# Plasmat® Futura

## Operating Manual

## Software Version 2.6

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B BRAUN
SHARING EXPERTISE

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CE 0123

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## TABLE OF CONTENTS

# 1. SAFE HANDLING

## 1.1 ABOUT THESE INSTRUCTIONS FOR USE

These instructions for use form an integral part of the Plasmat® Futura machine. They describe the appropriate and safe use of the Plasmat® Futura machine at all stages of operation.

| | |
|---|---|
| ! | The Plasmat® Futura machine must always be used in accordance with the instructions for use.<br>Always keep the instructions for use at the Plasmat® Futura machine for later use.<br>Pass on instructions for use to any future user of the Plasmat® Futura machine. |

### 1.1.1 Validity

**Art.no.**

These instructions for use apply to Plasmat® Futura machines with the article numbers (art. no.):

- 7062100
- 706210A (110 V/120 V)

**Software version**

These instructions for use apply to software version 2.6.

### 1.1.2 Target Group for the Instructions for Use

The target group for these instructions for use is specialist medical staff.

The H.E.L.P. apheresis should be applied and supervised only by physicians with sufficient experience in the execution of extracorporeal procedures for blood purification.

The Plasmat® Futura machine may only be used by persons instructed for its appropriate operation.

### 1.1.3 Warnings, Notices and Symbols in These Instructions for Use

Warnings in these instructions for use point out particular hazards for users, patients, third parties and the Plasmat® Futura machine. They also suggest measures that can be taken to avoid the respective hazard.

There are three levels of warning notices:

| Warning term | Meaning |
|---|---|
| DANGER | Imminent danger that can lead to death or serious injury if not avoided |
| WARNING | Potentially imminent danger that can lead to death or serious injury if not avoided |
| CAUTION | Potentially imminent danger that can lead to minor injuries or damage to equipment if not avoided |

The warning notices are highlighted in the following manner (see below example for a CAUTION warning):

| | |
|---|---|
|  CAUTION | **Here the type and source of the danger are listed, and possible consequences if measures are not followed!**<br>➢ **This is the list of measures to prevent the hazard.** |

| | |
|---|---|
| ! | This is the list of important information, directly or indirectly relating to safety and the prevention of damage |

| | |
|---|---|
| i | This is additional useful information concerning safe procedures, background information and recommendations. |

➢ This symbol marks the instructions for action.

### 1.1.4 Abbreviations

| | |
|---|---|
| BLD | Blood leak detector |
| BP | Blood pump |
| DAD | Dialysate air detector |
| DP | Dialysate pump |
| H | Plate warmer |
| HAK | Heparin adsorber clamp |
| HP | Heparin pump |
| LC | Load cell |
| PA | Arterial pressure |
| PBE | Prefilter pressure |
| PBP | Plasma/buffer pump |
| PDF | Dialyser pressure |
| PDI | Dialysate inlet pressure |
| PDPA | Precipitate filter/adsorber pressure drop |
| PPF | Precipitate filter pressure |

| | |
|---|---|
| PPL | Plasma pressure |
| PRP | Reinfusion pump |
| PV | Venous pressure |
| SAD | Safety air detector |
| SAK | Safety air clamp |
| TMP | Transmembrane pressure |

## 1.2 INTENDED USE AND INDICATION

The Plasmat® Futura machine can be used for implementing and monitoring extracorporeal treatments of plasma. The system can be used for patient treatment in a hospital and health center when prescribed by a physician.

> **!** **Plasmat® Futura machine may only be used in combination with the H.E.L.P. apheresis treatment system from B. Braun Avitum AG. Please refer to the instructions for use for the H.E.L.P. apheresis treatment system in Annex 5.**

The Plasmat® Futura is used in connection with the H.E.L.P. apheresis treatment unit for the therapeutic removal of LDL- and VLDL-cholesterol, lipoprotein(a) and fibrinogen from plasma and is indicated in the case of:

1. Patients suffering from severe lipometabolic disturbances that cannot be sufficiently controlled through diet or medication, such as
   a. homozygous form of familial hypercholesterolemia;
   b. heterozygous form of familial hypercholesterolemia or secondary hypercholestorolemia, where the plasma LDL cholesterol concentration cannot be sufficiently controlled despite maximum dietary and medicinal therapy, high risk of arteriosclerotic complications or manifest coronary heart disease;
   c. strong increase in plasma lipoprotein(a) concentration (> 60 mg/dl) and a high risk of arteriosclerotic complications or manifest coronary heart disease.
   Dietary and medicinal lipid lowering therapies should be continued in order to achieve optimum success with the H.E.L.P. apheresis therapy.
2. Patients with acute hearing loss (hearing loss ≥ 15 dB in 3 frequency bands in the affected ear in relation to the unaffected ear) if treatment is started within a maximum of 7 days after the occurrence of the event.
3. Patients suffering from acute hyperlipidemia or fibrinogenemia for whom an acute and effective lowering of fibrinogen, LDL cholesterol, VLDL cholesterol or lipoprotein(a) is medically indicated.

Should only be applied following rigorous individual benefit-risk evaluation.

## 1.3 CONTRAINDICATIONS

The H.E.L.P. apheresis treatment must not be applied in the case of

- Hemorrhagic diathesis
- Ulcers in the gastrointestinal area
- Haemorrhage
- Coagulation disorder and neoplasm
- Liver diseases
- Severe heart failure and valvular defect
- Condition following apoplexia
- Dementia
- During pregnancy and lactation
- Children and infants in whose case the extracorporeal volume is a limiting factor.

The doctor in charge of the treatment is responsible for choosing the suitable therapy, based on medical and analytical findings and the general health and condition of the patient.

## 1.4 SIDE EFFECTS

Occasionally, the occurrence of angina pectoris has been observed.
In rare cases, there are

- Heart rhythm irregularities and laboured breathing caused by the underlying disease
- Bradycardia
- Vasovagal syncopes
- Circulatory collapse
- Hypotonia
- Nausea/sickness
- Dizziness
- Headache
- Tiredness/exhaustion
- Tension and swelling of arms, hands and face
- Burning eyes
- Prolonged bleeding time
- Dyspnea
- Hypertonia
- Feeling hot, sweating
- Hypersensitivity reactions against the hydrophilic components of the tubing and filter material are generally rare in extracorporeal treatment procedures.

In isolated cases there is

- Iron deficiency anaemia
- Hypertonia and oedema formation in the case of patients with renal function impairment

In rare instances benzyl alcohol can cause hypersensitivity reactions in patients.

## 1.5 SPECIAL HAZARDS AND PRECAUTIONS

### 1.5.1 Special Patient Conditions

A particularly careful benefit-risk evaluation must be carried out before the application of the H.E.L.P. apheresis in the case of patients suffering from C1 esterase inhibitor deficiency or hereditary C3 deficiency.

In the case of patients with low initial values of iron and fibrinogen, it is recommended that the subsequent course of the respective serum concentration be monitored.


**Risk to patient due to thrombosis if the heparin is completely neutralised by protamin-chloride/ -sulphate.**

- **These substances should only be administered to reverse the heparin effect in the case of life-threatening haemorrhaging.**


**Risk to patient due to the elimination of parallel medication to differing extents. This means that the level of active substances in a patient who is receiving H.E.L.P. treatment can be lowered up to 60 %.**

- **If possible, any regularly prescribed medication should be taken after the H.E.L.P. treatment.**

Please refer also to the product information provided with the consumables.

### 1.5.2. Electrical Hazards

The Plasmat® Futura machine contains life-threatening high electrical voltages. Do not operate the machine and do not connect the machine to the power supply if the housing or the electrical cord is damaged in any way. A damaged Plasmat® Futura machine must be submitted for repairs or disposed of.

## 1.6 INTERACTION WITH OTHER DEVICES

It is recommend that the machine be connected to a dedicated circuit. When using the Plasmat® Futura machine in combination with other therapeutic

devices, it is recommended to use a connection line for electrical ground, since the leakage currents from all connected devices are additive.

### 1.6.1 Electromagnetic Interaction

The Plasmat® Futura machine was developed and tested in accordance with the valid standards for interference suppression and EMC. It cannot, however, be guaranteed that no electromagnetic interaction with other devices will occur.

Examples: mobile phones, computer tomograph (CT)

It is recommended that the use of mobile phones and other devices emitting strong electromagnetic radiation be restriced to a minimum distance from the Plasmat® Futura machine (refer to table in Chapter 9).

| | |
|---|---|
| ! | Operation of other therapeutic or diagnostic medical devices in conjunction with the Plasmat® Futura machine, or use of non medical devices directly near the Plasmat® Futura machine, should be carefully monitored. |

## 1.7 INFORMATION FOR THE OPERATOR

### 1.7.1 Training by Manufacturer Prior to Commissioning

The operator may only use the device after the manufacturer has trained the responsible staff based on these instructions for use.

### 1.7.2 Requirements on the User

| | |
|---|---|
| ! | Plasmat® Futura machine may be operated only by skilled personnel who are duly trained and instructed on its use according to the contents of this Operating Manual. |

The operator must ensure that the instructions for use are read and understood by all operators of the Plasmat® Futura machine.

Prior to using the Plasmat® Futura machine, check its condition for safe functioning.

### 1.7.3 Conformity

The Plasmat® Futura machine complies with the current requirements of the following generally applicable standards:

- ANSI/AAMI/IEC 60601-1:2001

Additional equipment connected to the analog or digital interfaces of the Plasmat® Futura machine must demonstrably meet the relevant IEC specifications (e.g. IEC 60950 for data processing devices and IEC 60601-1 for electromedical devices). Also, all configurations must conform with the current version of System Standard IEC 60601-1-1.
Connecting additional devices to the signal input or output components of the Plasmat® Futura machine constitutes a system configuration. And the user is responsible for ensure compliance with the current version of System Standard IEC 60601-1-1. In case of queries, please contact your local specialist dealer or technical service.

CE 0123

**Europe**

In Europe, the Plasmat® Futura is a class IIb device complying with the essential requirements of EC-Directive 93/42/EEC for Medical Products which is indicated by the CE mark.

### 1.7.4 Manufacturer's Responsibility

The manufacturer, assembler, installer or implementer shall only be responsible for effects on the safety, reliability and performance of the device, if:

- the assembly, expansion, readjustments, changes or repairs were carried out by the manufacturer's, assembler's or installer's authorized representative.
- the area where the machine is installed complies with the current relevant national requirements on the equipment of medical treatment rooms: (i. e. VDE 0100 part 710 and/or IEC stipulations).

The device may only be operated:

- if the manufacturer or an authorized person, acting on behalf of the manufacturer has carried out a functional check on site (initial commissioning),
- if the persons appointed by the operator to use the device have been trained in the correct handling, use and operation of the medical product with the aid of the Instructions for use, enclosed information and maintenance information.

