Part 8.1: Activating OCM measurement**



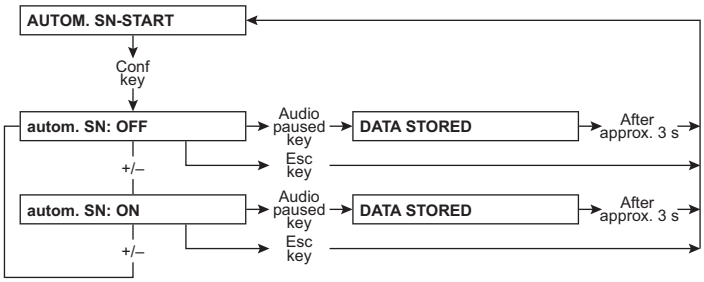
- **Part 8.2: Setting the OCM measurement delay time**



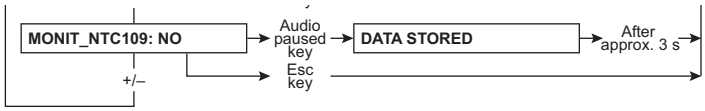
- **Part 8.3: Setting the OCM Kt/V warning level**



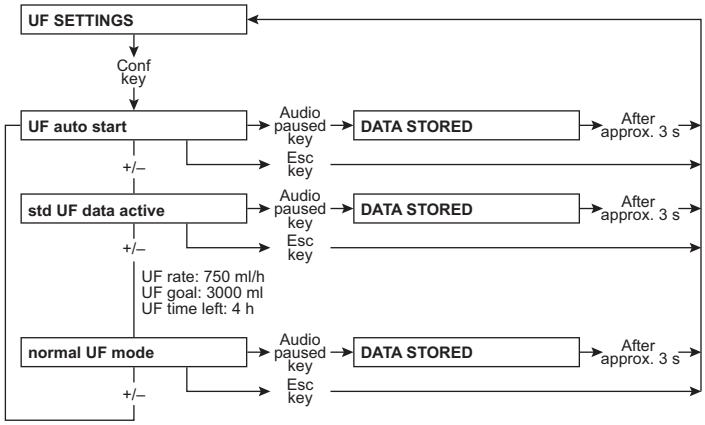
5.1.3.10 Part 9: Automatically starting Single-Needle mode



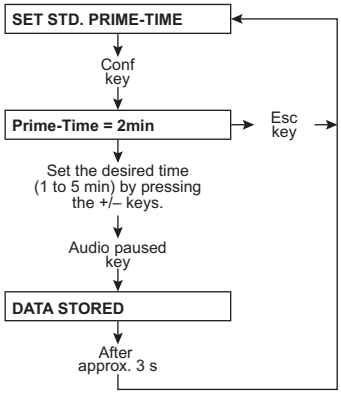
5.1.3.11 Part 10: Activating Monit_NTC 109



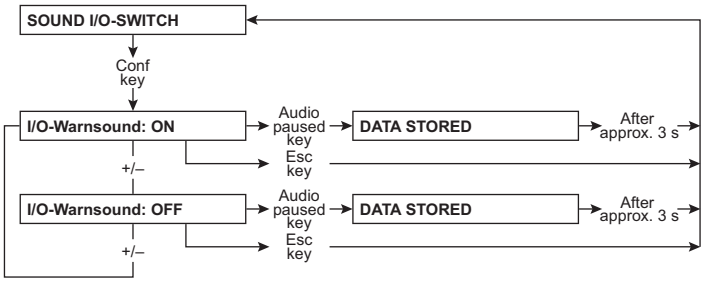
5.1.3.12 Part 11: UF settings



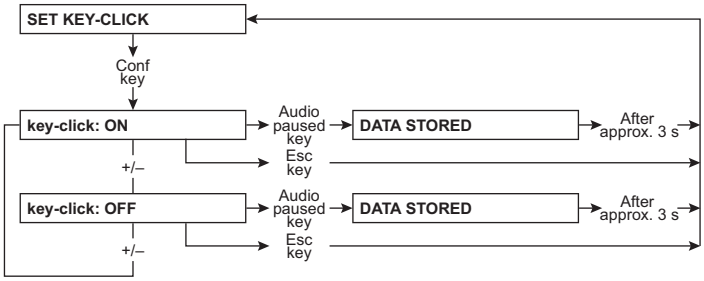
5.1.3.13 Part 12: Setting the priming time



5.1.3.14 Part 13: Sound I/O switch



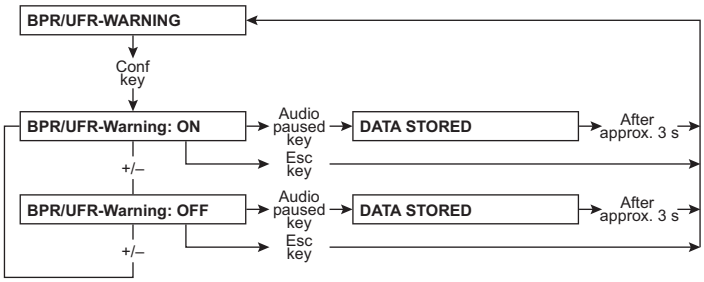
5.1.3.15 Part 14: Activating the key click



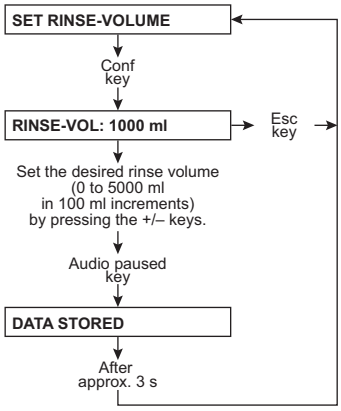
5.1.3.16 Part 15: Setting the BPR/UFR warning

Note

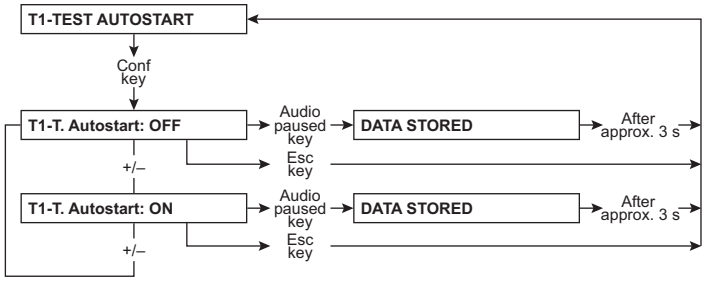
The BPR/UFR warning may be deactivated only for service work or when troubleshooting. In dialysis mode, the BPR/UFR warning must always be enabled, i.e. "ON".



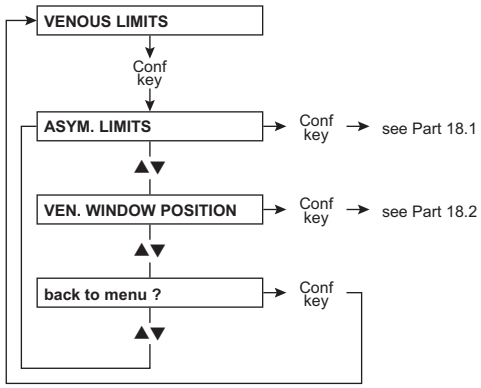
5.1.3.17 Part 16: Setting the rinse volume



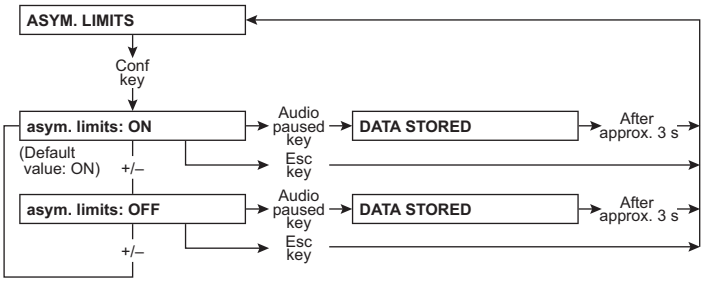
5.1.3.18 Part 17: T1 test autostart



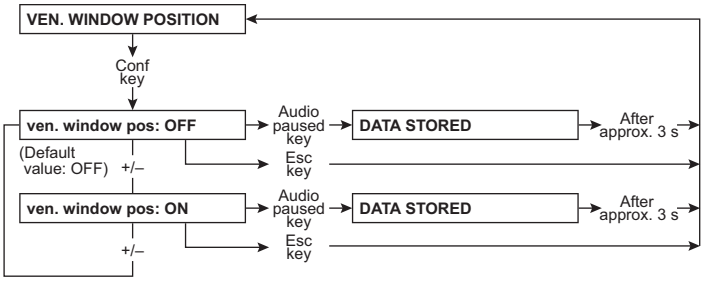
5.1.3.19 Part 18: Setting the venous alarm window



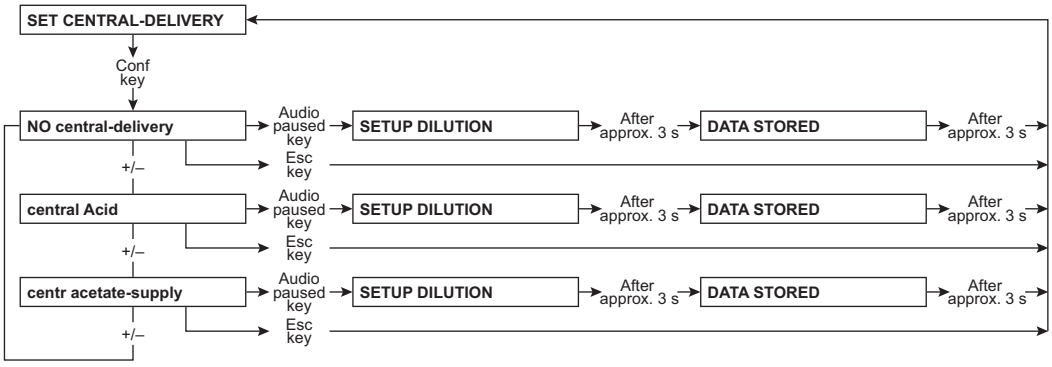
- **Part 18.1: Asymmetrical limits**



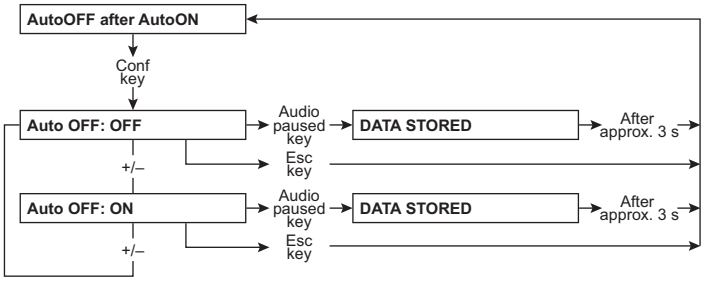
- **Part 18.2: Venous window position**



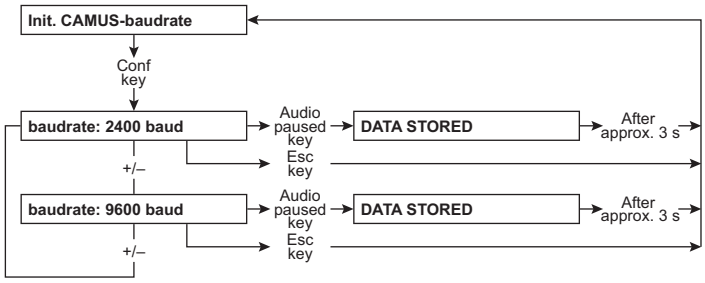
5.1.3.20 Part 19: Setting central delivery



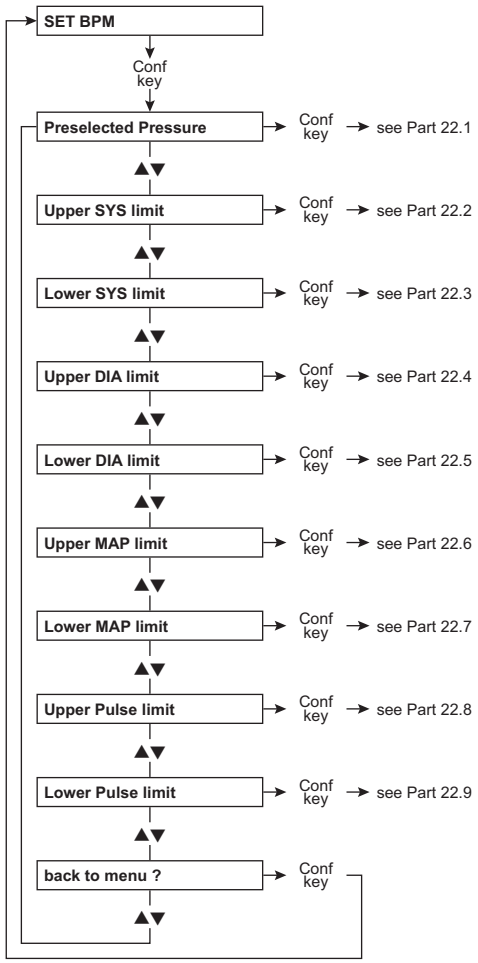
5.1.3.21 Part 20: AutoOFF after AutoON



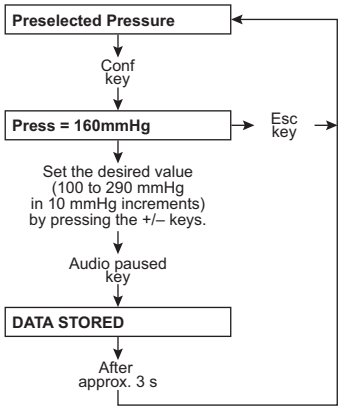
5.1.3.22 Part 21: CAMUS baud rate



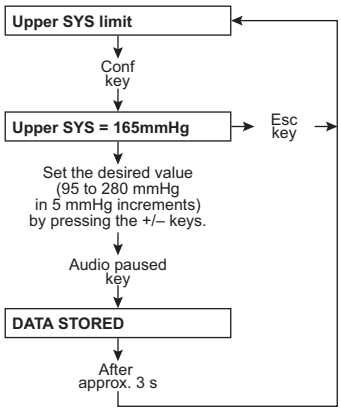
5.1.3.23 Part 22: BPM settings (optional)



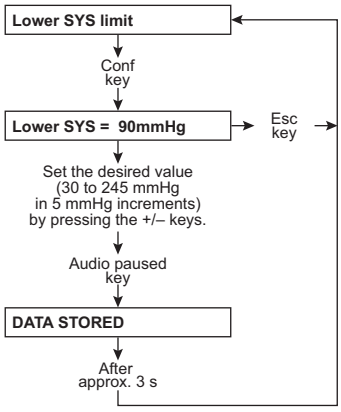
- **Part 22.1: Setting the preselected pressure**



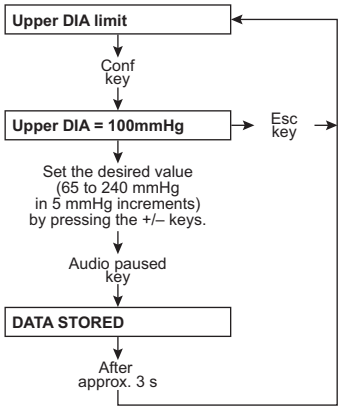
- **Part 22.2: Setting the upper systolic limit**



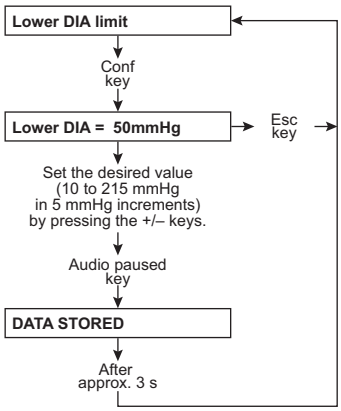
- **Part 22.3: Setting the lower systolic limit**



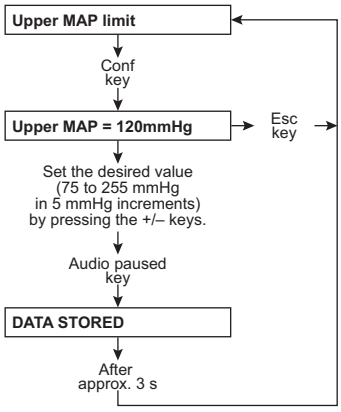
- **Part 22.4: Setting the upper diastolic limit**



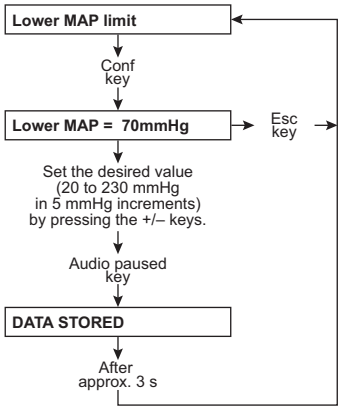
- **Part 22.5: Setting the lower diastolic limit**



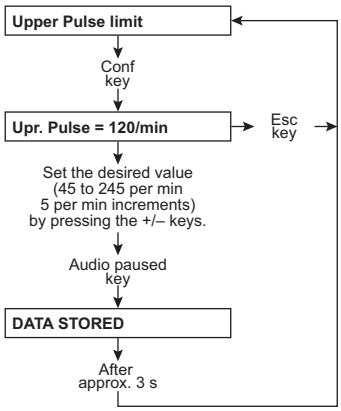
- **Part 22.6: Setting the upper MAP limit**



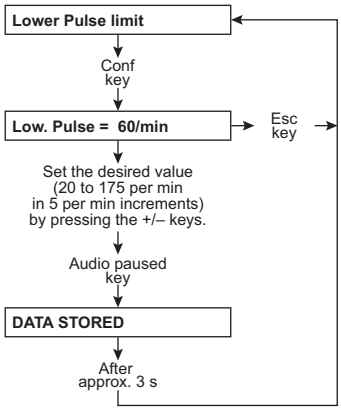
- **Part 22.7: Setting the lower MAP limit**



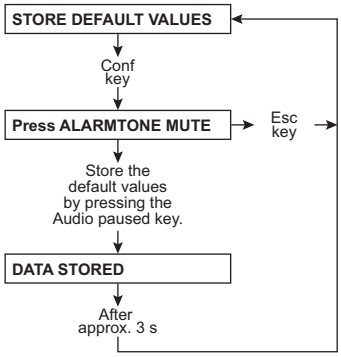
- **Part 22.8: Setting the upper pulse limit**



- **Part 22.9: Setting the lower pulse limit**



5.1.3.24 Part 23: Storing default values



5.1.3.25 SETUP MENU settings

The Service application can be used to transfer settings.
For further details, consult the Quick Guide (see chapter 5.4 page 5-74) for the Service Software.

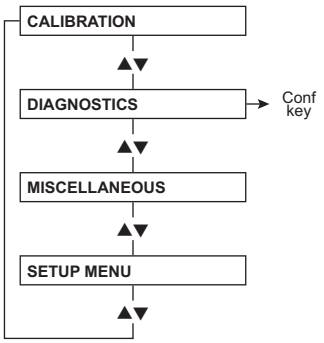
Menu item	Submenu	Default value	Value range Selectable options	Resolution
SET ALARM/WARN TIME	**Set ART-AL DELAYTIME**	5 s	0–5 s	1 s
	Set VEN-AL DELAYTIME	5 s	0–5 s	1 s
	Set FLOW-OFF W-TIME	30 min	30–60 min	15 min
	Set UF WARNING TIME	10 min	10/30 min	20 min
	Set MUTE-TIME	1 min	1-2 min	1 min
SETUP CLEANING PGM				
CLEANING Times	**Rinsing TIME**	15 min	5-30 min	1 min
	Hotrinse TIME	15 min	15-30 min	1 min
	Disinfection TIME	10 min	10–20 min	1 min
	Rinsing Free TIME	CPU1: DIP switch array 1, switch 8 is on "OFF" (Test flow 800 ml/min)		
		3 min	3-10 min	1 min
		For CDS: 5 min	5-10 min	1 min
		CPU1: DIP switch array 1, switch 8 is on "ON" (Test flow 500 ml/min)		
		4 min	4-10 min	1 min
		For CDS: 6 min	6-10 min	1 min
	Hot-Disinf TIME	10 min	10-20 min	1 min
	Mandatory Rinse TIME	CPU1: DIP switch array 1, switch 8 is on "OFF" (Test flow 800 ml/min)		
		15 min	15-30 min	1 min
		CPU1: DIP switch array 1, switch 8 is on "ON" (Test flow 500 ml/min)		
		15 min	15-30 min	1 min
	CITRO-Mandat-Ri-Time	CPU1: DIP switch array 1, switch 8 is on "OFF" (Test flow 800 ml/min)		
		10 min	10-25 min	1 min
		CPU1: DIP switch array 1, switch 8 is on "ON" (Test flow 500 ml/min)		
		10 min	10-25 min	1 min
	INTEGRATED-HR Time	15 min	15-40 min	1 min
DEFAULT Cleaning Pgm		**PGM 1: -R-**	**PGM 1: -R-** **PGM 2: -R- endless** **PGM 1: -F-HR-C-** **PGM 2: -F-HR-** **PGM 3: -IHR-** **PGM 1: -F-D-M-** **PGM 2: -F-HDIS-M-** **PGM 3: -F-D-M-HR-** **PGM 4: -F-HDIS-M-HR-**	

Menu item	Submenu	Default value	Value range Selectable options	Resolution
SETUP DILUTION	**Canister**	**1+34**	**1+34** **1+35.83 (NaCl 20)** **1+35.83 (NaCl 26)** **1+35.83 (Belgium)** **1+44 C** **1+44 ACF** **VARIABLE SETTING**	
	CDS	**1+34**	**1+34** **1+35.83 (NaCl 20)** **1+35.83 (NaCl 26)** **1+35.83 (Belgium)** **1+44 C** **1+44 ACF** **VARIABLE SETTING**	
	VARIABLE SETTING	– – – –	0.800-2.500 30.000-45.000 25-45 25-80	0.001 0.001 1 1
SET CONDUCT. LIMIT	**Cd Limit: 12.8 mS/cm**	12.8 mS/cm	12.8–14.0 mS/cm	0.1 mS/cm
INFO SOUND (C-PGM)		**Info sound: ON**	**Info sound: ON** **Info sound: OFF**	
SET DIAL PARAMETERS				
AdaptedFlow ON/OFF (with Adapted Flow option)		**AdaptedFlow: ON**	**AdaptedFlow: ON** **AdaptedFlow: OFF**	
SET Flow Parameter		**Flow[ml/min]:500** (AdaptedFlow: OFF) or **AdaptedFlow:F1.2** (AdaptedFlow: ON)	**Flow[ml/min]:300** **Flow[ml/min]:500** **Flow[ml/min]:800** **Value set in Dial.** **AdaptedFlow:F1.2** (only AdaptedFlow ON) **AdaptedFlow:F1.5** (only AdaptedFlow ON) **AdaptedFlow:Variable** F1.0–F2.0 without F1.2/F1.5 (only AdaptedFlow ON)	
SET Temp. Parameter	**Temp.[°C]:**	36.5 ?	35-39 °C or value set in Dial	0.5 °C
SET Na/Bic Parameter	**Base Na+ 135 mmol**	135 mmol	125–150 mmol or value set in Dial	1 mmol
	Prescribed Na+ 135 mmol	135 mmol	125–150 mmol (±13 mmol about the base value)	1 mmol
	Bicarbonate ±0 mmol	0 mmol	–8 to +8 mmol or value set in Dial	1 mmol
	Limit Na/Base 13 mmol	13 mmol	0-13 mmol however, prescribed Na^+, base Na^+	1 mmol
CALC.CUMUL.BLOOD-VOL		**during seq DIAL: YES**	**during seq DIAL: YES** **during seq DIAL: NO**	
OCM SETTINGS	**OCM MEASUREMENT**	**OCM Measurement: OFF**	**OCM Measurement: OFF** **OCM Measurement: ON**	
	OCM MEASURE DEL.TIME	18 s	1–70 s	1 s
	OCM KT/V WARNLEVEL	85 %	0–99 %	1 %
AUTOM. SN-START		**autom. SN: OFF**	**autom. SN: OFF** **autom. SN: ON**	
ACTIV. MONIT_NTC109		**MONIT_NTC109: YES**	**MONIT_NTC109: YES** **MONIT_NTC109: NO**	
UF SETTINGS		**UF auto start**	**UF auto start** **std UF data active** **Normal UF mode**	
SET STD. PRIME-TIME	**Prime-Time = 2 min**	2 min	1-5 min	1 min
SOUND I/O-SWITCH		**I/O-Warnsound: ON**	**I/O-Warnsound: ON** **I/O-Warnsound: OFF**	
ACTIV. KEY-CLICK		**Key-click: ON**	**Key-click: ON** **Key-click: OFF**	
BPR/UFR WARNING		**BPR/UFR warning: ON**	**BPR/UFR warning: ON** **BPR/UFR warning: OFF**	
SET RINSE-VOLUME	**RINSE-VOL: 1000 ml**	1000 ml	0–5000 ml	100 ml
T1-TEST AUTOSTART		**T1-T. Autostart: OFF**	**T1-T. Autostart: OFF** **T1-T. Autostart: ON**	

Menu item	Submenu	Default value	Value range Selectable options	Resolution
VENOUS LIMITS	**ASYM. LIMITS**	**asym. limits: ON**	**asym. limits: ON** **asym. limits: OFF**	
	VEN. WINDOW POSITION	**ven. window position: OFF**	**ven. window position: OFF** **ven. window position: ON**	
SET CENTRAL-DELIVERY		**NO central-delivery**	**NO central-delivery** **central Acid** **centr acetate-supply**	
AutoOFF after AutoON		**Auto OFF: OFF**	**Auto OFF: ON** **Auto OFF: OFF**	
Init. CAMUS baudrate		**baudrate: 2400 baud**	**baudrate: 2400 baud** **baudrate: 9600 baud**	
SET BPM	**Preselected Pressure**	160 mmHg	100–290 mmHg	10 mmHg
	Upper SYS limit	165 mmHg	95-280 mmHg	5 mmHg
	Lower SYS limit	90 mmHg	30-245 mmHg	5 mmHg
	Upper DIA limit	100 mmHg	65-240 mmHg	5 mmHg
	Lower DIA limit	50 mmHg	10-215 mmHg	5 mmHg
	Upper MAP limit	120 mmHg	75-255 mmHg	5 mmHg
	Lower MAP limit	70 mmHg	20-230 mmHg	5 mmHg
	Upper Pulse limit	120 1/min	45–245 1/min	5 1/min
	Lower Pulse limit	60 1/min	20-175 1/min	5 1/min
STORE DEFAULT VALUES			**Press Audio paused key**	

5.1.4 DIAGNOSTICS

The **DIAGNOSTICS** service menu can only be called in service mode.



5.1.4.1 DIAGNOSTICS, general information

In DIAGNOSTICS, all inputs and outputs of the hemodialysis device can be activated.
Activation refers to CPU1 (P.C.B. LP 1631), CPU2 (P.C.B. LP 632), as well as to the output board (P.C.B. LP 634) and the input board (P.C.B. LP 633-5).

This program allows technicians to make their own settings for checking error patterns.

DIAGNOSTICS provides the following menus:

READ INPUTS
READ ANALOG INPUTS
CPU1: RD ANALOG INP.
CPU2: RD ANALOG INP.
READ DIGITAL INPUTS
CPU1: RD DIGITAL INP
CPU2: RD DIGITAL INP
WRITE OUTPUTS
WRITE ANALOG OUTPUTS
CPU1: WR ANALOG OUTP
CPU2: WR ANALOG OUTP
WRITE DIGIT. OUTPUTS
CPU1: WR DIGIT. OUTP
CPU2: WR DIGIT. OUTP
INP/OUTP COMBINATION
CPU1: COMBINATION
CAN-COMPONENTS
HPU
BPM
Pressure test
Leakage test

The corresponding levels are displayed in the "**READ DIGITAL INPUTS**" menu via the fields ① to ④ in the display as well as the status indicators and the loudspeaker.

The *active* signal state (may indicate both voltage and no voltage) is indicated by 1111 on the display (fields ① to ④), by the operation status indicators being activated and by an audible signal.

The audible signal can be deactivated by pressing the **Audio paused** key. If the audible signal is deactivated, the **Audio paused** key flashes to alert the user.

The audible signal allows the operator to evaluate the signal state without having to have a view of the monitor. This is advantageous if measurements must be taken behind the device (e.g., hydraulics unit).

Note

In DIAGNOSTICS, the signals are listed in the order of their electric connection, i.e. in latch groups of 8 signals each according to the 8-bit data bus and according to the latch numbering on the wiring diagram (e.g., P.C.B. LP 633-5: CS_LATCH0 – CS_LATCH6).

The signals are not grouped by relationship (e.g., all bi*b*ag® signals in successive row). An exception here are the signals for activating the solenoid valves. If possible, these are listed in the menu by their number to facilitate finding an individual valve because, usually, several valves must be activated at the same time for trouble-shooting purposes.

Based on their assignment to latch groups, signals can be easily found in the menu by means of the wiring diagram - even if the signal name has changed. Already one known signal within one latch group is sufficient to find the renamed signal in the menu by counting.

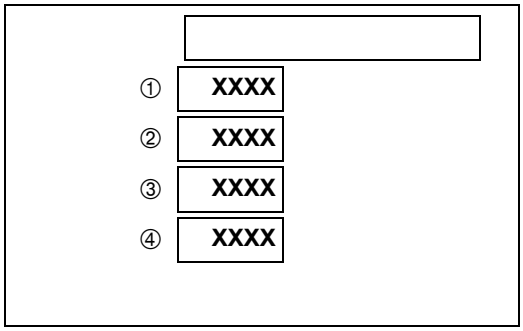
The voltage values specified can differ because of tolerances in the particular devices.

The **CPU1: RD DIGITAL INP** menu provides the **E:CPU1_KEY_TESTING** item. This menu item can be used to test the keys.

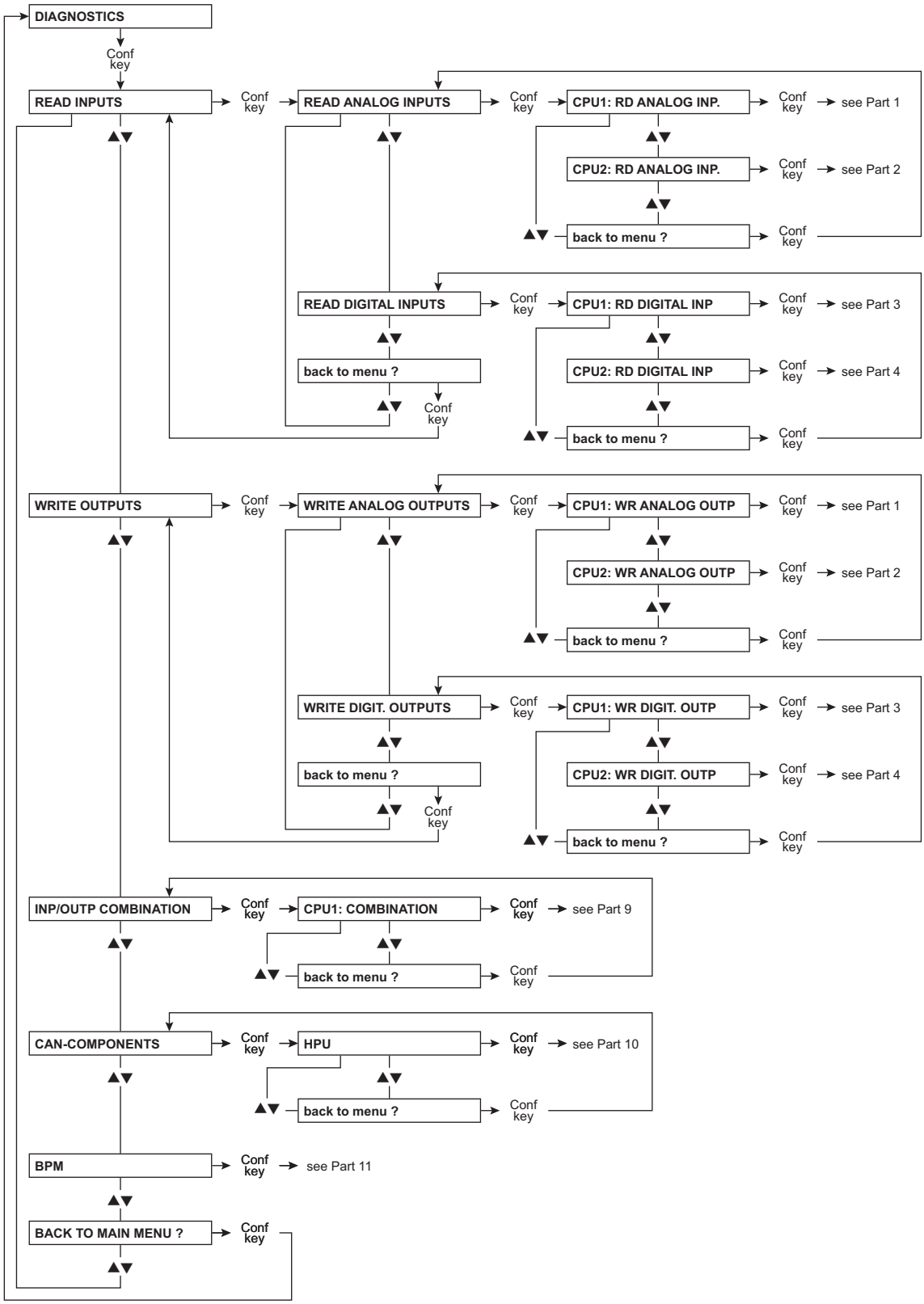
The key actuated is shown on the display.

The four **arrow keys**, the **On/Off** key and the **Conf** key are not implemented because their function can be checked by selecting the appropriate menu.

The fields ① to ④ in the display are defined as follows:



5.1.4.2 DIAGNOSTICS menu structure



Navigation

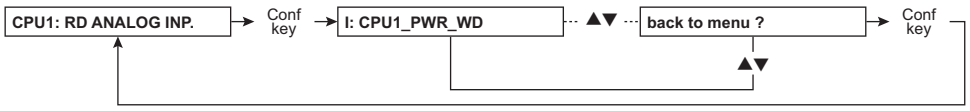
Menu display	Description
CPU1: RD ANALOG INP.	(see **Part 1** page 5-35)
CPU2: RD ANALOG INP.	(see **Part 2** page 5-37)
CPU1: RD DIGITAL INP	(see **Part 3** page 5-38)
CPU2: RD DIGITAL INP	(see **Part 4** page 5-44)
CPU1: WR ANALOG OUTP	(see **Part 5** page 5-47)
CPU2: WR ANALOG OUTP	(see **Part 6** page 5-48)
CPU1: WR DIGIT. OUTP	(see **Part 7** page 5-49)
CPU2: WR DIGIT. OUTP	(see **Part 8** page 5-54)
CPU1: COMBINATION	(see **Part 9** page 5-57)
HPU	(see **Part 10** page 5-58)
BPM	(see **Part 11** page 5-59)

5.1.4.3 Reading the analog inputs of CPU 1

- **Explanation**

Display (field ①): ADC digits
Display (field ④): Analog voltage (in 0.1 V), converted to the value at the input of P.C.B. LP 633-5

- **Part 1**



Menu item	Description
E: CPU1_PWR_WD	Voltage for watchdog monitoring 5 V, IC 27/26, ADC 107 (4.5–5.5 V)
E: CPU1_P_CONC	Not used 0 V, IC 27/27, ADC 0
E: CPU1_P_VEN	Venous pressure 0–12 V, IC 27/28, ADC 0–255
E: CPU1_BPR_VEN	Venous blood pump rate 0-10 V, IC 27/1, ADC 0-215 (Line diameter: 8 mm)

Menu item	Description
E: CPU1_PR_HDF	HDF blood pump rate 0-3.3 V, IC 27/1, ADC 0-72 (HDF on, line diameter: 8 mm)
E: CPU1_BPR_ART	Arterial blood pump rate 0-10 V, IC 27/2, ADC 0-215 (Line diameter: 8 mm)
E: CPU1_VEN_BPR_SET	Prescribed venous blood pump rate 0-8 V, IC 27/3, ADC 0-171 (Line diameter 8 mm)
E: CPU1_HDF_PR_SET	Prescribed HDF blood pump rate 0-2.7 V, IC 27/3, ADC 0-58 (HDF on, line diameter: 8 mm)
E: CPU1_ART_BPR_SET	Prescribed arterial blood pump rate 0-8 V, IC 27/4, ADC 0-171 (Line diameter 8 mm)
E: CPU1_REF1	AD 0 reference voltage 2.5 V, IC 27/5, ADC 128 (2.3-2.5 V)
E: CPU1_U_ACCU	Battery voltage e.g., 22 V, IC 28/26, ADC e.g., 184
E: CPU1_P_BIC	Not used 0 V, IC 28/27, ADC 0
E: CPU1_24V_EM	24V_EMERGENCY 24 V, IC 28/28, ADC 117 (22.5-26 V)
E: CPU1_P_ART	Arterial pressure 0-10.5 V, IC 28/1, ADC 0-225
E: CPU1_BLL_DIM	Blood leak dimness voltage 5.0 V, IC 28/2, ADC 108
E: CPU1_BLL	Blood leak voltage 5.0 V, IC 28/3, ADC 108
E: CPU1_COND_SIGNAL1	CD display 0-10.8 V, IC 28/4, ADC 0-231
E: CPU1_REF2	AD 1 reference voltage 2.5 V, IC 28/5, ADC 128 (2.3-2.5 V)
E: CPU1_FREE1	Not used 0 V, IC 29/26, ADC 0
E: CPU1_TEMP_DIAL2	Temperature NTC 109 0–12 V, IC 29/27, ADC 0–255
E: CPU1_COND_SIGNAL2	Not used 0 V, IC 29/28, ADC 0

Menu item	Description
E: CPU1_TEMP_DIAL3	NTC temperature (slot X12 / LP 941) 0–12 V, IC 29/1, ADC 0–255
E: CPU1_COND_SIGNAL3	CD cell (slot X13 / LP 941) 0-10.8 V, IC 29/2, ADC 0-231
E: CPU1_FREE2	Not used, input open IC 29/3
E: CPU1_U_BATT_SW	Voltage for audible alarm if battery relay off 10.6 V, IC 29/4, ADC 110
E:CPU1_REF3	AD 2 reference voltage 2.5 V, IC 29/5, ADC 128 (2.3-2.5 V)
Back to menu ?	

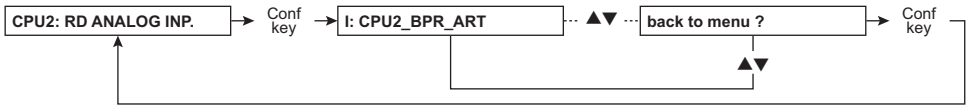
5.1.4.4 Reading the analog inputs of CPU 2

- **Explanation**

Display (field ①): ADC digits

Display (field ④): Analog voltage (in 0.1 V), converted to the value at the input of P.C.B. LP 632

- **Part 2**



Menu item	Description
E: CPU2_BPR_ART	Arterial blood pump 0-9.6 V, IC 12/12, ADC 0-223
E: CPU2_P_ART	Arterial pressure 0-10.6 V, IC 12/11, ADC 0-245
E: CPU2_P_VEN	Venous pressure 0–11 V, IC 12/10, ADC0–255
E: CPU2_P_DIAL	Dialysate pressure 0-10 V, IC 12/9, ADC 0-231
E: CPU2_COND_SIGNAL	CD display 0-10.8 V, IC 12/8, ADC 0-251
E: CPU2_TEMP_DIAL1	Temperature display 0-10.8 V, IC 12/7, ADC 0-251

Menu item	Description
E: CPU2_P_DIAL2	Control voltage for higher resolution Dialysate pressure 0-10.9 V, IC 12/6, ADC 0-252
E: CPU2_BLL_DIM	Blood leak dimness voltage 5.0 V, IC 12/5, ADC 116
E: CPU2_BLL	Blood leak voltage 5.0 V, IC 12/5, ADC 116
E: CPU2_+10V	D-A converter reference voltage / CPU 2 10 V, IC 12/5, ADC 234
E: CPU2_NC6	Not used 0 V, IC 12/5, ADC 0
Back to menu ?	

5.1.4.5 Reading the digital inputs of CPU 1

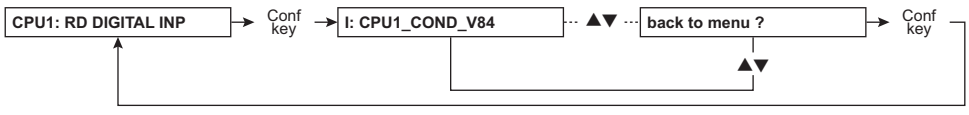
- **Explanation**

All fields (① to ④) in the display show 0000, operation status indicators red, yellow, green off:
Low level applied to latch on P.C.B. LP 633-5

All fields (① to ④) in the display show 1111, operation status indicators red, yellow, green on:
High level applied to latch on P.C.B. LP 633-5

If high level is applied, an audible alarm is active at the same time. This can be suppressed by pressing the **Audio paused** key. In this case, the **Audio paused** LED is lit.

- **Part 3**



Menu item	Description
E: CPU1_COND_V84	V 84 CD detection IC 19/2 Test by pulling off / short-circuiting the sensors
E: CPU1_LDA1	LD alarm channel 1 IC 19/3 Test LD, alarm / alarm-free
E: CPU1_OD_IN	AD optical system IC 19/4 Test optical system, opaque / non-opaque
E: CPU1_FL_SWITCH1	Float switch IC 19/5 Trigger water deficiency in calibration mode: 0 Open V 41 until water flows out of the overflow tube: 1
E: CPU1_CI	Balancing chamber switchover clock pulse IC 19/6
E: CPU1_ABG_BYP	Not used IC 19/7
E: CPU1_ABG_ON	Not used IC 19/8
E: CPU1_ABG_ALARM	Not used IC 19/9
E: CPU1_V43	Valve 43 IC 13/2 Test by opening / closing the valve
E: CPU1_V26	Valve 26 IC 13/3 Test by opening / closing the valve
E: CPU1_V24b	Valve 24b IC 13/4 Test by opening / closing the valve
E: CPU1_V24	Valve 24 IC 13/5 Test by opening / closing the valve
E: CPU1_UF_P1	Feedback from UF pump 1 IC 13/6 Test only possible in combination menu
E: CPU1_LDA2	LD alarm channel 2 IC 13/7 Preparation: LD alarm-free, and set CLAMP_CTRL (CPU 1: WR DIGIT. OUTPUT) to 1. Test: Initiate LD alarm
E: CPU1_SUB_W_P	Feedback from UF pump 2 IC 13/8

Menu item	Description
E: CPU1_LC11	IC 13/9
E: CPU1_REED_BIC	Bicarbonate reed contact IC 14/2 Actuate rinse chamber / bicarbonate reed contact
E: CPU1_BIBAG	Microswitch 137 / connector IC 14/3 Test by connecting / removing the bi*bag*®
E: CPU1_REED_RINSE	Concentrate reed contact IC 14/4 Actuate rinse chamber / concentrate reed contact
E: CPU1_BIBAG_C	Microswitch 138 / connector IC 14/5 Test by opening / closing the flap
E: CPU1_PSW_V102	Concentrate pressure switch IC 14/6 Test by building up / relieving pressure at the pressure switch
E: CPU1_PSW_V104	Bicarbonate pressure switch IC 14/7 Test by building up / relieving pressure at the pressure switch
E: CPU1_PWR_OFF	Power off IC 14/8
E: CPU1_HEP_ON	Heparin pump on IC 14/9 Switch heparin pump on / off
E: CPU1_LA32	IC 15/2
E: CPU1_SW_ON_OFF	Device On/Off key IC 15/3 Briefly press the On/Off key
E: CPU1_PWR_FAIL	Power failure detection IC 15/4
E: CPU1_SHUNT_OUTP	Shunt interlock microswitch IC 15/5 Both tubes in shunt interlock and shunt interlock closed: 0
E: CPU1_SHUNT_INP	Shunt interlock microswitch IC 15/6 Only red tube in shunt interlock and shunt interlock closed: 0
E: CPU1_SHUNT	Shunt interlock microswitch IC 15/7 Open/close shunt interlock
E: CPU1_SERV_EN	Not used IC 15/8

Menu item	Description
E: CPU1_LEV_SIGNAL	Level sensor (6) IC 15/9 Test by pulling off / short-circuiting the sensor pins (ESD precaution!)
E: CPU1_SN	Single-Needle switching IC 16/2 Single-Needle blood pump switching pressure reached: 0
E: CPU1_ADKS	Single-Needle blood pump fitted detector IC 16/3 Connect / disconnect blood pump (only when device is switched off)
E: CPU1_BPSB_ART	Arterial blood pump stop confirmation IC 16/4 Actuate the **Start/Stop** key on the arterial blood pump
E: CPU1_BPUS_ART	Arterial blood pump revolution stop IC 16/5 Arterial blood pump alarm field on: 0 (Clear by **Start/Stop** on blood pump)
E: CPU1_BPSB_VEN	Venous blood pump stop confirmation IC 16/6 Actuate the **Start/Stop** key on the venous blood pump
E:CPU1_BPUS_VEN	Venous blood pump revolution stop IC 16/7 Preparation: Set SNST (CPU1: WR DIGIT. OUTP.) to 1 and wait for alarm field. Venous blood pump on. Test: Clear the alarm field by pressing the **Start/Stop** on the venous blood pump.
E: CPU1_HEP_ALARM	IC 16/8 Initiate heparin pump alarm (e.g., by blocking the slide carriage)
E: CPU1_BIB_LEVEL	Not used IC 16/9
E: CPU1_EXT_ALARM	External alarm IC 20/2 Initiate an external alarm
E: CPU1_SERVICE_MODE	Switching Dialysis / Service mode IC 20/3 Toggle the service switch
E: CPU1_LEVEL_UP	Raise LD level IC 20/4 Actuate Raise level

Menu item	Description
E: CPU1_LEVEL_DOWN	Lower LD level IC 20/5 Preparation: LD alarm-free, set CLAMP_CTRL (CPU1: WR DIGIT. OUTP) to 1 Test: Actuate Lower level
E: CPU1_ADS_SN	Not used IC 20/6
E: CPU1_ACKN_CONC	Not used IC 20/7
E: CPU1_ACKN_BIC	Not used IC 20/8
E: CPU1_BIBAG_PSW	Pressure switch bi*bag*® IC 20/9 Test by building up / relieving pressure at the pressure switch
E: CPU1_RA21	Not used IC 21/2
E: CPU1_HDF_ON	HDF on IC 21/3 Press the HDF On/Off key
E: CPU1_V102	Feedback from valve 102 IC 21/4 Open / close valve
E: CPU1_V104	Feedback from valve 104, IC 21/5, Open / close valve
E: CPU1_CSS_REED	IC 21/6
E: CPU1_HEAT_CLK	IC 21/7
E: CPU1_BYP_REQ	IC 21/8
E: CPU1_CLP_REQ	IC 21/9
E: CPU1_LATCH7_FREE1	Not used IC 7/2
E: CPU1_LATCH7_FREE2	Not used IC 7/3
E: CPU1_LATCH7_FREE3	Not used IC 7/4
E: CPU1_LATCH7_FREE4	Not used IC 7/5
E: CPU1_LATCH7_FREE5	Not used IC 7/6

Menu item	Description
E: CPU1_LATCH7_FREE6	Not used IC 7/7
E: CPU1_LATCH7_FREE7	Not used IC 7/8
E: CPU1_LATCH7_FREE8	Not used IC 7/9
E: CPU1_DIP1: 00011100	DIP switch CPU 1, array 1 LP 1631/S1 (DIP switch 1–8) DIP switch position shown on the display (1: DIP switch ON)
E: CPU1_DIP2: 00000000	DIP switch CPU 1, array 2 LP 1631/S2 (DIP switch 1–8) DIP switch position shown on the display (1: DIP switch ON)
E: CPU1_DIP3: 0000000	DIP switch CPU 1, array 3 LP 1631/S3 (DIP switch 1-7) DIP switch position shown on the display (1: DIP switch ON)
E: CPU1_KEY_TESTING	Touch panel test P.C.B. LP 635/IC 73/2–6 The key actuated is shown on the display and the associated key LED is lit.
E: CPU1_RCU_KEY_TEST	Test of touch panel of RCU 4008 remote control The key actuated is shown on the display and the associated key LED is lit.
Back to menu ?	

5.1.4.6 Reading the digital inputs of CPU 2

- **Explanation**

All fields (① to ④) in the display show 0000, operation status indicators red, yellow, green off: Low level applied to latch on P.C.B. LP 632

All fields (① to ④) in the display show 1111, operation status indicators red, yellow, green on: High level applied to latch on P.C.B. LP 632

If high level is applied, an audible alarm is active at the same time. This can be suppressed by pressing the **Audio paused** key. In this case, the **Audio paused** LED is lit.

- **Part 4**

Menu item	Description
E: CPU2_NC3	Not used IC 4/2
E: CPU2_UF_P1	Feedback from UF pump 1 IC 4/3
E: CPU2_ACKN_AIRSEP	Feedback from air separation pump IC 4/4
E: CPU2_UF_P2	Feedback from UF pump 2 IC 4/5
E: CPU2_CI	Balancing chamber switching pulse IC 4/6
E: CPU2_V24	Feedback from valve 24 IC 4/7, open / close valve
E: CPU2_V24b	Feedback from valve 24b IC 4/8, open / close valve
E: CPU2_V26	Feedback from valve 26 IC 4/9, open / close valve
E: CPU2_V43	Feedback from valve 43 IC 5/2, open / close valve
E: CPU2_BL_Alarm	Blood pump rate switching SN / HDF IC 5/3
E: CPU2_PWR_OFF	Power off IC 5/4
E: CPU2_FL_SWITCH+5V	Float switch IC 5/5 Trigger water deficiency in calibration mode = 0 Open V 41 until water flows out of the overflow tube = 1
E: CPU2_LDA1	LD alarm channel 1 IC 5/6, LD alarm / alarm-free
E: CPU2_LDA2	LD alarm channel 2 IC 5/7 Preparation: LD alarm-free, and set CLAMP_CTRL (CPU1: WR DIGIT. OUTP) to 1 Test: Initiate LD alarm

Menu item	Description
E: CPU2_BPSB_VEN	Venous blood pump stop confirmation IC 5/8 Actuate the **Start/Stop** key on the venous blood pump
E: CPU2_BPSB_ART	Arterial blood pump stop confirmation IC 5/9 Actuate the **Start/Stop** key on the arterial blood pump
E: CPU2_V42	Not used IC 6/2
E: CPU2_BPST_ART	Feedback from arterial blood pump special control IC 6/3 Test by setting BPST_ART (CPU1: WR DIGIT. OUTP) to 1/0.
E: CPU2_BPUS_ART	Arterial blood pump revolution stop IC 6/4 Arterial blood pump alarm field on = 0 (Clear by **Start/Stop** on blood pump)
E: CPU2_BPST_VEN	Feedback from venous blood pump special control IC 6/5 Test by setting BPST_VEN (CPU1: WR DIGIT. OUTP) to 1/0.
E: CPU2_BPUS_VEN	Venous blood pump revolution stop IC 6/6 Preparation: Set SNST (CPU1: WR DIGIT. OUTP.) to 1 and wait for venous blood pump alarm field on. Test: Clear the alarm field by pressing the **Start/Stop** on the venous blood pump.
E: CPU2_ADKS	Single-Needle blood pump fitted detector IC 6/7 Fit / pull off blood pump (only when the device is turned off)
E: CPU2_LEVEL_UP	Raise LD level IC 6/8, actuate Raise level
E: CPU2_LEVEL_DOWN	Lower LD level IC 6/9 Preparation: LD alarm-free, set CLAMP_CTRL (CPU1: WR DIGIT. OUTP) to 1. Test: Actuate Lower level.
E: CPU2_RINSE	Concentrate reed contact IC 7/2 Actuate rinse chamber / concentrate reed contact
E: CPU2_V147	IC 7/3
E: CPU2_REED_BIC	Bicarbonate reed contact IC 7/4 Actuate rinse chamber / bicarbonate reed contact

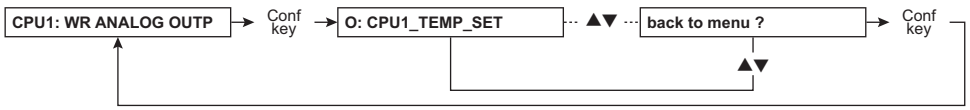
Menu item	Description
E: CPU2_PSW_104	Bicarbonate pressure switch IC 7/5 Test by building up / relieving pressure at the pressure switch
E: CPU2_V145	IC 7/6
E: CPU2_SHUNT_OUTP	Shunt interlock microswitch IC 7/7 Both tubes in shunt interlock and shunt interlock closed: 0
E: CPU2_SHUNT_INP	Shunt interlock microswitch IC 7/8 Only red tube in shunt interlock and shunt interlock closed: 0
E: CPU2_SHUNT	Shunt interlock microswitch IC 7/9, open / close shunt interlock
E: CPU2_ABG_ON	Not used IC 8/2
E: CPU2_SERVICE_MODE	Switching Dialysis / Service mode IC 8/3, toggle the service switch
E: CPU2_HOT_RINSE	Hot rinse switchover IC 8/4 Test by setting HOT_RINSE (CPU 1: WR DIGIT. OUTP) to 0/1)
E: CPU2_OD_OUT	AD optical system IC 8/5, optical detector dark / light
E: CPU2_SNST	Single-Needle control IC 8/6
E: CPU2_24V_SW	24 V switch IC 8/7
E: CPU2_SN	Single-needle switching IC 8/8, SN switching pressure reached: 0
E: CPU2_HEAT_RL_WATCH	Feedback from heater relay IC 8/9
E: CPU2_DIP1: 01100110	DIP switch CPU 2, array 1 IC 9/2–9 DIP switch position shown on the display (1: DIP switch ON)
E: CPU2_DIP2: 11000001	DIP switch CPU 2, array 2 IC 10/2–9 DIP switch position shown on the display (1: DIP switch ON)
Back to menu ?	

5.1.4.7 Setting the analog outputs of CPU 1

● **Explanation**

Display (field ②): DAC digits (adjustable by pressing the **+ / –** keys)
Display (field ④): Analog voltage on P.C.B. LP 634 in 0.1 V

● **Part 5**



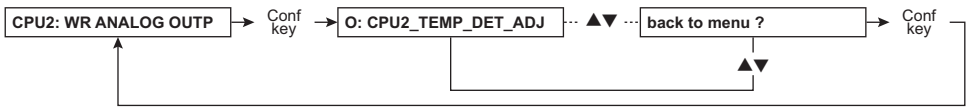
Menu item	Description
A: CPU1_TEMP_SET	Temperature set point IC 9-A_2 0–5 V (X634R/C20, 0.2–10 V)
A: CPU1_DAC_DIM	Dimness calibration voltage IC 9-A_1 0–5 V (X634R/A11, 0–5 V)
A: CPU1_TEMP_ADJ	Calibration voltage for temperature control IC 9-A_20 0–5 V (X634R/C21, 0–5 V)
A: CPU1_DAC_BLL	Blood leak calibration voltage IC 9-A_19 0–5 V (X634R/A12, 0–5 V)
A: CPU1_BIBAG_TEMP_AJ	Calibration voltage for temperature NTC (slot X12 / LP 941) IC 18-A_2 0–5 V (X634R/A13, 0–5 V)
A: CPU1_DAC_X2	Not used IC 18-A_1 0–5 V (X634R/C13, 0–5 V)
A: CPU1_STEUER_EP	Degassing pump speed setting IC 18-A_20 0–4.4 V (X634L/ between A, B, C 27 and A, B, C 28, 0–21 V)
A: CPU1_STEUER_FP	Flow pump speed setting IC 18-A_19 0–4.4 V (X634L/ between A, B, C 29 and A, B, C 30, 0–21 V)
Back to menu ?	

5.1.4.8 Setting the analog outputs of CPU 2

● **Explanation**

Display (field ②): DAC digits (adjustable by pressing the **+ / –** keys)
Display (field ④): Analog voltage on P.C.B. LP 632 in 0.1 V

● **Part 6**



Menu item	Description
A: CPU2_TEMP_DET_ADJ	Temperature display detuning IC 11/2, 0–10 V (X632/A 23, 0–10 V)
A: CPU2_DIAL_DET_ADJ	Dialysate pressure display detuning IC 11/1, 0–10 V (X632/C 20, 0–10 V)
A: CPU2_P_ADS_DET	Not used IC 11/20, 0–10 V (X632/A 20, 0–10 V)
A: CPU2_PV_DET	Venous pressure detuning IC 11/20, 0–10 V (X632/C 18, 1-9 V)
A: CPU2_PA_DET	Arterial pressure detuning IC 11/19, 0–10 V (X632/A 17, 4-7 V)
A: CPU2_COND_DET	CD display detuning IC 11/19, 0–10 V (X632/A 21, 0–10 V)
A: CPU2_HIGH_RES_OP	OP control voltage for higher dialysate pressure resolution IC 11/20, 0–10 V
Back to menu ?	

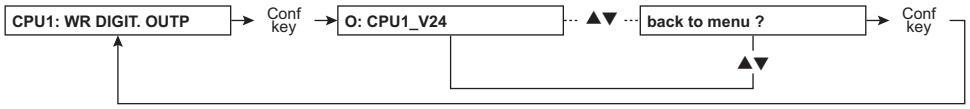
5.1.4.9 Setting the digital outputs of CPU 1

● **Explanation**

Display (field ②): 0000 = not active
1111 = active (level P.C.B. LP 634)

(adjustable by pressing the **+ / –** keys)

- **Part 7**



Menu item	Description
A: CPU1_V24	Valve 24 IC 10/19
A: CPU1_V24b	Valve 24b IC 10/13
A: CPU1_V26	Valve 26 IC 10/18
A: CPU1_V130	Valve 130 IC 10/17
A: CPU1_V30	Valve 30 IC 7/16
A: CPU1_V31	Valve 31 IC 12/19
A: CPU1_V32	Valve 32 IC 12/18
A: CPU1_V33	Valve 33 IC 12/17
A: CPU1_V34	Valve 34 IC 12/16
A: CPU1_V35	Valve 35 IC 12/15
A: CPU1_V36	Valve 36 IC 12/14
A: CPU1_V37	Valve 37 IC 12/13
A: CPU1_V38	Valve 38 IC 12/12
A: CPU1_V41	Valve 41 IC 7/13 (Valve automatically closes after a short time to prevent water from overflowing)
A: CPU1_V43	Valve 43 IC 7/15
A: CPU1_V84	Valve 84 IC 7/18 Note: Activation of valve V84 must be followed by a rinse program.

Menu item	Description
A: CPU1_V86	Valve 86 IC 7/17
A: CPU1_V87	Valve 87 IC 10/15
A: CPU1_V91	Valve 91 IC 10/14 Remark: If this menu item is exited (return to "**CPU1: WR DIGIT. OUTP.**"), the valve is closed.
A: CPU1_V99	Valve 99 IC 7/19 Remark: If this menu item is exited (return to "**CPU1: WR DIGIT. OUTP.**"), the valve is closed.
A: CPU1_V100	Valve 100 IC 4/17 Remark: If this menu item is exited (return to "**CPU1: WR DIGIT. OUTP.**"), the valve is closed.
A: CPU1_V102	Valve 102 IC 10/12 (The valve can only be activated if a mandatory rinse is not required)
A: CPU1_V104	Valve 104, IC 7/14 (The valve can only be activated if a mandatory rinse is not required)
A: CPU1_V126	Not used
A: CPU1_V145	Not used
A: CPU1_V147	Not used
A: CPU1_V172	Not used
A: CPU1_V173	Not used
A: CPU1_AIR_SEP_PUMP	Air separation pump IC 4/18, 19 (1111: running clockwise) Remark: The ASP stops running when this menu item is exited.
A: CPU1_STOP_EP	Degassing pump stop IC 4/16
A: CPU1_STOP_FP	Flow pump stop IC 4/15
A: CPU1_SET_UF1_ON	UF pump 1 activation IC 4/14 (0/1 jump = 1 stroke)
A: CPU1_SET_UF2_ON	UF pump 2 activation IC 4/13 (0/1 jump = 1 stroke)

Menu item	Description
A: CPU1_SET_EN_UF2	Not used IC 4/12
A: CPU1_SET_FLOW_ON	Flow on Data word to Gal 23: 0000 0010 (active, V 32 open) 0000 0011 (inactive, V 31, 32 opened)
A: CPU1_SET_FILL_PRG	Fill program Data word to Gal 23: 0000 1010 (V 32, 34 open)
A: CPU1_EMPTIING_PRG	Emptying-program Data word to Gal 23: 0001 0010 (V 32, 35 open)
A: CPU1_FILL_ONE_CHAM	Filling of a balancing chamber half Data word to Gal 23: 0100 0010 (V 32, 37 open)
A: CPU1_EMPTY_ONE_CHA	Emptying of a balancing chamber half Data word to Gal 23: 1100 0010 (V 32, 37, 38 open)
A: CPU1_CO_L:XXXXXXXX	Concentrate pump step number The data word to IC 2 is shown on the display and can be changed by pressing the UF Rate UP/DOWN keys. Requirement: concentrate connector reed contact open
A: CPU1_BI_L:XXXXXXXX	Bicarbonate pump step number Requirement: bicarbonate connector reed contact open
A: CPU1_ALARM_SOUND	Audible alarm IC 5/18, 19 to 1: active
A: CPU1_WARN_SOUND	Audible warning IC 5/18 to 1, 19 to 0: active
A: CPU1_INFO_SOUND	Info sound IC 5/18 to 0, 19 to 1: active
A: CPU1_CLK_OVERLAP	Balancing chamber dead time switchover IC 5/17 to 0: 1 kHz, to 1: 2 Hz
A: CPU1_EN_IN_PULSE	Intrinsic clock pulse switchover IC 5/16 to 0: intrinsic clock pulse; to 1: current increase switchover
A: CPU1_BC_PULSE	Balancing chamber switchover IC 5/15
A: CPU1_EN_STEP_PULS	Gal switchover IC 5/14
A: CPU1_BC_FUNCTION	Balancing chamber Gal switchover IC 5/13
A: CPU1_STEPPER_PULS	Intrinsic clock pulse IC 5/12

Menu item	Description
A: CPU1_FL_SWITCH_EN	V41 enable IC 7/12 Test: Set level to 1 with float switch down: V 41 open Set level to 0 with float switch down: V 41 closed
A: CPU1_SNST	Single-Needle control IC 13/19 Preparation: LD alarm-free, and set CLAMP_CTRL (**CPU1: WR DIGIT. OUTP.**) to 1. Test: SNST to 1: venous blood pump starts running once SN switchover pressure is reached
A: CPU1_CPU_OFF	Automatic turnoff IC 13/18 Device turns off in position 1
A: CPU1_EN_PF_AT	Power failure alarm enable IC 13/17 Preparation: WD_SET, set (**CPU2: WR DIGIT. OUTP.**) to 0. Test: The power failure alarm can be activated / deactivated with EN_PF_AT set to 0/1.
A: CPU1_PIC_RA3	Not used IC 13/16
A: CPU1_PROG_LOG1	Not used IC 13/14
A: CPU1_PROG_LOG2	Not used IC 13/13
A: CPU1_VENT_VALVE	LD aeration valve IC 13/12
A: CPU1_CLR_ALARM	Alarm clearing IC 11/18 Test: Initiate heparin pump alarm: alarm is cleared by setting CLR_ALARM from 0 to 1.
A: CPU1_HOT_RINSE	Hot rinse switchover IC 11/17
A: CPU1_TEST_BATT	Battery test IC 11/16
A: CPU1_CPU_AKKU	Battery relay IC 11/15
A: CPU1_HEAT_OFF	Heater blockage IC 11/14
A: CPU1_STAFF_CALL	Staff call IC 11/13

Menu item	Description
A: CPU1_TL_RED	External operation status indicator red IC 11/12 The associated operation status indicator LED of the display board is also activated.
A: CPU1_BPST_ART	Arterial blood pump special control IC 6/19
A: CPU1_BPSST_ART	Arterial blood pump special control IC 6/18
A: CPU1_CLAMP_CTRL	LD clamp control IC 6/17 Preparation: Air detector alarm-free
A: CPU1_BPST_VEN	Venous blood pump special control IC 6/16
A: CPU1_BPSST_VEN	Venous blood pump system stop IC 6/15 Preparation: Set SNST (CPU1: WR DIGIT. OUTP.) to 1 Test: Pressurize Single-Needle blood pump; turn blood pump on / off with BPSST_VEN.
A: CPU1_BL_ALARM	Blood pump rate switching Single-Needle / HDF IC 6/14
A: CPU1_TL_YELLOW	External operation status indicator yellow IC 6/13 The associated operation status indicator LED of the display board is also activated.
A: CPU1_TL_GREEN	External operation status indicator green IC 6/12 The associated operation status indicator LED of the display board is also activated.
A: CPU1_BP_FASTER	Blood pump rate adjustment (adjustable by pressing the **+ / –** keys) (RCU 4008) P.C.B. LP 922/X5.4
A: CPU1_BP_SLOWER	Blood pump rate adjustment – (RCU 4008) P.C.B. LP 922/X5.5
A: CPU1_OVERLAP_VALUE	Loads the dead time counter IC 3/12-19 (DAC 0–255 adjustable)
A: CPU1_V_ADS	Not used
A: CPU1_NC_I	Not used
A: CPU1_NC_II	Not used
A: CPU1_NC_III	Not used

Menu item	Description
A: CPU1_ACKN_FLOW	Not used
A: CPU1_ACKN_BL_ALARM	Not used
A: CPU1_DISPLAY_TEST	All LED displays are run through UF monitor display counts from 1 to 0
Back to menu ?	

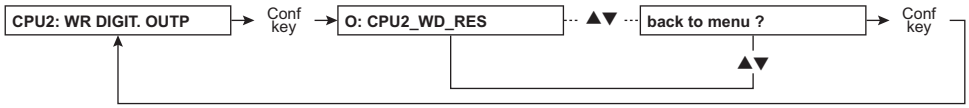
5.1.4.10 Setting the digital outputs of CPU 2

- **Explanation**

Display (field ②): 0000 = not active
1111 = active (level P.C.B. LP 632)

(adjustable by pressing the **+ / –** keys)

- **Part 8**



Menu item	Description
A: CPU2_WD_RES	Watchdog-Reset IC 24/18 Preparation: WD_SET, set (**CPU2: WR DIGIT. OUTP**) to 0 and back to 1. Test: Briefly set WD_RES to 0; if you reset to 1, WD relay is connected.
A: CPU2_WD_SET	Watchdog-Set IC 24/17 Watchdog relay drops, 24 V is switched off, audible signal is sounded. To reset the device, turn it off and on again. Else, calibration is not possible.
A: CPU2_V24_EN	V 24 enable IC 24/16 Preparation: Activate V 24 (**CPU1: WR DIGIT. OUTP**) Test: Switch valve on / off with V 24_EN
A: CPU2_V24B_EN	V 24b enable IC 24/15 Preparation: Activate V 24B (**CPU1: WR DIGIT. OUTP**) Test: Switch valve on / off with V 24B_EN
A: CPU2_UF_P_CTRL	UF pump 1 activation IC 24/14, 0/1 jump = 1 stroke Preparation: Set CPU2_UF_P_EN to 1.

Menu item	Description
A: CPU2_UF_P_EN	UF pump enable IC 24/13
A: CPU2_CPU2_ALARM	Audible alarm initiated by CPU 2 IC 24/12
A: CPU2_UF_P2_CTRL	UF pump 2 activation IC 24/11, 0/1 jump = 1 stroke Preparation: Set CPU2_UF_P_EN to 1.
A: CPU2_4066_ENABLE_1	Analog switch for P_ADS_DET IC 20/13 (X632/A20)
A: CPU2_4066_ENABLE_2	Analog switch for reference voltage +10 V IC 27/5
A: CPU2_4066_ENABLE_3	Analog switch for PV_DET IC 20/6 (X632/C18)
A: CPU2_4066_ENABLE_4	Analog switch for PA_DET IC 20/12 (X632/A17)
A: CPU2_4066_ENABLE_5	Analog switch, not used IC 27/13
A: CPU2_4066_ENABLE_6	Analog switch for COND_DET IC 20/5 (X632/A21)
A: CPU2_4066_ENABLE_7	Analog switch for BLL_DIM IC 27/6
A: CPU2_4066_ENABLE_8	Analog switch for BLL IC 27/12
A: CPU2_SN_ART	Single-Needle arterial control X632/A15
A: CPU2_LDSA	Audible LD alarm weakened X632/C16 Preparation: LD alarm-free, and set CLAMP_CTRL (**CPU1: WR DIGIT. OUTPUT**) to 1 Test: Set LDSA to 1 to close the venous occlusion clamp on the air detector.
A: CPU2_ODSA	Optical LD system weakened X632/C15
A: CPU2_CLAMP_CTRL	Air detector clamp control X632/C10 Preparation: Air detector alarm-free
A: CPU2_NC5	Not used X632/B25
A: CPU2_NC7	Not used X632/B10
A: CPU2_BLL_DET	Blood leak detector detuning X632/A25

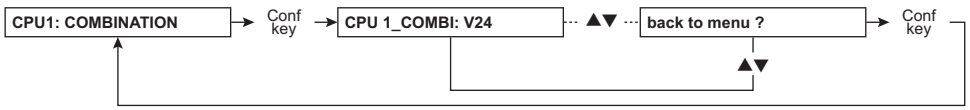
Menu item	Description
A: CPU2_SN_EN	Single-Needle enable X632/C19
A: CPU2_NC10	Not used X632/B4
A: CPU2_V26	Valve 26 X632/A6
A: CPU2_V42	Not used X632/C4
A: CPU2_V43	Valve 43 X632/C5
A: CPU2_VENT_DSAFE	Diasafe vent valve X632/B5
A: CPU2_EM_HEAT_OFF	Heater relay X632/A9 After having been activated, the relay switches off again for safety reasons.
A: CPU2_NC8	Not used X632/B9
A: CPU2_NC9	X632/C6 IC 29/13
A: CPU2_LED1	P.C.B. LP 632 LED 1 IC 21/19
A: CPU2_LED2	P.C.B. LP 632 LED 2 IC 21/18
A: CPU2_LED3	P.C.B. LP 632 LED 3 IC 21/17
A: CPU2_LED4	P.C.B. LP 632 LED 4 IC 21/16
A: CPU2_LED5	P.C.B. LP 632 LED 5 IC 21/15
A: CPU2_LED6	P.C.B. LP 632 LED 6 IC 21/14
A: CPU2_LED7	P.C.B. LP 632 LED 7 IC 21/13
A: CPU2_LED8	P.C.B. LP 632 LED 8 IC 21/12
Back to menu ?	

5.1.4.11 Setting / reading the digital outputs of CPU 1

- **Explanation**

Display (field ①): Feedback/ / input (in addition, the 3 operation status indicator LEDs are lit with 1111)
Display (field ②): Activation / output (adjustable by pressing the **+ / –** keys)

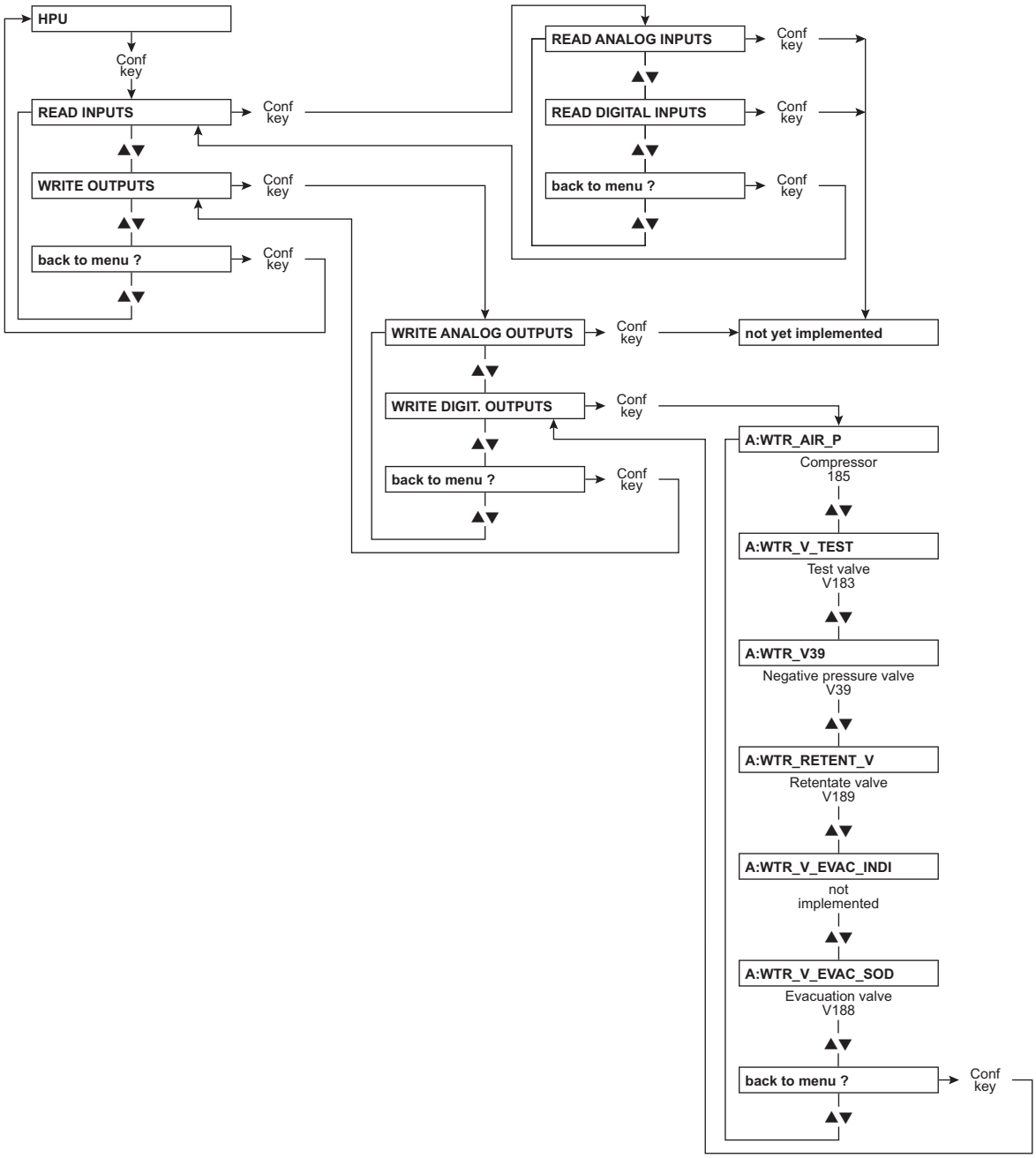
- **Part 9**



Menu item	Description
CPU 1_COMBI: V24	Valve 24 Activation P.C.B. LP 634/IC 10/19 Feedback P.C.B. LP 633-5/IC 13/5
CPU 1_COMBI: V24b	Valve 24b Activation P.C.B. LP 634/IC 10/13 Feedback P.C.B. LP 633-5/IC 13/4
CPU 1_COMBI: V26	Valve 26 Activation P.C.B. LP 634/IC 10/18 Feedback P.C.B. LP 633-5/IC 13/3
CPU 1_COMBI: V43	Valve 43 Activation P.C.B. LP 634/IC 7/15 Feedback P.C.B. LP 633-5/IC 13/2
CPU 1_COMBI: V102	Valve 102 Activation P.C.B. LP 634/IC 10/12 Feedback P.C.B. LP 633-5/IC 21/4 (The valve can only be activated if a mandatory rinse is not required)
CPU 1_COMBI: V104	Valve 104, Activation P.C.B. LP 634/IC 7/14, acknowledgement P.C.B. LP 633-5/IC 21/5 (the valve can only be activated if a mandatory rinse is not required)
CPU 1_COMBI: UF1_PUMP	UF pump 1 Activation P.C.B. LP 634/IC 4/14 Feedback P.C.B. LP 633-5/IC 13/6 (If setting from 0 to 1 = 1 stroke; feedback is brief jump to 1)
CPU 1_COMBI: AIR_SEP	ASP activation / deactivation
Back to menu ?	

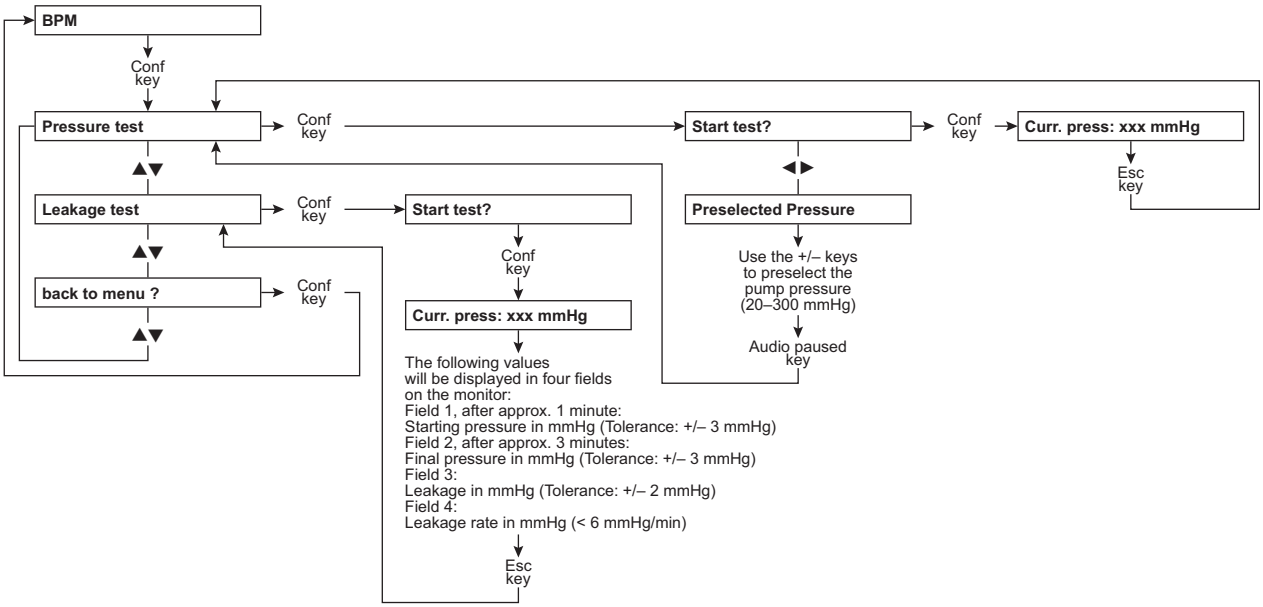
5.1.4.12 HPU

● **Part 10**



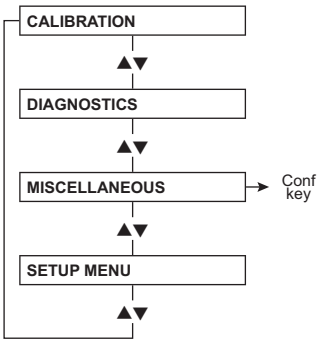
5.1.4.13 BPM (option)

● **Part 11**

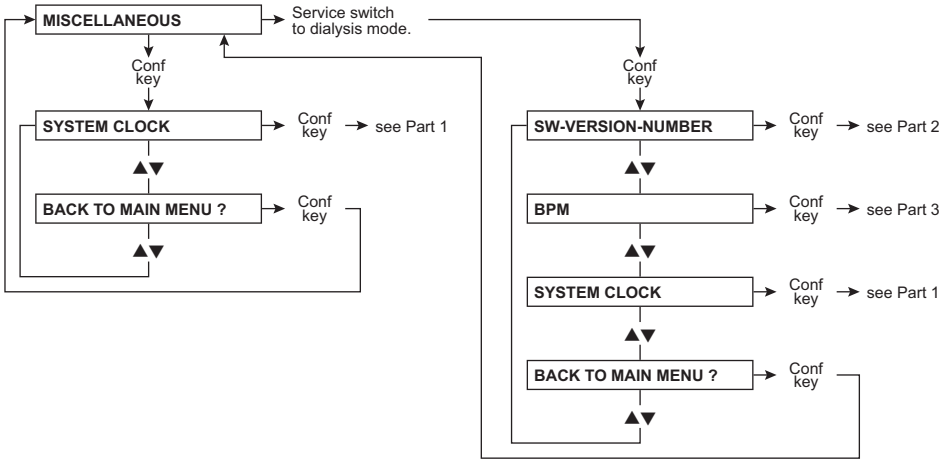


5.1.5 MISCELLANEOUS

The **MISCELLANEOUS** service menu can only be called in service mode.

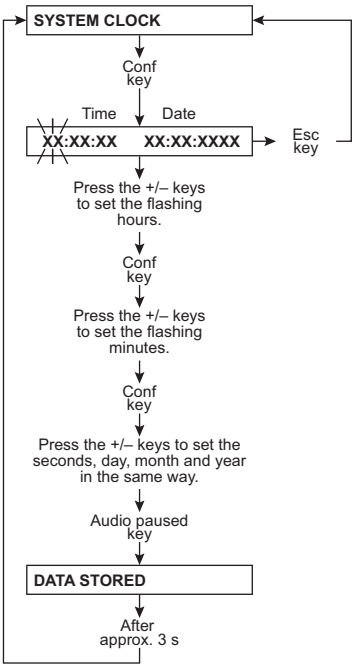


5.1.5.1 MISCELLANEOUS menu structure



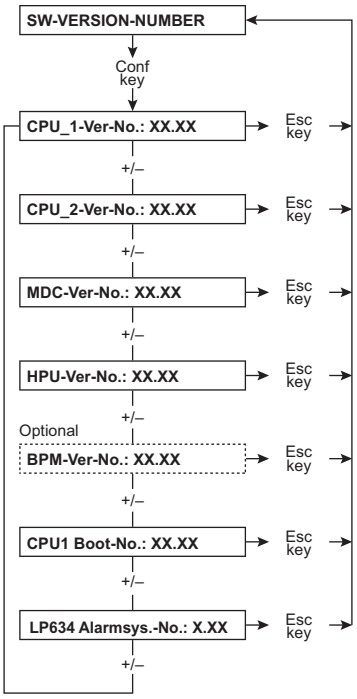
5.1.5.2 System clock

- **Part 1**



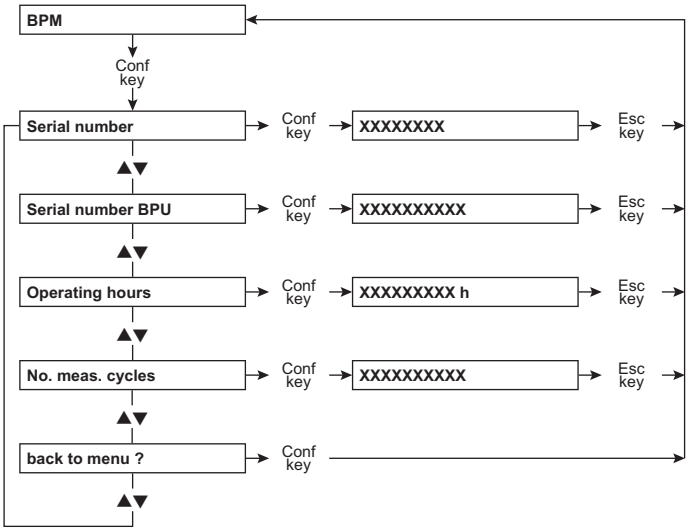
5.1.5.3 SW-VERSION-NUMBER

● **Part 2**



5.1.5.4 BPM (option)

● **Part 3**



5.1.6 CALIBRATION

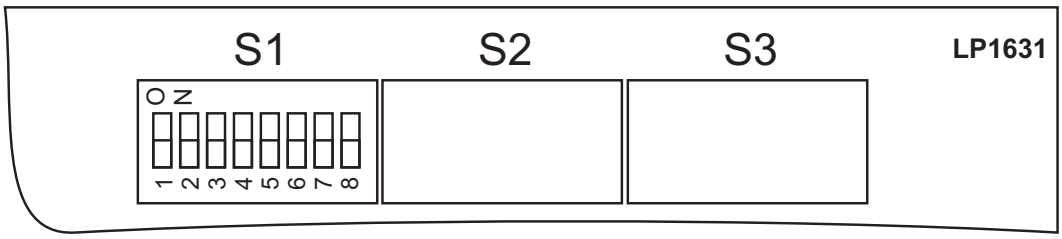
For a description of the **CALIBRATION** service menu, please refer to Chapter **Calibration / adjustment** (see chapter 9.1 page 9-1).

5.2 DIP switch overview

5.2.1 P.C.B. LP 1631 (CPU 1) DIP switch array 1

Note

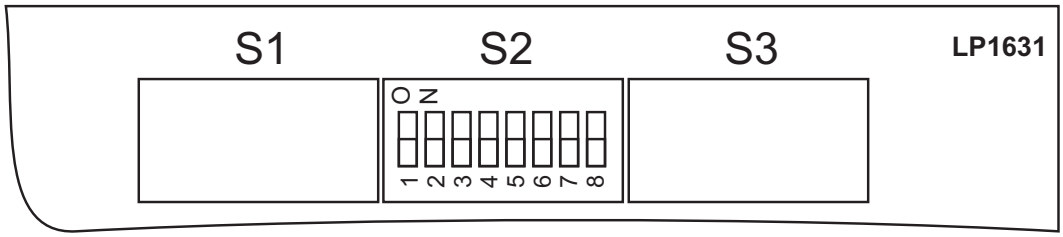
DIP switch 6 (array 1) is provided for service purposes / trouble-shooting only and must be set to position OFF for dialysis mode.



DIP switch / Position	Function
1 **2** ON ON OFF ON *ON* *OFF* OFF OFF	**Maximum UF rate** 1000 ml/h 2000 ml/h *3000 ml/h* 4000 ml/h
3 ON *OFF*	*not assigned*
4 ON *OFF*	*not assigned*
5 ON *OFF*	*not assigned*
6 ON *OFF*	**CRC/RAM Test** Skip *Go*
7 ON *OFF*	**Heater rod** 1300 W (at 100 to 127 V) *1600 W (at 220 to 240 V)*
8 ON *OFF*	**Test and cleaning flow** T1 test 500 ml/min / cleaning 600 ml/min *T1 test 800 ml/min / cleaning 800 ml/min*

The basic position on delivery is in *italics*.
"No assignment" requires the OFF position.

5.2.2 P.C.B. LP 1631 (CPU 1) DIP switch array 2

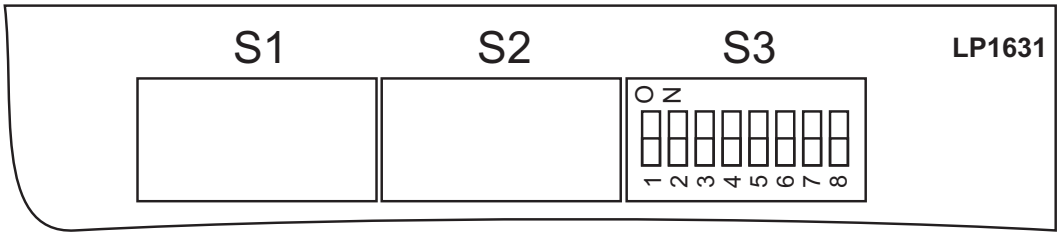


DIP switch / Position	Function
1 ON *OFF*	**CAL mode** Mode 0 *Mode 1*
2 **3** ON ON OFF ON ON OFF *OFF* *OFF*	**External alarm input** Not valid RO system Patient bell *External alarm*
4 ON OFF	**Remote control** Device with remote control Device without remote control
5 *ON* OFF	**COMMCO P.C.B. LP 763** *Approved* Disabled
6 ON *OFF*	**COMMCO** Special protocol *Default protocol*
7 * *ON* OFF	**Rinse section test (exclusive CDS)** *Active* Not active
8 ON OFF	**Central Delivery System** Installed Not installed

The basic position on delivery is in *italics*.
"No assignment" requires the OFF position.

* DIP switch 7 is no longer relevant if DIP switch 8 is set to ON.

5.2.3 P.C.B. LP 1631 (CPU 1) DIP switch array 3



DIP switch / Position						Function
1	**2**	**3**	**4**	**5**	**6**	**Language setting**
OFF	OFF	OFF	OFF	OFF	OFF	English
ON	OFF	OFF	OFF	OFF	OFF	German
OFF	**ON**	OFF	OFF	OFF	OFF	French
ON	**ON**	OFF	OFF	OFF	OFF	Portuguese
OFF	OFF	**ON**	OFF	OFF	OFF	Spanish
ON	OFF	**ON**	OFF	OFF	OFF	Czech
OFF	**ON**	**ON**	OFF	OFF	OFF	Russian
ON	**ON**	**ON**	OFF	OFF	OFF	Turkish
OFF	OFF	OFF	**ON**	OFF	OFF	Polish
ON	OFF	OFF	**ON**	OFF	OFF	Bulgarian
OFF	**ON**	OFF	**ON**	OFF	OFF	Greek
ON	**ON**	OFF	**ON**	OFF	OFF	Arabic
OFF	OFF	**ON**	**ON**	OFF	OFF	Slovenian
ON	OFF	**ON**	**ON**	OFF	OFF	Serbian
OFF	**ON**	**ON**	**ON**	OFF	OFF	Romanian
ON	**ON**	**ON**	**ON**	OFF	OFF	Lithuanian
OFF	OFF	OFF	OFF	**ON**	OFF	Macedonian
ON	OFF	OFF	OFF	**ON**	OFF	Croatian
OFF	**ON**	OFF	OFF	**ON**	OFF	Chinese
ON	**ON**	OFF	OFF	**ON**	OFF	Hebrew
OFF	OFF	**ON**	OFF	**ON**	OFF	Swedish

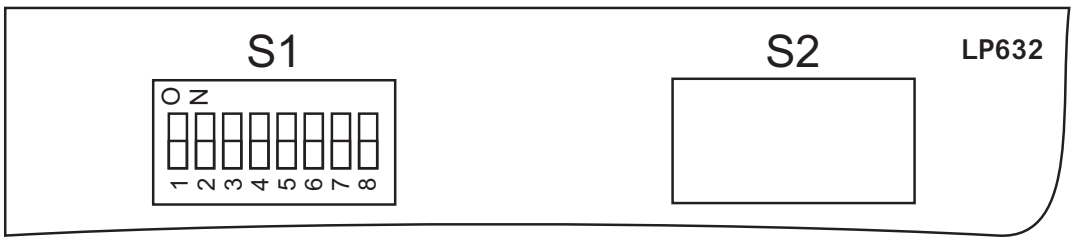
DIP switch / Position	Function
7 ON *OFF*	**Software update with SD-card** Active *Not active*
8 ON OFF	 *not assigned*

The basic position on delivery is in *italics*.
"No assignment" requires the OFF position.

5.2.4 P.C.B. LP 632 (CPU 2) DIP switch array 1

Warning

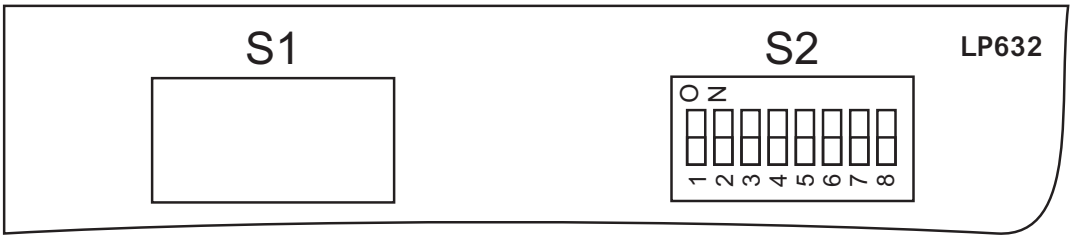
DIP switch 3 (array 1) allows skipping test runs that are requested by the device. If the switch is set such that a test run can be skipped, then it must be noted that the operator has the possibility of evading the automatic test of the safety systems. The person requesting such a setting is responsible for this procedure.



DIP switch / Position	Function
1 ON *OFF*	 *not assigned*
2 ON *OFF*	**T1 Test** Serial sequence *Parallel sequence*
3 ON *OFF*	**T1 Test** Skip *Mandatory*
4 ON *OFF*	**Test Service** ON (single test steps can be selected; dialysis mode not possible) *OFF (automatic T1 test)*
5 ON *OFF*	**Cyclic PHT** Every 2 minutes and events display (Service) *Every 12.5 minutes, alarm output only with cyclic PHT alarm*
6 *ON* OFF	**Cyclic PHT** *ON* OFF
7 ON *OFF*	**Air Detector** Not permitted *with P.C.B. LP 450-2*
8 ON *OFF*	 *not assigned*

The basic position on delivery is in *italics*.
"No assignment" requires the OFF position.

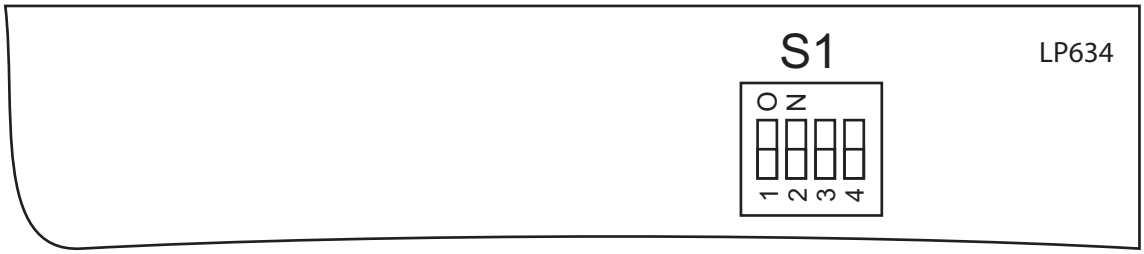
5.2.5 P.C.B. LP 632 (CPU 2) DIP switch array 2



DIP switch / Position	Function
1 *ON* OFF	**DIASAFE® *plus*** *ON* OFF
2 ON *OFF*	 *not assigned*
3 ON *OFF*	 *not assigned*
4 *ON* OFF	**Hydraulics unit** *With HPU* Not permitted
5 ON *OFF*	**V39 Test** OFF *ON*
6 ON *OFF*	**Fast heater for HDIS** Inactive *Active*
7 ON *OFF*	 *not assigned*
8 ON *OFF*	 *not assigned*

The basic position on delivery is in *italics*.
"No assignment" requires the OFF position.

5.2.6 P.C.B. LP 634: DIP switch (array 1)



DIP switch / Position				Function		
				Software ≥ 11.4		Software < 11.4
				EC ≥ 265	EC < 265	
1	2	3	4			
OFF	*OFF*	*OFF*	*OFF*	*Selection field for the alarm system in the **Treatment modes*** menu.*	Not permitted	Not permitted
ON	OFF	OFF	OFF	Acute alarm system	Not permitted	Not permitted
OFF	ON	OFF	OFF	Standard alarm system	Standard alarm system	Standard alarm system

The basic position on delivery is in *italics*.
Do not change the system settings from those given above!

If an alarm system is set for which the staff has not been trained yet, instructions must be given prior to the first treatment.

In the **Treatment types** menu, you can select between the **Acute** alarm system (default setting) or the **Standard** alarm system.

5.3 Software update

Preparation

Switch the device off, dismount the monitor rear, pull out the monitor.

Perform software update

Concerning CPU 2, the update is still performed by replacing the EPROM.

With software version 11.00 or higher, the update of CPU 1 and MDC-II (monitor board) is performed using the SD-card:

1. P.C.B. LP 1631 (CPU 1): field 3, set DIP switch 7 to ON.
2. P.C.B. LP 1631: insert SD card
3. Turn the device on
4. The update is performed automatically.
   P.C.B. LP 1631: While CPU 1 is updated, LED D1 is flashing. As soon as the update of CPU 1 is complete, D1 will be illuminated. Then D3 flashes until the update of the MDC-II board is complete. As soon as the update is complete, D3 will be illuminated.
   The flashing frequency of the LEDs D1 and D3 is approx. 2 Hz in case of an error approx. 6 Hz). In the event of an error, the LEDs D4 to D8 serve for evaluating the error
   (see **Error code table** page 5-72).
5. Turn the device off
6. Re-set DIP switch 7 to OFF
7. The SD-card may be removed or remain inserted

5.3.1 Error code table

If an error occurs during the update, the LEDs D4 to D8 will binarily show the status of the error. D8 shows the lowest and D4 the highest value.

LED 4	LED 5	LED 6	LED 7	LED 8	No. (dec.)	Meaning / measure
				X	1	No valid application present / perform update
			X		2	SD-card is not inserted or can not be initialized / Insert or change SD-card
			X	X	3	Sub-folder not present or more than one valid update file present / Check update files on SD-card
		X			4	Processor internal flash can not be initialized / Repeat update (change P.C.B. LP 1631, if necessary)
		X		X	5	Processor internal flash can not be deleted / Repeat update (change P.C.B. LP 1631, if necessary)
		X	X		6	Processor internal flash can not be read / Repeat update (change P.C.B. LP 1631, if necessary)
		X	X	X	7	A sector of the SD-card can not be read / Re-write the SD-card or use a new SD-card
	X				8	Evaluation of the Intel-Hex data faulty / Re-write the SD-card or use a new SD-card
	X			X	9	Data record (Intel Hex Record) too long / Re-write the SD-card or use a new SD-card
	X		X		10	Program status error (system error) Repeat update (change P.C.B. LP 1631, if necessary)
	X		X	X	11	Invalid exception (system error) / Repeat update (change P.C.B. LP 1631, if necessary)
	X	X			12	Starting adress of the data record transferred was uneven / Re-write the SD-card or use a new SD-card
	X	X		X	13	The memory location to be written on in the update client could not be deleted / Repeat update (change MDC-II board, if necessary)
	X	X	X		14	Timeout for Flash writing / reading operation in the Update Client has expired / Repeat update (change MDC-II board, if necessary)
	X	X	X	X	15	Memory location in the update client not written on correctly / Repeat update (change MDC-II board, if necessary)
X					16	Transfer buffer underrun / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)

LED 4	LED 5	LED 6	LED 7	LED 8	No. (dec.)	Meaning / measure
X				X	17	Transfer buffer overflow / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X			X		18	CRC error occured in file / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X			X	X	19	Address conflict, prediction address in the update deviates from the update file / communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X		X			20	Communication error between CPU1 and the update client / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X		X		X	21	Client did not respond to the update request / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X		X	X		22	Data block acknowledge – error 1 / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X		X	X	X	23	Data block acknowledge – error 2 / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X	X				24	Data block acknowledge – error 3 / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X	X			X	25	Data block acknowledge – error 4 / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)
X	X		X		26	Data block acknowledge – error 5 / Communication error, repeat update (change LP 1631 or MDC-II board, if necessary)

5.4 Service program (Quick Guide)

Quick Guide – PC service software 4008

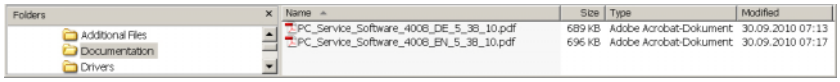
The Quick Guide is located on the CD for the **PC Service Software 4008**. The Service Software is installed on a PC (e.g., the technician's laptop). In addition, you also have the option – e.g., for a new installation – of accessing the Quick Guide directly from the CD without installing the Service Software.

Accessing the Quick Guide

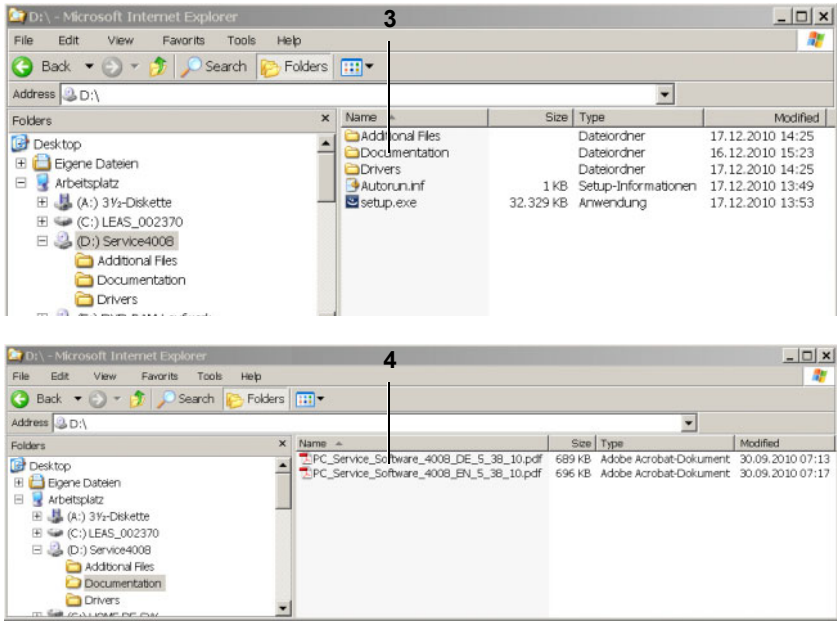
Three options for accessing the Quick Guide are described below:

1. Precondition: **PC Service Software 4008** is installed.
   With the **Service Software 4008** application open, use "Help" from the menu bar to access the Quick Guide, as follows:
   → "Help“ → "Help Topics“ (**1**)
   or:
   → „Help“ → „Context Help“ (**2**) (see Fig. below)

2. Precondition: **PC Service Software 4008** is installed.
   Using Windows Explorer, you can access the subdirectory "Documentation" from the directory in which the Quick Guide was installed. The Quick Guide is made available as a PDF file in this "Documentation" folder. Depending on the installation type, the "Documentation" folder will contain one or both of the German and English PDF files.



3. Insert the Service Software CD into the PC drive (e.g., laptop) – there is no need to carry out the installation and it can be simply cancelled. Using Windows Explorer, you can access the subdirectory "Documentation" directly from the folder on the corresponding drive (**3**). The "Documentation" folder contains the German and the English version of the Quick Guide in PDF format (**4**) (see following Fig.).



6 TSC / maintenance

6.1 Important information for TSC / maintenance procedures

Checks

This chapter includes the Technical Safety Checks (TSC) and the maintenance procedures (MA) to be performed.

Technical Safety Checks (TSC) must be carried out every 2 years (24 months).

Performance of the Technical Safety Checks must be recorded in the Medical Device Register.

The maintenance procedures (MA) are a recommendation of the manufacturer. The maintenance procedures have to be carried out after 2 years (24 months) at the latest and serve to prevent malfunctions.

The explanations on the TSC / MA test report
are applicable to the TSC / MA test report and for the TSC test report.

Tester's qualification

The initial start-up must be performed by the service of the manufacturer or a person authorized by them.

The checks must only be carried out by persons, who, based on their training, knowledge and on-hand experience, are qualified to carry out such checks in a proper manner. Furthermore, the persons, who carry out the checks, may not be subjected to outside instructions with regards to these checks.

Warning

Commissioning steps, extensions, adjustments, calibrations, maintenance measures, 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 document require the availability of the necessary technical measuring equipment and accessories.

Specifications

The technical specifications must be adhered to.

Warning

When the device is returned to use, check that the pressure of the water supply meets the prescribed minimum pressure.

Precautions

Before turning power on, repair any visible damage.

Prior to opening the device and when working on the open device, the following precautions have to be observed:
– Protect the components against ingress of liquids.
– Do not touch live parts (connectors of the power cable or heater).
– Disconnect and connect all jacks, connectors and components only when the device is turned off.

ESD precautions

When repairing the device and when replacing spare parts, observe the applicable ESD precautions.

6.2 Accessories and supplies

The following articles are required for carrying out the TSC / MA.

Product	Position	Description
TSC and maintenance set		For TSC and maintenance of a device.
Tubing set		For testing the venous occlusion clamp.
Unisilkon grease, L 250 L, (10-g tube)		Use only in places described in the explanations.
Snap-hat battery (2.8 V / 48 mAh)	P.C.B. LP 632	Replace if required.
Battery CR 1225, Lithium (3 V / 42 mAh)	P.C.B. LP 1631	Replace every 4 years.
Powerpack, lead (18 V)	Back of base	Replace every 4 years.
Label set		Change labels only if required.
Solenoid valve adapter fitting, one port	V84	Replace every 2 years, only if, Puristeril 340, Puristeril *plus* are used.

6.3 TSC / MA test report

See the following pages.

This report differs from the TSC test report in the first column Type (e.g., TSC, MA) and the maintenance items (see chapter 6.5 page 6-32).

4008 S (Version V10) **TSC / MA test report** FRESENIUS MEDICAL CARE

Technician's name:	**Customer / customer no.:**	
Device type including option(s) / Software version:	**Serial no.:**	**Inventory no.:**
Service report no.:	**Operating hours:**	**Equipment code:**

Type	No.	Description	Operating condition	Corr.	Meas. value	✓
	1	**Visual inspections**				
TSC	1.1	The fuse accessible from the outside corresponds to the indicated value or seal is undamaged.	Off	–	–	❑
TSC	1.2	Labels and identifications are present and legible.	Off	–	–	❑
TSC	1.3	Mechanical condition permits further safe use. No signs of damages or contamination affecting correct function.	Off	–	–	❑
TSC	1.4	Rotor(s) cleaned. Rotor(s) on the line roller pump(s) show no signs of damage and are fully functional. Color coding of rotor(s) checked.	Off	–	–	❑
TSC	1.5	Power cable not damaged.	Off	–	–	❑
	2	**Preventive measures**				
MA	2.1	Sealing plungers in suctions rods replaced and lubricated; rivets replaced.	Off	❑ Yes ❑ No	_____	❑
MA	2.2	Detent rubber seal of the rinse chambers checked for proper functioning.	Off	–	–	❑
MA	2.3	Filters (F71 and F72) of the suction tubes replaced.	Off	–	–	❑
MA	2.4	Vent valve (V92), check valve (V117, with option CDS) replaced.	Off	–	–	❑
MA	2.5	Filter / filter sieve replaced: F74 (before UF pump), F76 (after V43), F148 (between V100 and rinse chamber), F149 (between V99 and rinse chamber), F119 (with option CDS), filter of the disinfectant suction tube	Off	–	–	❑
MA	2.6	Dialysate filter (F73) or sieve replaced.	Off	–	–	❑
MA	2.7	O-rings in dialyzer couplings replaced.	Off	–	–	❑
MA	2.8	Sampling valve functioning properly.	Off	–	–	❑
MA	2.9	Fan filter replaced.	Off	–	–	❑
MA	2.10	Running band and tube segment of air separation pump replaced.	Off	–	–	❑
MA	2.11	Disinfection valve (V84) replaced after 2 years (only if Puristeril is used).	Off	–	–	❑
MA	2.12	Filter (F210) replaced (if present).	Off	–	–	❑
MA	2.13	bi*bag*® connector, O-rings replaced.	Off	–	–	❑
MA	2.14	There are no dirty or shabby tubes.	Off	–	–	❑
MA	2.15	*Every 4 years only:* Battery and accumulator changed.	Off	–	–	❑
	3	**General checks**				
TSC	3.1	Check of the DIP switches P.C.B. LP 1631 (CPU 1): – Without Central Delivery System: Array 2, switch 7 is on ON – With Central Delivery System: Array 2, switch 8 is on ON Check of the DIP switches P.C.B. LP 632 (CPU 2): – Array 1, switch 3 is on OFF – Array 2, switch 5 is on OFF	Off	–	–	❑
	4	**DIASAFE® *plus***				
MA	4.1	DIASAFE® *plus* filter life checked.	Off	–	–	❑
MA	4.2	Hydrophobic filter (F111) and hydrophobic filter / test valve (F184) replaced.	Off	–	–	❑

Type	No.	Description	Operating condition	Corr.	Meas. value	✓
	5	**bi*b*ag®**				
MA	5.1	Switching pressure of PSW 134 checked: 130 mbar +30 mbar	DIAGNOSTICS	–	–	❑
	6	**OCM**				
MA	6.1	Temperature / conductivity compensation test completed.	CALIBRATION	–	–	❑
	7	**Check of the hydraulics** All pressures must be checked with undampened pressure gauges!				
MA	7.1	Water inlet pressure (reduced): 0.9 bar to ±1.4 bar	CALIBRATION	–	–	❑
MA	7.2	Loading pressure: 1.45 bar ±0.05 bar	CALIBRATION	–	–	❑
MA	7.3	Degassing pump negative pressure: 0.81 bar to ±0.85 bar	CALIBRATION	–	–	❑
MA	7.4	Relief pressure of balancing chamber at 800 ml/min: Relief pressure: 2.2 bar ±0.05 bar	CALIBRATION	–	–	❑
	8	**Ultrafiltration system and membrane pumps**				
TSC	8.1	UF pump: 1 stroke = 1 ml, 60 strokes = 60 ml ±0.5 ml	CALIBRATION	–	_____	❑
MA	8.2	Concentrate pump calibration: Volume removal / number of strokes	CALIBRATION	–	–	❑
MA	8.3	Bicarbonate pump calibration: Volume removal / number of strokes	CALIBRATION	–	–	❑
	9	**Extracorporeal components**				
MA	9.1	Arterial pressure display checked with reference device.	CALIBRATION	–	–	❑
MA	9.2	Venous pressure display checked with reference device.	CALIBRATION	–	–	❑
TSC	9.3	Blood pumps: Check of the blood pump rate (BP-Rate CHECK)	CALIBRATION	–	–	❑
TSC	9.4	Single-Needle switching pressure checked according to table.	CALIBRATION	–	–	❑
	10	**Dialysis mode**				
MA	10.1	Dialysate pressure: – Zero point checked (flow off) – Slope checked	CALIBRATION	–	–	❑
TSC	10.2	Power failure alarm – continuous sound – text displayed: Power Failure	Preparation	–	–	❑
TSC	10.3	Air separation: Activating the air separation pump. Text display with further air separation and blood detected (optical detector dark): Fill program	Preparation	–	–	❑
TSC	10.4	Blood pump stop alarm checked.	Preparation	–	–	❑
TSC	10.5	Venous occlusion clamp closes after blood alarm.	Preparation	–	–	❑
TSC	10.6	Pressure of approx. 2 bar in the venous bubble catcher. Pressure may not drop by more than 0.1 bar within 3 minutes.	Preparation	–	–	❑
TSC	10.7	Conductivity display checked with reference device (bi*b*ag® used!).	Preparation	–	–	❑
TSC	10.8	Desired temperature: 36.5 °C (±0.2 °C) checked with reference device	Dialysis	–	_____ °C	❑
	11	**BPM (option)**				
MA	11.1	Tube connection properly connected to device.	Off	–	–	❑
MA	11.2	Internal blood pressure module, printed circuit boards, cable connections properly attached.	Off	–	–	❑
TSC	11.3	Leakage test: Pressure leakage rate less than 6 mmHg/min	DIAGNOSTICS	–	_____	❑
TSC	11.4	Pressure test: (Pressure values / tolerance)	DIAGNOSTICS	–	–	❑
		– 250 mmHg / ±3 mmHg			_____	
		– 200 mmHg / ±3 mmHg			_____	
		– 150 mmHg / ±3 mmHg			_____	
		– 100 mmHg / ±3 mmHg			_____	
		– 50 mmHg / ±3 mmHg			_____	
TSC	11.5	Safety valve: Emptied at 320 mmHg ±10 mmHg	DIAGNOSTICS	–	–	❑
TSC	11.6	Blood pressure measurement performed.	Preparation	–	–	❑

Type	No.	Description	Operating condition	Corr.	Meas. value	✓
	12	**Checking the electrical safety** According to (DIN) EN 62353:2008, IEC 62353:2007				
TSC	12.1	Visual inspection performed according to item 1.	Off	–	–	❑
TSC	12.2	Measurement of the protective earth resistance performed. Max. 0.3 Ω (with power cable)	Off	–	_____ Ω	❑
TSC	12.3	Device leakage current measured. ❑ Differential current measurement according to figure 5 ***or*** ❑ Direct measurement according to fig. 4	Preparation	–	–	❑
		Nominal voltage of power supply: _____ V		–	–	
		Device leakage current mains polarity 1: _____ µA		–	–	
		for line voltage: _____ V		–	–	
		Scaled to nominal voltage (maximum 500 µA, see Additional requirements)		–	_____ µA	
		Device leakage current mains polarity 2: _____ µA		–	–	
		for line voltage: _____ V		–	–	
		Scaled to nominal voltage (maximum 500 µA, see Additional requirements)		–	_____ µA	
	13	**Functional test**				
TSC	13.1	T1 test performed	T1 Test	–	–	❑

Applied measurement equipment:

Temperature, conductivity, pressure
(Type, serial number):

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

Remarks:

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

The device has been released for further use (attach inspection label).	❑ Yes ❑ No
Date of next inspection:	
Remarks:	

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

Warning

On completion of these procedures it is imperative to run a disinfection.

6.4 Explanations on the test report – TSC / MA
TSC, explanations on test report

Identification

Technician's name:
Surname and last name of technician.

Device type including option(s) / software version:
Device name with possible options or extras. Software version, if available.

Service report no.:
Number of the service call.

Customer / customer no.:
Final customer's number.

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

Inventory no.:
Inventory number assigned to the device.

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

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

Re 1 **Visual inspections**

Operating condition: Off

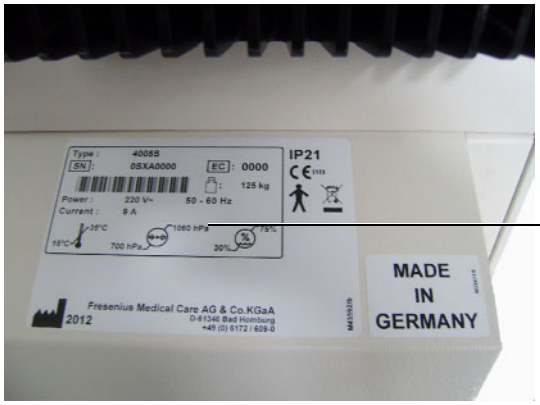
Re 1.1 The battery fuse accessible (see illustration below) **(1)** from the outside corresponds to the indicated value.

Alternative to checking the fuse: If the seal is undamaged, the battery fuse does not have to be checked.

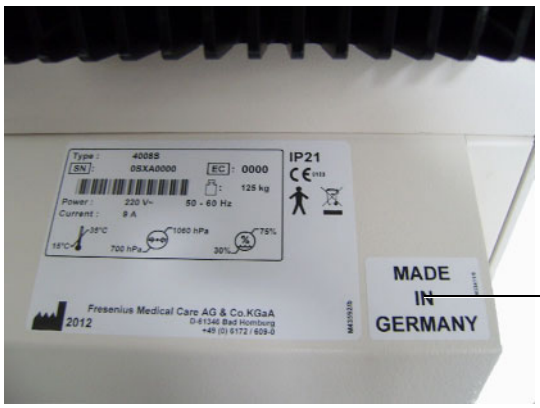
Re 1.2

Labels and identifications are present and legible (with illustrations below).

1 2 x label "Type label complete device“
Check device specification:
Serial number
Equipment code



2 1 x label "Made in Germany"



3 2 x labels to paste over "traffic light symbol" and "warning symbol" (monitor / chassis unit)

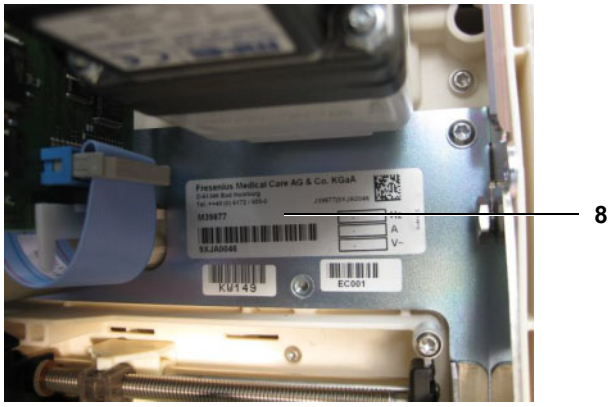
4 1 x label "Type label monitor unit / chassis unit“

5 1 x label "Hot surface“

6 1 x label "Power supply unit type label“

7 1 x label "Hydraulic unit type label“

8 1 x label "Type label EBM“

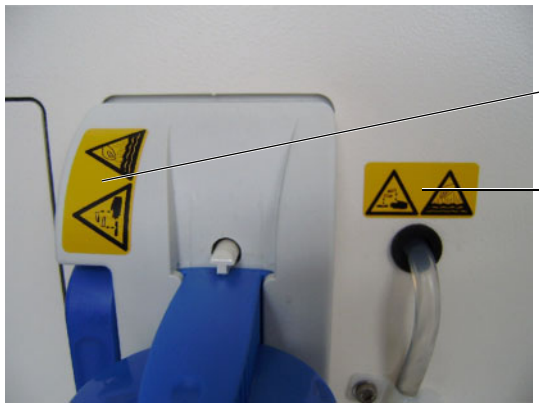


9 1 x label "Insert dialyzer lines here“

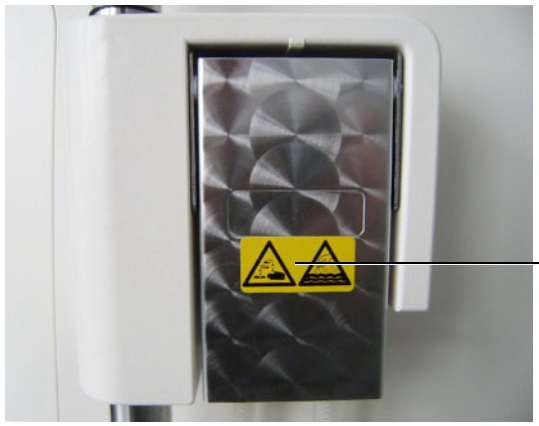
10 1 x label "Refer to instruction manual/booklet“

11 1 x label „Hot rinse“ (DIASAFE® *plus*)

12 1 x label „Hot rinse“ (overflow tube)



13 1 x label „Hot rinse“ (shunt interlock)



14 1 x label „Hot rinse“ (disinfection solution)

15 1 x label „Potential equalization“

16 1 x label "To / from dialyser“

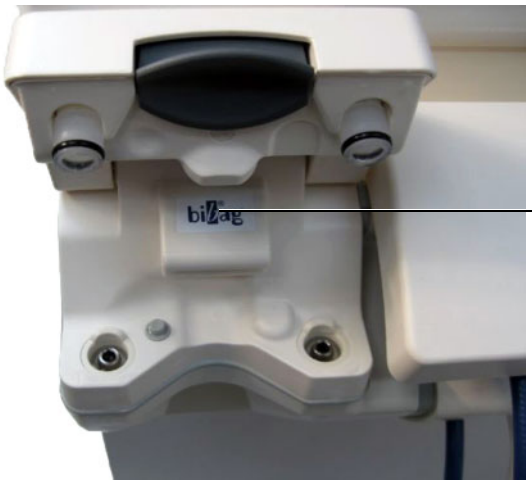
17 1 x label "CDS warning label“ (option)

18 1 x label "Water input / drain, max. 6 bar“

19 1 x label „max. 5 kg“ (IV pole)

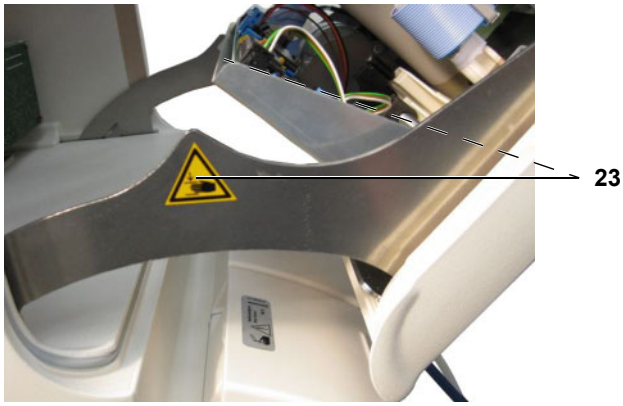
20 1 x label „Hot rinse“ (bi*b*ag® connector, on the outside)

21 1 x label „bi*b*ag®“ (bi*b*ag® connector, on the inside)

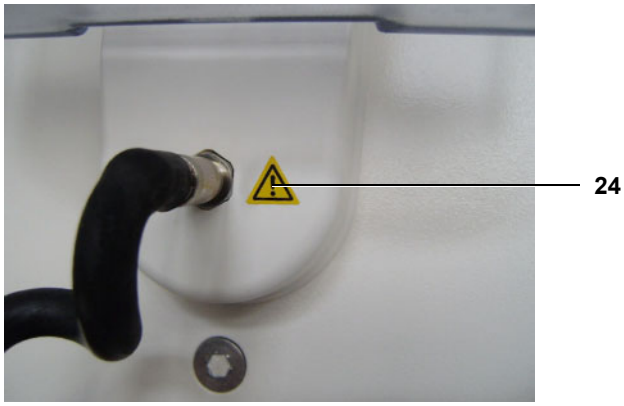


22 1 x label „Hot rinse“ (sealing cap, on the outside)

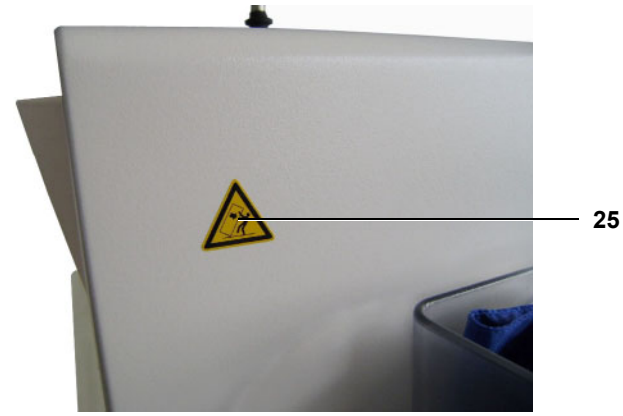
23 2 x Label "Warning label risk of hand injury"
(EBM hinge bracket on the left and on the right)



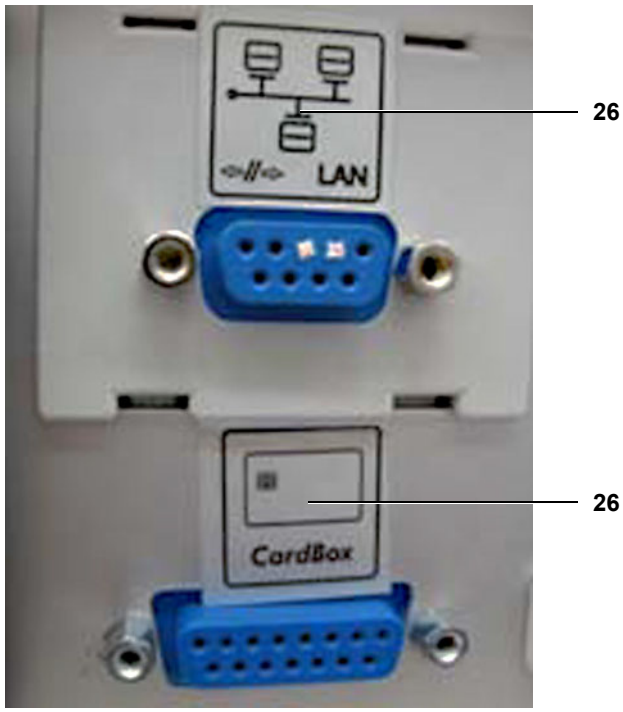
24 1 x label „Warning“ (BPM connection)



25 2 x labels "Tipping hazard" (housing left and housing right)



26 Bed-Side-Link (option):
2 x label: „LAN“ and „CardBox“



27 Country-specific labels:

27.1 Additional label for the People's Republic of China:
1 x label "CCC" (to the right of the "Type label complete device“ on the outside)
1 x label "China RoHS" (to the right of the "Type label complete device“ on the outside)

27.2 Additional label for Russia
1 x label "Service address" (to the left of the "Type label complete device“ on the outside)

Re 1.3

Mechanical condition permits further safe use. There are no signs of damage or contamination affecting proper function of the device.

To be checked:
– Tubings and cuff of BPM (option)

Re 1.4

Rotor(s) cleaned. Rotor(s) on the line roller pump(s) show no signs of damage and are fully functional. Color coding of rotor(s) checked.

– Clean rotor(s) when when dismantled.
– Check all rotor(s) parts for general damage.
– Check grip disk **(1)** for tightness and damage.
– Check all line rollers **(2) (4)** and all guide pulleys **(3)** for damage, wear and obstructions.
– Check the colors of the guide pulleys **(3)**
(blood pump / single-needle pump: white / transparent).
– Insert rotor(s) into the correct stator(s).

Re 1.5

Power cable not damaged.

Re 2

Preventive measures

Operating condition: Off

Re 2.1

Replace the sealing plunger in the concentrate and in the bicarbonate suction tube and grease it with silicone compound. If necessary, replace the rivets of the suction tubes.

Re 2.2

Check the detent rubber seal of the rinse chambers for proper functioning.

Re 2.3

Replace the filters in the suction tubes:
– Filter / concentrate (F71)
– Filter / bicarbonate (F72)

Re 2.4

Replace the vent valve (V92).
With CDS option, replace the concentrate check valve (V117).

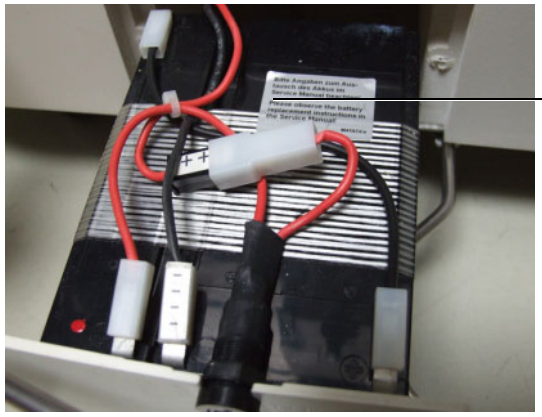
Re 2.5	Replace filters / filter sieves: – Filter / UF (F74), before UF pump – Filter / fill valve (F76), after V43 – Filter / rinse valve 100 (F148), between rinse valve (V100) and rinse chamber (H90b) – Filter / rinse valve 99 (F149), between rinse valve (V99) and rinse chamber (H90a) – Filter / concentrate (F119) - with CDS option – Filter of disinfectant suction tube
Re 2.6	Replace filter sieve in dialyzer tube, replace complete filter / dialysate (F73), if necessary.
Re 2.7	Replace O-rings in dialyzer couplings. Grease the O-rings with Unisilkon grease before installation.
Re 2.8	Check the sampling valve (V116) in the dialysate circuit tubing for proper function and replace the complete valve, if necessary.
Re 2.9	Clean or replace the fan filter in the monitor.
Re 2.10	Check of the air separation pump (P97): Replace the running band and the tube segment. Observe direction of delivery.
Re 2.11	Disinfection valve (V84) must be replaced after 2 years. *Only applicable if Puristeril is used*.
Re 2.12	Replace filter / degassing orifice (F210) (if present).
Re 2.13	bi*b*ag® connector (H136), replace O-rings. Grease the O-rings with Unisilkon grease before installation.
Re 2.14	Replace shabby and/or dirty tubes.

Re 2.15

Every 4 years only: Battery and accumulator changed.

Operating condition: Off

– Accumulator **(1)**



Change accumulator **(1)**:
– Remove old accumulator.
– Install the new accumulator.
– Check polarity (connect as shown in the illustration).

– Battery **(2)**

Change the P.C.B. LP 1631 battery **(2)**:
– Remove the old battery from its socket.
– Insert new battery into the socket.
– Check polarity.
– Use gentle pressure to insert the battery into the socket.

Re 3 **General checks**

Re 3.1

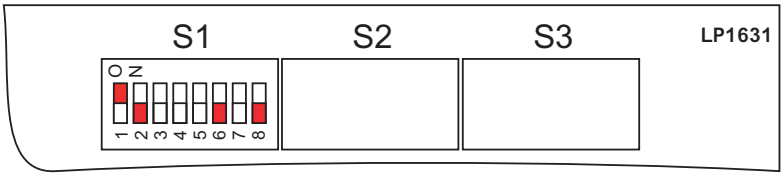
Check of DIP switches

Operating condition: Off

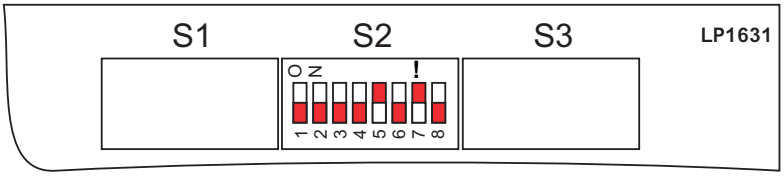
The basic settings of the DIP switches are marked red in the illustrations below.
A detailed overview can be found in chapter 5
(see chapter 5.2 page 5-64).

Check of the DIP switches P.C.B. LP 1631 (CPU 1):

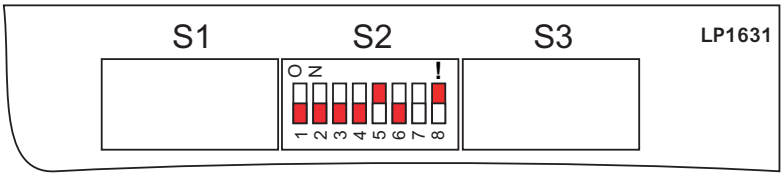
– P.C.B. LP 1631: Array 1
(switch 3, 4, 5 to OFF and switch 7 depending on the heater rod)



– Without Central Delivery System:
P.C.B. LP 1631: Array 2, switch 7 is on ON

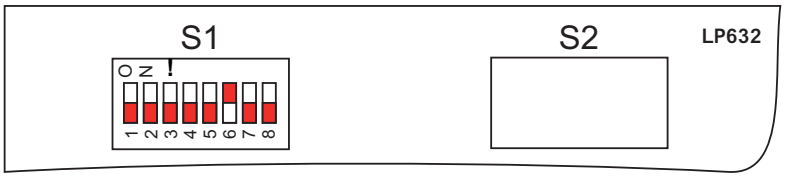


– With Central Delivery System:
P.C.B. LP 1631: Array 2, switch 8 is on ON
(switch 7 is no longer relevant!)

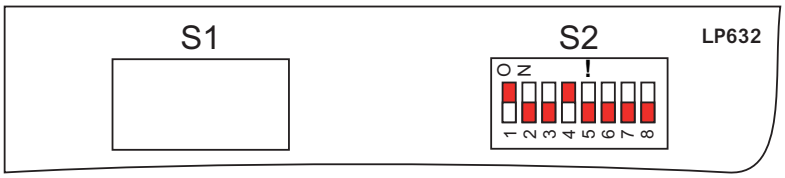


Check of the DIP switches P.C.B. LP 632 (CPU 2):

– P.C.B. LP 632: Array 1, switch 3 is on OFF



– Array 2, switch 5 is on OFF



Re 4 **DIASAFE® *plus***

Re 4.1 Check of the DIASAFE® *plus* filter life,
maximum filter life: 12 weeks.
Operating condition: Off

Re 4.2	Replace hydrophobic filter (F111) and hydrophobic filter / test valve (F184). Operating condition: Off
Re 5	**bi*b*ag®**
Re 5.1	bi*b*ag® pressure transducer (S134) „PSW 134“: Check the switching pressure. The maximum switching pressure is 130 mbar+30 mbar. Operating condition: Service mode / DIAGNOSTICS
Re 6	**OCM**
Re 6.1	Temperature / conductivity compensation test completed. Check the display difference between conductivity measurement cell (CD7) and OCM conductivity measurement cell (CD110). Calibration is required if the difference is > 0.05 mS. Operating condition: Service mode / CALIBRATION
Re 7	**Check of hydraulics** *All pressures must be checked with undampened pressure gauges!*
Re 7.1	Check water inlet pressure (reduced) and correct if necessary. Operating condition: Service mode / CALIBRATION Connect a pressure gauge upstream of the water inlet valve (V41) (measuring point A in the HU). With the water inlet valve (V41) closed, the pressure must be between 0.9 bar and 1.4 bar.
Re 7.2	Check the loading pressure of the balancing chamber and, if required, correct it. Operating condition: Service mode / CALIBRATION Connect a pressure gauge to the pressure side of the degassing pump (measuring point B in HU). The pressure must be 1.45 bar ±0.05 bar.
Re 7.3	Check the negative degassing pump pressure. Operating condition: Service mode / CALIBRATION Connect a pressure gauge to the suction side of the degassing pump (measuring point D in HU). The negative pressure must be between 0.81 bar and 0.85 bar.
Re 7.4	Check balancing chamber relief pressure at a flow of 800 ml/min (relief valve A78).

Operating condition: Service mode / CALIBRATION

Connect a pressure gauge to the pressure side of the flow pump (measuring point C in HU). Relief pressure: 2.2 ±0.05 bar.

Re 8 **Ultrafiltration system and membrane pumps**

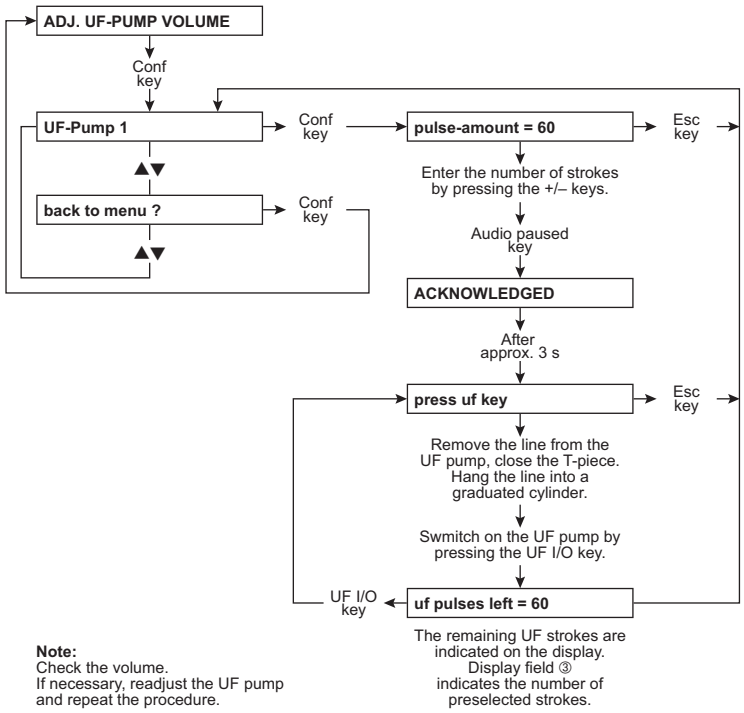
Re 8.1 Check the UF pump delivery volume.

Operating condition: Service mode / CALIBRATION

Collect 60 ml dialysate in an appropriate measuring cylinder in dialysis mode. 60 strokes = 60 ml ±0.5 ml.

If necessary, correct the setting of the UF pump:

Measuring the volume of the UF pump in liters
(see chapter 9.1.12 page 9-12)



Note

Measuring cylinder accuracy: ±0.5 %.

Note

When using scales as a measuring instrument, please ensure that concentrate is not connected.

Re 8.2 Measure the volume of the concentrate pump in liters or compare with an appropriate reference device. If necessary, make settings according to calibration instructions.

Operating condition: Service mode / CALIBRATION

Re 8.3

Measure the volume of the bicarbonate pump in liters or compare with an appropriate reference device.
If necessary, make settings according to calibration instructions.

Operating condition: Service mode / CALIBRATION

Re 9 **Extracorporeal components**

Re 9.1

Arterial pressure transducer.

Operating condition: Service mode / CALIBRATION

Check the zero calibration.
The system displays 0 mmHg if the arterial pressure inlet is open against atmosphere.

Check the slope of the pressure transducer. After loading the pressure transducer with approx. 200 mmHg, the display of the device must show the same measured value as the external comparison instrument (tolerance ±10 mmHg). Deviations have to be corrected in the service mode under CALIBRATION.

Re 9.2

Venous pressure transducer

Operating condition: Service mode / CALIBRATION

Check the zero calibration.
The system displays 0 mmHg if the venous pressure inlet is open against atmosphere.

Check the slope of the pressure transducer.
After loading with approx. 300 mmHg, the external comparison instrument used must show the same value as the display of the hemodialysis device (tolerance ±10 mmHg). Deviations have to be corrected in the service mode under CALIBRATION.

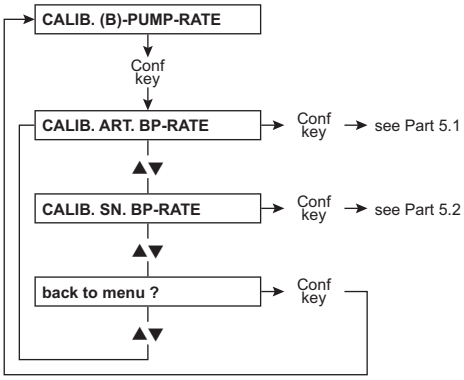
Re 9.3

Arterial and Single-Needle blood pump.

Operating condition: Service mode / CALIBRATION

Check the blood pump rate under
CALIB. (B)-PUMP-RATE.

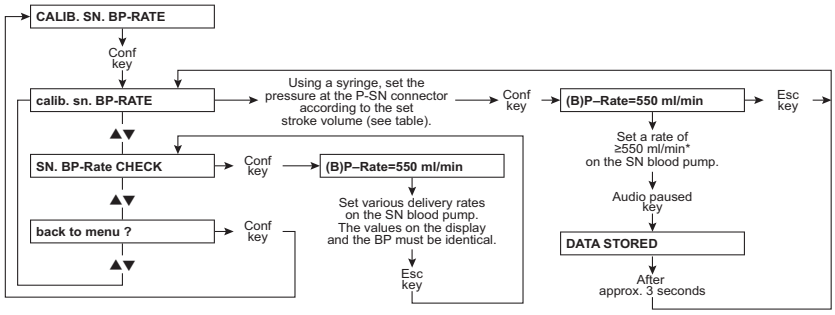
Calibrating the blood pump rate **(see chapter 9.1.8 page 9-9)**



Re 9.4

Check Single-Needle switching pressure according to table.

Operating condition: Service mode / CALIBRATION



Note: Set the line diameter to 8 mm before starting the calibration procedure and press Start/Stop on the blood pump.

* The BP rate of 550 ml/min represents a default value. It can be changed using the ▲▼ (+/–) keys.

Check the upper switching points according to the table below. The upper switching point depends on the stroke volume.

The lower switching point is fixed (75 mmHg).

Stroke volume (ml)	10	15	20	25	30	35	40	45	50
Switching point (mmHg) ±7 mmHg	110	130	150	172	195	219	244	270	299

Re 10

Dialysis mode

Re 10.1

Dialysate pressure check

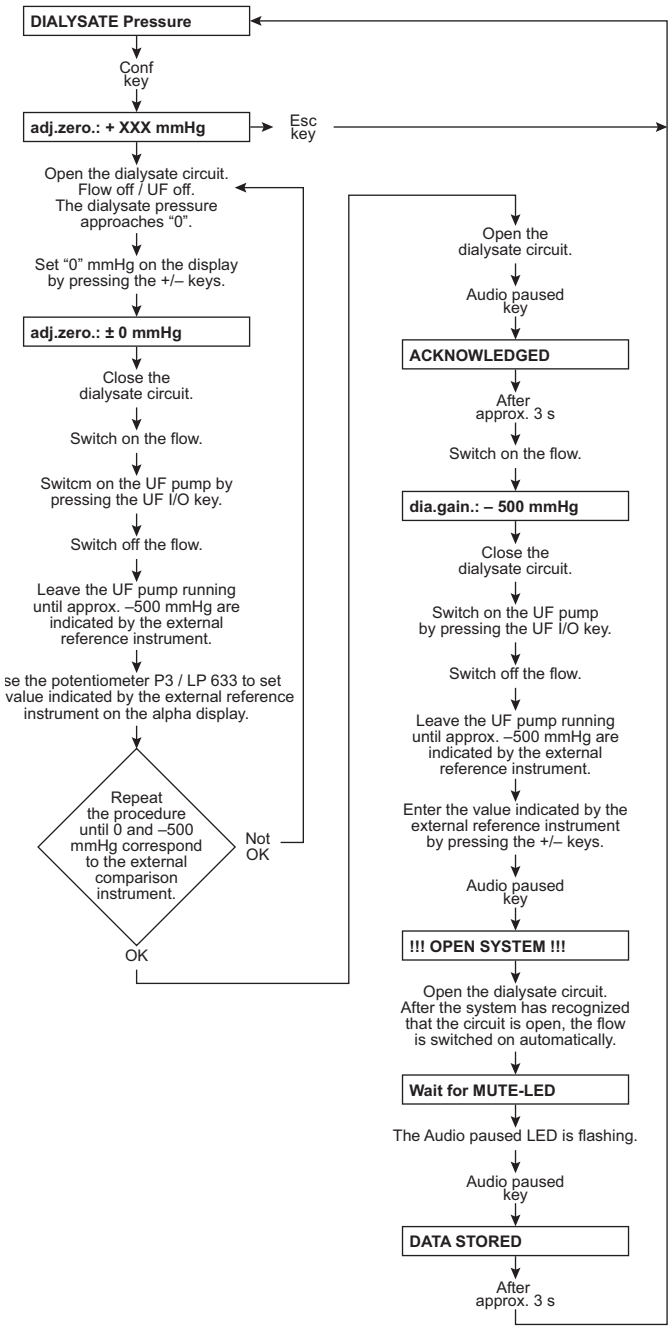
Operating condition: Service mode / CALIBRATION

To be observed when checking the zero point:

– Venous pressure inlet open against atmosphere
– Flow off

Check zero point. With the dialysate circuit open, the water level must be approx. 10 cm above the shunt interlock. Check slope.

Dialysate pressure **(see chapter 9.1.39 page 9-35)**



Re 10.2

Power failure alarm

Operating condition: Preparation

Continuous sound after disconnecting the power plug or switching the power supply unit off **(1)**.

Display message: **Power Failure**

Re 10.3

Check the air separation

Operating condition: Preparation

Suck in air via the dialyzer couplings.
Air separation pump is activated.
Device enters fill program if further air is detected in relation to dialysate flow.
Text display when blood detected (optical detector dark): **Fill program**

Re 10.4

Check the blood pump stop alarm.

Operating condition: Preparation

– Set blood pump delivery rate > 0 ml/min (blood pump must rotate).
– Open blood pump door and check immediate stoppage of rotor.
– Check triggering of blood pump stoppage alarm after max. 30 seconds (setup settings: 15 / 30 seconds).
  Red status indicator (LED) on blood pump is lit,
  operating status indicator (traffic light) is lit or flashing red,
  message on the screen: *Alarm – Bloodpump-stop*.

Re 10.5

Air Detector
The venous occlusion clamp must close in the event of a blood alarm.

Operating condition: Preparation

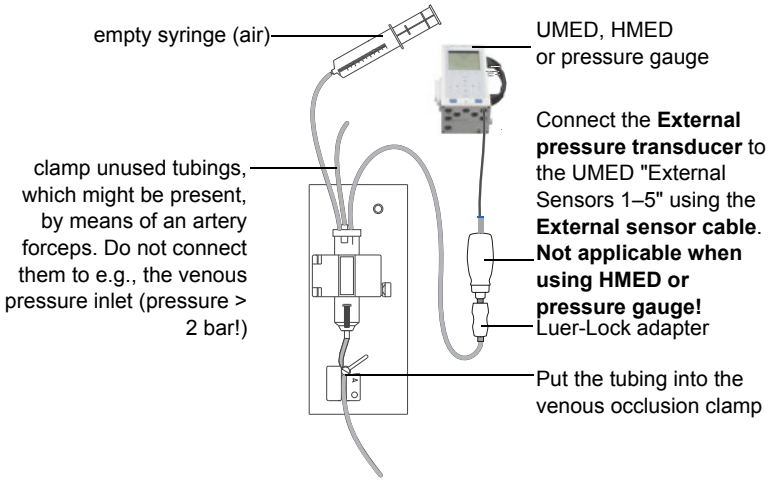
Re 10.6

Air detector, check the venous occlusion clamp.
Pressure may not drop by more than 0.1 bar within 3 minutes.

Operating condition: Preparation

The venous occlusion clamp is closed (blood alarm).

– Insert the venous bubble catcher into the air detector (ultrasonic detector). For the moment, do not place the line in the venous occlusion clamp.
– Manually open the venous occlusion clamp, hold it and insert the tubing.
– Release the venous occlusion clamp. The venous occlusion clamp closes.
– Use the syringe to generate a pressure of approx. 2 bar (see **Checking the venous occlusion clamp** page 9-51).
– The pressure may not drop by more than 0.1 bar within 3 minutes.



Re 10.7

Conductivity display checked, bi*b*ag® connected.

– CD unit
– CD ref.

Operating condition: Preparation

The device must be entirely closed during this check!

Check the conductivity display.
Connect the bi*b*ag®. Measure the conductivity using a comparison instrument connected between the dialyzer couplings.
The value must be the same as the value displayed by the hemodialysis device. Remove any differences by running a calibration program.

Re 10.8

Desired temperature 36.5 °C ±0.2 °C checked with reference device.

Operating condition: Dialysis

The device must be entirely closed during this check!

Check the desired temperature of 36.5 °C±0.2 °C using a reference meter connected between the dialyzer couplings.

– Optical detector = dark (NTC 109 is active)
– Flow = 500 ml/min

Remove any differences by running a calibration program.

Re 11 **BPM (option)**

Re 11.1 Check that the tube connector is correctly attached to the device.

Operating condition: Off

Re 11.2 Check the attachment of the internal blood pressure module, of the printed circuit boards and all cable connections.

Operating condition: Off

Re 11.3 Leakage test. Pressure leakage rate < 6 mmHg/min.
Select the DIAGNOSTICS main menu in the Service mode.
In DIAGNOSTICS: Select BPM.
In BPM: Select leakage test.
The tube and the blood pressure cuff must be wrapped around a rigid metal vessel.
Press the **Conf** key (testing time approx. 4 minutes).
Read the maximum leakage rate from the 4th field. The maximum pressure leakage rate must be < 6 mmHg/min.

Operating condition: Service mode / DIAGNOSTICS

Re 11.4 Pressure test.
Select the DIAGNOSTICS main menu in the Service mode.
In DIAGNOSTICS: Select BPM.
In BPM: Select the pressure test.
Remove tube and blood pressure cuff from the pressure connector (4).
Connect a rigid metal vessel (1), a pressure gauge (2), and an aspirator bulb with drain valve (3) to the pressure connector.
Press the **Conf** key.
Set the appropriate test pressure using the drain valve. Wait until the pressure has stabilized. Check the test pressure.

Pressure values / tolerance:

– 250 mmHg / ±3 mmHg
– 200 mmHg / ±3 mmHg
– 150 mmHg / ±3 mmHg
– 100 mmHg / ±3 mmHg
– 50 mmHg / ±3 mmHg

Operating condition: Service mode / DIAGNOSTICS

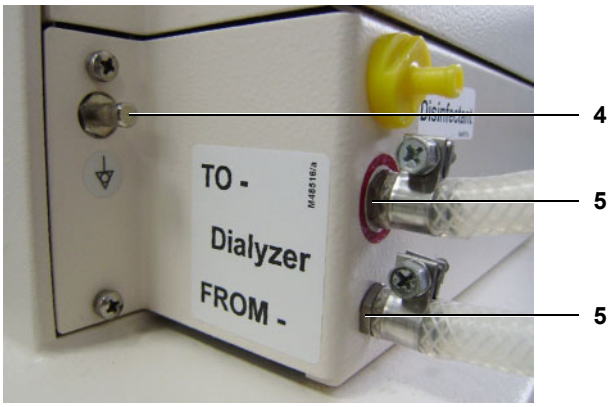
Re 11.5	Safety valve Empty the device at 320 mmHg ±10 mmHg. Operating condition: Service mode / DIAGNOSTICS Select the DIAGNOSTICS main menu. In DIAGNOSTICS: Select BPM. In BPM: Select the pressure test. Tube and blood pressure cuff connected. The blood pressure cuff must be wrapped around a rigid metal vessel. Preselected pressure 300 mmHg. Press the **Conf** key. Once the pressure has reached approx. 300 mmHg, increase the pressure by slowly pressing the blood pressure cuff. If 320 mmHg ±10 mmHg is exceeded, the cuff must deflate immediately. A **BPM error E90** is displayed.
Re 11.6	Blood pressure measurement Perform a measurement in manual mode. Plausibility check of the results. Operating condition: Preparation
Re 12	**Checking the electrical safety** According to (DIN) EN 62353:2008, IEC 62353:2007
Re 12.1	Perform visual inspection. Operating condition: Off – Fuses accessible from the outside comply with the indicated values. – Labels and identifications are present and legible. – Mechanical condition permits further safe use. – No damage or contaminations detectable. – Power cable not damaged.
Re 12.2	Protective earth resistance measured. Max. 0.3 Ω (with power cable). Operating condition: Off The protective earth resistance must be checked on the following measurement points. The exact measuring points are indicated in the figures.

– Heater rod - outward measurement point (screw head) **(1)** on the bottom right on the rear side of the device

– Screw head **(2)** / monitor rear

– Screw head **(3)** / power supply unit

– Potential equalization bolts **(4)** / back of device, lower left
– Dialyzer tube connectors (adapters) (**5**) / lower left of device rear

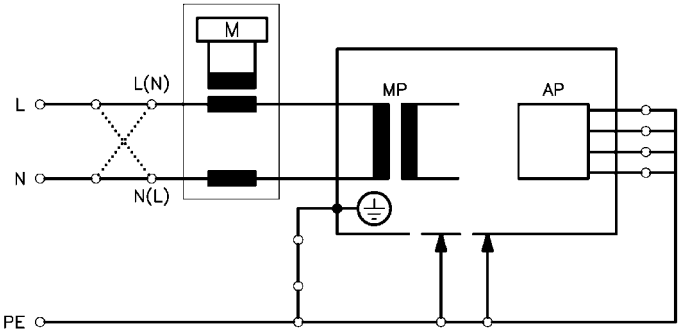


Re 12.3

Measure the device leakage current.
Complete the VDE measurement report, remains with the device.

Operating condition: Preparation

Differential current measurement according to figure 5:

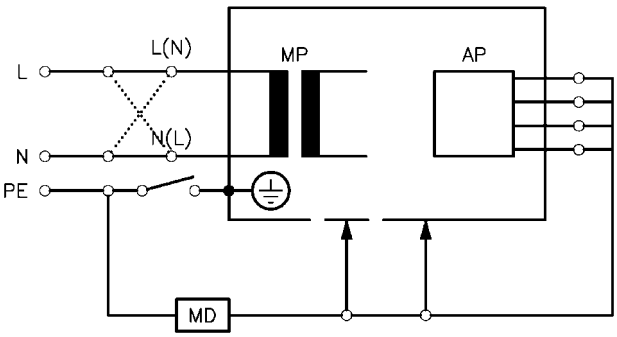


or

Direct measurement according to fig. 4:

The unit under test must be insulated when installed.

All earth connections (e.g. potential equalization, ...) have to be removed.



Basic conditions:
– Measurement of the protective earth resistance performed.
– Perform the measurement in dialysis or preparation mode with the device at operating temperature.
– Dialysate:
  Dialysis temperature: ≥ 36.5 °C
  Dialysate flow: ≥ 300 ml/min
  Conductivity: ≥ 13 mS/cm
– When performing a direct measurement, the following precautions also must be observed:
  The device must be insulated when installed.
  All external connections must have been removed from the device.

The line voltage during the measurement will be recorded, as well as the maximum device leakage current of both mains polarities, scaled to the nominal voltage of the power supply. Maximum device leakage current: 500 µA

Example:
Line voltage during measurement: 225 V
Device leakage current:
mains polarity 1: 180 µA
mains polarity 2: 120 µA
Maximum value of both mains polarities: 180 µA
Nominal voltage of power supply: 230 V
Scaled to nominal voltage 184 µA
(180 µA: 225 V x 230 V = 184 µA
Device leakage current < 500 µA: OK

Additional requirements:
1) If the value scaled to the nominal voltage 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.
2) If the device leakage current has considerably increased since the last measurement or has continuously increased since the first measurement (slow 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:
Device leakage current: 470 µA
Last measured value: 450 µA
470 + (470 – 450) = 470 + 20 = 490 (-> successfully passed!)

Example 2:
Device leakage current: 470 µA
Last measured value: 390 µA
470 + (470 – 390) = 470 + 80 = 550 (-> not passed!)

Re 13 **Functional test**

Re 13.1 T1 test performed.

Operating condition: T1 Test

T1 test passed without errors.

Confirming the test

Applied measurement equipment:
Type and serial number of the test equipment used.

Remarks:
Any irregularities which occurred during the test are documented in this section.

Date, signature, stamp
The person performing the test must confirm with his signature, date and stamp that the test has been performed.

Assessing the test

The device has been released for further use (attach inspection label).

It must be ensured that the intended use of the device will not present a hazard to patients, operators and other third parties.

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

Date of next inspection:
The next inspection date has to be entered in the report.
The intervals prescribed by the manufacturer must be observed.

Remarks:
Any irregularities which occurred during the assessment are documented in this section.

Date, signature, stamp
Assessment of the check must be confirmed with the date, the signature of the person performing the check and a stamp.

6.5 Test report – TSC

See the following pages.

The explanations on this report can be found on the previous pages (see chapter 6.4 page 6-6).

TSC report numbering

Numbers, which are not listed here, are not included in the TSC. They are part of the Maintenance procedures.

4008 S (Version V10) **Test report – TSC** FRESENIUS MEDICAL CARE

Technician's name:	Customer / customer no.:	
Device type including option(s) / Software version:	Serial no.:	Inventory no.:
Service report no.:	Operating hours:	Equipment code:

No.	Description	Operating condition	Corr.	Meas. value	✓
1	**Visual inspections**				
1.1	The fuse accessible from the outside corresponds to the indicated value or seal is undamaged.	Off	–	–	❑
1.2	Labels and identifications are present and legible.	Off	–	–	❑
1.3	Mechanical condition permits further safe use. No signs of damages or contamination affecting correct function.	Off	–	–	❑
1.4	Rotor(s) cleaned. Rotor(s) on the line roller pump(s) show no signs of damage and are fully functional. Color coding of rotor(s) checked.	Off	–	–	❑
1.5	Power cable not damaged.	Off	–	–	❑
3	**General checks**				
3.1	Check of the DIP switches P.C.B. LP 1631 (CPU 1): – Without Central Delivery System: Array 2, switch 7 is on ON – With Central Delivery System: Array 2, switch 8 is on ON Check of the DIP switches P.C.B. LP 632 (CPU 2): – Array 1, switch 3 is on OFF – Array 2, switch 5 is on OFF	Off	–	–	❑
8	**Ultrafiltration system and membrane pumps**				
8.1	UF pump: 1 stroke = 1 ml, 60 strokes = 60 ml ±0.5 ml	CALIBRATION	–	_____	❑
9	**Extracorporeal components**				
9.3	Blood pumps: Check of the blood pump rate (BP-Rate CHECK)	CALIBRATION	–	–	❑
9.4	Single-Needle switching pressure checked according to table.	CALIBRATION	–	–	❑
10	**Dialysis mode**				
10.2	Power failure alarm – continuous sound – text displayed: Power Failure	Preparation	–	–	❑
10.3	Air separation: Activating the air separation pump. Text display with further air separation and blood detected (optical detector dark): Fill program	Preparation	–	–	❑
10.4	Blood pump stop alarm checked.	Preparation	–	–	❑
10.5	Venous occlusion clamp closes after blood alarm.	Preparation	–	–	❑
10.6	Pressure of approx. 2 bar in the venous bubble catcher: Pressure may not drop by more than 0.1 bar within 3 minutes	Preparation	–	–	❑
10.7	Conductivity display checked with reference device (bi*bag*® used!)	Preparation	–	–	❑
10.8	Desired temperature: 36.5 °C (±0.2 °C) checked with reference device	Dialysis	–	_____ °C	❑
11	**BPM (option)**				
11.3	Leakage test: Pressure leakage rate less than 6 mmHg/min	DIAGNOSTICS	–	_____	❑
11.4	Pressure test: (Pressure values / tolerance)	DIAGNOSTICS	–		❑
	– 250 mmHg / ±3 mmHg		–	_____	
	– 200 mmHg / ±3 mmHg		–	_____	
	– 150 mmHg / ±3 mmHg		–	_____	
	– 100 mmHg / ±3 mmHg		–	_____	
	– 50 mmHg / ±3 mmHg		–	_____	
11.5	Safety valve: Emptied at 320 mmHg ±10 mmHg	DIAGNOSTICS	–	–	❑
11.6	Blood pressure measurement performed.	Preparation	–	–	❑

No.	Description	Operating condition	Corr.	Meas. value	✓
12	**Checking the electrical safety** According to (DIN) EN 62353:2008, IEC 62353:2007				
12.1	Visual inspection performed.	Off	–	–	❑
12.2	Protective earth resistance measured. Max. 0.3 Ω (with power cable)	Off	–	_____ Ω	❑
12.3	Device leakage current measured. ❑ Differential current measurement according to figure 5 ***or*** ❑ Direct measurement according to fig. 4	Preparation	–	–	❑
	Nominal voltage of power supply: _____ V		–	–	
	Device leakage current mains polarity 1: _____ µA		–	–	
	for line voltage: _____ V		–	–	
	Scaled to nominal voltage (maximum 500 µA, see Additional requirements)		–	_____ µA	
	Device leakage current mains polarity 2: _____ µA		–	–	
	for line voltage: _____ V		–	–	
	Scaled to nominal voltage (maximum 500 µA, see Additional requirements)		–	_____ µA	
13	**Functional test**				
13.1	T1 test performed.	T1 Test	–	–	❑

Applied measurement equipment:

Temperature, conductivity, pressure
(Type, serial number):

_____

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

_____

Remarks:

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

The device has been released for further use (attach inspection label).	❑ Yes ❑ No
Date of next inspection:	
Remarks:	

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

Warning

On completion of these procedures it is imperative to run a disinfection.

7 Error messages

7.1 T1 Test

7.1.1 Prerequisites for starting and running the test

Error message	Description
Power Failure	Power failure while the test is in progress.
Dialines not conn?	The dialysate lines are not in the shunt interlock.
Shunt cover open?	The shunt interlock is open.
Connect Conc. Line **Wrong conc. supply**	The concentrate connector is in the rinse chamber, or concentrate is not connected at all. The error message depends on the Central Delivery System preselected in the SETUP MENU.
Blood Sensed by OD	The optical detector senses blood in the system.
Flow alarm	Dialysate inlet or dialysate outlet tube kinked, malfunctions in the hydraulics.
Water alarm	Water supply interrupted.
XXX not calibrated	A valid calibration value is missing in the NOVRAM.

7.1.2 Bypass test

Error message	Description
F01 Bypass	The heater relay is switched off. – Acknowledgement (H_REL_W, X639/A12) → X632/A10 not 0 V
F02 Bypass	The heater relay cannot be switched off by CPU2. – Acknowledgement (H_REL_W, X639/A12) → X632/A10 not 12 V – Control line (EM_H_OFF, X632/A9) → X639/A17 not 12 V
F03 Bypass	The temperature measurement range is set to hot rinse. – Control line (HOTRINSE, X634R/C24) → X639/A20 not 0 V – Acknowledgement (HOTRINSE, X634R/C24) → X632/A26 not 0 V
F04 Bypass	The extended bypass cannot be correctly switched by CPU2 (V24 = off, V26 = on, V24B = off). – Acknowledgement (V24, X637/C1) → X632/A4 not 24 V – Acknowledgement (V26, X637/C2) → X632/A6 not 0 V – Acknowledgement (V24B, X637/C23) → X632/A5 not 24 V

Error message	Description
F05 Bypass	The extended bypass cannot be correctly switched off by CPU2 (V24 = on, V26 = off, V24B = on). – Acknowledgement (V24, X637/C1) → X632/A4 not 0 V – Acknowledgement (V26, X637/C2) → X632/A6 not 24 V – Acknowledgement (V24B, X637/C23) → X632/A5 not 0 V
F06 Bypass	CPU1 fails to set the temperature control to hot rinse. – Control line (HOTRINSE, X634R/C24) → X639/A20 not 12 V – Acknowledgement (HOTRINSE, X634R/C24) → X632/A26 not 12 V
F07 Bypass	The extended bypass cannot be correctly switched by CPU1 (V24 = off, V26 = on, V24B = off). – Acknowledgement (V24, X637/C1) → X632/A4 not 24 V – Acknowledgement (V26, X637/C2) → X632/A6 not 0 V – Acknowledgement (V24B, X637/C23) → X632/A5 not 24 V
F08 Bypass	CPU1 fails to reset the temperature control to dialysis. – Control line (HOTRINSE, X634R/C24) → X639/A20 not 0 V – Acknowledgement (HOTRINSE, X634R/C24) → X632/A26 not 0 V
F09 Bypass	The extended bypass cannot be correctly switched off by CPU1 (V24 = on, V26 = off, V24B = on). – Acknowledgement (V24, X637/C1) → X632/A4 not 0 V – Acknowledgement (V26, X637/C2) → X632/A6 not 24 V – Acknowledgement (V24B, X637/C23) → X632/A5 not 0 V
F95 Bypass	System error

7.1.3 Opt. detector test

Error message	Description
F01 opt. Detector	CPU1 interprets the optical detector in a different way than does CPU2. – Acknowledgement (OD_OUT, X633L/C7) → X632/A30 and the digital input of P.C.B. LP 633-5 measure different levels
F02 opt. Detector	CPU2 fails to recognize blood in the system. – Acknowledgement (OD_OUT, X633L/C7) → X632/A30 not 0 V. – Detuning (ODSA, X632/C15) → X351/7 not 12 V.
F03 opt. Detector	CPU1 fails to recognize blood in the system. – Acknowledgement (OD_OUT, X633L/C7) → and the digital input of P.C.B. LP 633-5 – Detuning (ODSA, X632/C15) → X351/7 not 12 V.
F04 opt. Detector	CPU2 recognizes that the optical detector senses opaque fluid (required because of the test in the cleaning program). – Acknowledgement X632/A30 not 12 V. – AD28 defective
F95 opt. Detector	System error

7.1.4 Blood system test

Error message	Description
F09 Blood System	Acknowledgement that CPU2 recognizes that the arterial blood pump is inactive (blood pump not running). – Acknowledgement (BPSB_ART, X348a/6) → X632/A11 not 12 V. – Control line (BPSST_ART, X634L/B14) → X348a/1 not 12 V or (BPST_ART, X634L/A14) → X348a/3 not 12 V
F10 Blood System	Acknowledgement that CPU1 recognizes that the arterial blood pump is inactive (blood pump not running). – Acknowledgement (BPSB_ART, X348a/6) → X633/A11 not 12 V – Control line (BPSST_ART, X634L/B14) → X348a/1 not 12 V or (BPST_ART, X634L/A14) → X348a/3 not 12 V – Level is raised during the T1 test
F11 Blood System	The arterial blood pump cannot be stopped by CPU1. CPU2 recognizes that the arterial blood pump remains active. – Control line (BPSST_ART, X634L/B14) → X348a/1 not 0 V as well as (BPST_ART, X634L/A14) → X348a/3 not 0 V – Acknowledgement (BPSB_ART, X348a/6) → X632/A11 not 0 V. – The level is raised during the T1 test, or the up/down key on the air detector is blocked and the level is constantly raised.
F12 Blood System	The arterial blood pump cannot be stopped by CPU1. CPU1 recognizes that the arterial blood pump remains active. – Control line (BPSST_A, X634L/B14) → X348a/1 not 0 V as well as (BPST_ART, X634L/A14) → X348a/3 not 0 V – Acknowledgement (BPSB_ART, X348a/6) → X633/A11 not 0 V
F13 Blood System	*If Single-Needle pump connected (= ADKS active)*. Acknowledgement that CPU2 detects that the pump is inactive (pump is not running). – Acknowledgement (BPSB_VEN, X348V/6) → X632/B11 not 12 V – Control line (BPSST_VEN, X634L/B15) → X348V/1 not 12 V or (BPST_VEN, X634L/ A15) → X348V/3 not 12 V – Transistor T9 on P.C.B. LP 754 defective. – IC5 on P.C.B. LP 632 defective.
F14 Blood System	*If Single-Needle pump connected (= ADKS active).* Acknowledgement that CPU1 detects that the pump is inactive (pump is not running). – Acknowledgement (BPSB_VEN, X348V/6) → X633L/A13 not 12 V – Control line (BPSST_VEN, X634L/B15) → X348V/1 not 12 V or (BPST_VEN, X634L/A15) → X348V/3 not 12 V – IC16 on P.C.B. LP 633-5 defective. – P.C.B. LP 633-5 recognizes Single-Needle pump although it is not connected.

Error message	Description
F15 Blood System	*If Single-Needle pump connected (= ADKS active).* The Single-Needle pump cannot be stopped by CPU1. CPU2 detects that the pump remains active. – Control line (BPSST_VEN, X634L/B15) → X348V/1 not 0 V as well as (BPST_VEN, X634L/A15) → X348V/3 not 0 V – Acknowledgement (BPSB_VEN, X348V/6) → X632/B11 not 0 V – Transistor T9 on P.C.B. LP 754 defective. – IC5 on P.C.B. LP 632 defective. – During the test the lines are inserted on the Single-Needle pump using the **Start/Stop** key. – P.C.B. LP 633-5 recognizes Single-Needle pump although it is not connected.
F16 Blood System	*If Single-Needle pump connected (= ADKS active).* The Single-Needle pump cannot be stopped by CPU1. CPU1 detects that the pump remains active. – Control line (BPSST_VEN, X634L/B15) → X348V/1 not 0 V as well as (BPST_VEN, X634L/A15) → X348V/3 not 0 V – Acknowledgement (BPSB_VEN, X348V/6) → X633L/A13 not 0 V – IC16 on P.C.B. LP 633-5 defective. – P.C.B. LP 633-5 recognizes Single-Needle pump although it is not connected.
F17 Blood System	*Check of ADKS signal (= ADKS not active)*. Although the recognition of the venous blood pump (ADKS) is not acknowledged, the 24 V supply voltage of the pump can be switched off. – Acknowledgement line (ADKS, X348V/7) → X633L/A10 not 12 V – Acknowledgement (BPSB_VEN, X348V/6) → X633L/A13 not 12 V – Acknowledgement (BPSB_VEN, X348V/6) → X632/B11 not 12 V – IC16 on P.C.B. LP 633-5 defective.
F18 Blood System	*Check of BPUS signal (CPU2 P.C.B. LP 632)*. At the beginning of the test step a maximum of 40 seconds may pass until rotation has stopped. If the blood pump is being activated, the rotation stop alarm must have been cleared. – Acknowledgement line (BPUS, X348A/8) → X632/A13 not 0 V – Acknowledgement line (BPUS, X348A/8) → X632/A13 not 12 V – Blood pump speed is set to “0”: preset speed during the T1 test

Error message	Description
F19 Blood System	*Check of BPUS signal (CPU1 P.C.B. LP 1631 via LP 633-5)* At the beginning of the test step a maximum of 40 seconds may pass until rotation has stopped. If the blood pump is being activated, the rotation stop alarm must have been cleared. – Acknowledgement line (BPUS, X348A/8) → X633L/ A12 not 0 V – Acknowledgement line (BPUS, X348A/8) → X633L/ A12 not 12 V
F20 Blood System	Check of the actual arterial blood pump rate. The actual rate of the arterial blood pump is not zero. The actual rate of the arterial blood pump does not increase. If SN is installed: The actual rate of the venous blood pump is not zero. The actual rate of the venous blood pump does not increase. – Acknowledgement line (BPR_ART, X348A/10) → X633L/B3 not 0 V or acknowledgement line (BPR_ART, X348A/10) → X632/A14 not 0 V – Acknowledgement line (BPR_ART, X348A/10) → X633L/B3 no increase or acknowledgement line (BPR_ART, X348A/10) → X632/A14 no increase If SN is installed: – Acknowledgement line (BPR_VHDF, X348V/10) → X633L/B4 not 0 V – Acknowledgement line (BPR_VHDF, X348V/10) → X633L/B4 no increase
F95 Blood System	System error

7.1.5 Ven. pressure system test

Error message	Description
F01 Venous	CPU1 (input board) shows a venous zero point deviation of more than ±12 mmHg (60 seconds). – Control (VENT_VALVE, X634R/C18) → X351/1 of the vent valve in the LD is defective – Acknowledgement (P_VEN, X351/4) → X633L/B5 that the voltage value is outside the zero point tolerance – P-venous has not been calibrated
F02 Venous	CPU2 shows a venous zero point deviation of more than ±12 mmHg (60 seconds). – Control (VENT_VALVE, X634R/C18) → X351/1 of the vent valve in the LD is defective – Acknowledgement (P_VEN, X351/4) → X632L/C17 that the voltage value is outside the zero point tolerance – P-venous has not been calibrated

Error message	Description
F03 Venous	With detuning in positive direction, the achieved change in the venous display is less than 100 mmHg (7 seconds). – The test detuning is defective (PV_DET, X632/C18) → X351/2 – Acknowledgement (P_VEN, X351/4) → X633L/B5, the change in voltage is too low – P-venous has not been calibrated
F04 Venous	The deviation in the measured value between CPU1 and CPU2 is higher than ±12 mmHg (if P_{ven} > 100 mmHg). – Acknowledgement (P_VEN, X351/4) → X633L/B5 and X632/C17 measure different voltage values – P-venous has not been calibrated
F95 Venous	System error

7.1.6 Air detector test

Error message	Description
F01 Air Detector	CPU1 interprets the air detector signal in a different way than does CPU2. – Acknowledgements (LDA1, X351/14) → X632/C13 and X633L/C10 recognize different signal levels
F02 Air Detector	The air detector alarm is not recognized by CPU2. – Acknowledgement (LDA1, X351/14) → X632/C13 not 0 V – Transmission weakening (LDSA, X632/C16) → X351/10 not 12 V
F03 Air Detector	Air detector clamps acknowledgement (CPU2) activated (venous line clamp closed). – Acknowledgement (LDA2, X351/6) → X632/C14 not 24 V – Clamp control (CLP_CTL, X634/C14) → X351/8 not 12 V. – Clamp control (CLP_CTL, X632/C10) → X351/8 not 12 V
F04 Air Detector	Air detector clamps acknowledgement (CPU1) activated (venous line clamp closed). – Acknowledgement (LDA2, X351/6) → X633L/C13 not 24 V – Clamp control (CLP_CTL, X634/C14) → X351/8 not 12 V. – Clamp control (CLP_CTL, X632/C10) → X351/8 not 12 V
F05 Air Detector	The blood alarm signal has not been cleared (indicates an alarm). – Acknowledgement (BL_AL, X634L/C15) → X632/C21 not 12 V
F06 Air Detector	Closing of the air detector clamp via the CPU2 control line was not possible. – Clamp control (CLP_CTL, X632/C10) → X351/8 not 0 V – Acknowledgement (LDA2, X351/6) → X632/C14 not 0 V
F07 Air Detector	Opening of the air detector clamp via the CPU2 control line was not possible. – Clamp control (CLP_CTL, X632/C10) → X351/8 not 12 V – Acknowledgement (LDA2, X351/6) → X632/C14 not 24 V
F08 Air Detector	Closing of the air detector clamp via the CPU1 control line was not possible, or CPU2 acknowledgement is incorrect. – Clamp control (CLP_CTL, X634/C14) → X351/8 not 0 V. – Acknowledgement (LDA2, X351/6) → X632/C14 not 0 V

Error message	Description
F09 Air Detector	Closing of the air detector clamp via the CPU1 control line was not possible, or CPU1 acknowledgement is incorrect. – Clamp control (CLP_CTL, X634/C14) → X351/8 not 0 V. – Acknowledgement (LDA2, X351/6) → X633L/C13 not 0 V
F10 Air Detector	The blood alarm message is missing. – Acknowledgement (BL_AL, X634L/C15) → X632/C21 not 0 V
F11 Air Detector	Air detector clamps acknowledgement (CPU2) activated (venous line clamp closed). – Acknowledgement (LDA2, X351/6) → X632/C14 not 24 V – Clamp control (CLP_CTL, X634/C14) → X351/8 not 12 V. – Clamp control (CLP_CTL, X632/C10) → X351/8 not 12 V
F12 Air Detector	Air detector clamps acknowledgement (CPU1) activated (venous line clamp closed). – Acknowledgement (LDA2, X351/6) → X633L/C13 not 24 V – Clamp control (CLP_CTL, X634/C14) → X351/8 not 12 V. – Clamp control (CLP_CTL, X632/C10) → X351/8 not 12 V
F13 Air Detector	The blood alarm signal has not been cleared (indicates an alarm). – Acknowledgement (BL_AL, X634L/C15) → X632/C21 not 12 V
F14 Air Detector	Raise level key on the air detector is constantly active. – Acknowledgement (LEVEL_UP, X351/3) → X632/C11 not 0 V
F15 Air Detector	Acknowledgement of the supply voltage for the ultrasonic output stage not between 6.5 and 13.5 V after 3 seconds. – Adapter board AD28 not connected – Acknowledgement (X351/11 X633L/25A jumper to X633L/B7) not 12 V – Relay on AD28 failed to drop.
F16 Air Detector	Acknowledgement of the supply voltage for the ultrasonic output stage after 3 seconds not > 14.5 V. – Adapter board AD28 not connected – Acknowledgement (X351/11 → X633L/ 25A jumper to X633L/B7) not voltage of 16 V / 24 V – Relay on AD28 is not controlled – No 10 Hz signal at ALARM_REST (X351/12)
F17 Air Detector	Acknowledgement of the supply voltage for the ultrasonic output stage not between 6.5–13.5 V after 3 seconds. – Adapter board AD28 not connected – Acknowledgement (X351/11 X633L/25A jumper to X633L/ B7) not 12 V – Relay on AD28 failed to drop.
F95 Air Detector	System error

7.1.7 Display test

Error message	Description
F01 Display	CPU1 failed to start the display test within 5 seconds. – The “test started” information transmitted via the serial interface is missing
F02 Display	CPU1 failed to complete the display test within 120 seconds. – The “Test passed” information transmitted via the serial interface is missing
F95 Display	System error

7.1.8 Art. pressure system test

Error message	Description
F01 Arterial	With detuning in negative direction, the change achieved on the arterial display is less than 100 mmHg (2 seconds). – Acknowledgement (P_ART, X348A/7) → X633L/B12, insufficient voltage change – Test detuning defective (PA_DET, X632/A17) → X348A/9
F02 Arterial	With detuning in positive direction, the change achieved on the arterial display is less than 100 mmHg (2 seconds). – Acknowledgement (P_ART, X348A/7) → X633L/B12, insufficient voltage change – Test detuning defective (PA_DET, X632/A17) → X348A/9
F95 Arterial	System error

7.1.9 Battery test

Error message	Description
F01 Battery	CPU1 failed to complete the battery test within 5 seconds. – The “Test passed” information transmitted via the serial interface is missing
F02 Battery	The battery charge is insufficient for emitting an audible alarm over 1 min (maybe no battery connected). – The battery voltage (U_ACCU, ...) → X633L/B21 dropped below 17.6 V. – Acknowledgement (U_ACCU, ...) → X633L/B21 of the battery voltage defective.
F03 Battery	Test circuit on P.C.B. LP 639 defective. – The test level is incorrect (TESTBATT, X634R/C23) → X639/A10, no 12 V pulse (100 ms) – Fuse in the base is defective – R39 on P.C.B. LP 647 defective, possibly caused by flickering power supply unit
F95 Battery	System error

7.1.10 Blood leak test

Error message	Description
F01 Blood Leak	Blood leak channel and dimness not in alarm-free condition during the T1 test. – Dimness channel contaminated (calcium precipitate, etc.) – Acknowledgement (BLL, X637/A18) → X633L/B10 voltage value within the alarm tolerances (< 3 V / ≥ 8 V) – Acknowledgement (BLL_DIM, X637A/21) → X633L/B11 voltage value within the alarm tolerances (< 1.5 V / ≥ 8 V) – DAC_BLL or DAC_DIM not within the tolerances (check calibration)
F02 Blood Leak	The blood leak alarm / dimness alarm is not recognized during test detuning. – Acknowledgement (BLL, X637/A18) → X633L/B10 voltage value not within the alarm tolerances (≥ 3 V) – Acknowledgement (BLL_DIM, X637A/21) → X633L/B11 voltage value not within the alarm tolerances (≥ 1.5 V) – Test detuning (BLL_DET, X632/A25) → X633L/B27 not 5 V – Calibration of DAC_BLL or DAC_DIM is too high – Detuning (DAC_DIM, X634R/A11) → X633L/C3 impossible – Dimness calibration is set to potentiometer calibration (BR6 from pos. 1/2 to 2/3)
F03 Blood Leak	After test detuning, the blood leak channel and dimness fail to enter the alarm-free state. – Dimness channel contaminated (calcium precipitate, etc.) – Acknowledgement (BLL, X637/A18) → X633L/B10 voltage value within the alarm tolerances (<3 V / ≥ 8 V) – Test detuning (BLL_DET, X632/A25) → X633L/B27 not 0 V – Acknowledgement (BLL_DIM, X637A/21) → X633L/B11 voltage value within the alarm tolerances (< 1.5 V / ≥ 8 V) – DAC_BLL or DAC_DIM not within the tolerances (check calibration)
F95 Blood Leak	System error

7.1.11 Temperature test

Error message	Description
F01 Temperature	The temperature measuring range is not set to hemodialysis. – Control line (HOTRINSE, X634R/C24) → X639/A20 not 0 V – Acknowledgement (HOTRINSE, X634R/C24) → X632/A26 not 0 V
F02 Temperature	The actual temperature is less than 35.0 °C (test running time > 15 minutes). – Calibrate the temperature – The heater rod has failed – Acknowledgement (T_DIAL1, X633L/B16) → X632/A24, voltage got stuck.
F03 Temperature	The actual temperature is higher than 39.0 °C (test running time 15> 15 minutes). – Calibrate the temperature – The regulating sensor (NTC-2) is defective – Acknowledgement (T_DIAL1, X633L/B16) → X632/A24, voltage got stuck.

Error message	Description
F04 Temperature	The temperature failed to stabilize within 15 minutes. – Acknowledgement (T_DIAL1, X633L/B16) → X632/A24 is steadily changing (change > 0.3 °C/15 sec).
F05 Temperature	Detuning in positive direction not higher than 3 °C (10 seconds). – Acknowledgement (T_DIAL1, X633L/B16) → X632/A24 change in voltage insufficient. – Detuning (T_DETADJ, X632/A23) X633R/C21 insufficient
F06 Temperature	The monitor sensor indicates a constant value. – NTC-3 defective
F07 Temperature	The test release is missing (max. test running time is 10 minutes). – Run-time problem (software).
F08 Temperature	CPU1 failed to transmit a bi*b*ag® status message within 3 seconds. – Run-time problem (software).
F09 Temperature	bi*b*ag® NTC_BIB detuning not higher than 1 °C. – Acknowledgement (NTC_BIB, X633R/C15) → ADW on P.C.B. LP 633-5, change in voltage insufficient – Detuning (BIBAG_TE, X634R/A13) → X633R/A20 insufficient
F10 Temperature	bi*b*ag® temperature display outside of measuring range (15 to 45 °C) – Acknowledgement (NTC_BIB, X633R/C15) → ADW on P.C.B. LP 633-5
F95 Temperature	System error

7.1.12 Negative pressure test (negative pressure holding test)

Error message	Description
F01 neg. Pressure	During the start phase a negative pressure of more than 450 mmHg has developed (max. test running time 120 seconds). – The hydraulic system is contaminated, – the air separation pump started running
F02 neg. Pressure	Setting the dialysate pressure to the test pressure (–300 mmHg to –450 mmHg) was not possible (max. test running time 120 seconds). Upon repetition of measurement, the range was extended from –260 mmHg to –490 mmHg. – Leakage in the hydraulic system – The UF pump is defective
F03 neg. Pressure	The working point (116 digits) of the differential amplifier cannot be set correctly (max. test running time 120 seconds). – Pressure variations are too large – The D-A converter (IC11) on P.C.B. LP 632 is defective – The operational amplifier (IC1/IC3) on P.C.B. LP 632 is defective – Acknowledgement (P_DIAL, X633L/B6) → X632/A29 is defective – CI signal is missing (P.C.B. LP 632 → X632/B22).