### 1.7.5 Technical Changes

B. Braun Avitum AG reserves the right to change the products in line with further technical developments.

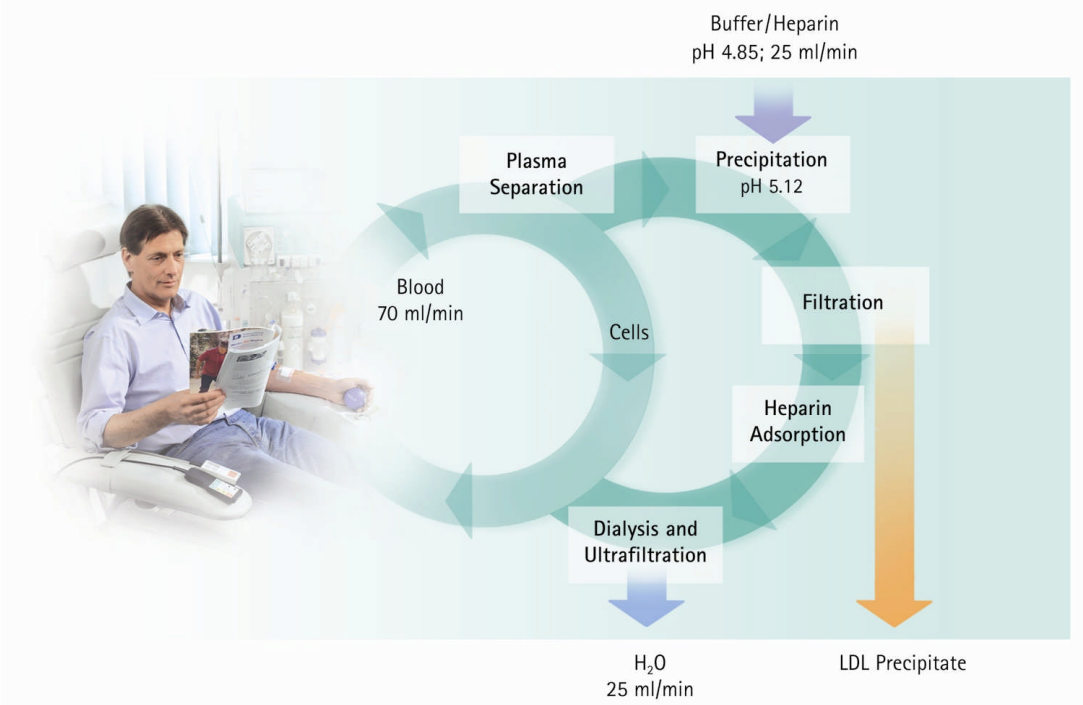
## 1.8 DISPOSAL

Plasmat® Futura machines may be returned to the manufacturer for disposal in accordance with the applicable disposal guidelines.

# 2. PRODUCT DESCRIPTION

## 2.1 PRINCIPLE

Plasmat® Futura is a plasma therapy unit that, together with the H.E.L.P. apheresis treatment unit (see instructions for use in Annex 5), performs H.E.L.P. apheresis therapy. H.E.L.P stands for Heparin-induced Extracorporeal LDL Precipitation.




The first step of the procedure is plasma separation. The cellular blood components are directly reinfused to the patient along with the treated plasma. The plasma is mixed with a heparinized acetate buffer at a ratio of 1:1. LDL, fibrinogen and Lp(a), together with the heparin, form a precipitate in the acid pH range that is filtered out in the subsequent step. Excessive heparin is removed from the treated plasma using a heparin adsorber. In the last step, the plasma is adjusted to its initial volume and initial physiological pH value using bicarbonate dialysis and then reinfused into the patient along with the cellular blood components.

## 2.2 FUNCTION

The blood pump (BP) delivers the blood from the patient's venous access to the plasma filter. The blood flow is controlled via an arterial pressure transducer (PA). The heparin pump (HP) controls the heparin output for anticoagulation in the arterial line. The blood inlet pressure into the plasma filter is monitored via the prefilter pressure (PBE) of the arterial air chamber..

Blood that is separated in the plasma filter is returned via the venous line to the venous air chamber where it is mixed with the treated plasma which flows back via the reinfusion line. The reinfusion volume is equivalent to the volume of the separated plasma. The venous air chamber monitors blood reinfusion via a venous pressure transducer (PV). The venous line is monitored by a safety air detector (SAD) and closed by a safety air clamp (SAK) as soon as air is detected in the system.

The separated plasma is monitored after the plasma filter by a blood leak detector (BLD). Plasma flow is regulated via measurement of plasma pressure (PPL).

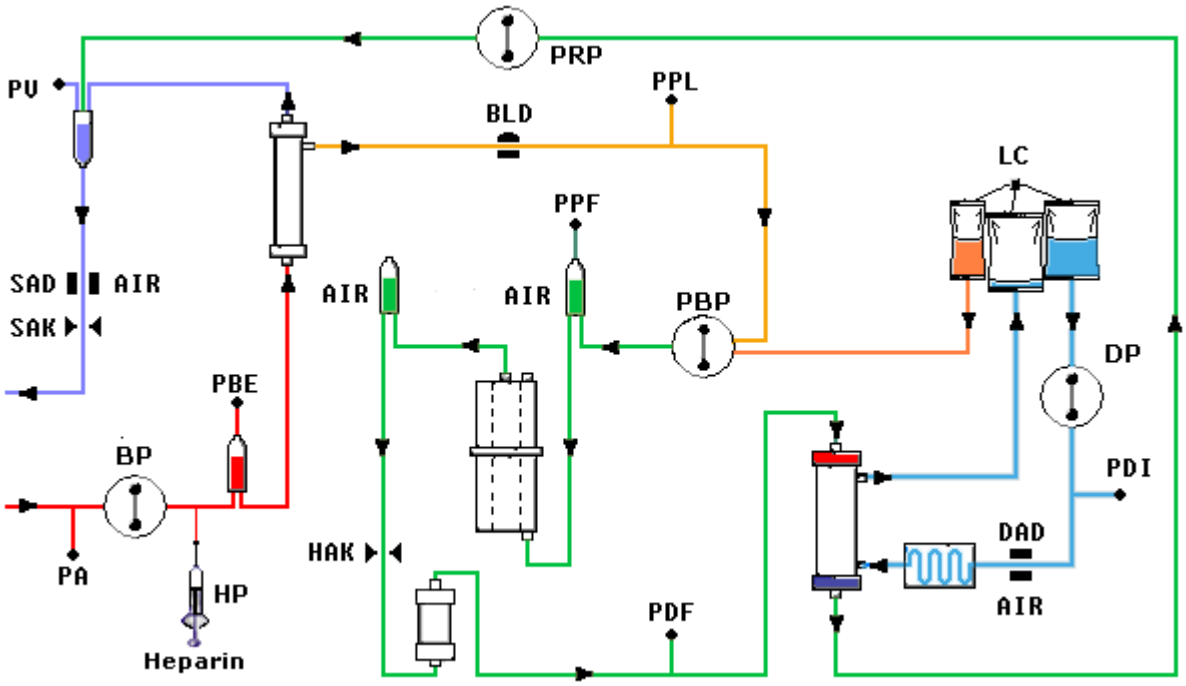
Plasma and heparinized acetate buffer are delivered via a plasma/buffer pump (PBP), in which a double pump segment is inserted, to the precipitate air chamber. Plasma and heparinized acetate buffer are mixed at a ratio of 1:1. The resulting precipitate is filtered in the subsequent precipitate filter. The precipitate filter pressure transducer (PPF) monitors the inlet pressure of the precipitate filter. The precipitate air chamber level valve and sensor control the fluid level in the precipitate air chamber.

The filtrate which is free from LDL is routed via the heparin adsorber air chamber to the heparin adsorber where the excessive heparin is removed. The heparin air chamber level valve and sensor control the fluid level in the heparin air chamber. The automatic clamp (HAK) in front of the heparin adsorber closes in case of a bypass during therapy.

In the dialyzer, the plasma is dialyzed with a sterile bicarbonate solution at a ratio of at least 1:4. The physiological pH-value of the plasma is restored and the induced volume removed by dialysis and ultrafiltration. The dialyzer pressure (PDF) monitors the inlet pressure of the dialyzer. The ultrafiltration rate, bicarbonate dialysate and buffer solution are balanced by the load cell (LC).

Dialysate is delivered via the dialysate pump (DP). The solution is heated in a plate warmer before flowing through the dialyzer. The dialysate air detector (DAD) detects air in the dialysate line. The pressure on the dialysate side is monitored via the inlet pressure of the dialysate (PDI).

After dialysis, plasma is delivered via the reinfusion pump (PRP) to the venous air chamber and together with the blood from the plasma separation is reinfused to the patient via the venous line.




After the dialysis, the plasma is delivered via the reinfusion pump (PRP) to the venous air chamber and together with the blood from the plasma separation reinfused to the patient via the venous line.

### Pumps

| | |
|---|---|
| **BP** | Blood pump |
| **HP** | Heparin pump |
| **PBP** | Plasma/buffer pump |
| **PRP** | Reinfusion pump |
| **DP** | Dialysate pump |

### Sensors

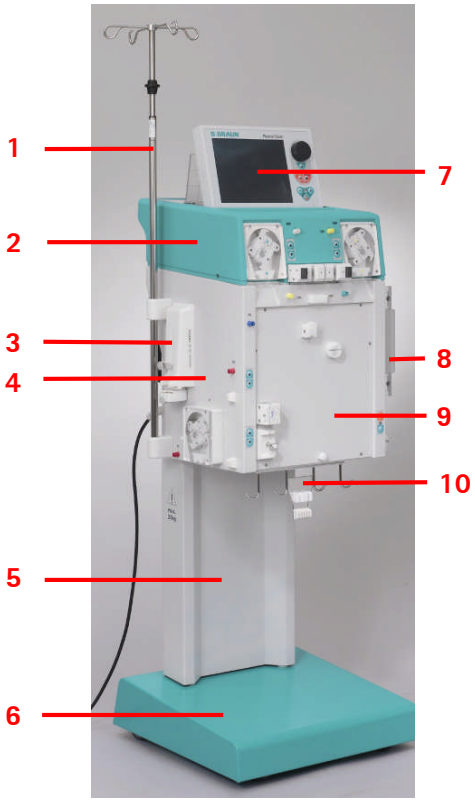
| | |
|---|---|
| **PA** | Arterial pressure |
| **PBE** | Prefilter pressure |
| **PV** | Venous pressure |
| **PPL** | Plasma pressure |
| **PPF** | Precipitate filter pressure |
| **PDF** | Dialyzer pressure |
| **PDI** | Dialysate inlet pressure |
| **SAD** | Safety air detector |
| **BLD** | Blood leak detector |
| **DAD** | Dialysate air detector |
| **LC** | Load cell |

### Actuators

| | |
|---|---|
| **SAK** | Safety air clamp |
| **HAK** | Heparin adsorber clamp |