Error message	Description
F04 neg. Pressure	Completion of pressure measurement was not possible (max. test running time 120 seconds). – The D-A converter (IC11) on P.C.B. LP 632 is defective – The operational amplifier (IC1/IC3) on P.C.B. LP 632 is defective – Acknowledgement (P_DIAL, X633L/B6) → X632/A29 is defective
F05 neg. Pressure	The air separation pump started running during the measurement phase. – Acknowledgement (ACKN_ASP, X634L/B10) → X632/A19 not 0 V. – ASP has been interrupted electrically
F06 neg. Pressure	Negative pressure holding test failed. The dialysate pressure drop exceeds ±40 mmHg (related to ten balancing chamber switching cycles). – Leakage in the hydraulic system
F07 neg. Pressure	Current increasing pulses were not recognized (min. 2 x). – No 5 V balancing chamber pulses (CI. X634R/A23) → X632/B22
F95 neg. Pressure	System error

7.1.13 Positive pressure test (positive pressure holding test)

Error message	Description
F01 pos. Pressure	The mandatory filling program of CPU1 has not been completed (10 seconds). – The solenoid valve V43 is not closed
F24 pos. Pressure	V24 valve error. – Acknowledgement (V24, X637/C1) → X632/A4 not 24 V
F25 pos. Pressure	No pressure increase above 150 mmHg (change in pressure) after valve switching. – Control signals of V24 and V24B mistaken for each other – Leakage in the external system (shunt interlock, dialysate lines, etc.)
F26 pos. Pressure	No pressure compensation after opening of V43 (–125 mmHg to 55 mmHg). – V24 got stuck (mechanically open) – V43 not open – V26 leaky
F27 pos. Pressure	No pressure compensation after opening of V43 (–125 mmHg to 55 mmHg). – V24 got stuck (open mechanically) – V43 not open – V189 (retentate valve) leaking
F02 pos. Pressure	The loading pressure cannot be measured via the solenoid valve V26 in the hydraulic system (P-Dial. < 600 mmHg, 15 seconds). – Solenoid valve V26 mechanically not open – Solenoid valve V43 mechanically not closed The balancing chamber is switched to passage during this test sequence. V24, V24B and V43 are closed; V26 is open.

Error message	Description
F03 pos. Pressure	The hydraulic system cannot be deaerated via the solenoid valve V43; the zero point of –125 to 55 mmHg has not been reached (15 seconds). – Solenoid valve V26 mechanically not closed – Solenoid valve V43 mechanically not open – Zero point outside the –125 to 55 mmHg range. The balancing chamber is switched to passage during this test sequence. V24, V24B and V26 are closed; V43 is open.
F04 pos. Pressure	The first working point (220 digits) of the differential amplifier cannot be set. – Pressure variations are too large – The D-A converter (IC11) on P.C.B. LP 632 is defective – The operational amplifier (IC1/IC3) on P.C.B. LP 632 is defective – Acknowledgement (P_DIAL, X633L/B6) → X632/A29 is defective
F05 pos. Pressure	Test detuning results in a change in the measuring range of more than 95 mmHg (60 seconds). – The operational amplifier (IC2) on P.C.B. LP 632 is defective – Acknowledgement (P_DIAL, X633L/B6) X632/A29, change in voltage too large – Detuning defective (P_DETADJ, X632/C20) → X633R/C22 – The balancing chamber valve V36 or V38 (drain valve) is leaky
F06 pos. Pressure	Test detuning results in a change in the measuring range of less than 85 mmHg (60 seconds). – The D-A converter (IC11) on P.C.B. LP 632 is defective – Acknowledgement (P_DIAL, X633L/B6) → X632/A29, change in voltage insufficient – Detuning defective (P_DETADJ, X632/C20) → X633R/C22 – V26 leaky
F07 pos. Pressure	After detuning in the test there is a difference (P. diff > ±9 mmHg). between the display and the differential amplifier. – The voltage divider R23/R9 or the operational amplifier IC2 is defective – The operational amplifier IC1/IC3 is defective – The balancing chamber valve V36 or V38 (drain valve) is leaky
F08 pos. Pressure	Test detuning results in a change in the measuring range of more than 400 mmHg (20 seconds). – The operational amplifier (IC2) on P.C.B. LP 632 is defective – Acknowledgement (P_DIAL, X633L/B6) X632/A29, change in voltage too large – Detuning defective (P_DETADJ, X632/C20) → X633R/C22
F09 pos. Pressure	Test detuning results in a change in the measuring range of less than 350 mmHg (20 seconds). – The D-A converter (IC11) on P.C.B. LP 632 is defective – Acknowledgement (P_DIAL, X633L/B6) → X632/A29, change in voltage insufficient – Detuning defective (DIAL_DET_ADJ, X632/C20) → X633R/C22
F10 pos. Pressure	The second working point (116 digits) of the differential amplifier cannot be set correctly. – The D-A converter (IC11) on P.C.B. LP 632 is defective – The operational amplifier (IC1/IC3) on P.C.B. LP 632 is defective

Error message	Description
F11 pos. Pressure	Change in the dialysate pressure after closing of the solenoid valve V43 (zero point change from –20 mmHg to +80 mmHg within 15 seconds). – The solenoid valve V24B is not closed – The balancing chamber valve V36 or V38 (drain valve) is leaky The balancing chamber is switched to passage during this test sequence. V43, V24B and V26 are closed; V24 is open.
F12 pos. Pressure	The loading pressure cannot be measured via the solenoid valves V24 and V24B in the hydraulic system (P-Dial. < 600 mmHg, 15 seconds). – Solenoid valve V24 or V24B mechanically not open The balancing chamber is switched to passage during this test sequence. V43 and V26 are closed; V24 and V24B are open.
F13 pos. Pressure	The hydraulic system cannot be deaerated via the solenoid valve V43; (P-Dial. not equal to –125 to 55 mmHg, 20 seconds). – The solenoid valve V24 is not closed – V43 neither opens electrically nor mechanically The balancing chamber is switched to passage during this test sequence. V24 and V26 are closed; V24B and V43 are open.
F14 pos. Pressure	Zero point change after closing of solenoid valve V43 (20 seconds). Standard: P-Dial. not equal to –125 to 55 mmHg. The balancing chamber is switched to passage during this test sequence. V24, V26 and V43 are closed; V24B is open.
F15 pos. Pressure	The loading pressure is below 780 mmHg ± 30mmHg (10 seconds). – The loading pressure is too low
F16 pos. Pressure	During the start phase, the pressure dropped below 620 mmHg (measuring tolerance: ±30 mmHg, max. test running time 120 seconds). – Major leakage in the hydraulic system – The UF pump spring is defective – The loading pressure is too low – The air separation pump fails to occlude – Relief valve A78 or V43 is leaky
F17 pos. Pressure	During the start phase, it was not possible to reduce the dialysate pressure to a value below 760 mmHg (measuring tolerance: ±30 mmHg, test running time 120 seconds). – The loading pressure is too high – The UF pump is defective
F18 pos. Pressure	The working point (116 digits) of the differential amplifier cannot be set correctly (test running time 120 seconds). – The pressure variations in the system are too large
F19 pos. Pressure	Completion of pressure measurement was not possible (max. test running time 120 seconds). – The D-A converter (IC11) on P.C.B. LP 632 is defective – The operational amplifier (IC1/IC3) on P.C.B. LP 632 is defective – Acknowledgement (P_DIAL, X633L/B6) → X632/A29 is defective

Error message	Description
F20 pos. Pressure	Positive pressure holding test failed. A pressure drop by more than ±80 mmHg/min was detected in the hydraulic system during flow-off. – Leakage in the hydraulic system – The UF pump spring is defective – The air separation pump fails to occlude – Relief valve leaking – V84 leaking
F21 pos. Pressure	The dialysate pressure cannot be set to a value between 460 and 760 mmHg ±30 mmHg (10 seconds). – The heat exchanger is defective – Problem in the hydraulic system
F22 pos. Pressure	The air separation pump is not running during the test phase (2 seconds). – Control line (AIR_SEP+/A22) → ASP/... not 24 V – Control line (AIR_SEP–/C22) → ASP/... not 0 V – Acknowledgement (ACKN_ASP, X634L/B10) → X632/A19 not 12 V.
F23 pos. Pressure	Pressure drop in the hydraulic system during the measuring phase (8 seconds). Change larger than +4 digits or larger than -8 digits. – Leakage in the pump segment of the air separation pump – Leakage in the heat exchanger – Acknowledgement (P_DIAL, X633L/B6) X632/A29, change in voltage too large
F24 – F27	See between F01 and F02
F28 pos. Pressure	ASP functional test (running and delivery test) – ASP line segment is occluded – ASP line segment has been incorrectly inserted (check direction of delivery) – ASP is not running (electrically or mechanically). – V87 electrically or mechanically closed
F95 pos. Pressure	System error

7.1.14 UF function test

Error message	Description
F01 UF Function	The pause between the strokes of the UF pump 1 was shorter than 220 ms. Correct volume delivery is not ensured due to too short a return. – The pump rate emitted by CPU1 is too high
F02 UF Function	The pulse time for the UF pump 1 is shorter than 180 ms. Correct volume delivery is not ensured due to too short an emission time. – The monoflop on P.C.B. LP 634 is defective (IC42/R82/C47)
F03 UF Function	The pulse time for the UF pump 1 is longer than 500 ms. A maximum rate of 5000 ml/h is not possible. – The monoflop on P.C.B. LP 634 is defective (IC42/R82/C47)
F04 UF Function	No activity of the UF pump 1 during the test (5 seconds). – Acknowledgement (UF_P1, X637/B23) → X632/A7, no LOW pulses. – Control line (UF_P1, X634L/ABC23) X637/B23, no LOW pulses.

Error message	Description
F05 UF Function	The UF pump 1 cannot be stopped by CPU2. – Control line (UF_P_EN, X632/C28) → X634R/A22 not 5 V. – The reset input at IC42/pin 3 on P.C.B. LP 634 is defective
F06 UF Function	The UF pump acknowledgement from CPU1 is faulty. – Acknowledgement (UF_P1, X637/B23) → X633L/C14, no LOW pulses.
F07 UF Function	The change in pressure after a stroke is less than 20 mmHg. – The UF pump 1 is mechanically defective – Acknowledgement (UF_P1_CTL, X632/C27) → X634R/A24, no LOW pulses
F09 UF Function	Dialysate pressure is outside the measuring range (15 seconds). – UF pressure transducer defective. – The D-A converter (IC11) on P.C.B. LP 632 is defective – The operational amplifier (IC1/IC3) on P.C.B. LP 632 is defective
F95 UF Function	System error

7.1.15 Conductivity test

Error message	Description
F01 Conductivity	The conductivity failed to be within the scale limits or to stabilize within 10 minutes (±0.1 mS/10 sec). – Concentrate is not connected – Acknowledgement (COND_SIG, X633L/B8) → X632/A22, voltage outside the measuring range or unstable
F02 Conductivity	Detuning in positive direction not more than 0.5 mS (10 seconds). – Acknowledgement (COND_SIG, X633L/B8) → X632/A22 insufficient – Detuning (COND_DET, X632/A21) X633L/B31 insufficient
F03 Conductivity	Detuning in negative direction not more than 0.5 mS (10 seconds). – Acknowledgement (COND_SIG, X633L/B8) → X632/A22 insufficient – Detuning (COND_DET, X632/A21) X633L/B31 insufficient
F04 Conductivity	The conductivity cell indicates a constant value. – The CD cell is defective
F05 Conductivity	CPU1 failed to transmit a bi*b*ag® status message within 3 seconds. – Run-time problem (software).
F06 Conductivity	The bi*b*ag® CD detuning is not more than 1 mS/cm. – Acknowledgement (COND_SIGNAL3, X633R/A12) → MP TP3 on P.C.B. LP 633-5, change in voltage insufficient – Detuning (COND_DET, X632/A21) X633L/B31 insufficient

Error message	Description
F07 Conductivity	The bi*b*ag® CD display is outside of the measuring range. – Acknowledgement (COND_SIGNAL3, X633R/A12) → MP TP3 on P.C.B. LP 633-5 – Conductivity outside the expected detuning range caused by wrong concentrate on the bicarbonate port or temperature too low
F08 Conductivity	CPU1 fails to increase the working point (when the conductivity is < 40 mS/cm uncompensated) for the bi*b*ag® conductivity by > 5 digits. – Detuning (HOT_RINSE, X634R/C24 → X633R/A16) not 12 V – P.C.B. LP 633-5 T2 or IC26 defective
F95 Conductivity	System error

7.1.16 DIASAFE plus test/ HPU test

Error message	Description
F01 DIASAFE plus **F01 HPU**	Present options and DIP switch settings do not match. CPU1 system status (MST), HPU status and DIP switch / array 2 changed during the test running time. – DIASAFE plus: CPU2: Array 2, DIP switch 2 not OFF CPU2: Array 2, DIP switch 3 not OFF – MST transmitted by CPU1 not matching with the set DIP switch of array 2. – DIP switch / array 2 changed during the test running time. – HPU logged off
F34 DIASAFE plus	Pressure holding test failed to be passed. Max. number of treatments exceeded? – Diasafe filter membranes leaking / worn.
F02 DIASAFE plus **F02 HPU**	Dialysate outlet pressure (DA1) outside the permissible range (10 seconds). Test range for DA1 –25 mmHg² P_dial ² 55 mmHg – Acknowledgement DA1 (P_DIAL, X633L/B6) → X632/A29 – Acknowledgement DA2 (see HPU diagram)
F03 DIASAFE plus **F03 HPU**	Cross comparison of both pressure transducers (DA1 / DA2) is outside the acceptable tolerance (10 seconds). P(DA2) == P(DA1) ±20 mmHg – Acknowledgement DA1 (P_DIAL, X633L/B6) → X632/A29 – Acknowledgement DA2 (see HPU diagram)
F41 DIASAFE plus **F41 HPU**	The test valve V183 is leaking. Pressure increase in the system of DP(DA2) > 30 mmHg within 4 seconds. – V183 open, contaminated, or mechanically defective – HPU, output stage etc. defective
F42 DIASAFE plus **F42 HPU**	No pressure increase of DP(DA2) > 200 mmHg within 4 seconds after opening the test valve V183 in the system. – V183 fails to open, mechanically defective – Compressor P185 defective, not running – HPU, V183 and / or compressor P185 output stage etc. defective

Error message	Description
F43 DIASAFE plus **F43 HPU**	The lower pressure test range of DP(DA2) > 300 mmHg failed to be achieved within 1 second after closing the test valve V183. – HPU, output stage etc. defective
F44 DIASAFE plus **F44 HPU**	The upper pressure test range of DP(DA2) 750 mmHg was exceeded within 4 seconds after closing of the test valve V183. – HPU, output stage etc. defective
F04 DIASAFE plus	The air separation pump P97 is running although valve V43 is closed. – HPU, output stage etc. defective
F26 DIASAFE plus	Insufficient test pressure (P < 750 mmHg) in the system. – Hydraulics system leaking
F27 DIASAFE plus	After the valve V189 opened, the pressure drop in the system was insufficient (DP < –70 mmHg). – Valve V189 electrically or mechanically not open – Diasafe filter strongly contaminated – Filter before / after V43 strongly contaminated
F28 DIASAFE plus	Pressure increase in the system fails to exceed P > 760 mmHg. – Diasafe filter membrane leaking (major leakage) – No Diasafe filter installed
F29 DIASAFE plus	Pressure holding test failed to be passed. Excess pressure drop within a measurement time of 30 seconds (DP > –10 mmHg). – Diasafe filter membrane leaking
F30 DIASAFE plus	During the pressure holding test valve V189 was closed (according to electronic acknowledgement). – Valve control failed
F31 DIASAFE plus **F31 HPU**	Fill phase has been stopped. Valve(s) V26 open and / or V24, V24b closed (according to electronic acknowledgement), or failure to perform 25 or 15 balancing chamber switchings within 120 seconds. – Valve control failed – Balancing chamber switchings failed (e.g., only “Eigentakt”)
F34 DIASAFE plus	See error message between F01 and F02 DIASAFE plus
F41 DIASAFE plus	See error message between F01 and F02 DIASAFE plus
F42 DIASAFE plus	See error message between F03 and F04 DIASAFE plus
F43 DIASAFE plus	See error message between F03 and F04 DIASAFE plus
F44 DIASAFE plus	See error message between F03 and F04 DIASAFE plus
F95 DIASAFE plus **F95 HPU**	System error

7.2 Device error during cleaning programs

7.2.1 V84 monitoring

Error message	Description
Rinse Failure F01	End of the rinse-free program in Dis I – V. Conductivity has been recognized via V84, although the valve is still closed. This error message can be acknowledged by pressing the **Cleaning** key.
Rinse Failure F21	Disinfectant suction phase in Dis I – IV. Maximum permissible UF pump strokes (160) during the suction phase exceeded. Error message cannot be acknowledged. Turn the device off and back on again.
Rinse Failure F02	Disinfectant suction phase in Dis I – IV. Conductivity has not been recognized via V84, and the **Disinfectant empty** message has been acknowledged twice. Error message cannot be acknowledged. Turn the device off and back on again. Program Dis V (device with HPU). No conductivity detected via concentrate level sensor, and **Disinfectant empty** message acknowledged twice. Error message cannot be acknowledged. Turn the device off and back on again.
Rinse Failure F03	End of the suction phase in Dis I – IV. Conductivity has been recognized via V84, although the valve is already closed. This error message can be acknowledged by pressing the **Disinfection** key.
Rinse Failure F04	End of the suction phase in Dis I – IV. Float switch fails to detect fluid on completion of the disinfectant suction phase. Aeration of the disinfectant container! Error message cannot be acknowledged. Turn the device off and back on again.

F01, **F02** and **F03** cause the V84 monitoring flag to be set. I.e. after one of these error messages has occurred, Bergström or ISO-UF dialysis is no longer possible, since it is not possible to switch the flow off. The V84 malfunction can be eliminated by correctly performing Dis I – IV. Another possibility of correcting the problem can be found in the service mode (by a service technician only) in the NOVRAM menu item (clear V84 malfunction).

7.2.2 PSW (pressure switch) monitoring during free rinsing (only with devices with CDS)

Error message	Description
Rinse Failure F05	Rinse-free program with following Dis or HDIS or mandatory rinse as individual program in Dis I – V. It was impossible to open the pressure switch for PSW_104 (S124) (bicarbonate). – Pressure on distribution piping > 500 mbar (according to specification, the permissible pressure is max. 500 mbar). Pressure peaks on distribution piping: Frequently occurs in distribution pipings with user points if e.g., several patients are disconnected simultaneously and disinfection is started. – Switching point of pressure switch too low: Desired= 700 mbar ±20 mbar – Check acknowledgement of pressure switch on P.C.B. LP 633-5: Concentrate: X633L/A20
Rinse Failure F06	Rinse-free program with following Dis or HDIS or mandatory rinse as individual program in Dis I – V. It was impossible to open the pressure switch for PSW_102 (S123) (concentrate). – Pressure on distribution piping > 500 mbar (according to specification, the permissible pressure is max. 500 mbar). Pressure peaks on distribution piping: Frequently occurs in distribution pipings with user points if e.g., several patients are disconnected simultaneously and disinfection is started. – Switching point of pressure switch too low: Desired= 700 mbar ±20 mbar – Check acknowledgement of pressure switch on P.C.B. LP 633-5: Concentrate: X633L/A20
Rinse Failure F07	Rinse-free program, Dis, HDIS, or mandatory rinse in Dis I to V. Pressure drop during the monitoring phase on PSW_104 (S124) (bicarbonate) or pressure build-up impossible. – Check switching point of pressure switch – Check loading pressure (possibly splinter or contamination in orifice 151, remove and purge the tubing from both ends) – Check negative pressure and orifice (89) (for this purpose, remove and purge the tubing from both ends) – Check CDS valve (104) – Check tightness of CDS path – Check acknowledgement of pressure switch on P.C.B. LP 633-5: Bicarbonate: X633L/A19 – Cartridge filter (F210) upstream of degassing pump clogged or wrong filter (filter for disinfectant container) installed. Filters can be distinguished by different adapters.

Error message	Description
Rinse Failure F08	Rinse-free program, Dis, HDIS, or mandatory rinse in Dis I – V. Pressure drop during the monitoring phase on PSW_102 (S123) (concentrate) or pressure build-up impossible. – Check switching point of pressure switch – Check loading pressure (possibly splinter or contamination in orifice 151, remove and purge the tubing from both ends) – Check negative pressure and orifice (89) (for this purpose, remove and purge the tubing from both ends) – Check the check valve (117) and filter (119). – Check CDS valve (102) – Check tightness of CDS path – Check acknowledgement of pressure switch on P.C.B. LP 633-5: Concentrate: X633L/A20 – Cartridge filter (F210) upstream of degassing pump clogged or wrong filter (filter for disinfectant container) installed. Filters can be distinguished by different adapters.
Rinse Failure F09	Five minutes before the end of the mandatory rinse in Dis I – V. The pressure switch PSW_104 (S124) (bicarbonate) or PSW_102 (S123) (concentrate) did not open after pressure reduction. See Rinse Failure F12.
Rinse Failure F12	Rinse-free program with following Dis or HDIS or mandatory rinse as individual program in Dis I – V. The pressure switch for PSW_104 (S124) (bicarbonate) and for PSW_102 (S123) (concentrate) could not be opened. – Membrane pumps fail to run – V102 or V104 fails to open – Pressure on distribution piping > 500 mbar (according to specification, the permissible pressure is max. 500 mbar). Pressure peaks on distribution piping: Frequently occurs in distribution pipings with user points if e.g., several patients are disconnected simultaneously and disinfection is started. – Switching point of pressure switch too low: Desired= 700 mbar ±20 mbar – Check acknowledgement of pressure switch on P.C.B. LP 633-5: Bicarbonate: X633L/A19

Error message	Description
Rinse Failure F13	Rinse-free program with following Dis or HDIS or mandatory rinse as individual program in Dis I – V. Pressure drop during the monitoring phase on PSW_104 (S124) (bicarbonate) and PSW_102 (S123) (concentrate) or pressure build-up impossible. – Check switching point of pressure switch – Check loading pressure (possibly splinter or contamination in orifice 151, remove and purge the tubing from both ends) – Check negative pressure and orifice (89) (for this purpose, remove and purge the tubing from both ends) – Check the check valve (117) and filter (119). – Check CDS valve (102/104) – Check tightness of CDS path – Check acknowledgement of pressure switch on P.C.B. LP 633-5: Bicarbonate: X633L/A19 Concentrate: X633L/A20 – Cartridge filter (F210) upstream of degassing pump clogged or wrong filter (filter for disinfectant container) installed. Filters can be distinguished by different adapters.

In case of **F07**, **F08** and **F13**, the **DO NOT SWITCH OFF !!** message can, in addition, be alternately displayed.

However, this message is displayed only if a mandatory rinse program is requested, since the concentrate and bicarbonate lines still have to be emptied before the device is switched off.

7.2.3 Rinse section test (check of V91, V99, V100) (only devices with CDS)

Error message	Description
Rinse Failure F11	Three minutes before the end of the mandatory rinse in Dis I – V. The pressure switch PSW_102 (S123) (concentrate) did not open after pressure reduction. – Pressure on distribution piping > 500 mbar (according to specification, the permissible pressure is max. 500 mbar). Pressure peaks on distribution piping: Frequently occurs in distribution pipings with user points if e.g., several patients are disconnected simultaneously and disinfection is started. – Switching point of pressure switch too low: Desired= 700 mbar ±20 mbar – Membrane pumps fail to run – V102 fails to open electrically or mechanically – Check acknowledgement of pressure switch on P.C.B. LP 633-5: X633L/A20
V91/V100 Failure	Three minutes before the end of the mandatory rinse in Dis I – V. V91 or V100 cannot be opened. – V91 or V 100 fail to open electrically: P.C.B. LP 634: V91 = X634L/A12; V100 = X634L/C13 – V 91 or V 100 mechanically not open: Check filter (148) before V100, or valves clogged – V99 constantly open (electrically P.C.B. LP 634: X634L/B12 or mechanically) – V 102 not open – Pressure switch for PSW_102 (S 123) fails to switch
V99 Failure	Three minutes before the end of the mandatory rinse in Dis I – V. V99 cannot be opened. – V 99 fails to open electrically: P.C.B. LP 634: X634L/B12 – V 99 fails to open mechanically: Check filter (149) before V99, or V99 clogged – Pressure switch for PSW_102 (S123) fails to open
V130 Failure	Three minutes before the end of the mandatory rinse in Dis I – V. V130 cannot be opened. – V130 electrically defective: P.C.B. LP 634: X634L/A4 – V130 mechanically defective or clogged – Pressure switch for PSW_102 (S123) fails to open – Check the tubing arrangement for the bicarbonate suction line and the bi*b*ag® block
V188 Failure	V188 fails to open. – V188 electrically defective – V188 mechanically defective or clogged – Pressure switch for PSW_102 (S123) fails to open
Rinse Failure F14	Shortly before the end of the mandatory rinse in Dis I – V. Rinse section test not completed correctly. Possibly caused by flow problems.

7.2.4 Rinse section test (check of V91 and V98) (only devices without CDS)

Error message	Description
Rinse Failure F14	Three minutes before the end of the mandatory rinse in Dis I – V. It was not possible to readjust the flow to 750 ml/min ±50 ml/min. V91 defective.
V91 Failure	Three minutes before the end of the mandatory rinse in Dis I – V. After V91 has opened, a flow > 950 ml/min failed to develop. V91 or valve V98 defective.
Rinse Failure F14	Shortly before the end of the mandatory rinse in Dis I – V. Rinse section test not completed correctly. Possibly caused by flow problems.

7.2.5 Rinse section test (check of V91, V99, V100, V130) (only devices without CDS)

Error message	Description
Rinse Failure F15	Three minutes before the end of the mandatory rinse in Dis I – V. DS (bi*b*ag® pressure switch 134) could not be opened at the beginning of the test. – Check pressure switch: Switching point: desired value: 130 mbar +30 mbar – Suction error of bicarbonate pump – V91 constantly electrically or mechanically open – V99/100 constantly electrically or mechanically closed
V91 Failure	Three minutes before the end of the mandatory rinse in Dis I – V. It is impossible to build up pressure on DS (bi*b*ag® pressure switch 134) via V91. – Pressure switch fails to close mechanically: check switching point – V91 fails to open electrically: P.C.B. LP 634: X634L/A12 – V91 fails to open mechanically (possibly clogged) – V130 electrically not closed: P.C.B. LP 634: X634L/A4 – V130 fails to close mechanically (possibly clogged) – bi*b*ag® connector leaking (check O rings) – Sealing on the bicarbonate suction tube leaking – Check acknowledgement of pressure switch on P.C.B. LP 633-5: X633L/A8 – V99 constantly electrically or mechanically open
V100 Failure	Three minutes before the end of the mandatory rinse in Dis I – V. It is impossible to build up pressure on DS (bi*b*ag® pressure switch 134) via V100. – V100 fails to open electrically: P.C.B. LP 634: X634L/C13 – V100 fails to open mechanically (possibly clogged) – V91 constantly electrically or mechanically open – Concentrate pump fails to pump – Filter (148) clogged – Pressure switch fails to open

Error message	Description
Rinse Failure F16	Three minutes before the end of the mandatory rinse in Dis I – V. DS (bi*b*ag® pressure switch 134) cannot be closed. V99 or V130 is leaking. – V91 fails to open electrically or mechanically – V99 constantly electrically or mechanically open – V130 constantly electrically or mechanically open – Sealing on the concentrate suction tube leaking – Pressure switch fails to close
V99 Failure	Three minutes before the end of the mandatory rinse in Dis I – V. DS (bi*b*ag® pressure switch 134) cannot be opened. V99 does not open. – V99 fails to open electrically or mechanically – V100 fails to open electrically or mechanically – Pressure switch fails to open – V91 electrically or mechanically open – Filter (149) before V99 clogged
Rinse Failure F17	Three minutes before the end of the mandatory rinse in Dis I – V. DS (bi*b*ag® pressure switch 134) cannot be closed. – V91 fails to open electrically or mechanically – V130 electrically or mechanically open – V100 electrically or mechanically open – Pressure switch fails to close
V130 Failure	Three minutes before the end of the mandatory rinse in Dis I – V. DS (bi*b*ag® pressure switch 134) cannot be opened. – V130 fails to open electrically or mechanically – Pressure switch fails to open – Check the tubing arrangement for the bicarbonate suction line and the bi*b*ag® block – Bicarbonate line squeezed at strain relief – Narrowing in the reducer on the bi*b*ag® connector
Rinse Failure F 20	Impossible to close the pressure switch (134) via V91 / 100 – V91 fails to open electrically or mechanically – V130 / V188 electrically or mechanically open – Pressure switch fails to close
V188 Failure	The pressure on pressure switch (134) cannot be reduced via V188. – V188 fails to open electrically or mechanically – Pressure switch fails to open – Check the tubing arrangement for the concentrate suction line and the air separation block – Concentrate line squeezed at strain relief
Rinse Failure F14	Shortly before the end of the mandatory rinse in Dis I – V. Rinse section test not completed correctly. Possibly caused by flow problems.

7.2.6 V39 Test

Error message	Description
V39 Failure	On opening V39 a difference in pressure (averaged value V39 open – averaged value V39 closed) is detected on the dialysate pressure transducer (182): bi*b*ag® device: < 20 mmHg – V39 fails to open / close electrically or mechanically (possibly hydraulic processing unit defective) – It is impossible to re-adjust the degassing pump (P.C.B. LP 634). – V91, V99, V100 fails to open electrically or mechanically – Dialysate pressure transducer (182) defective or not calibrated (possibly HPU P.C.B. LP 941 defective) – Filter 210 (before degassing orifice) clogged

7.2.7 Further messages which may be displayed before or during a cleaning program

Error message	Description
Blood Sensed by OD	Start of a cleaning program in RI I to II, HR I to III, Dis I to V. The optical detector in the air detector module recognizes blood.
Shunt cover open	Start of a cleaning program or during a cleaning program in RI I to II, HR I to III, Dis I to V. The shunt interlock is not closed.
Dialines not conn	Start of a cleaning program in RI I to II, HR I to III, Dis I to V. The dialysate couplings are not connected to the shunt interlock.
No LD alarm	Priming of the blood lines in RI I to II, HR I to III, Dis I to V. The drip chamber in the air detector module does not recognize any alarm.
Conc line not conn	Start of a cleaning program in RI I to II, HR I to III, Dis I to V, or end of the disinfectant suction phase in Dis V. The concentrate suction tube is not connected to the rinse chamber. Reconnect the concentrate suction tube to the rinse chamber.
Bic line not conn	Start of a cleaning program in RI I to II, HR I to III, Dis I to V, or end of the disinfectant suction phase in Dis V. The bicarbonate suction tube is not connected to the rinse chamber. Reconnect the bicarbonate suction tube to the rinse chamber.
Voltage Failure	During a cleaning program in RI I to II, HR I to III, Dis I to V. The supply voltages 24 V / 12 V are not consistent. This error can be acknowledged for 8 seconds by pressing the respective program key.
CPU-II failed	During a cleaning program in RI I to II, HR I to III, Dis I to V. The watchdog relay has dropped. Communication (RxD or TxD) may be disturbed.

Error message	Description
High temperature	During a cleaning program in RI I to II, HR I to III, Dis I to V. Temperature > 41 °C, >90 °C during HR; > 91 °C during IHR. The device continues to run. The alarm tone can be acknowledged. Upon error elimination, the message is automatically cleared.
Low temperature	During a cleaning program in RI I to II, HR I to III, Dis I to V. Temperature < 33 °C; < 78.5 °C during HR. The device continues to run. The alarm tone can be acknowledged. Upon error elimination, the message is automatically cleared.
Water alarm	During a cleaning program in RI I to II, HR I to III, Dis I to V. The float switch transmits the “no water available” message for more than 10 seconds. The balancing chamber has stopped; V41 is permanently open. Upon error elimination, the message is automatically cleared.
Water alarm	During a cleaning program in RI I to II, HR I to III, Dis I to V. For more than 30 seconds, the float switch fails to signal that water is required (not applicable to recirculation programs). The device continues to run. Upon error elimination, the message is automatically cleared.
Flow Alarm	During a cleaning program in RI I to II, HR I to III, Dis I to V. A current rise pulse is not recognized for more than 12 seconds. The device continues to run at “Eigentakt” (10 seconds). Upon error elimination, the message is automatically cleared.
Upper Flow Alarm	During a cleaning program in RI I to II, HR I to III, Dis I to V. The cleaning flow increases >1000 ml/ min. The program has stopped. The error can be acknowledged by pressing the respective cleaning program key.
UF pump failed	During a cleaning program in RI I to II, HR I to III, Dis I to V. The UF pump has stopped or the rate deviates (2800 ml/h < UFR < 6000 ml/h). The program has stopped. The error can be acknowledged by pressing the respective cleaning program key.
Dial. Valve failed	During a cleaning program in RI I to II, HR I to III, Dis I to V. V24 or V24B is closed although it should be open. The program has stopped. The error message can be acknowledged by pressing the respective program key.
Bypass Valve failed	During a cleaning program in RI I to II, HR I to III, Dis I to V. V26 is closed although it should be open. The program has stopped. The error message can be acknowledged by pressing the respective program key.
V102 Failure	During a cleaning program in RI I to II, HR I to III, Dis I to V. V102 electrically opened. 24 V will be turned off. The error cannot be acknowledged.

Error message	Description
V104 Failure	During a cleaning program in RI I to II, HR I to III, Dis I to V. Error during activation or acknowledgement of V104. 24 V will be turned off. The error cannot be acknowledged.
Float-Switch Failure	During a disinfectant program in the suction phase in Dis I to V. The lower switching point of the float switch is not reached within 20 seconds. The program has stopped.
Connect Disinfectant	Disinfectant suction phase in Dis V. Request to connect the disinfectant.
Press CONFIRM key	Disinfectant suction phase in Dis V. After the disinfectant has been connected, the Confirm key on the menu panel must be pressed to start the suction procedure. The program has stopped.
Please Wait	Disinfectant suction phase in Dis V. Disinfectant is drawn in via the concentrate pump.
Disinfectant empty ?	Disinfectant suction phase in Dis I – V. Dis V: After the disinfectant has been drawn in, the float switch does not recognize any fluid. Dis I to IV, Dis VI: The V84 monitoring unit does not recognize any conductivity.
Disinf-Temp. too high	Transition to disinfection in Dis I – V. Temperature at the end of the rinse-free procedure > 40 °C. Again and again, the rinse-free procedure is prolonged by 1 minute. An audible warning is sounded after 4 minutes. The message is automatically cleared, and it cannot be acknowledged.
Rinse required!	During stored mandatory rinse in Dis I – V. The mandatory rinse has been stopped (e.g., the device has been switched off).
Rinse after Disinf.	Selection of a cleaning program, although a mandatory rinse has been requested in HR. A disinfection program has been stopped and subsequently a rinsing or hot rinsing program started.
Power Failure	During a cleaning program in RI I to II, HR I to III, Dis I to V. Line voltage failed.
BIBAG cover open	Upon start of a cleaning program in RI I to II, HR I to III, Dis I to V. The bi*b*ag® connector is not closed (flap not closed).
Heater Error	During the CDS rinsing phase at the end of a hot rinsing program or a hot disinfection program in CDS: HR I to III, Dis II to IV. The heater signal (P.C.B. LP 633-5: X633R/A26) is not changing for > 40 seconds.
Accumulator empty!	Battery voltage < 17.2 V ±2.5 % Only in the event of a power failure during the cleaning programs. If the voltage drops below 17 V, the device will switch off.

7.3 Error messages after turning power on

Error message	Description
ROM ERROR	System error. Execute software update (MDC-II). Change the MDC-II board, if required.
BIOS ERROR	System error. Change the MDC-II board, if required.
BRAM #XXX XXXX XXXX	System error. Turn the device off and back on again, initialize the NOVRAM. Then recalibrate or load the current NOVRAM data.
RAM ERROR	System error. Turn the device off and back on again. Change the MDC-II board, if required.
Keyboard Error	Short-circuit on the keyboard. Turn the device off and back on again. Check the plugs for proper connection, possible short-circuit on the keys, change the front panel, if necessary.
Watchdog Error	This error message can only be displayed shortly after turning power on. Turn the device off and back on again. Check the WD relay and components. Check CPU2/CPU1. Check the plug connectors on the monitor.
XX (not calibrated)	NOVRAM error upon test request. Turn the device off and back on again. Recalibrate the function indicated.
NTC 109 switched off	No valid value has been filed during start in the NOVRAM. The temperature difference between NTC109 and NTC3 is too high. Switch off NTC 109 in the SETUP MENU, or recalibrate the temperature.

7.4 Error messages during treatment

Error message	Description
Voltage Failure	The supply voltages 24 V / 12 V are not consistent. The device enters the safe state and must be switched off / on. – The 12 V or 24 V operating voltage is outside of the permissible range: 24 V: > 26 V / < 22.5 V 12 V: > 12.8 V / < 11.0 V – Check the power supply unit – Power adapter OK: Check the voltages on P.C.B. LP 633-5: +12 V: X633R/A, C31 +24 V: 24V_EM: X633L/B20
24 V Switched Off	The 24 V supply voltage has fallen below 5 V. The device enters the safe state and must be switched off / on. – Check the power supply unit – Power adapter OK: Check the voltages on P.C.B. LP 633-5: +24V_EM: X633L/B20 – Remove all P.C.B.s. If the device is running: Turn the device off, reconnect all P.C.B.s while the device is switched off; determine the defective P.C.B. and repair it. – Completely loosen the hydraulic compartment connections *Caution:* J1 must now be fitted on P.C.B. LP 630 since, as the device will otherwise not be able to perform the watchdog test! Be absolutely sure to remove the jumper again for hemodialysis operation! With the device running, check the short circuit in the hydraulic compartment for 24 V supply and the valves and pumps for short circuit.
CPU-II failed	CPU2 fails to communicate via the serial interface. The device enters the safe state and must be switched off / on. – The software versions of CPU1 and CPU2 do not match – Hardware defect on CPU2
Profile time diff.	Deviation in time between CPU1 and CPU2. The error message is emitted 60 seconds after the start of the profile. – The clock module on CPU1 (IC 14) is defective or calibrate the time in case of layout < D
Cyclic PHT F01	Balancing error – System leakage – Applicable to Diasafe devices: CPU2, array 2, DIP switch 1 is not in position ON
Cyclic PHT F02	Balancing error – System leakage – Applicable to Diasafe devices: CPU2, array 2, DIP switch 1 is not in position ON
Cyclic PHT F03	IC1 or IC3 on P.C.B. LP 632 is defective, or device leakage
Cyclic PHT F04	It was not possible to complete the test within a specific time interval

Error message	Description
V84 malfunction	Conductivity is detected at the V84 electrodes. This error message is emitted for the first time at the end of the T1 test. The error can be acknowledged for the duration of one hemodialysis procedure by pressing the Dialysis Start key. It is, however, not possible to switch off the flow (Bergström- / ISO-UF operating mode). Should the error occur during Flow OFF, the flow is switched on automatically. – First of all, it must be verified whether a Rinse Failure F01, F02 or F03 occurred during the previous disinfection procedure (see listing of cleaning program errors). Should this be the case, a disinfection program I – IV (not Dis V) must be completed correctly. The problem can also be corrected using the CALIBRATION service menu, NOVRAM menu item (clear V84 malfunction). – Should this not be possible, the error memory of the device can be read out. – Should this neither be possible, the test described below can be performed: Remove the disinfectant. Turn the device off and back on again. Perform or skip the T1 test. Should the error message be displayed again at the end of the T1 test, it was generated by a Rinse Failure F01, F02 or F03 and can be cleared only by taking the measures described above. Should the message not be displayed again, a second test can be performed: Reconnect the disinfectant. Set the UF rate and switch on the UF unit. Should the error occur at this moment, there is a leakage on V84 (see listing of cleaning program errors).
Shunt Cover open (temporarily)	– P.C.B. LP 633-5 C24 (100 nF) temporarily short-circuited – Shunt interlock defective (check switches)
Voltage Failure (temporarily)	– P.C.B. LP 633-5 C84 (100 nF) temporarily short-circuited
UF1 volume - Error	Failure to pass the test for an UF pump. The fill volume for the secondary air separator is outside the tolerance of 100 ml ±4 ml. Possible cause: – The UF pump fails to deliver correctly (not calibrated or mechanical defect) – If the test result is > 104 ml, the problem can also be caused by air coming from a poorly deaerated dialyzer
F327 UF failure	Pause between two UF1 pump strokes less than 220 ms. Possible cause: – CPU1 defective
F328 UF failure	Pulse time of one UF1 pump stroke less than 180 ms. Possible cause: – Controlling monoflop on LP 634 defective
F329 UF failure	Pulse time of one UF1 pump stroke exceeds 500 ms. Possible cause: – Controlling monoflop on LP 634 defective

Error message	Description
F330 UF failure	Pick-up time of the UF1 pump exceeds 10 seconds. Possible cause: – Controlling output stage on LP 634 defective
F331 UF failure	Theoretical / actual rate of the UF1 pump deviates by more than ±10 %. Possible cause: – System error
F332 UF failure	UF1 pump stopped for more than the maximum time period. Possible cause: – Controlling output stage on LP 634 defective – UF pump interruption – System error
F333 UF failure	Volume changes by more than 10 ml during prescribed standstill (only monitored if "Blood detected" (optical detector dark)). Possible cause: – System error
F341 UF failure	Mechanical UF1 pump failure. Possible cause: – Broken spring – Contaminated sieve
F350 UF failure	A difference of more than 100 ml between the CPU1 and the CPU2 volume is detected during an UF data transfer after turning the UF unit on. Possible cause: – System error
F351 UF failure	CPU2 could not detect plausibility of the CPU1 UF parameters. Possible cause: – System error
F352 UF failure	CPU2 UF deviation compared to the theoretical UF target volume. Possible cause: – System error
F354 UF failure	UF rate exceeds the maximum rate allowed. Possible cause: – System error

Error message	Description
F361 UF failure	CPU1 sent the UF parameter set to CPU2 and has not received a release from CPU2 after a timeout of 30 seconds. Possible cause: – System error
F363 UF failure	CPU2 did repeatedly not receive a complete UF parameter set. Possible cause: – System error
F364 UF failure	UF1 volume change although the UF goal has already been reached. Possible cause: – System error

7.4.1 HPU (hydraulic processing unit) error messages

Error message	Description
HPU Error F00	The HPU logs off with index STATUS_ER; no bit is set in the error bit field. – Problem on P.C.B. LP 941 – Problem on CAN distributor board – Problem on P.C.B. LP 763 – Problem on P.C.B. LP 630
HPU Error F01	The cyclic communication has failed for more than 2 seconds. – System error
HPU Error F02	The response to an event violated the time-out. – System error
HPU Error F03	An error occurred in the program sequence. – System error
HPU Error F04	Voltage drop (24V_SW) during HPU operation. – 24 V voltage supply on P.C.B. LP 941 failed (watchdog dropped)
HPU Error F05	Watchdog test failed to be passed. – Watchdog circuit on P.C.B. LP 941
HPU Error F06	Reference voltage monitoring detected an error. – Reference voltage circuit on P.C.B. LP 941 is defective.
HPU Error F07	The HPU was logged off by the monitor. Will not be displayed since CPU1 has already stopped the communication. – System error
HPU Error F08	General valve malfunction: – System error
HPU Error F09	Compressor error(185) – MV43 defective or activated – Compressor 185 defective or activated – Error on P.C.B. LP 941

Error message	Description
HPU Error F10	Malfunction of valve MV39 – MV39 defective or activated – Error on P.C.B. LP 941
HPU Error F11	Malfunction of the test valve (183) – MV43 defective or activated – MV183 defective or activated – Error on P.C.B. LP 941
HPU Error F12	Malfunction of the evacuation valve (188) – MV188 defective or activated – Error on P.C.B. LP 941
HPU Error F13	Malfunction of the retentate valve (189) – MV189 defective or activated – Error on P.C.B. LP 941
HPU Error F14	Defective component on P.C.B. LP 941 – Error on P.C.B. LP 941
HPU Error F15	Error in the HPU software. Valves are activated incorrectly. – System error
HPU Error F98	Proceeding to the T1 test is not allowed after restart. – System error
HPU Error F99	HPU fails without logging off. – Damaged cable or similar problem – HPU logged off by CPU1 – CRC error in the transfer HPU → CPU1 – The electrical test (VDE) was performed directly after turning the device on. Turn the device on at least 2 minutes before the test.

7.4.2 Blood pump (arterial) error messages

Error message	Description
E.01	Line diameter outside the permissible range
E.02	Undefined hex switch position
E.03	Uncalibrated arterial pressure transducer
E.04	Run-time monitoring error during Single-Needle operation
E.05	Single-Needle stroke volume outside the permissible range
E.06	Single-Needle pressure thresholds outside the range of values of the AD converter
E.08	Stop alarm
E.09	Error during A-D conversion
E.12	Rotary monitoring error (Hall sensor)
E.13	Monitoring error with regard to current sensing resistors
E.14	Monitoring error with regard to current sensing resistors
E.15	Speed monitoring error

7.4.3 Heparin pump error messages

Error message	Description
E01	Watchdog error
E02	*Gate array error (no interrupt INTO triggered)*
E03	NOVRAM error
E04	Spike error (HP)
E05	Hex switch position error
E06	Voltage monitoring error
E11	*Optical sensor (Step error / error in direction of rotation)*
E20	*Time basis error gate array <- -> microcontroller*
E21	Interrupt INT0 constantly triggered by gate array (no main loop runs)
E22	Error serial communication between CPU1 and LP 950
E55	*Optical sensor (no pulses)*

7.4.4 BPM module error messages

Error message	Description
BPM: Measurement value outside the alarm limits	Blood pressure cuff not correctly connected. Leakage in pressure tubing. Alarm limits not adjusted to the patient.
BPM: Measurement not successful	It was not possible to determine a measurement value.
BPM: Option not available	BPM option not installed. Due to the error **FXX BPM error** the BPM option is no longer available during the current treatment.
E02 BPM error (Remove the cuff from the patient!)	Module does not respond anymore
E03 BPM error (Remove the cuff from the patient!)	Module reset
E06 BPM error (Remove the cuff from the patient)	BPM Rcv buffer vent
BPM: Cuff cannot be inflated.	CPU-P1 pressure < 25 mmHg 15 seconds after the start of a measurement
BPM: Inflation time limit exceeded	Inflation time > 70 seconds
BPM: Cuff pressure lower than preselected pressure	CPU-P1 pressure < 40 % of the desired pressure
BPM: Measuring time limit exceeded	Measurement time > 175 seconds
BPM: Maximum cuff pressure exceeded	CPU-P1 pressure > 320 mmHg
BPM: Inflation pressure reached too quickly.	Inflation pressure reached too quickly.
Exx BPM error (Remove the cuff from the patient!)	Sample array overflow
E25 BPM error (Remove the cuff from the patient!)	PulsCount array overflow
E26 BPM error (Remove the cuff from the patient!)	StepCount array overflow
E70 BPM error (Remove the cuff from the patient!)	Auto-zero error. A failure is detected if the CPU-P1 pressure is > ±9 mmHg or the pressure change is > ±1 mmHg 5 seconds after starting a measurement.

Error message	Description
E72 BPM error (Remove the cuff from the patient!)	Pressure difference between CPU-P1 and CPU-P2 on 1st stage > 20 mmHg
E73 BPM error (Remove the cuff from the patient!)	Vcc-CPU-P2 error
E77 BPM error (Remove the cuff from the patient!)	RetryCount array overflow
E78 BPM error (Remove the cuff from the patient!)	CPU-P2 time stamp error
E79 BPM error (Remove the cuff from the patient!)	Unknown error occurred
E80 BPM error (Remove the cuff from the patient!)	EEPROM data invalid
E81 BPM error (Remove the cuff from the patient!)	I²C bus hardware or checksum error
E82 BPM error (Remove the cuff from the patient!)	CRC error of the CPU-P2 program memory
F83 BPM error (Remove the cuff from the patient!)	CPU-P1 pressure zero point drift after T1 test
E84 BPM error (Remove the cuff from the patient!)	CPU-P2 pressure zero point drift after T1 test
E85 BPM error (Remove the cuff from the patient!)	AD values during calibration not acceptable (offset / gradient)
E86 BPM error (Remove the cuff from the patient!)	CPU-P2 pressure > 300 mmHg for more than 15 seconds
E87 BPM error (Remove the cuff from the patient!)	Interval pause < 30 seconds
E90 BPM error (Remove the cuff from the patient!)	CPU-P2 pressure > 330 mmHg for more than 300 ms.

Error message	Description
E91 BPM error (Remove the cuff from the patient!)	CPU-P2 pressure > 15 mmHg for more than 180 seconds
E93 BPM error (Remove the cuff from the patient!)	CPU-P1 reference voltage deviation. Valid range: 1.4-1.6 V
E94 BPM error (Remove the cuff from the patient!)	Deviation +12V pump voltage. Valid range: 11-13 V
E95 BPM error (Remove the cuff from the patient!)	Vcc CPU-P1 deviation. Valid range: 4.6-5.4 V
E96 BPM error (Remove the cuff from the patient!)	Deviation of the calibration parameters between RAM and EEPROM
E97 BPM error (Remove the cuff from the patient!)	Actuator status deviation
E98 BPM error (Remove the cuff from the patient!)	Pressure change during measurement ≤ 3 mmHg / 5 milliseconds within 25 seconds. Monitoring will then be active in order to detect a pressure stage.
E99 BPM error (Remove the cuff from the patient!)	Pressure difference between CPU-P1 and CPU-P2 on 1st stage > 20 mmHg

8 Tools (service equipment)

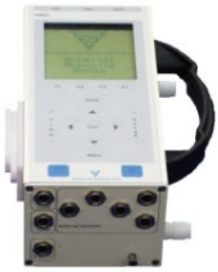
Warning

The precision of the measuring equipment used during calibration plays an important role for the accuracy of the OCM measurement.

The measuring equipment used for calibrating the conductivity must have a precision of 0.05 mS/cm in a temperature range of 35 °C to 39 °C.

We recommend using UMED measuring equipment as supplied by the manufacturer.

HMED pressure measuring instrument with case (set)



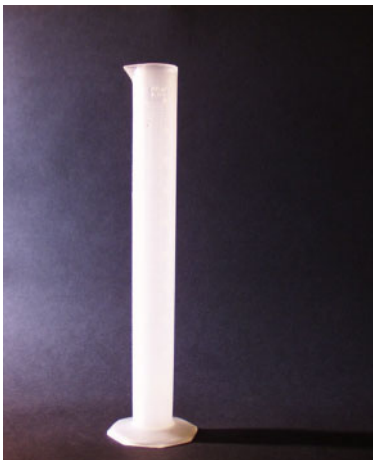
Universal measuring device UMED with case (set)
(temperature, conductivity, pressure)

Secutest VDE test device
(without printer module)

Printer module

Carrying case (not illustrated)

Service Software Set 4008



Measuring cylinder 100 ml

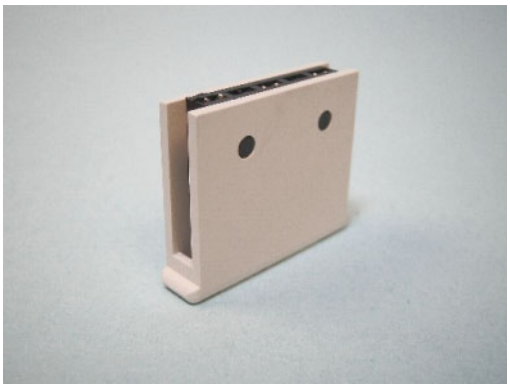
ESD service kit

ESD workshop kit

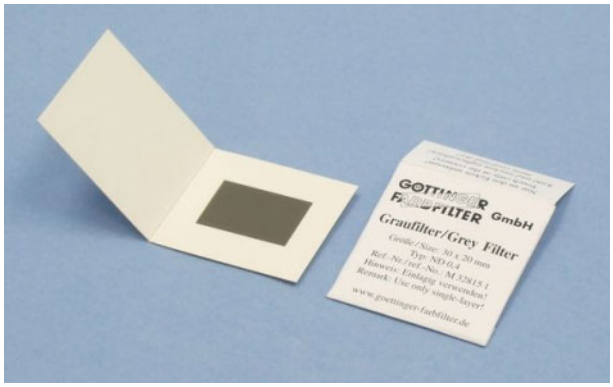
Extraction tool for ICs

Electronic pocket scales

Adjustment set for 22-mm air detector



Calibration connector for bi*b*ag®
Conductivity / temperature



ND grey foil filter 0.4

Deep hexagon socket wrench
for Luer-Lock

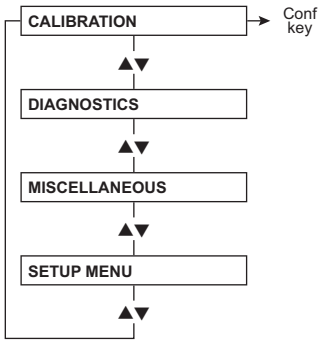
9 Calibration / adjustment

9.1 CALIBRATION

Note

If detected before starting calibration on the hydraulics unit, potential deposits must be removed by running an appropriate disinfection program.

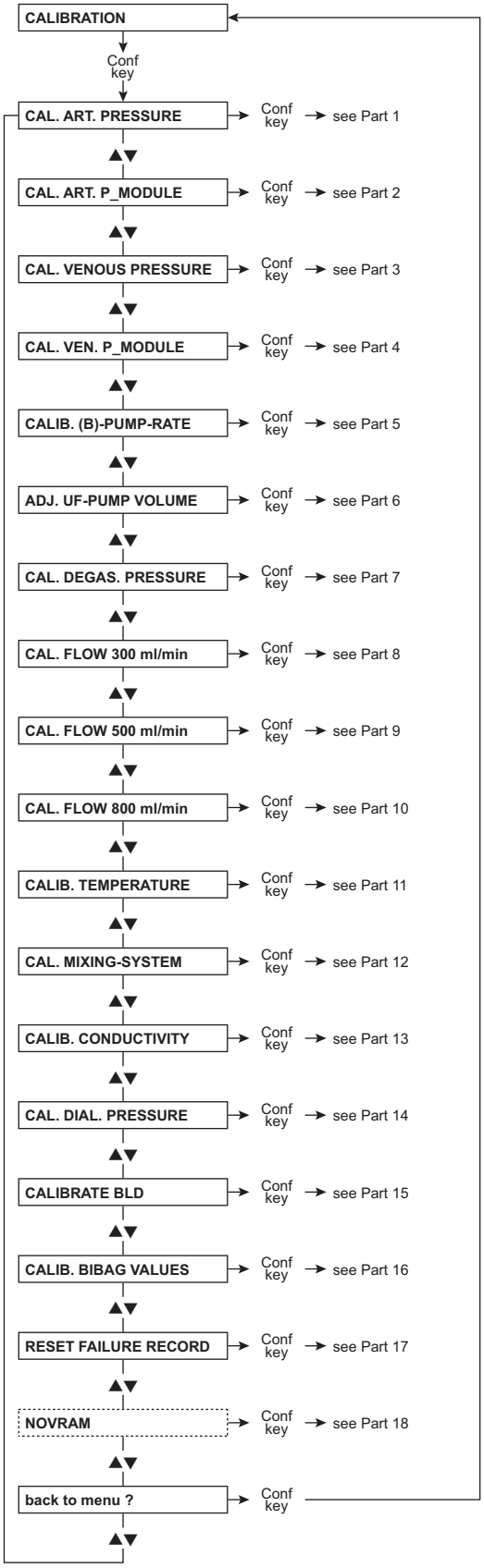
The **CALIBRATION** service menu can only be called in service mode.



9.1.1 Settings without menu display

Settings without menu display	Description
Setting the blood pump stop alarm	(see chapter 9.1.5 page 9-6)
Calibrating the Single-Needle blood pump (Single-Needle pressure) (optional)	(see chapter 9.1.11 page 9-11)
Adjusting the current increasing pulse	(see chapter 9.1.15 page 9-14)
Setting the Hall sensors in the heparin pump	(see chapter 9.1.46 page 9-39)

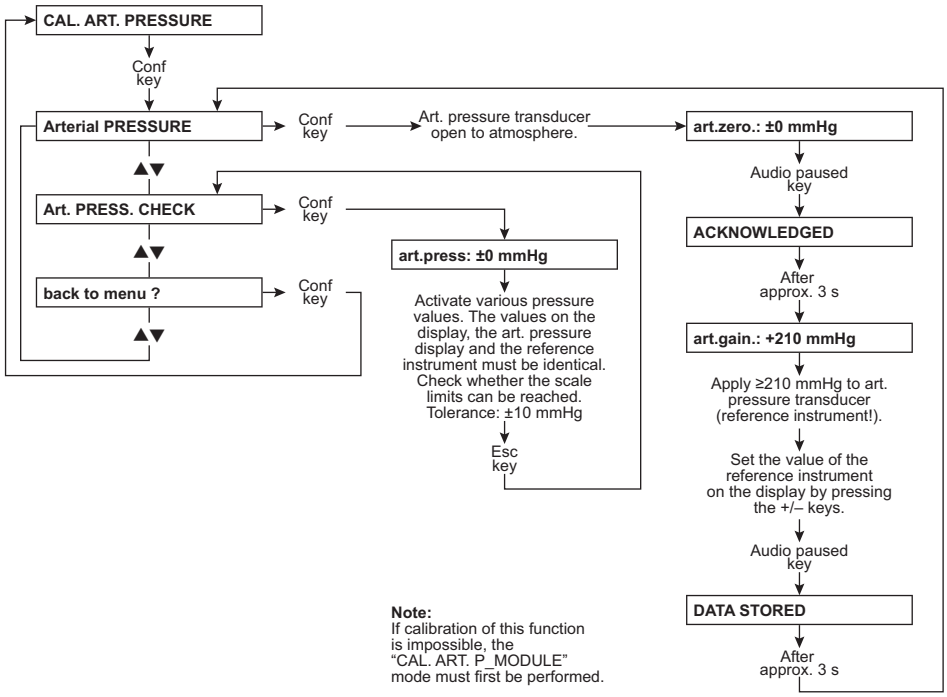
9.1.2 CALIBRATION menu structure



Navigation

Menu display	Description
CAL. ART. PRESSURE	(see chapter 9.1.3 page 9-4)
CAL. ART. EBM	(see chapter 9.1.4 page 9-5)
CAL. VENOUS PRESSURE	(see chapter 9.1.6 page 9-7)
CAL. VEN. EBM	(see chapter 9.1.7 page 9-8)
CALIB. (B)-PUMP-RATE	(see chapter 9.1.8 page 9-9)
ADJ. UF PUMP VOLUME	(see chapter 9.1.12 page 9-12)
CAL. DEGAS. PRESSURE	(see chapter 9.1.13 page 9-13)
CAL. FLOW 300 ml/min	(see chapter 9.1.14 page 9-13)
CAL. FLOW 500 ml/min	(see chapter 9.1.17 page 9-15)
CAL. FLOW 800 ml/min	(see chapter 9.1.18 page 9-16)
CALIB. TEMPERATURE	(see chapter 9.1.19 page 9-16)
CAL. MIXING-SYSTEM	(see chapter 9.1.23 page 9-20)
CALIB. CONDUCTIVITY	(see chapter 9.1.31 page 9-27)
CAL. DIAL. PRESSURE	(see chapter 9.1.38 page 9-34)
CALIBRATE BLD	(see chapter 9.1.42 page 9-37)
CALIB. BIBAG VALUES	(see chapter 9.1.43 page 9-38)
RESET FAILURE RECORD	(see chapter 9.1.44 page 9-38)
NOVRAM	(see chapter 9.1.45 page 9-39)

9.1.3 Part 1: Calibrating the arterial pressure



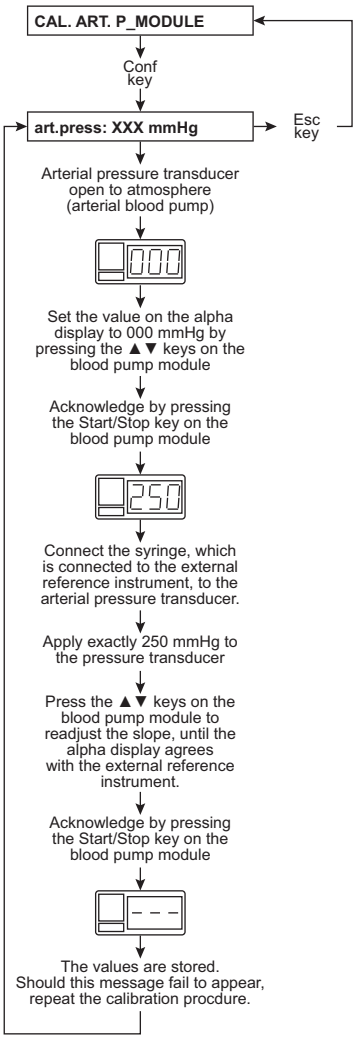
Note

The accuracy of the pressure gauge used must correspond to that of the UMED or HMED.

The accuracy of the pressure gauge used must at least correspond to the following values:
–1 to 2 bar: ±5 mbar
2 to 8 bar: ±20 mbar

9.1.4 Part 2: Calibrating the pressure in the arterial blood pump

Set the hex switch on P.C.B. LP 624 (pos. 1) to position F.
If the error message **E02** appears on the blood pump display, reset it with the **Start/Stop** key.

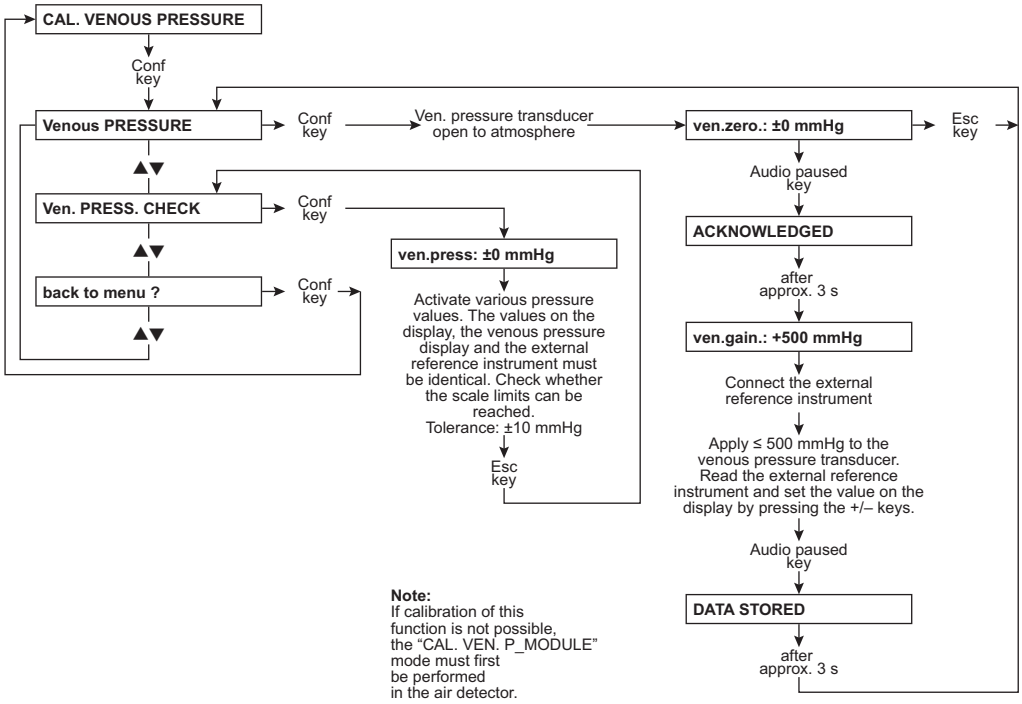


Reset the hex switch to position 2 in the final step.

9.1.5 Without menu display: Setting the blood pump stop alarm

Set the hex switch on P.C.B. LP 624 (pos. 1) to position B.
If the error message **E02** appears on the blood pump display, reset it with the **Start/Stop** key.

9.1.6 Part 3: Calibrating the venous pressure

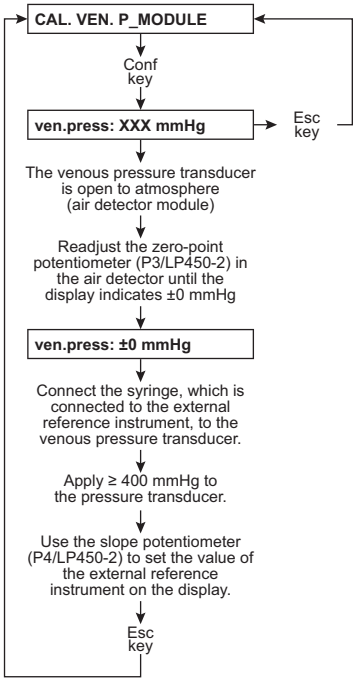


Note

The accuracy of the pressure gauge used must correspond to that of the UMED or HMED. The accuracy of the pressure gauge used must at least correspond to the following values:

-1 to 2 bar ±5 mbar
2 to 8 bar ±20 mbar

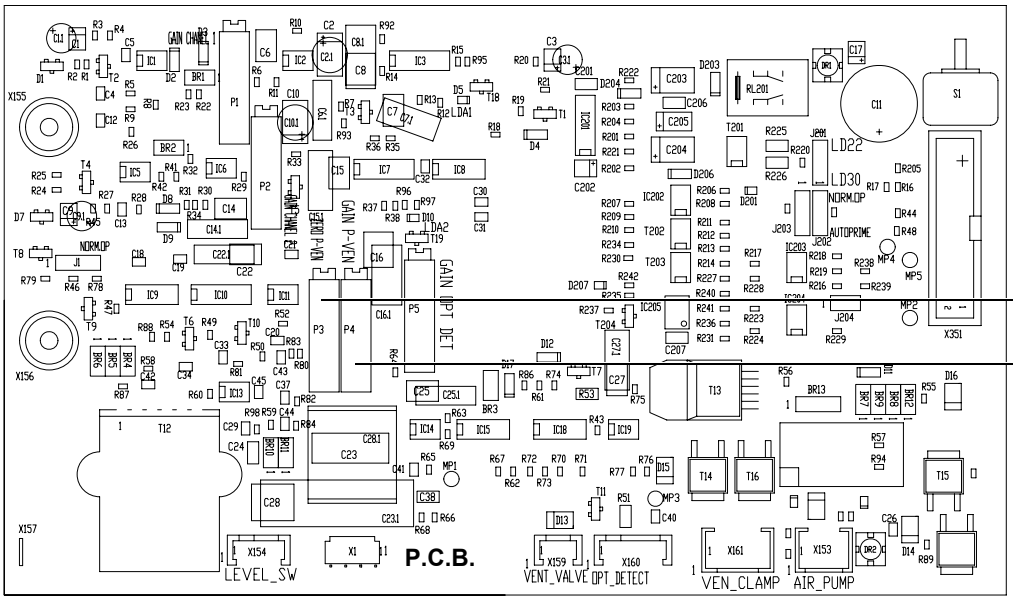
9.1.7 Part 4: Calibrating the venous pressure measurement in the air detector



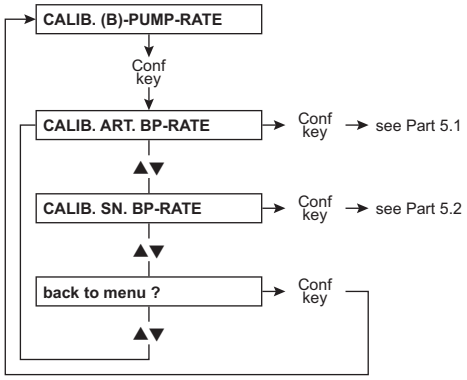
Note:
Check zero point and slope;
if necessary, repeat the procedure.

Note:
When adjusting the
air detector,
execute the
CAL. VENOUS PRESSURE
menu item.

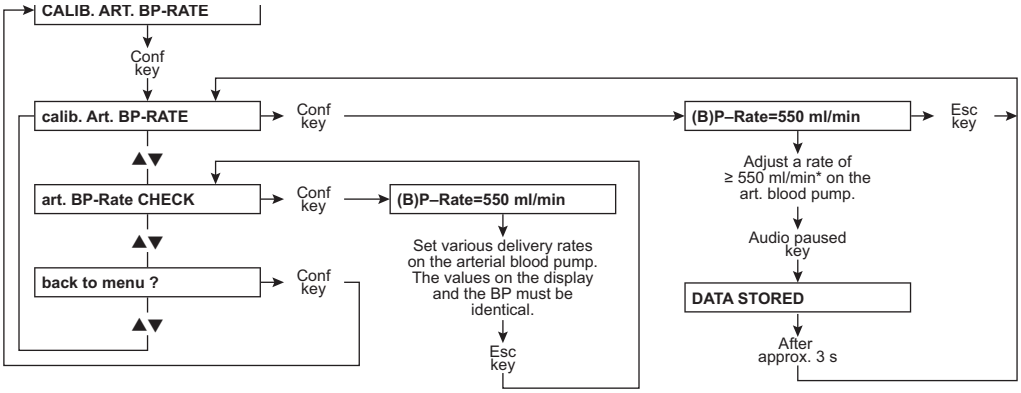
Fig.: P.C.B. LP 450-2



9.1.8 Part 5: Calibrating the blood pump rate



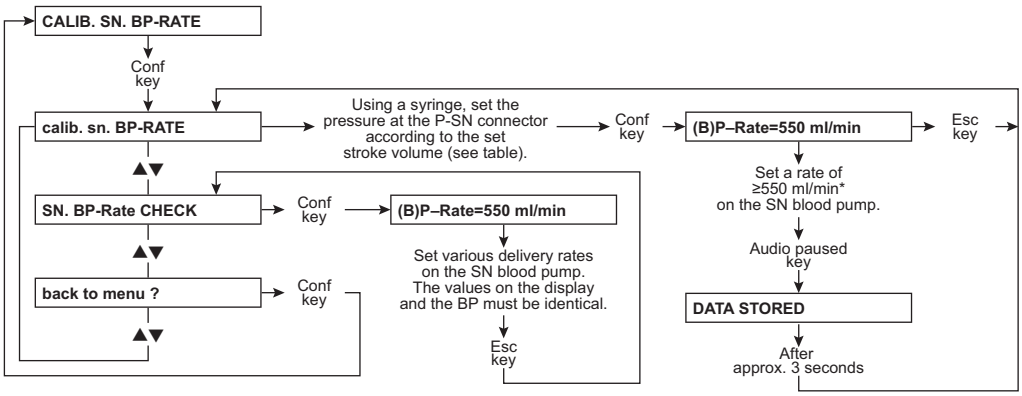
9.1.9 Part 5.1: Calibrating the arterial blood pump rate



Note: Set the line diameter to 8 mm before starting the calibration procedure and press **Start/Stop** on the blood pump.

* The BP rate of 550 ml/min represents a default value. It can be changed using the ▲▼ (+/–) keys.

9.1.10 Part 5.2: Calibrating the SN blood pump rate (option)



Note: Set the line diameter to 8 mm before starting the calibration procedure and press Start/Stop on the blood pump.

* The BP rate of 550 ml/min represents a default value. It can be changed using the ▲▼ (+/–) keys.

Single-Needle pump: the lower switching point is fixed (75 mmHg).

– the upper switching point depends on the stroke volume, see table below:

Stroke volume (ml)	10	15	20	25	30	35	40	45	50
Upper switching point (mmHg) ±7 mmHg	110	130	150	172	195	219	244	270	299

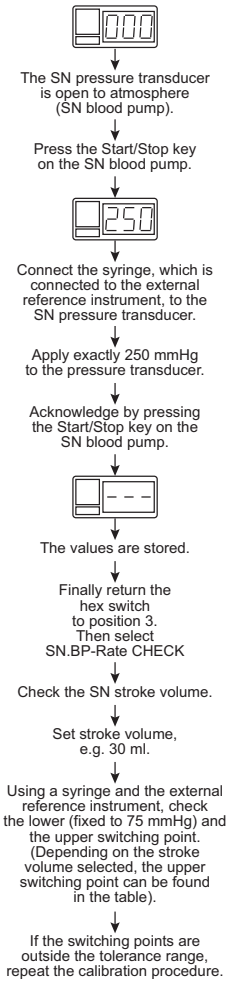
● **Setting the Single-Needle stroke volume**

1. Simultaneously press the ▼ and **Start/Stop** keys.

2. Press the ▲ and ▼ (+ / –) keys to set the stroke volume and confirm with **Start/Stop**.

9.1.11 Without menu display: Calibrating the Single-Needle blood pump (Single-Needle pressure) (optional)

Set the hex switch on P.C.B. LP 624 (pos. 1) to position F.
If the error message **E02** appears on the blood pump display, reset it with the **Start/Stop** key.



Single-Needle pump: the lower switching point is fixed (75 mmHg).

– the upper switching point depends on the stroke volume, see table below:

Stroke volume (ml)	10	15	20	25	30	35	40	45	50
Upper switching point (mmHg) ±7 mmHg	110	130	150	172	195	219	244	270	299

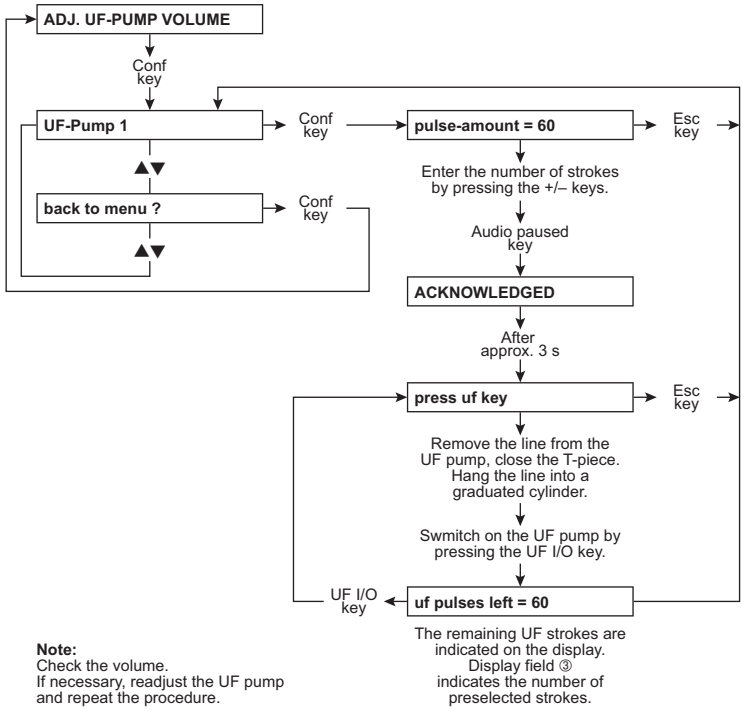
Note

If necessary, change the Single-Needle stroke volume (see chapter 9.1.10 page 9-10):

– Simultaneously press the ▼ and **Start/Stop** keys.

– Press the ▲ and ▼ (+ / –) keys to set the stroke volume and confirm with **Start/Stop**.

9.1.12 Part 6: Measuring the volume of the UF pump in liters



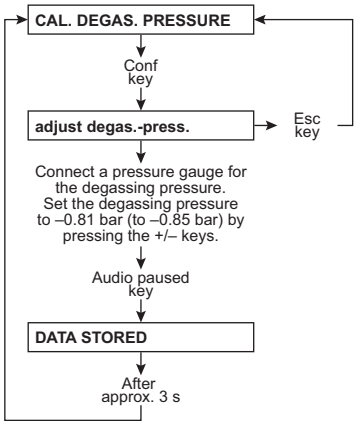
Note

Measuring cylinder accuracy: ±0.5 %.

Note

When using scales as a measuring instrument, please ensure that concentrate is not connected.

9.1.13 Part 7: Calibrating the degassing pressure



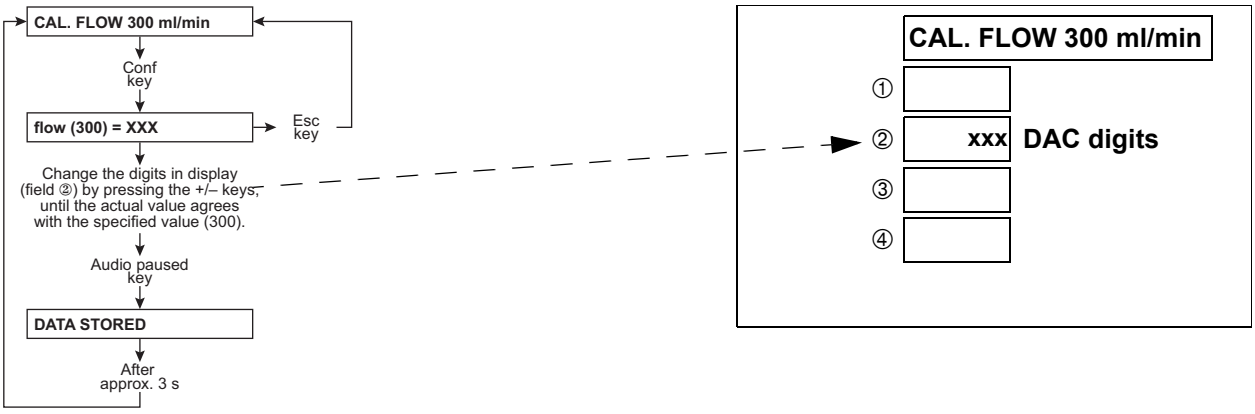
The following messages may appear:

– fill program active

– !!! set flow on !!!

Also refer to degassing pump pressure (see chapter 9.2.2 page 9-43).

9.1.14 Part 8: Calibrating the 300 flow rate



Note

If the 300 / 500 / 800 flow rates cannot be set or flow alarm problems are incurred after "Calibrate flow", maybe the setting of the current increasing pulse must be changed.

Note

The flow selected first is accompanied by the **DIASAFE-filling act.** message which is displayed for the duration of 17 balancing chamber switchings.

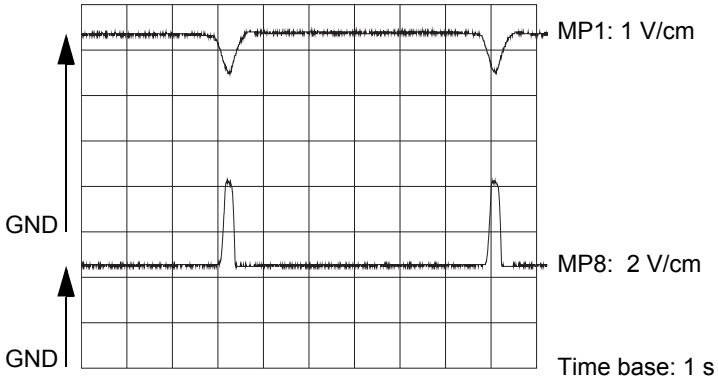
9.1.15 Without menu display: Adjusting the current increasing pulse

– Select **CAL. FLOW 300**, display: **flow (300) = XXX**

– The actual flow XXX must be approx. 300; correct with **+ / –** if necessary.

– Connect an oscilloscope to P.C.B. LP 634: MP8, MP1 and ground MP7.

– Using P1, adjust the current increasing pulse according to the figure below. Ensure that the actual flow (XXX on the display) remains at approx. 300; readjust with **+ / –** if necessary.



9.1.16 Alternative method of adjusting the current increase (if an oscilloscope is not available)

– Select **CAL. FLOW 300**. There may be two device reactions.
Either it initiates regular balancing chamber switchings. In this case, proceed as described for case 1.
Or the device is in intrinsic pulse mode ("Eigentakt"). Then proceed as described for case 2.

Case 1: The device runs with regular balancing chamber switchings.

– Display: **flow (300) = XXX**

– If necessary, correct the flow with the **+ / –** keys until the actual flow is approx. 300.

– Turn potentiometer P1 in anti-clockwise direction (wait for at least 10 seconds after each revolution!) until the device switches to intrinsic pulse mode ("Eigentakt").

– Display: **flow (300) = 147**

– Turn potentiometer P1 in clockwise direction (wait for at least 10 seconds after each half revolution!) until the actual flow is again approx. 300.

– Turn potentiometer P1 in clockwise direction for another 2 revolutions.

Case 2: The device is in intrinsic pulse mode ("Eigentakt").

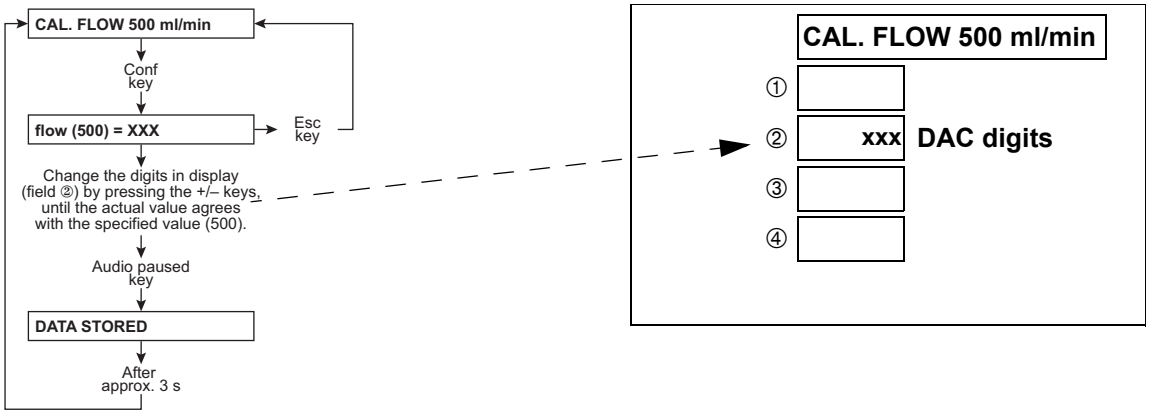
– Display: **flow (300) = 147**

– Turn potentiometer P1 in clockwise direction until the device switches from intrinsic pulse mode ("Eigentakt") to regular balancing chamber switching mode (wait for approx. 10 seconds after each revolution!).
– Display: **flow (300) = XXX**
– If necessary, correct the flow with the **+ / –** keys until the actual flow is approx. 300.
– Turn potentiometer P1 in anti-clockwise direction (wait for at least 10 seconds after each revolution!) until the device switches to intrinsic pulse mode ("Eigentakt").
– Display: **flow (300) = 147**
– Turn potentiometer P1 in clockwise direction (wait for at least 10 seconds after each half revolution!) until the actual flow is again approx. 300.
– Turn potentiometer P1 in clockwise direction for another 2 revolutions.

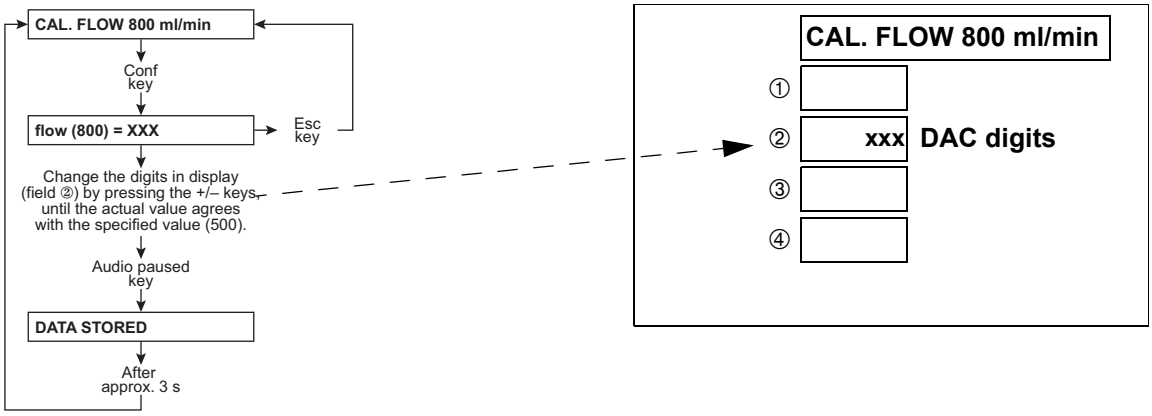
Note

After having adjusted the current increasing pulse, check and, if necessary, readjust the 300 / 500 / 800 flow rate settings.

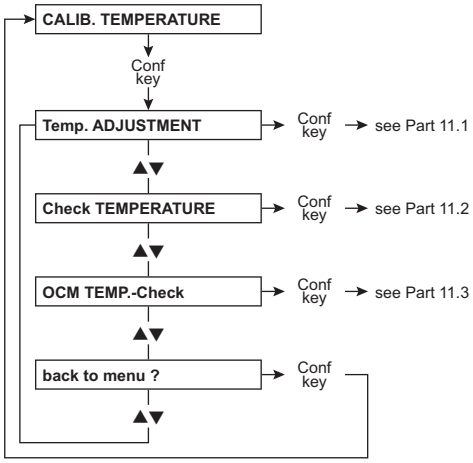
9.1.17 Part 9: Calibrating the 500 flow rate



9.1.18 Part 10: Calibrating the 800 flow rate



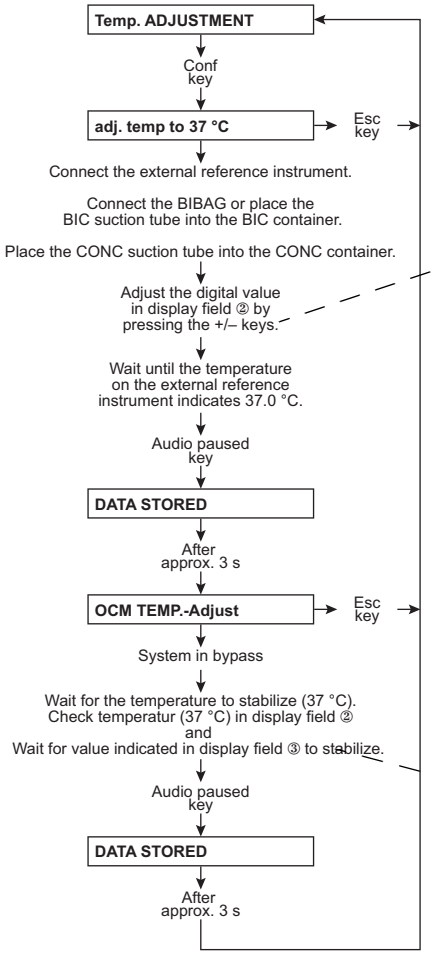
9.1.19 Part 11: Calibrating the dialysate temperature

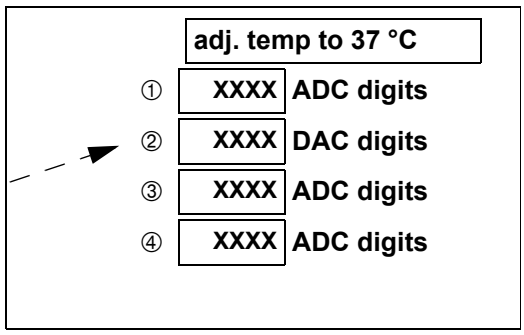


Note

Accuracy of the measuring instrument to be connected externally: ±0.2 °C.

9.1.20 Part 11.1: Setting the dialysate temperature



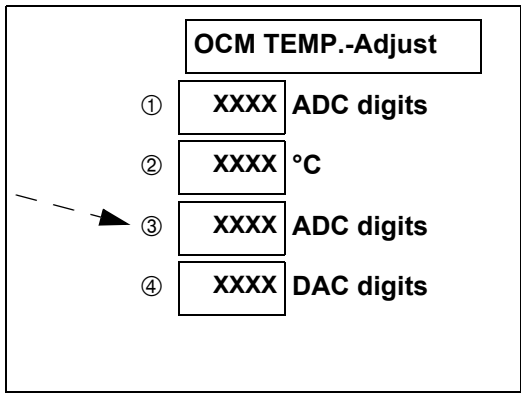


① NTC3, 8 bit

② Controlled variable, 8 bit

③ NTC3, 12 bit

④ NTC109, 8 bit
if NTC 109 activated in SETUP MENU



① NTC3, 12 bit

② NTC3 temperature

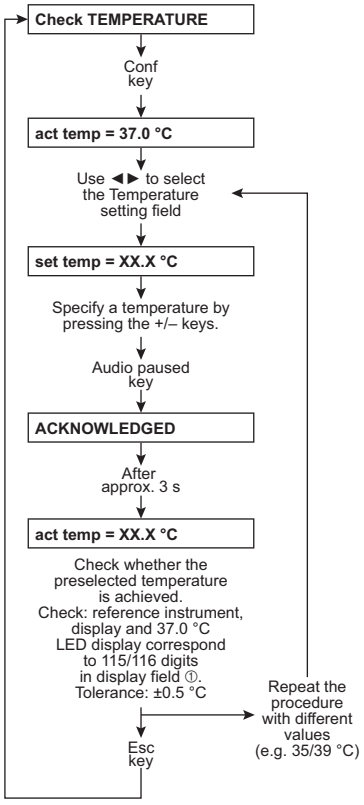
③ NTC4, 12 bit

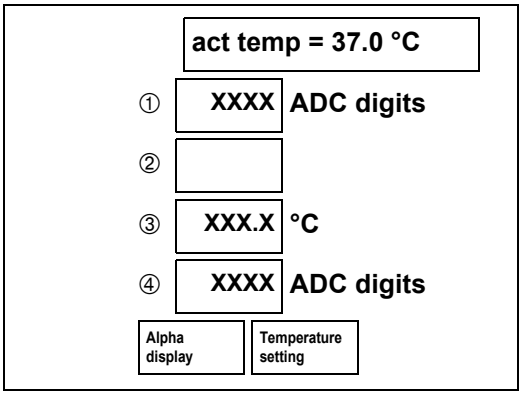
④ Dynamic measuring range switching

Note

The hydraulic unit must be installed, the rear wall closed and the DIASAFE® *plus* must be covered.