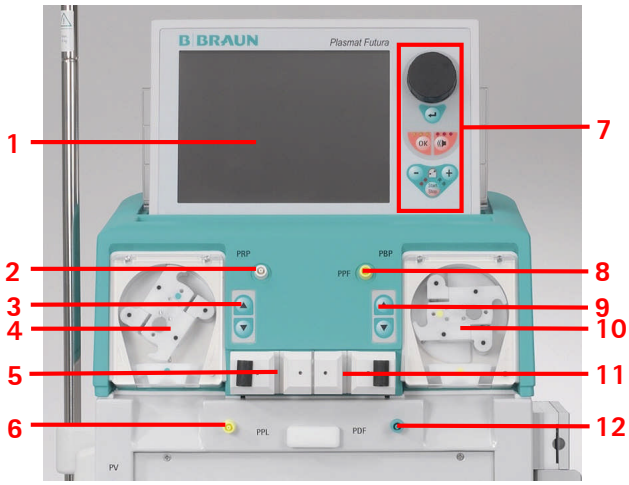
## 2.3 MACHINE

### 2.3.1 Front View



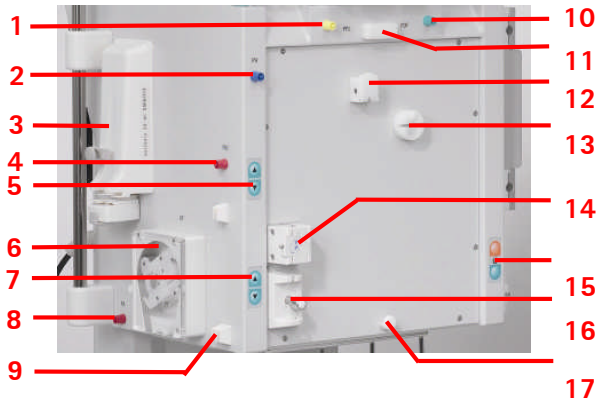

1. IV-pole (height-adjustable)
2. Upper module
3. Heparin syringe pump
4. Central module
5. Base column
6. Base with brake
7. LCD graphic monitor
8. Plate warmer
9. Front panel with attachment for the H.E.L.P. Futura kit
10. Bag holder/load cell

### 2.3.2 Upper Module




1. LCD graphic color monitor
2. Connection to valve for automatic level setting in the heparin adsorber air chamber (HCLD)
3. Manual control for level setting in the heparin adsorber air chamber (HCLD)
4. Reinfusion pump (PRP)
5. Holder for heparin adsorber air chamber (HCLD) with sensor for level monitoring
6. Plasma pressure (PPL) transducer
7. Monitor controls (see 2.2.1)
8. Precipitate filter pressure (PPF) transducer
9. Manual control for level setting of precipitate filter air chamber (PCLD)
10. Plasma/buffer pump (PBP)
11. Holder for precipitate filter air chamber (PCLD) with sensor for level monitoring
12. Dialyzer pressure (PDF) transducer

### 2.3.3 Central Module




1. Plasma pressure (PPL) transducer
2. Venous pressure (PV) transducer
3. Heparin syringe pump (calibrated for 30 ml Omnifix®)
4. Prefilter pressure (PBE) transducer
5. Manual level regulator for venous air chamber
6. Blood pump
7. Manual level regulator for arterial air chamber
8. Arterial pressure (PA) transducer
9. Holder for arterial chamber
10. Dialyzer filter pressure (PDF) transducer
11. Upper holder for H.E.L.P. Futura kit
12. Blood leak detector (BLD)
13. Heparin adsorber clamp (HAK)
14. Venous safety air detector (SAD)
15. Brake pushbuttons for releasing/applying the brake
16. Safety air clamp (SAK)
17. Lower holder for H.E.L.P. Futura kit

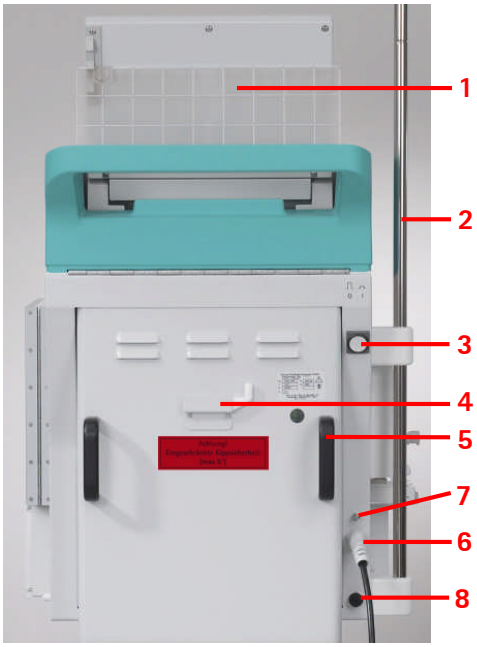

1. Plate warmer
2. Dialysate pump (DP)
3. Brake pushbuttons (apply/release)
4. Dialysate inlet (PDI) pressure transducer
5. Dialysate (DAD) air detector

### 2.3.4 Controls on the Central Module

The level adjustment in the respective chamber is performed with the directly adjacent **level adjustment buttons**. The ▲ button raises the level in the chamber, the ▼ button lowers the level.

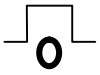
If the machine is switched on, with the red **brake locking button**, the brake can be applied. The brake can then be released with the green **brake release button**.

### 2.3.5 Rear of the Machine



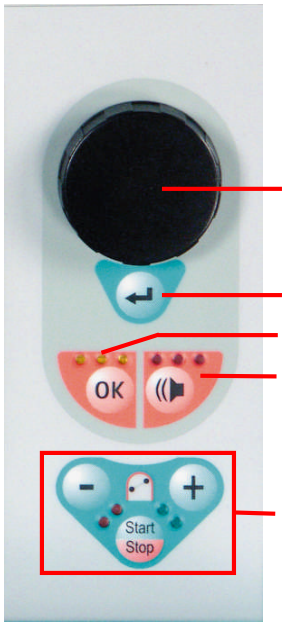

1. Monitor support
2. IV-pole
3. On/Off switch
4. Handcrank for pumps
5. Handles
6. Mains connection
7. Connection for potential equalization
8. Trend Viewer connector (optional)

### 2.3.6 Symbols on the Machine

| | |
|---|---|
|  | Observe Instructions for use<br>Observe safety information |
|  | Application device type B<br>Classification acc. to IEC 60601-1 |
|  | Electrical ground |
|  | Plasmat® Futura OFF |
|  | Plasmat® Futura ON |
|  | Alternating current |
|  | Schematic illustration on safety air detector (SAD) showing the correct way of installing the tube |
|  | Trend Viewer connector (optional) |

## 2.4 MONITOR

### 2.4.1 Monitor Controls




The **rotary knob** moves the cursor on the screen.
Display in lines:
Clockwise rotation - the cursor moves from left to right
Counterclockwise rotation - the cursor moves from right to left
Display in columns:
Clockwise rotation - the cursor moves from top to bottom
Counterclockwise rotation - the cursor moves from bottom to top

The set parameters are accepted by pressing the **key**.

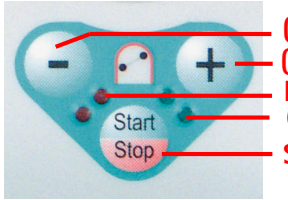
The **OK key** confirms important actions, such as

- Phase change (e.g. change from the priming/rinsing phase to the therapy phase).
- Quitting the <**Parameter Setting**> menu.
- Acknowledging messages that require immediate action (e.g. prompt for turning over the dialyzer during the priming and rinsing phase).

When this key is active, the **yellow LEDs** above it light. These LEDs blink during adjustment of parameters with relevance to patient safety.

Whan an acoustic alarm occurs, switch off the alarm with the **key**. After elimination of the cause of the alarm, acknowledge the alarm with the **key** and continue with the respective phase.
When this key is active, the **red LEDs** above it light.

**Alarms initiated by opening a pump cover are reset by closing the pump cover.**

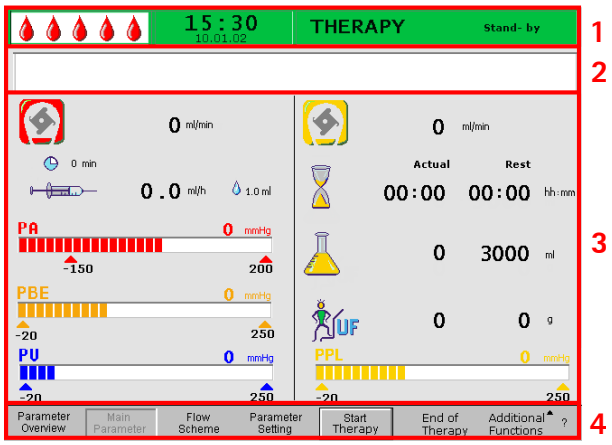



**Keys for operating the blood pump**

The **key** and the **key** lower or raise the delivery rate of the blood pump.
If the blood pump stops during an alarm, the **red LEDs** light. If the blood pump runs, the **green LEDs** light. If both LEDs blink alternately, the blood pump

has stopped and must be started manually with the Start Stop **key**. The running blood pump can also be stopped with this key.

### 2.4.2 Monitor Layout and Functions




1 **Status bar**: The status bar indicates the activity of the blood pump, the current time and date, therapy phase (priming, therapy, reinfusion) and current status of the phase (stand by, running).

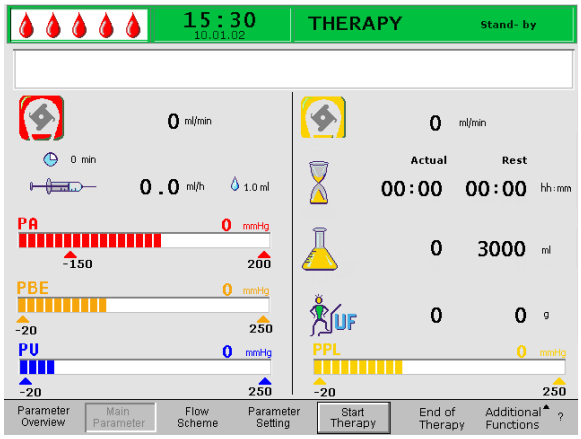
2 **Alarm/Note line**: This area of the monitor displays alarm texts and warning messages.

3 **Display area**: This area displays all parameters which are relevant in the current phase.

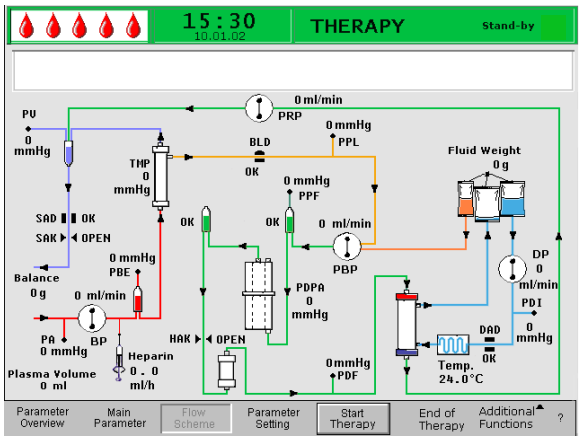
4 **Menu bar**: The menu bar displays the different menu items that can be selected depending on the treatment phase. Functions are selected with the rotary knob and activated with the key.

Three display variants can be selected for the display area.