9.1.21 Part 11.2: Check the dialysate temperature





① NTC3; 8 bit

②

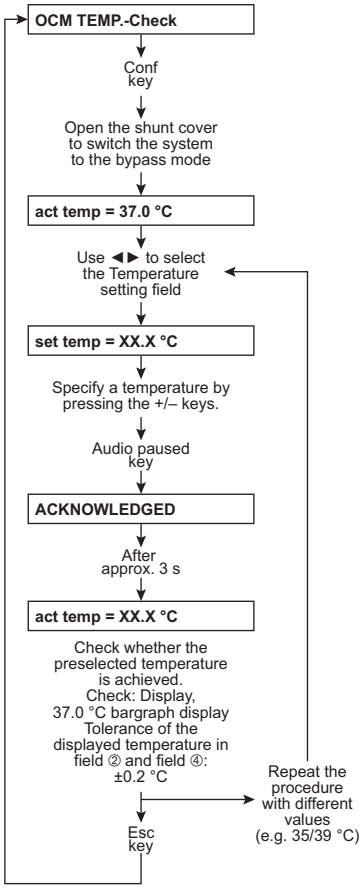
③ NTC109; temperature

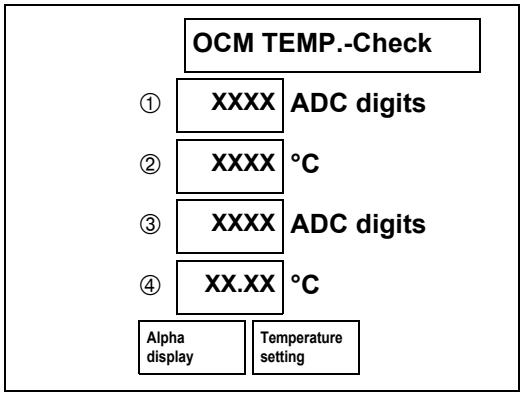
④ NTC109; 8 bit

Note

The hydraulic unit must be installed, the rear wall closed and the DIASAFE® *plus* must be covered.

9.1.22 Part 11.3: Checking the dialysate temperature for OCM





① NTC3; 12 bit

② NTC3; temperature

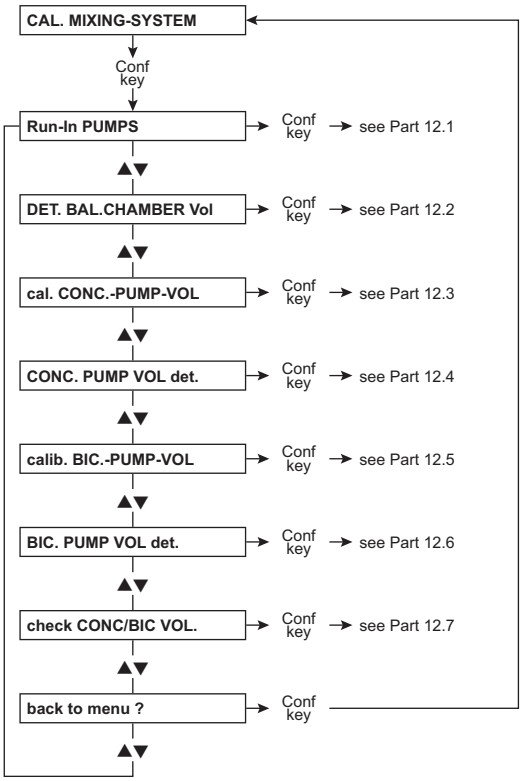
③ NTC4; 12 bit

④ NTC4; temperature

Note

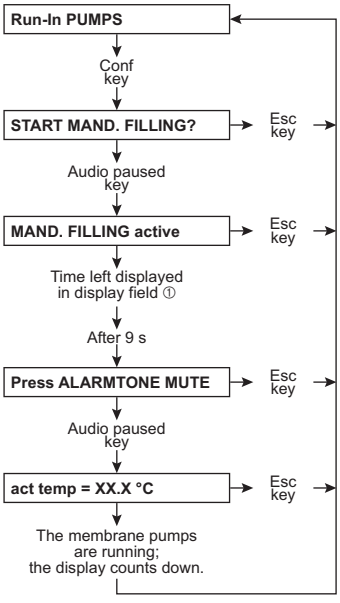
The hydraulic unit must be installed, the rear wall closed and the DIASAFE® *plus* must be covered.

9.1.23 Part 12: Calibrating the mixing system

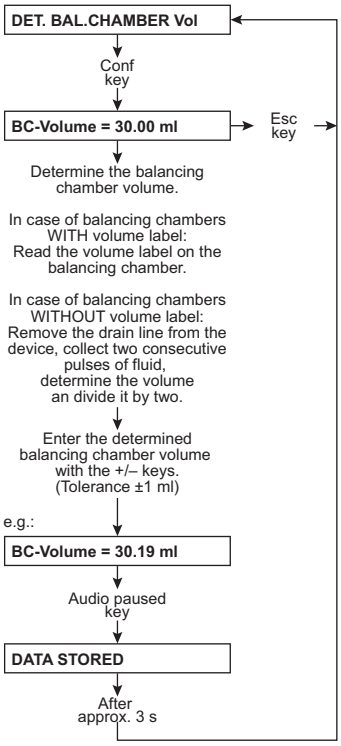


9.1.24 Part 12.1: Running in the membrane pumps

The membrane pumps must be run in to adjust the concentrate and the bicarbonate pump to operating temperature before their volume is measured in liters.
The concentrate tubes (bicarbonate / concentrate) are located in a container filled with water.



9.1.25 Part 12.2: Determining the balancing chamber volume



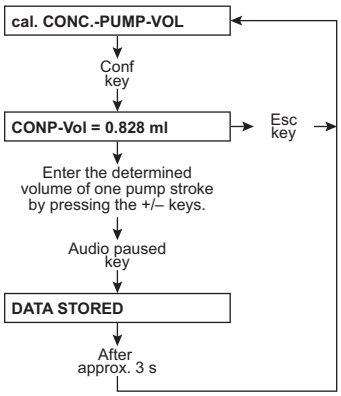
Note

Measuring cylinder accuracy: ±0.5 %.

Note

When using scales as a measuring instrument, please ensure that concentrate is not connected.

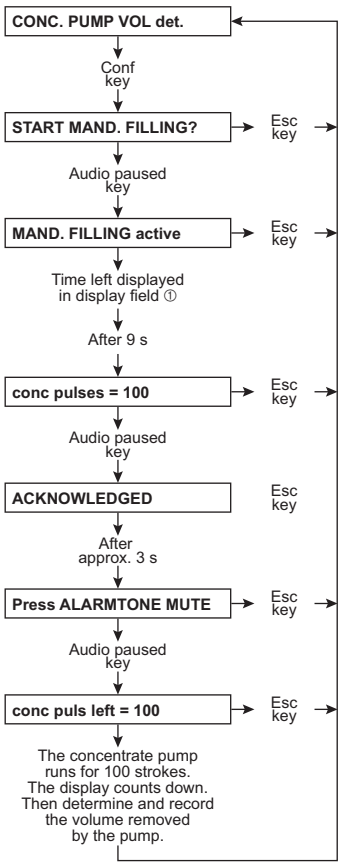
9.1.26 Part 12.3: Calibrating the concentrate pump stroke



Note

Measuring cylinder accuracy: ±0.5 %.

9.1.27 Part 12.4: Measuring the volume of the concentrate pump in liters



Notes:

100 strokes are factory-set. This setting can be changed by pressing the +/– keys (depending on the graduated cylinder used). However, when returning to “CAL. MIXING-SYSTEM”, the display will indicate the factory setting again.

Check the volume and, if necessary, repeat the procedure.

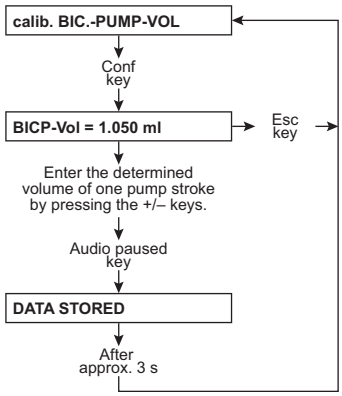
Note

Measuring cylinder accuracy: ±0.5 %.

Note

When using scales as a measuring instrument, please ensure that concentrate is not connected.

9.1.28 Part 12.5: Calibrating the bicarbonate pump stroke



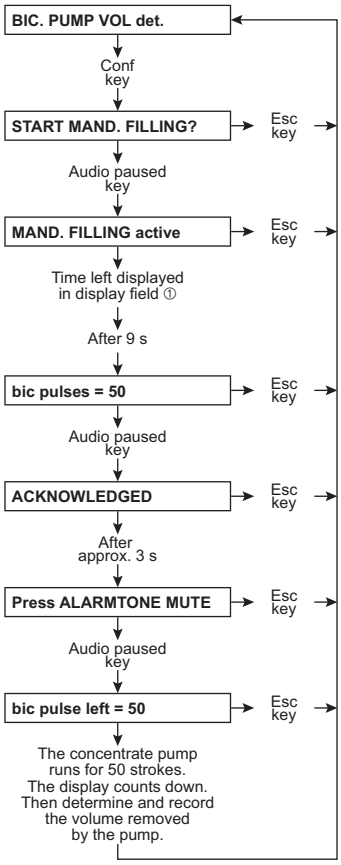
Note

Measuring cylinder accuracy: ±0.5 %.

Note

When using scales as a measuring instrument, please ensure that concentrate is not connected.

9.1.29 Part 12.6: Measuring the volume of the bicarbonate pump in liters



Notes:

100 strokes are factory-set. This setting can be changed by pressing the +/– keys (depending on the graduated cylinder used). However, when returning to “CAL. MIXING-SYSTEM”, the display will indicate the factory setting again.

Check the volume and, if necessary, repeat the procedure.

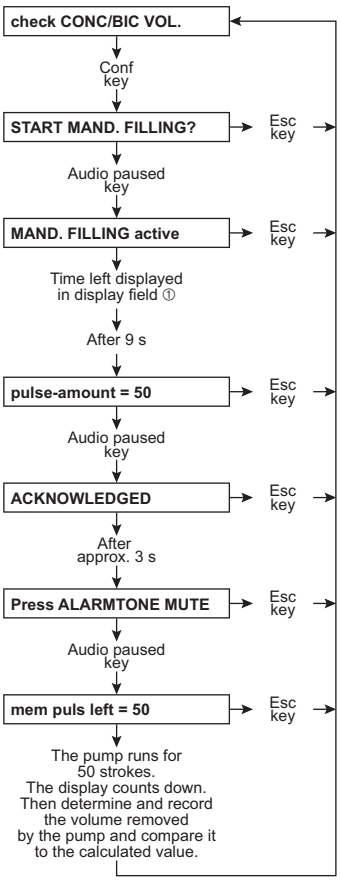
Note

Measuring cylinder accuracy: ±0.5 %.

Note

When using scales as a measuring instrument, please ensure that concentrate is not connected.

9.1.30 Part 12.7: Checking the concentrate and bicarbonate volumes



Notes:

This test step permits verification of the concentrate or bicarbonate pump volumes in accordance with the parameters entered for the mixing system (mixing ratio, BC volume, conc. and bic. pump volume).

The pump whose suction tube is pulled off is activated.

50 strokes are factory-set. This setting can be changed by pressing the +/– keys (depending on the graduated cylinder used). However, when returning to “CAL. MIXING-SYSTEM”, the display will indicate the factory setting again.

Note

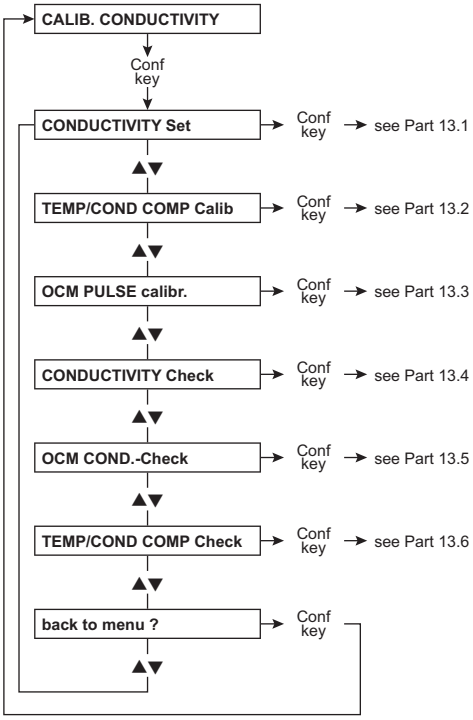
Measuring cylinder accuracy: ±0.5 %.

Note

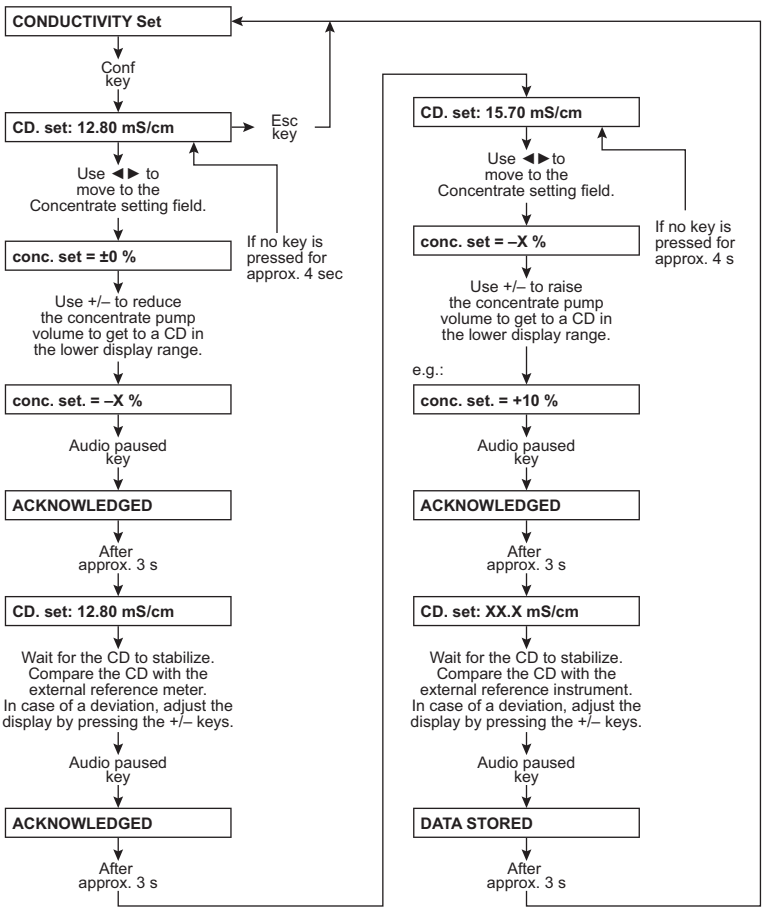
When using scales as a measuring instrument, please ensure that concentrate is not connected.

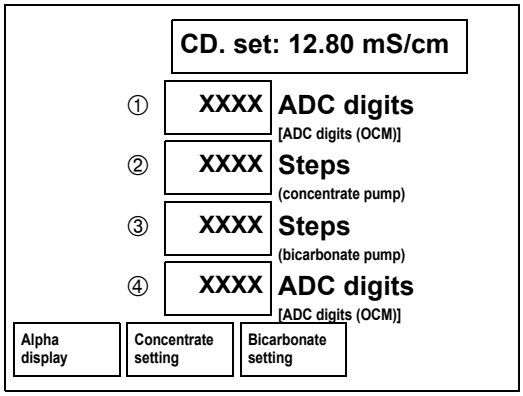
9.1.31 Part 13: Calibrating the conductivity

The values given below are examples.



9.1.32 Part 13.1: Conductivity setting





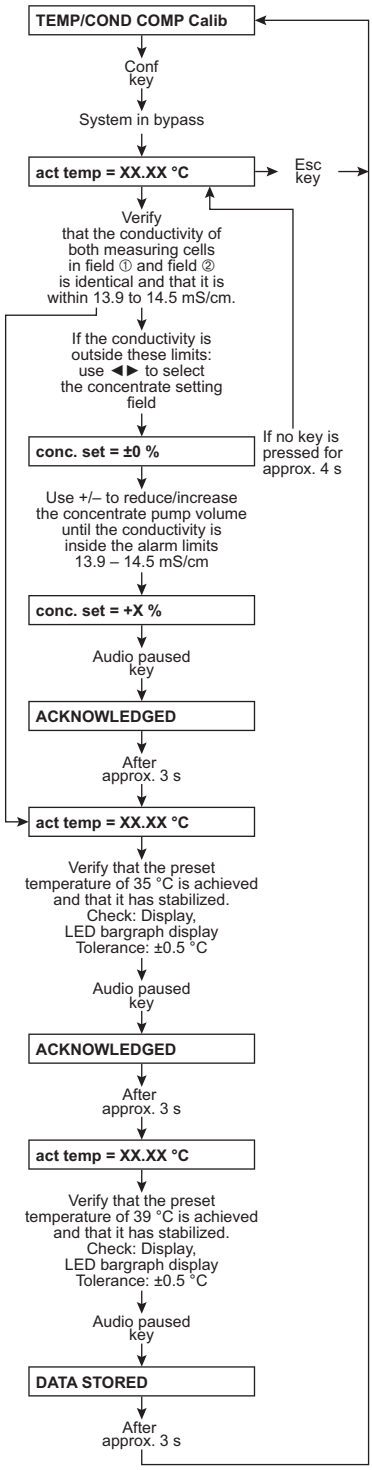
① CD cell 7; 12 bit / 8 bit switching

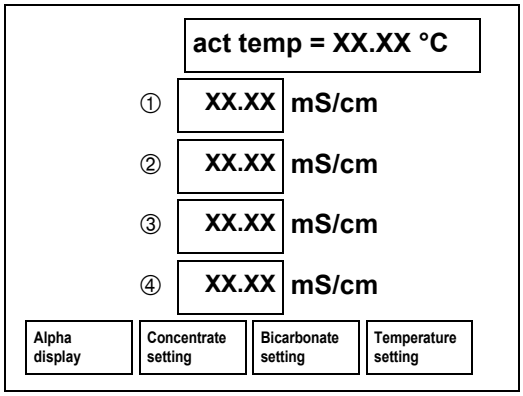
② Steps for concentrate pump

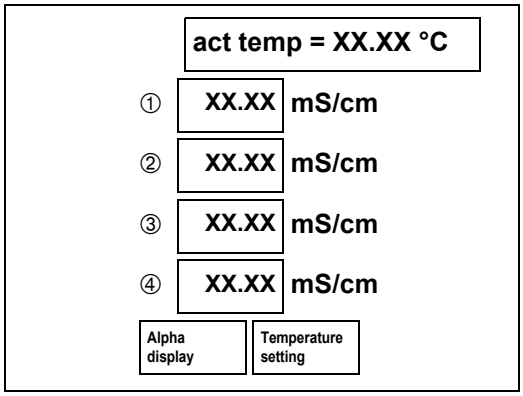
③ Steps for bicarbonate pump

④ CD cell 110; 12 bit / 8 bit switching

9.1.33 Part 13.2: Temperature/conductivity compensation setting







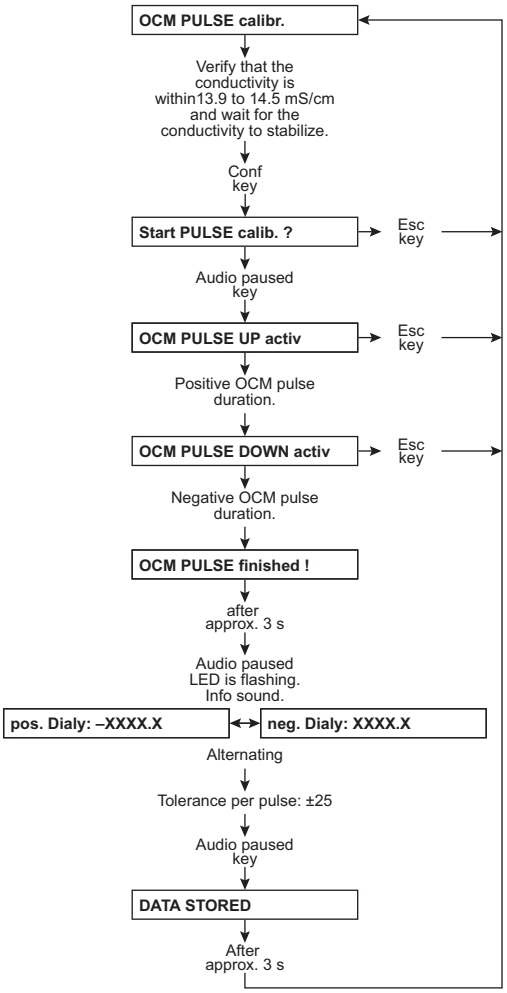
① CD cell 7,
value in mS/cm after 35 °C confirm

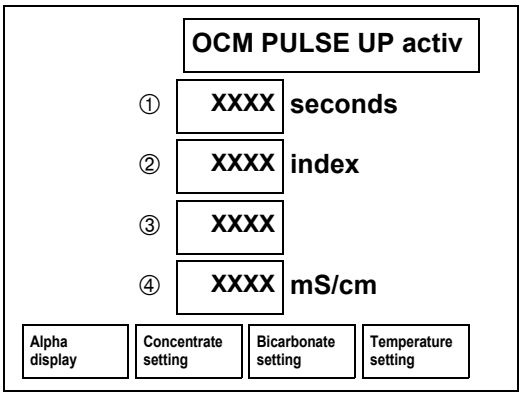
② CD cell 7, current value in mS/cm

③ CD cell 110,
value in mS/cm after 35 °C confirm

④ CD cell 110, current value in mS/cm

9.1.34 Part 13.3: Calibrating the OCM pulse





① Time having elapsed since pulse calibration

② counter

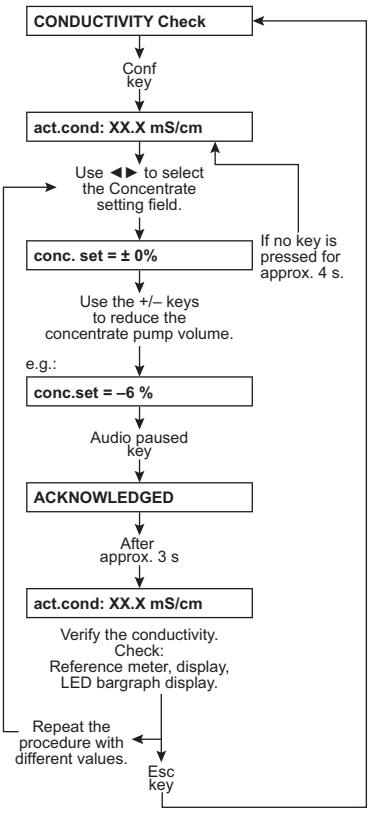
③ Concentrate adjustment

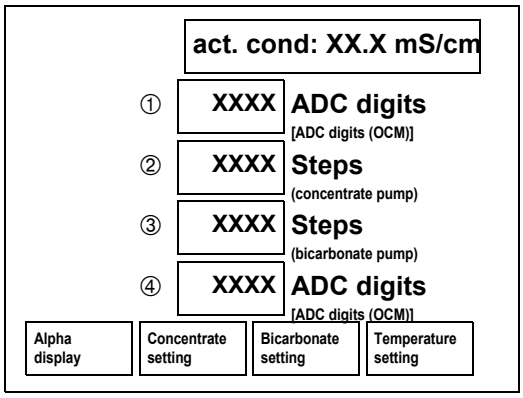
④ CD cell 7, compensated CD value

Note

If the value is outside ±25, the conductivity measuring system of the hemodialysis device must be checked.

9.1.35 Part 13.4: Conductivity test





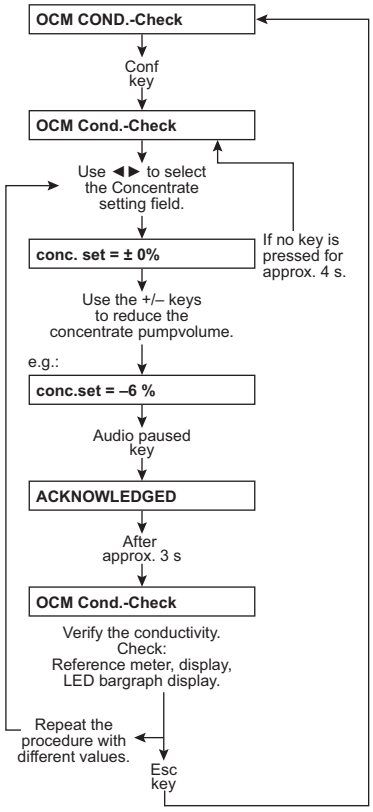
① CD cell 7; 12 bit / 8 bit switching

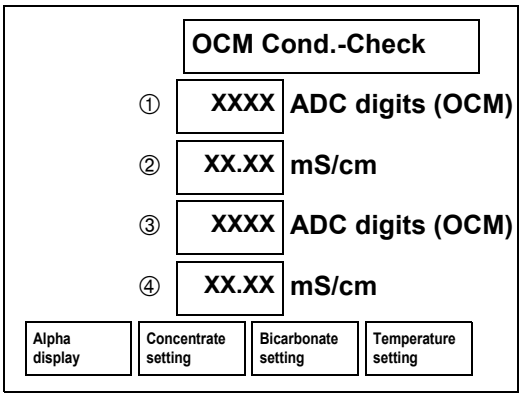
② Steps for concentrate pump

③ Steps for bicarbonate pump

④ CD cell 110; 12 bit / 8 bit switching

9.1.36 Part 13.5: Checking the OCM conductivity





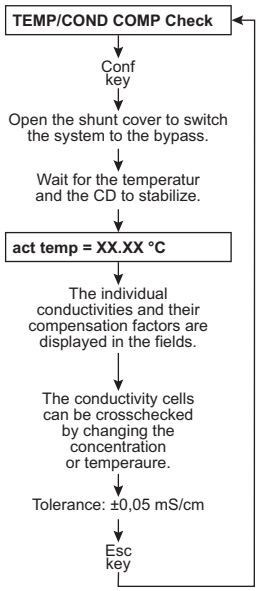
① CD cell 7; 12 bit

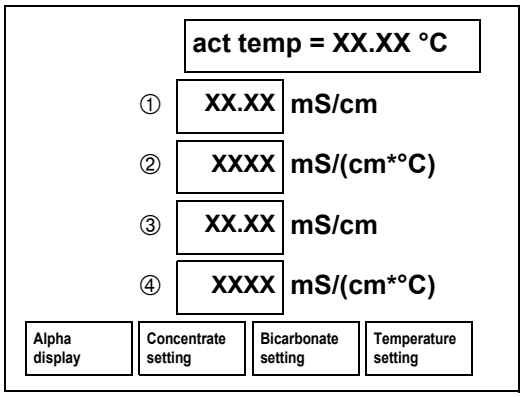
② CD cell 7

③ CD cell 110; 12 bit

④ CD cell 110

9.1.37 Part 13.6: Temperature / conductivity compensation test





① CD cell 7, compensated

② CD cell 7, compensation factor

③ CD cell 110, compensated

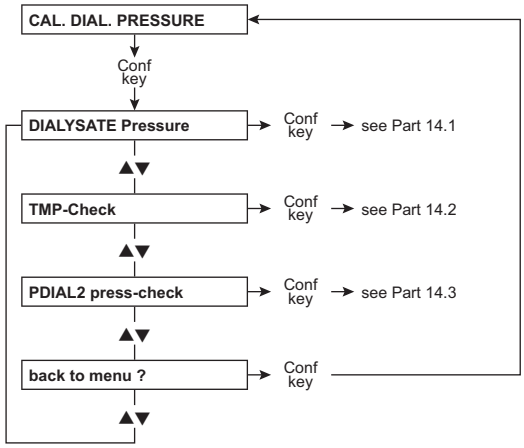
④ CD cell 110, compensation factor

Note

The temperature / conductivity compensation test allows checking the two conductivity cells (7, 110) against each other.

The tolerance of the two conductivity cells may not exceed 0.05 mS/cm. If this tolerance is exceeded, the OCM pulse must be calibrated.

9.1.38 Part 14: Calibrating the dialysate pressure



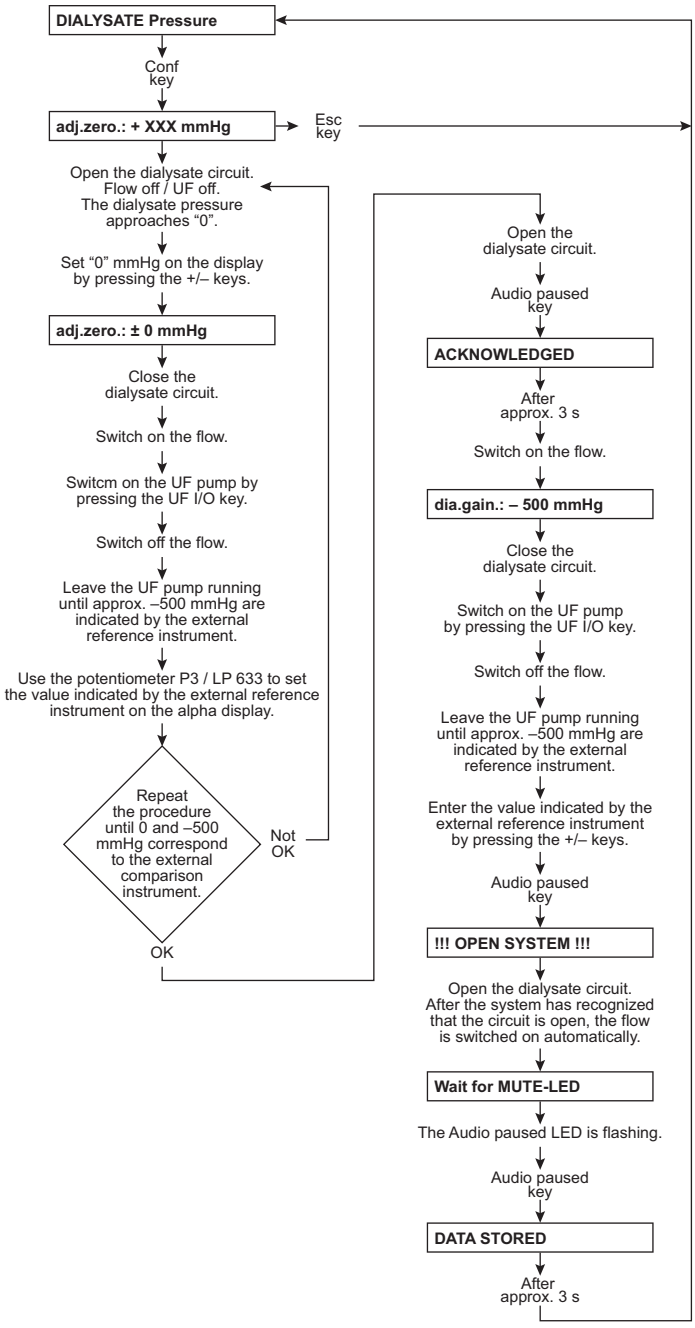
Note

The accuracy of the pressure gauge used must correspond to that of the UMED or HMED.

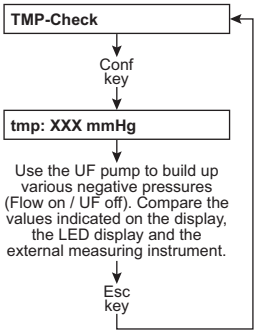
The accuracy of the pressure gauge used must at least correspond to the following values:

-1 to 2 bar ±5 mbar
2 to 8 bar ±20 mbar

9.1.39 Part 14.1: Dialysate Pressure



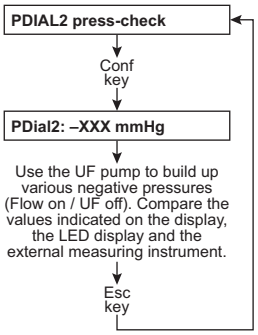
9.1.40 Part 14.2: TMP-Check



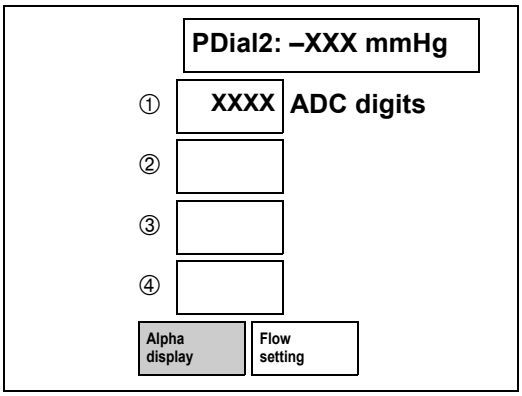
Note:
Observe the venous pressure!

Note:
Switch the flow on and off again once in a while, to maintain the operating temperature of the pressure transducer.

9.1.41 Part 14.3: PDIAL2 press-check



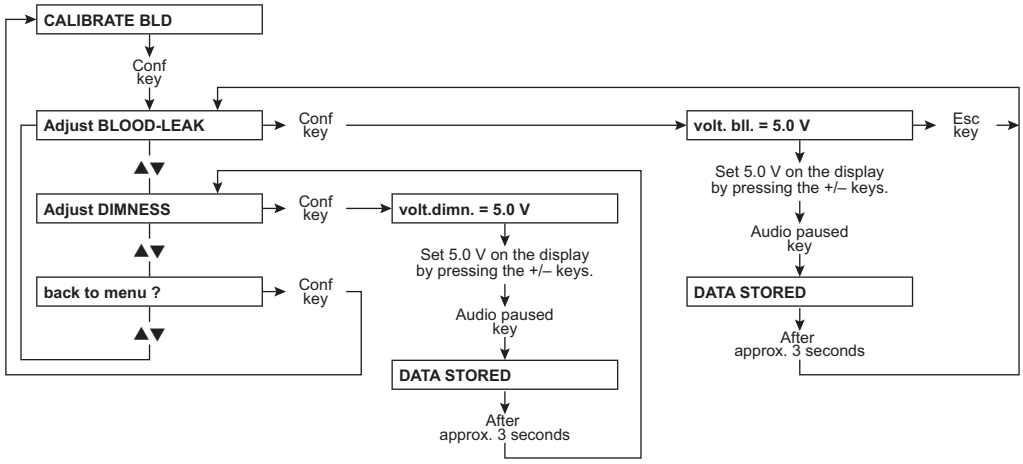
Note:
Observe the venous pressure!



Use the following steps to check flow compensation:

– Use the **Arrow keys** to select the **Flow setting** field.
– Set the flow by pressing the **+ / –** keys
– Confirm with **Audio paused** key

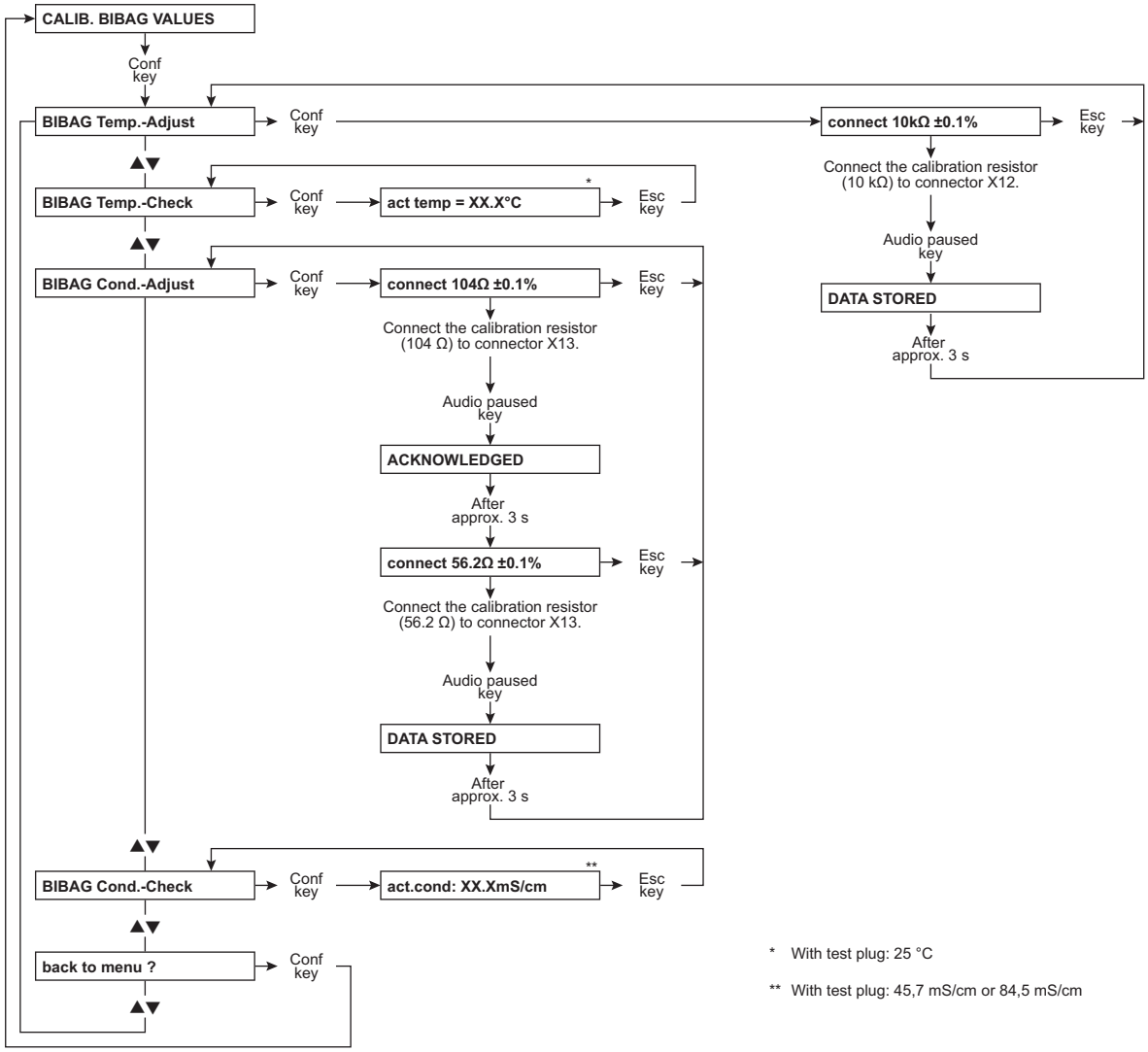
9.1.42 Part 15: Blood leak voltage



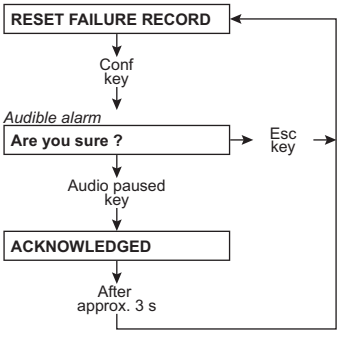
Tolerance for blood-leak voltage: 5 V ±0.2 V.
Tolerance for dimness voltage: 5 V ±0.3 V.

Note: If values deviate check the glass burette for contamination.
Close the housing; temperature 37 °C; avoid incident light from an external source.

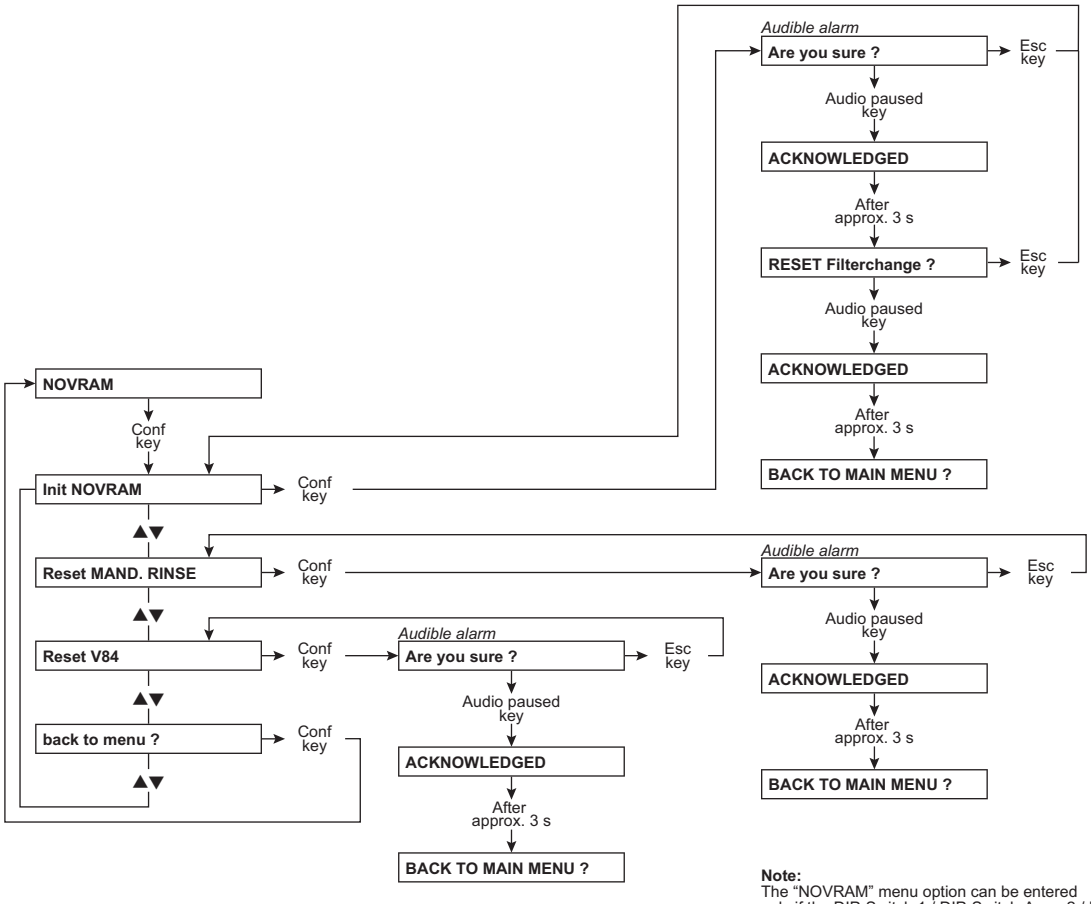
9.1.43 Part 16: Calibrating the bi*bag*® values



9.1.44 Part 17: Reset the failure record



9.1.45 Part 18: Initializing the NOVRAM, clearing the mandatory rinse, erasing a V84 malfunction



Note:
The “NOVRAM” menu option can be entered only if the DIP-Switch 1 / DIP-Switch-Array 2 / LP 1631 is activated in the service mode. To this end and depending on its initial position, the switch must be actuated once and then be reset to its initial position.

9.1.46 Without menu display: Setting the Hall sensors in the heparin pump

Setting Hall sensor 1

– Briefly press the ▲ key (syringe plunger holder moves to its upper end position)

– Disconnect Hall sensor 2 (remove plug)

– Insert syringe (e.g., type BD / Fresenius 20 ml)

– Key the ▼ key pressed (until the syringe plunger holder has reached its lower end position).

– Adjust Hall sensor 1, so that the the bottom of the plunger and the end of the syringe's scale (0 ml) are on the same level.

The must not be any mechanical noise. If the error message **E55** occurs during the Hall sensor adjustment, the message can be acknowledged by pressing the **Start/Stop** key. If Hall sensor 1 was adjusted, the error message **E55** must not occur anymore.

Each time Hall sensor 1 was adjusted, the complete setting for Hall sensor 1 have to be repeated.

– After adjusting Hall sensor 1, Hall sensor 2 has to be re-connected.

– Briefly press the ▲ key (syringe plunger holder moves to its upper end position).

Setting Hall sensor 2

– Press and hold the ▼ key until the syringe plunger holder is approx. 2 cm before its lower end position.

– Manually turn the threaded spindle in delivery direction (one scale line on the syringe).

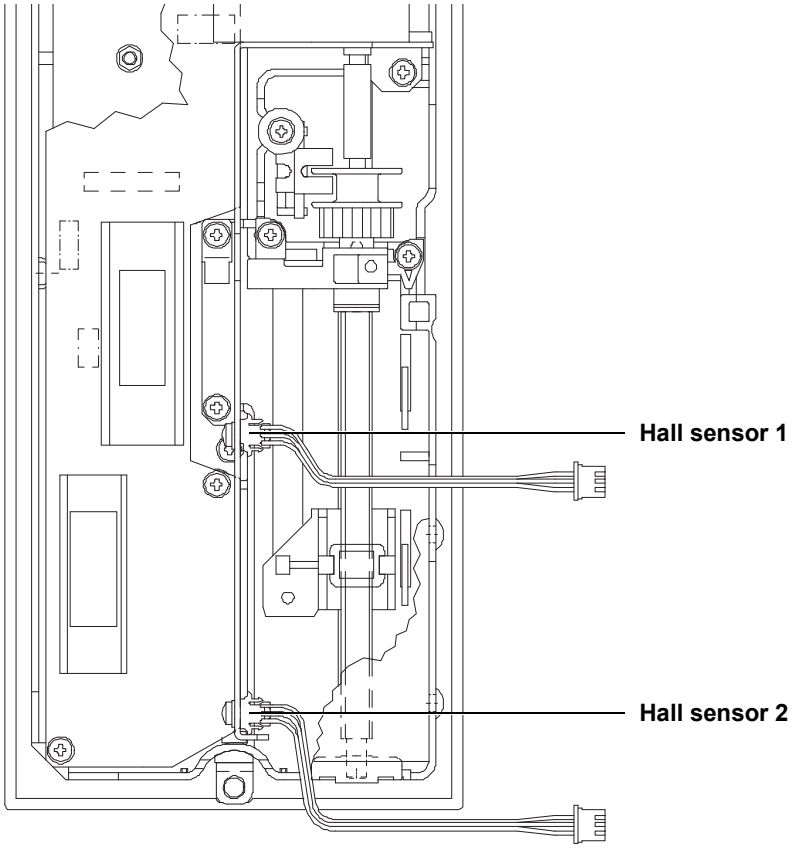
– Key the ▼ key pressed (until the syringe plunger holder has reached its lower end position).

– Adjust Hall sensor 2 so that the bottom of the plunger is pressed against the bottom of the syringe.

The must not be any mechanical noise. If the error message **E55** occurs during the Hall sensor adjustment, the message can be acknowledged by pressing the **Start/Stop** key. If Hall sensor 2 was adjusted, the error message **E55** must not occur anymore.

Each time Hall sensor 2 was adjusted, the complete setting for Hall sensor 2 have to be repeated.

– Briefly press the ▲ key (syringe plunger holder moves to its upper end position).


Hall sensor 1
Hall sensor 2

9.2 Hydraulics unit

Note

Measuring equipment for measurement points in the hydraulic unit:
UMED, HMED or pressure gauge
with a measuring range of –1 to +2.2 bar.

9.2.1 Reduced water inlet pressure

Measuring equipment UMED, HMED or pressure gauge

Measurement point Hydraulics, measurement port A

Condition Flow on

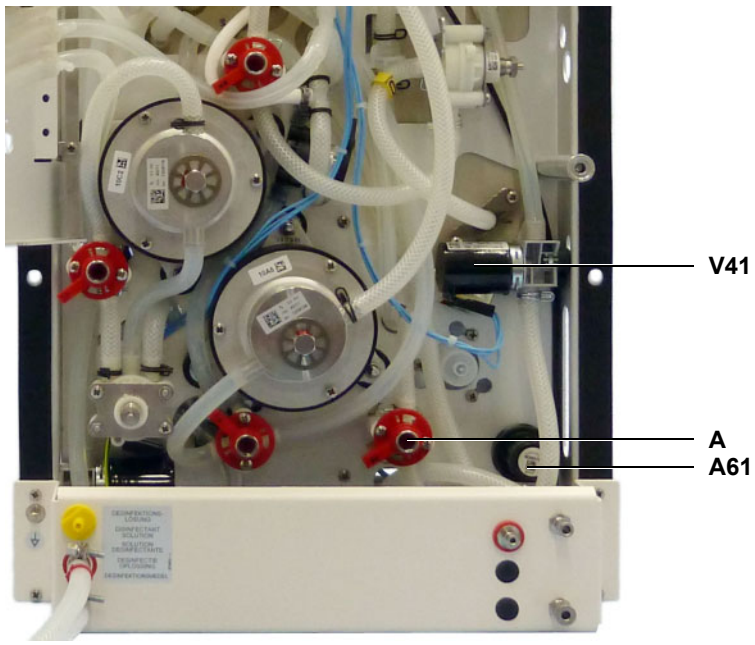
Check / adjustment

Checking the reduced water inlet pressure:

– Connect the measuring equipment to measurement port A.
– Measure11 the water pressure with solenoid valve MV41 closed.
Desired value of water inlet pressure: 0.90–1.40 bar
If it deviates from the desired value, the water inlet pressure must be adjusted.

Adjusting the reduced water inlet pressure:

– Pull back the knurled nut on the pressure reducing valve A61.
– Turn the knurled nut to set the water pressure to the desired value (clockwise: "+", counterclockwise: "–").
– Push the knurled nut back in.



9.2.2 Degassing pump pressure

Note

If the pressure of the degassing pump was changed, make sure to check the loading pressure and readjust, if necessary.

Measuring equipment

UMED, HMED or pressure gauge

Measurement point

Hydraulics, measurement port D

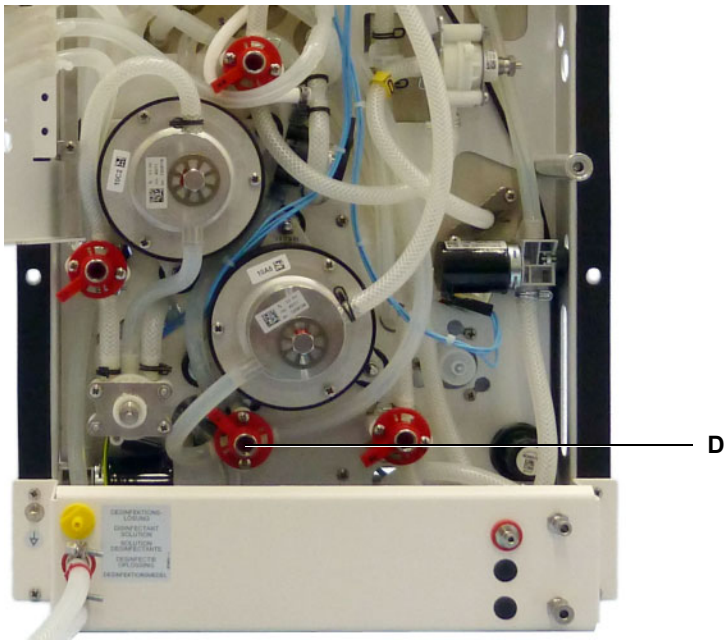
Check / adjustment

Checking the degassing pump pressure:

– Connect the measuring equipment to measurement port D.
– Measure the pressure of the degassing pump.
Desired value of degassing pump pressure: –0.81 bis –0.85 bar
If it deviates from the desired value, the pressure of the degassing pump must be adjusted.

Adjusting the pressure of the degassing pump:

– Enter the **CALIBRATION** service menu, select and start the option **CAL. DEGAS. PRESSURE**
(see **Part 7: Calibrating the degassing pressure** page 9-13).



9.2.2.1 Calibration of the negative degassing pressure on installation sites situated at higher altitudes

If devices are operated on sites situated at higher altitudes (observe sea level), the specified negative degassing pressure cannot be reached. The calibration has to be performed as follows:

The setting for the degassing pump has to be increased in increments from a low speed until no significant increase of the degassing pump pressure can be detected anymore. This setting can also be saved.

9.2.3 Balancing chamber loading pressure

Note

If the loading pressure was changed, make sure to check the degassing pump pressure and readjust, if necessary.

Measuring equipment

UMED, HMED or pressure gauge

Measurement point

Hydraulics, measurement port B

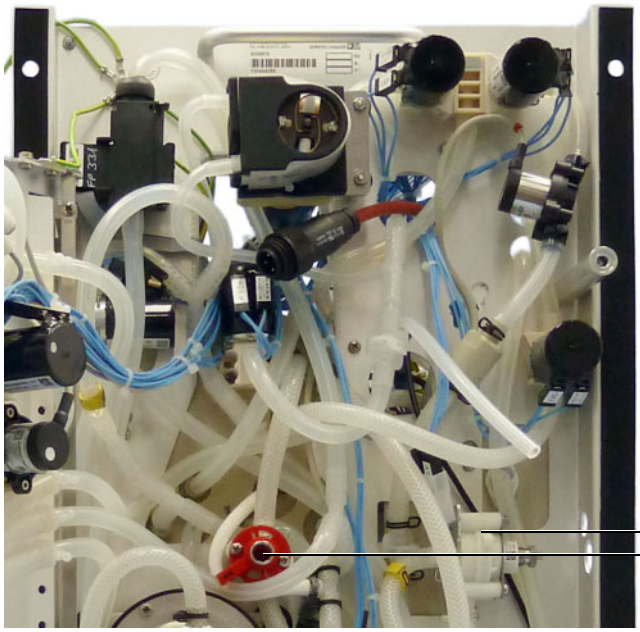
Check / adjustment

Checking the loading pressure of the balancing chamber:

– Connect the measuring equipment to measurement port B.
– Measure the loading pressure of the balancing chamber.
Desired value of the balancing chamber loading pressure:
1.45 bar ±0.05 bar
If it deviates from the desired value, the loading pressure of the balancing chamber must be adjusted.

Adjusting the loading pressure of the balancing chamber:

– Use the loading pressure valve A65 to adjust the loading pressure to the desired value. Turning the adjusting screw clockwise will increase the loading pressure.



9.2.4 Flow pump pressure

Measuring equipment UMED, HMED or pressure gauge

Measurement point Hydraulics, measurement port C

Condition A dialysate flow of 800 ml/min must have been preselected.

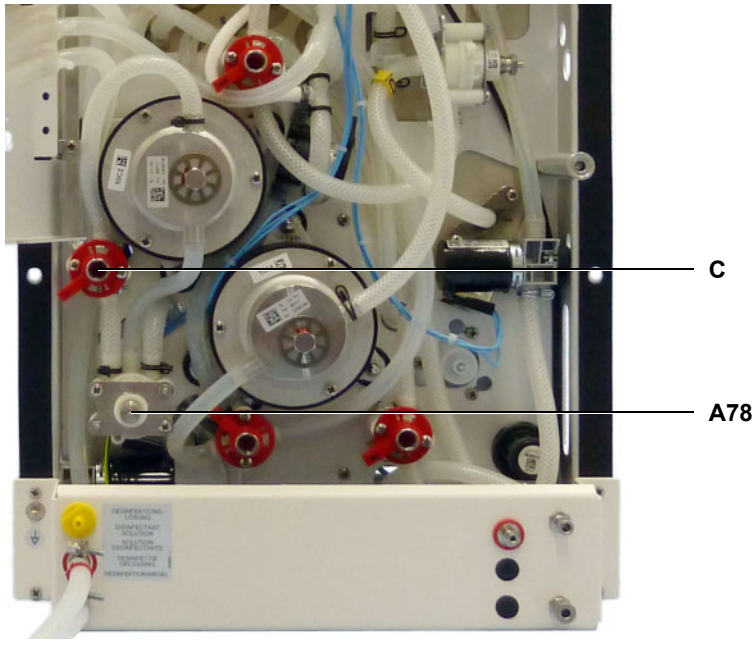
Check / adjustment

Checking the pressure of the flow pump

– Connect the measuring equipment to measurement port C.
– Turn the water supply off; Alarm **Insufficient water**, balancing chamber has stopped.
– Measure the pressure at the flow pump. The desired pressure value of the flow pump depends on the loading pressure set:
  Loading pressure: 1.45 bar ±0.05 bar
  Flow pump pressure: 2.2 bar ±0.05 bar
– If it deviates from the desired value, the pressure of the flow pump must be adjusted.

Adjusting the pressure of the flow pump

– Use the relief valve A78 to adjust the rated value.



9.2.5 UF pump volume

Note

When using scales as a measuring instrument, please ensure that concentrate is not connected.

Measuring equipment

Scales or measuring cylinder, tolerance ±0.5 %

Measurement point

Hydraulic unit open

Condition

The CALIBRATION service menu is selected.

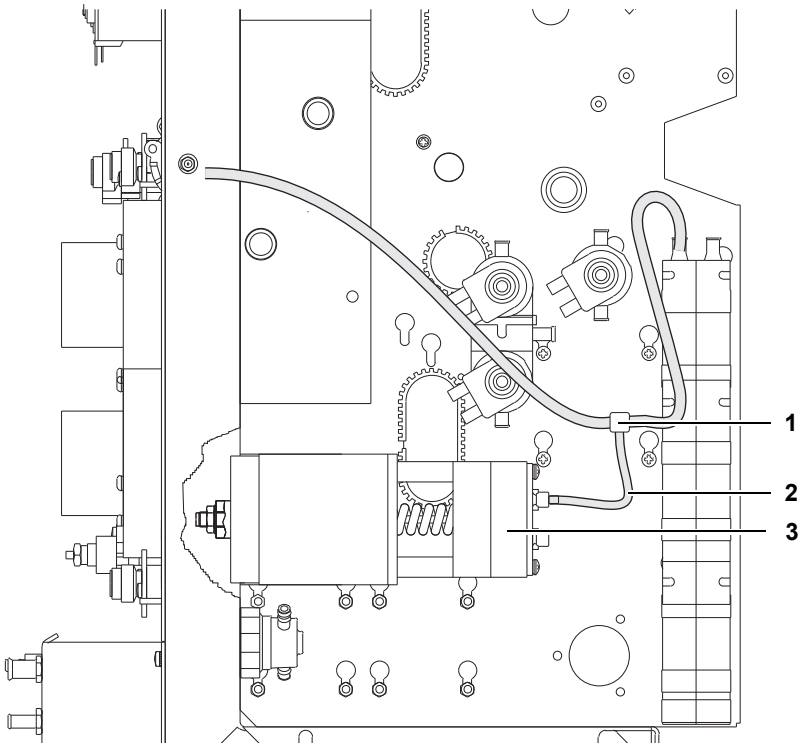
Check / adjustment

Checking the UF pump volume:

– Remove the drain line / UF (2) of the UF pump (3) from the T-piece (1) **and** close the T-piece!
– Place the drain line / UF (2) in the measuring cylinder.
– Enter the **CALIBRATION service menu,** select and start the option **ADJ. UF PUMP VOLUME 1** (see **Part 6: Measuring the volume of the UF pump in liters** page 9-12).
  Desired value for UF pump:
  1 stroke = 1 ml, 60 strokes = 60 ml ±0.5 ml

Adjusting the UF pump:

– Remove the protective cap
– Loosen the lock nut
– Change the delivery volume, using the adjusting screw (turning the adjusting screw clockwise reduces, turning it counter-clockwise increases the stroke volume).
– Retighten the lock nut
– Verify the delivery volume



9.2.6 CDS (Central Delivery System) pressure switch

Measuring equipment

UMED, HMED or pressure gauge (e.g., 0–1 bar, accuracy ±1 %) and syringe. Measurement setup see the following figures.

Measurement point

Hydraulic unit open

Condition

CDS connector must be depressurized.
The pressure compensation port on the pressure switch (PSW 123) must be open against atmosphere.
The lines of the measuring equipment should be as short as possible.
The device is in the Service mode.

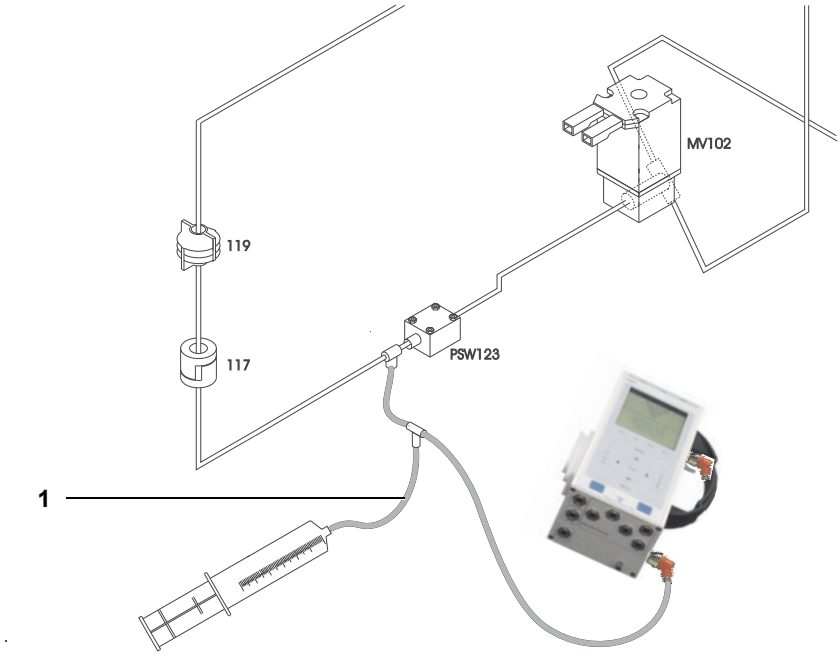
Check / adjustment

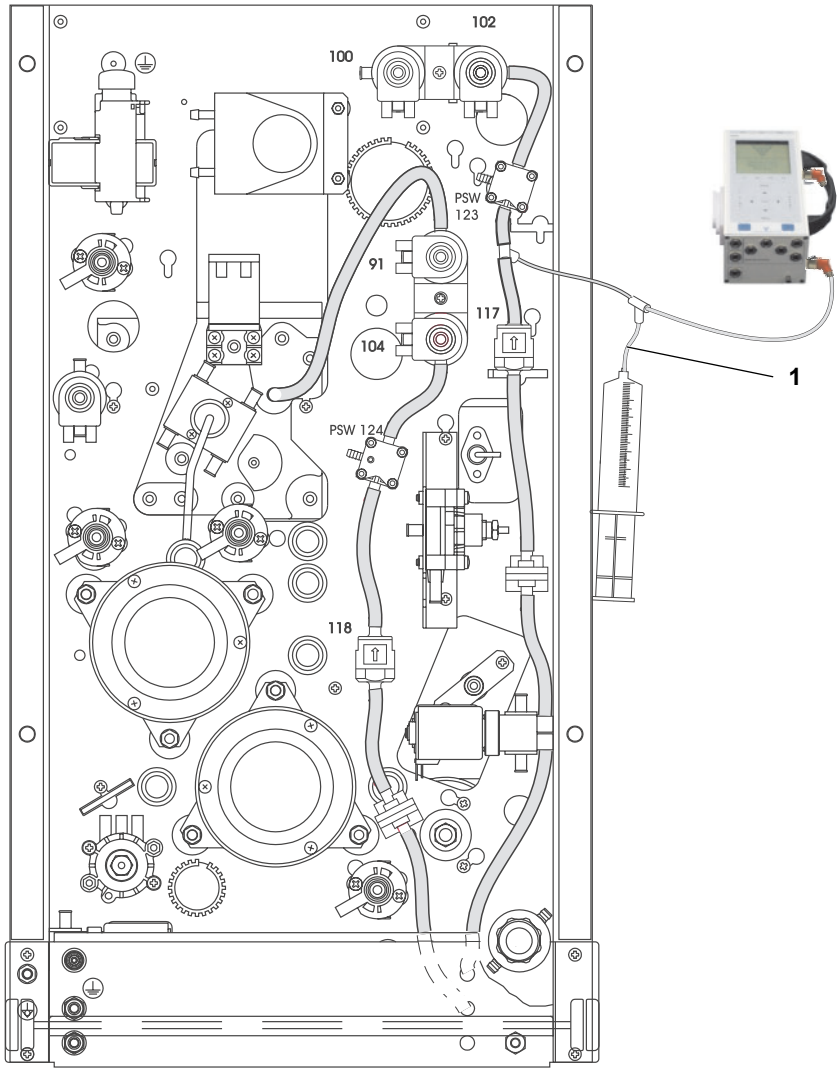
Connect the measuring equipment as illustrated in the diagram below.

– Select the DIAGNOSTICS service menu, continue with:
READ INPUTS
READ DIGITAL INPUTS
CPU1: RD DIGITAL INP
E: CPU1_PSW_V102

– Activate the audible alarm by pressing the **Audio paused** key (depressurized: alarm on).
– If this menu option has been selected, the solenoid valve 102 is closed.
– Use the syringe to build up a pressure of 0.7 bar.
– Use an artery forceps to clamp the line (**(1)**), so that a pressure of 0.7 bar continues to act on the pressure switch.
– Check the switching point by means of the audible alarm. Desired value:
Pressure switch (Envec): 0.68–0.72 bar.

Fig.: CDS pressure switch (PSW 123)




102
100
PSW
123
91
117
104
1
PSW 124
118

9.2.7 Verification of the bi*b*ag® pressure transducer (Envec)

General notes on the bi*b*ag® pressure transducer

The calibration described below can be performed by means of a multimeter or the DIAGNOSTICS service menu.

To read the corresponding signal, you must select the menu option **E: CPU1_BIBAG_PSW** in the diagnostic program.

The calibration of the pressure switch is not possible. The pressure switch is set to a fixed position and can be checked in the DIAGNOSTICS service menu.

The audible signal can be activated by pressing the **Audio paused** key.

Selection in the DIAGNOSTICS service menu

1. The DIAGNOSTICS service menu can only be called in service mode.

– The device must be switched off.
– Set the Service switch to ON (up).
– Turn the device on.
  Wait briefly, until the Service mode screen is displayed.
– Use the ▲ and ▼ keys to select DIAGNOSTICS.
  Press the **Confirm** key to confirm the selection.

2. In the DIAGNOSTICS service menu, continue as follows:

– Use the ▲ and ▼ keys to select DIAGNOSTICS.
  Press the **Confirm** key to confirm the selection.
– Use the ▲ and ▼ keys to select READ INPUTS.
  Press the **Confirm** key to confirm the selection.
– Use the ▲ and ▼ keys to select READ DIGITAL INPUTS.
  Press the **Confirm** key to confirm the selection.
– Use the ▲ and ▼ keys to select CPU1: RD DIGITAL INP.
  Press the **Confirm** key to confirm the selection.
– Use the ▲ and ▼ keys to select E: CPU1_BIBAG_PSW.
  Press the **Confirm** key to confirm the selection.
– The active levels **0000** or **1111** are shown on the display.

Checking the switching point

Check the pressure switch PSW 134.

The maximum switching pressure is 130 mbar +30 mbar.

– Connect a pressure gauge (e.g. HMED), a syringe and the bi*b*ag® connector to the bi*b*ag® connector using a tubing and the T-connector.

– Slowly increase the pressure by means of the syringe - meanwhile permanently observe the display of the pressure gauge and the display of the dialysis device - until the active level switches from **0000** to **1111** on the display (E: CPU1_BIBAG_PSW) and an audible alarm is sounded.

Measured switching pressure: 130 mbar +30 mbar.

Note

In the menu item **E: CPU1_BIBAG_PSW**, the active level is identified by **1111**.

The active level of the circuit output is LOW (< 1 V).

9.3 Air Detector

9.3.1 Calibration of air detector LD 22

Fig.: 450-2

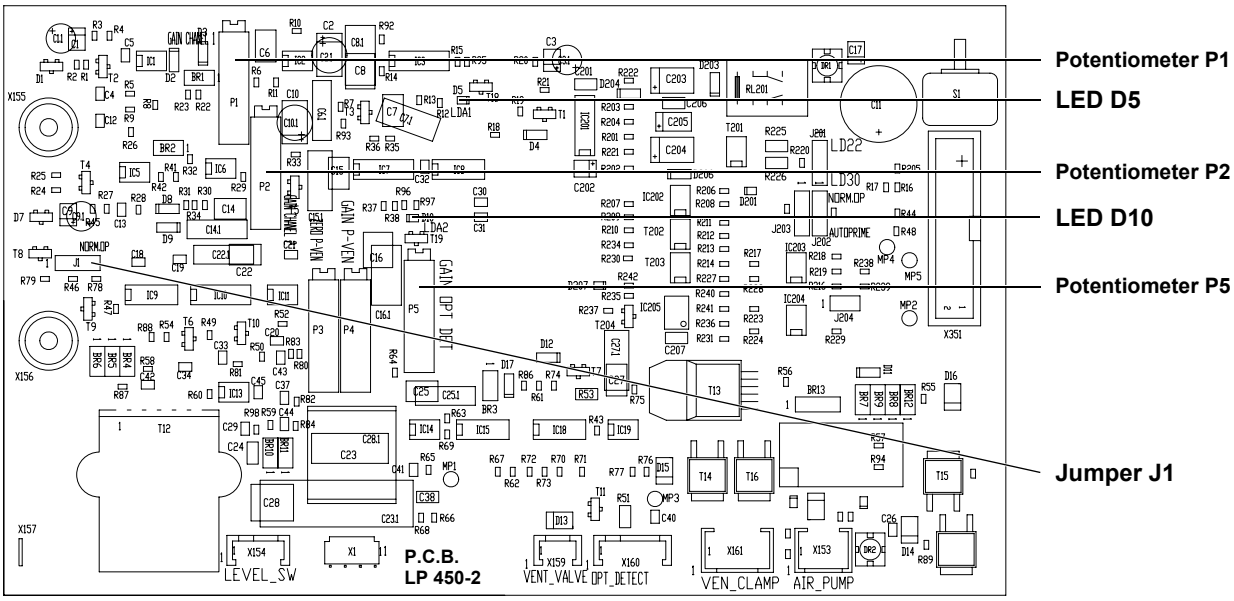


Fig.: Checking the venous occlusion clamp

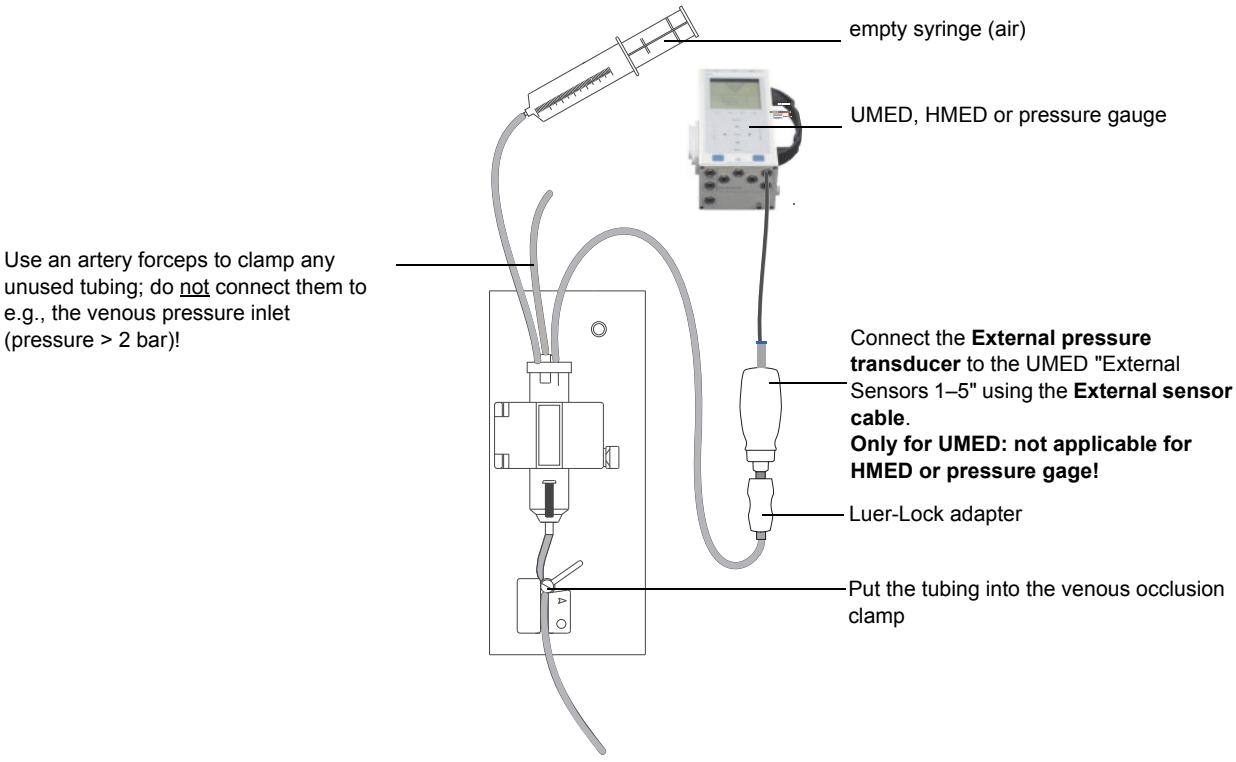
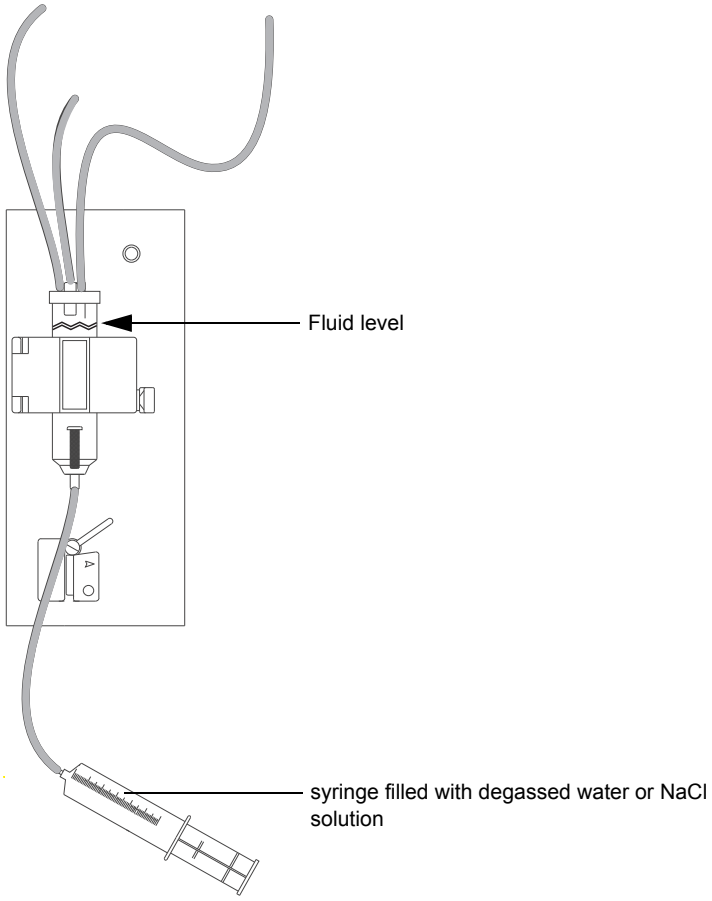


Fig.: venous bubble catcher in the AD



Warning

For a calibration of the air detector, the device must be in the Service mode. The ambient temperature should be between 15 °C and 35 °C.

Warning

The calibration using the set for the air detector calibration is only valid for devices running with Fresenius tubing systems.

Observe the “use by” date!

9.3.1.1 Adjustment using the set for air detector calibration (see adjustment instructions)

As an alternative, an adjustment is also possible without the set for air detector calibration (see chapter 9.3.1.4 page 9-55).

Measuring equipment

UMED, HMED or pressure gauge, adjusting block and checking (reference) block

Measurement point

Air Detector

Calibrating the air detector

The device must be in the Service mode,
the jumper J1 / P.C.B. LP 450-2 must be set to the calibration position.

- Fill the spherical recesses of the adjusting block with grease and use a spattle to remove any excess grease so that only the recesses are completely filled with grease.
- Place the greased adjusting block into the drip chamber holder (with the bevelled edges first). It must be ensured that the ultrasonic sensors click correctly into place in the spherical recesses of the block. The adjusting block must not touch the holder wall, but must hang freely between the sensors.
- Turn potentiometer 1 and potentiometer 2 on P.C.B. LP 450-2 clockwise, until the LED D5 and LED D10 on P.C.B. LP 450-2 are dark.
  Slowly (attention: time constant) turn potentiometer 1 counterclockwise, until LED D5 lights.
  Slowly (attention: time constant) turn potentiometer 2 counterclockwise, until LED D10 lights (see figure LP 450-2).
- Set jumper J1 / P.C.B. LP 450-2 to the operation position.
  LED D5 and LED D10 must both be dark.
- Take the adjusting block out of the drip chamber holder.
  Remove residual grease using lint-free cloth and a permissible disinfectant.

Checking the air detector

- Fill the spherical recesses of the test block with grease and use a spattle to remove any excess grease so that only the recesses are completely filled with grease.
- Place the greased test block into the drip chamber holder. It must be ensured that the ultrasonic sensors are correctly positioned in the spherical recesses of the test block. The test block must not touch the holder wall, but must hang freely between the sensors.
- LED D5 and LED D10 on P.C.B. LP 450-2 must both be illuminated. If one or both LEDs are not illuminated, the calibration must be repeated.
- Take the test block out of the drip chamber holder.
  Remove residual grease using lint-free cloth and a permissible disinfectant.
- In addition, the venous occlusion clamp has to be checked and the optical detector has to be calibrated and checked
  (see chapter 9.3.1.2 page 9-54).

9.3.1.2 Checking the venous occlusion clamp

The device must be in the Service mode,
the jumper J1 / P.C.B. LP 450-2 must be set to the operation position.

– Insert the venous bubble catcher into the air detector (ultrasonic detector). For the moment, do not place the line in the venous occlusion clamp.

– Manually open the venous occlusion clamp, hold it and insert the tubing.

– Release the venous occlusion clamp. The venous occlusion clamp closes.

– Use the syringe to generate a pressure of approx. 2 bar (see **Checking the venous occlusion clamp** page 9-51).

– The pressure may not drop by more than 0.1 bar within 3 minutes.

– Calibrate and check the optical detector (see chapter 9.3.1.3 page 9-54)

9.3.1.3 Calibrating and checking the optical detector

Calibrating the optical detector

Use the grey filter, single-laid.

DIAGNOSTICS service menu: **Read digital inputs CPU 1**, select the menu item **E: CPU1_OD_IN**:

– Install the grey filter, single-laid; close the flap.

– Slowly turn potentiometer P5 on P.C.B. LP 450-2 clockwise, until the UF display indicates **1111**.

– Slowly turn potentiometer P5 counterclockwise, until the display jumps to **0000**.
Avoid incident light from external sources.

– Check the optical detector.

Checking the optical detector

Use the grey filter, single-laid.

DIAGNOSTICS service menu: **Read digital inputs CPU 1**, select the menu item **E: CPU1_OD_IN**:

– Install the grey filter, single-laid; close the flap

– The display changes from **1111** to **0000**

9.3.1.4 Alternative: Adjustment without the set for air detector calibration

As an alternative, an adjustment is also possible using the set for air detector calibration (see chapter 9.3.1.1 page 9-53).

Measuring equipment

UMED, HMED or pressure gauge,
venous bubble catcher with syringe filled with degassed water or NaCl solution (see **venous bubble catcher in the AD** page 9-52).

Measurement point

Air Detector

Calibrating the air detector

The device must be in the Service mode,
the jumper J1 / P.C.B. LP 450-2 must be set to the calibration position.

– Insert the venous bubble catcher into the air detector (ultrasonic detector); for the moment, do not insert the line into the venous occlusion clamp.
– Fill the venous bubble catcher. The fluid level must be set to approx. 10 mm above the top edge of the sensor holder.
– Turn potentiometer 1 and potentiometer 2 on P.C.B. LP 450-2 clockwise, until the LED D5 and LED D10 on P.C.B. LP 450-2 are dark.
  Slowly (attention: time constant) turn potentiometer 1 counterclockwise, until LED D5 lights.
  Slowly (attention: time constant) turn potentiometer 2 counterclockwise, until LED D10 lights (see figure LP 450-2).
– After completion of the calibration procedure, set the jumper J1 / P.C.B. LP 450-2 back to the operation position.

Checking the air detector

– Lower the fluid level in the venous bubble catcher:
  An alarm must be emitted. LED D5 and LED D10 light.
  If one or both LEDs are not illuminated, the calibration procedure must be repeated.
– Raise the fluid level in the venous bubble catcher:
  It must be possible to clear the alarm; both LEDs must be off.
– Remove the venous bubble catcher from the air detector.
– In addition, the venous occlusion clamp has to be checked and the optical detector has to be calibrated and checked (see chapter 9.3.1.2 page 9-54).

10 Servicing / repair

10.1 Precautions for working on the hemodialysis device

Installing and removing components

Unless described otherwise, installation of components is in reverse component removal order.

To be observed after working on the hemodialysis device

A disinfection, a T1 test and a check of the electrical safety must be performed after working on the hemodialysis device.

To be observed after stopping a disinfection program

After a disinfection program has been stopped or if the device is to be preserved, the hemodialysis device must be disconnected from the water supply after a maximum of 3 days.

Warning

When the device is returned to use, check that the pressure of the water supply meets the prescribed minimum pressure.