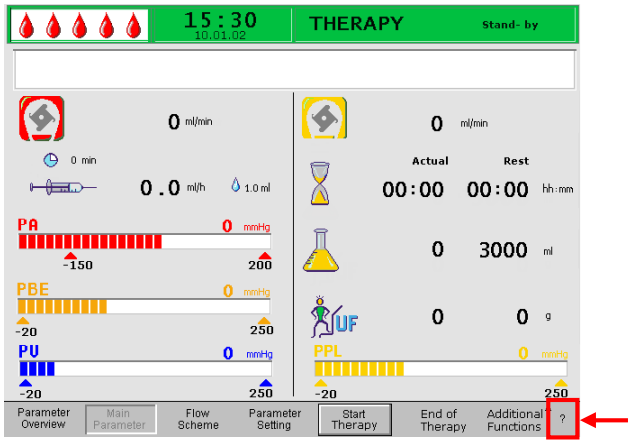
- Main Parameter



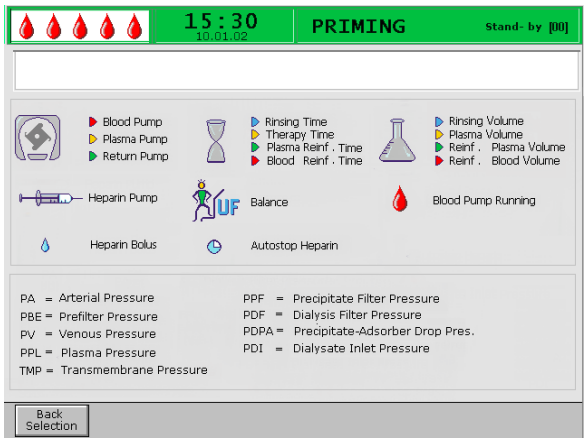

- Parameter Overview




- Flow Scheme




The Help screen can be selected from any screen with the **?** key.




The symbols and abbreviations used for the different pressures in the display areas are explained on the Help screen.
To return to the previous screen select <**Back Selection**> or the screen returns automatically after 30 seconds.

## 2.5 CONSUMABLES

The treatment unit for the Plasmat® Futura comprises the following:

### 2.5.1 H.E.L.P. Futura Set

The H.E.L.P. Futura set includes all line systems and filters required for performing H.E.L.P. treatment:

- **H.E.L.P. Futura kit** with
  - H.E.L.P. precipitate filter
  - H.E.L.P. ultrafilter SMC 1,8

- **Haemoselect M 0,3 m² plasma filter**

- **H.E.L.P. heparin adsorber**

- **Arterial line**

- **Dialysate line**



- **1 x 5 l empty bag for rinse solution (1)**
- **3 x 7 l drain bags (2)**

### 2.5.2 Solutions

The H.E.L.P. treatment unit includes, in addition to the H.E.L.P. Futura set, all solutions required for performance of a treatment:

- **2 x 3000 ml H.E.L.P. 0.9 % NaCl sodium chloride solution**

- **1 x 3000 ml H.E.L.P sodium acetate buffer**

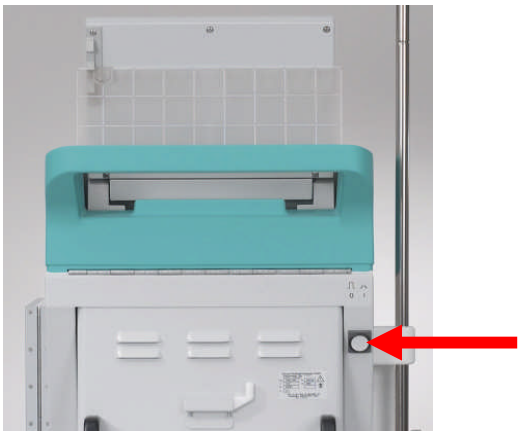
- **1 x 30 ml H.E.L.P. heparin sodium (300,000 IU)**

- **3 x 5000 ml H.E.L.P. BicEl bicarbonate solution in the double-chamber bag**

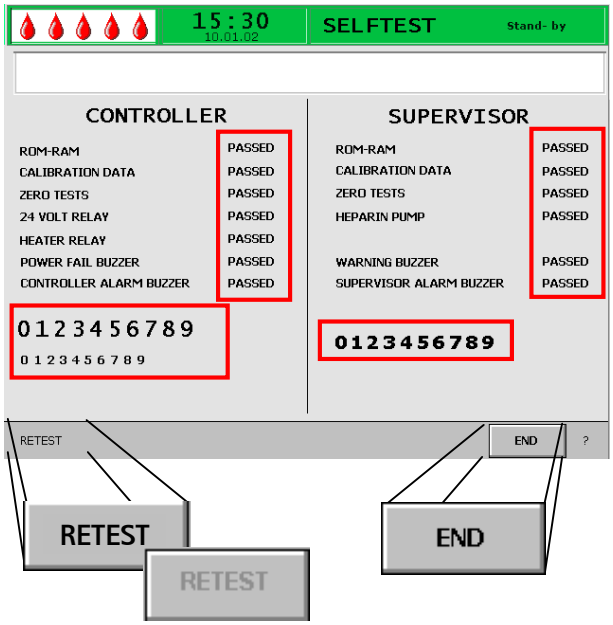
- **1 x 2000 ml H.E.L.P. 0.9% NaCl sodium chloride solution in the double-chamber bag (500 ml/1500 ml) for reinfusion**

# 3. PREPARATION

## 3.1 SWITCHING ON AND SELF-TEST



**Switching on**
Switch on the Plasmat® Futura with the On/Off switch on the rear of the machine.
Make sure that the machine brake is locked during the treatment.




**Hardware Self-Tests**
After the machine has been switched on, the system performs a series of hardware self-tests.
The screen shows the **controller tests** on the left side and the **supervisor tests** on the right side.

The <**Retest**> menu item blinks during the self-test.

Positive self-test:
- All tested positions are marked with "PASSED".
- All three rows of numbers are completely presented in the correct sequence (0 1 2 3 4 5 6 7 8 9) completely and in the three fonts that can be displayed by the machine.

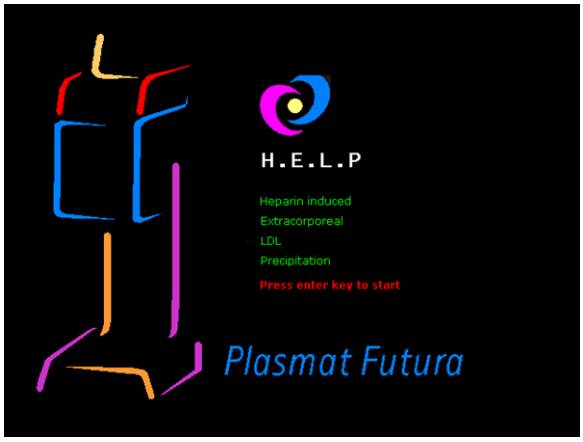
After a positive self-test, the <**End**> menu item is automatically activated. Confirm with the  key to change to the Start screen

Negative self-test:
- The affected positions are marked "Failed" and/or
- The rows of numbers are not in the correct sequence or incomplete.

The <**Retest**> function is automatically selected in this case. Confirm with the  key to start the retest.
See Annex 4 for detailed information concerning the self-tests.

| | |
|---|---|
| ! | The different acoustic signals of the machine are also tested during the self-test. Please make sure the acoustic signals are audible.<br>Make sure that all LEDs are blinking. |

| | |
|---|---|
| ! | ➢ During the self-test, make sure that the load cell is not equipped with solutions and the pressure transducers are not screwed to the respective connections!<br>➢ Preparations for therapy may start only when all self-tests are performed successfully. |




After a successful self-test, the **Start screen** is displayed.
The preparation of solutions can now begin and the Plasmat® Futura set up for operation.

## 3.2 PREPARING THE SOLUTIONS

**H.E.L.P. 0.9% Nacl, physiological saline solution**

- Remove the outer packaging of the saline bag.
- Fill a syringe with 1.5 ml heparin (5.000 IU / ml).
- Remove the cannula from the syringe.
- Remove the screw cap from one of the Luer-lock connectors of the bag and insert the syringe.
- Break the seal of the bag.
- Inject the 1.5 ml heparin into the saline bag.
- Carefully mix the heparin with the saline solution.
- Prepare the second bag in the same manner.

**Bicarbonate Solution H.E.L.P. BicEL**

- Remove the outer packing from the bag.
- Place the bag on a firm base and press the smaller chamber of the bag with both hands until the seal seam between the two chambers is opened over its full length.
- Move the bag several times to and fro so that the two solutions are well mixed.
- Prepare the other bag accordingly.

**Acetate Buffer Solution**

- Remove the outer packaging of the acetate buffer bag.
- Fill a syringe with 30 ml H.E.L.P. heparin sodium solution for extracorporeal application.
- Remove the cannula from the syringe.
- Remove a Luer-lock connector from the acetate buffer bag and insert the syringe.
- Break the seal.
- Inject the 30 ml H.E.L.P. heparin sodium solution into the acetate bag
- Carefully mix the H.E.L.P. heparin sodium solution with the acetate buffer.

## 3.3 SETTING UP THE BAGS

**Physiological Saline Solution Bag/Empty Bag**
Hang the following on the IV-pole of the machine:

- One 5L-empty bag with the connectors upturned.
- One prepared bag with physiological saline solution.
- One double-chamber bag with the physiological saline solution for reinfusion.

**Physiological Saline Solution/Dialysate/Drain Bag**
On the load cell hang:

- One second prepared bag with physiological saline solution.
- Three prepared bags with dialysate.
- Three drain bags with the large clamps closed.

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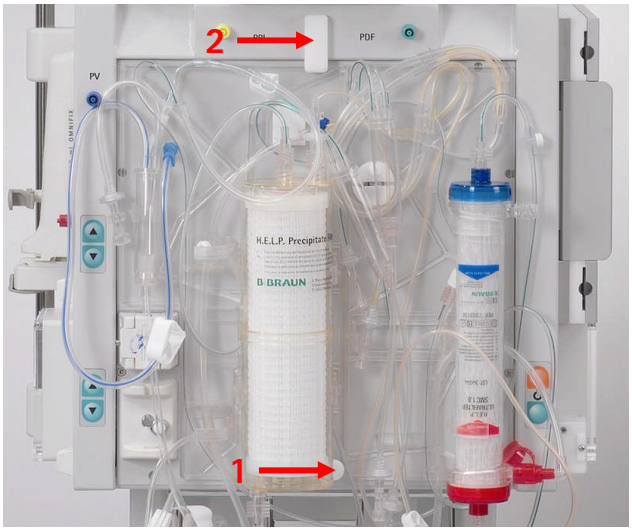
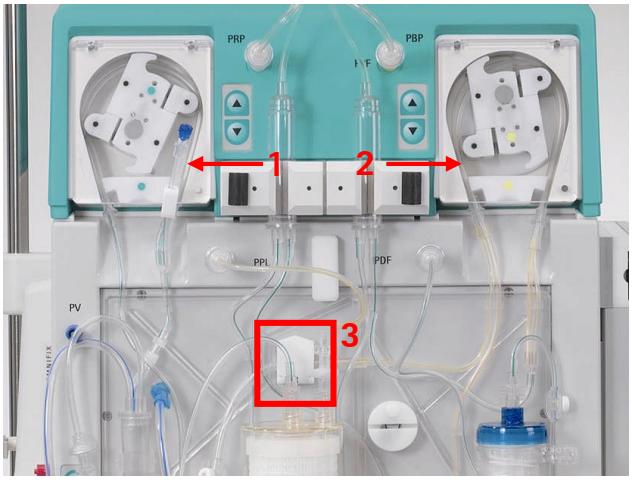
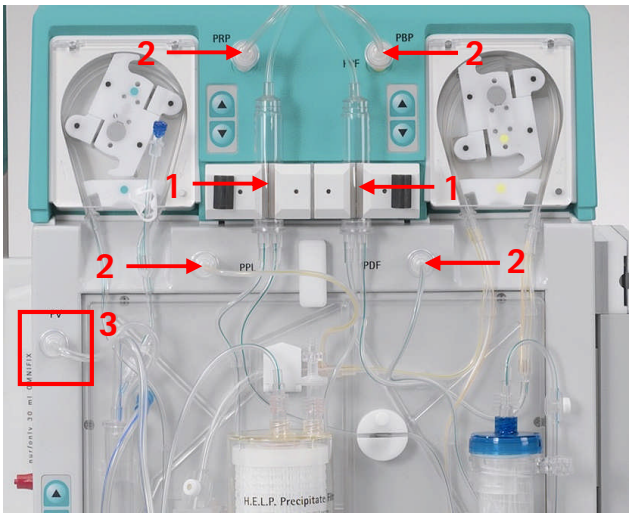
## 3.4 SETTING UP THE H.E.L.P. FUTURA SET



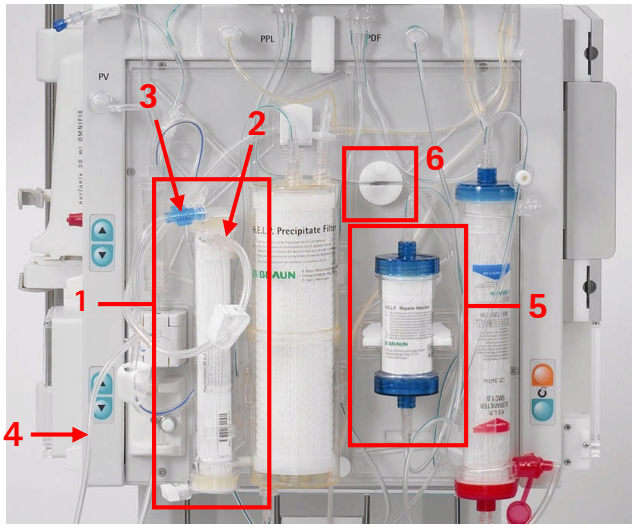

**(1)** Place the plastic plate of the H.E.L.P. Futura kit on to the lower support on the machine. Press the plate against the front of the machine.
**(2)** Secure the plate with the upper rotary attachment knob (**2**).



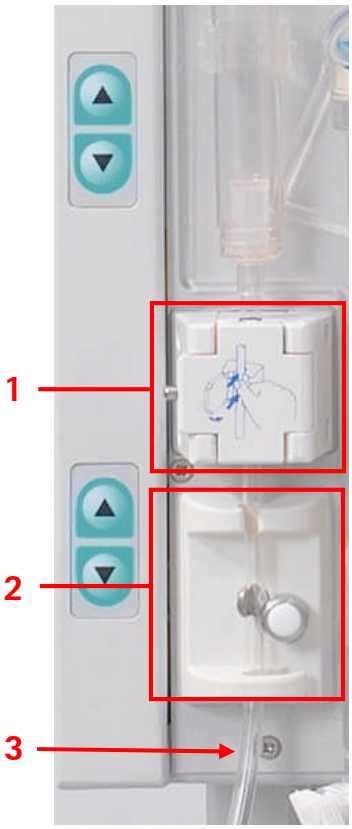

**(1)** Place the pump segment of the reinfusion line into the reinfusion pump (marked green).
**(2)** Place the pump segments of the plasma/buffer line successively into the plasma/buffer pump (marked brown and yellow).
**(3)** Place the plasma line coming from the plasma filter into the blood leak detector BLD.
**(4)** Check whether the pump segments are inserted in the correct orientation.



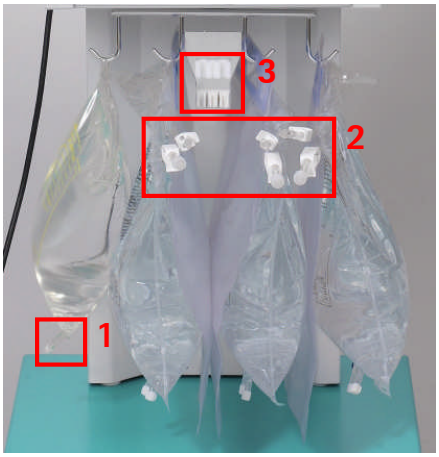

**(1)** Place the two air chambers into the holders as shown. Lock them in place in the holder by turning the black lock.
**(2)** Screw on the four pressure transducers as shown.
**(3)** Place the venous air chamber into the holder provided and screw on the venous pressure transducer as shown.



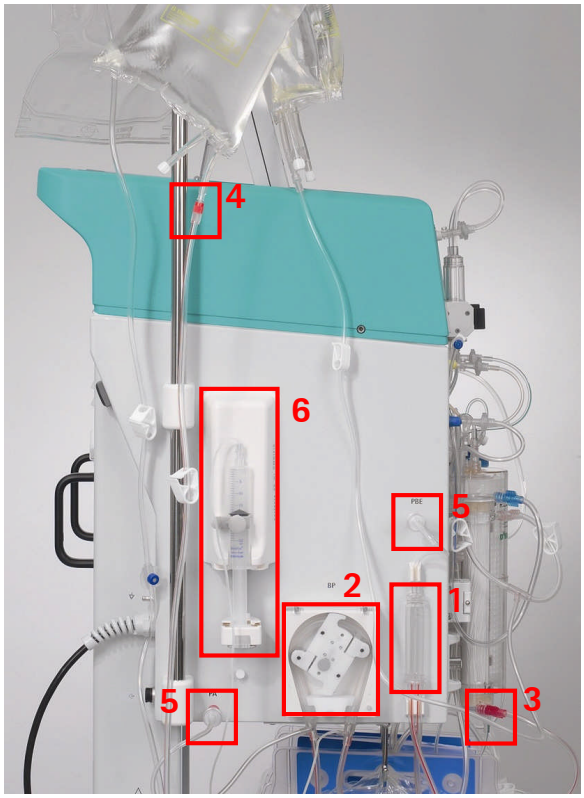

**(1)** Mount the plasma filter in its holder.
**(2)** Connect the plasma line including the reinfusion line to the top right of the plasmafilter.
**(3)** Connect the venous line to the top left of the plasma filter.
**(4)** Connect the reinfusion line to the 1500 ml compartment of the double chamber bag with the saline solution. Break the seal and fill the line manually until the saline solution reaches the plasma line. Then close the clamp at the reinfusion line.
**(5)** Mount the heparin adsorber in its holder and connect the inlet line and outlet line.
**(6)** Place the feeder line to the heparin adsorber into the automatic clamp HAK. Make sure that the line is correctly inserted in the clamp.




**(1)** Place the venous line into the safety air detector SAD.
**(2)** and into the safety air clamp SAK.
**(3)** Connect the venous line to the 5L-empty bag which is hanging on the IV-pole.

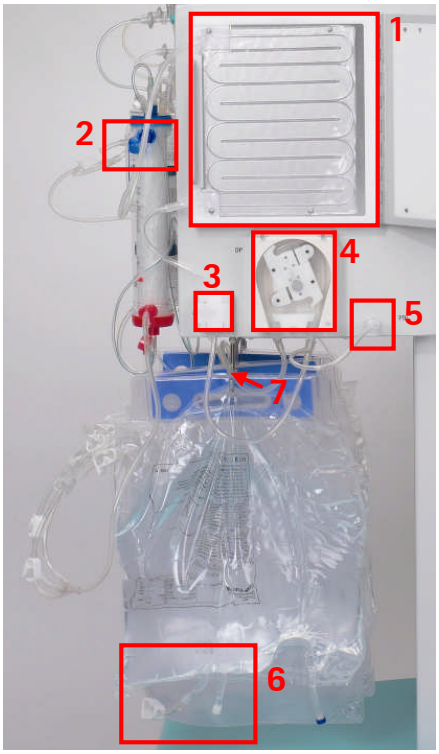



**(1)** Connect the buffer line to the prepared saline bag on the load cell.
**(2)** Connect the ultrafiltrate lines to the three drain bags.
**(3)** Insert the buffer line into the holder provided on the load cell.




**Setting Up the Arterial Line**

**(1)** Place the arterial air chamber into the holder.
**(2)** Place the pump segment of the arterial line into the blood pump.
**(3)** Connect the arterial feeder line to the inlet of the plasma filter.
**(4)** Connect the arterial line to the prepared saline bag which is hanging on the IV-pole.
**(5)** Screw on the two pressure transducers as shown in the Figure.
**(6)** Fill a syringe (30 ml Omnifix® Perfusor syringe) with heparin saline mixture and connect it with the heparin line. Vent the heparin line manually up to the T-piece. Make sure that no air bubbles are left in the line. Mount the syringe on the holder of the heparin pump.
Recommendation: 16 ml 0.9% NaCl + 4 ml heparin (5000 IU/ml) corresponding to a concentration of 1000 IU heparin/ml




**Setting Up the Dialysate Line**

**(1)** Insert the heating bag into the plate warmer.

**(2)** Connect the blue inflow line to the dialyzer. Make sure that the Hansen connector is firmly seated.
Note: Connect red with red and blue with blue!

**(3)** Place the blue inflow line into the dialysate air detector (DAD).

**(4)** Insert the pump segment of the dialysate line into the dialysate pump.

**(5)** Screw on the pressure transducer.

**(6)** Connect the prepared dialysate bag to the distributor of the dialysate line and break the seal.

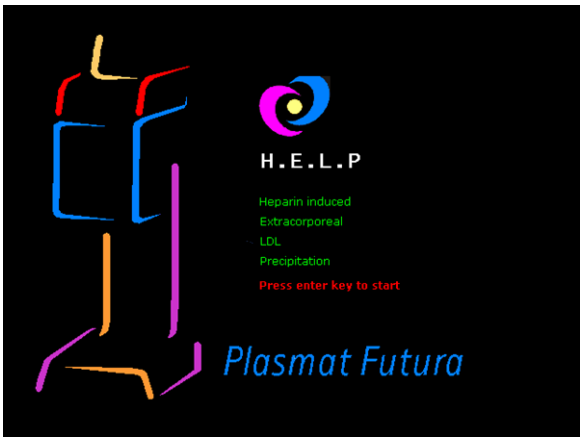
**(7)** Insert the dialysate inlet line into the provided holder of the load cell.