10.2 Equipment

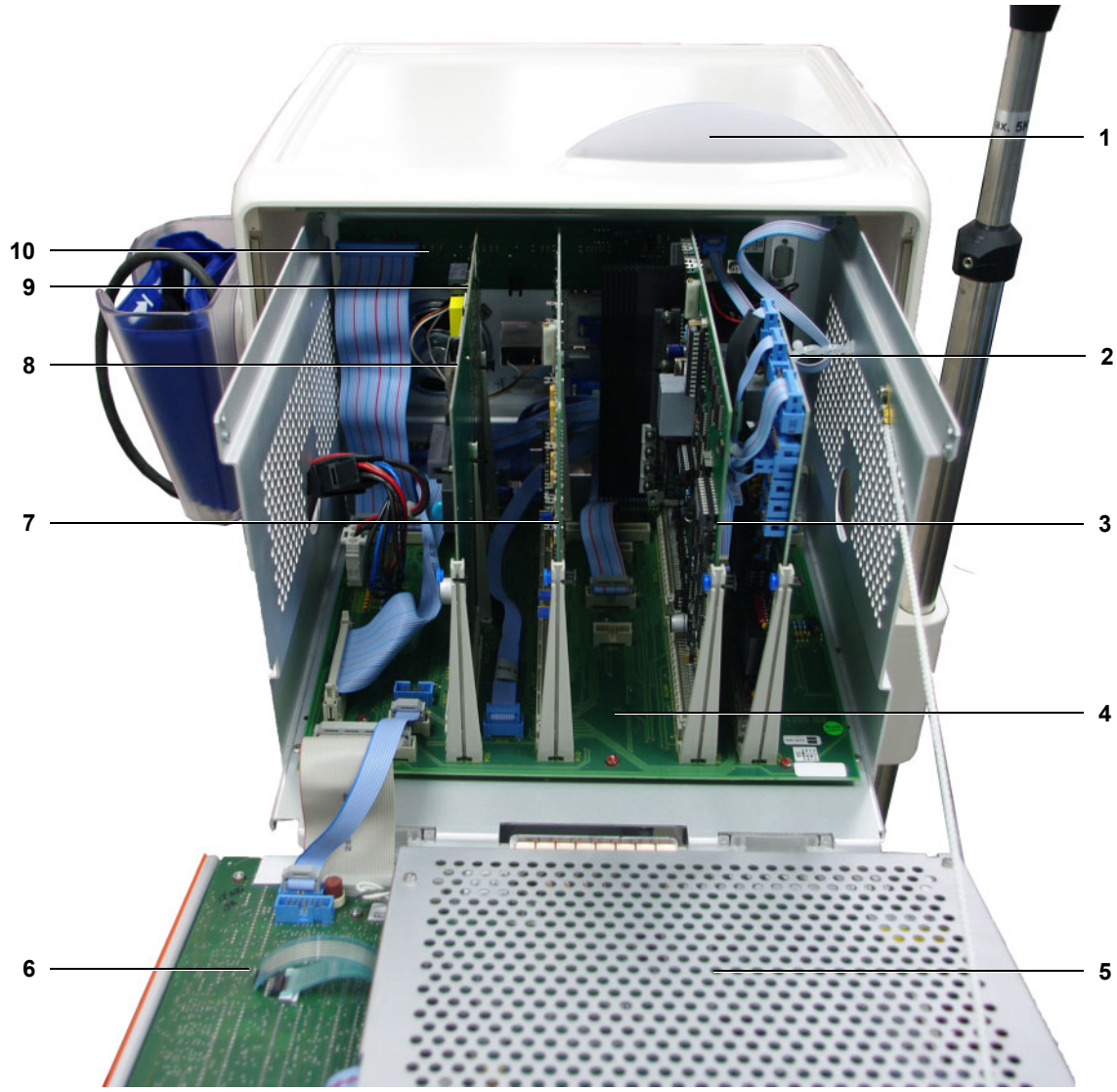
Closing plug set
for hydraulic tubings

Unisilkon grease

Anti-tamper fixing
(low-/medium-/high-strength screwlock)

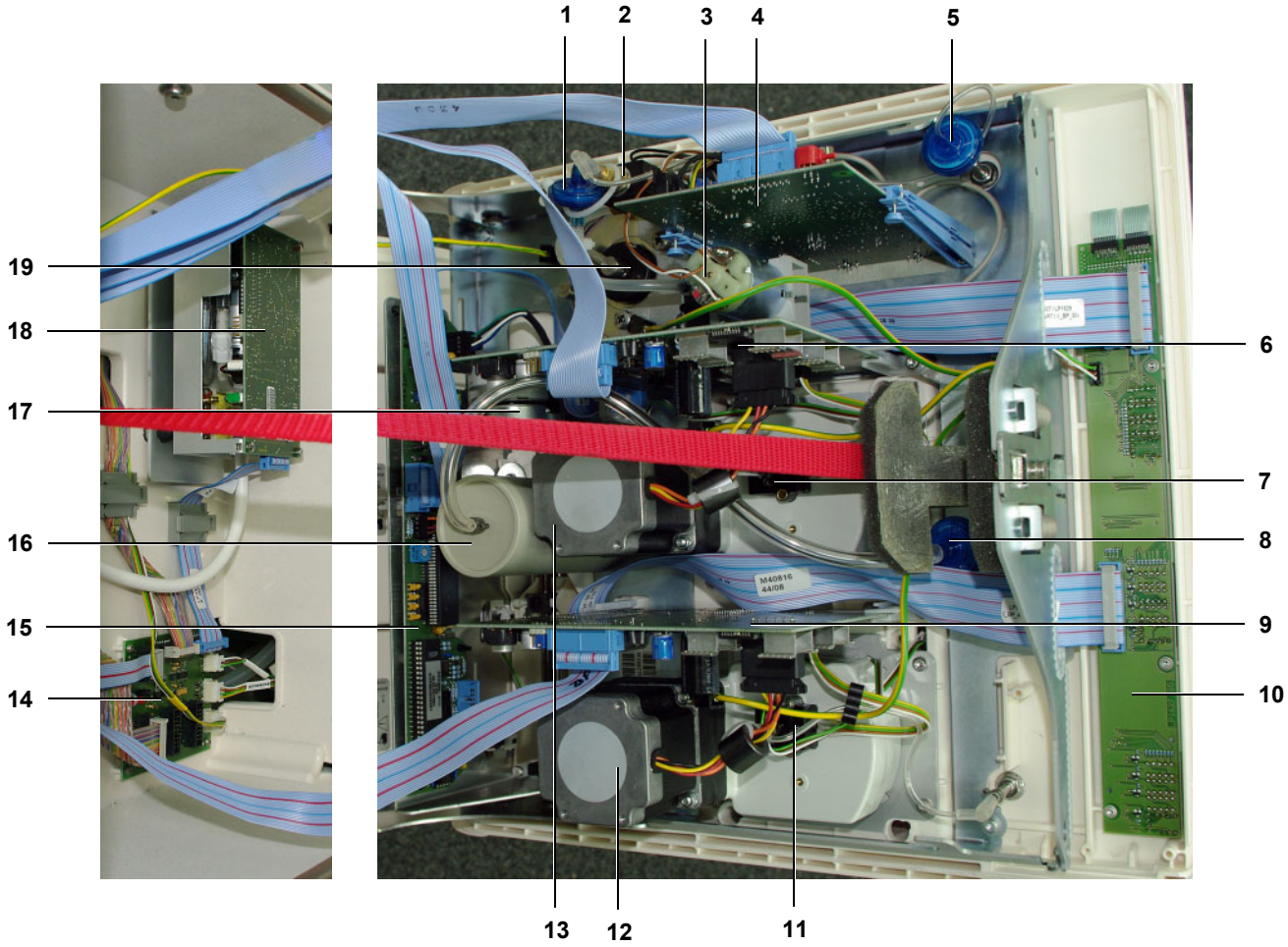
10.3 Component overview

10.3.1 Monitor



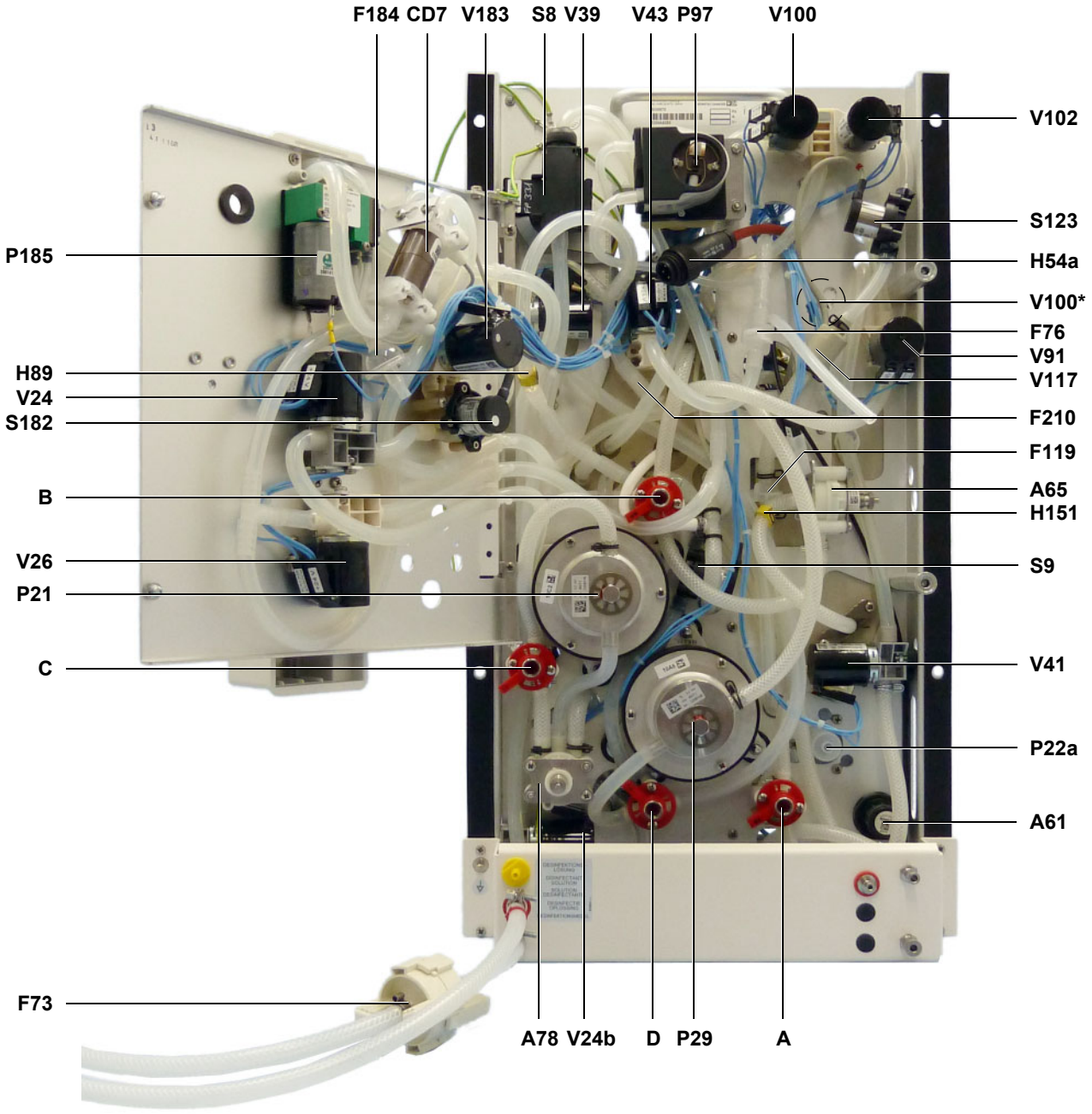
1	Operation status indicator (traffic light) with P.C.B. LP 1131	**6**	P.C.B. LP 922 Display board
2	P.C.B. LP 763 Interface board	**7**	P.C.B. LP 633-5 Input board
3	P.C.B. LP 634 Output board	**8**	P.C.B. LP 1631 CPU 1
4	P.C.B. LP 630 Motherboard	**9**	P.C.B. LP 632 CPU 2
5	MDC-II board	**10**	P.C.B. LP 636 External connectors

10.3.2 Extracorporeal Blood Circuit Module (EBM)



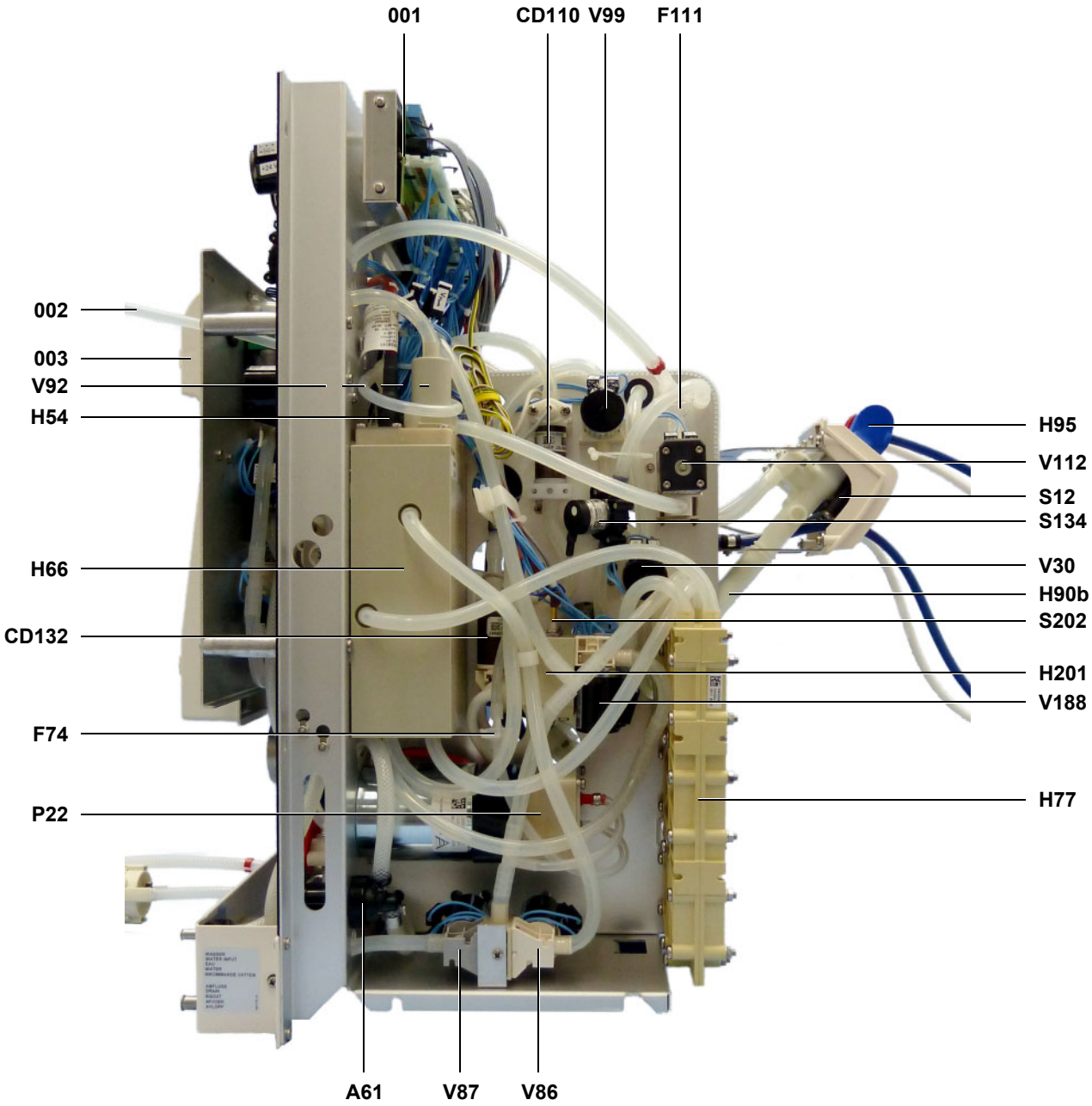
1	Hydrophobic filter with 0.25 mm hole	**11**	Arterial pressure transducer
2	Ventilation valve	**12**	Arterial blood pump stepper motor
3	Compressor	**13**	SN blood pump stepper motor (optional)
4	P.C.B. LP 450-2 for air detector	**14**	P.C.B. LP 1628 Distributor
5	Venous hydrophobic filter	**15**	P.C.B. LP 950 for heparin pump
6	P.C.B. LP 624 Single-Needle blood pump (optional)	**16**	Compliance chamber
7	Single-Needle pressure transducer (optional)	**17**	Heparin pump drive
8	SN hydrophobic filter (optional)	**18**	BPM module (optional)
9	P.C.B. LP 624 Arterial blood pump	**19**	Rotary magnet, venous occlusion clamp
10	P.C.B. LP 1627 Display		

10.3.3 Hydraulics rear



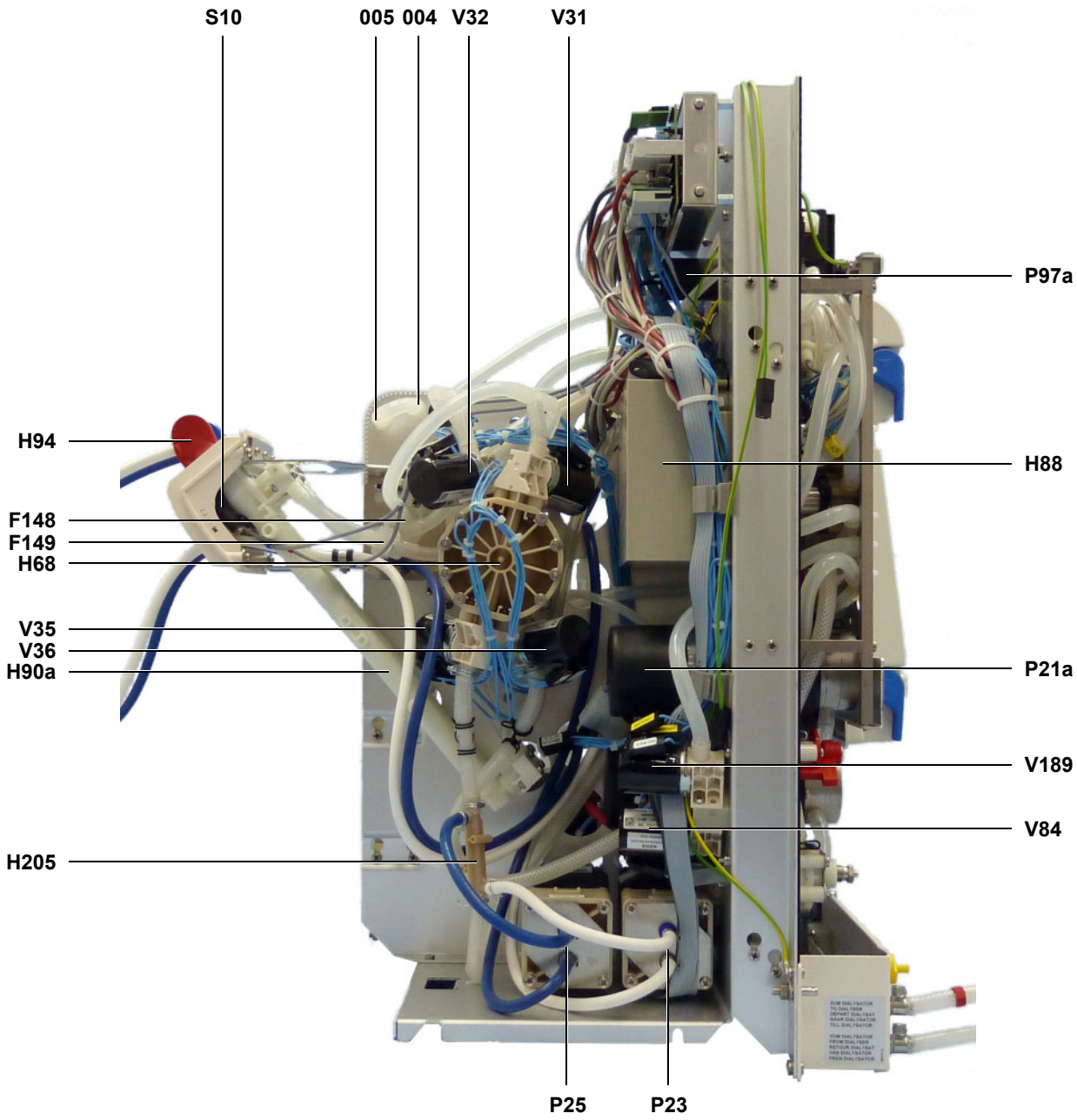
Hydraulics legend (see chapter 10.3.6 page 10-8)

10.3.4 Hydraulics, lateral view from the left



Hydraulics legend (see chapter 10.3.6 page 10-8)

10.3.5 Hydraulics, lateral view from the right



Hydraulics legend (see chapter 10.3.6 page 10-8)

10.3.6 Hydraulics legend

Hydraulics measurement points

A	Reduced water inlet pressure
B	Loading pressure
C	Flow pump pressure
D	Degassing pump pressure

Setting elements

A61	Pressure reducing valve
A65	Loading pressure valve
A78	Relief valve

Conductivity cells

CD7	Conductivity measuring cell
CD110	OCM conductivity cell
CD132	bi*b*ag® conductivity cell

Filter

F71	Filter / concentrate (in H94)
F72	Filter / bicarbonate (in H95)
F73	Filter / dialysate
F74	Filter / UF
F76	Filter / fill valve
F111	Hydrophobic filter
F119	Concentrate filter
F148	Filter (rinse valve 100)
F149	Filter (rinse valve 99)
F184	Hydrophobic filter
F210	Filter

Hydraulic components

H54	Heater rod
H54a	Heater rod connection
H66	Heater block
H68	Balancing chamber
H77	Heat exchanger
H88	Multifunction block
H89	Degassing orifice
H90a	Concentrate rinse chamber
H90b	Bicarbonate rinse chamber
H94	Concentrate suction tube
H95	Bicarbonate suction tube
H151	Control valve
H201	Air separation chamber, concentrate
H203	Air separation chamber, bicarbonate (hidden by H201)
H205	Mixing point (concentrate/bicarbonate)

Pumps

P21	Flow pump
P21a	Flow pump drive
P22	UF pump
P22a	UF pump adjusting screw
P23	Concentrate pump
P25	Bicarbonate pump
P29	Degassing pump
P97	Air separation pump
P97a	Air separation pump drive
P185	Compressor

Temperature sensors

PT2	Temperature sensor (in H66)
PT3	Temperature sensor (in CD7)
PT4	OCM temperature sensor (in CD110)
PT109	Temperature sensor (in CD7)
PT133	bi*b*ag® temperature sensor (in CD132)

Other sensors

S5	Float switch (in H66)
S6	Level sensor (in H88)
S8	Blood leak detector
S9	Pressure transducer
S10	Concentrate reed contact
S12	Bicarbonate reed contact
S115	Disinfection valve sensor (hidden, on V84)
S123	Pressure switch for V102
S134	bi*b*ag® pressure transducer
S182	Pressure transducer 2
S202	Concentrate level sensor
S204	Bicarbonate level sensor (hidden by S202)

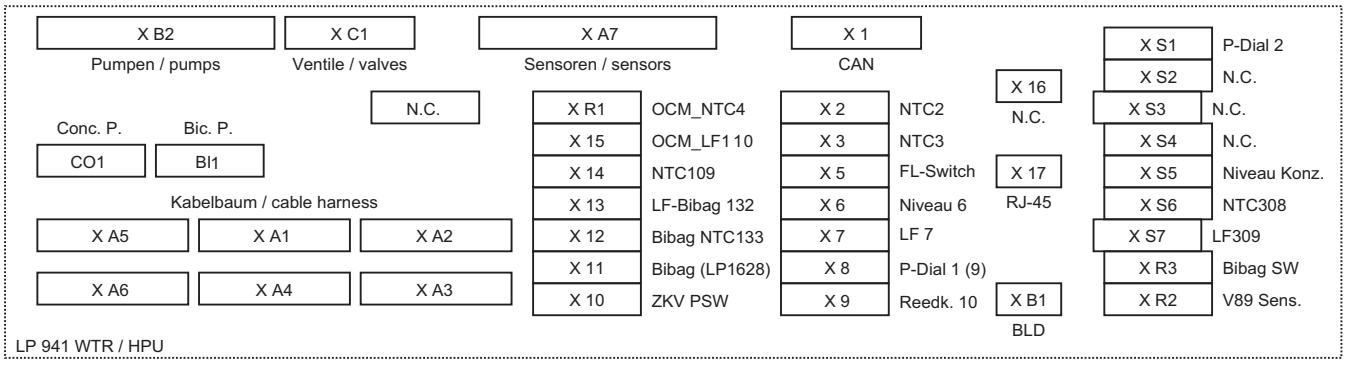
Valves

V24	Dialyzer inlet valve
V24b	Dialyzer outlet valve
V26	Bypass valve
V30	Outlet valve
V31	Balancing chamber valve 1
V32	Balancing chamber valve 2
V33	Balancing chamber valve 3 (hidden by V31)
V34	Balancing chamber valve 4 (hidden by V32)
V35	Balancing chamber valve 5
V36	Balancing chamber valve 6
V37	Balancing chamber valve 7 (hidden by V35)
V38	Balancing chamber valve 8 (hidden by V36)
V39	Negative pressure valve
V41	Water inlet valve
V43	Fill valve
V84	Disinfection valve
V86	Recirculation valve
V87	Drain valve
V91	Rinse valve
V92	Ventilation valve
V98	Rinse valve
V99	Rinse valve
V100	Rinse valve
V100*	Alternative V100 location if the CDS option is not provided
V102	Central concentrate delivery valve (optional)
V112	Ventilation valve
V117	Concentrate check valve
V130	bi*b*ag® emptying valve (hidden by V188)
V183	Test valve
V188	Evacuation valve
V189	Retentate valve

Miscellaneous

001	Hydraulic processing unit
002	Overflow tube
003	DIASAFE® *plus* connector
004	Port to bi*b*ag® connector
005	Port from bi*b*ag® connector
V92	Ventilation valve

10.3.7 Assignment of the hydraulic processing unit (HPU)



10.4 Assembly of components

10.4.1 Self-cutting screws

Many components are screwed into the plastic housing by means of self-cutting screws.

To be observed when screwing in the screws:

1. Screw-in the screw in axial direction. Screw head and component surfaces must be in parallel, positioned one upon the other.
2. Do not groove a new thread.

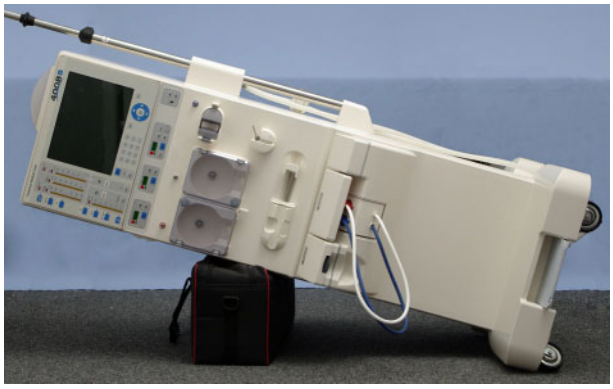
In order to do so, turn the attached screw anti-clockwise with slight pressure until a slight locking into the thread can be felt. While applying only little force, turn the screw clockwise until it screws into the thread.

10.4.2 Torques

All electromagnetic valves:	**1.2 Nm**
Drive of gear pumps and anti-vibration mounts:	**6.5 Nm**
Gear pumps (pump on drive), membrane pumps, UF pump, heat exchanger:	**1.2 Nm**
Potential equalization bolt:	**6.5 Nm**
Luer-Lock:	**2.3 Nm**
Rotary magnet and heat conduction plate:	**1.3 Nm**
Heating block with float switch:	**1.5 Nm**

10.5 Housing and cart

10.5.1 Tilting the device

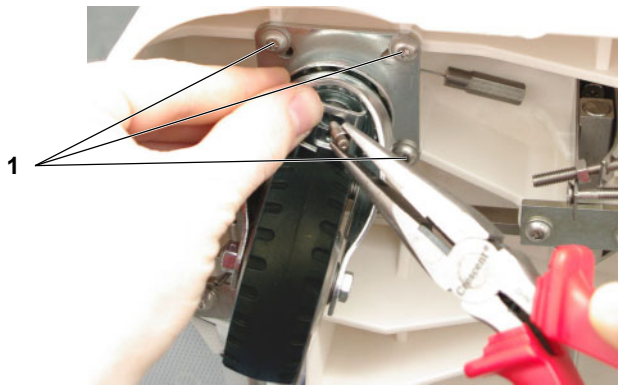


Place a padded object on the floor and tilt the device to the left onto that object.

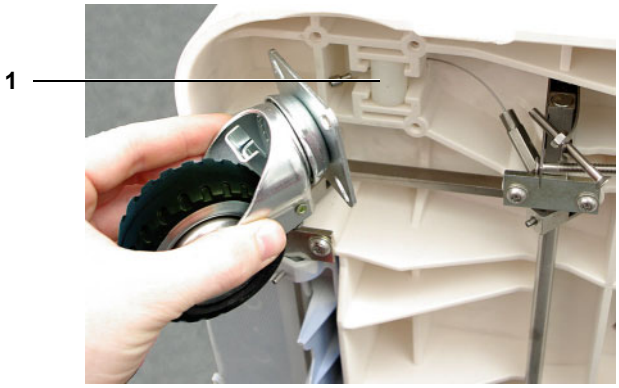
If the device is provided with the BPM option, remove the cuff and shelf beforehand. Ensure that the pressure port does not touch the floor or the padded object so as to prevent it from getting damaged.

10.5.2 Brake rollers

Unscrew the lock nut (**2**) and the brake cable (**1**).



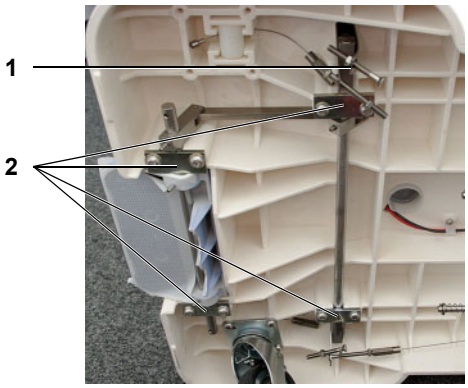
Slightly press on the brake and unmount the brake cable. Then dismount the brake roller by unscrewing the 4 screws (**1**).



Dismount the brake roller. Remove the guide roller (**1**) underneath.

Ensure that only one brake roller model is installed (flat brake roller / shaped brake roller).

10.5.3 Brakes



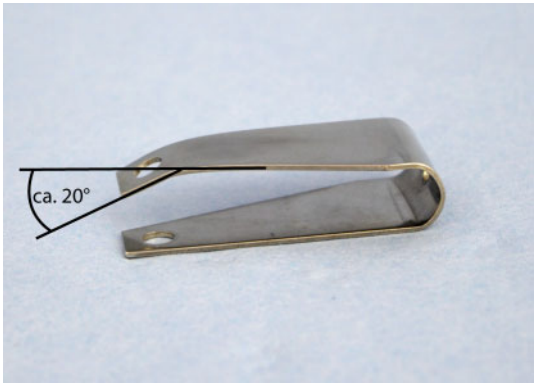
Detach all brake cables from the screws.

Remove the lock nuts and screws from the spring plates (**1**). Short forward cables with M5x45 flat head screws; long rearward cables with M5x55 flat head screws.

Remove 4 clamping strips (**2**) with 2 screws each.

Remove the brake shaft with brake pedal (**1**).

The spring plates can each be removed with 1 screw.

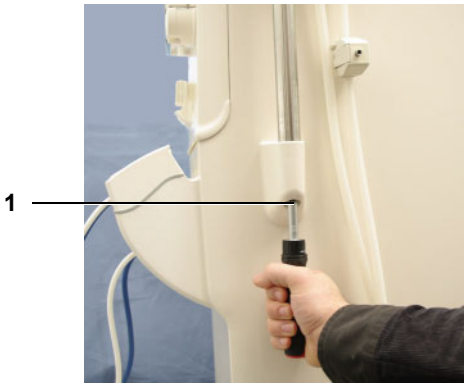


If a spring plate is replaced, one of its sides must be chamfered by approx. 20°.

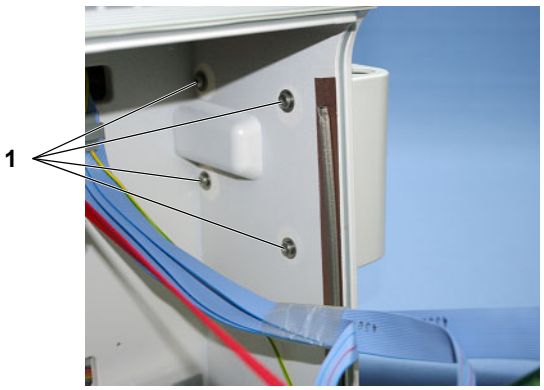
To adjust the brake, tighten the screw in the brake cable while moving the roller until you feel the brake action. Turn the screw back until the roller is again free to move. Lock the nut to secure the position.

10.5.4 Shunt interlock

10.5.4.1 Shunt interlock complete



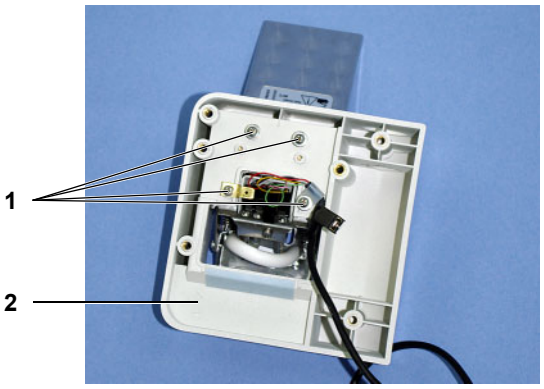
Remove the screw (**1**) and pull out the IV pole to the top.



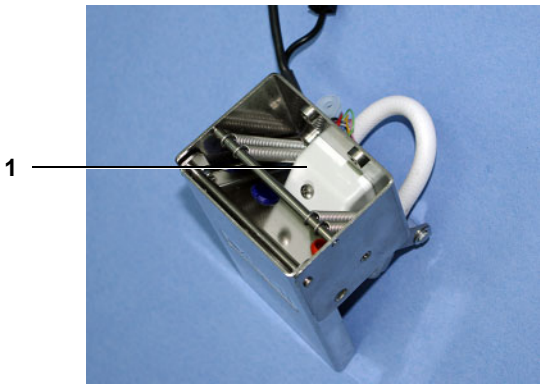
Pull off the shunt interlock connector from the monitor and open the cable tie if necessary. Open the EBM (see chapter 10.9.1 page 10-42), and unscrew the shunt interlock from the device with 4 screws **1**.

➢ After replacement or repair, check the following:
– Function
– Switching states in the Diagnostics menu
– Color coding

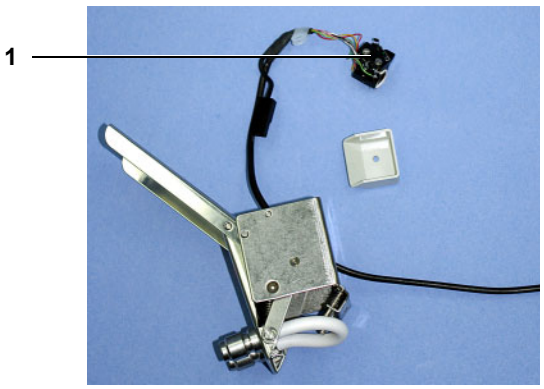
10.5.4.2 Microswitch



Unscrew 4 screws (**1**) and remove the shunt interlock housing (**2**).



Unscrew the microswitch covering (**1**).



Pull out the microswitch (**1**) including cable to the top.

10.6 Power supply unit and battery

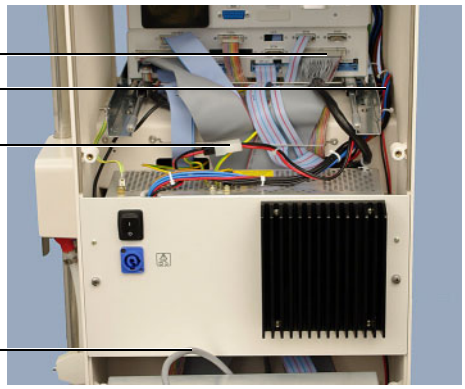
10.6.1 Removing the power cable

Unscrew the microswitch securing bolt (**1**).

Pull back the detent mechanism (**1**), turn the connector to the left until it stops, and pull off the connector.

When installing, check the detent mechanism.

10.6.2 Power supply unit

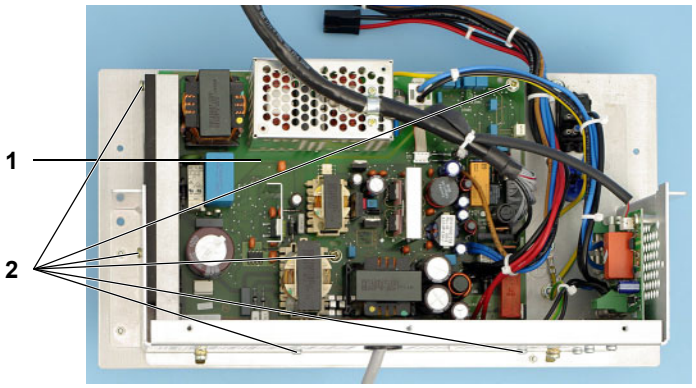


Pull off the cable from the monitor (**1**) and the cable from the motherboard (**2**), disconnect the heater rod cable (**4**), disconnect the EBM power supply (**3**), pull off or unscrew the ground cables, remove 2 screws, and pull the power supply unit out of the housing to the rear.

After replacement or repair, check the voltages in the calibration menu, calibrate the temperature, and check the temperature.

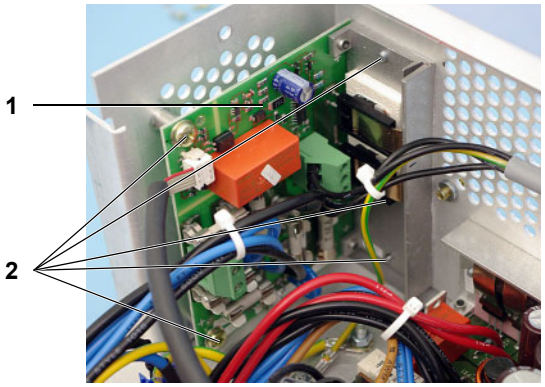
10.6.2.1 Power board

Unscrew the cover plate (**1**) with 4 screws (**2**).



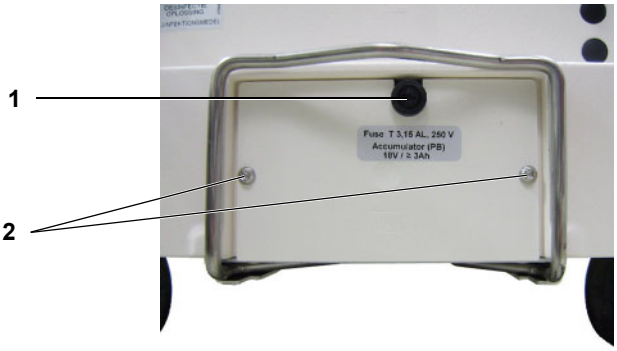
Pull off the cable from the power board (**1**), remove 6 screws (**2**), and dismount the power board.

10.6.2.2 Heater board



Disconnect all cables from the heater board (**1**). Remove 5 screws (**2**) and dismount the heater board.

10.6.3 Battery

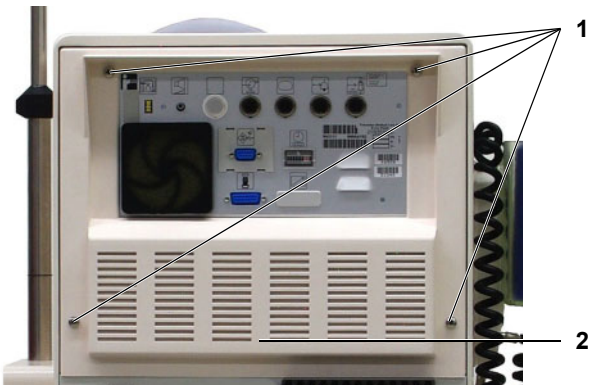


The battery and the battery fuse (**1**) are located on the rear bottom of the hemodialysis device, behind the disinfectant container holder. Remove the screws (**2**) to dismount the battery.

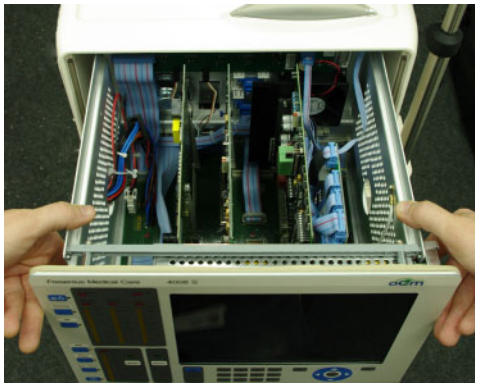
Observe polarity when changing the accumulator.
Connect up as shown in the following figure.

10.7 Monitor

10.7.1 Opening the monitor

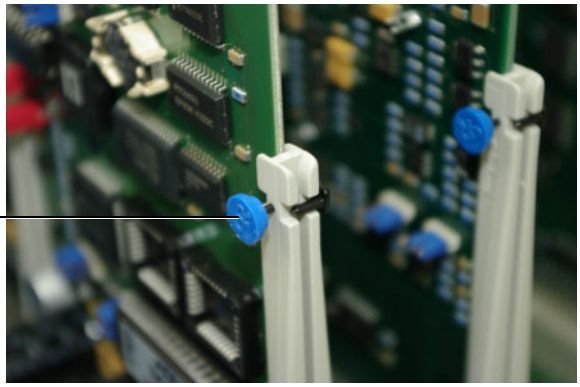


Remove the screws (**1**) and the cover (**2**) and push the monitor to the front.



Slightly press the side panels outwards and open the monitor front.

10.7.2 Removing and installing the printed circuit boards

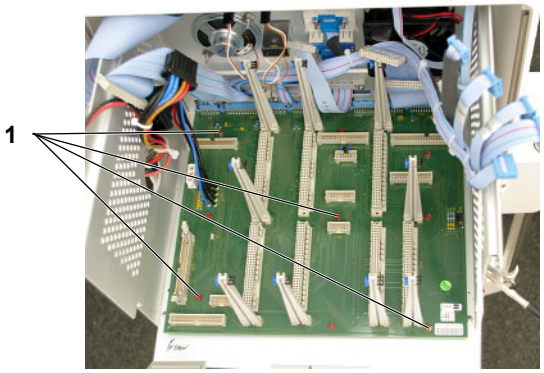


Before removing the fitted printed circuit boards (P.C.B.s LP 1631, LP 632, LP 633-5, LP 634, LP 763), unlock the P.C.B. securing mechanism (**1**) by pressing the blue button.

Note

When replacing the P.C.B.s, the **Calibration and test steps after repair** (see chapter 10.10 page 10-51) must be observed.

10.7.3 P.C.B. LP 630 Motherboard

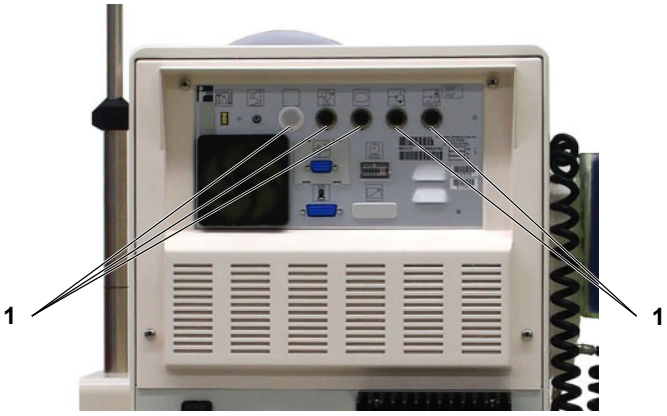


Remove the plug-in boards from the monitor. Pull off all cables from P.C.B. LP 630. Unscrew P.C.B. LP 630 with 9 nuts (**1**).

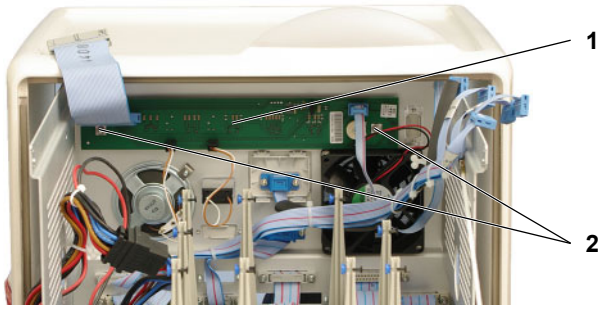
When installing, secure the nuts with anti-tamper fixing.

After replacement or repair, check the jumpers.

10.7.4 P.C.B. LP 636 External I/O board



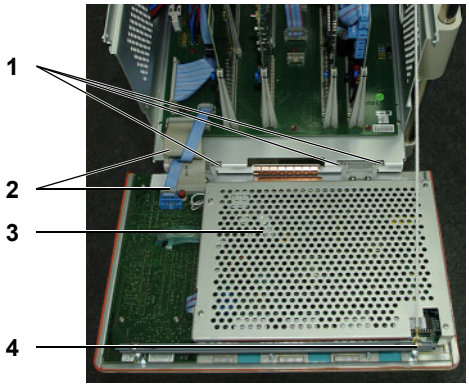
Remove 5 screw caps (**1**) from the rear of the monitor.



Pull off all cables from P.C.B. LP 636 (**1**). Remove 2 nuts (**2**) and remove P.C.B. LP 636.

10.7.5 Display

10.7.5.1 Removing the complete front panel



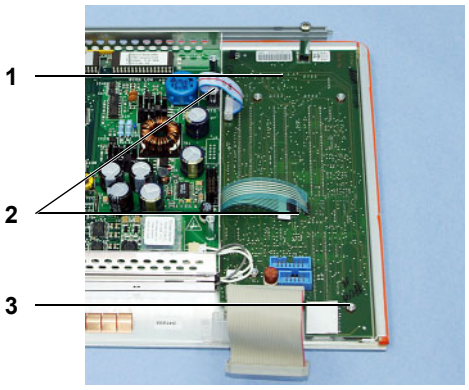
Pull off the cables (**2**). Remove the screw (**4**) and the holding cord.

Press back the detent mechanisms (**1**) and remove the front panel from the device.

Unscrew the perforated plate (**3**) with 4 screws.

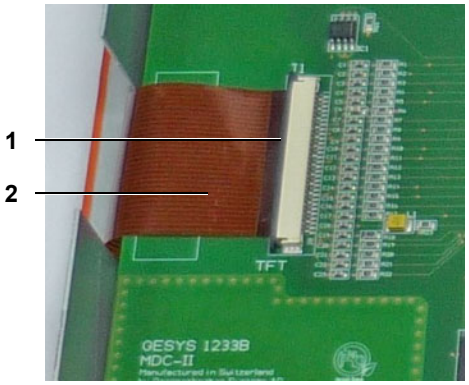
After replacement or repair, run the display test and the key test.

10.7.5.2 P.C.B. LP 922



Pull off the 3 cables (**2**), remove the 4 nuts (**3**), and dismount P.C.B. LP 922 (**1**).

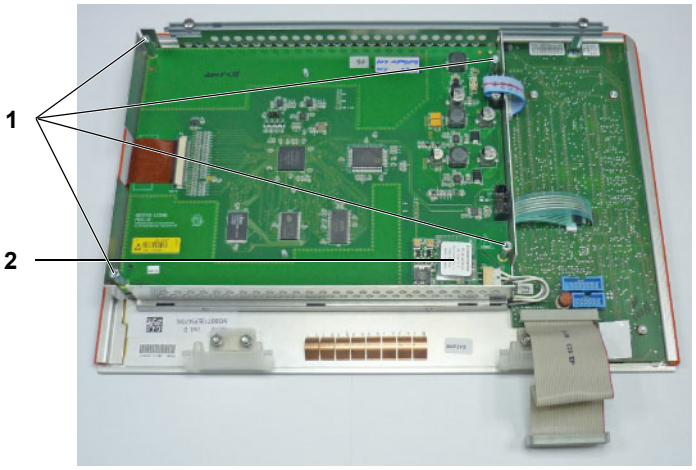
10.7.5.3 MDC-II board and backlight inverter



Pull off the cables from the MDC-II board.

Pull back the closure (**1**) from the 30-pin display cable (**2**), and pull out the cable.

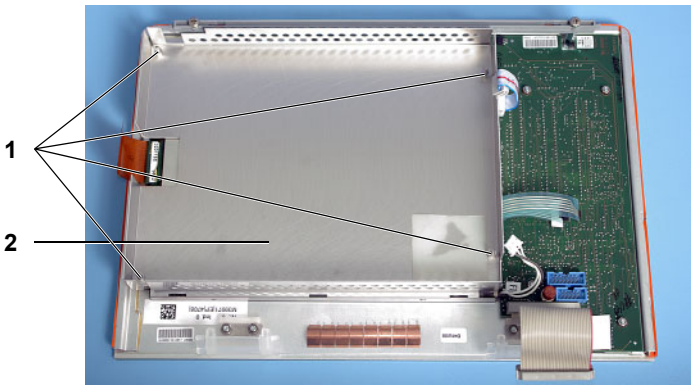
When installing, insert the cable deeply; then close the closure.



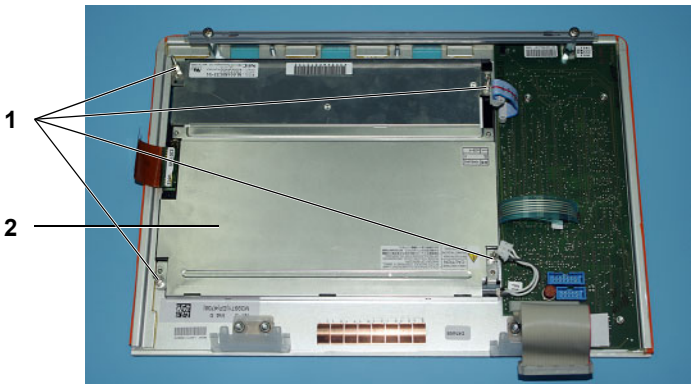
Screw off the 4 threaded rods (**1**) and lift out the MDC-II board.

The backlight inverter (**2**) can be soldered off from the bottom side of the MDC-II board.

10.7.5.4 TFT display

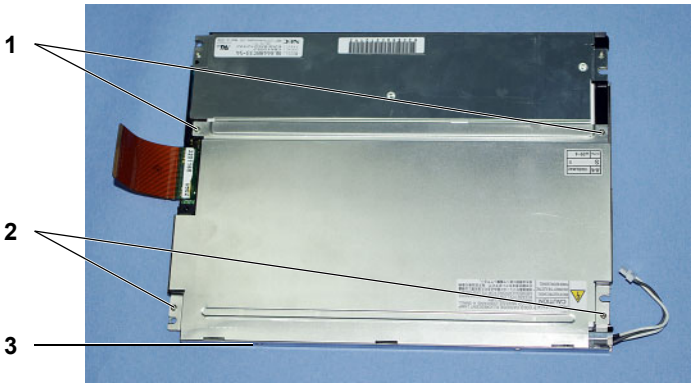


Remove the spacing bolts and screws (**1**), and lift out the sheet (**2**).



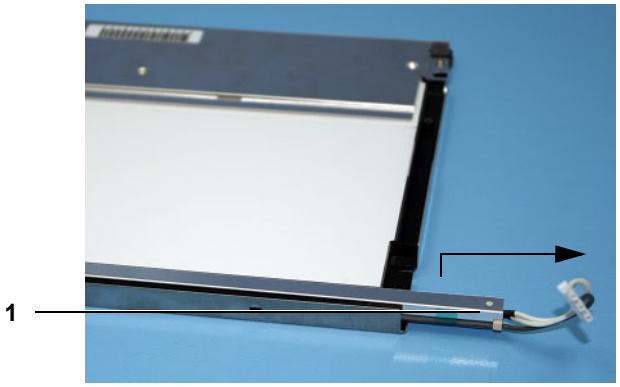
Pull off the ribbon cable, remove the threaded rods with 2 washers (**1**) each, and lift out the TFT display (**2**).

10.7.5.5 Backlighting



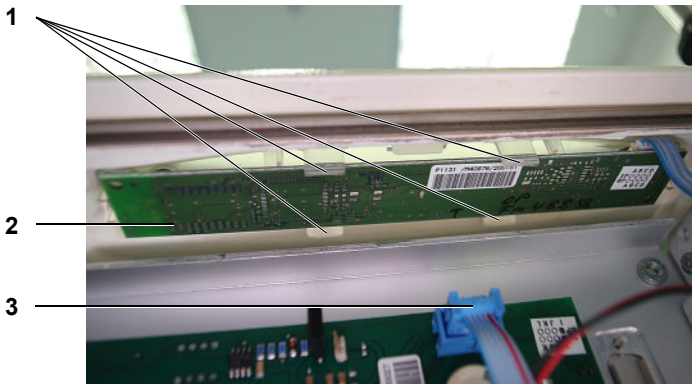
Remove the screws (**2**) and self-cutting screws (**1**), and press in the detent mechanism (**3**).

Lift the display (**2**) a little out of the frame (**3**), and remove the rear plate (**1**) while turning the display.

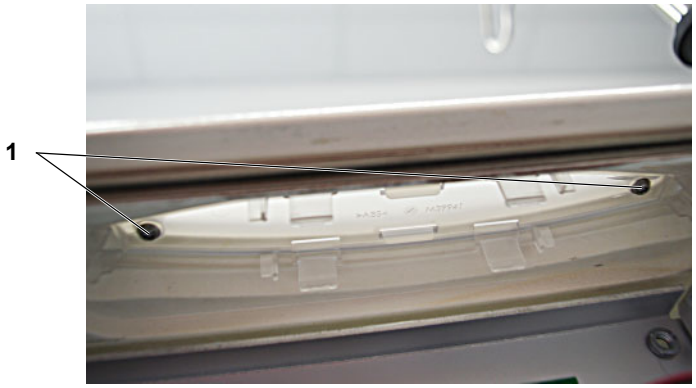


Lift up the backlight (**1**) a little at the sides and pull it out of the TFT display.

10.7.6 Operation status indicator (traffic light)



Remove the plug-in boards from the monitor. Pull off the connector (**3**) from P.C.B. LP 636. Press back the detent mechanisms (**1**) and remove P.C.B. LP 1131 (**2**).

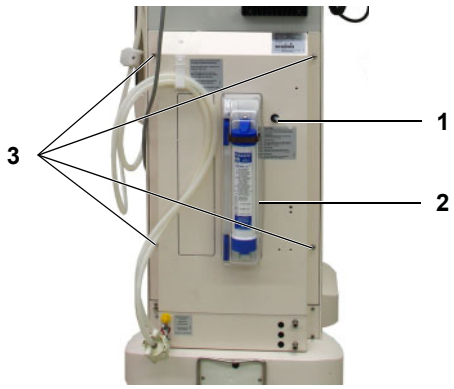


Unscrew the screws (**1**) to remove the status indicator housing.

After replacement or repair, check the flows.

10.8 Hydraulics unit

10.8.1 Completely removing the hydraulic unit



Remove the DIASAFE® cover (**2**), unscrew 4 screws (**3**), remove the rear wall.

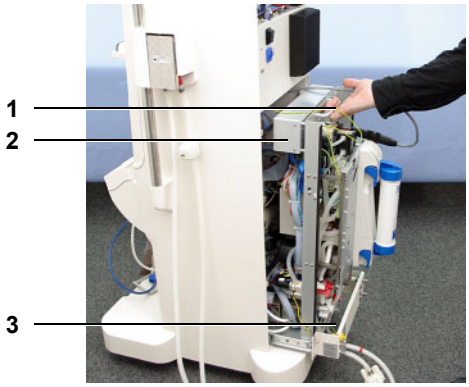
When installing, place the overflow tube (**1**) through the opening.

Warning

Improper placing of the overflow tube will impede the exit air and overflow of the hemodialysis device.

Defect in the hydraulics unit

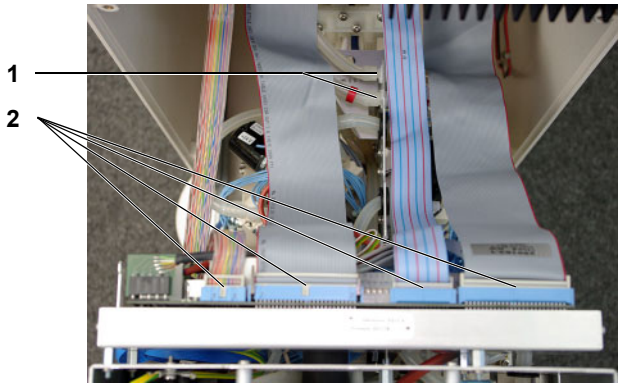
When closing the hydraulics rear wall, always place the overflow tube through the opening provided. Do not kink or squeeze the tubing inside.



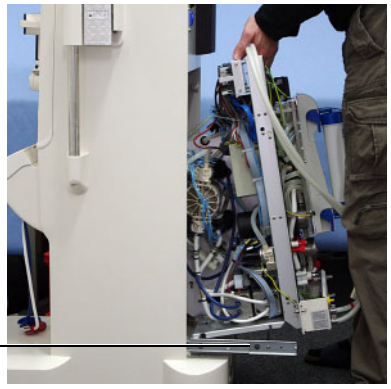
Pull out the suction rods. Pull out the hydraulics unit at the handle (**1**). Pull off the ground cable in the housing. To ensure stability, fold down the hydraulics unit stand (**3**).

Press the buttons on the side to open the cover of the HPU (**2**) and remove the cover.

When installing, thread the concentrate tubes outwards while ensuring that the rinse chamber seal is properly seated.

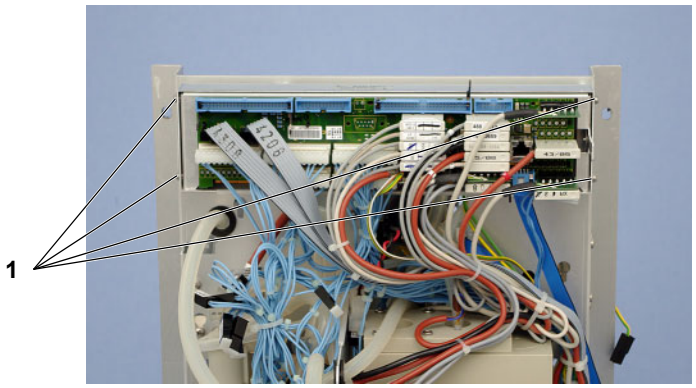


If necessary for repair purposes, you can also completely remove the hydraulics unit from the device. To do so, pull the connecting cables (**2**) from the HPU, disconnect the heater rod cables, and pull the tubes running to the bi*b*ag® connector (**1**).



First lift the hydraulics unit out of its guide (**1**) at the rear, then lift it out completely.

10.8.2 P.C.B. LP 941 HPU with distribution bar



Press in the the buttons (**1**) on the side and pull off the cover.

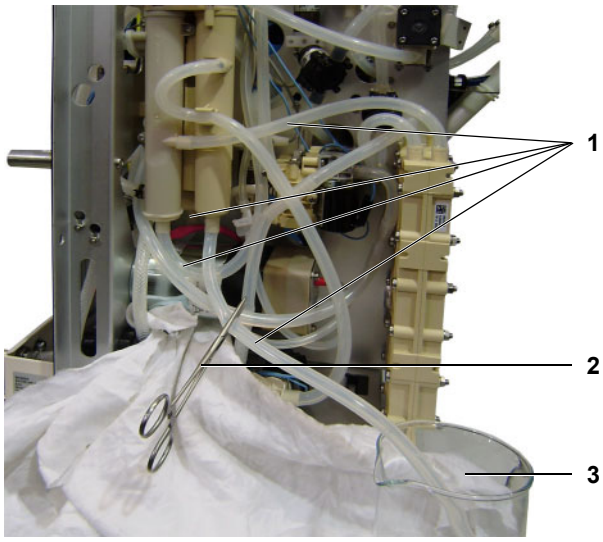
To remove P.C.B. LP 941, pull off all cables, press in the side buttons deeply, and pull out the HPU. Connector pin assignment (see chapter 10.3.7 page 10-9).

After replacement or repair, calibrate PDial2 and adjust the TMP.

10.8.3 Heater block, heater rod and float switch

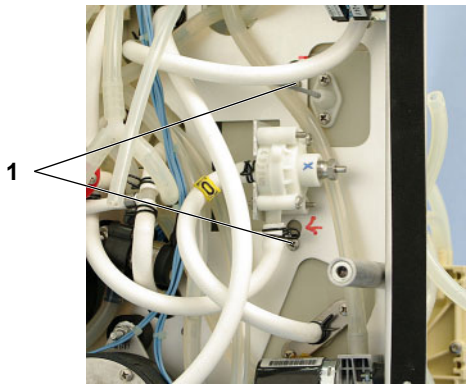
10.8.3.1 Heater block complete

● **Removal**



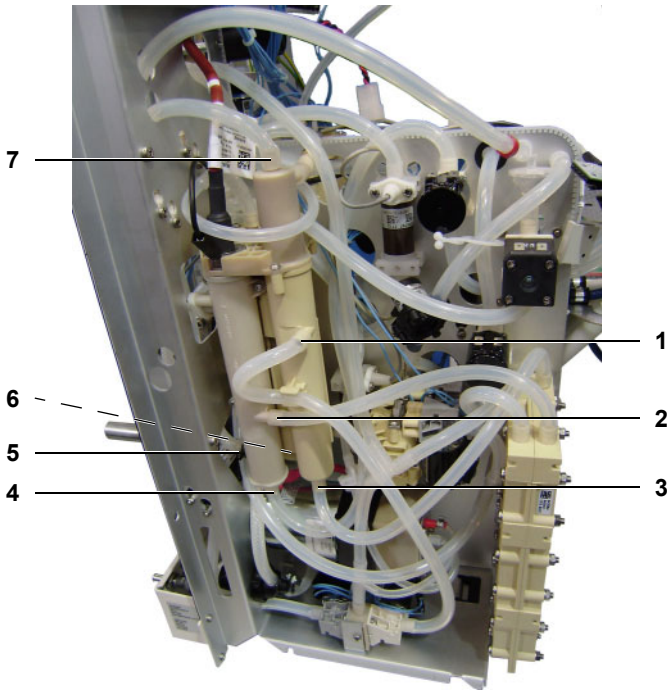
To disassemble the heating block completely, proceed as follows:

– Pull the float switch plug and the PT2 temperature sensor out of the HPU.
– Pull the float switch cable and the PT2 temperature sensor cable out of the cable harness.
– Protect the components underneath the heater block from leaking fluid with a cloth.
– Disconnect each tube **(1)** with a tube clamp **(2)**.
– Pull the tubes **(1)** off the respective components.
– Insert all tube ends into a collection vessel **(3)**.
– Open the tube clamp (**2**) and collect the fluid.
– Pull off all other tubes from the heater block.
– Seal off all tubes with plugs.



– Unscrew 2 screws (**1**).
– Lift the heating block slightly and remove it.

● **Installation**



Install the BPM in reverse order.

When installing, ensure proper tubing arrangement:

1 to valve V86

2 to heat exchanger input

3 to heat exchanger output

4 to valve V99

5 to orifice H151

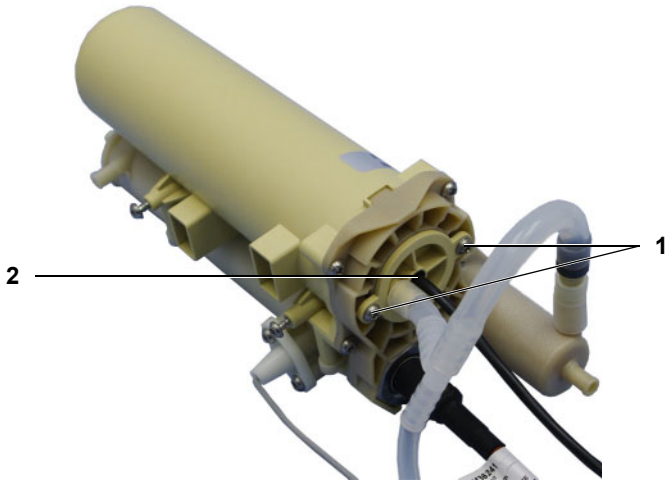
6 to filter 210

7 to valve V41

After replacement or repair, check the temperature.

10.8.3.2 Float switch

● **Removal**



To remove the float switch, complete the following tasks:

– Remove the 2 screws (**1**).
– Pull out the float switch **(2)**.

● **Installation**

Install the BPM in reverse order.

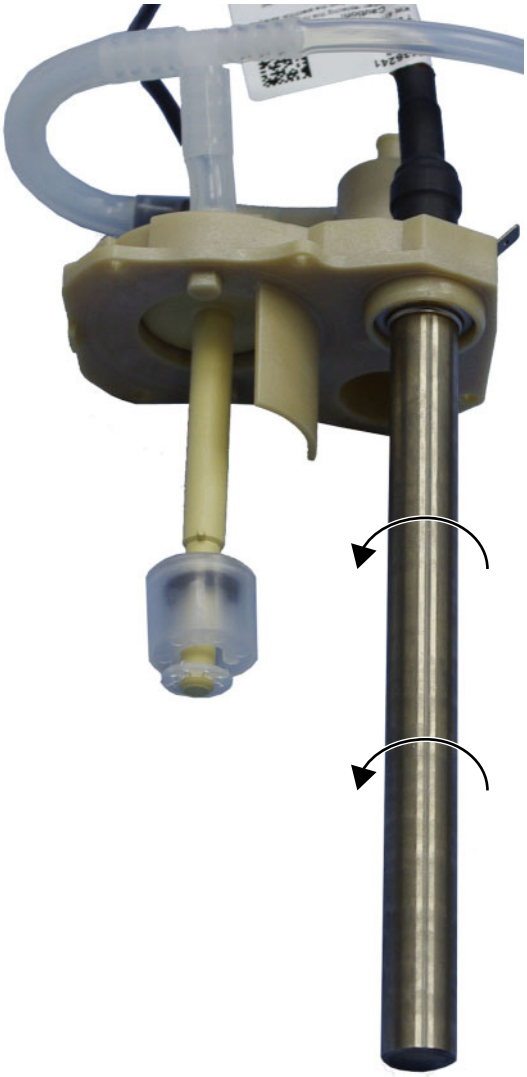
When re-installing, check the following:
– Ensure the seal **(1)** is properly inserted.
– Ensure the tabs **(2)** point in the direction of the float switch.
– Observe the wrench torque (see chapter 10.4.2 page 10-10).

10.8.3.3 Heater rod

● **Removal**

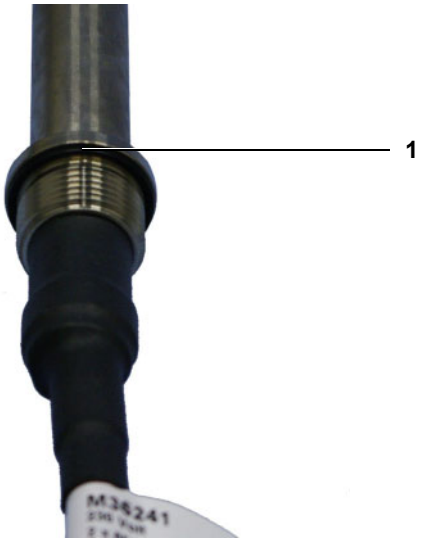
To disassemble the heating rod, proceed as follows:
– Remove 5 screws **(1)** from the heating block cover.
– Pay attention to the seals and carefully remove the heating block cover.

– Unscrew the strain relief (**1**) from the cap (**2**).
– Unscrew the cap (**2**) from the connector (**3**).
– Open the connector's strain relief.
– Release the cable wires **(4)**.
– Expose the cables.

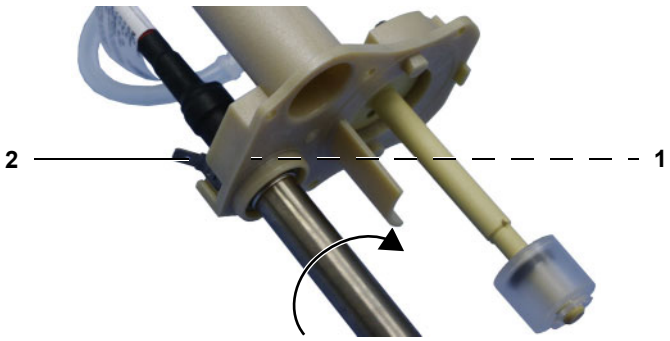


– Turn the heating rod counterclockwise.
– Remove the heating rod.

● **Installation**



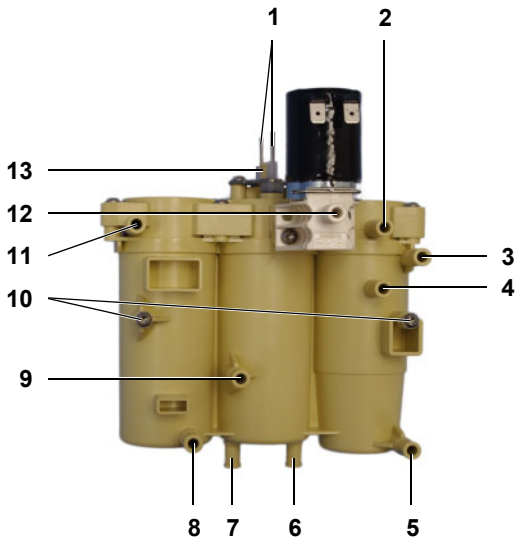
When re-installing, proceed as follows:
– Insert the new seal correctly.



– Insert the nut **(1)** with protective conductor **(2)** as shown in the illustration.
– Insert the heating rod.
– Turn the heating rod clockwise hand tight.
– Install the heating rod connector.

– Seals **(1)** are inserted correctly.
– Replace the heating block cover.
– Tighten the 5 screws with the appropriate torque
(see chapter 10.4.2 page 10-10).

10.8.4 Multifunction block



Pull off the cable from V43 (**12**) and the level sensor (**1**).

Protect the other hydraulic components from leaking fluid. Pull off the tubes and collect the fluid (see chapter 10.8.3.1 page 10-25).

Unscrew 2 screws (**10**) and remove the multifunction block.

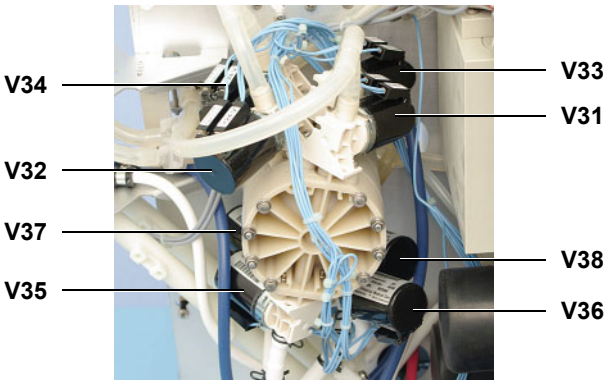
When installing, ensure proper tubing arrangement.

After replacement or repair, run the degassing test and the fill program.

Legend, multi-function block

1 Level sensor
2 to pressure measuring point B
3 to degassing pump P29
4 to valve V91
5 to dosing point H205
6 to pressure transducer S9
7 to filter F74 / sensor S115
8 to V39 / orifice H89
9 to CD cell CD110
10 Screws
11 to pressure measuring point D
12 V43, to filter F76
13 to air separation pump P97

10.8.5 Balancing chamber



Pull off the tubes and cables from the valves. Unscrew the screws and remove the balancing chamber. When installing, ensure proper tubing arrangement according to flow diagram and proper wiring.

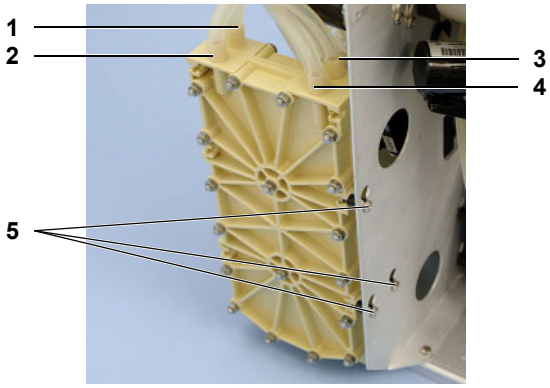
After replacement/repair, you must perform the following steps for balancing chambers **with** a volume label:

– Read off and calibrate the chamber volume from the balancing chamber (see chapter 9.1.25 page 9-21)
– Check flows
– Check conductivity

After replacement/repair, you must perform the following steps for balancing chambers **without** a volume label:

– Measure and calibrate the chamber's volume in liters (see chapter 9.1.25 page 9-21)
– Check flows
– Check conductivity

10.8.6 Heat exchanger



Pull off the tubes, unscrew the screws (5), lift the heat exchanger a little and remove it.

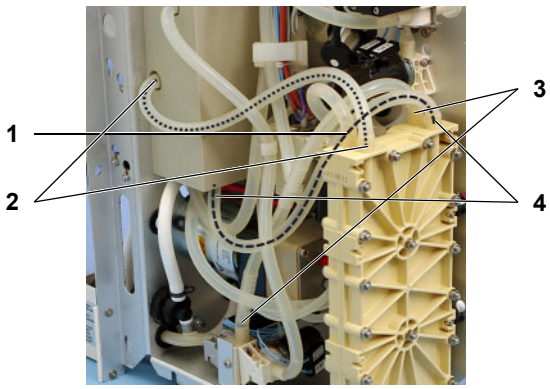
The heat exchanger is operated based on the counter-current principle:

1 Inlet of chamber A

2 Outlet of chamber B

3 Outlet of chamber A

4 Inlet of chamber B



When installing, ensure proper arrangement of the tubes:

1 to valve V30

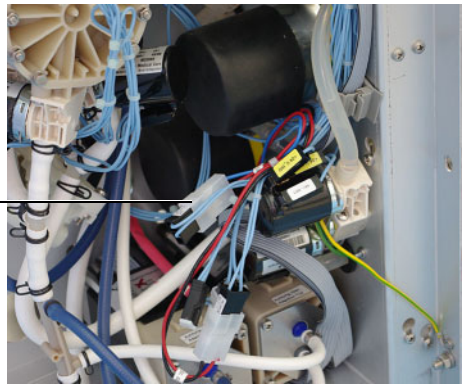
2 to inlet of heater block H66b

3 to valve V87

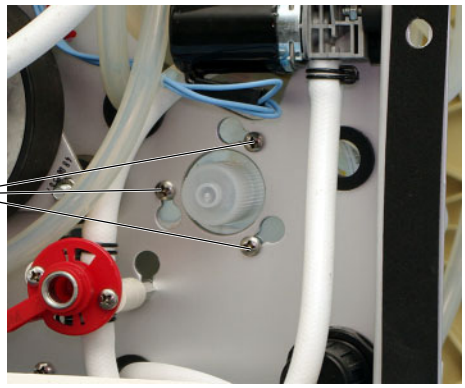
4 to outlet of heater block H66a

After replacement or repair, check the flows.

10.8.7 UF pump

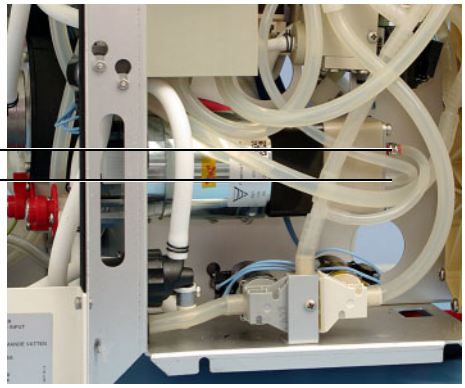


Pull off the marked connecting cable 22 (**1**).



Unscrew 3 screws (**1**), and turn and remove the UF pump.

After replacement or repair, measure the UF pump volume in liters.

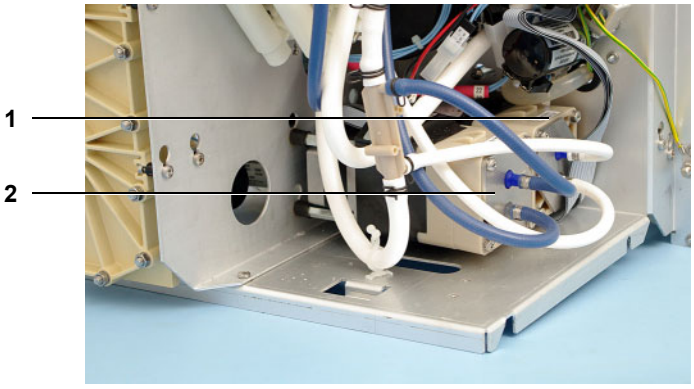


When installing ensure that the pump outlet (red) faces upwards and the tubing arrangement is correct:

1 Outlet (red) to V86 / V87 / heat exchanger

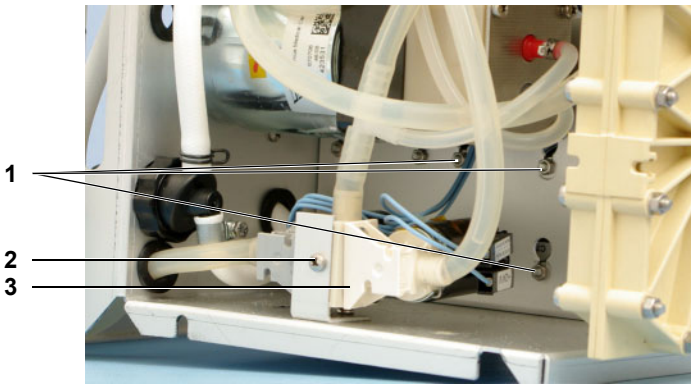
2 Inlet (white) to filter F74

10.8.8 Membrane pump (Conc/Bic)

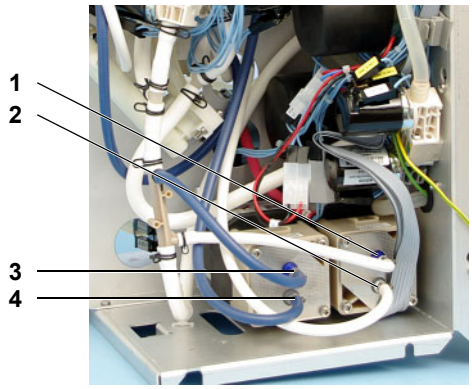


Remove the tubes.

Pull off the cable from the HPU; slot CO1 for concentrate pump (**1**), slot BI1 for bicarbonate pump (**2**).



Remove the screw (**2**) and press the valve block (**3**) to the side. Unscrew 4 nuts (**1**), lift the membrane pump a little and remove it.



When installing, ensure that the pump outlet (blue) faces upwards and secure the tubes with new tube clamps.

Concentrate pump tubing:

1 Outlet (blue) to dosing point H205

2 Inlet (white) to air separation chamber H201

Bicarbonate pump tubing:

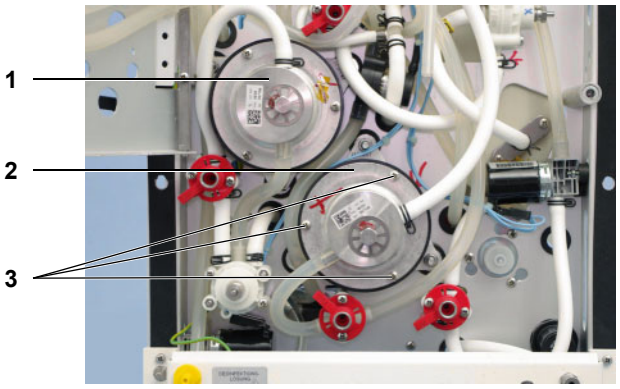
3 Outlet (blue) to dosing point H205

4 Inlet (white) to CD cell CD132

After replacement or repair, measure the membrane pump volume in liters, calibrate, check conductivity.

10.8.9 Gear pump

10.8.9.1 Pump

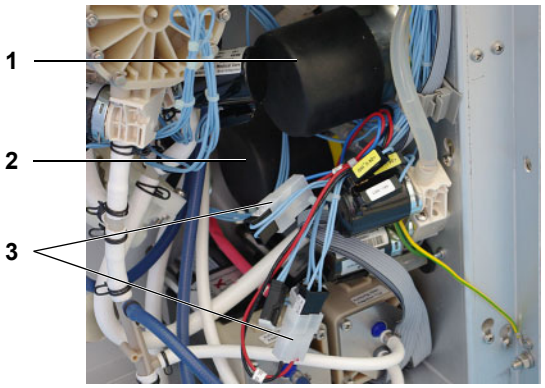


Unscrew the flow pump (**1**) and degassing pump (**2**) with 3 screws (**3**).

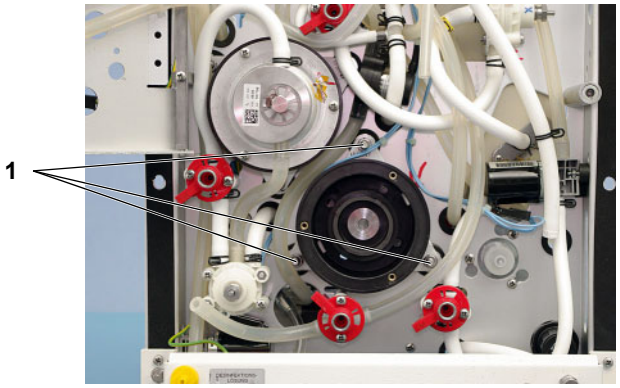
After replacement or repair of the flow pump, set the flow rates, check the relief pressure, and adjust the current increase.

After replacement or repair of the degassing pump, set the degassing and loading pressures.

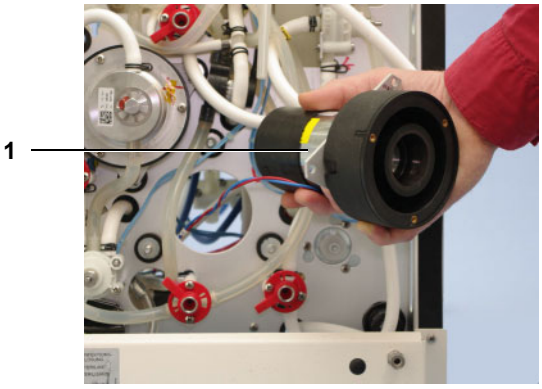
10.8.9.2 Motor



Pull off the marked connecting cable (**3**) from the motor; cable 29 for degassing pump (**2**), cable 21 for flow pump (**1**).



Unscrew the motor with 3 nuts using a saw ring (**1**).

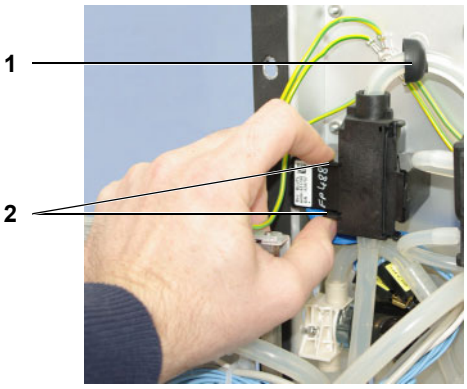


Pull out the motor (**1**) including cable.

After replacement or repair of the flow pump motor, set the flow rates, check the relief pressure, and adjust the current increase.

After replacement or repair of the degassing pump motor, set the degassing and loading pressures.

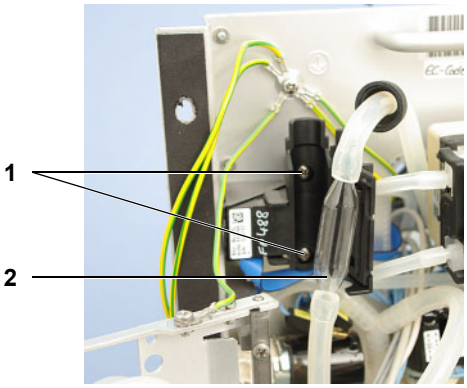
10.8.10 Blood leak detector



Slide the cap (**1**) on the tubing upwards.

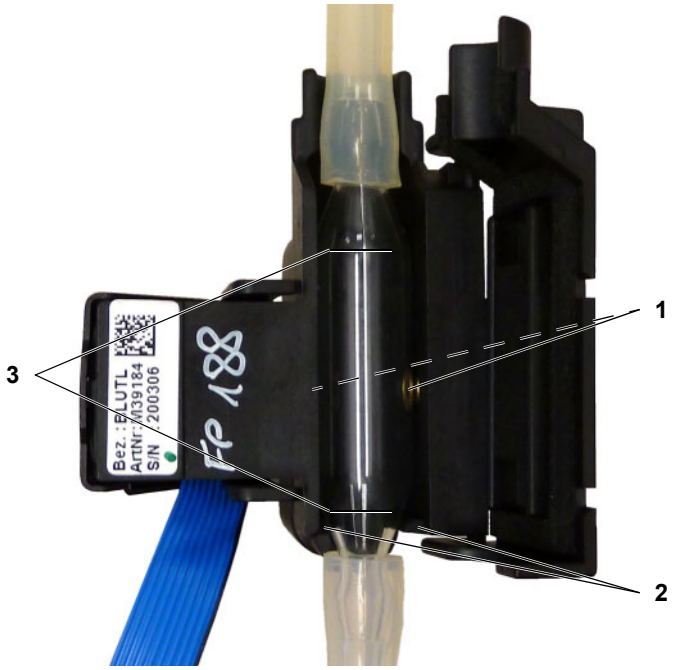
Press in the detent mechanisms (**2**) and open the blood leak detector.

Be absolutely sure to avoid fingerprints and other contaminations on the glass cuvette during repair.



Remove the glass cuvette (**2**).

Unscrew the blood leak detector with 2 screws (**1**).



Installation:

Install by performing the steps in the logical reverse order.

Insert the cuvette **(3)**, being careful to **avoid** fingerprints or other soiling. Any fingerprints or other soiling will invalidate measurement results.

Check the position of the cuvette.
– The cuvette must be placed in the cylindrical area **(3)** next to the sensor **(1)**.
– The cuvette must lie with the cuvette body flat against position **(2)**.

After repair or replacement, calibrate blood leak and dimness
(see chapter 9.1.42 page 9-37).

10.8.11 Valves (type)

Valve name	Installed as
Solenoid valve with 1 adapter, low kv value	V31-38, V43, V86, V89, V100, V102, V183, V188, V130
Solenoid valve with 2 adapters, low kv value	V26, V39, V89, V99
Solenoid valve with 1 adapter, high kv value	V41, V87
Solenoid valve with 2 adapters, high kv value	V24, V24b, V30, V91
Solenoid valve for disinfection	V84
Check valve on heater block	V92
Check valve	V117
Ventilation valve	V112

10.8.12 Disinfection valve V84 with CD monitor

Warning

Risk of caustic burning!

To prevent any skin contact with the disinfectant, wear protective gloves.

When working with acidic substances:
Wear goggles!
Observe the safety precautions of the disinfectant used!

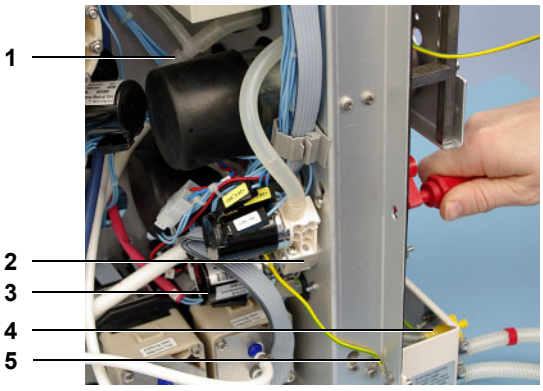
In the event of contact with acid:
Eye: Immediately flush with flowing water for 15 minutes.
Skin: Use soap under flowing water for neutralization.
Ingestion: Do not induce vomiting, but have the person affected drink plenty of still water. Seek medical advice.

Warning

Microbiological risks!

A defect of the disinfection valve can result in disinfectant in the container becoming diluted with fluid entering it and thus reducing the disinfecting effect.

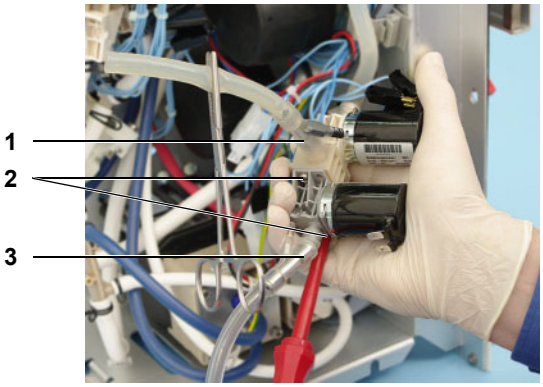
The disinfectant container must be replaced following repair.



Remove the screw on the rear of the hydraulics unit and detach the valve block (**2**). If necessary, unscrew the ground cable from the potential equalization bolt (**5**).

Pull off the tubes from the branch (**1**) and from the disinfectant connector (**4**).

Pull off the cable from V84 (**3**).



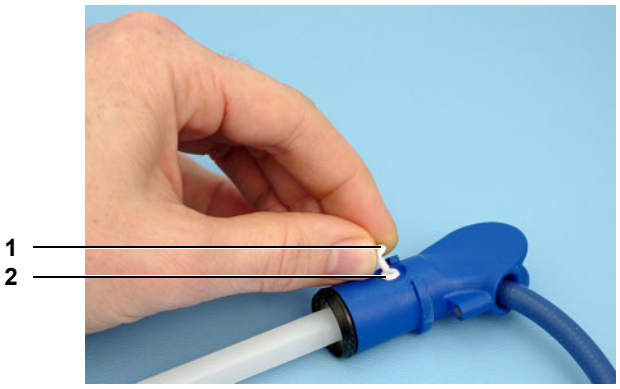
Pull of the CD monitor from the valve block (**1**) and from valve V84 (**3**).

Unscrew V84 with 2 screws (**2**).

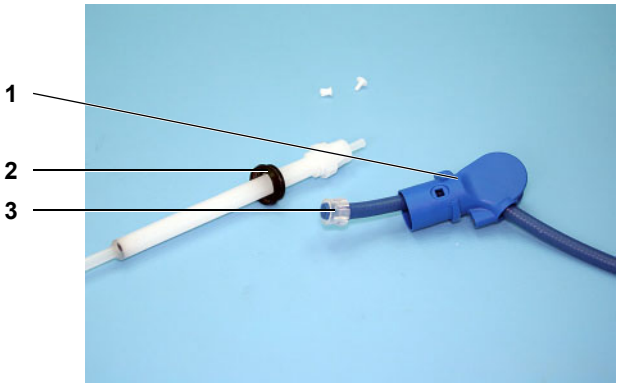
After replacement or repair, check the flows.

10.8.13 Suction tube

10.8.13.1 Suction rod, rivet, sealing plunger



First remove the head part (**1**), then the spreading body (**2**) of the rivet.



Pull off the grip (**1**) from the suction rod.

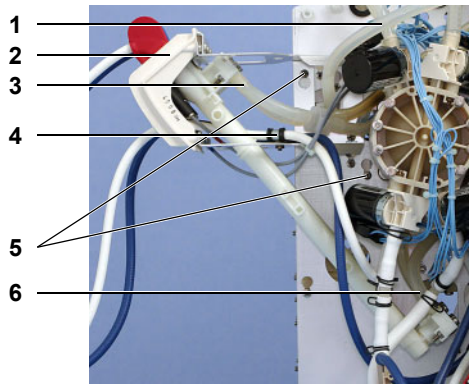
Pull off the tube with the tube clamp (**3**).

Pull out the sealing plunger (**2**) in forward direction.

When installing, ensure proper seating of the sealing lip; if necessary, correct with tweezers.

10.8.14 Rinse chamber

10.8.14.1 Adapter with rinse chamber



Pull off the reed switch cable from the HPU.

Pull off the inlet tubes (**6**) and rinse tubes (**3**).

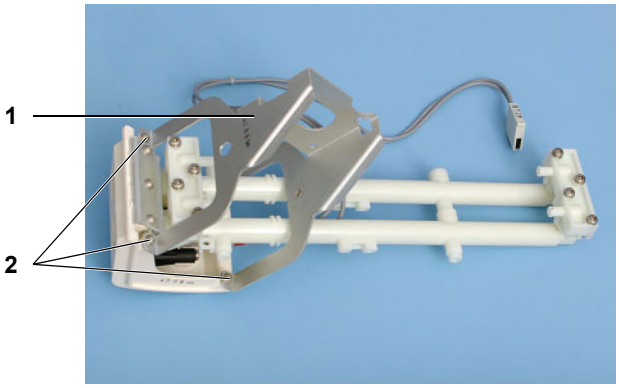
Take the suction rods out of the rinse chamber, disconnect it from the tubes, remove the screw (**4**), and pull the tubes inwards and out of the rinse chamber adapter (**2**).

Disconnect the tube (**1**) running to the balancing chamber from the T-piece. Unscrew the screws (**5**), lift the rinse chamber a little and remove it.

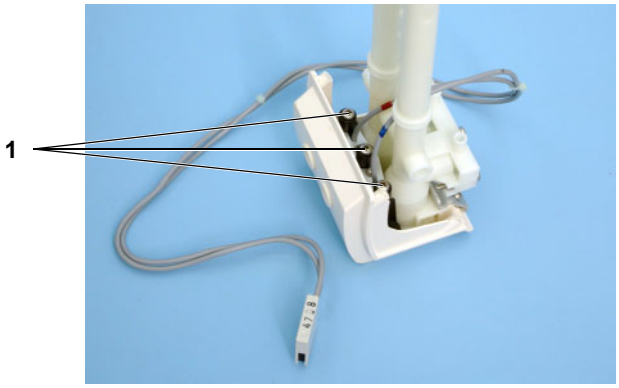
When installing, ensure proper tubing arrangement according to flow diagram.

After replacement or repair, run a rinse section test.

10.8.14.2 Reed switch



Unscrew the carrier plate (**1**) with 4 screws (**2**).



Unscrew the reed switch from the rinse chamber adapter with 3 screws (**1**) and washers.

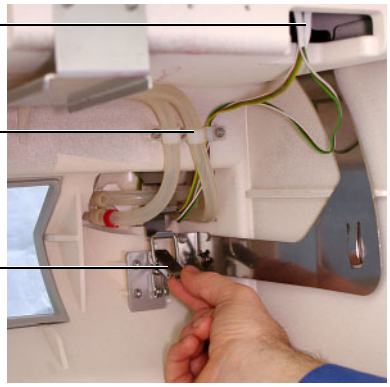
After replacement or repair, run a functional test in the Diagnostics menu.

10.8.15 bi*b*ag® connector

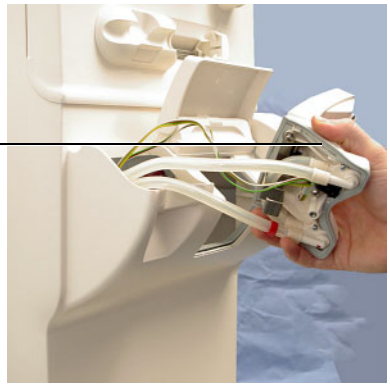
10.8.15.1 bi*b*ag® connector complete

Unscrew the screw (**1**).

When installing, use Loctite 243 to secure the screws.



Pull off the cable (**1**) from P.C.B. LP 1628, take the cables and tubes out of the holder (**2**), and open buckle (**3**).

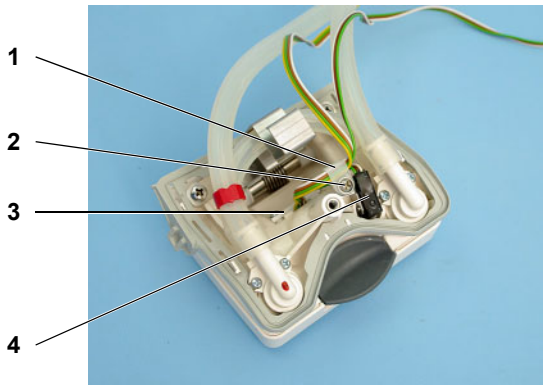


Pull out the bi*b*ag® connector with tubes and cables.

While installing, ensure proper seating of the seal (**1**).

After replacement or repair, check the switching states in the Diagnostics and Functions menu.

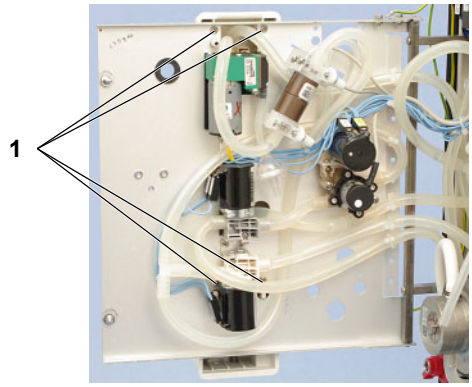
10.8.15.2 Microswitch



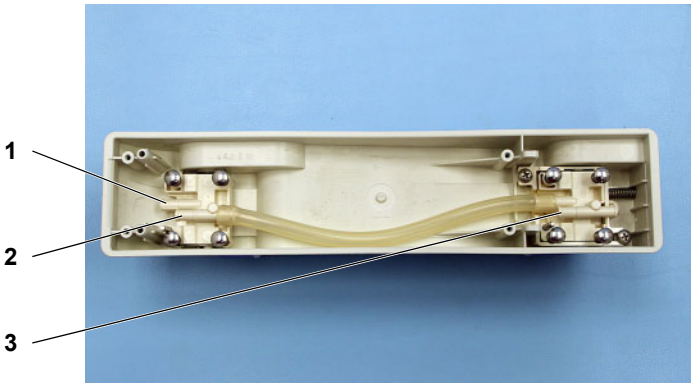
Remove the screw (**2**), remove the cable holder (**1**), dismount the microswitch (**4**).