# 4. PRIMING

## 4.1 AUTOMATIC PRIMING AND RINSING

## 4.2 PARAMETER SETTING

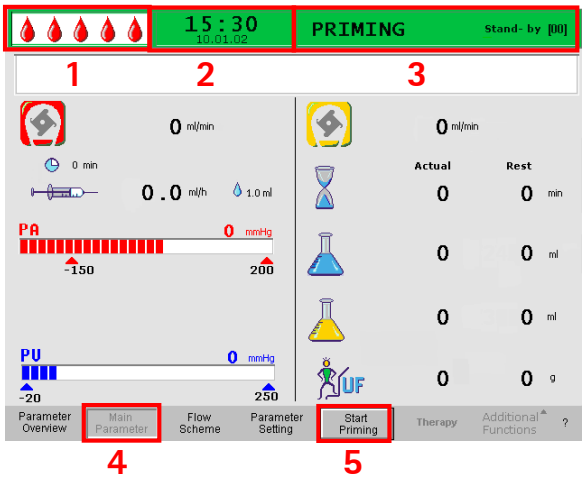
## 4.1 AUTOMATIC PRIMING AND RINSING




On the Start screen, the following message is displayed blinking and in red:

**Press enter key to start!**

If the machine has been prepared as described in the previous chapter, press the key to begin priming and rinsing the system.




**Status bar**

**(1)** Display of blood pump activity
Blood pump stands still: One still, four blinking drops
Blood pump runs: Increasing and decreasing number of drops.

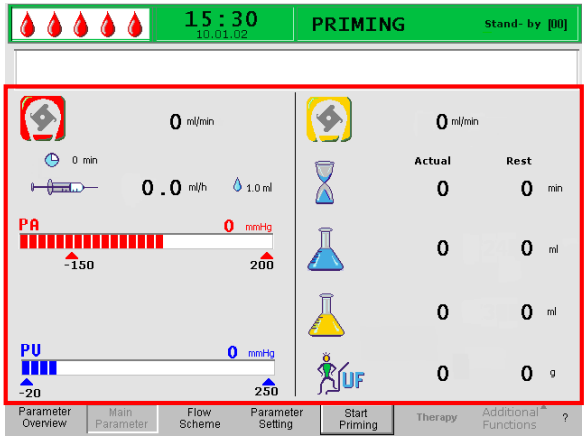
**(2)** Current time and date

**(3)** Current phase (<**Priming**>) and step in the priming phase (<**Stand-by [00]**>)

**Menu bar**

**(4)** The Main Parameter screen is displayed by default. The active screen display is indicated by the display of the recessed <**Main Parameter**> menu item in the menu bar.

**(5)** In the menu bar, the cursor is already positioned on <**Start Priming**>. The label changes between black and gray (blinking). This shows that an input is expected from the user.




## Display area


Blood flow in ml/min


Heparin flow in ml/h

Heparin bolus in ml

Autostop heparin in min

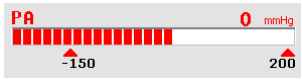

Plasma flow in ml/min


Rinsing time [Actual/Rest] in min


Rinsing volume [Actual/Rest] in ml

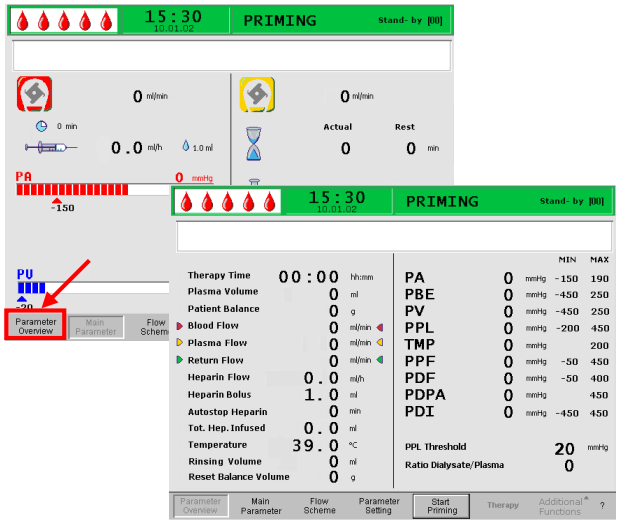

Plasma volume [Actual/Rest] in ml

Balance in g

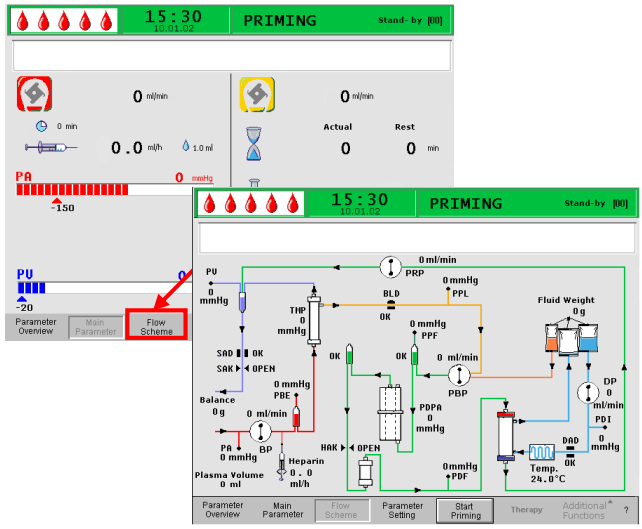


Arterial pressure in mmHg

Venous pressure in mmHg



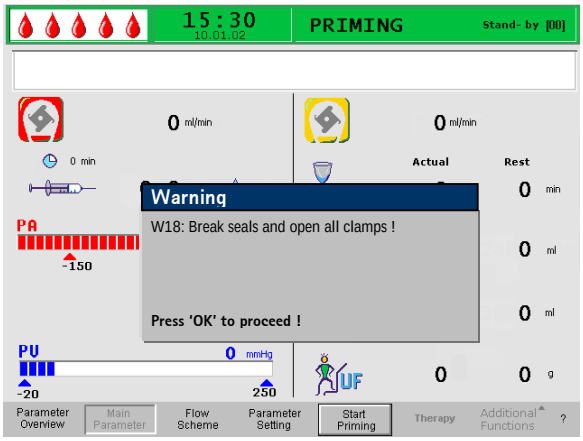

When <**Parameter Overview**> is selected in the menu bar, the screen display changes to Parameter Overview.




By selecting the <**Flow Scheme**> menu item in the menu bar, the display changes to the Flow Scheme. When in the <**Flow Scheme**> screen and the <**Parameter Setting**> menu item is selected in the menu bar, the screen changes to the Parameter Overview.

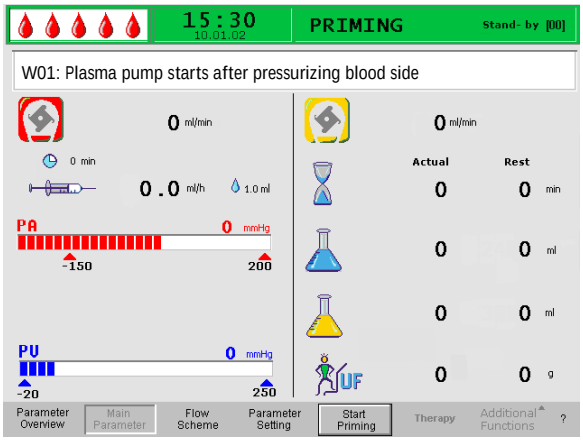
### Final System Check

- Ensure that all connections between the line system and the filters have been made.
- Tighten all screw locks as well as the Hansen connectors again.
- Make sure that the lines are not kinked.
- Make sure that the electrolyte solution is mixed with the bicarbonate solution and the sealing seam is completely open.
- Make sure that the break seals of the saline bags on the IV-pole and the load cell are open.
- Make sure that the break seals of the dialysis fluid bags are open.
- Ensure that the clamps at the unused ports of the empty bags are closed.




The prompt <**W18: Break seals and open all clamps!**> appears in the Warning window.

- Press the OK key to continue.
- The <**Start Priming**> command in the menu bar blinks (the label changes between black and gray). This shows that an input is expected from the user.




After starting priming by selecting <**Start Priming**>, the message <**W01: Plasma pump starts after pressurizing blood side**> is displayed in the message line.

### *Automatic Filling of Blood Side*

During automatic filling, the arterial line, the plasma filter and the venous line are rinsed and filled by default with 600 ml saline solution.

- Start filling the arterial line by pressing the ↵ key.

**Step 1/2**

The arterial line, the plasma filter and the venous line are filling. The preset blood flow rate is 150 ml/min.

**Step 3**

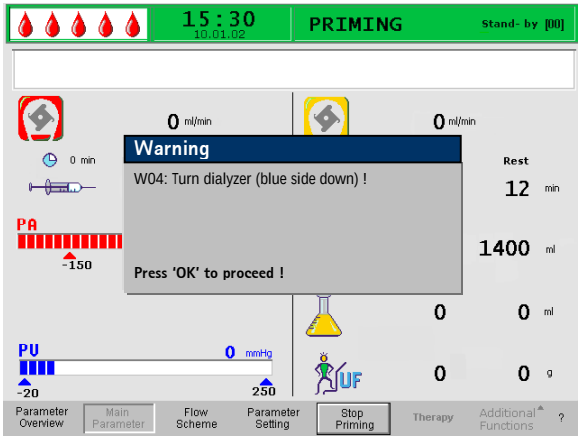
The safety air clamp (SAK) opens and then closes again and the level of the arterial chamber is set accordingly. This vents the plasma filter.

**Step 4**
The plasma/buffer pump starts and the precipitate filter is filled. This step is completed when the level monitoring of the precipitate filter air chamber (PCLD) detects fluid and the balance test 1 has been completed.

**Step 5**
Filling the heparin adsorber air chamber (HCLD)

**Step 6**
Leakage test of the heparin adsorber clamp

**Step 7**
The heparin adsorber clamp (HAK) opens. The level detection in the heparin adsorber air chamber and the venting of the connection line to the heparin adsorber are performed. This step includes the filling of the dialyzer on the plasma side.




**Step 8**
The Warning window prompts with<**W04: Turn dialyzer (blue side down) !**>.

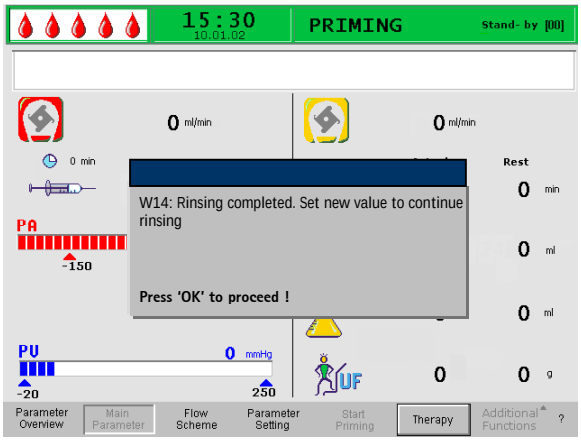
Turn the dialyzer by 180°, with the blue side pointing downward.

Press the OK key to continue.

**Step 9**
The dialysate side filling of the dialyzer is performed during this step.
The balance test 2, the DAD test, the heating test, the venous pressure test as well as the reinfusion pump test are performed in this step.