To dismount the Hall switch, unscrew the screws from the holding block (**3**) and pull out the Hall switch.

10.8.16 Filter holder for DIASAFE® *plus*



Unscrew the filter holder with 4 screws (**1**), pull off the tubes.



When installing, ensure proper tubing arrangement:

1 to valve V189

2 to CD cell CD7

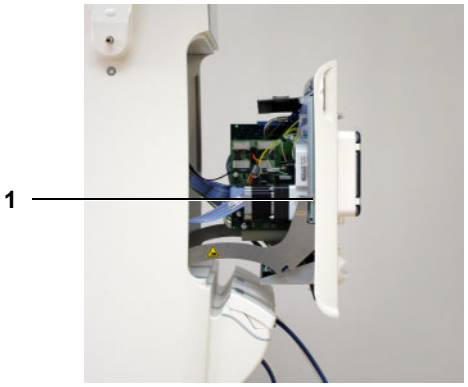
3 to valve / balancing chamber

10.9 Extracorporeal Blood Circuit Module (EBM)

10.9.1 Opening and closing the EBM, service position

Unlock the locking mechanism (**1**) on the left side of the device and swing out the EBM to the front.

Pull out the open EBM a little and turn it into its vertical service position. The EBM clicks into place.



Close the EBM (**1**) in reverse order. To do so, initially press the detent mechanisms outwards.

10.9.2 Pneumatic unit contamination

Warning

Risk of infection

Contamination of the hemodialysis device with blood results in a risk of infection.

The following must be observed to avoid an infection:

– Wear safety gloves.

– Disinfect your hands after removing the gloves.

– Wear surgical mask and goggles if there is a risk of splashes and aerosoles.

Clean and disinfect the device before coming into contact.

Warning

Risk of infection

Contamination of the hemodialysis device with blood results in a risk of infection.

If fluid may have passed through the hydrophobic filter, the device must be checked for contamination after the treatment. If it is contaminated, the device must be removed from service. Before starting the device again, all affected parts must be replaced in accordance with the manufacturer's specifications.

Checking the EBM front

Check the housing front in the vicinity of the Luer-lock connectors for residual blood, fluid and precipitation, especially at the following positions:

– venous pressure transducer

– Single-Needle pressure transducer (optional)

– arterial pressure measurement unit

Checking the EBM inside

Open the EBM

Imperatively check the following components of the pneumatic unit and replace them in case of contamination:

– venous pressure transducer

– Single-Needle pressure transducer (optional)

– Arterial pressure measurement unit

– Compressor unit

– Internal compliance chamber for Single-Needle (optional)

– Hydrophobic filter

When replacing a component, also replace the pneumatic tubing.

The complete pneumatic unit (see components mentioned above) must be replaced if it is not possible to definitely detect the components that have been contaminated with blood or fluid.

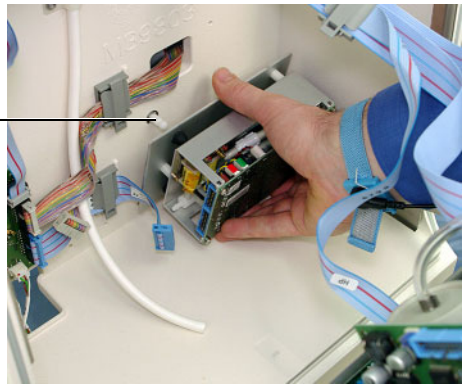
Checking the housing main part

If blood or fluid enters into the housing main part or into other components (e.g., P.C.B. LP 450-2, P.C.B. LP 950, BPM, etc.), these must be cleaned or replaced.

Hydrophobic filter

Check hydrophobic filters inside the device to find out whether they are wetted with fluid.

10.9.3 BPM (option)

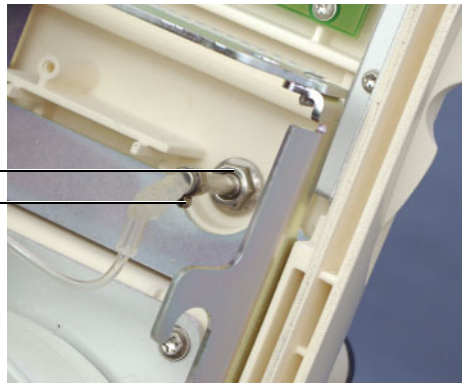


To remove the BPM module, pull of the connecting cable and the tube. Pull off the BPM module from the detent bolt (**1**) and remove it.

Install the BPM in reverse order.

After replacement or repair, run a leakage test, perform a pressure test and check safety valve.

10.9.4 Luer-Lock connection cone

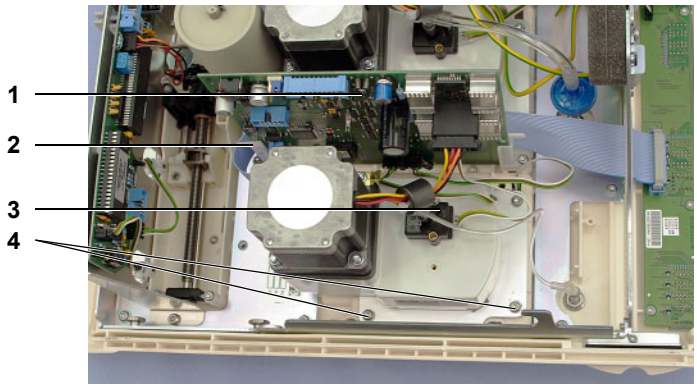


Cut the tube clamp (**2**) open and remove it. Pull off the rube, remove the nut (**1**).

When installing, use a new tube and a new tube clamp.

10.9.5 Blood pump

10.9.5.1 Stepper motor with gear



Remove the blood pump rotor.

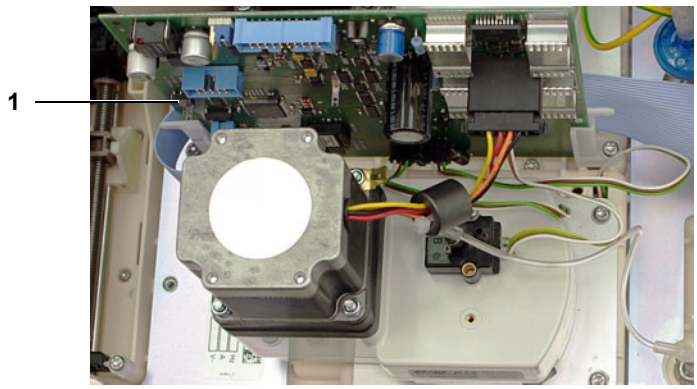
Pull off all cables from P.C.B. LP 624 (**1**). Press back the detent mechanisms (**2**) and remove P.C.B. LP 624.

Unscrew the pressure transducer (**3**).

Remove the stepper motor including gear with 4 screws (**4**).

After replacement or repair, run a functional test.

10.9.5.2 P.C.B. LP 624 pump control

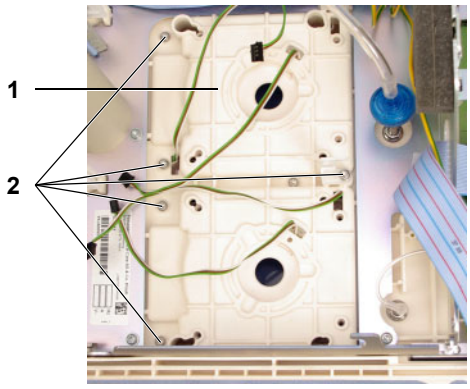


Set the hex switch (**1**). Use the hex switch to set the blood pump rate for special control to 100 ml/min.

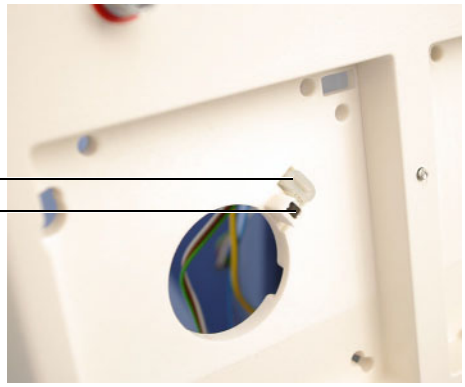
P.C.B. LP 624 for arterial blood pump:
hex switch on switch position 2.

P.C.B. LP 624 for Single-Needle blood pump (optional):
hex switch on switch position 3.

10.9.5.3 Hall sensor for rotor



Unscrew the blood pump stator (**1**) or double stator (SN option) with 2 or 5 screws (**2**), respectively. Pull out the stator including cable to the front.

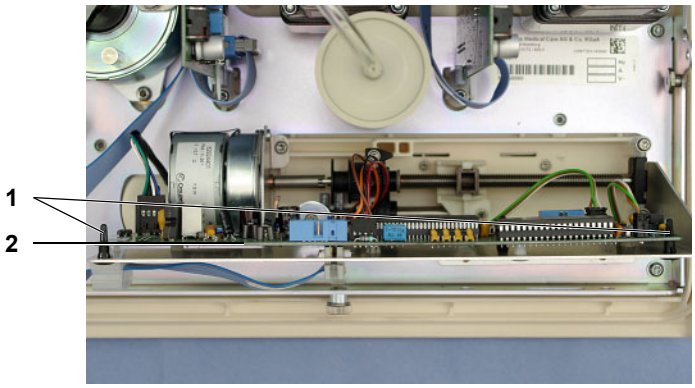


Pull out the tube segment (**1**). Take the Hall sensor (**2**) out of the recess and pull it out in inward direction.

After replacement or repair, run a functional test.

10.9.6 Heparin pump

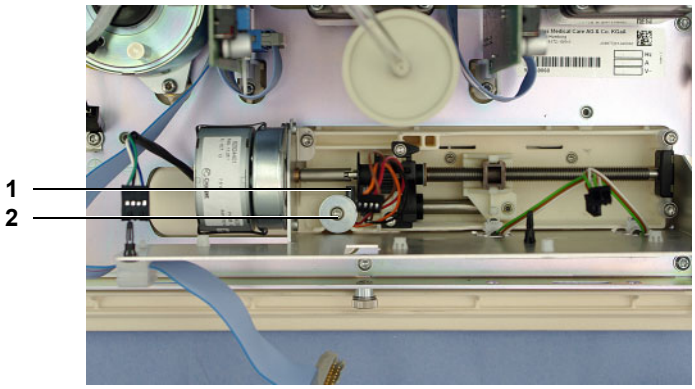
10.9.6.1 P.C.B. LP 950



Pull off all cables from P.C.B. LP 950 (**2**). Press in the detent mechanisms (**1**) and remove P.C.B. LP 950.

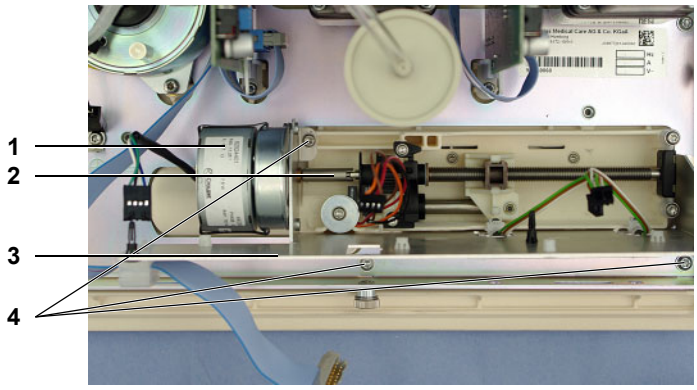
After replacement or repair, set the hex switches (see **Syringe type table** page 11-26), calibrate the Hall sensors, and check for proper functioning.

10.9.6.2 Optical sensor



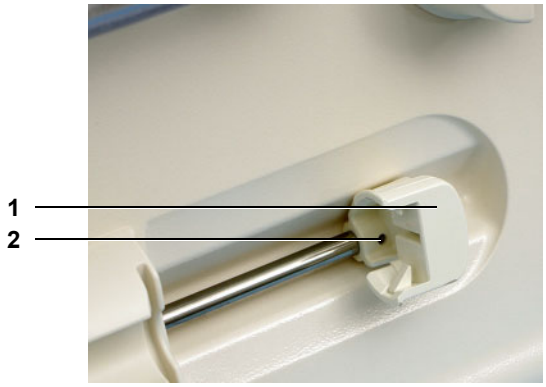
Remove the screw (**2**) and washer, and remove the optical sensor (**1**).

10.9.6.3 Drive

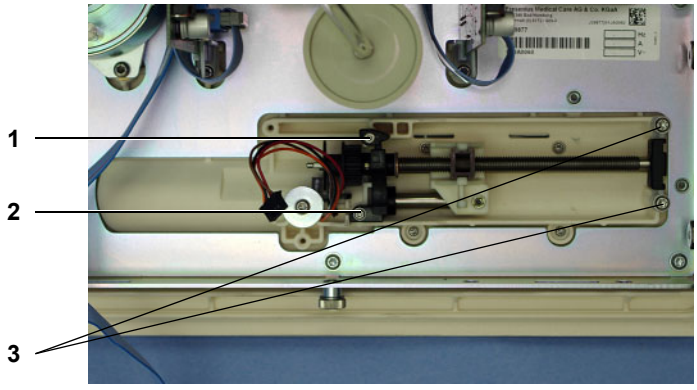


Remove 3 screws (**4**) and remove the retaining plate (**3**) with drive (**1**). To achieve this, turn the shaft (**2**) into an appropriate position if necessary. Then unscrew the motor from the retaining plate.

10.9.6.4 Mechanics



Remove the screw (**2**) and pull out the syringe plunger holder (**1**).



Remove the screws (**1, 2, 3**) and pull out the mechanics.

Used screws and torques:

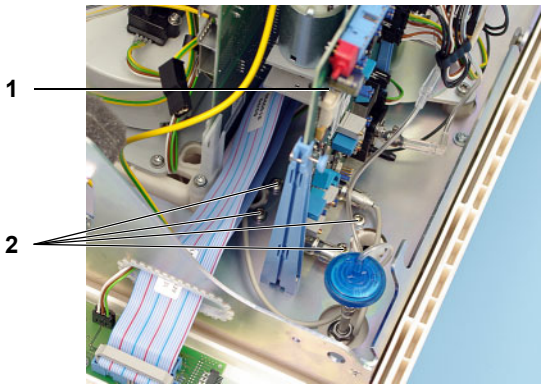
1 30x25 (0.6 Nm)

2 30x20 (0.6 Nm)

3 40x20 (1.1 Nm)

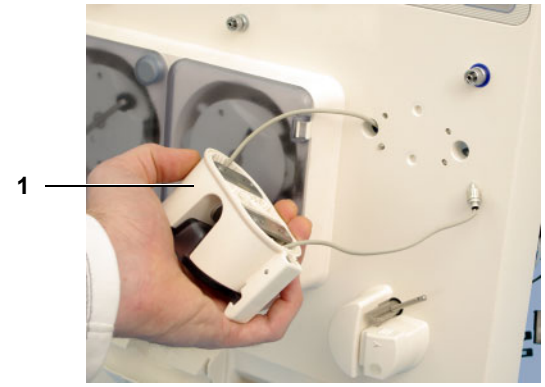
10.9.7 Drip chamber holder

10.9.7.1 Drip chamber holder complete



Pull off all cables from P.C.B. LP 450-2, open the P.C.B. securing mechanism, and remove P.C.B. LP 450-2 (**1**).

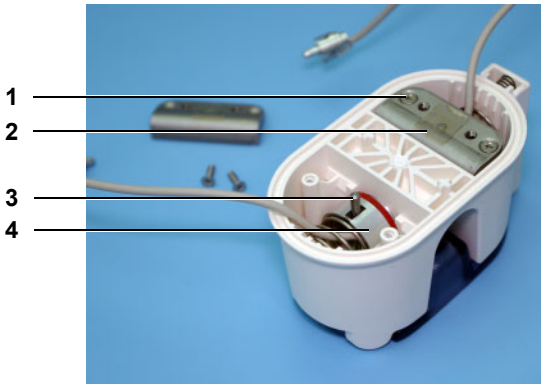
Remove the 4 screws (**2**).



Remove the drip chamber holder (**1**) including cable from the device.

After replacement or repair, calibrate the ultrasonic sensors.

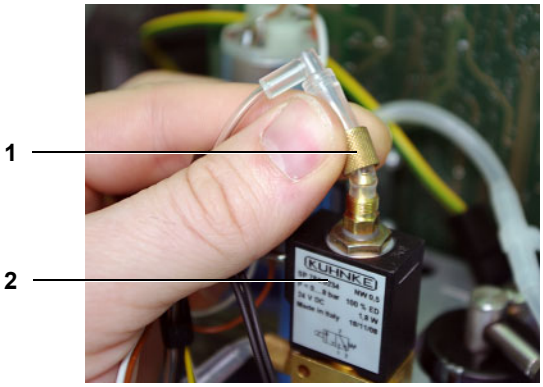
10.9.7.2 Ultrasonic sensors



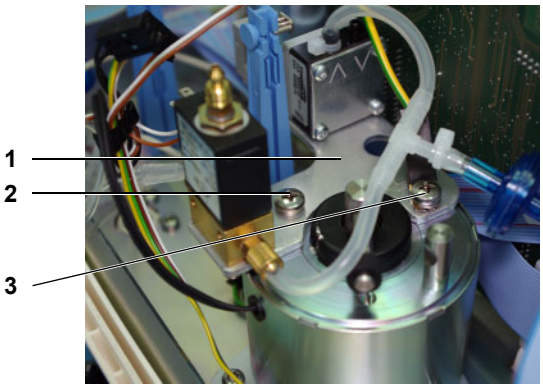
Unscrew 2 screws (**1**), and remove the angle (**2**). Pull out the cylinder pin (**3**), press back the spring, and pull out the ultrasonic sensor(**4**) including spring.

When installing, stick a new adhesive tape to the angle to secure the cylinder pin.

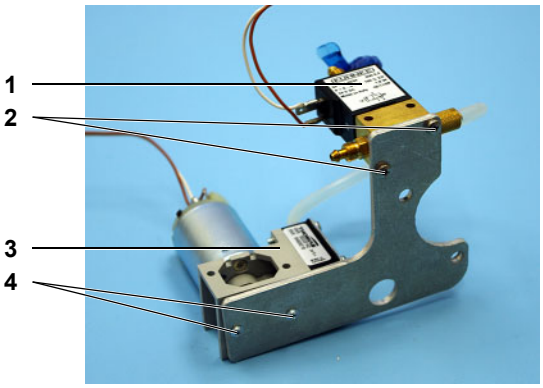
10.9.8 Compressor / ventilation valve



Remove the tubes from the ventilation valve (**2**). To do so, unscrew each nut (**1**) and pull off the tube.



Remove a screw with spring washer (**2**) and a screw with spring washer, ground cable and the toothed lock washer (**3**) and dismount the carrier plate (**1**).

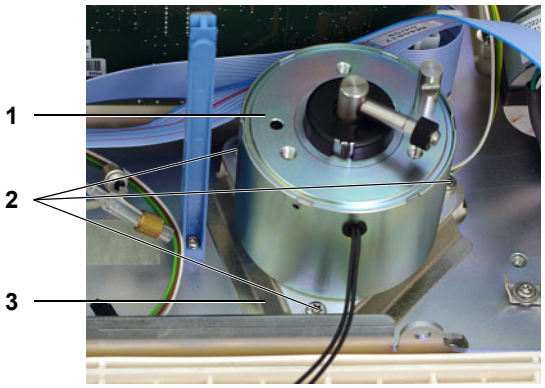


Unscrew the compressor (**3**) with 2 screws (**4**) or unscrew the vent valve (**1**) with 2 screws (**2**) from the carrier plate.

After replacement or repair, run a functional test.

10.9.9 Venous occlusion clamp with rotary magnet, bolt

Turn the bolt (**1**) out of the venous occlusion clamp (**2**).



Unscrew the rotary magnet (**1**) and the heat conduction plate (**3**) with 3 screws with spring washer (**2**).

When installing, ensure that the distance from the optical detector to the venous occlusion clamp is 1.0 mm ±0.2 mm.

Screw a new bolt into the venous occlusion clamp – secure with Loctite 243.

After replacement or repair, run a functional test.

10.10 Calibration and test steps after repair

Warning

A disinfection, a T1 test and a check of the electrical safety must be performed after working on the hemodialysis device, irrespective of the table below.

Replacement / repair	Calibration steps, test steps
Printed circuit boards	
Power supply unit (power board, heater board)	Check voltages (calibration menu), calibrate temperature, perform temperature test
P.C.B. LP 630 Motherboard	Check jumpers (see **P.C.B. LP 630 Motherboard** page 11-54)
P.C.B. LP 1631 CPU 1	Set the DIP switches, install current software version, initialize Novram, make setup settings or import data, calibrate, set time
LP 632 CPU 2; snap-hat battery	Set DIP switches, import calibration data or make the necessary calibrations
P.C.B. LP 633-5 Input board	Calibrate blood pump rate, arterial and venous pressure, blood leak, bi*ba*g® values (temperature and conductivity), TMP, temperature, conductivity and OCM. Check pressure transducer 1 and 2 (hydraulics). Check all analog signals. Check jumpers BR4 (see **P.C.B. LP 633-5 layout I** page 11-58).
P.C.B. LP 634 Output board	Set DIP switches, set current increase, flows, pressures (hydraulics unit), temperature, degassing pump, blood leak, dimness
P.C.B. LP 636 External connectors	Jumper J1 must not be connected (see **P.C.B. LP 636 External I/O board** page 11-61), check status indicator for proper functioning
P.C.B. LP 763 Multi-interface board	Check DIP switches, check BPM (option)
Display, P.C.B. LP 922; MDC-II board; backlighting, touch panel	Install current software in MDC-II and set the language version (if MDC-II board was replaced), display test, key test
P.C.B. LP 950 for heparin pump	Set hex switches (see **Syringe type table** page 11-26), calibrate Hall sensors
P.C.B. LP 1131 Operation status indicator (traffic light)	Check status indicator for proper functioning
P.C.B. LP 450-2 for air detector	Set jumpers, calibrate air detector sections, optical detector, venous pressure (see **P.C.B. LP 450-2 Air detector control (LD)** page 11-50).
P.C.B. LP 624 Blood pump	Set hex switches, calibrate arterial pressure, check line diameter, blood pump rate, stroke rate / volume (SN)
P.C.B. LP 1628 Distributor	Check bi*ba*g® switching states, check BPM (option) for proper functioning
P.C.B. LP 941 HPU	Calibrate PDial2, calibrate TMP

Replacement / repair	Calibration steps, test steps
EBM	
Shunt interlock, microswitch	Check diagnostics, functions
BPM module (optional)	Check leakage test, pressure test and safety valve
Arterial pressure transducer	calibrate arterial pressure
Venous pressure transducer	calibrate venous pressure
SN pressure transducer (optional)	Check stroke rate / volume
Luer-Lock connection cone	Leakage Test
Arterial blood pump stepper motor	Functional test
Single-Needle blood pump stepper motor (optional)	Functional test
Hall sensor for rotor	Functional test
Hall switch for cover	Functional test
Heparin pump; P.C.B. LP 950; optical sensor	Set hex switches (see **Syringe type table** page 11-26), calibrate Hall sensors
Drip chamber holder, sensors	Calibrate ultrasonic sensors
Compressor	Functional test
optical detector, venous occlusion clamp	Set distance to 0.8–1.2 mm
Hydraulics unit	
Balancing chamber	Measure balancing chamber volume in liters (only if no volume label), read off balancing chamber volume (only with volume label), calibrate balancing chamber volume, check flows and conductivity
Heat exchanger	Check flows
UF pump	Measure volume in liters
Conc./bic. membrane pump	Measure volume in liters, calibrate, check CD
Blood leak detector	Calibrate blood leak, calibrate dimness
Degassing orifice	Set degassing pressure, check loading pressure
Heater block, heater rod	Check temperature
Temperature sensor	Temperature calibration
Float switch	Functional test
Flow pump	Set flows, check relief pressure, adjust current increase
Degassing pump	Degassing pressure, loading pressure
TMP pressure transducer (S9, S182)	Adjustment
Pressure switch bi*bag*®	Diagnostics, check

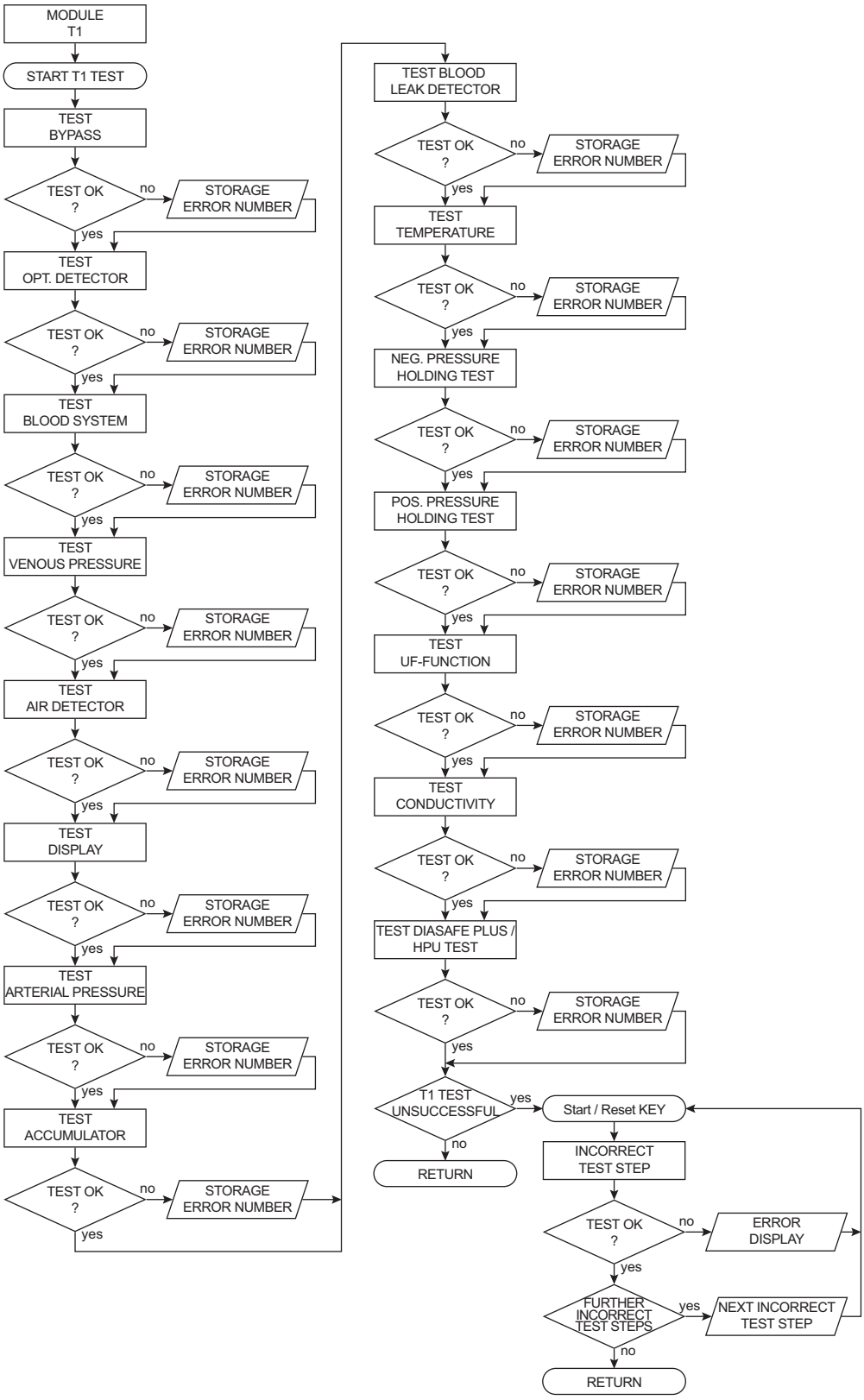
Replacement / repair	Calibration steps, test steps
CDS pressure switch (option)	Diagnostics, check
OCM conductivity cell	Calibrate OCM, calibrate CD
Conductivity measuring cell bi*b*ag®	Functional test with bi*b*ag®
Conductivity measuring cell (CD7)	Calibrate CD, calibrate temperature
MF block, level sensor	Degassing check, fill program
Rinse chamber, suction rod, filters, reed contacts	Rinse section test
bi*b*ag® connector, microswitch	Diagnostics
P.C.B. LP 759-4 sensor bi*b*ag®	Diagnostics
Ventilation valve V112	Diagnostics
bi*b*ag® drain valve V130	Check with bi*b*ag®
Evacuation valve V188	Check ventilation after air has been sucked in
Retentate valve V189	Filter test (in T1 Test)
All other valves	T1 test and disinfection without error message

11 Functional description

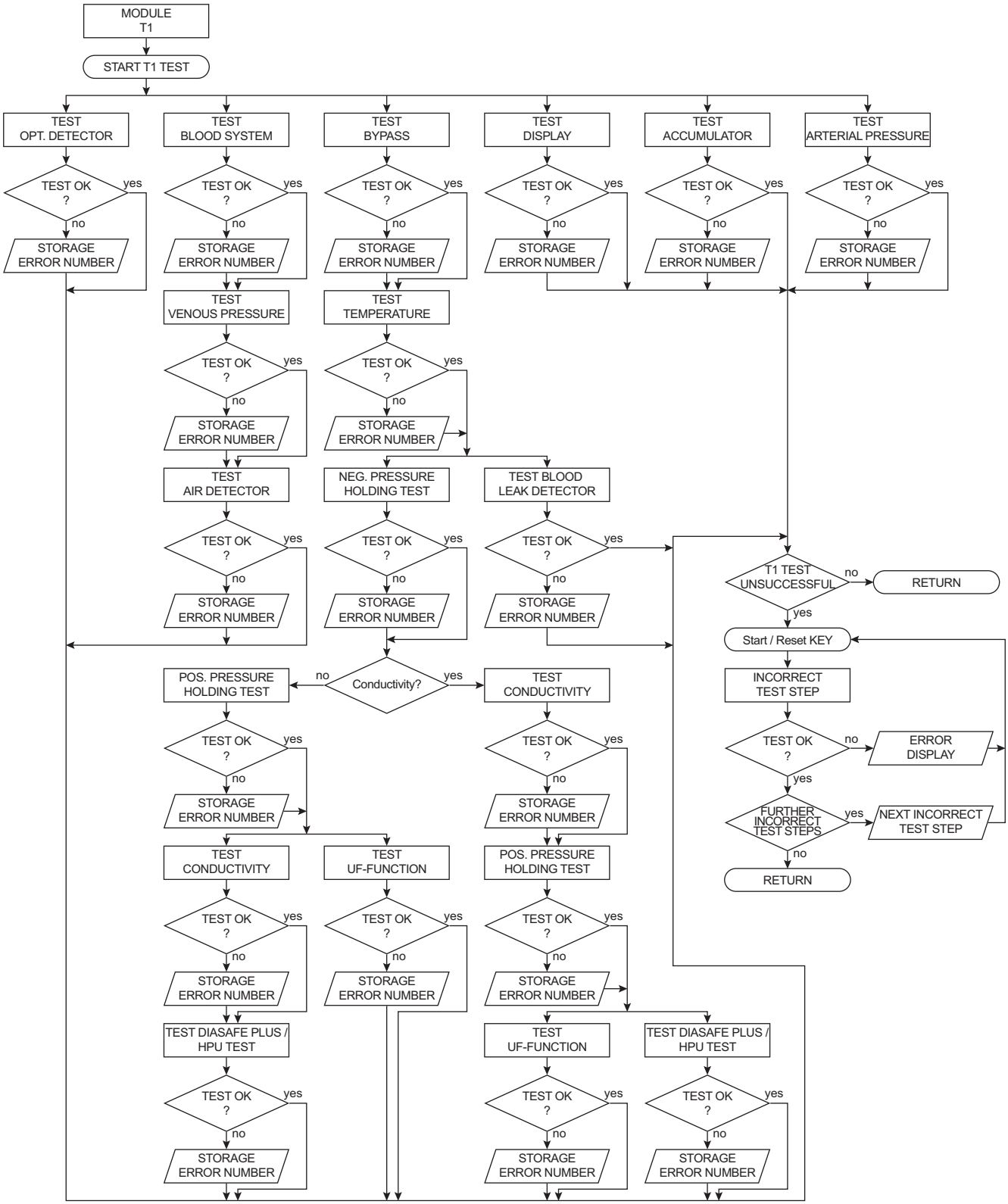
11.1 Functional description

11.1.1 T1 test description

11.1.1.1 T1 test flow diagram, serial run



11.1.1.2 T1 test flow diagram, parallel run



11.1.1.3 Overview of the individual test sections

Navigation

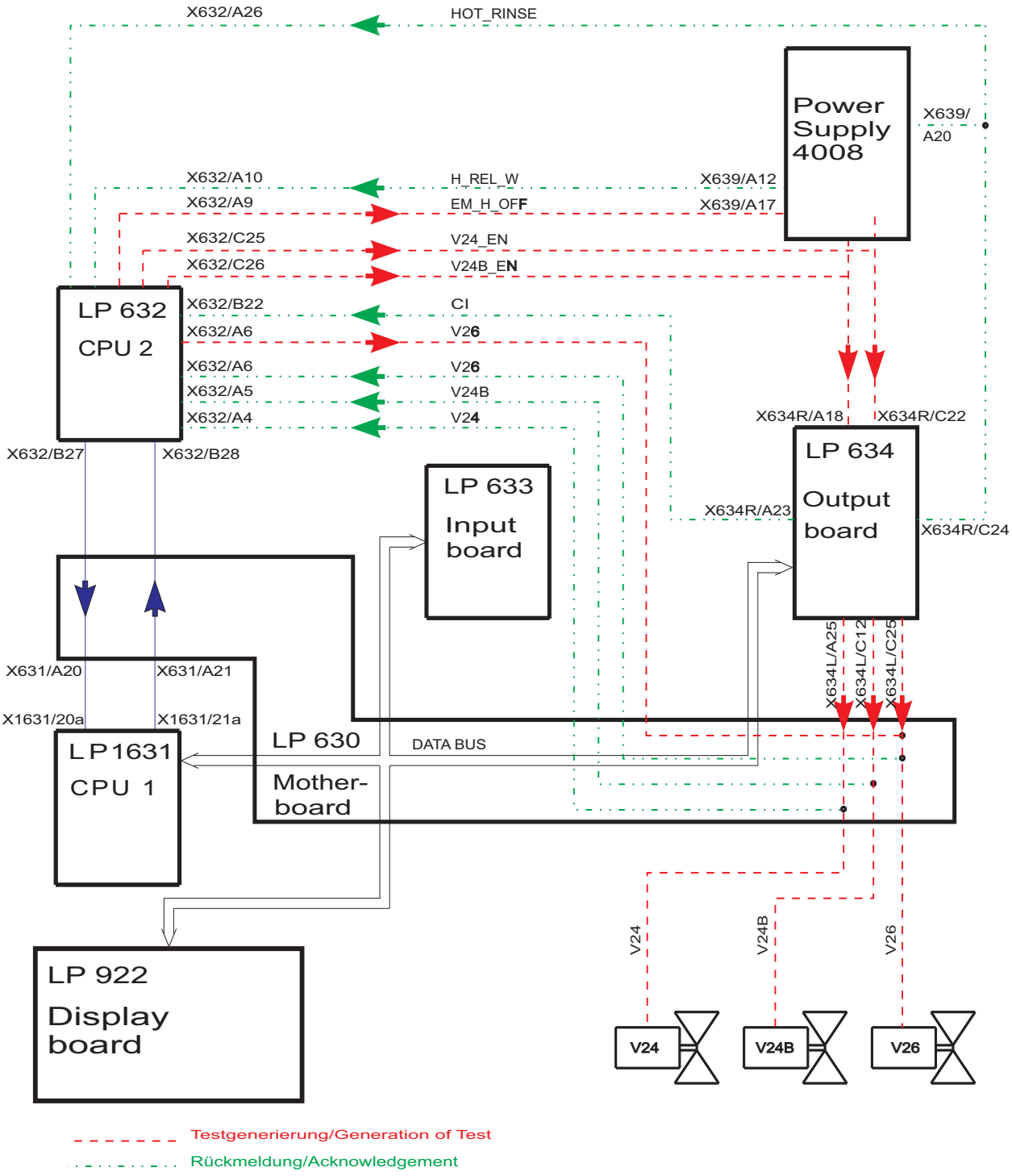
Test	Test description
Bypass	(see chapter 11.1.1.4 page 11-5)
Opt. Detector	(see chapter 11.1.1.5 page 11-6)
Blood System	(see chapter 11.1.1.6 page 11-7)
Ven. Pressure System	(see chapter 11.1.1.7 page 11-8)
Air Detector	(see chapter 11.1.1.8 page 11-9)
Display	(see chapter 11.1.1.9 page 11-10)
Art. Pressure System	(see chapter 11.1.1.10 page 11-11)
Battery	(see chapter 11.1.1.11 page 11-12)
Blood Leak	(see chapter 11.1.1.12 page 11-13)
Temperature	(see chapter 11.1.1.13 page 11-14)
Neg. Pressure Holding	(see chapter 11.1.1.14 page 11-15)
Pos. Pressure Holding	(see chapter 11.1.1.15 page 11-16)
UF Function	(see chapter 11.1.1.16 page 11-17)
Conductivity	(see chapter 11.1.1.17 page 11-18)
Diasafe plus / HPU test	(see chapter 11.1.1.18 page 11-19)

11.1.1.4 Bypass test

Test description

Check of the following functions:

- Heater relay
- Bypass (electric)
- Check of the temperature range switching function

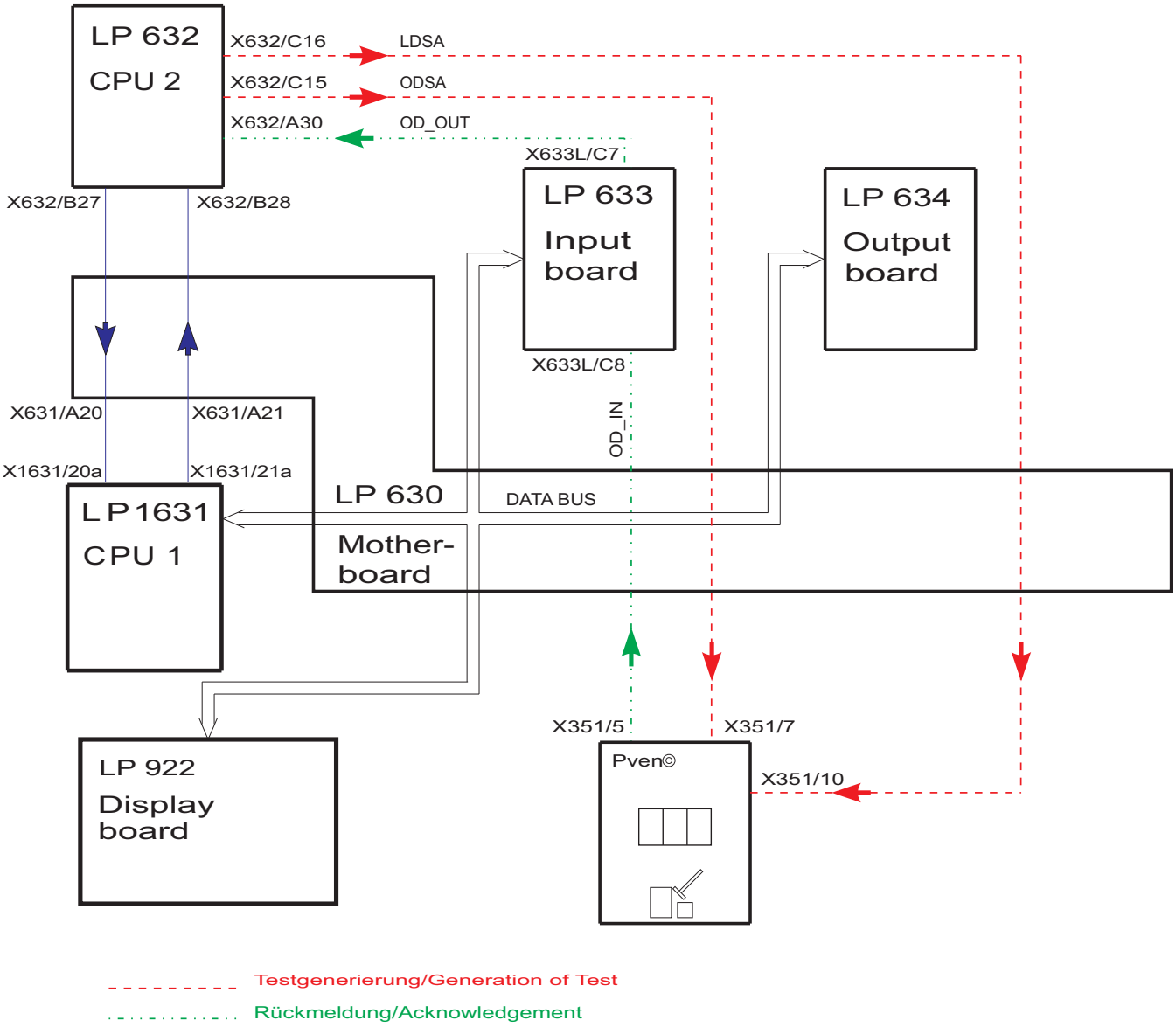


11.1.1.5 Optical detector test

Test description

Attenuate the optical detector.

Check the feedback from the optical detector.

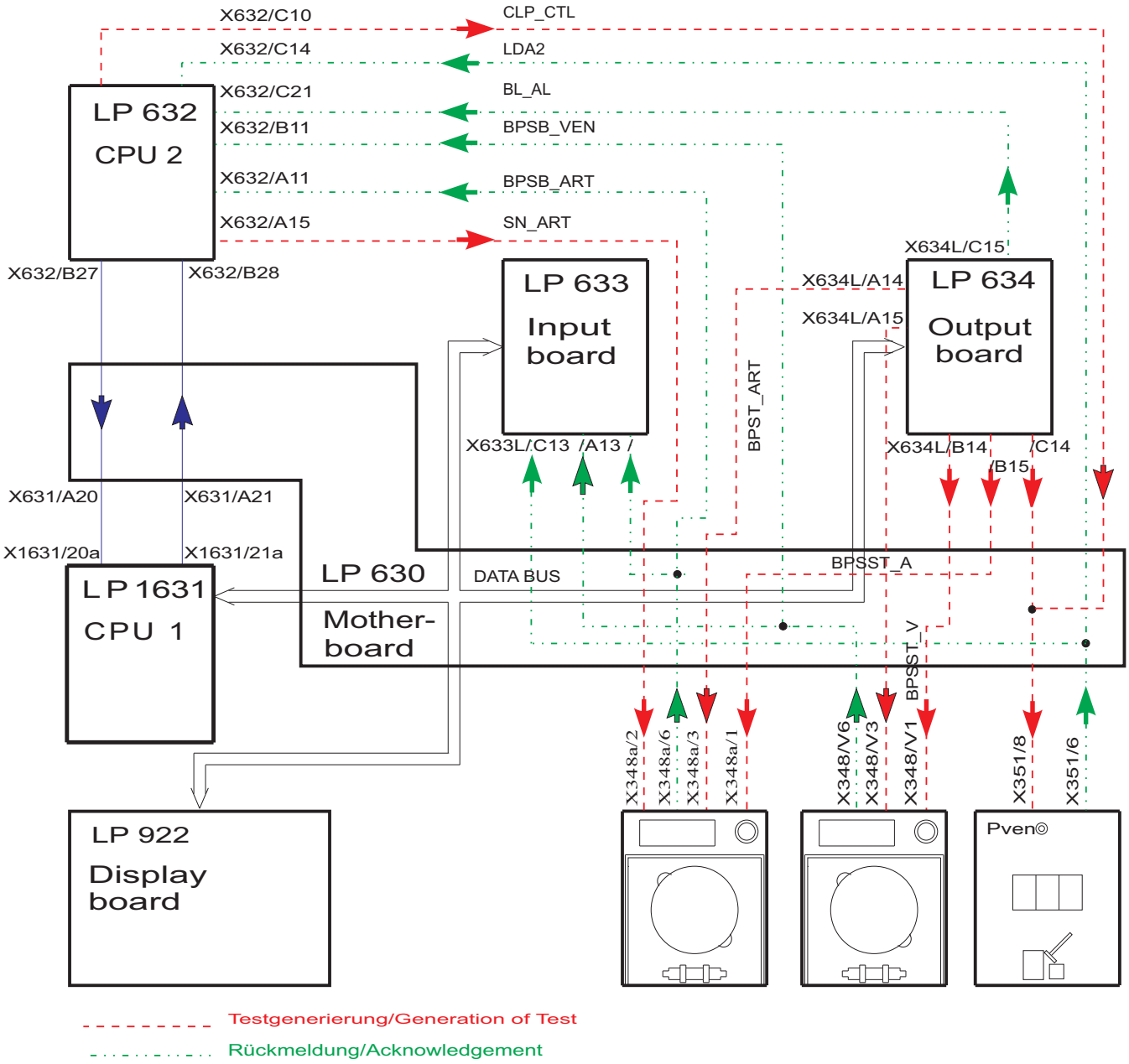


11.1.1.6 Blood system test

Test description

Check of the following functions:

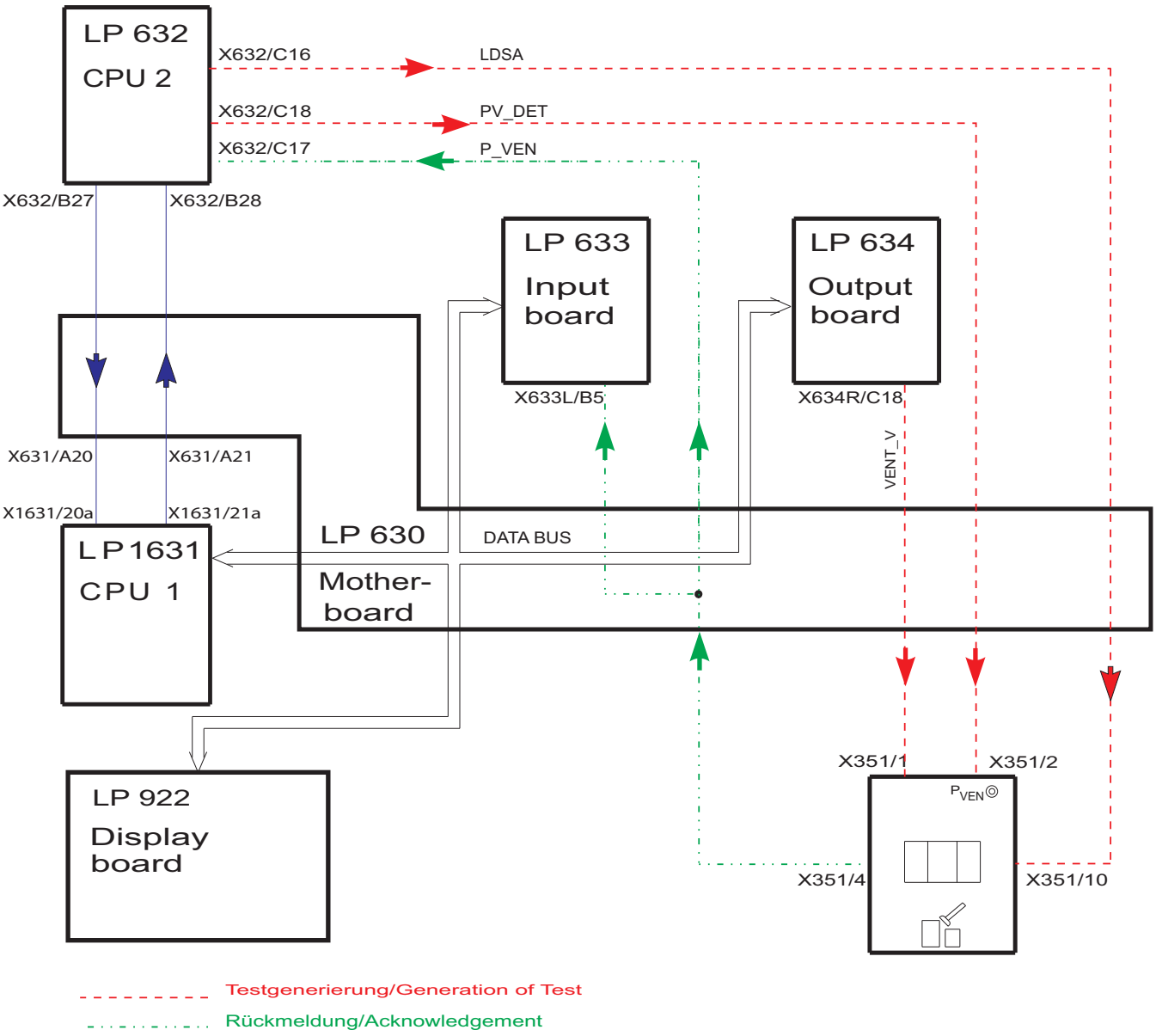
- Blood alarm acknowledgement
- Blood pump stop



11.1.1.7 Venous pressure system test

Test description

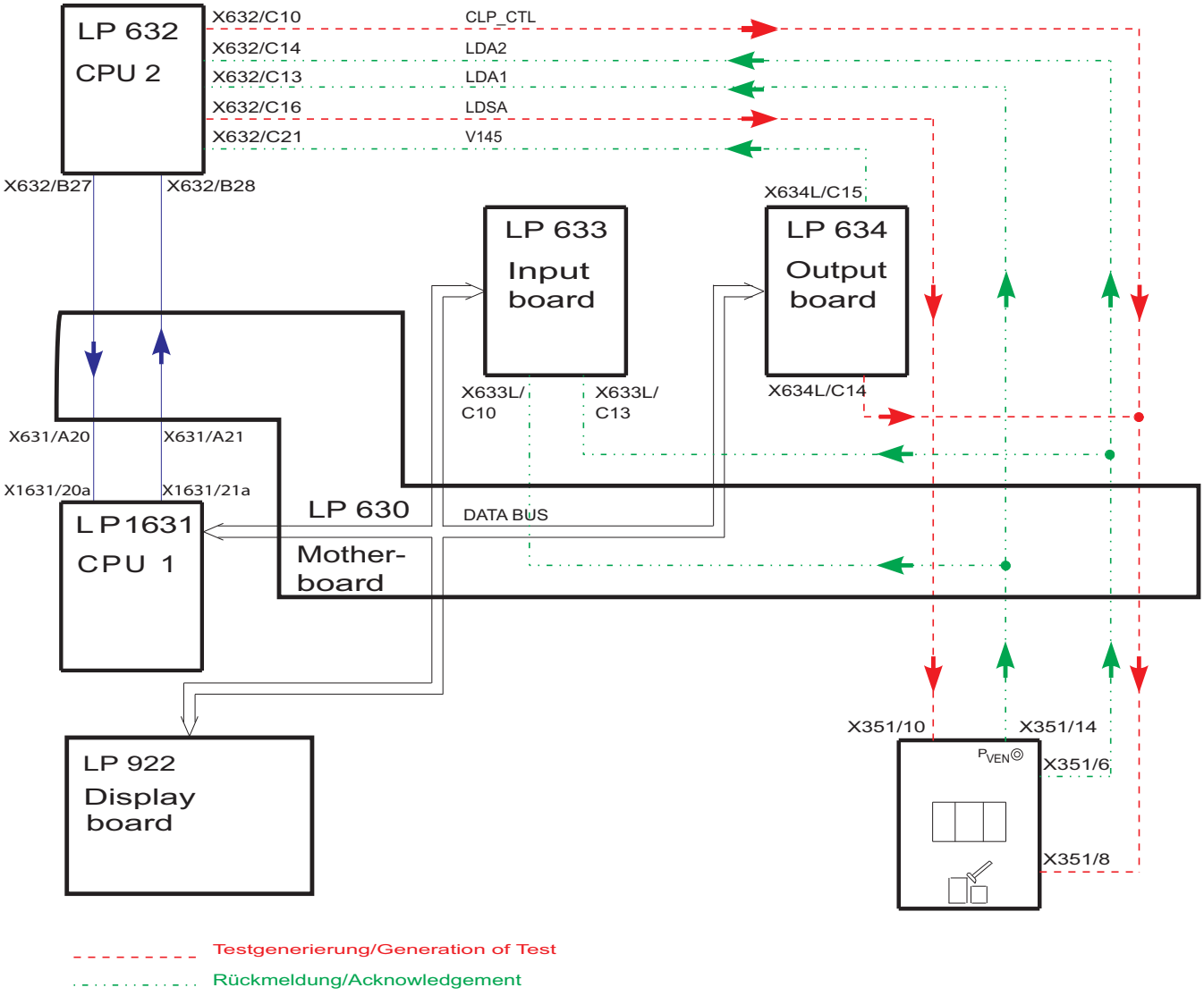
Check the lower limit by verifying the venous zero point.
Check the upper limit by detuning the venous pressure unit in positive direction
(the venous line clamp remains closed while the test is in progress).



11.1.1.8 Air detector test

Test description

– Test the air detector by checking the alarm state.
– Turn off the venous line clamp in the air detector module.



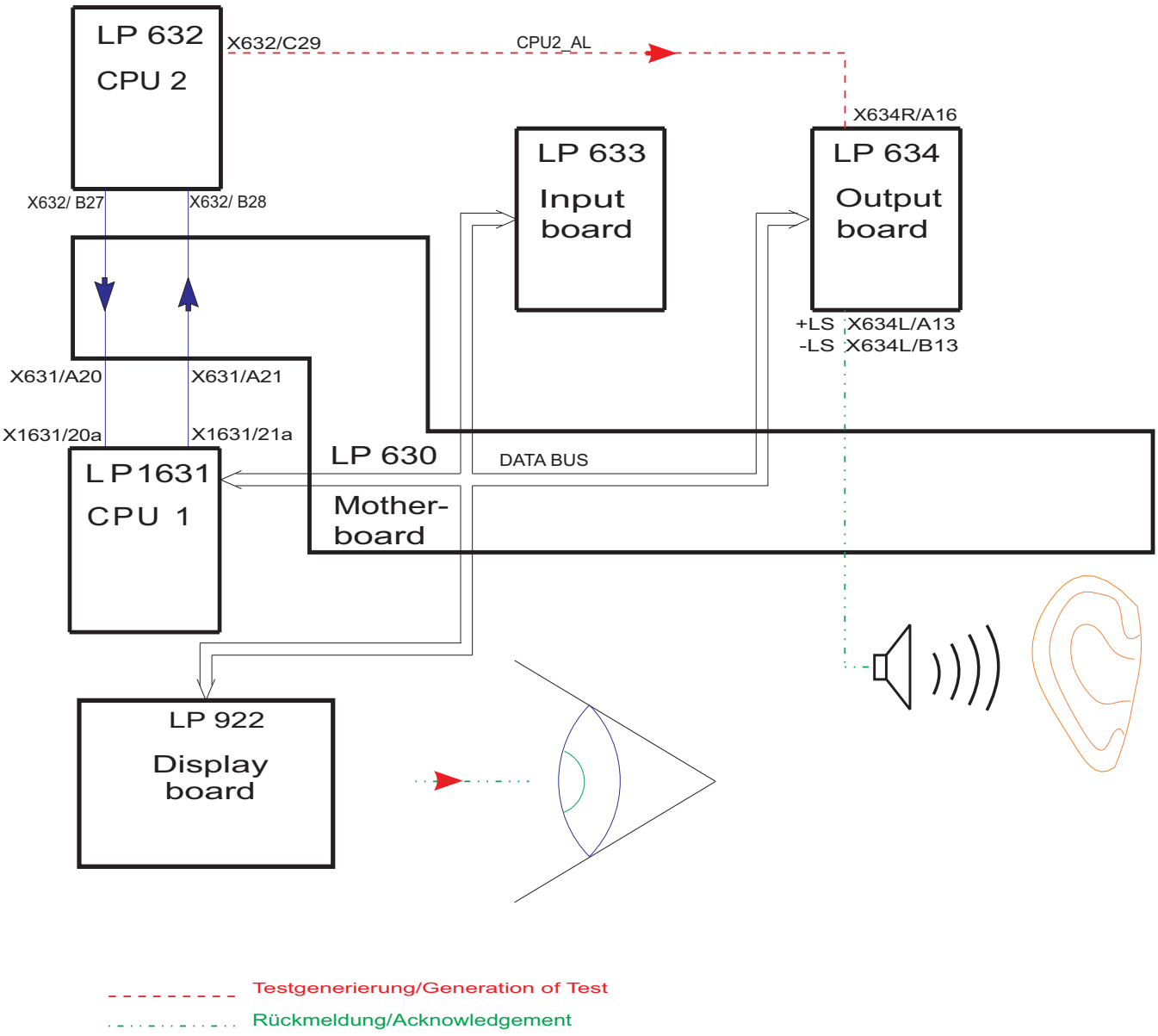
11.1.1.9 Display test

Test description

Check of the monitor indicators

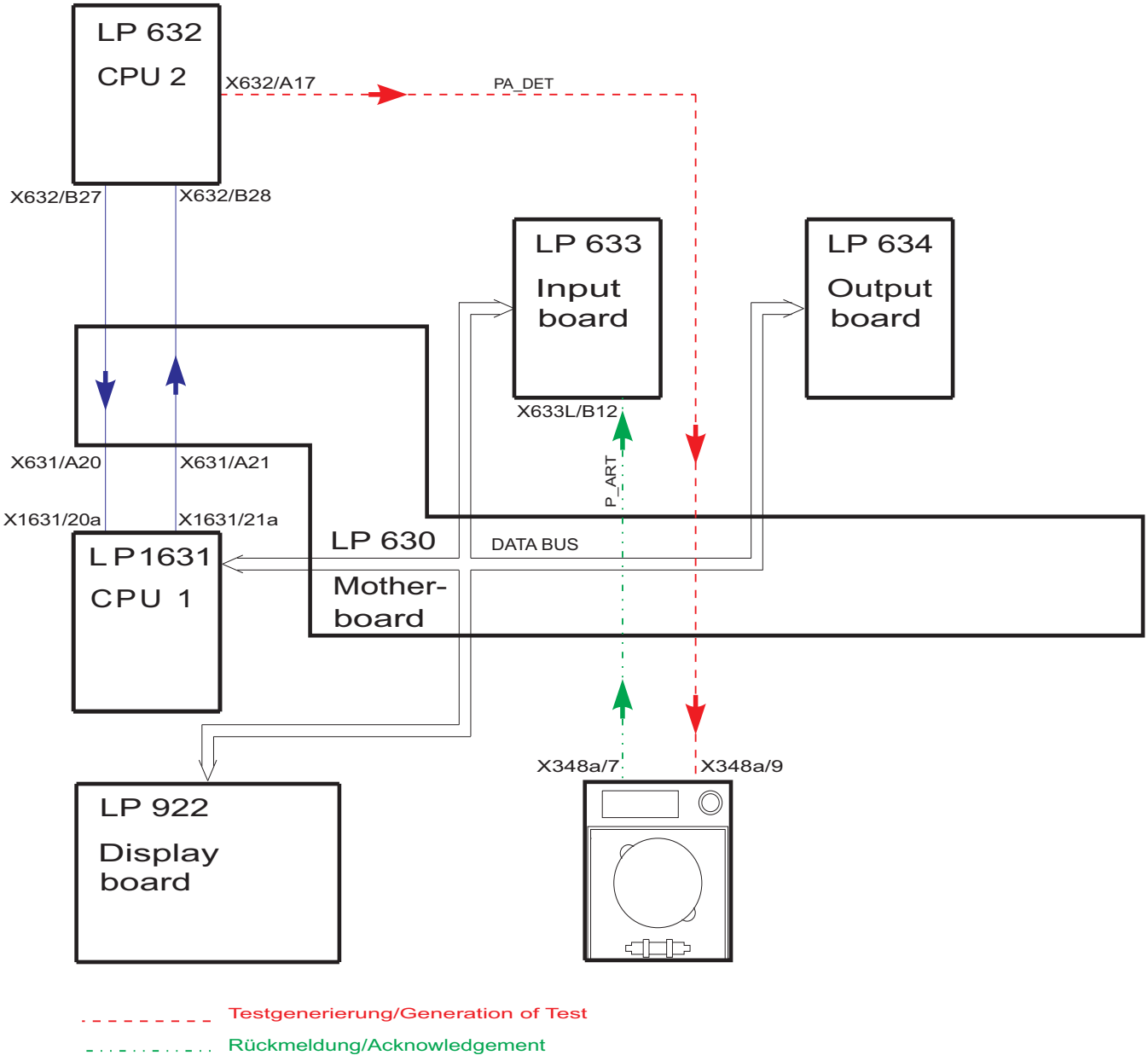
- Display test
- Status LED
- Alarm LED
- Bargraph
- CPU1 / CPU2 audible alarm

The display test must be monitored by the operator!



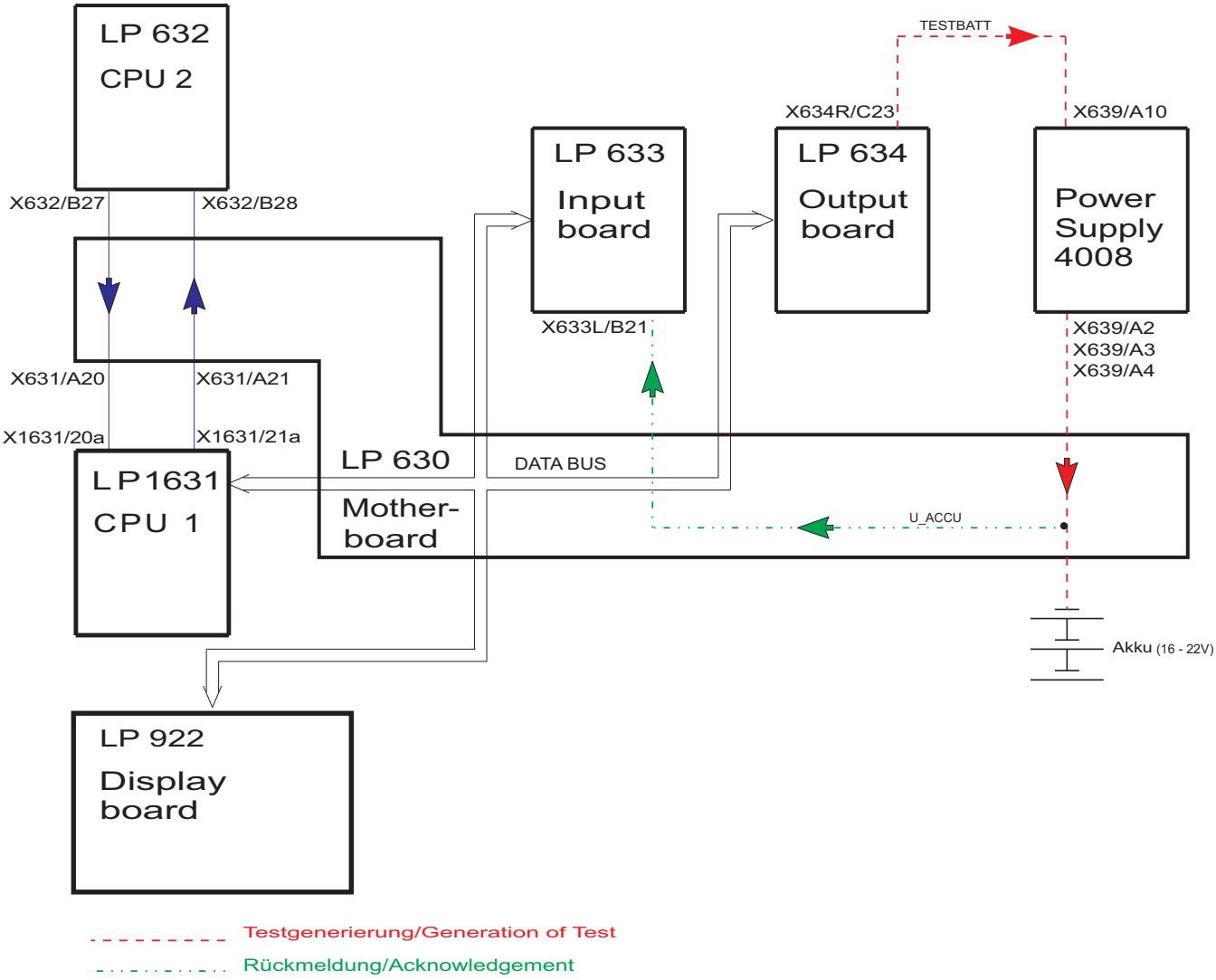
11.1.1.10 Arterial pressure system test

Test description Test the arterial pressure unit by electronically detuning it in positive or negative direction.



11.1.1.11 Battery test

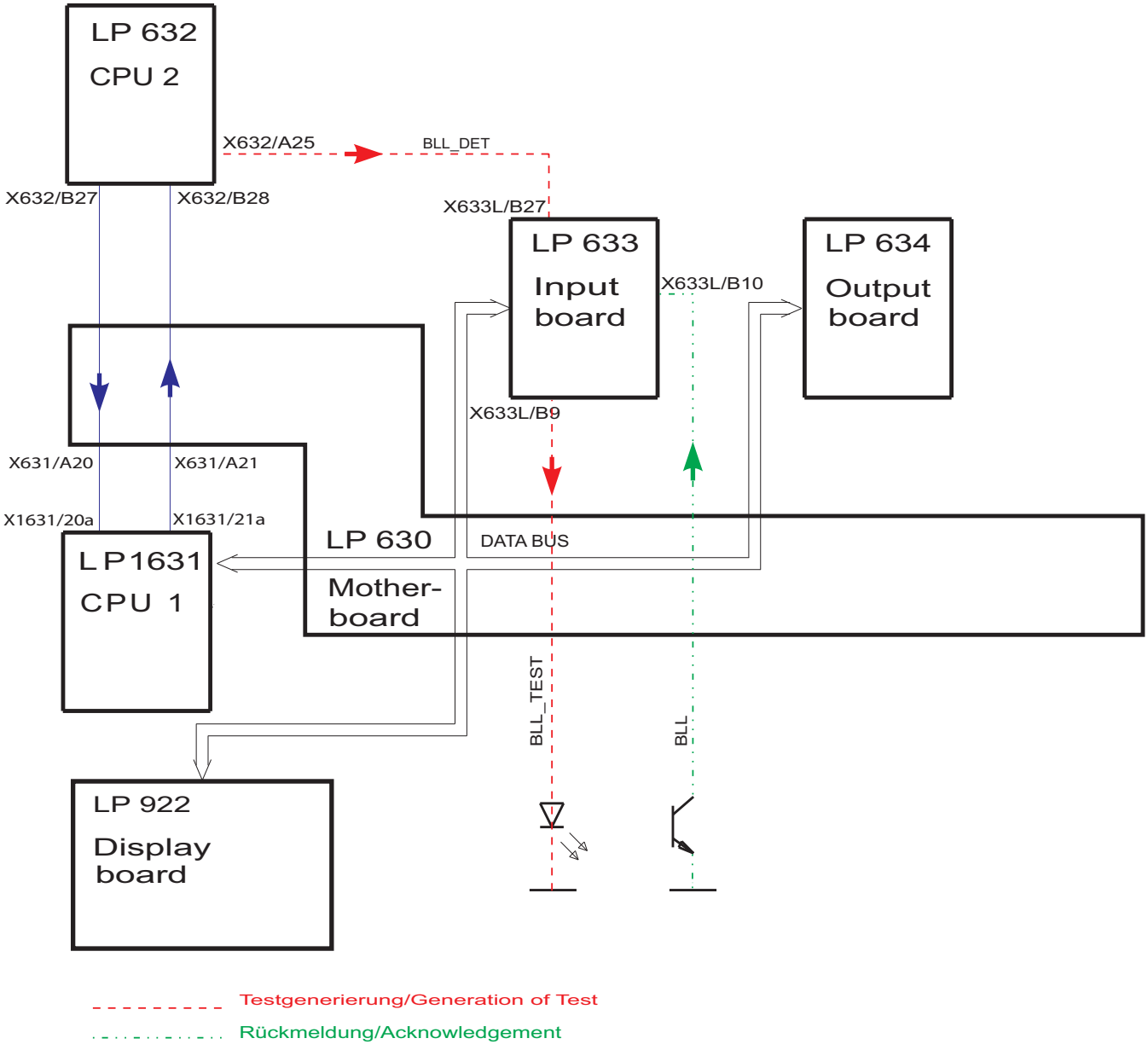
Test description Check the battery voltage under load.



11.1.1.12 Blood leak test

Test description

Test the blood leak detector by lowering the capacity of the transmitter diode.

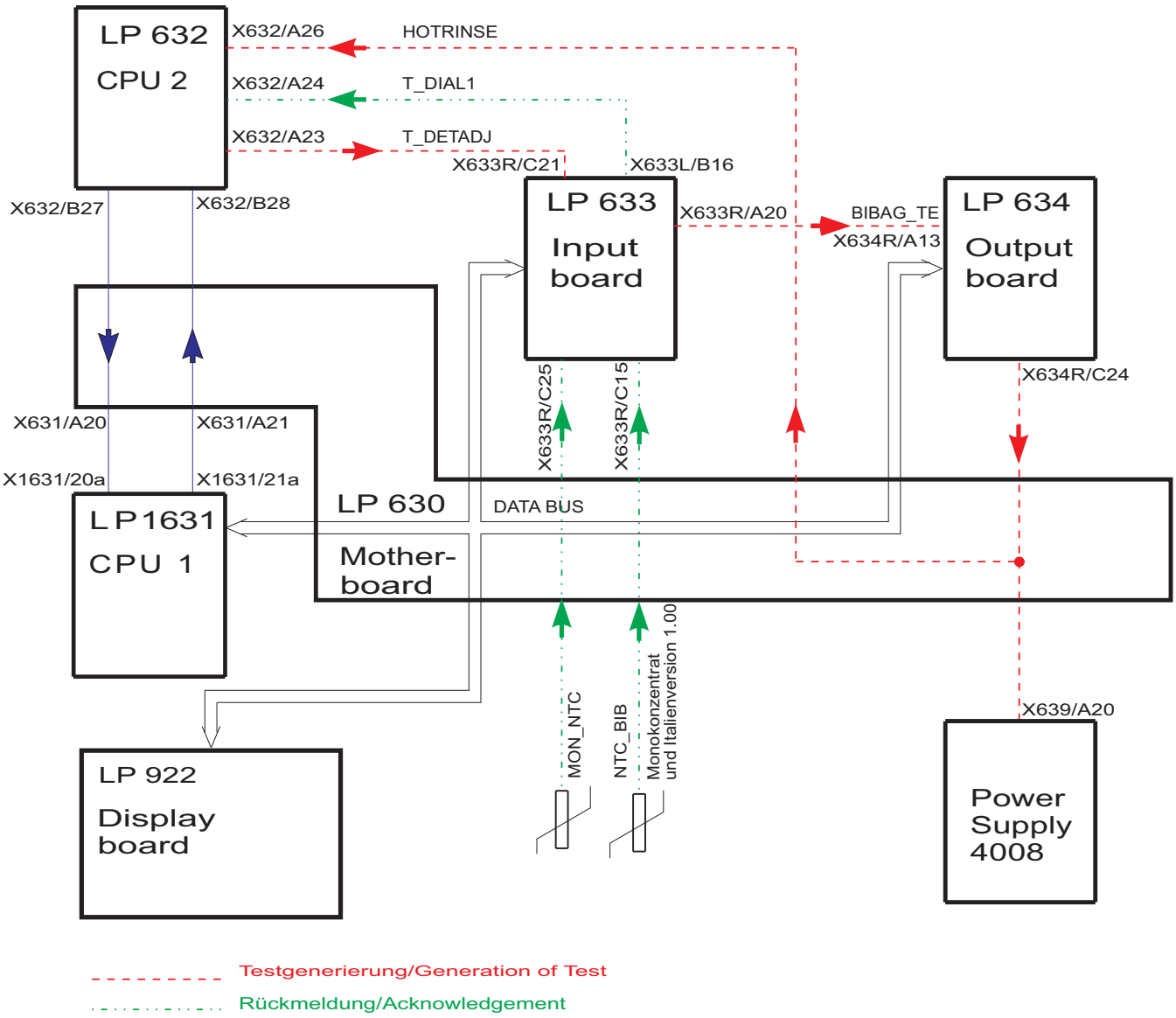


11.1.1.13 Temperature test

Test description

Test the upper alarm limit by electronically detuning the temperature display in positive direction.

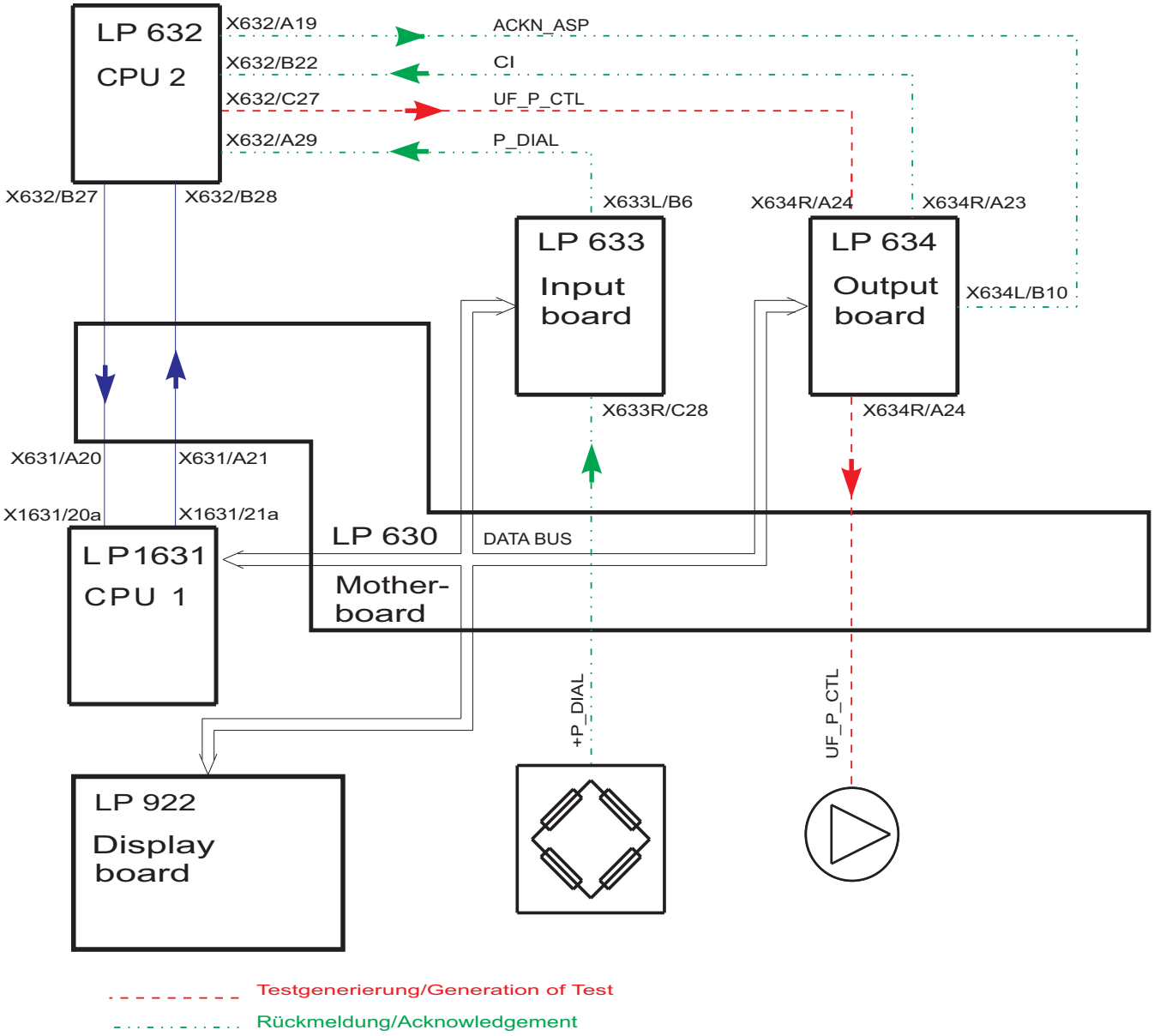
Figure



11.1.1.14 Negative pressure holding test

Test description

Within a defined time period, the actual value of the dialysate pressure transducer may change within certain limits only.



11.1.1.15 Positive pressure holding test

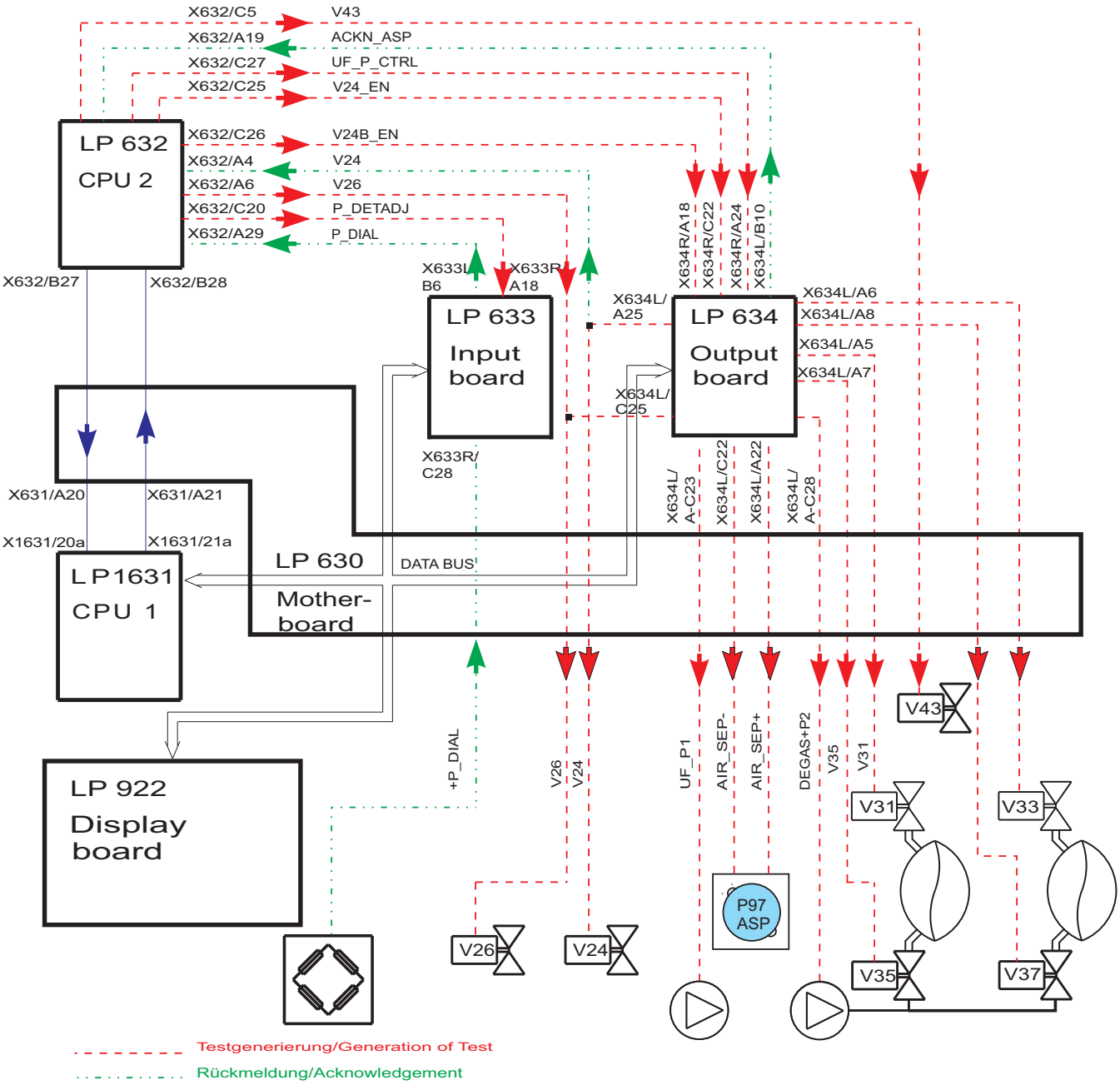
Test description

Check valves V24, V24b and V26 for proper functioning (mechanically).

Test the TMP pressure unit by electronically detuning it in positive direction.

With the dialysate flow off, apply positive pressure to the balancing system. The actual value of the dialysate pressure transducer is now monitored within a defined time period.

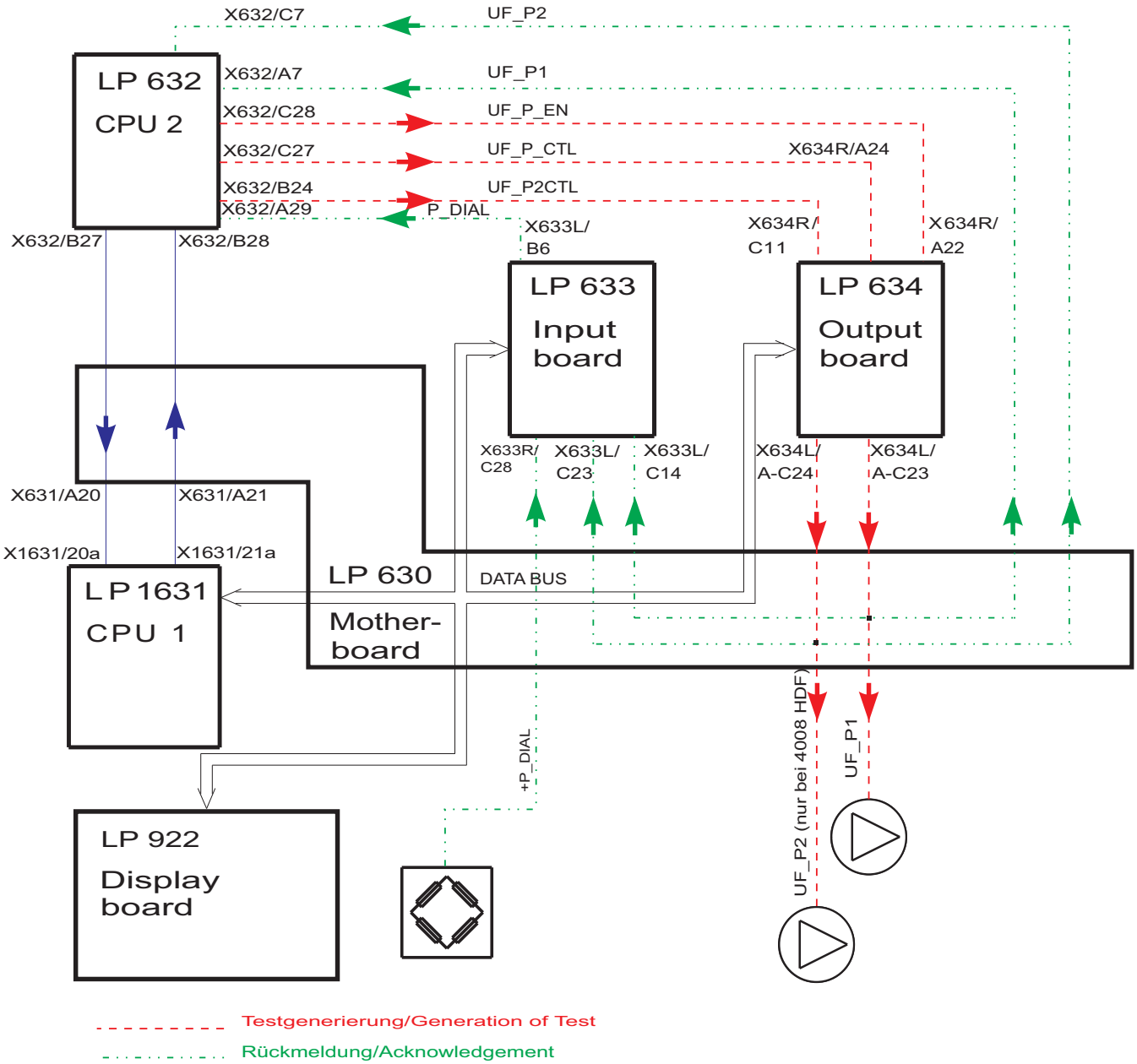
Test the pump segment of P97.



11.1.1.16 UF function test

Test description

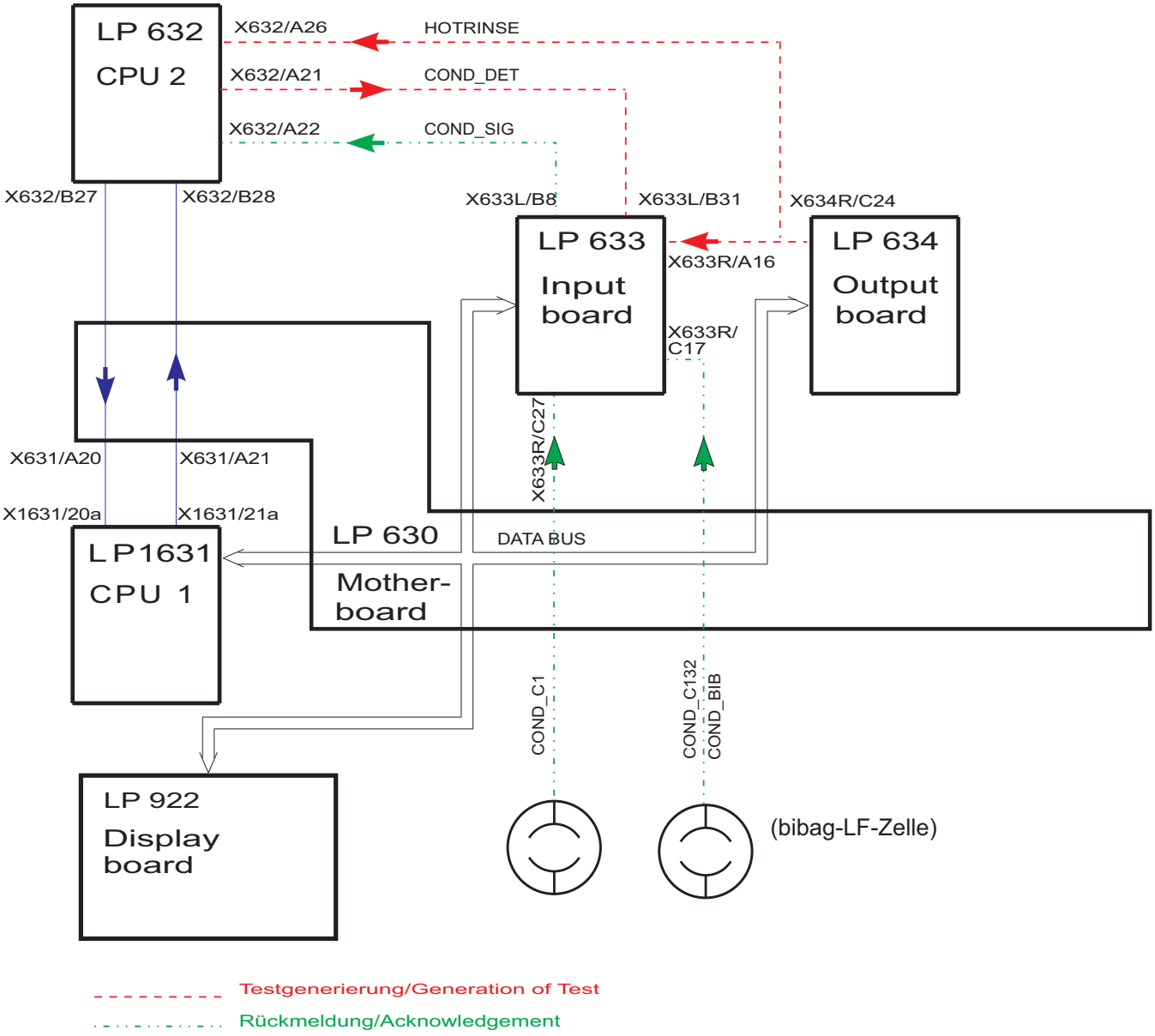
- CPU1 activates the UF pump with a defined rate.
- CPU2 checks the UF pump.
- CPU2 disables the control line of the UF pump and checks it for standstill.
- Check the UF counter.



11.1.1.17 Conductivity test

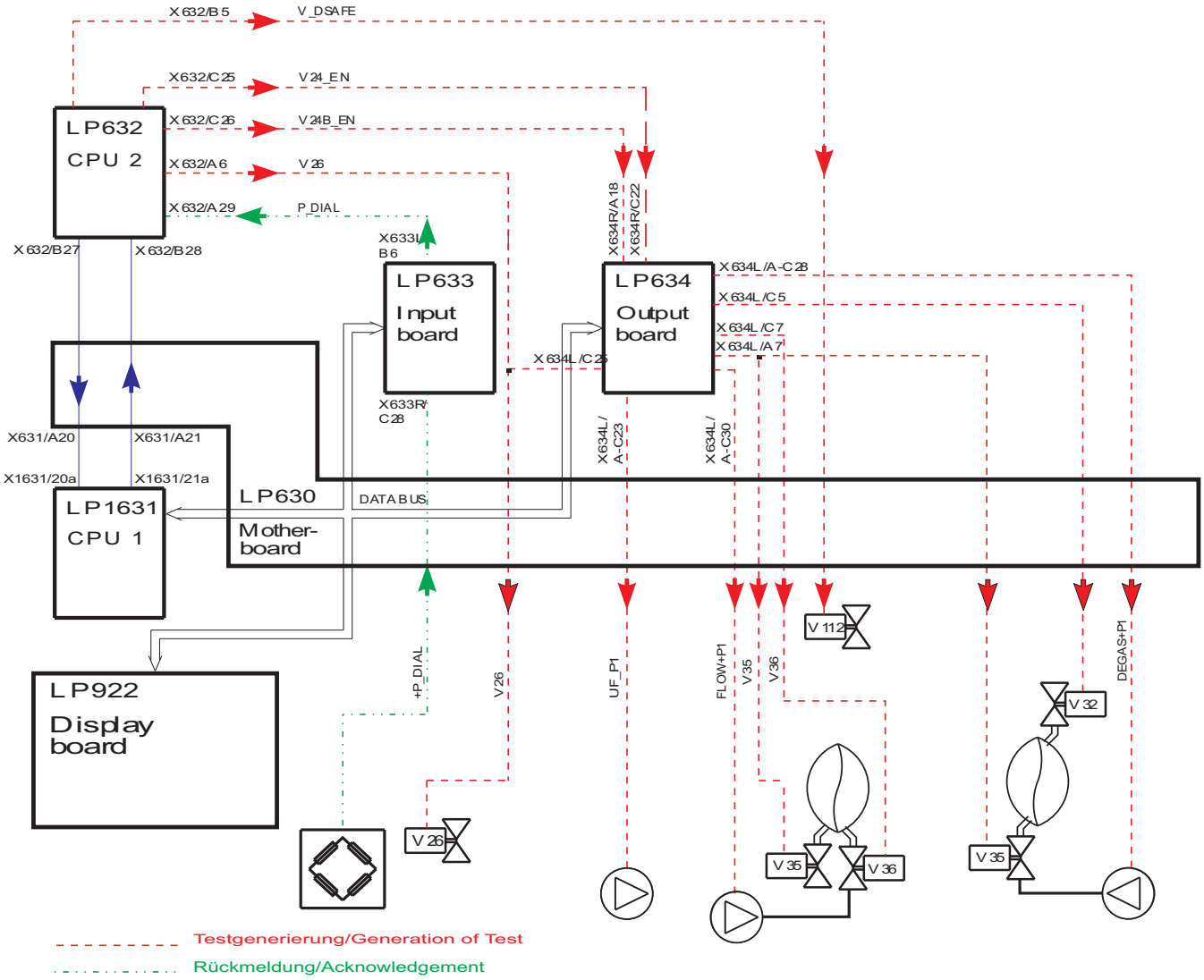
Test description

Test the alarm limits by electronically detuning the conductivity either by +5 % or by –5 %.



11.1.1.18 DIASAFE plus test/ HPU test

Test description Volume test of the inner capillaries and pressure holding test.

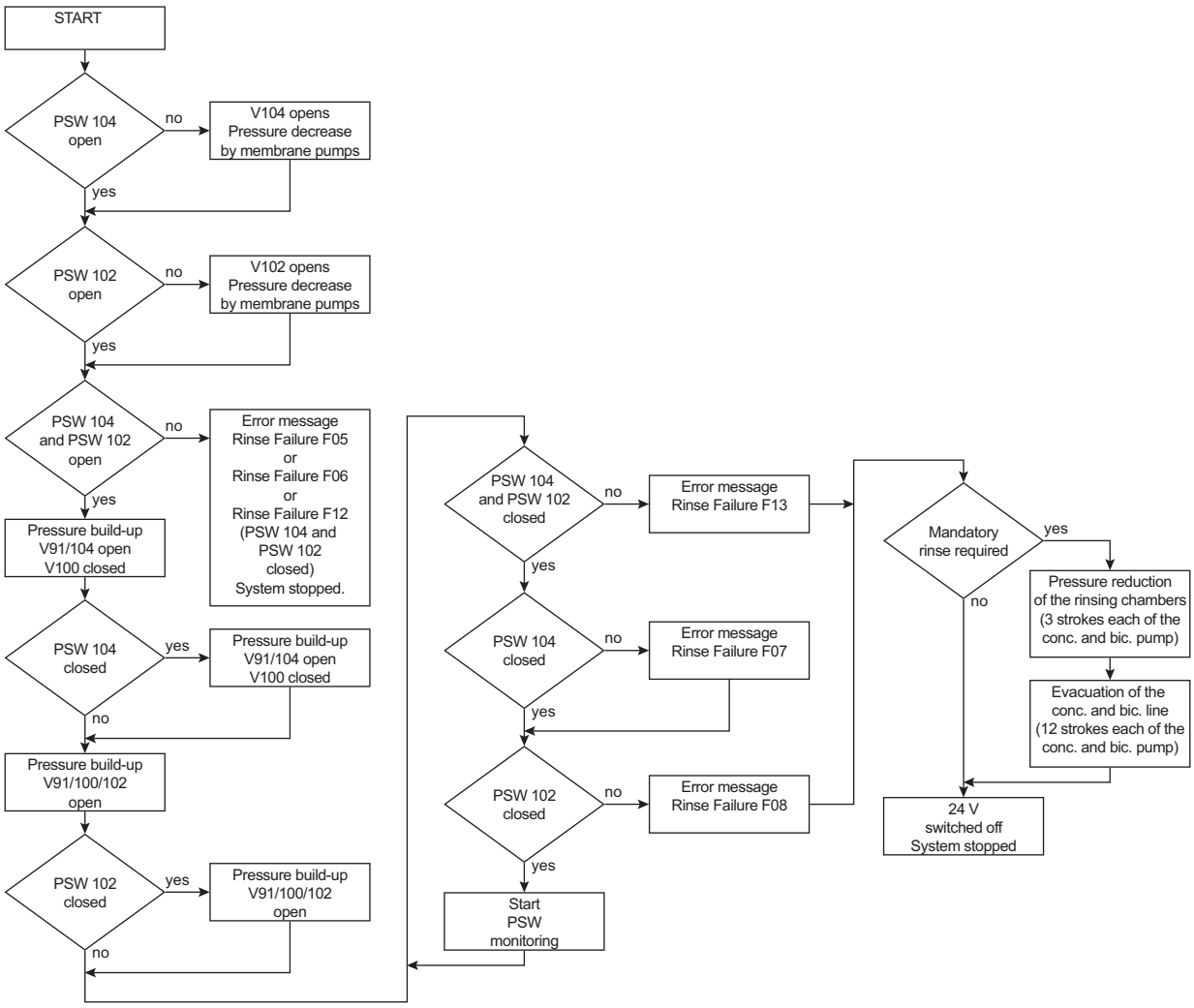


11.1.2 Tests during cleaning programs

11.1.2.1 PSW (pressure switch) monitoring during free rinsing (only with devices with CDS)

Requirements for the PSW test:

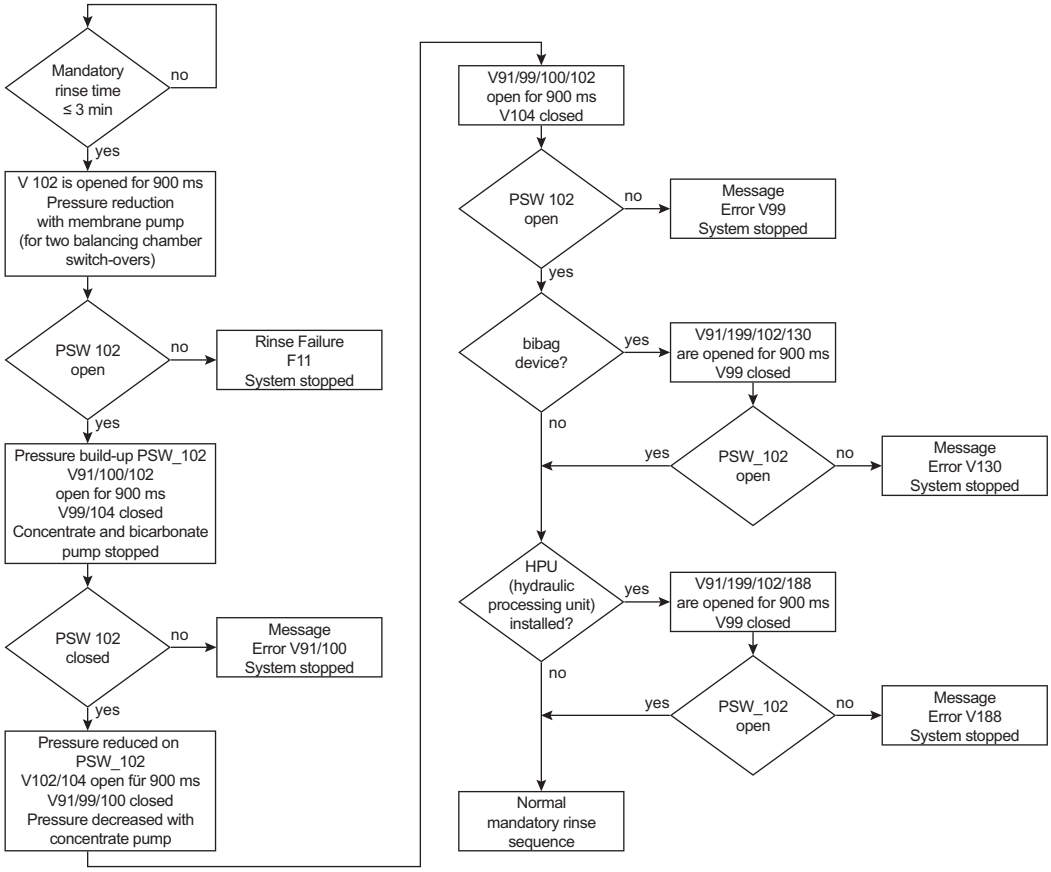
– P.C.B. LP 1631 (CPU 1): Field 2, DIP switch 8 to ON
– Rinse free with subsequent disinfection or heat disinfection (Dis. I – V)
or
Run a mandatory rinse as single program



The pressure switch is designed as a normally open switch

Switching point of the pressure switch (Envec) 700 mbar ±20 mbar

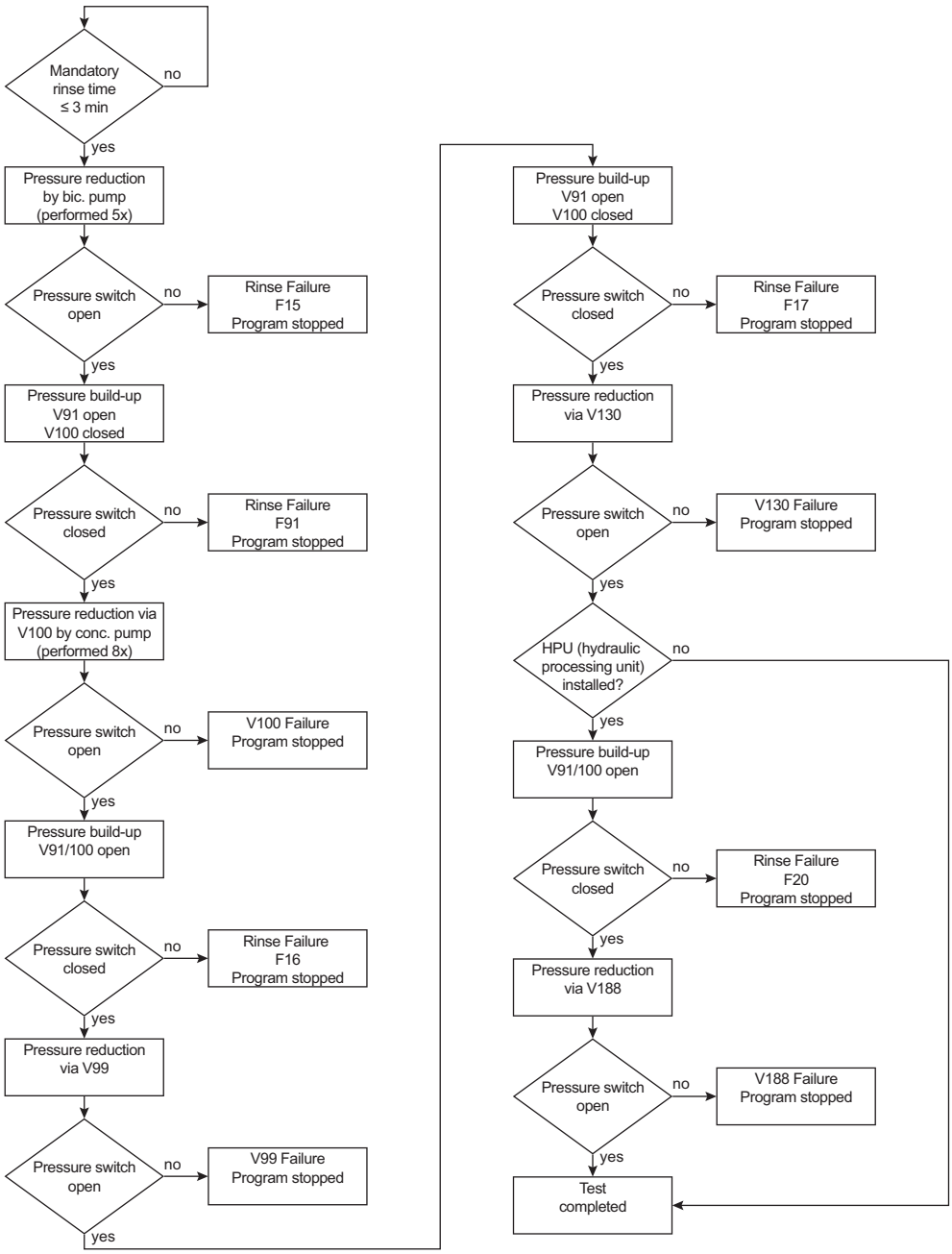
11.1.2.2 Rinse section test (check of V91, V99, V100) (only devices with CDS)



11.1.2.3 Rinse section test (check of V91, V99, V100, V130) (only devices without CDS)

PSW 134 is used for the test evaluation. The following requirements must be met for carrying out the rinse section test:

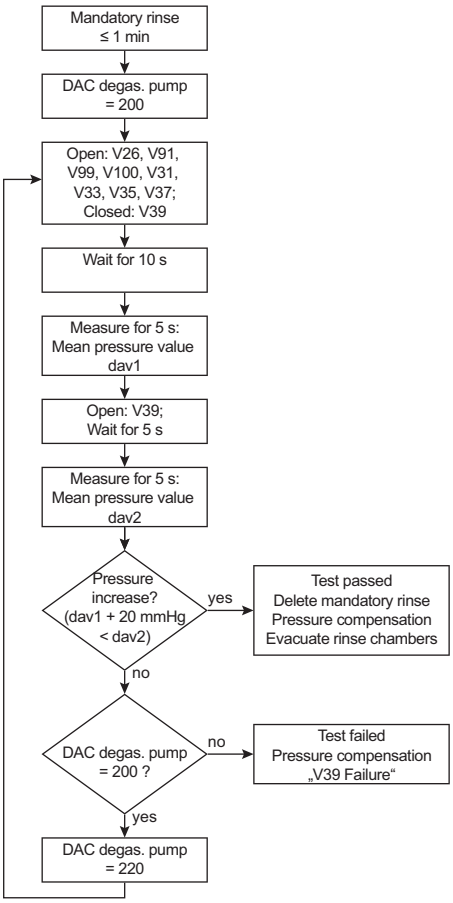
– The test is only carried out in mandatory rinse mode and during the last 3 minutes.
– P.C.B. LP 1631 (CPU 1): Field 2, DIP switch 7 to ON



11.1.2.4 V39 Test

The following requirements must be met for carrying out the V39 test:

– The test is only carried out in mandatory rinse mode and during the last minute.
– P.C.B. LP 632 (CPU 2): Field 2, DIP switch 5 to OFF



11.1.3 Description of the modules

11.1.3.1 Arterial blood pump

The arterial blood pump ensures a sufficient blood flow in the extracorporeal blood circuit. It is absolutely necessary that sterility is maintained and that the blood is prevented from becoming contaminated.

The blood pump is designed as roller pump and integrated into the EBM of the hemodialysis device. The blood line is installed between a stator, which, with its rolling surface bent in a circle, represents a thrust bearing, and a rotor, which is provided with rollers and pivoted in the stator. The pressure of the rollers causes the development of a narrow or seal. If the rollers are moving in the direction of delivery, the blood is pushed in this direction.

A microprocessor controls the stepper motor with quartz accuracy, depending on the selected delivery rate, the set line diameter, and the monitor signals.

The pressure measuring equipment comprises of a piezo-resistive pressure transducer. The pressure- proportional voltage is indicated on the monitor on a quasi-analog LED scale.

Hex switch: 2 (100 ml/min, special control of the blood pump rate)

Functions of the blood pump:

– RAM and CRC test after power on
– Control and monitoring of the function by a dual-processor system
– Emergency stop in case of an alarm: stop detection (15 or 30 seconds)
– Setting of the speed to 100 ml/min during priming
– Measurement of the arterial pressure or the Single-Needle pressure (depending on the model concerned)
– Semi-automatic insertion / removal of the line segment

11.1.3.2 Single-Needle blood pump (optional)

Essentially, the Single-Needle blood pump (SN) is identical with the arterial blood pump. The difference lies in the Single-Needle control. During Single-Needle operation, the pressure outlet of the compliance vessel is connected to the pressure connector of the Single-Needle pump. The pressure transducer is protected by a hydrophobic filter both in the external and the internal tubing system.

Hex switch: 3 (100 ml/min, special control of the blood pump rate)

The Single-Needle stroke volume can be set within a range from 10 ml to 50 ml in increments of 5 ml.

To adjust it, first press the **Start/Stop** key and the ▼ key simultaneously.
Then change the value by using the ▲ and ▼ keys.

The lower switching point is fixed to 75 mmHg.

The upper switching point depends on the stroke volume:

Stroke volume (ml)	10	15	20	25	30	35	40	45	50
Switching point (mmHg) ± 7 mmHg	110	130	150	172	195	219	244	270	299

11.1.3.3 Heparin pump

Since the blood passes through an extracorporeal circuit during hemodialysis, the risk of coagulation would be imminent within a short time. The heparin pump permits continuous heparinization of the blood, thus prolonging the coagulation time. The heparin volume required during dialysis differs from patient to patient and must be determined by a physician.

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. A Hall sensor signals when the piston has reached its upper end of travel. The safety system of the pump comprises of a speed monitoring device (slotted disc with optical sensor) and a motor current monitoring function.

Assignment of the hex switch of the heparin pump:

Warning

Do not change the position of the hex switch during operation.

Warning

The syringes classified as **approved** among the syringes indicated below were successfully tested with the device.

If syringes that are classified as **not approved** in the table below are used, it is the responsibility of the responsible organization to ensure correct function of the device.

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the hemodialysis device resulting from the use of non-approved or unsuitable consumables or accessories.

Syringe type table

Hex switch position	Syringe type	Release as part of overall approval
0	**20 ml BD / Fresenius**	**approved**
1	30 ml Fresenius	not approved
2	50 ml Fresenius	not approved
3	10 ml BD	not approved
4	30 ml BD	not approved
5	50 ml BD	not approved
6	20 ml Terumo	not approved
7	30 ml Terumo	not approved
8	50 ml Terumo	not approved
9	20 ml JMS	not approved
A	20 ml Nipro	not approved
B	20 ml Weigao	not approved
C	not assigned	–
D	not assigned	–
E	not assigned	–
F	not assigned	–

Heparin pump functions:

– RAM and CRC test after power on
– Delivery rate adjustable between 0.1 ml and 10 ml in increments of 0.1 ml
– Stop time adjustable between 0 min and 2 h in increments of 1 min
– Bolus administration

11.1.3.4 Air Detector

Air entering the patient's extracorporeal blood circuit may cause an air embolism. In order to catch limited amounts of air and to separate accompanying air bubbles, the venous blood line is expanded (venous bubble catcher). A major task of the air detector is to monitor the filling level in the venous drip chamber.

The protection system against air infusion uses the method of ultrasonic transmission. Ultrasonic converters are attached on either side of the venous bubble catcher. At periodic intervals of approx. 90 ms, a transmitting resonator generates attenuated ultrasonic vibrations at a natural resonance of approx. 90 kHz, which are absorbed by a receiving resonator. The amplitude of the signal received is dependent upon the medium between the converters. Its value is at its minimum with the venous bubble catcher empty (air) and at its maximum with bubble-free

fluids. The amplitude decreases with increasing air content (foam). The signal path is fail-safe up to and including the receiving resonator, i.e. the failure of any component always leads to a smaller amplitude and, thus, to an alarm. Starting at the receiving resonator, the signal voltage is always sent onto two independent receiver paths. As soon as the signal is too weak, one of these receiver paths causes the blood pump to stop and the other the venous line clamp to close.

The ▲ and ▼ keys are used to both raise and lower the blood level in the venous bubble catcher. As long as the ▲ key is pressed, the venous line clamp closes. The deaeration valve in the air detector module opens, and the blood level rises. The blood pump runs at reduced speed (100 ml/min). As long as the ▼ key is pressed, the venous line clamp remains open. The deaeration valve in the air detector module opens, the ventilation pump is running, and the blood level sinks. The blood pump runs at the preselected speed.

11.1.3.5 Optical Detector

The optical detector serves to detect if there is blood or NaCl solution or air in the venous return line downstream of the venous bubble catcher. In the hemodialysis device, the hemodialysis phase is defined by presence of a dark medium and the preparation phase by presence of a clear medium.

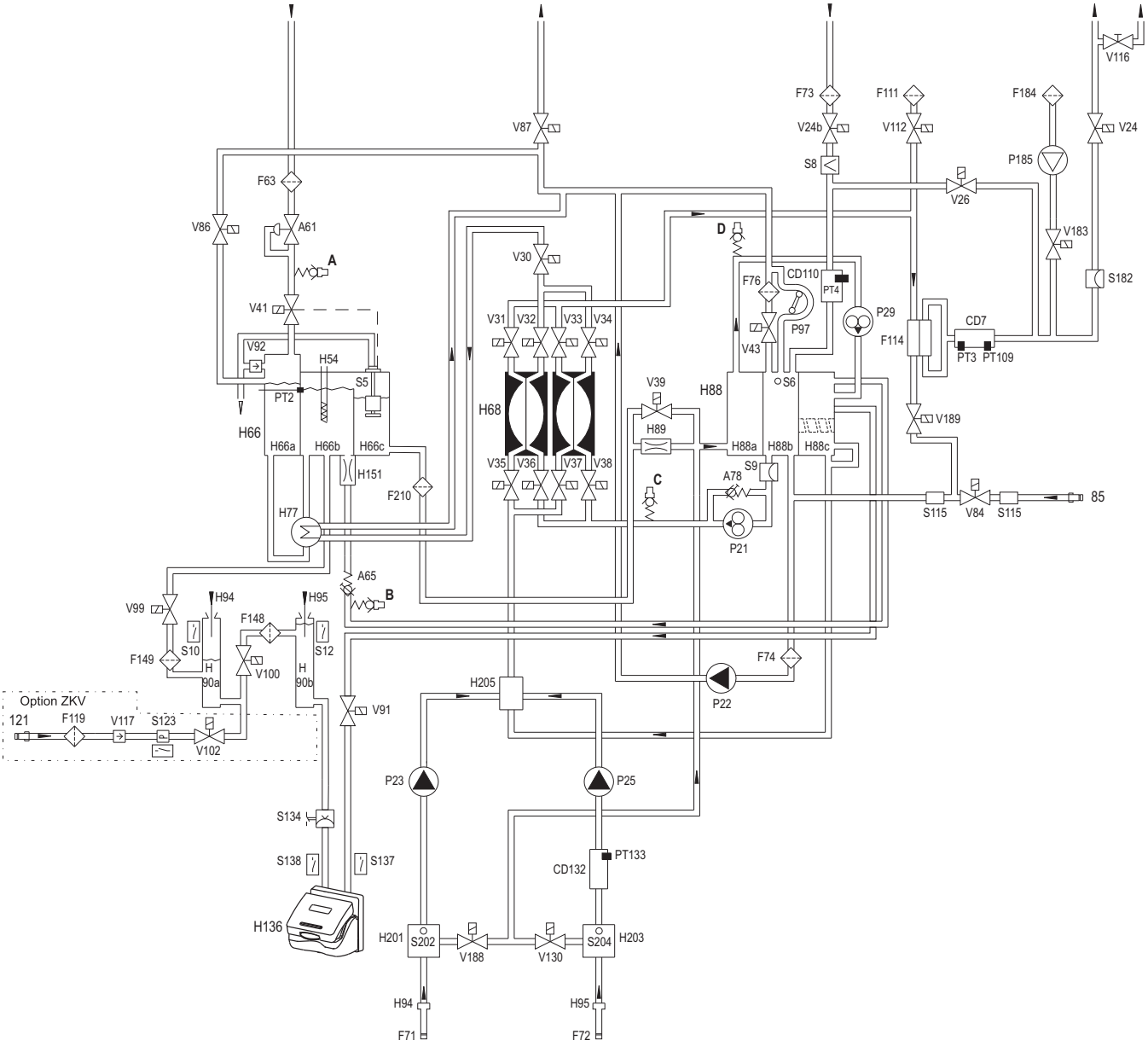
11.1.3.6 Venous pressure measurement

The venous pressure measuring equipment comprises of a piezo-resistive pressure transducer provided on the P.C.B. with following operational amplifier. The pressure-proportional output voltage is supplied onto the logic P.C.B. in the monitor. There, the pressure is indicated on a quasi-analog LED scale, and the transmembrane pressure is computed by determining the difference between the dialysate pressure and the venous pressure.

11.1.4 Functional description of the hydraulic unit

11.1.4.1 Hydraulic flow diagram

Fig.: Flow diagram



● Legend (hydraulic flow diagram)

PT2	Temperature sensor (in H66)
PT3	Temperature sensor (in CD7)
PT4	OCM temperature sensor (in CD110)
S5	Float switch (in H66)
S6	Level sensor (in H88)
CD7	Conductivity measuring cell
S8	Blood leak detector
S9	Pressure transducer
S10	Concentrate reed contact
S12	Bicarbonate reed contact
P21	Flow pump
P22	UF pump
P23	Concentrate pump
V24	Dialyzer inlet valve
V24b	Dialyzer outlet valve
P25	Bicarbonate pump
V26	Bypass valve
P29	Degassing pump
V30	Outlet valve
V31	Balancing chamber valve 1
V32	Balancing chamber valve 2
V33	Balancing chamber valve 3
V34	Balancing chamber valve 4
V35	Balancing chamber valve 5
V36	Balancing chamber valve 6
V37	Balancing chamber valve 7
V38	Balancing chamber valve 8
V39	Negative pressure valve
V41	Water inlet valve
V43	Fill valve
H54	Heater rod
A61	Pressure reducing valve
F63	Filter / water inlet
A65	Loading pressure valve
H66	Heater block
H66a	Water inflow chamber
H66b	Heater rod chamber
H66c	Float chamber
H68	Balancing chamber
F71	Filter / concentrate (in H94)
F72	Filter / bicarbonate (in H95)
F73	Filter / dialysate
F74	Filter / UF
F76	Filter / fill valve
H77	Heat exchanger
A78	Relief valve
V84	Disinfection valve
85	Disinfectant connector
V86	Recirculation valve
V87	Drain valve
H88	Multifunction block
H88a	Degassing chamber
H88b	Secondary air separator
H88c	Primary air separator
H89	Degassing orifice
H90a	Concentrate rinse chamber
H90b	Bicarbonate rinse chamber
V91	Rinse valve
V92	Ventilation valve
H94	Concentrate suction tube
H95	Bicarbonate suction tube
P97	Air separation pump
V99	Rinse valve
V100	Rinse valve
V102	Central concentrate delivery valve (optional)
PT109	Temperature sensor (in CD7)
CD110	Conductivity cell (OCM)
F111	Hydrophobic filter
V112	Ventilation valve
F114	Dialysate filter (DIASAFE® *plus*)
S115	Disinfection valve sensor
V116	Sampling valve
V117	Concentrate check valve
F119	Concentrate filter
121	Central Delivery System (concentrate connector)
S123	Pressure switch for V102
V130	bi*bag*® drain valve
CD132	bi*bag*® conductivity cell
PT133	bi*bag*® temperature sensor
S134	bi*bag*® pressure transducer
H136	bi*bag*® connector
S137	bi*bag*® microswitch 1
S138	bi*bag*® microswitch 2
F148	Filter (rinse valve 100)
F149	Filter (rinse valve 99)
H151	Control valve
S182	Pressure transducer 2
V183	Test valve
F184	Hydrophobic filter (test valve)
P185	Compressor
V188	Evacuation valve
V189	Retentate valve
H201	Air separation chamber (concentrate)
S202	Level sensor (concentrate)
H203	Air separation chamber (bicarbonate)
S204	Level sensor (bicarbonate)
H205	Mixing point (concentrate / bicarbonate)
F210	Filter (degassing orifice)

Hydraulics measurement points:

A	Reduced water inlet pressure
B	Loading pressure (balancing chamber)
C	Flow pump pressure
D	Degassing pump pressure

11.1.4.2 Description of the hydraulic unit

As soon as the water inlet valve V41 opens, the water flows through the pressure reducing valve A61 into the water inlet chamber H66a of the heater block H66 and across the heat exchanger H77 into the heater rod chamber H66b.

The concentrate pump P23 admixes the concentrate to the inflowing water per balancing chamber phase.

The vent tubing prevents pressure from building up in chambers H66b and H66c. In the HOT RINSE mode, the developing vapor can escape through the vent tubing.

While it is rising, the fluid is warmed up to the preset temperature by the heater H54. The heater is controlled by the temperature sensor PT2.

From chamber H66b, the dialysate flows into the chamber H66c. Incorporated in this chamber is the float switch S5, which controls the solenoid valve V41, thus ensuring the correct fluid level.

The degassing pump P29 draws in the dialysate via the degassing orifice H89. This generates a negative pressure of approx. 0.8 bar.

In the lines and the following degassing chamber H88a, the dialysate is degassed to a level which is sufficient for hemodialysis.

Via the degassing pump P29, dialysate and released air are directed tangentially into the primary air separator H88c, where air bubbles and the airless dialysate are separated. The air accumulates at the top of the chamber H88c. Then, together with the recirculation flow and via the loading pressure valve A65 as well as the chamber H66c, the air escapes into the atmosphere.

Chamber H88c is provided with a separating disc (standard hydraulics only), which serves to prevent bicarbonate, if added, from being recirculated via the heater rod chamber H66b.

At the bottom of chamber H88c, the degassed dialysate is pressed out and into the balancing chamber H68 by means of the loading pressure.

Together with the eight solenoid valves V31 to V38, the balancing chamber H68 constitutes the balancing system. Each of the two sections of the balancing chamber comprises of two compartments separated by an elastic membrane each. Hence, there are two chambers with four spaces:

– **F1** and **F2**: fresh solution
– **A1** and **A2**: used solution (waste)

As soon as one of the chambers (A1 or A2) is filled with dialysate, the solenoid valves are reversed in groups of four. The valves are reversed by the electronic evaluation of the current rise pulse of the drive motor of the flow pump P21; this pulse is created upon membrane abutment. Within the filling phase, F1 or F2 is filled with fresh dialysate by means of the loading pressure. In order to obtain a continuous flow, a second chamber is switched parallel to the first chamber. The second chamber is operated at an inverse sequence.

Each time the chamber is changed over (maximum deflection of the membrane), all valves are closed for approx. 100 ms (dead time).

From the balancing chamber H68, the dialysate flows through the conductivity cell CD7 with integrated temperature sensor PT3. The measured conductivity values are indicated on the monitor in mS/cm, related to 25 °C.

The temperature sensor PT3 has the following functions:

– Temperature compensation of the conductivity display
– Indication of the dialysate temperature

Should the actual values (temperature or conductivity) of the dialysate exceed or fall below the limit settings, the bypass valve V26 opens, and the dialyzer inlet valve V24 is closed. The device is now in the bypass mode. The dialysate is discharged into the drain not via the dialyzer, but via the secondary air separator H88b and the balancing chamber H68.

If the actual conductivity and temperature values of the dialysate are within the set limits, the dialyzer inlet valve V24 opens. The bypass valve V26 is closed. The dialysate flows to the dialyzer.

After the dialyzer, the dialysate which is now loaded with the urinary excreted substances flows via the filter F73, the dialyzer outlet valve V24b and the blood leak detector S8 into the secondary air separator H88b. The secondary air separator H88b comprises of the pressure transducer S9 and the level sensor S6.

A warning will be emitted by the blood leak detector S8 in case of blood losses of 0.5 ml per minute, for a hematocrit of 0.25.

Together with the venous return pressure, the signal of the pressure transducer S9 is evaluated and indicated on the monitor as TMP. The fluid level in the secondary air separator H88b is monitored by the level sensor S6. The secondary air separator H88b ensures that no air can enter the balancing chamber H68. Any presence of air bubbles in the balancing chamber H68 would cause balancing errors.

The dialysate is pressed through the flow pump P21 into the balancing chamber H68. As mentioned above, the balancing chamber valves are reversed by the current rise pulses of the drive motor of the flow pump P21. Using the speed of the flow pump P21, the dialysate flow can be adjusted in the dialysis program: 300, 500 and 800 ml/min. In the cleaning programs, the flow of the dialysate is fixed.

The relief valve A78 is used to limit the pressure of the flow pump P21 before the balancing chamber to approx. 2 bar.

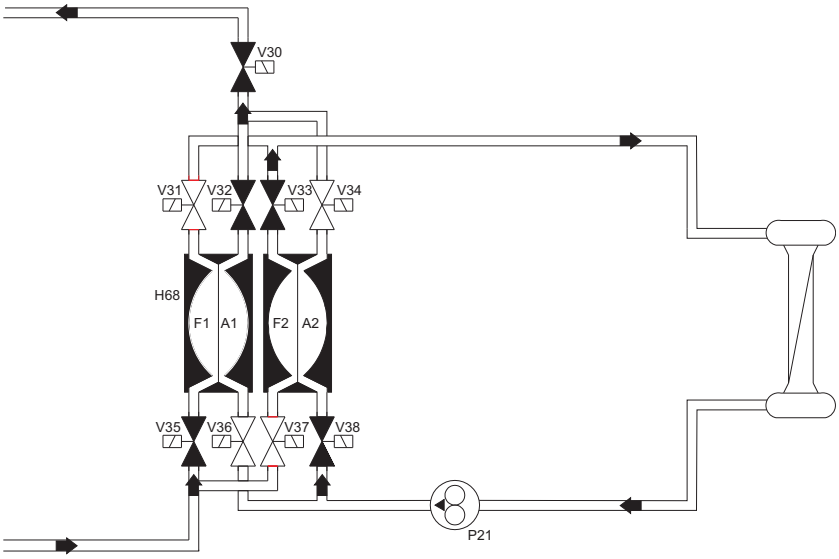
After the balancing chamber H68, the dialysate flows though the outlet valve V30, the heat exchanger H77 and the drain valve V87 into the drain.

The recirculation valve V86 and the drain valve V87 serve to recirculate fluid during the hot rinsing and disinfection programs.

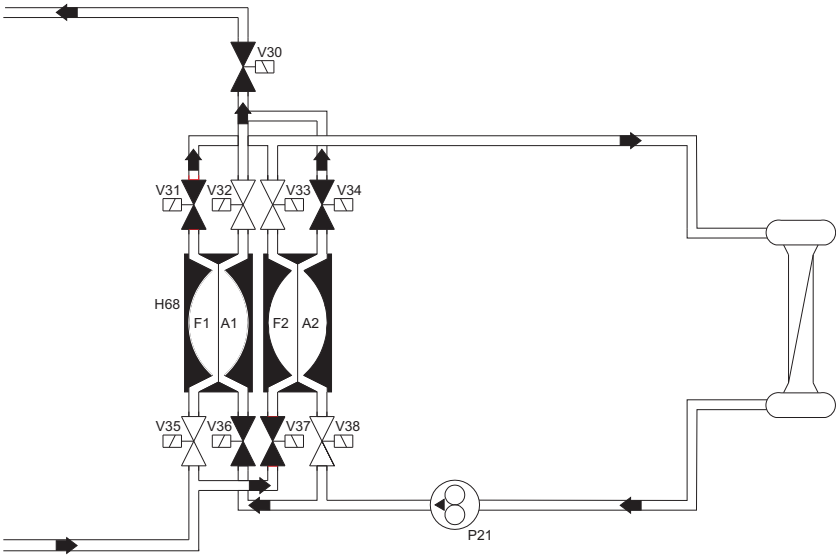
11.1.4.3 Functional principle of the balancing chamber

- **Standard program**

1. cycle:



2. cycle:



1. cycle: Closed valves: V31, V34, V36 and V37

F1 is filled with fresh solution

A1 used solution is discharged into the drain

F2 fresh solution is forced into the dialyzer

A2 is filled with used solution

2. cycle: Closed valves: V32, V33, V35 and V38

F1 fresh solution is forced into the dialyzer

A1 is filled with used solution

F2 is filled with fresh solution

A2 used solution is discharged into the drain

This system ensures that equal amounts of fluid enter and exit the dialyzer. This results in an exact balancing of the dialysate and, in conjunction with the UF pump P22, a controlled volumetric ultrafiltration.

- **Secondary air separation via air separation pump P97**

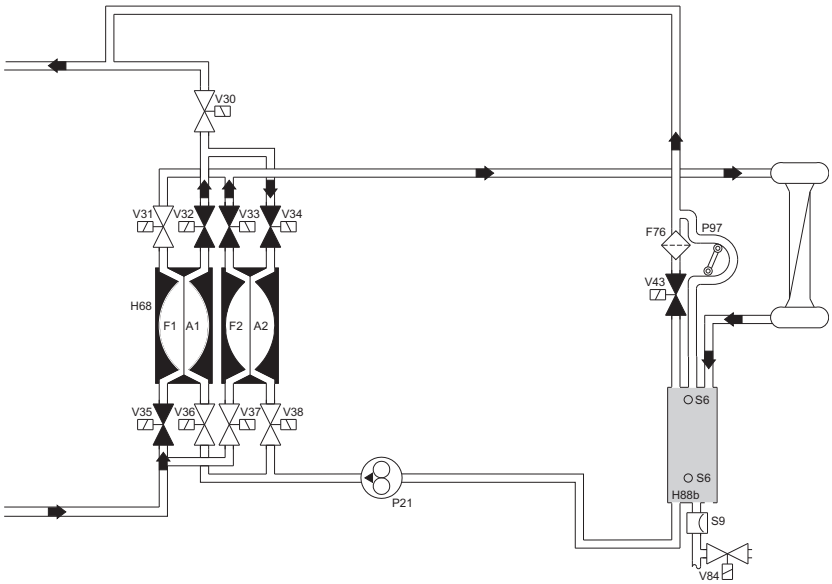
As soon as the fluid level in the secondary air separator H88b has dropped below the level sensor S6, this sensor activates the air separation pump P97. Should the fluid level not have reached the level sensor S6 within a given time period, the FILL PROGRAM is started.

Note

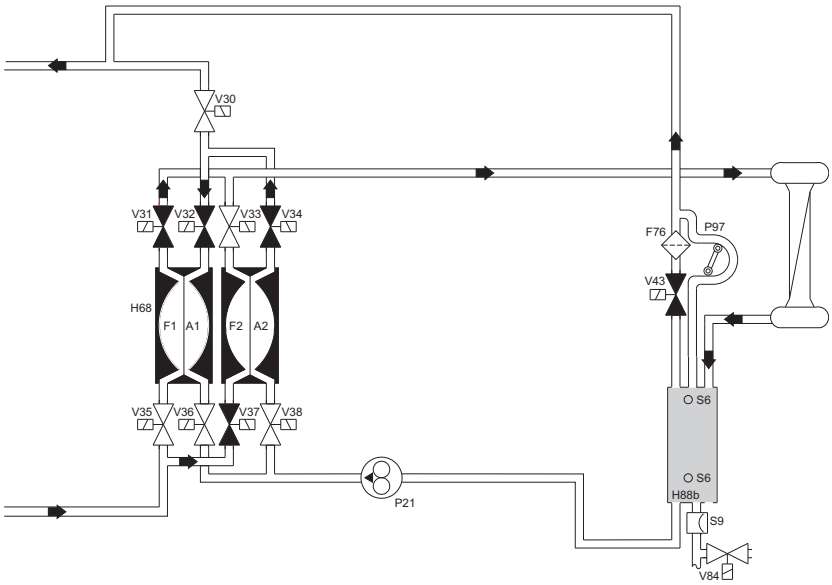
In order to detect the fluid level, the level sensor S6 requires a fluid with a certain minimum conductivity, which is definitely achieved in all dialysis programs. Separation of air is only required for the dialysis programs. In all other programs, the air separation pump P97 and the fill valve V43 are force-actuated.

- **Fill program: Air separation by fill valve V43 at atmospheric pressure**

1. cycle:



2. cycle:



If not enough air was separated and the fluid level is still below the level sensor S6, the FILL PROGRAM is activated. The fill valve V43 opens. The air can escape into the drain.

1. cycle:
Chamber F1 is filled. This forces the fluid from chamber A1 into chamber A2. The fluid is then forced by chamber A2 via the dialyzer and into the secondary air separator H88b.

2. cycle:
Chamber F2 is filled. This forces the fluid from chamber A2 into chamber A1. The fluid is then forced by chamber A1 via the dialyzer and into the secondary air separator H88b.

Filling is performed in this way to prevent a change in conductivity. As is the case in the standard program, here as well one stroke of the concentrate pump P23 is still accomplished per balancing chamber cycle (30 ml).

A fill program is always activated at the beginning of hemodialysis (to fill the dialyzer). Should it be activated during the treatment (Blood detected (optical detector dark)), this is shown on the display.

Note

Repeated activation of the fill program during treatment indicates a defect (leakages).

11.1.4.4 CDS - Central Delivery System (option)

The Central Delivery System is connected to the concentrate connector 121. The concentrate flows into the rinse chamber via the inlet filter F119 and valve 102. Through the connected concentrate suction tube H94, the concentrate pump P23 delivers the concentrate to the mixing point.

During dialysis, the rinse valves V91, V99 and V100 are closed. Valve V102 (option) is open.

During the cleaning programs, valve V102 (option) is closed. During the suction phase of concentrate pump and bicarbonate pump, the rinse valves V91 and V99 open for 500 ms upon each balancing chamber switching cycle. Rinse valve V100 is open.

To check the tightness of valve V102 (option), the pressure switch is tested during the rinse phase with following disinfection or heat disinfection or during mandatory rinse. To perform this test, pressure is applied to the lines between check valve V117 and valve V102 (option). The pressure switch S123 is used to monitor the pressure. Three minutes before the mandatory rinse program is completed, a functional test of rinse valve V91, V99 and V100 is performed.

11.1.4.5 Program runs in cleaning programs

- **Cleaning program flow diagrams – overview**

End of dialysis		
Rinse PGM 1: –R– PGM 2: –R– endl.	Hot rinse PGM 1: –F–HR–C– PGM 2: –F–HR– PGM 3: –IHR– / –IHR–C–	Disinfection (cleaning) PGM 1: –F–D–M– PGM 2: –F–HDIS–M– PGM 3: –F–D–M–HR– PGM 4: –F–HDIS–M–HR– PGM 5: –F–D(F)–M–
Dialysis		

- **Explanation of abbreviations used**

PGM	Program
R	Rinse
R endl.	Rinse endless
F	Free rinsing
HR	Hot rinse
C	Cooling rinse
D	Disinfection
D(F)	Cleaning Disinfectant is sucked in from the front (concentrate suction tube)!
HDIS	Hot disinfection
M	Mandatory rinse
IHR	Integrated hot rinse

- **Notes on the program runs**

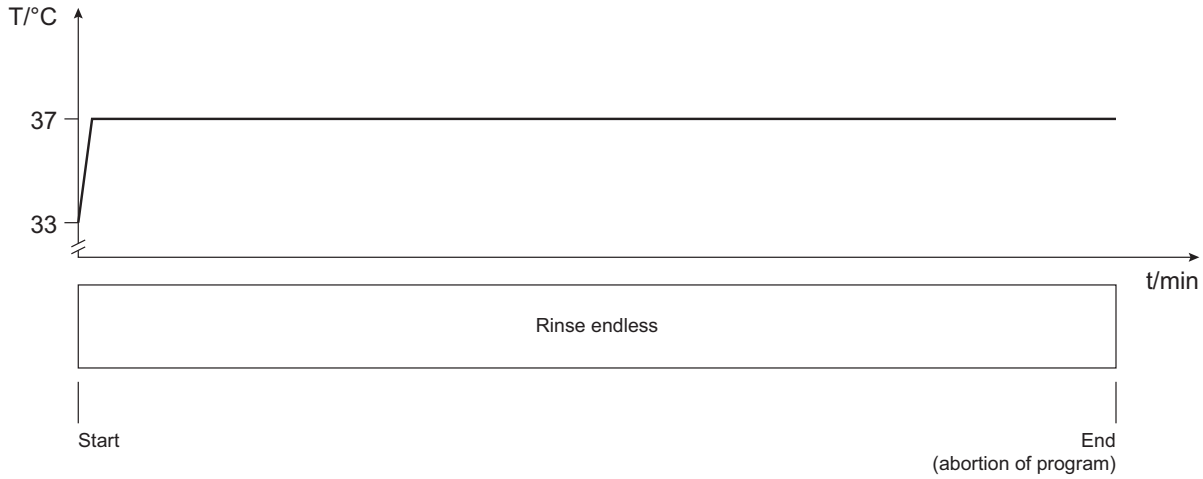
The rinse chamber is emptied at the end of the set program for approx. 1 min.

The time specifications are based on the factory setting. Shorter or longer program times can be set at any time with the SETUP MENU (see chapter 5.1.3 page 5-3).

- **Rinse**

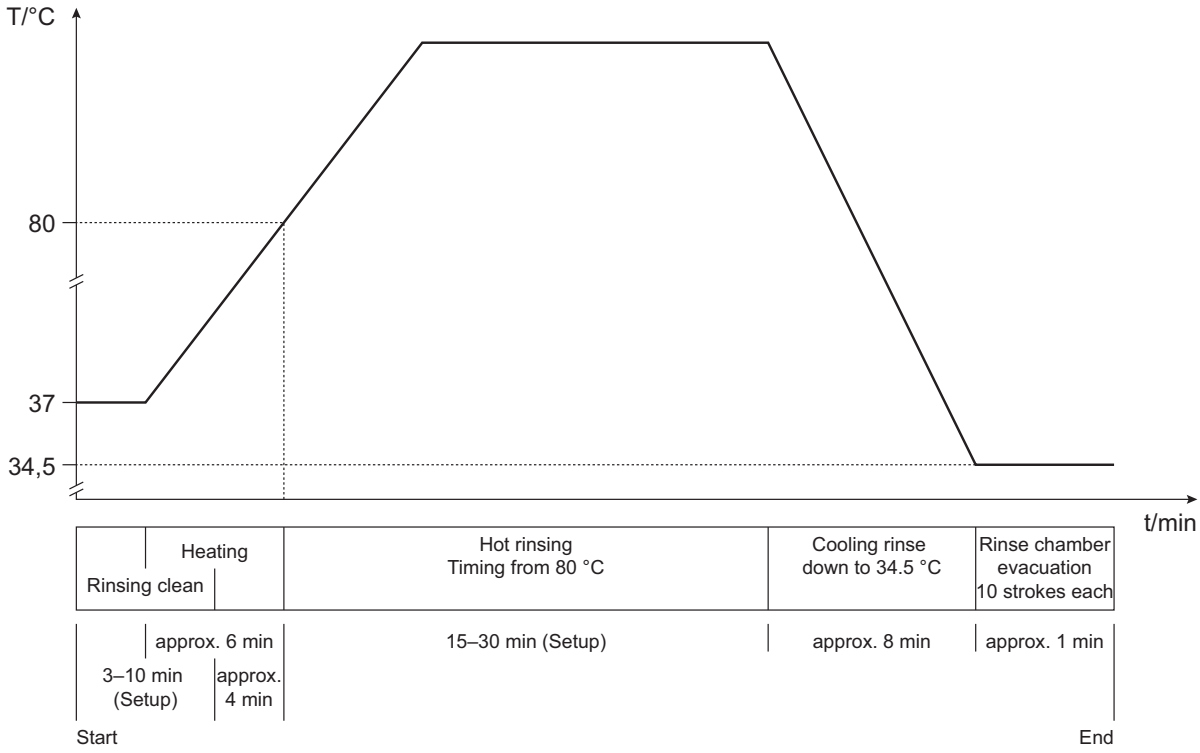
PGM 1: –R–

PGM 2: –R– endl. (endless)

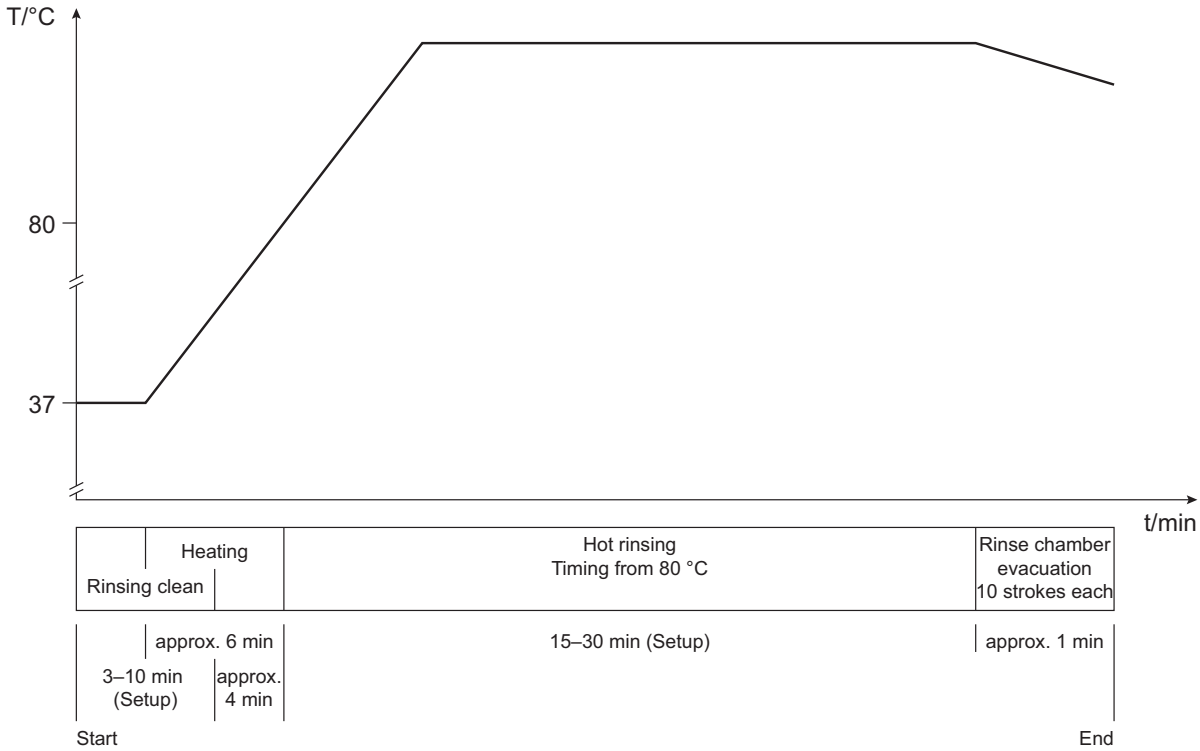


- **Hot rinse**

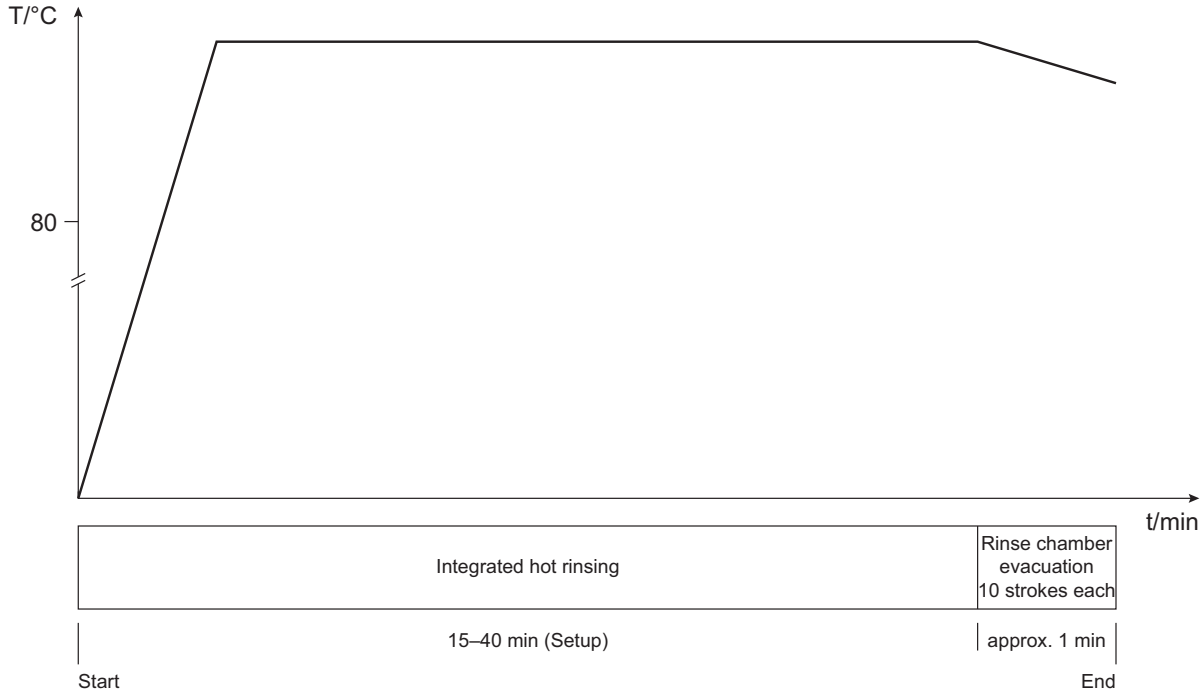
PGM 1: –F–HR–C–



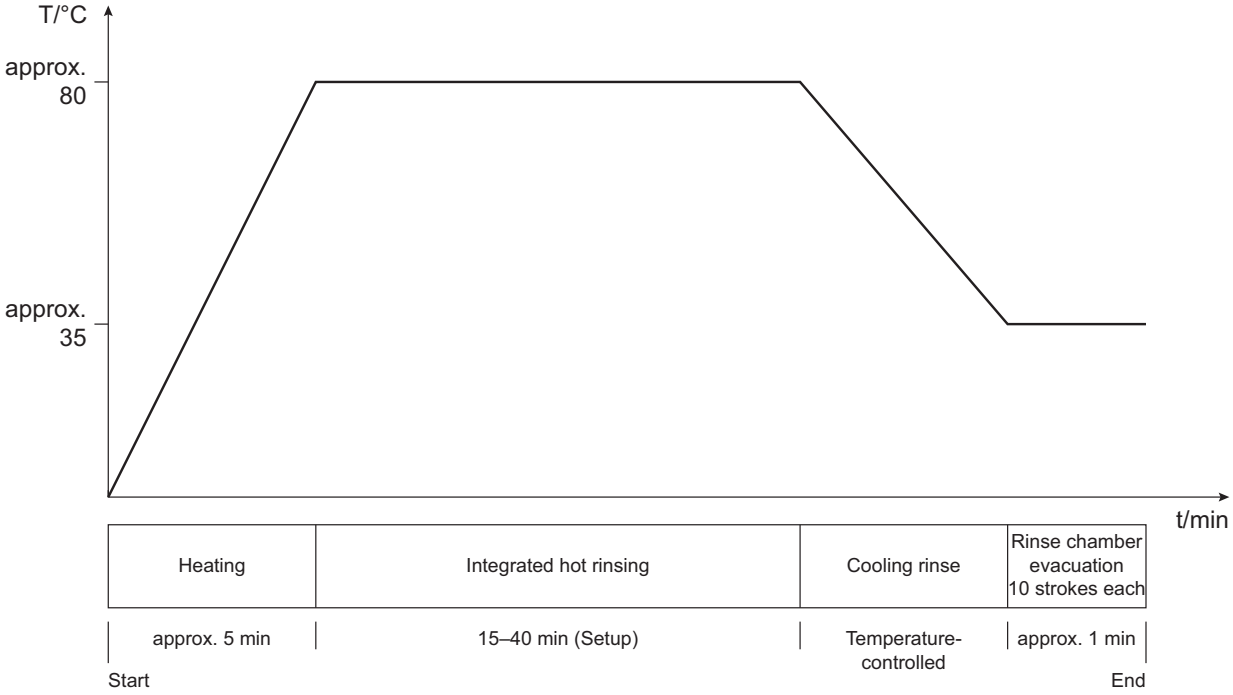
PGM 2: –F–HR–



PGM 3: –IHR–

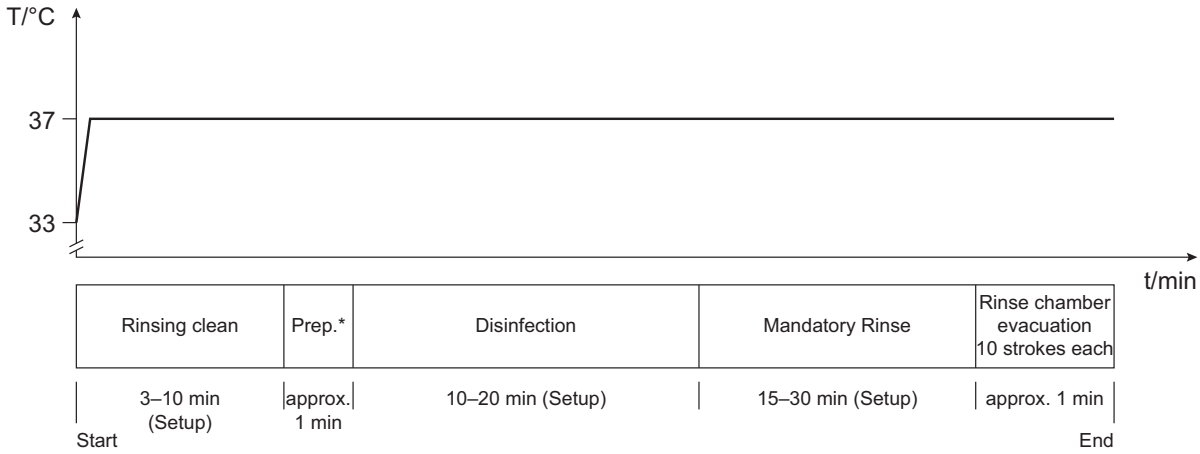


PGM 3: –IHR–C–



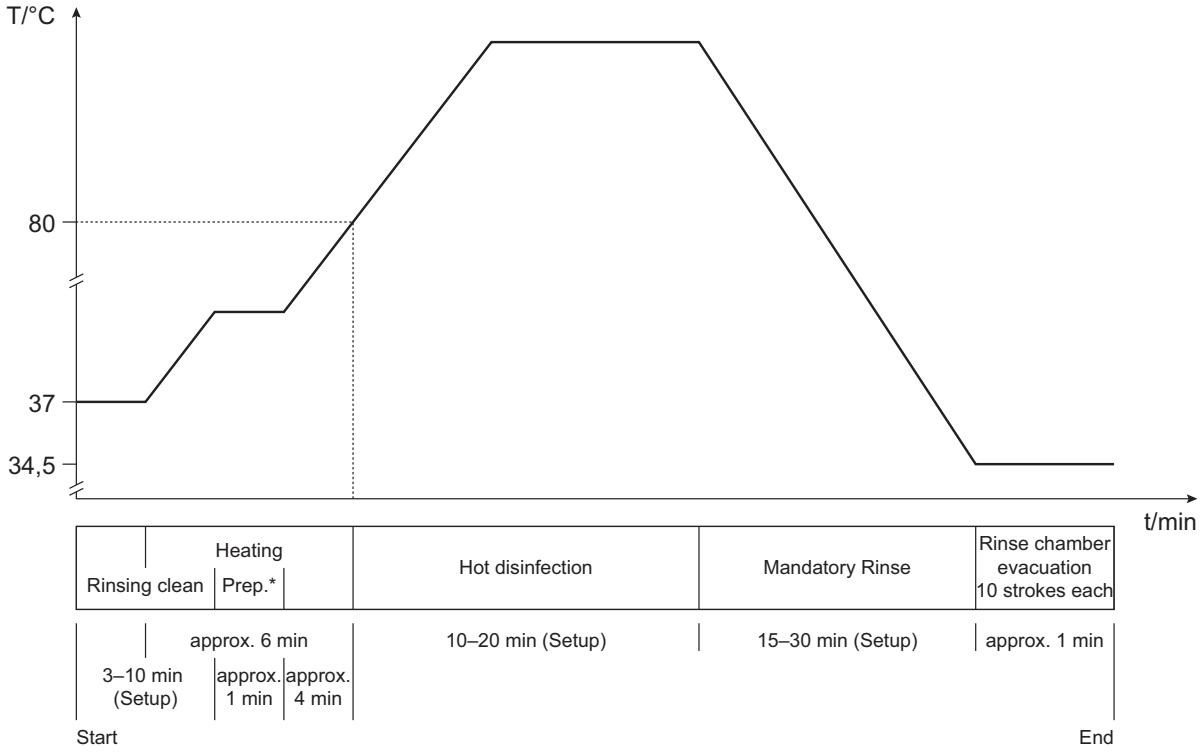
● Disinfection (cleaning)

PGM 1: –F–D–M–



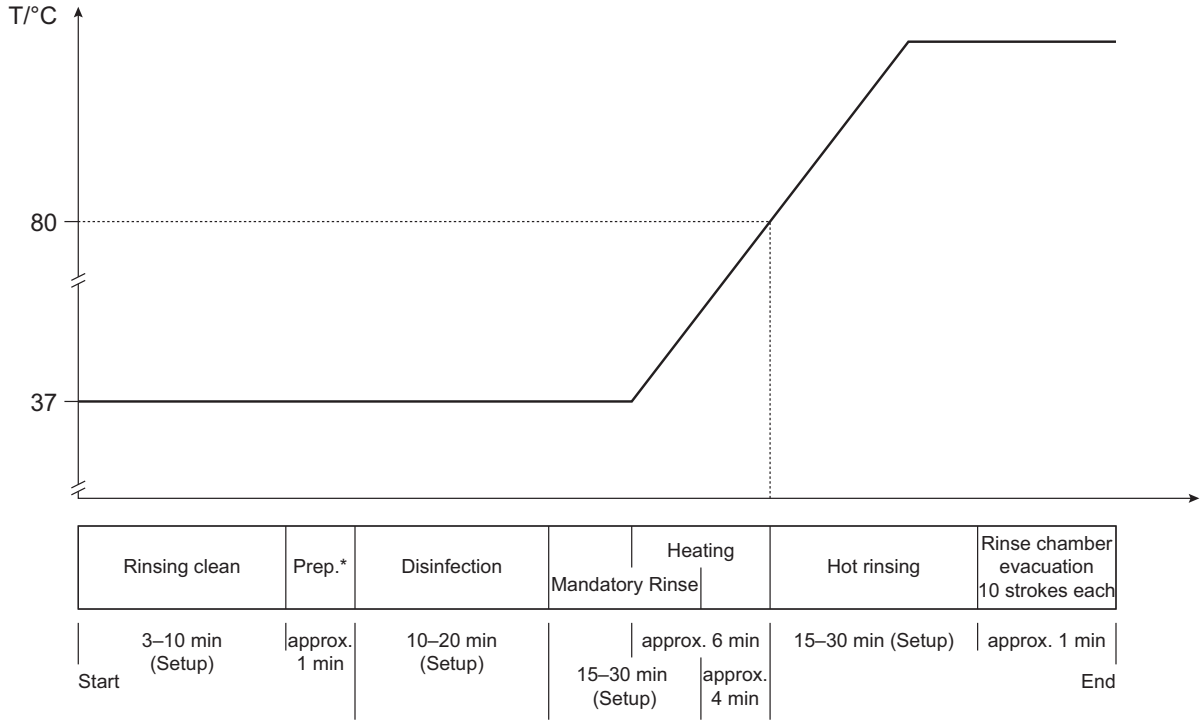
Prep.*: preparation phase:
Heater off.
Set the level of the float switch chamber below the lower switching point of the float switch by 1 balancing chamber changeover and 4 UF pump strokes.
Aspiration of disinfectant for 50 UF-pump strokes.

PGM 2: –F–HDIS–M–



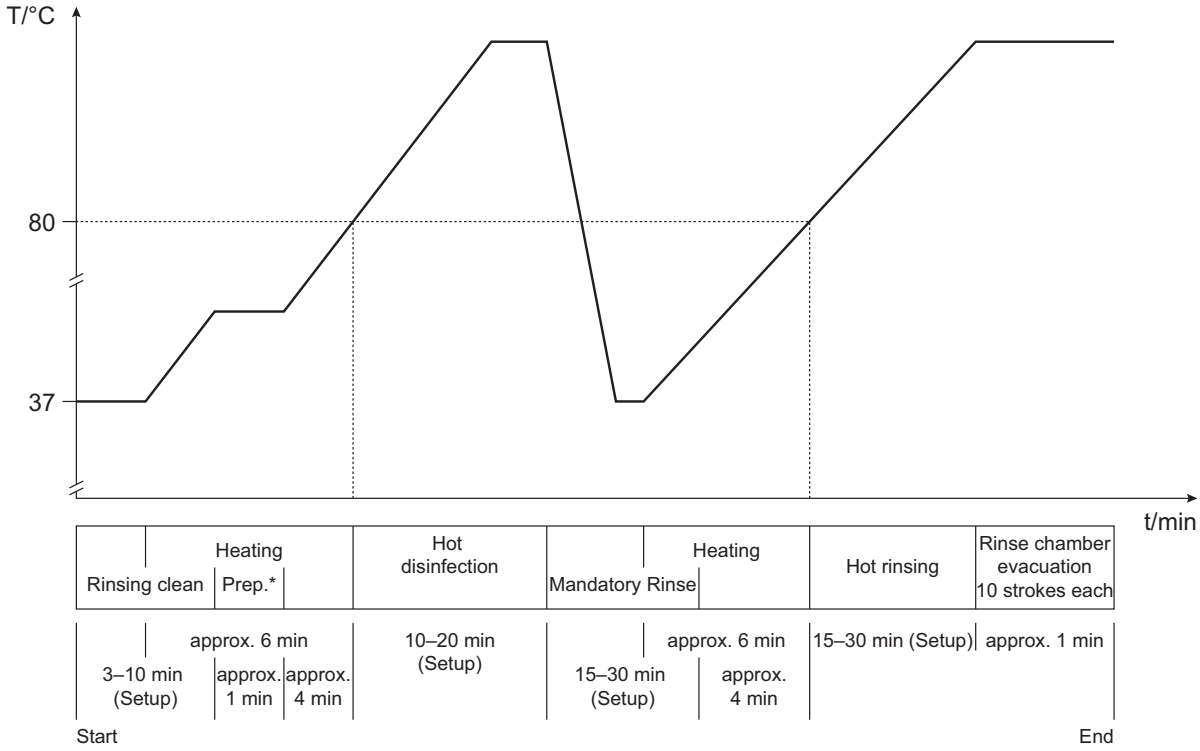
Prep.*: preparation phase:
Heater off.
Set the level of the float switch chamber below the lower switching point of the float switch by 1 balancing chamber changeover and 4 UF pump strokes.
Aspiration of disinfectant for 50 UF-pump strokes.

PGM 3: –F–D–M–HR–



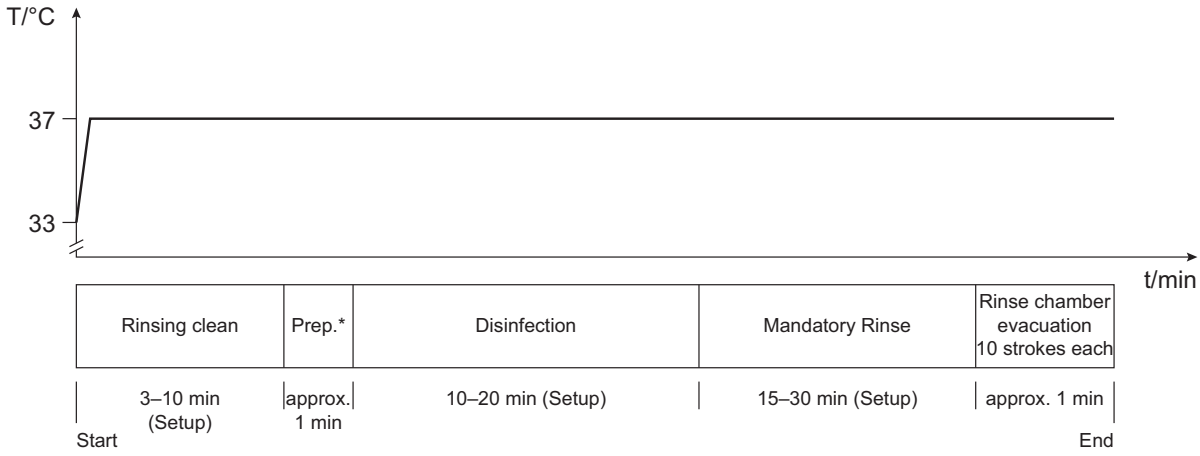
Prep.*: preparation phase:
Heater off.
Set the level of the float switch chamber below the lower switching point of the float switch by 1 balancing chamber changeover and 4 UF pump strokes.
Aspiration of disinfectant for 50 UF-pump strokes.

PGM 4: –F–HDIS–M–HR–



Prep.*: preparation phase:
Heater off.
Set the level of the float switch chamber below the lower switching point of the float switch by 1 balancing chamber changeover and 4 UF pump strokes.
Aspiration of disinfectant for 50 UF-pump strokes.

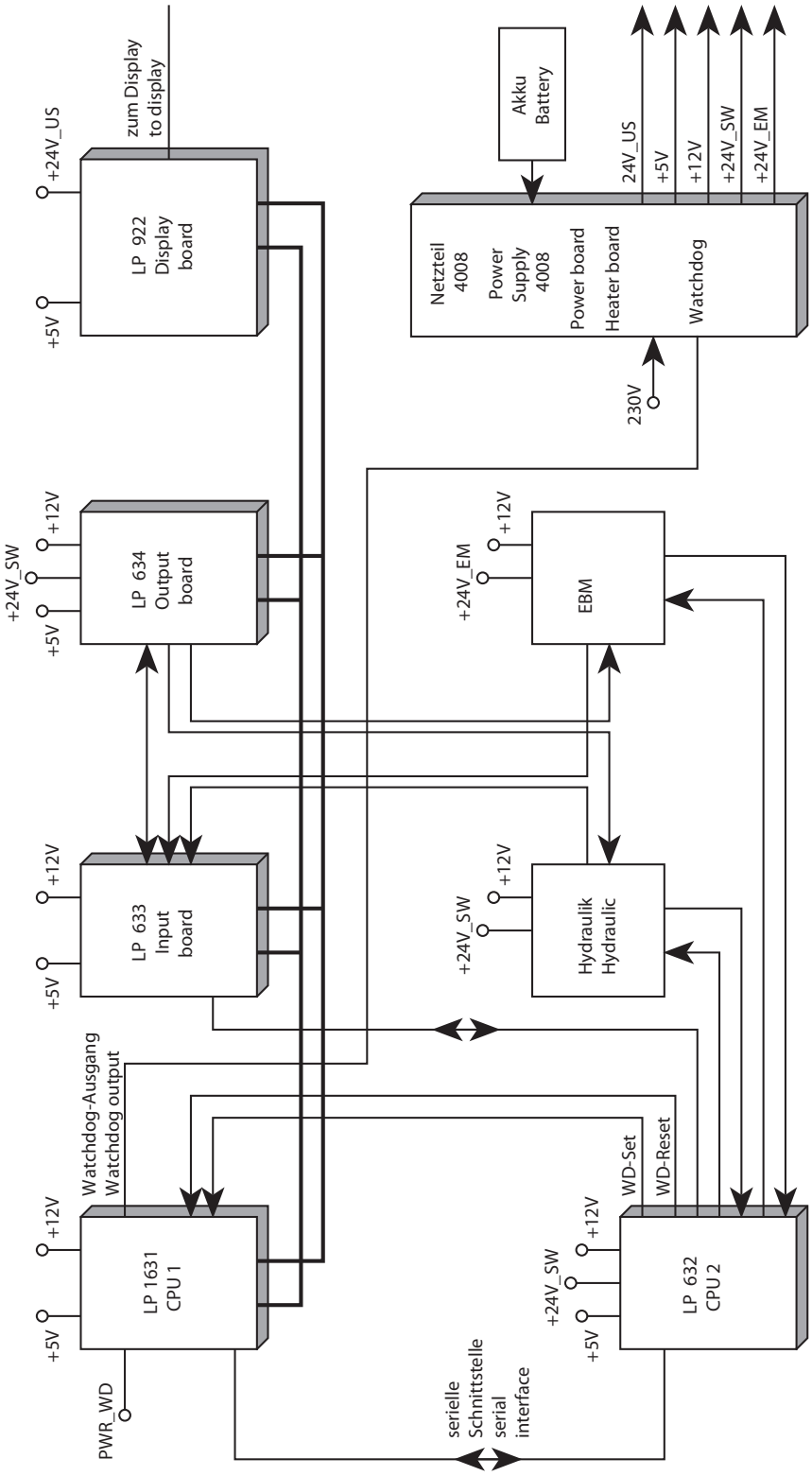
PGM 5: –F–D(F)–M–



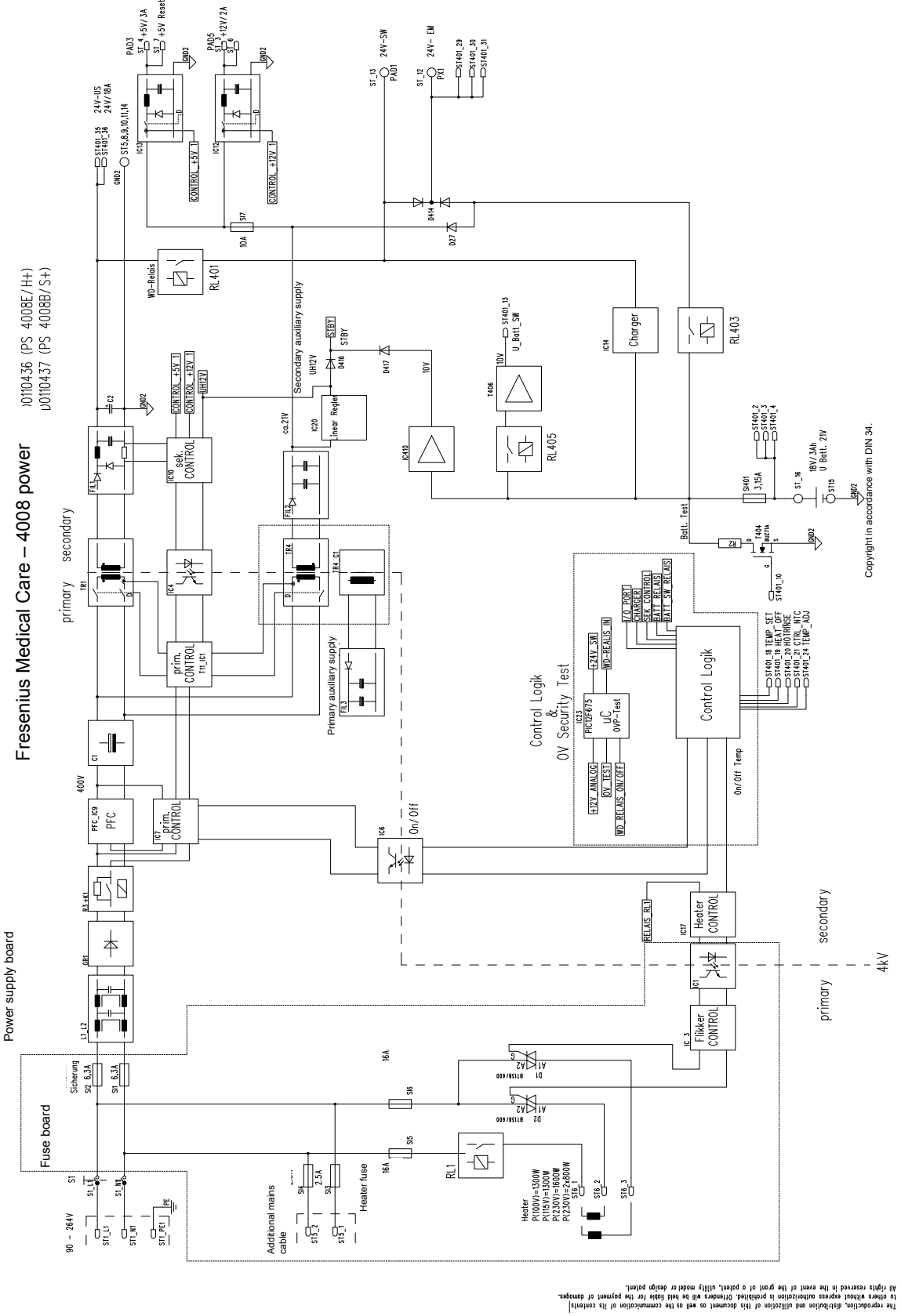
Prep.*: preparation phase:
Heater off.
Set the level of the float switch chamber below the lower switching point of the float switch by 23 UF pump strokes.
Aspiration of disinfectant for 32 concentrate pump strokes à 330 steps.