**Step 10**
The setting of the level of the venous air chamber is performed.

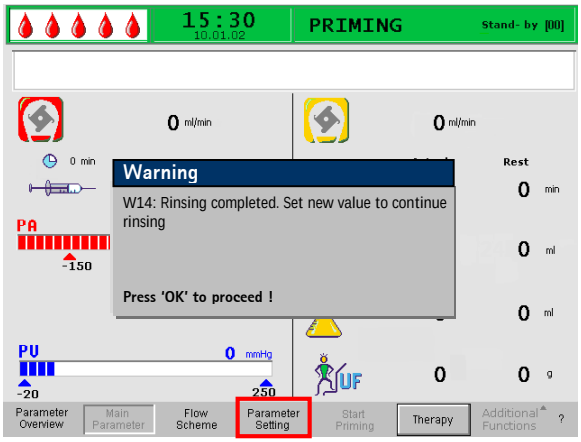
Status 2005-12-16




### Step 11

This step is completed when the minimum rinsing volume of 2400 ml is reached. The following message is displayed in the Warning window: <**W14: Rinsing completed. Set new value to continue rinsing Continue with 'OK!**>

- Press the OK key to confirm the reaching of the minimum rinsing volume.
- If the minimum rinsing volume is sufficient, you can now start with the therapy.




### Step 12

Optional rinsing

This step allows rinsing of the system beyond the minimum rinsing volume.

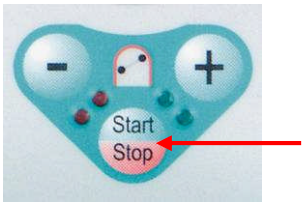
If you wish to increase the rinsing volume:

- Select the <**Parameter Setting**> command in the menu bar.
- Select the <**Rinsing volume**> parameter and change this parameter. The rinsing volume can be set to a value of up to 20 l.
- Then select the <**Start Priming**> command in the menu bar. When the rinsing volume has been reached, all pumps stop automatically.

For more details on increasing the rinsing volume, see also the Chapters 4.2.1 and 4.2.2.

| | |
|---|---|
| ! | When increasing the rinsing volume over 2400 ml, make sure that sufficient saline solution is available. If required, change the bags on the load cell and on the IV-pole. |

Status 2005-12-16




### Additional Manual Rinsing of Blood Side

If you wish to increase the rinsing volume in the blood circuit:

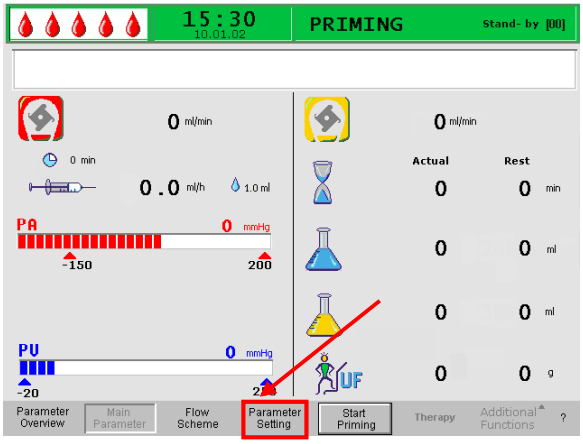
- Start the blood pump with the Start key.
- When you have sufficiently rinsed the blood side, press again the Stop key to finish rinsing.

| | |
|---|---|
| ! | When increasing the rinsing volume, make sure that sufficient saline solution is available.<br>If required, change the bags on the IV-pole. |

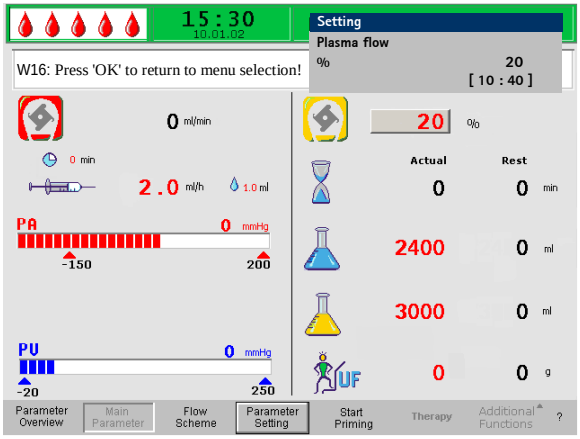
Status 2005-12-16

## 4.2 PARAMETER SETTING

### 4.2.1 Parameter Setting in the <Main Parameter> Screen




To set the parameters, select the <**Parameter Setting**> menu item with the cursor in the <**Main Parameter**> screen and activate it with the  key.




All parameters which can be changed are displayed in red. The currently selected parameter has a gray background. The range which can be selected is displayed in the Setting window. Using the rotary knob, you can select the individual parameters.

The following parameters can be set in the priming and rinsing phase:

 Plasma flow rate (%)

 Rinsing volume (ml)

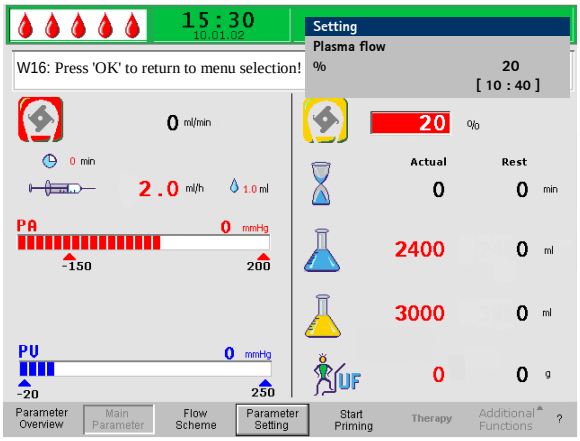
 Plasma volume (ml)

 Balance (g)

 Heparin flow rate (ml/min)

 Heparin bolus (ml)

 Autostop heparin (min)




Press the ↵ key to select the parameter to be changed. The field is shown with a red background and white labeling. Perform the desired change using the rotary knob and confirm it with the ↵ key. The changing of the following parameters must be confirmed with the OK key since they are relevant to patient safety:

- Plasma flow rate
- Plasma volume
- Balance
- Heparin bolus
- Heparin flow rate

If a parameter is relevant to patient safety. the currently set value is shown in the Setting window above the setting range. In addition, the LEDs above the OK key blink.

To quit the screen for setting the parameters, press the OK key. The cursor changes back to the menu bar of the Main Parameter screen and the menu item <**Start Priming**>.

If you do not perform any settings for more than 15 seconds, the screen automatically changes back to the previously selected screen.

The following parameters can be set in the priming and rinsing phase:

**Plasma flow**

| | |
|---|---|
| Default setting: | 20 % of blood flow |
| Range: | 10 ÷ 40 % of blood flow |
| Step size: | 1 % of blood flow |

i

The plasma flow is limited to a maximum of 40 % of the blood flow, and 50 ml/min.
If the blood flow is changed manually, the plasma flow is automatically changed according to the set ratio.
The plasma flow is set in % of blood flow, and is displayed in ml/min.

**Rinsing volume**

The rinsing volume can be increased beyond the set minimum rinsing volume of 2400 ml.

| | |
|---|---|
| Default setting: | 2400 ml |
| Range: | 2400 ÷ 20000 ml |
| Step size: | 100 ml |

**Plasma volume**

| | |
|---|---|
| Default setting: | 3000 ml |
| Range: | 100 ÷ 6000 ml |
| Step size: | 50 ml |

| | |
|---|---|
| ! | With a plasma volume > 3000 ml, it must be taken into account that the acetate buffer bag and the dialysate bags must be changed. |

**Balance**

| | |
|---|---|
| Default setting: | 0 g |
| Range: | -600 ÷ 0 g |
| Step size: | 50 g |

| | |
|---|---|
| ! | This is not an ultrafiltration within the context of a dialysis. This option provides the possibility of additionally removing the existing physiological saline solution or to balance the physiological saline solution required for blood reinfusion. When setting a balance, it must be observed that this changes the hematocrit value of the blood and could make the separation of plasma sometimes more difficult. |

| | |
|---|---|
| CAUTION | **Risk to the patient due to hypotension in rare cases.**<br>➢ **Change the therapy as prescribed by the supervising physician.** |

**Heparin bolus**

| | |
|---|---|
| Default setting: | 1 ml |
| Range: | 0 ÷ 10 ml |
| Step size: | 0.5 ml |

**Heparin flow**

| | |
|---|---|
| Default setting: | 2 ml/h |
| Range: | 0 ÷ 10 ml/h |
| Step size: | 0.5 ml/h |

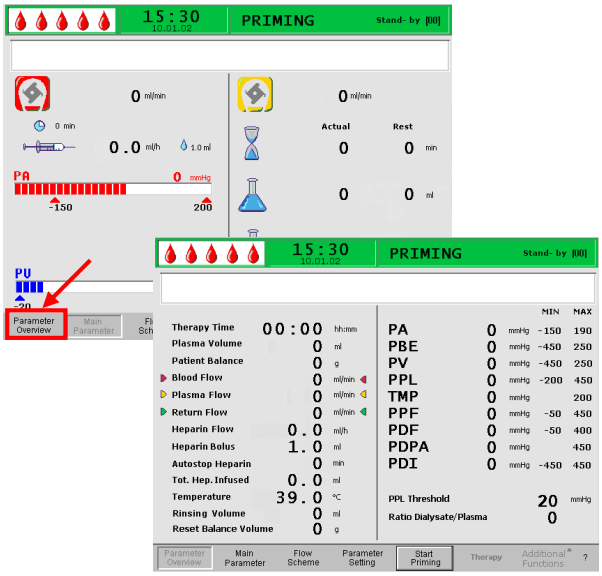
| | |
|---|---|
| CAUTION | **Risk to patient due to insufficient or too high heparinisation.**<br>➢ **Use only 30 ml Omnifix® Luer Lock syringes from B. Braun Melsungen AG. Calibration of the heparin syringe pump is ensured only with use of the Omnifix© Luer Lock syringe.** |

**Autostop Heparin**

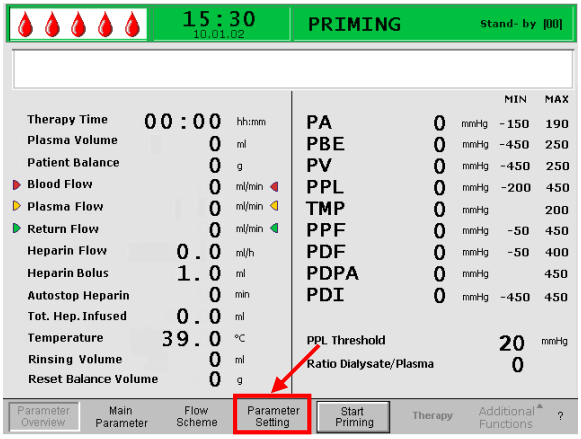
| | |
|---|---|
| Default setting: | 0 min |
| Range: | 0 ÷ 60 min |
| Step size: | 5 min |

Autostop heparin indicates how long before the end of the therapy the heparin administration is stopped. If the therapy time is increased after the heparin pump is switched off, the heparin pump starts again automatically.