11.2 Block diagrams / wiring diagrams / P.C.B. layouts

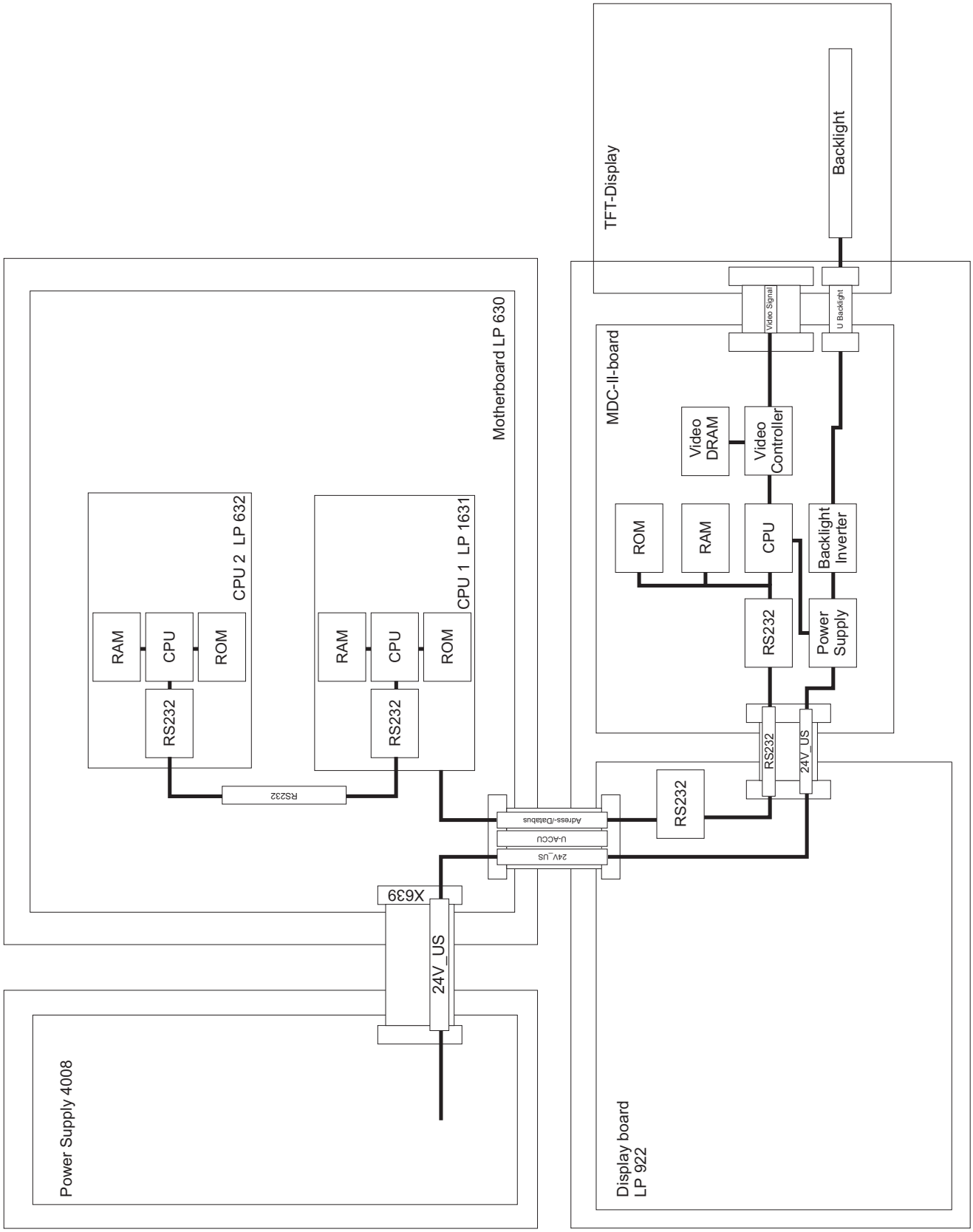
11.2.1 4008 S block diagram



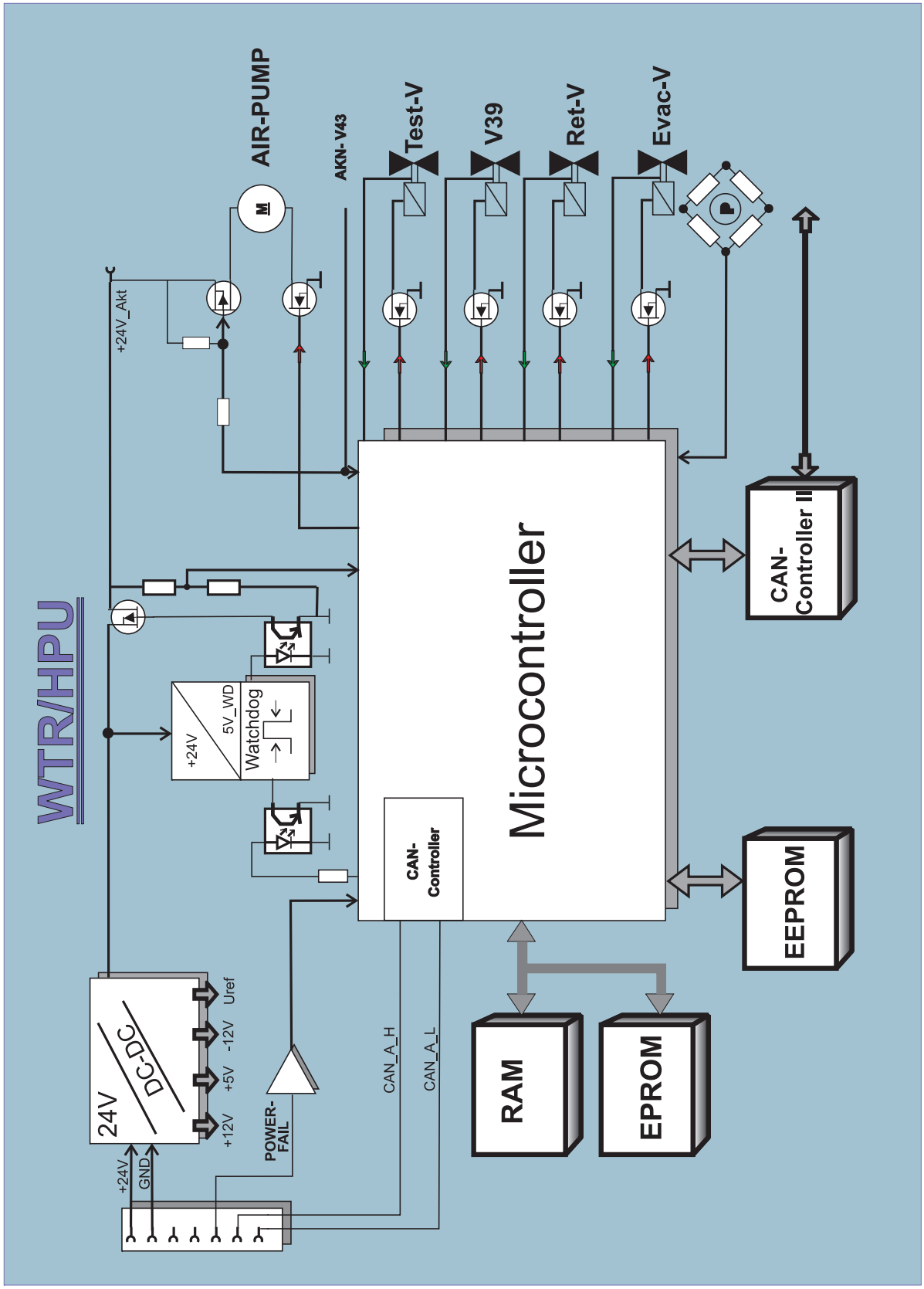
11.2.2 Voltage supply block diagram



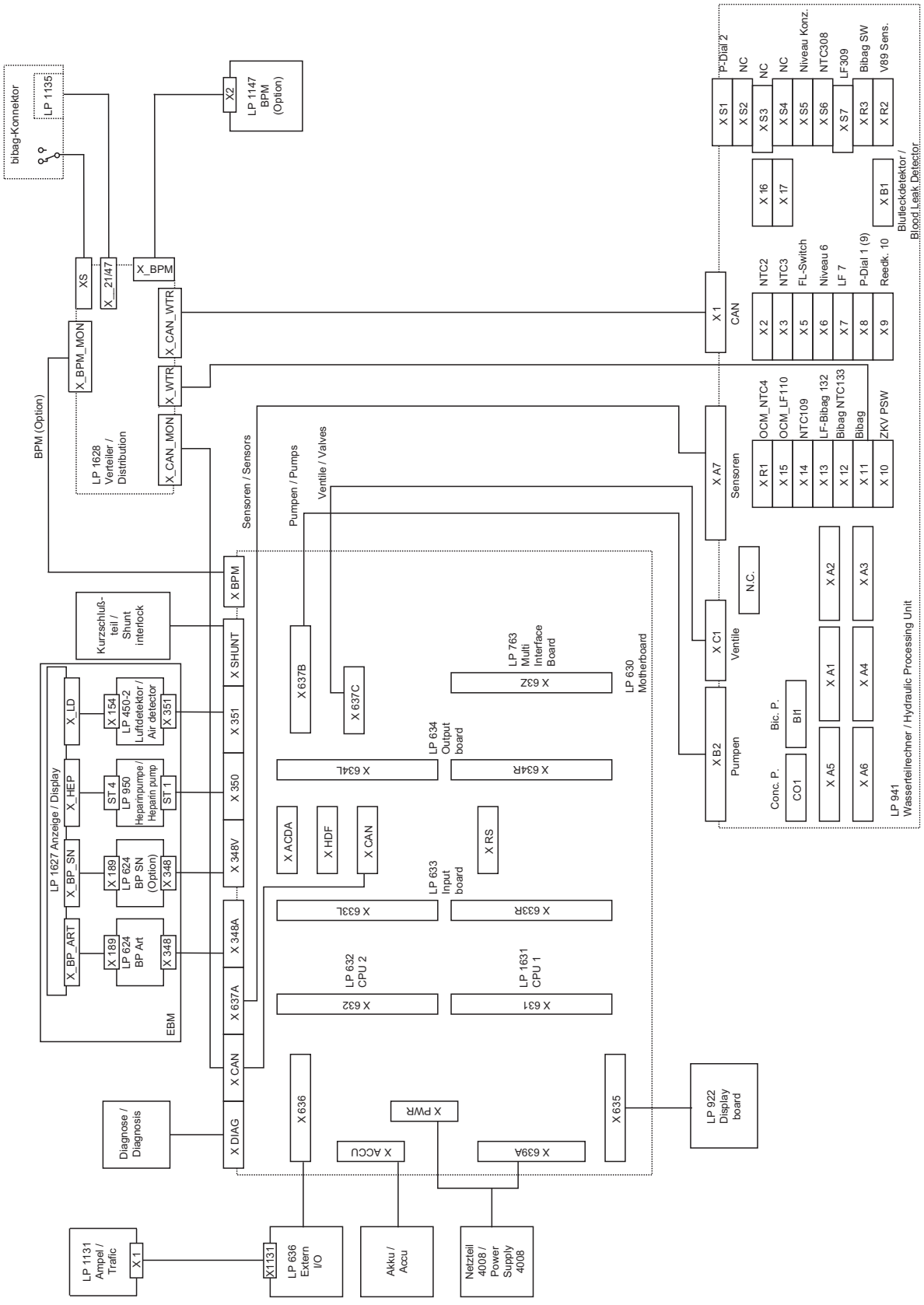
11.2.3 Monitor block diagram



11.2.4 HPU block diagram (hydraulic processing unit)



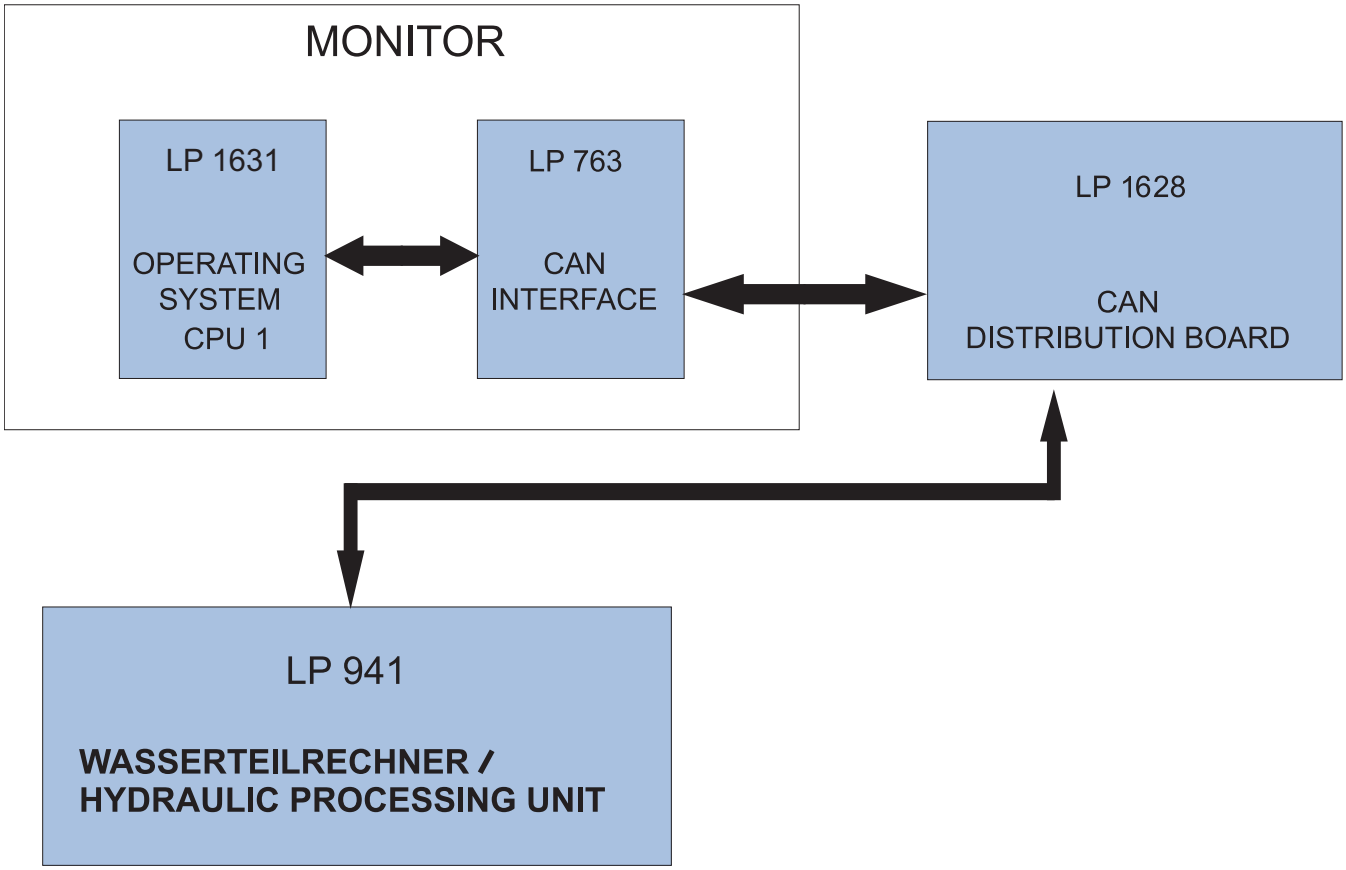
11.2.5 HPU wiring diagram (hydraulic processing unit)



● Legend (HPU wiring diagram)

X A1 UF pump (22), flow pump (21), degassing pump (29), Air separation pump (97)
X A2 valves (V24, V24B, V26, V30, V41, V43, V84, V91, V112)
X A3 balancing chamber valves (V31–V38), valves (V86, V87)
X A4 CDS, V99, V100, V102, V126, V130
X A5 V183, V188, V189, V9, compressor (185)
CO1 Concentrate pump, conductivity cell
BI1 Bicarbonate pump
X R1 OCM_NTC4
X 2 NTC2
X 3 NTC3
X 5 Float switch
X 6 Level sensor (6)
X 7 Conductivity measuring cell
X 8 Dialysate pressure transducer (1)
X 9 Reed contact (10) concentrate
X 10 CDS pressure switch
X 11 bi*b*ag®
X 12 bi*b*ag® NTC (133)
X 13 bi*b*ag® conductivity cell
X 14 NTC109
X 15 OCM conductivity cell (110)
X S1 Dialysate pressure transducer 2 (182)
X S2 NC
X S3 NC
X S4 NC
X S5 Concentrate level sensor (202)
X S6 NTC INDI (308)
X S7 INDI conductivity cell (309)

11.2.6 CAN communication connection diagram



11.2.7 P.C.B. LP 450-2 Air detector control (LD)

Fig.: P.C.B. LP 450-2 signal diagram

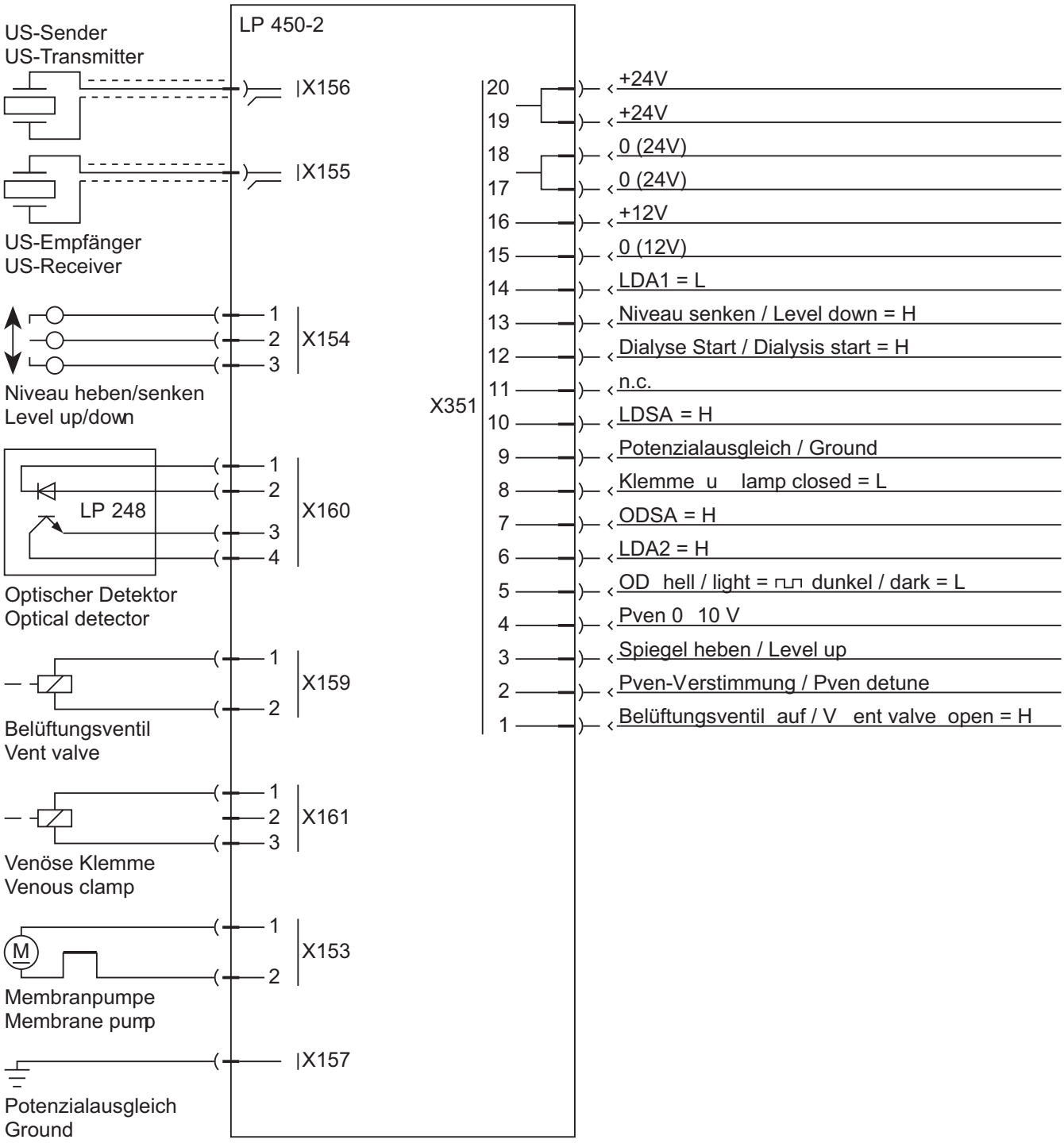
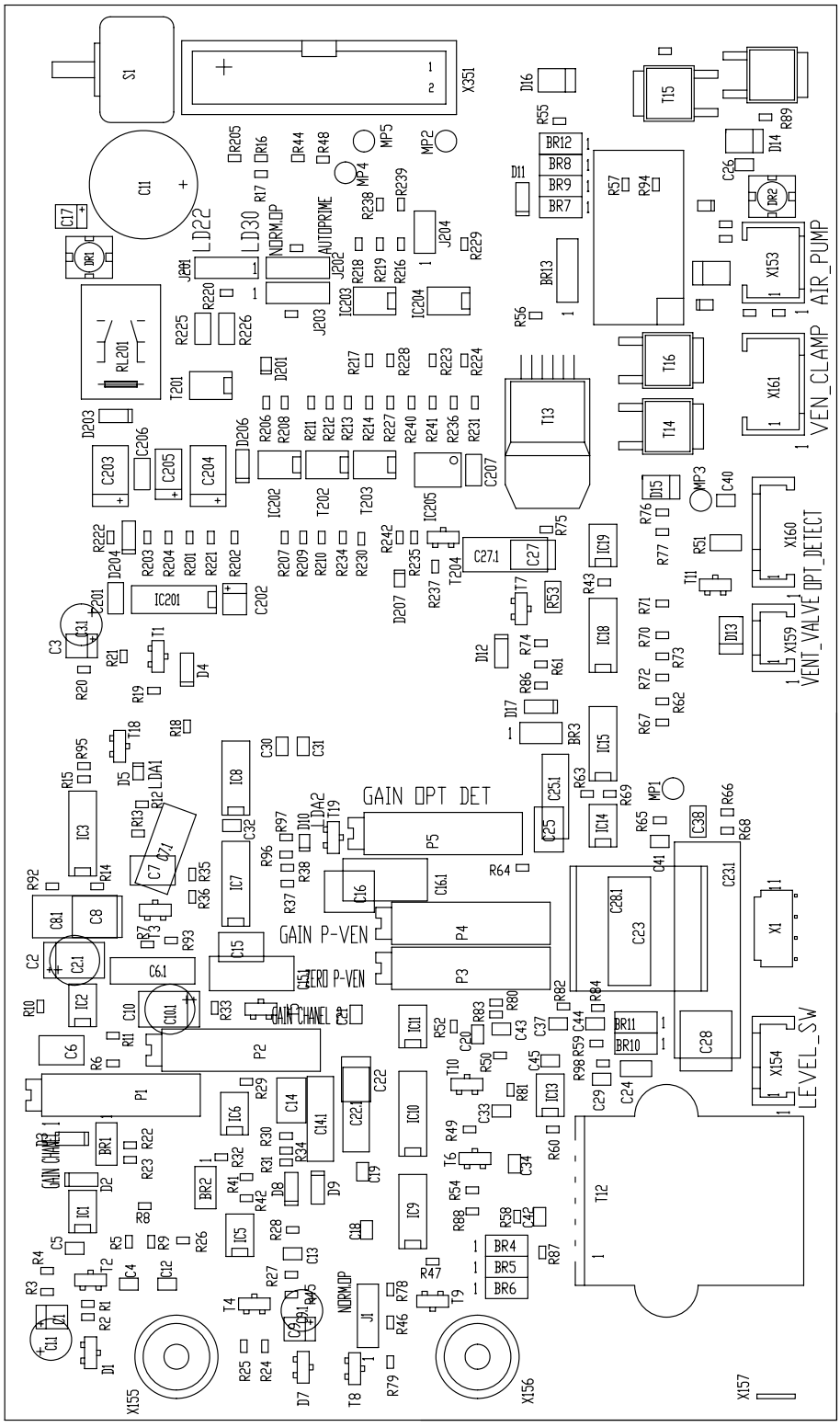


Fig.: P.C.B. LP 450-2 layout M



SYSTEM	BR 4	5	6	7	8	9	10	11	12	13
A 1008 D	X	0	0	0	X	X	X	0	X	0 1/2
A 2008 D	0	0	X	0	X	X	X	0	0	1/2
A 2008 D.E/USA	0	0	X	0	X	X	X	0	0	0 3/2
A 2008 BSS	0	0	X	0	X	X	0	X	0	X 1/2
2008 E	0	0	X	X	0	0	0	X	0	1/2
4008	0	0	X	X	0	0	X	0	X	1/2
4008 ADS	0	0	X	X	0	0	X	0	X	1/2
ART	0	0	X	X	0	0	X	0	X	1/2

POS.	ART	ADS	4008
R59	LP450	LP450-1	LP450-2
J202/J203	1M33	2M43	1M33
J201	1-2 NORMAL OPERATION	1-2 NORMAL OPERATION	2-3 AUTOPRIME OPERATION
J204	nicht bestückt / not fitted	nicht bestückt / not fitted	1-2 LD 22 / 2-3 LD 30
	nur bei Autoprime / only for Autoprime	nur bei Autoprime / only for Autoprime	bestückt / fitted

BR 1	2	TK
0	0	30mm
X	X	22mm

JUMPER 1 MODE	
CALIBRATION	NORMAL OPERATION
1-2	2-3

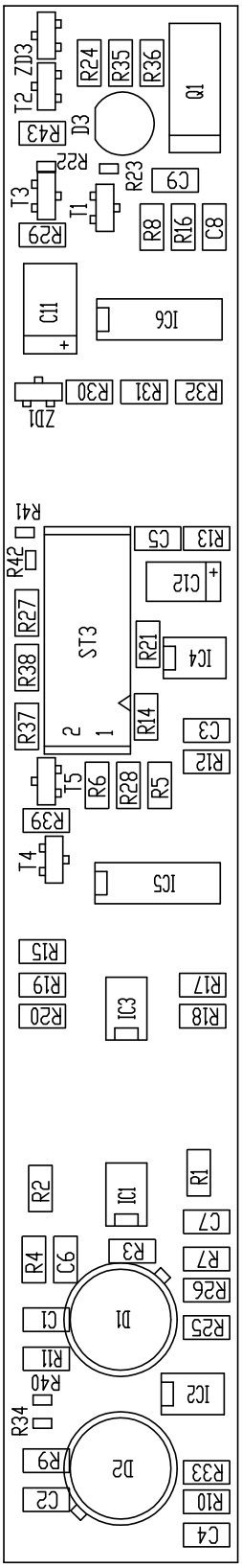
BRÜCKEN: X=GESCHLOSSEN /0=OFFEN
LINKS : X=FITTED /0=NOT FITTED

BR3: nur geschlossen für Funktion Heben/Senken
BR3: only fitted for function level up/down

Ersatzlieferung:
Generell uncodiert, Brücken je nach Einsatz (Luftdetektortyp)
Spare Parts:
Generally not coded, set link depending on use (level det. type)

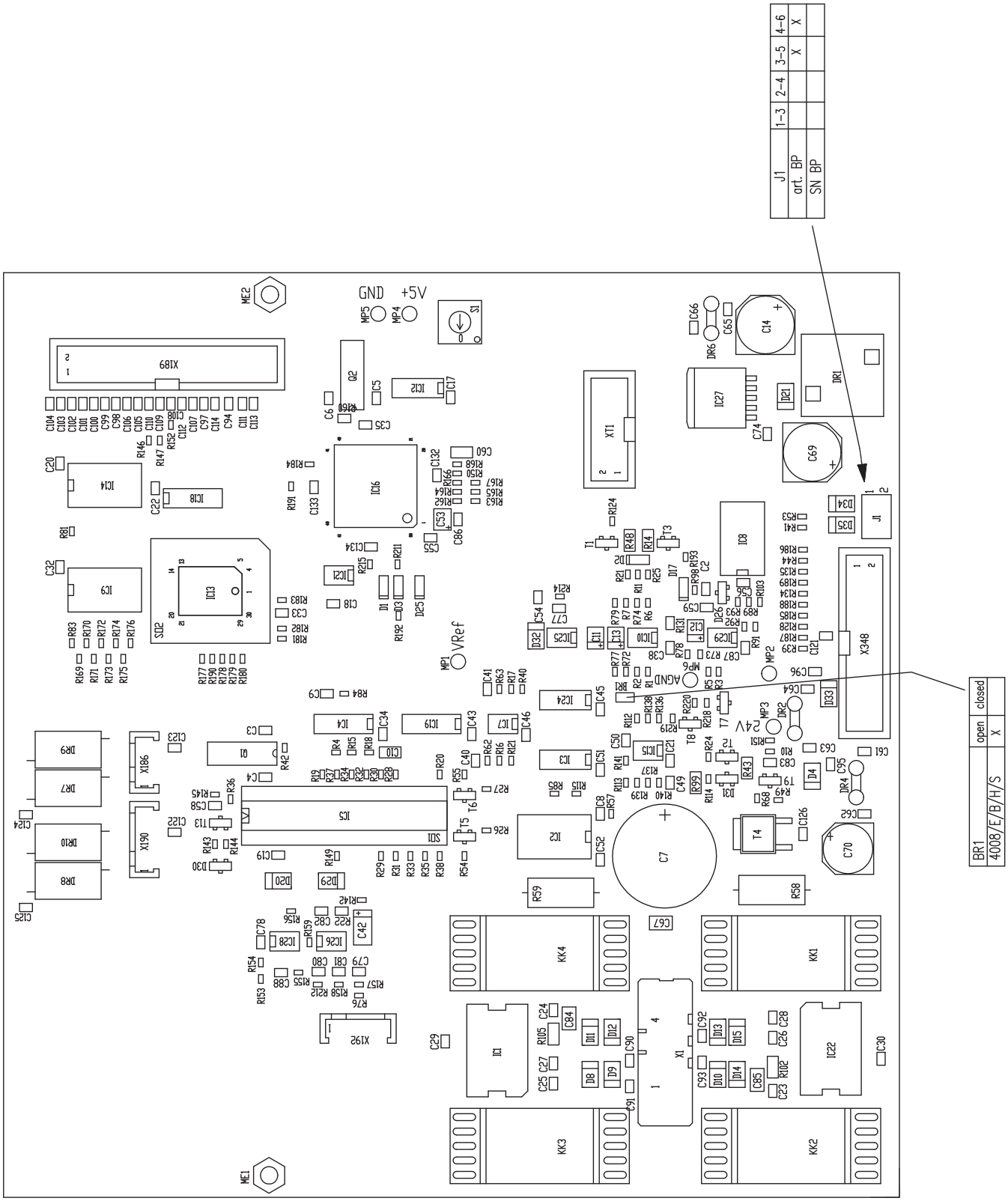
11.2.8 P.C.B. LP 493 Blood leak detector

Fig.: P.C.B. LP 493 layout I



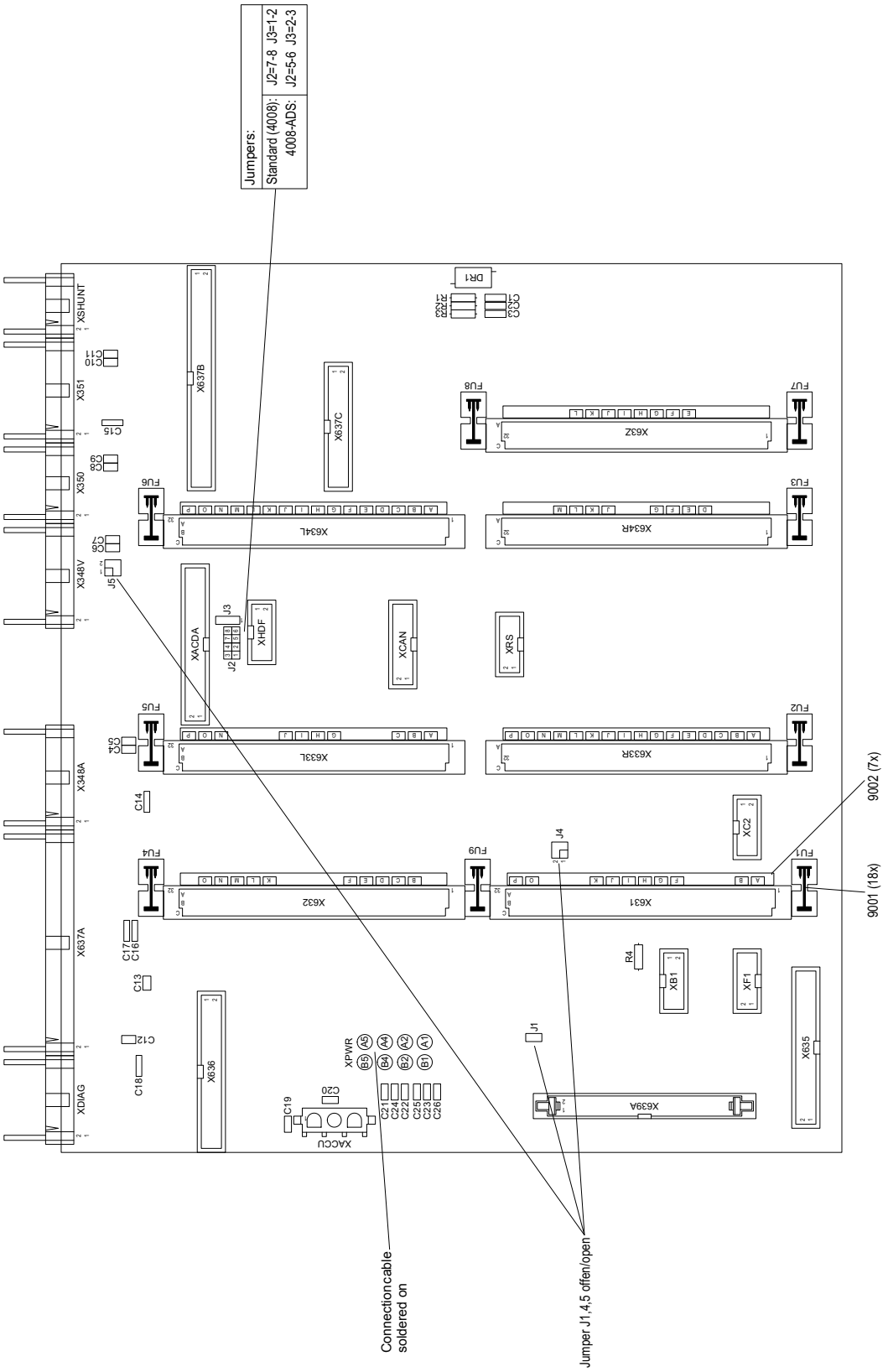
11.2.9 P.C.B. LP 624 Pump control, arterial blood pump / Single-Needle blood pump (option)

Fig.: P.C.B. LP 624 layout L



11.2.10 P.C.B. LP 630 Motherboard

Fig.: P.C.B. LP 630 layout O



11.2.11 P.C.B. LP 632 CPU 2

Fig.: P.C.B. LP 632-5 block diagram (SMT)

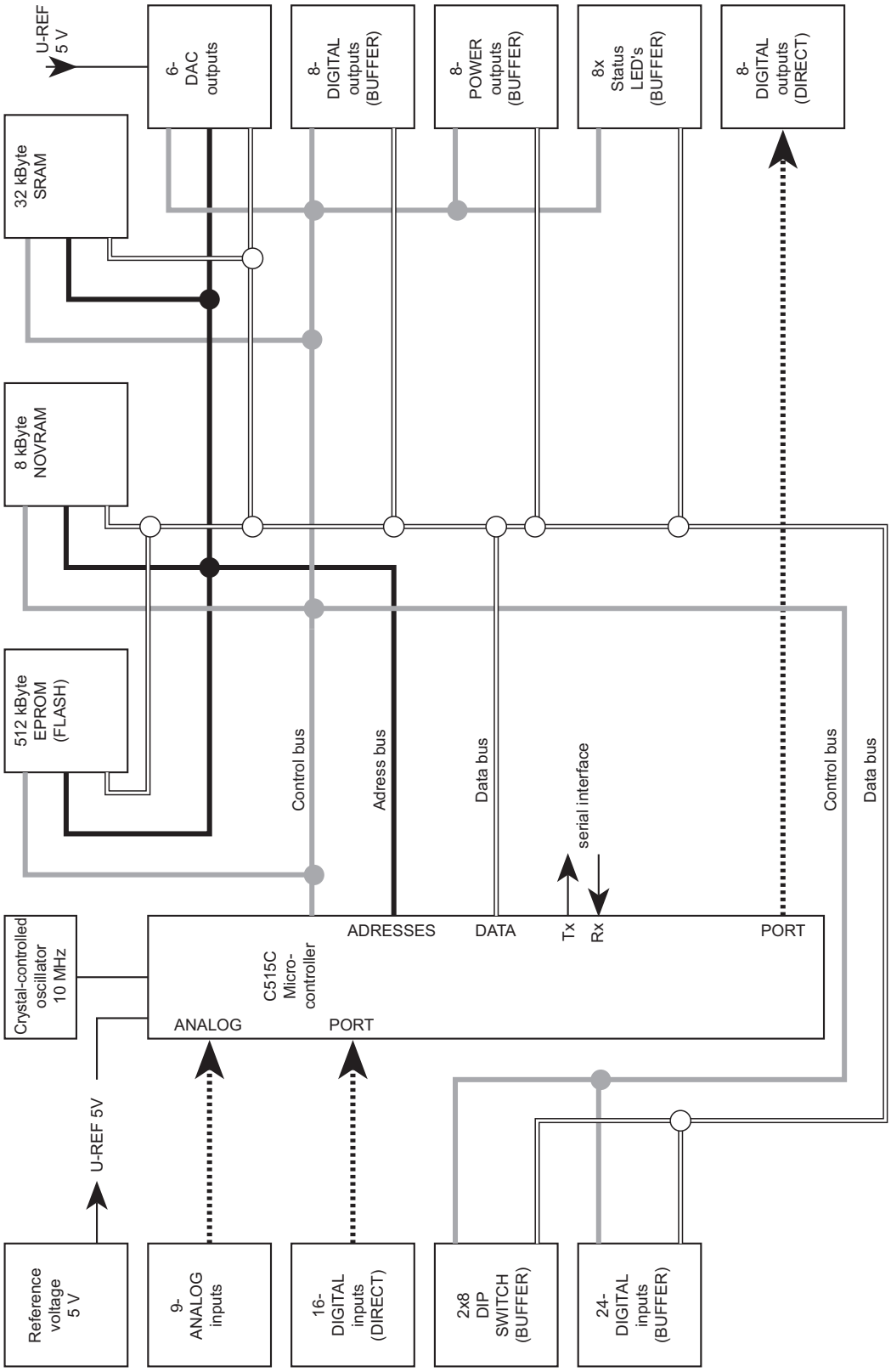
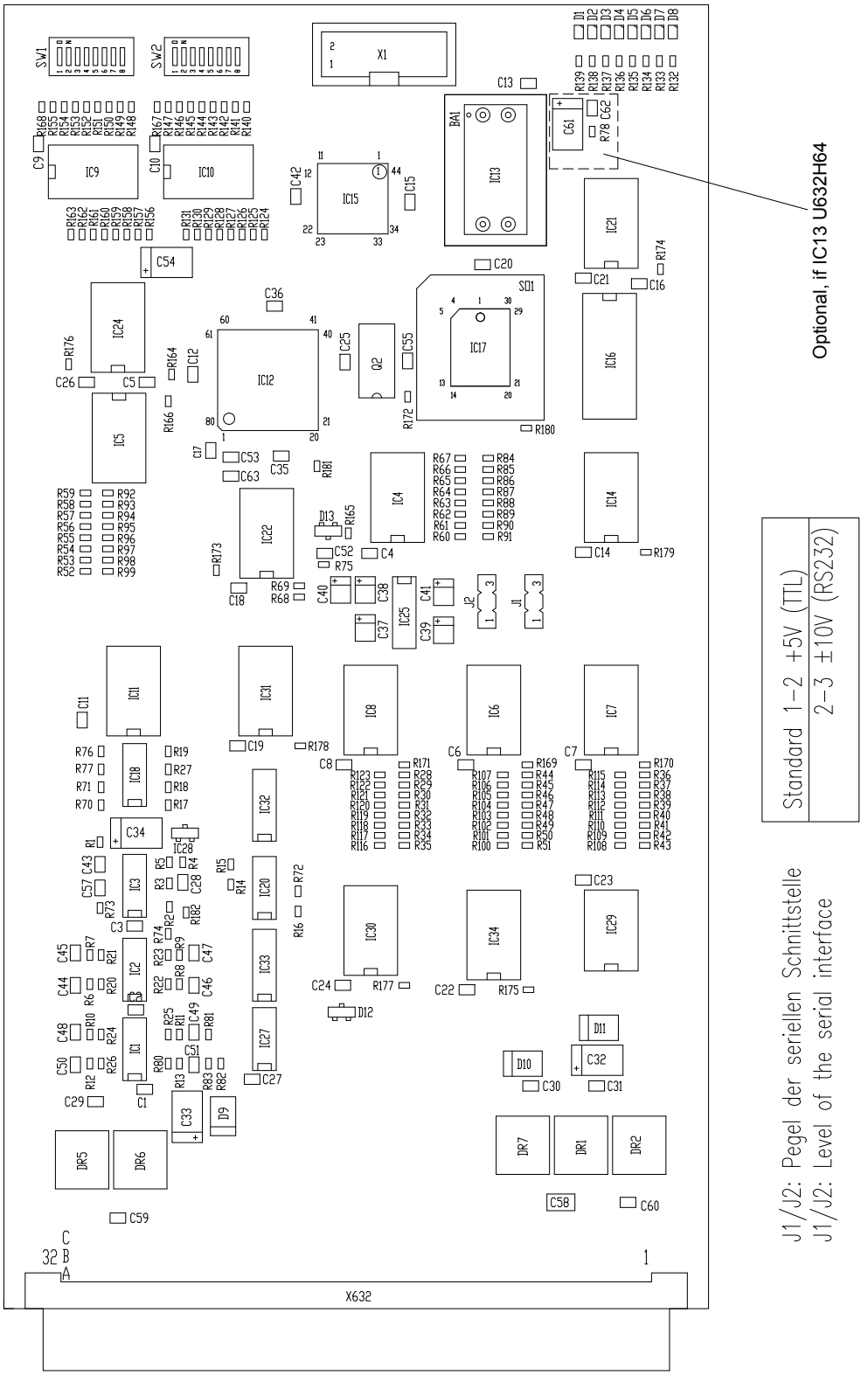


Fig.: P.C.B. LP 632 layout M



11.2.12 P.C.B. LP 633-5 Input board

Fig.: P.C.B. LP 633-5 block diagram

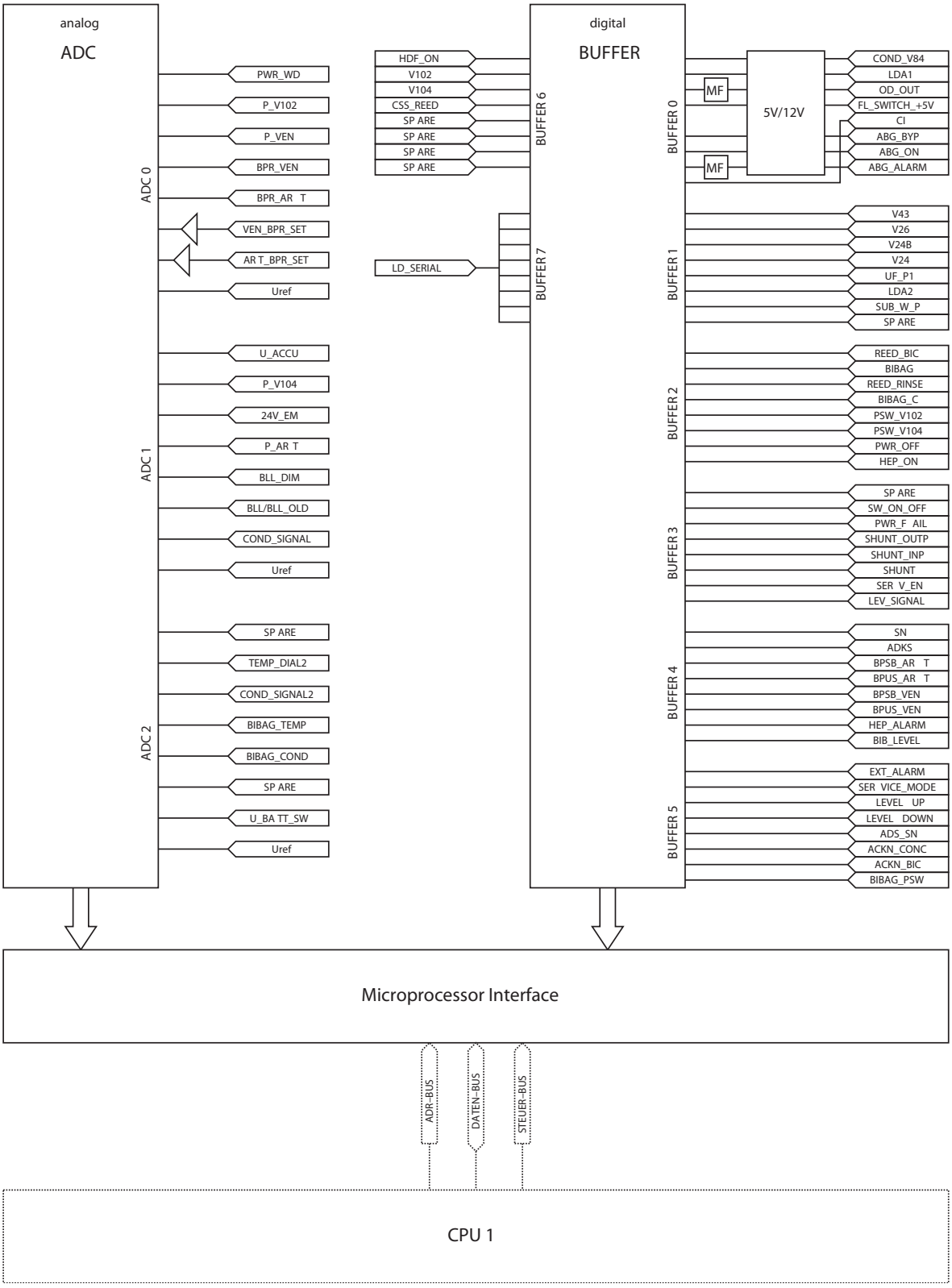
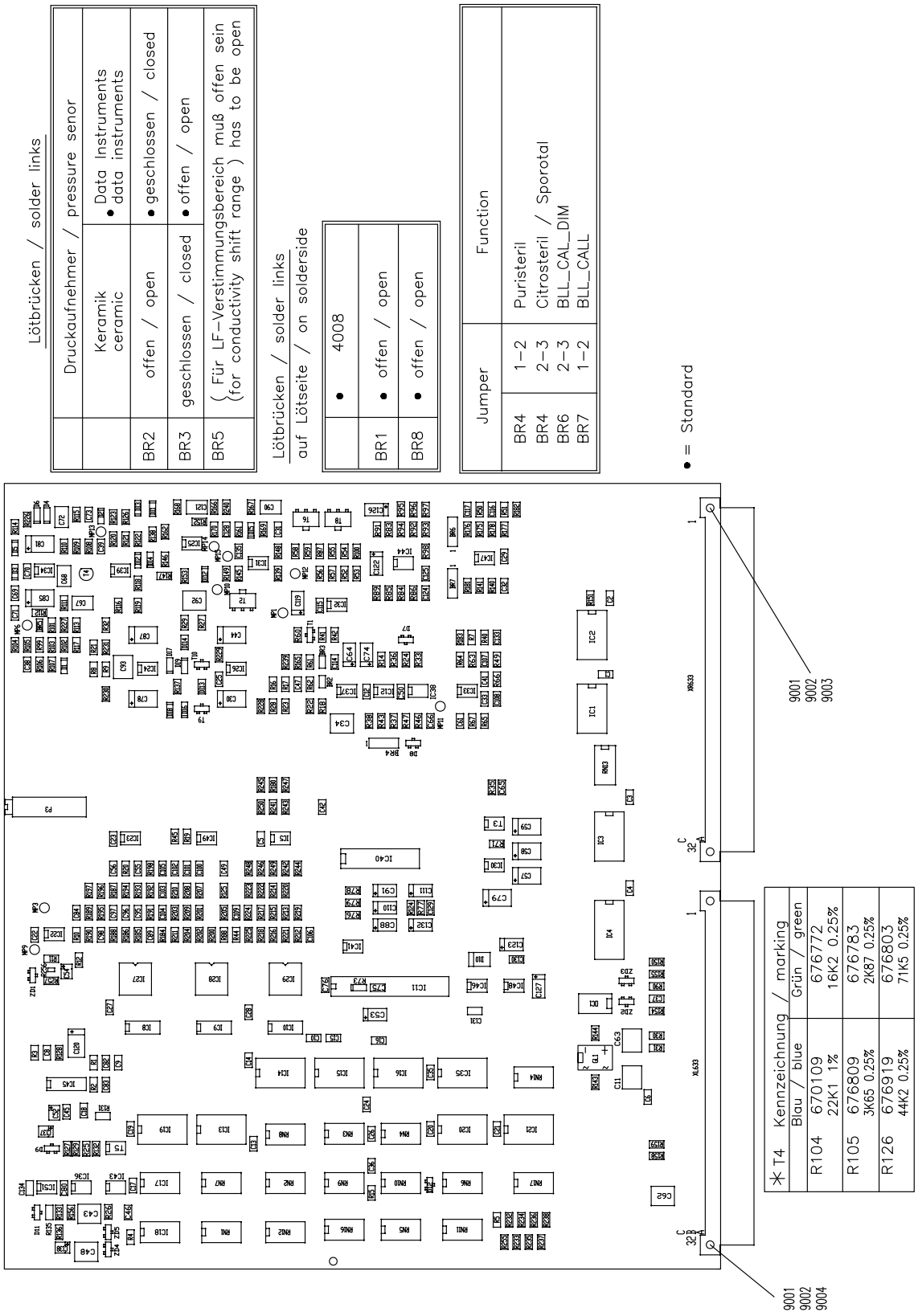


Fig.: P.C.B. LP 633-5 layout I



11.2.13 P.C.B. LP 634 Output board

Fig.: P.C.B. LP 634 Output board block diagram

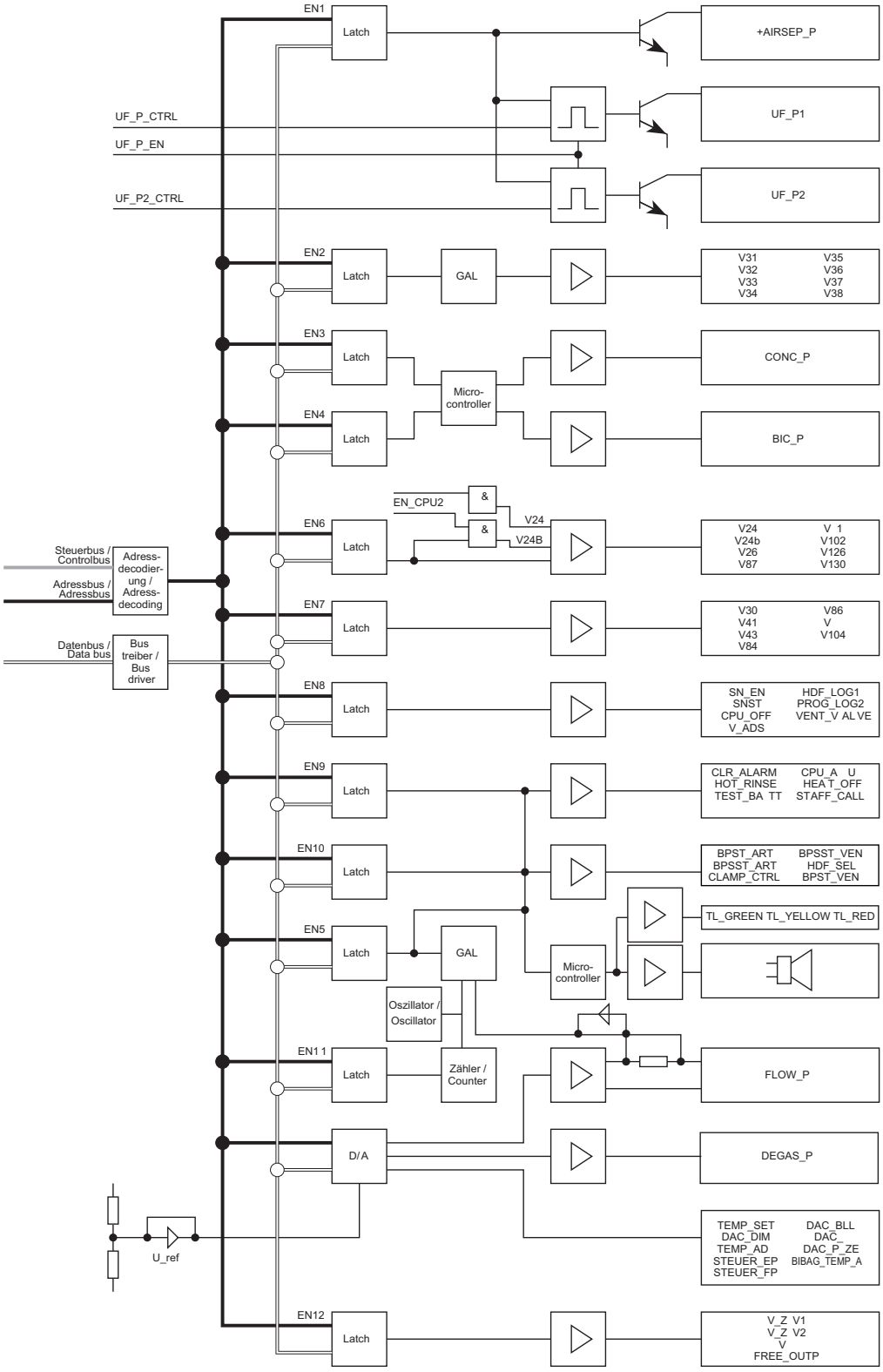
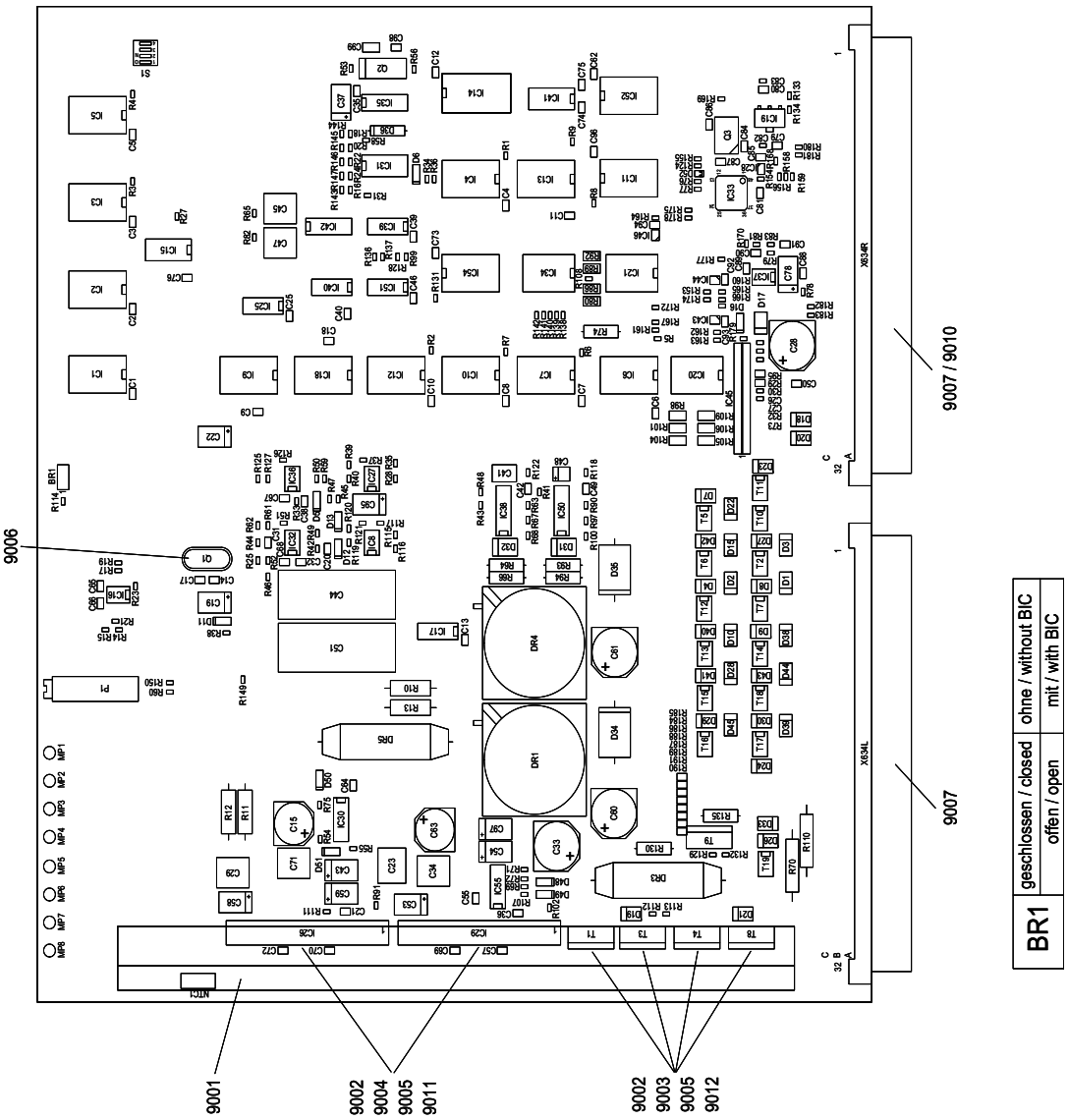


Fig.: P.C.B. LP 634 layout Q

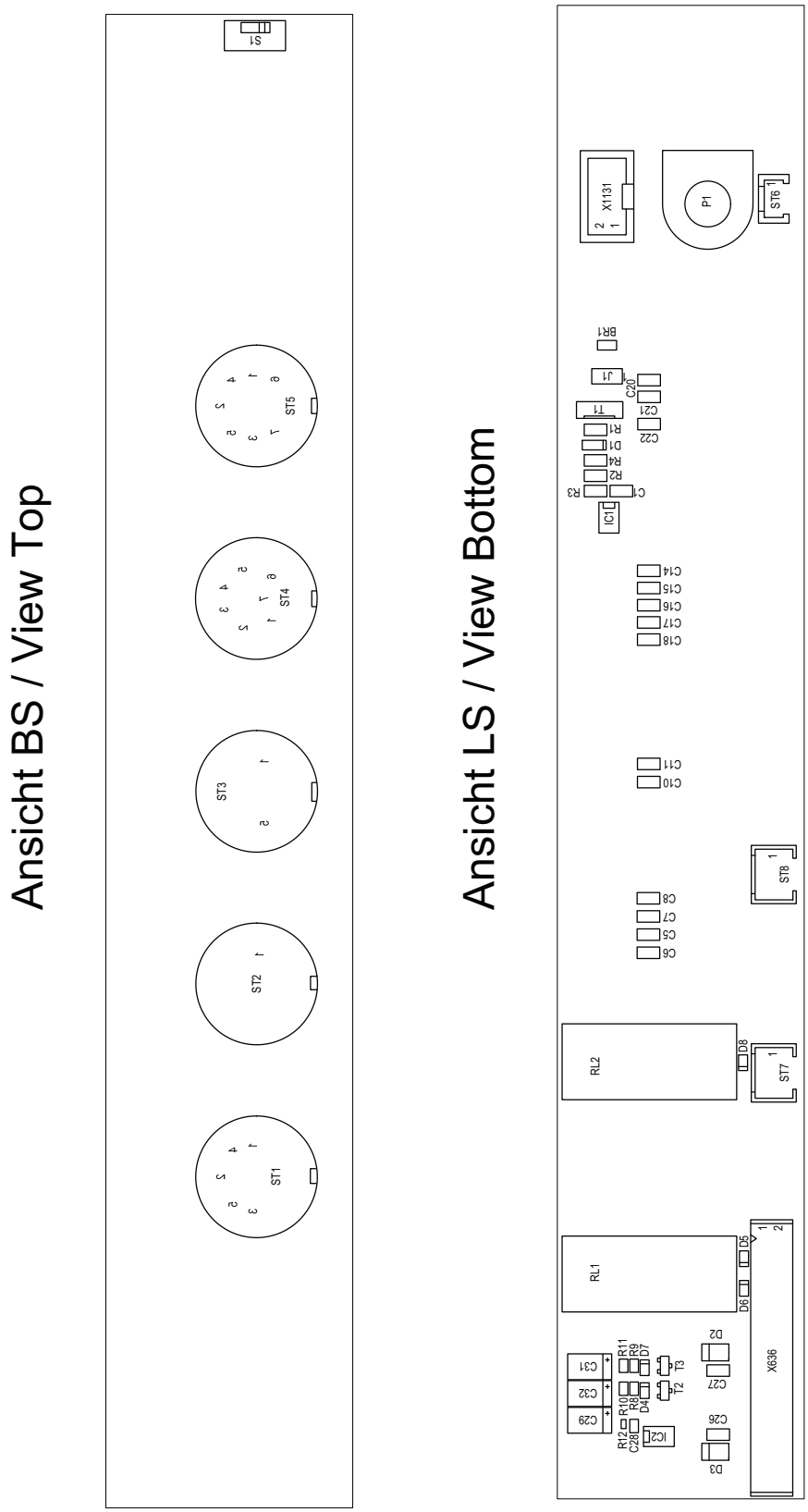
DIP-Switch S1

1	2	3	4	
OFF	OFF	OFF	OFF	I²C-SW-MODE
ON	OFF	OFF	OFF	ACUTE 4008
OFF	ON	OFF	OFF	STANDARD 4008
ON	ON	OFF	OFF	STANDARD ART (SW1.10)
OFF	OFF	ON	OFF	ACUTE ART (SW1.10)



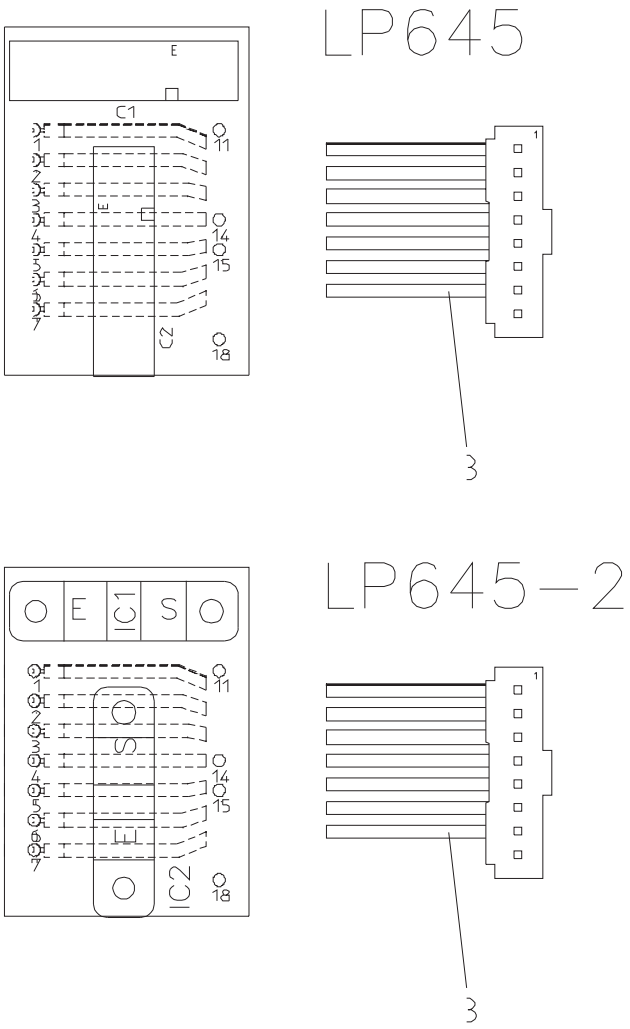
11.2.14 P.C.B. LP 636 External I/O board

Fig.: P.C.B. LP 636 layout J



11.2.15 P.C.B. LP 645 membrane pump optical sensor

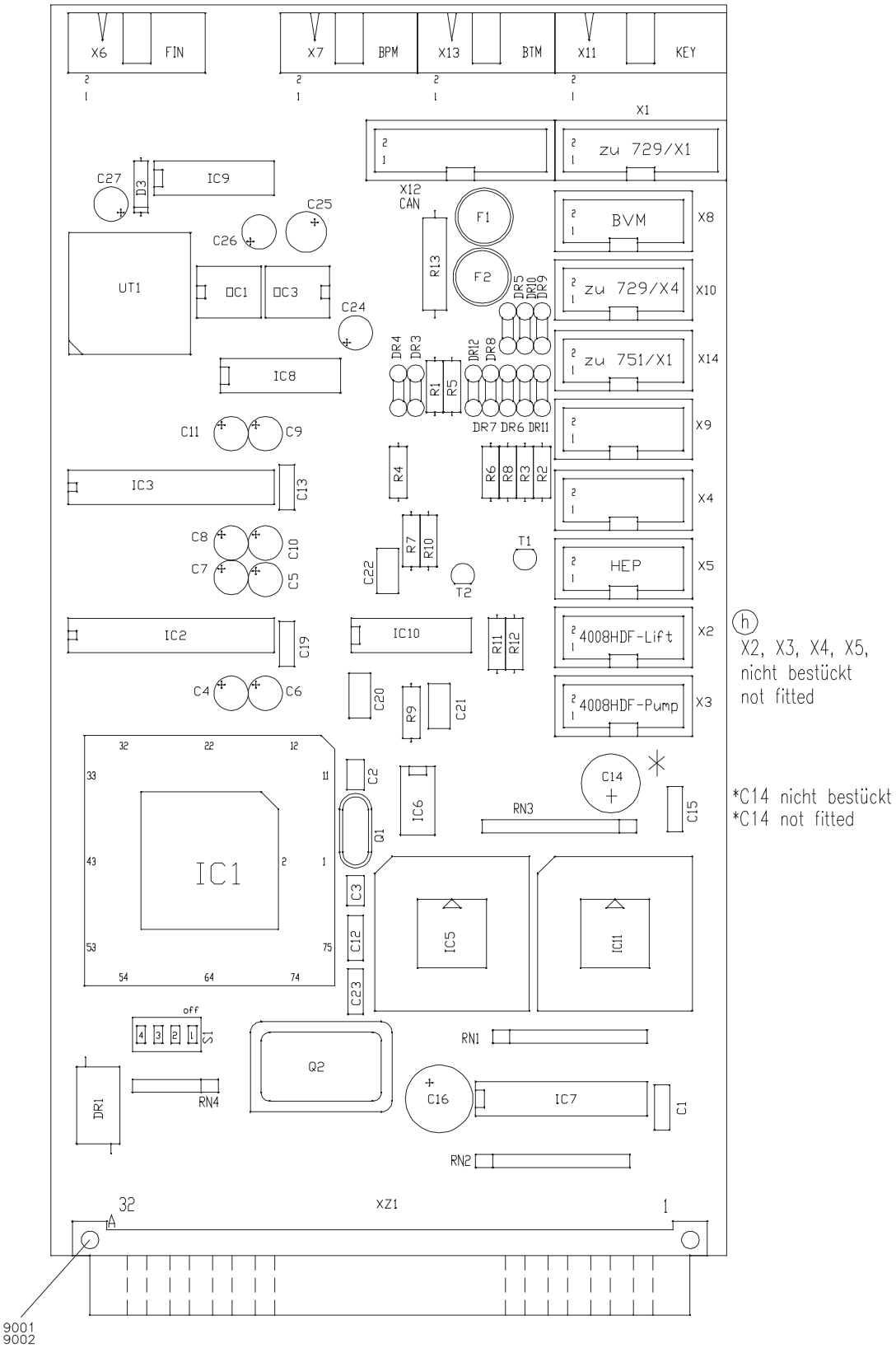
Fig.: P.C.B. LP 645 layout A



Difference 671003 to 673362 ; length of Connecting cable + transmissive switches IC1/IC2
Unterschied 671003 zu 673362 ; Länge der Anschlußkabel + Gabellichtschranken IC1/IC2

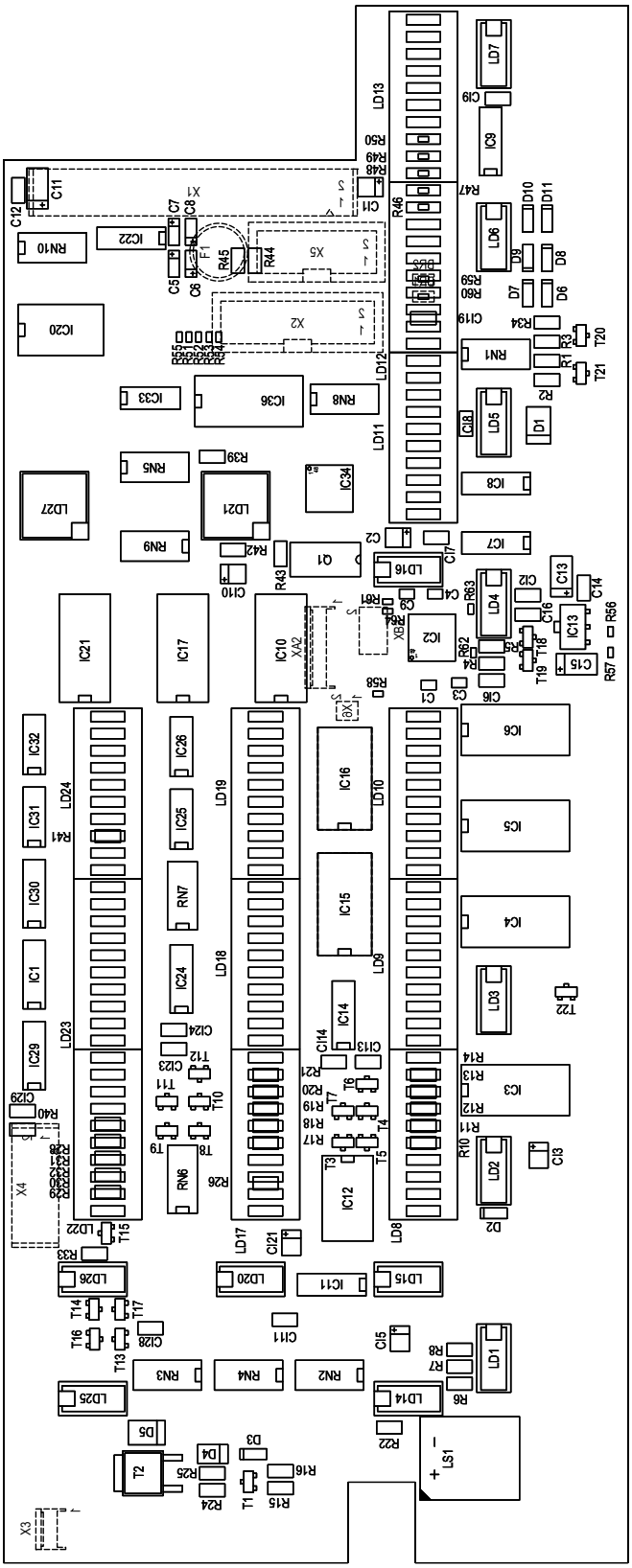
11.2.16 P.C.B. LP 763 Multi-interface board (COMMCO III)

Fig.: P.C.B. LP 763 layout D



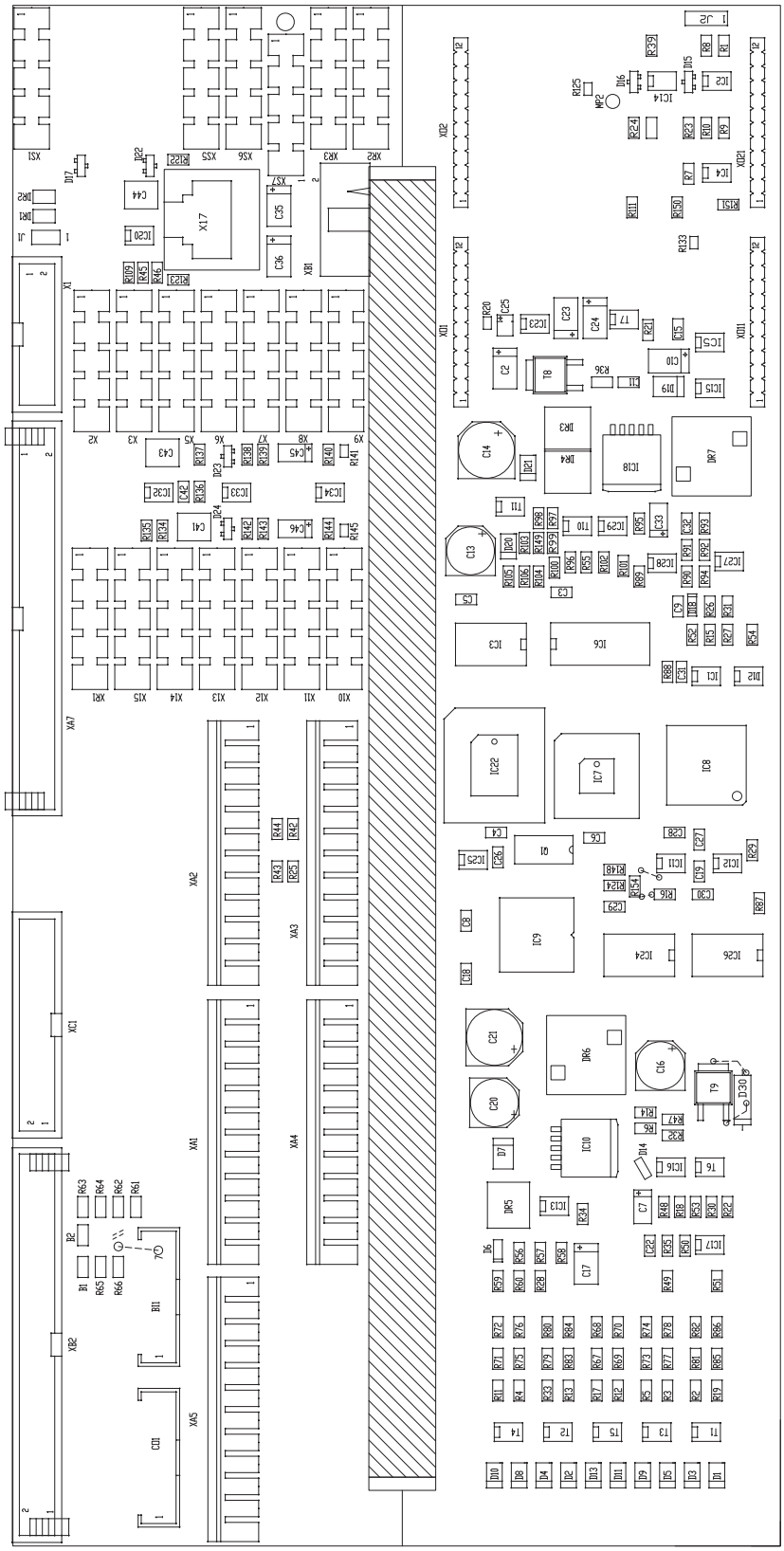
11.2.17 P.C.B. LP 922 Display board

Fig.: P.C.B. LP 922 layout K



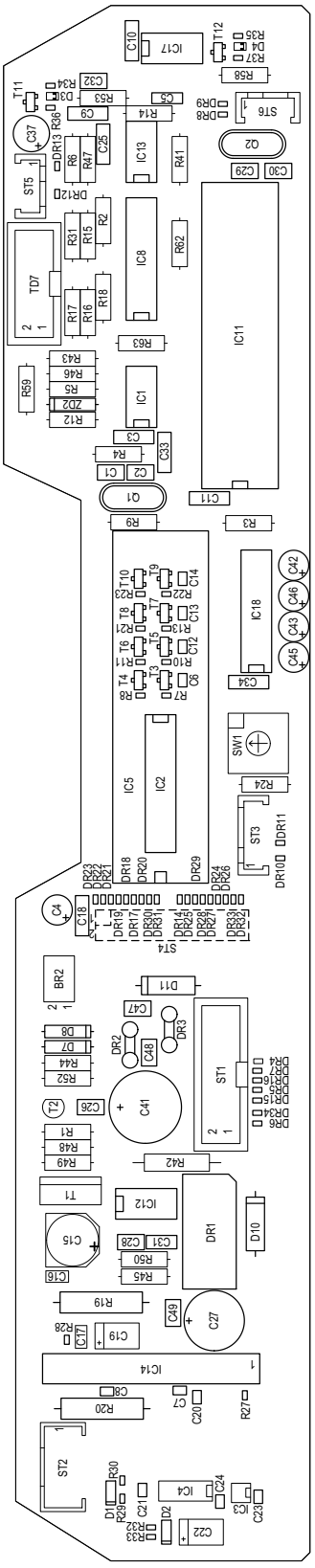
11.2.18 P.C.B. LP 941 HPU (hydraulic processing unit)

Fig.: P.C.B. LP 941 layout B



11.2.19 P.C.B. LP 950 Control board (HEP)

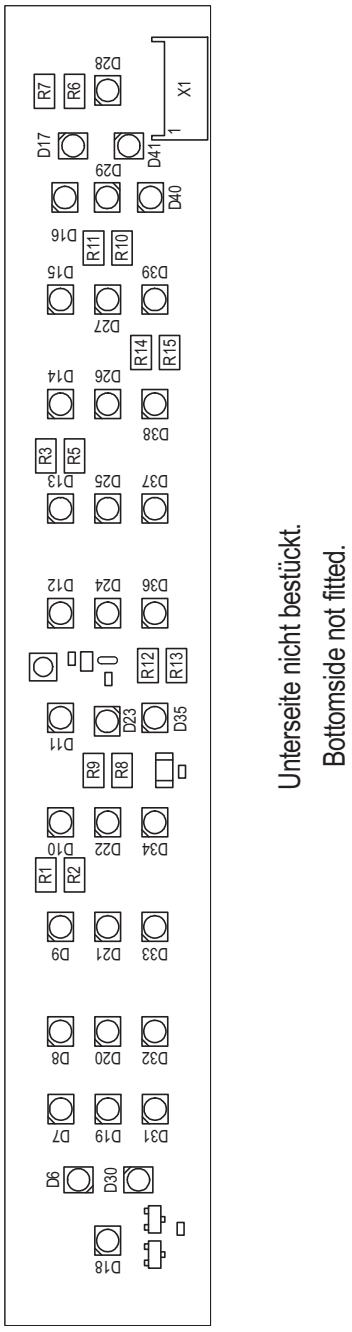
Fig.: P.C.B. LP 950 layout M



Ersatzteilnr. (mit Controller u. SW) für Endgeräte: Spareparts (with Controller a. SW) for Machines:	
M47254	4008E/B/H/S/ARrTplus/Art/Prometheus
M46988	4008S V10
M46169	MFT

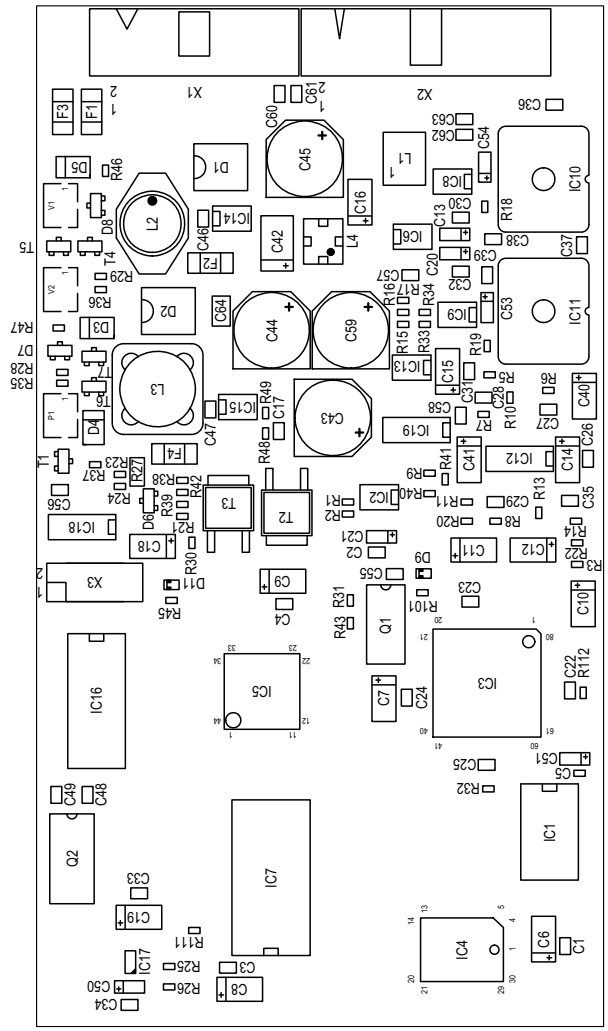
11.2.20 P.C.B. LP 1131 Operation status indicator (traffic light)

Fig.: P.C.B. LP 1131 layout E



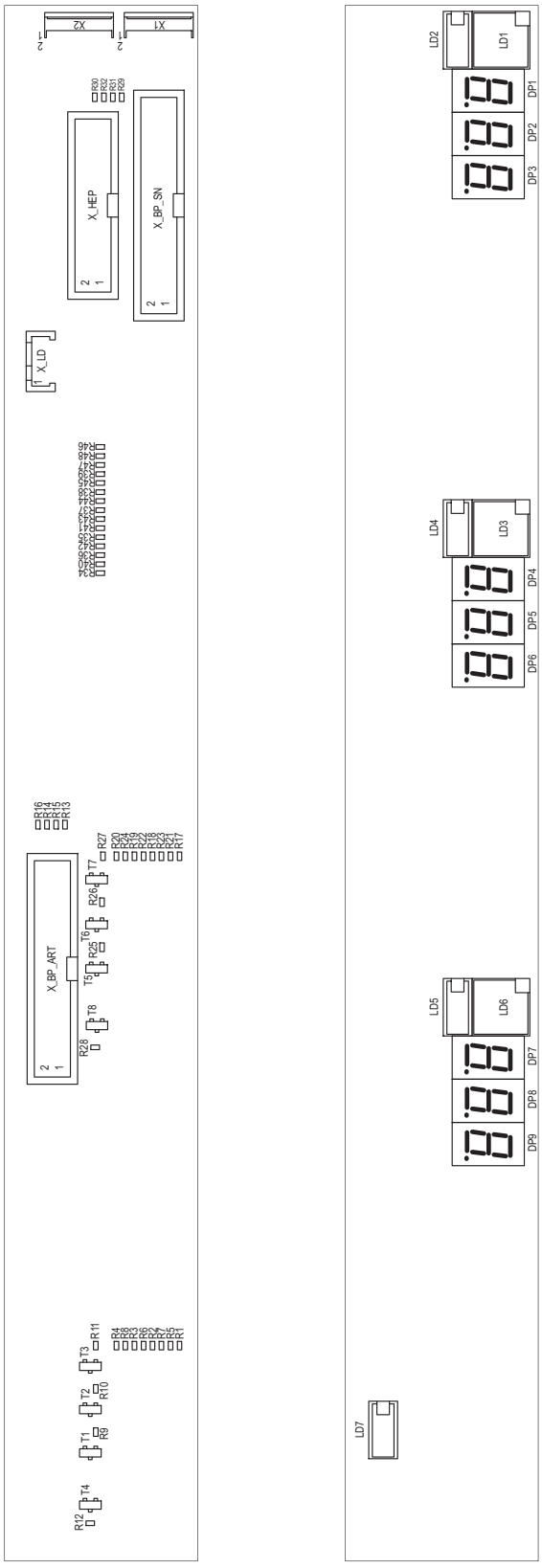
11.2.21 P.C.B. LP 1147 BPM (optional)

Fig.: P.C.B. LP 1147 layout C



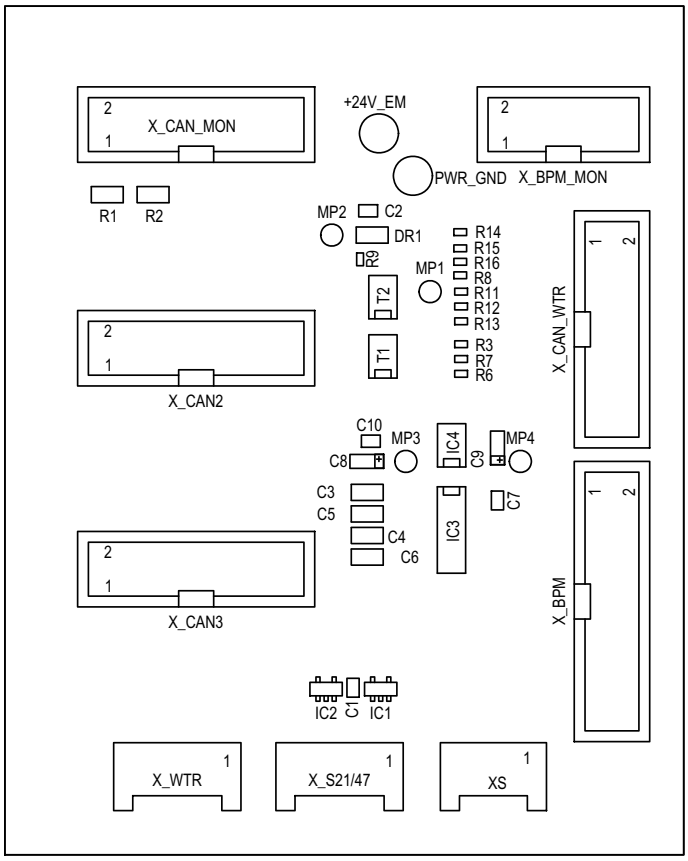
11.2.22 P.C.B. LP 1627 Display, EBM SN (optional)

Fig.: P.C.B. LP 1627 layout 0



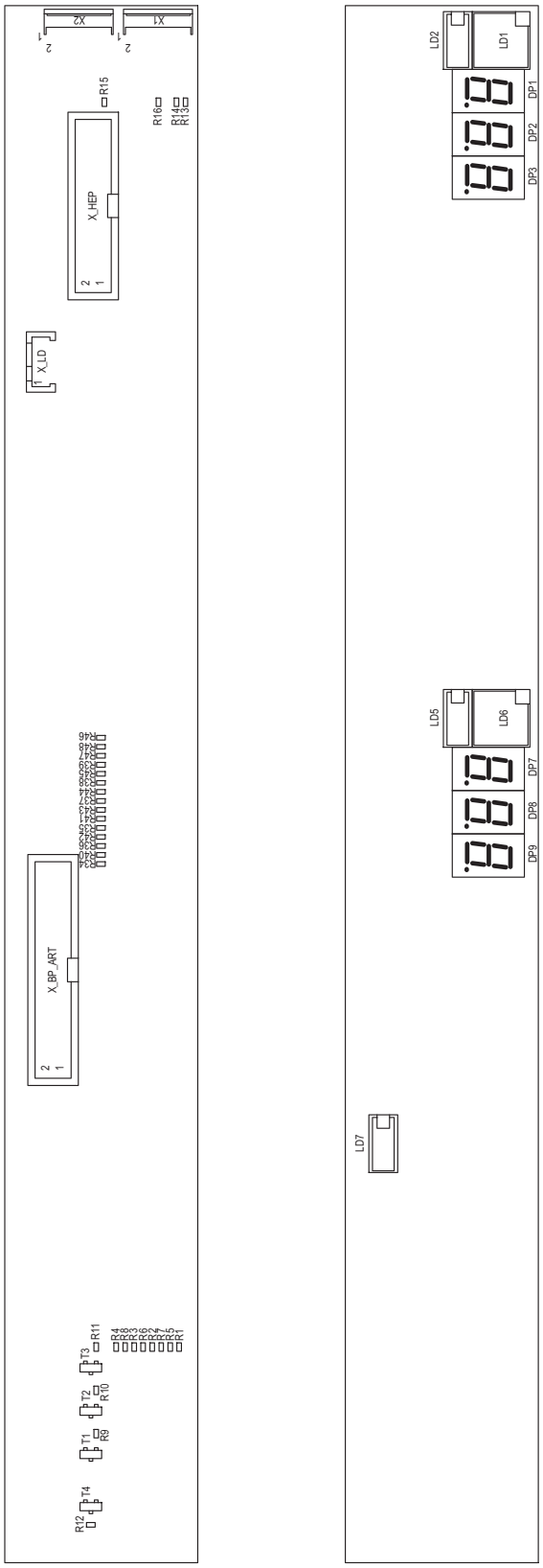
11.2.23 P.C.B. LP 1628 Distributor board

Fig.: P.C.B. LP 1628 layout 0



11.2.24 P.C.B. LP 1629 EBM display

Fig.: P.C.B. LP 1629 layout 0



11.2.25 P.C.B. LP 1631 CPU 1

Fig.: P.C.B. LP 1631 block diagram

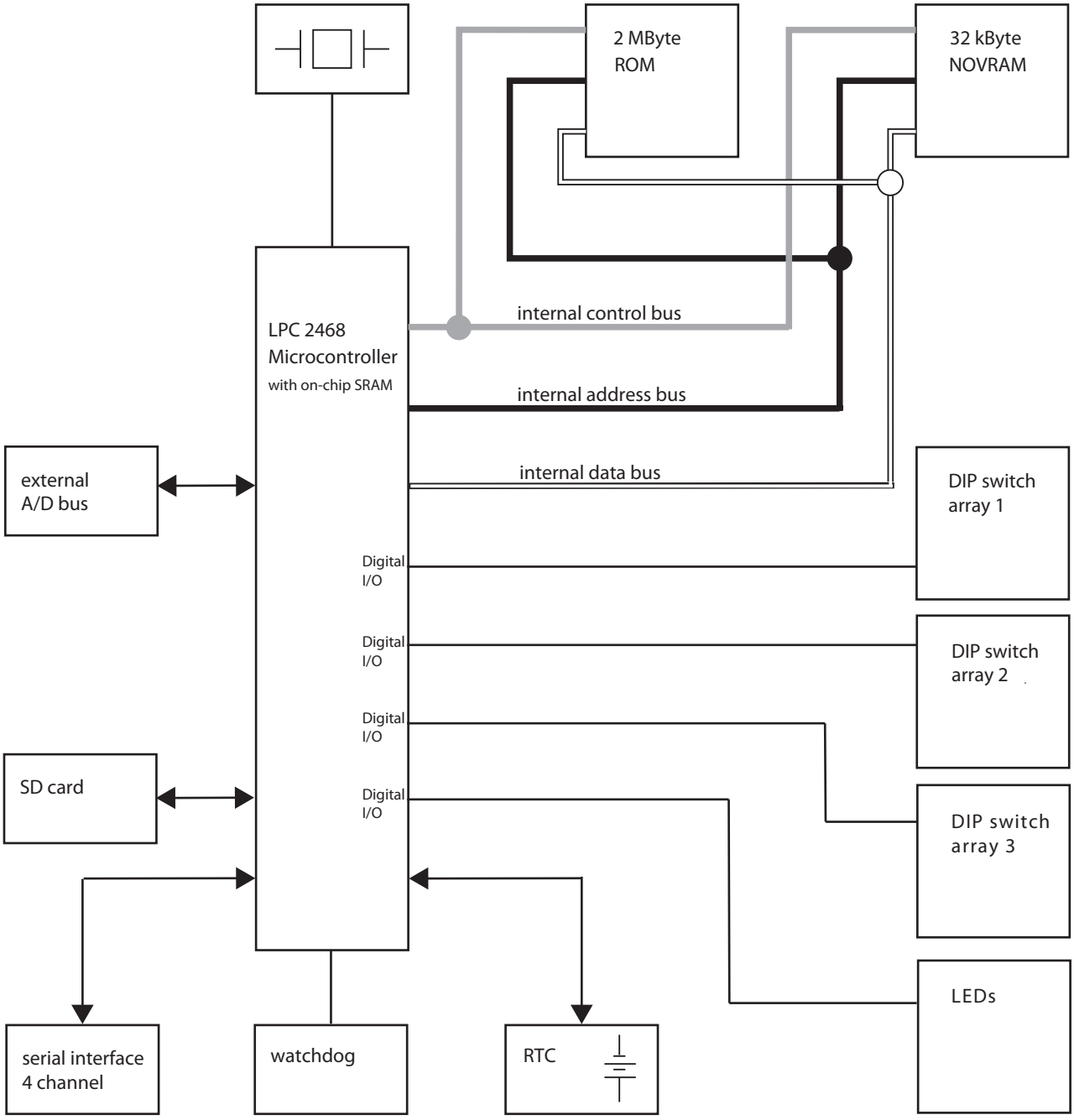
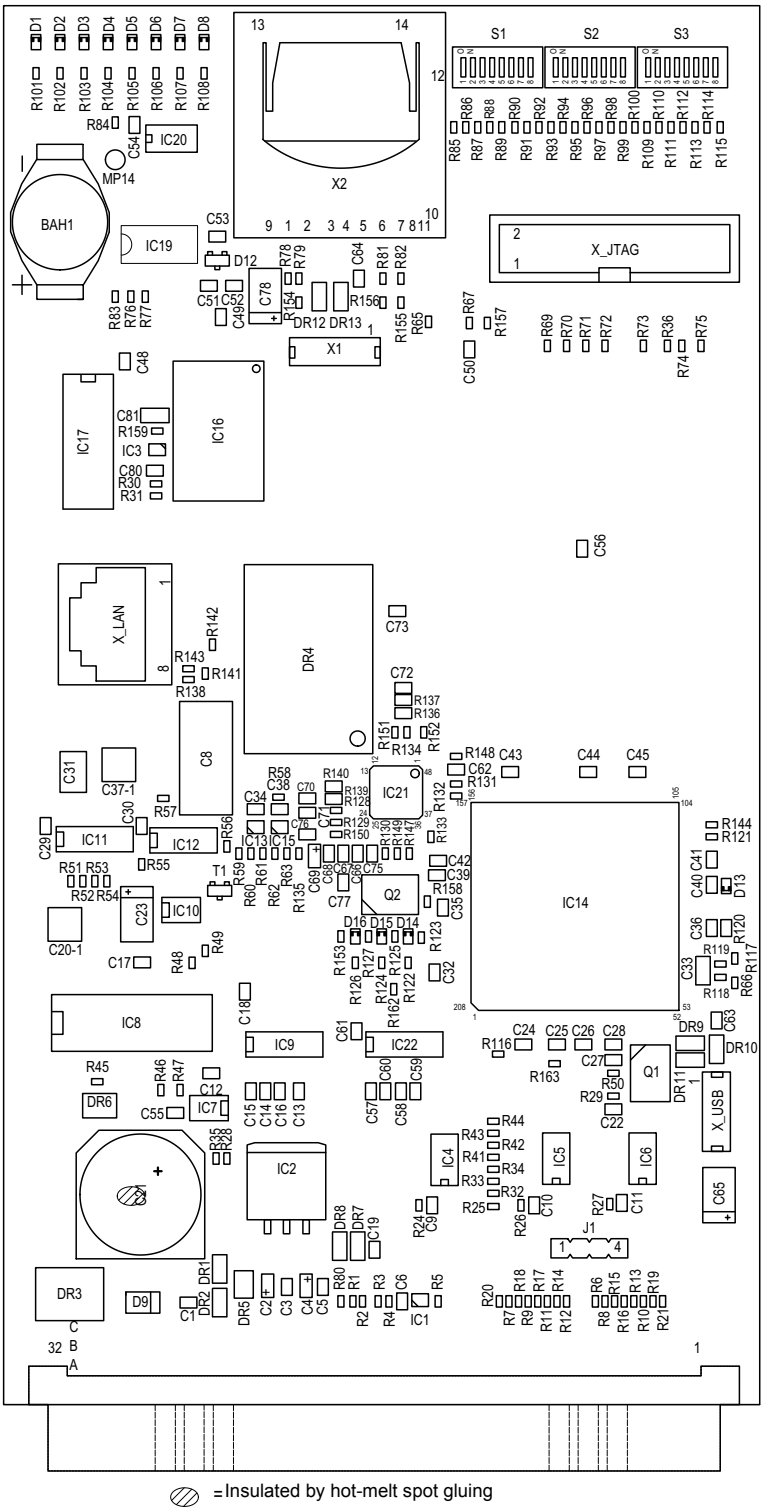
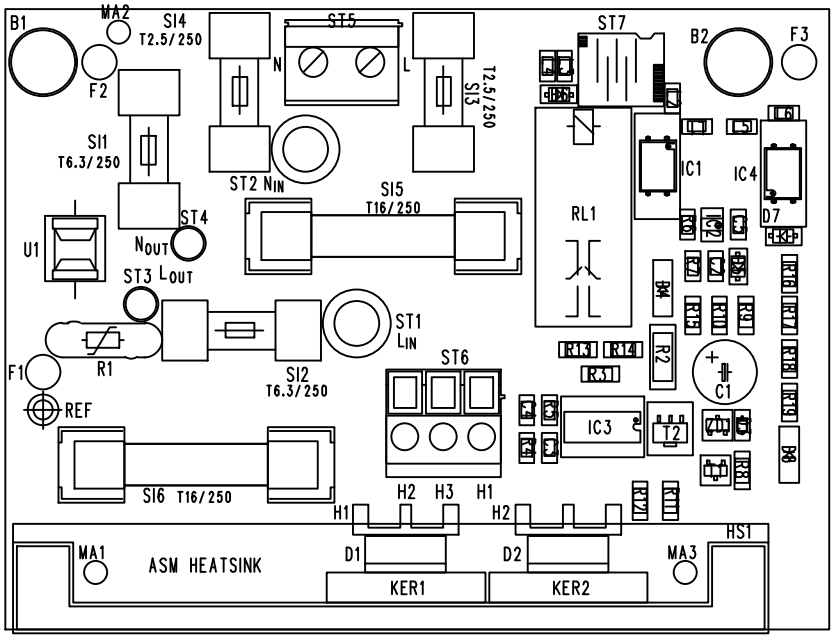


Fig.: P.C.B. LP 1631 layout E



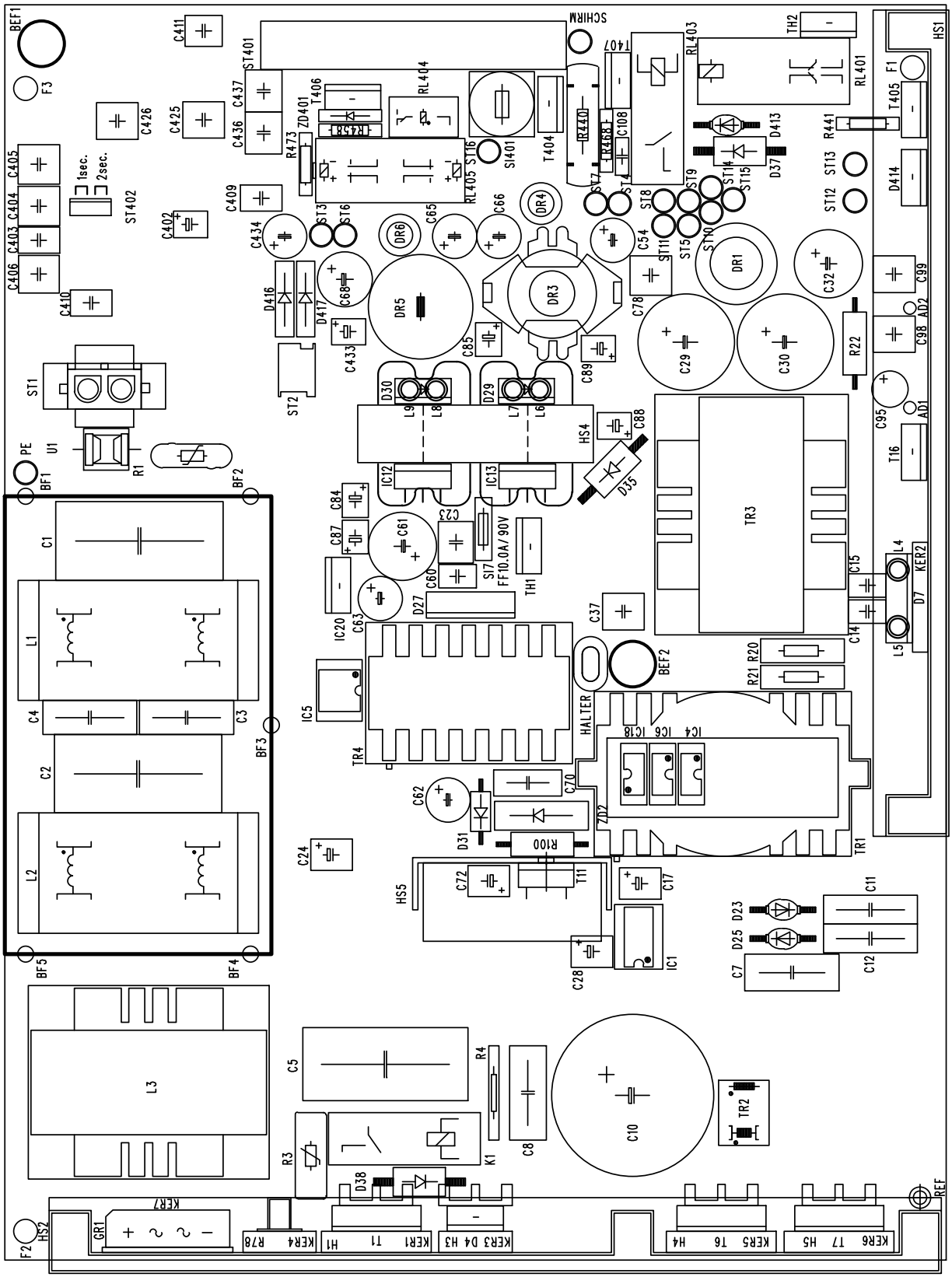
11.2.26 Heater board (4008 power supply unit)

Fig.: Heater board layout



11.2.27 Power board (4008 power supply unit)

Fig.: Power board layout



12 Appendix

Chapter without content