### 4.2.2 Parameter Setting in the <Parameter Overview> Screen




Using the rotary knob and the  key, change to the <**Parameter Overview**> screen.




To set the parameters, select the <**Parameter Setting**> menu item with the cursor in the <**Parameter Overview**> screen and activate it with the  key.

For a better overview, blood flow (red), plasma flow (yellow) and reinfusion flow (green) are marked with colored arrows in the Parameter Overview.


All parameters which can be changed are displayed in red. The currently selected parameter has a gray background. The Setting window displays the allowable range. Using the rotary knob, select the individual parameters.

The following parameters can be set in the priming and rinsing phase:

- Plasma volume (ml)
- Balance (g)
- Plasma flow in %
- Heparin flow (ml/h)
- Heparin bolus (ml)
- Autostop heparin (min)
- Temperature (°C)
- Rinsing volume (ml)
- PA min (mmHg)
- PA max (mmHg)
- PV MIN window (mmHg)
- PV MAX window (mmHg)
- PPL min (mmHg)
- TMP max (mmHg)
- PPF min (mmHg)
- PDF min (mmHg)
- PDF max (mmHg)
- PDPA max (mmHg)
- PPL Threshold (mmHg)
- Ratio Dialysate/Plasma


Press the ↵ key to activate the parameter to be changed. The field is shown with a red background and white labeling. Perform the desired change using the rotary knob and confirm it with the ↵ key. The changing of the following parameters must be confirmed with the OK key since they are relevant for safety:

- Plasma flow rate
- Plasma volume
- Balance
- Heparin flow rate
- Heparin bolus
- PV MIN window (mmHg)
- PV MAX window (mmHg)
- Ratio Dialysate/Plasma

If a parameter is relevant for safety, the currently set value is shown in the Setting window above the setting range. In addition, the LEDs above the OK key blink.

WARNING

**Risk to patient due to blood loss since increasing the PV MIN window elevates the likelihood of an unrecognised removal of the venous access.**

- ➢ **Do not cover the venous access.**
- ➢ **Keep the patient under continuous surveillance.**

To quit the screen for setting the parameters, press the OK key. The cursor changes back to the menu bar of the Parameter Overview screen and the menu item <Start Priming>

If you do not perform any settings for more than 15 seconds, the screen automatically changes back to the previously set screen.

In addition to the parameters listed in chapter 4.2.1., the following parameters can be entered:

**Temperature**
- Default setting: 39°C
- Range: 34 ÷ 40°C
- Step size: 0.5°C

**PA min**
- Default setting: -150 mmHg
- Range: -250 ÷ 80 mmHg
- Step size: 10 mmHg

**PA max**
- Default setting: 100 mmHg
- Range: 0 ÷ 200 mmHg
- Step size: 10 mmHg

**PV window Min**
- Default setting: 20 mmHg
- Range: 10 ÷ 40 mmHg
- Step size: 5 mmHg

**PV window Max**
- Default setting: 40 mmHg
- Range: 20 ÷ 100 mmHg
- Step size: 5 mmHg

**PPL min**
- Default setting: -10 mmHg
- Range: -20 ÷ 10 mmHg
- Step size: 1 mmHg

**TMP max**
- Default setting: 100 mmHg
- Range: 20 ÷ 200 mmHg
- Step size: 10 mmHg

**PPF min**
- Default setting: -20 mmHg
- Range: -50 ÷ 50 mmHg
- Step size: 5 mmHg

**PDF min**
- Default setting: -50 mmHg
- Range: -50 ÷ 0 mmHg
- Step size: 5 mmHg

**PDF max**
- Default setting: 350 mmHg
- Range: 10 ÷ 400 mmHg
- Step size: 10 mmHg

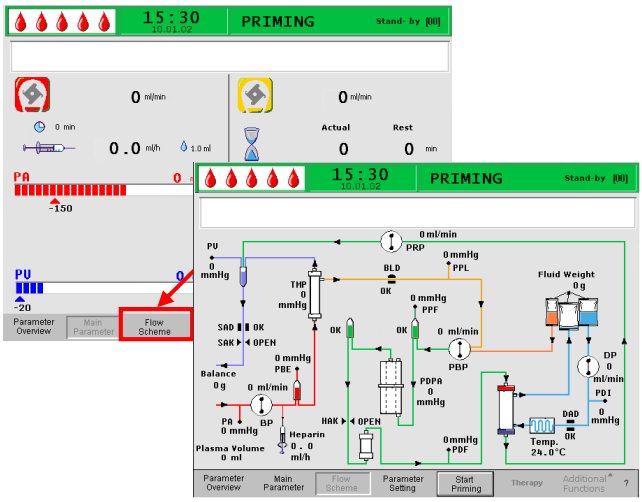
**PDPA max**
- Default setting: 150 mmHg
- Range: 50 ÷ 350 mmHg
- Step size: 10 mmHg

**PPL Threshold**
- Default setting: 20 mmHg
- Range: -10 ÷ 120 mmHg
- Step size: 5 mmHg

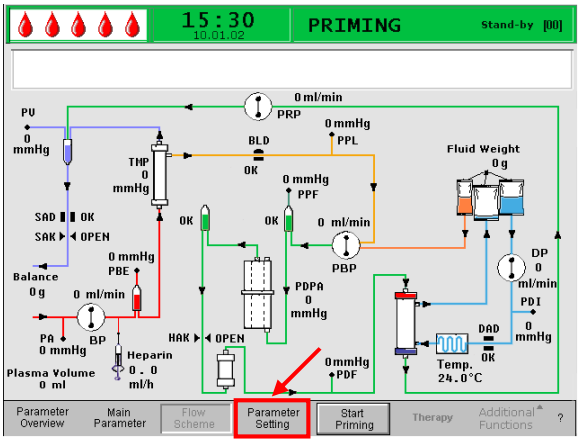
**Ratio Dialysate/Plasma**

| | |
|---|---|
| Default setting: | 4 |
| Range: | 4 ÷ 12 |
| Step size: | 1 |

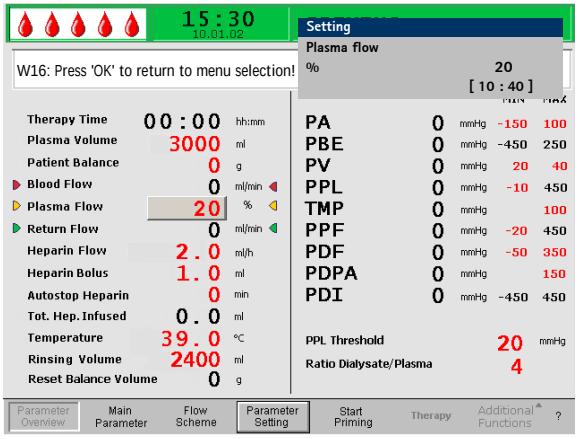
### 4.2.3 Parameter Setting in the <Flow Scheme> Screen




Using the rotary knob and the  key, change to the <**Flow Scheme**> screen.

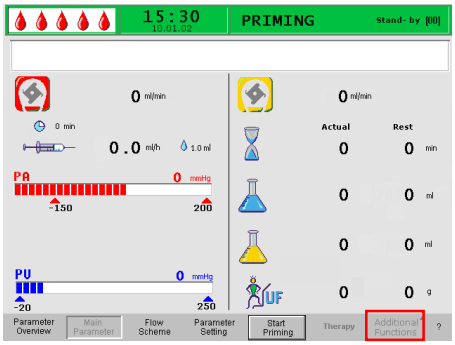


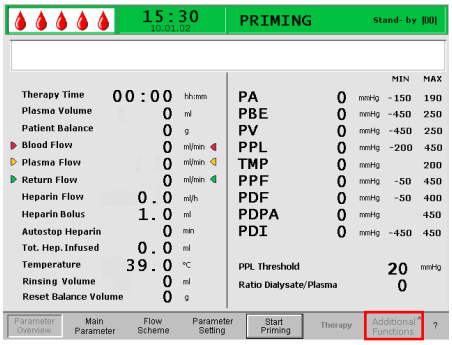

To set the parameters, select the <**Parameter Setting**> menu item with the cursor in the <**Flow Scheme**> screen and activate it with the  key.

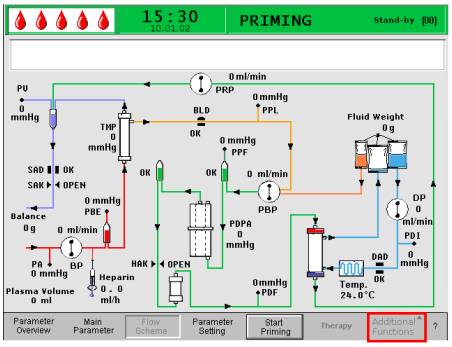



The screen changes to the Setting screen of the Parameter Overview and you can perform here all settings as described in chapter 4.2.2.

### 4.2.4 Additional Functions



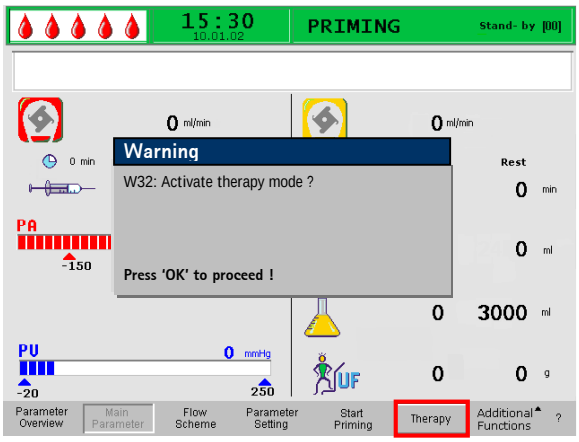

During Priming and Rinsing in the <**Main Parameter**>, <**Parameter Overview**>, and <**Flow Scheme**> screens, the <**Additional Functions**> menu item is not active.

**i**

New Therapy:
To cancel the priming and rinsing phase and return to the Start screen, switch off the machine and switch it on again while pressing the  key.

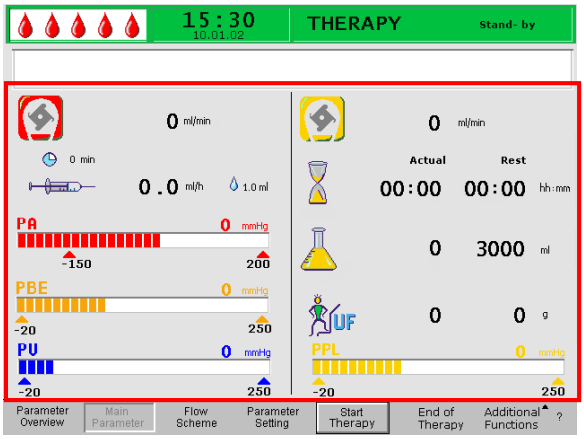
# 5. THERAPY

## 5.1 Starting the Therapy




- After the completion of the priming and rinsing phase, select the <**Therapy**> menu item in the menu bar and confirm with the ↵ key
- The following message is displayed in the warning window <**W32: Activate therapy mode ?**> Confirm the message with the OK key.

The change to the therapy phase is possible only when the minimum rinsing volume of 2400 ml has been reached.




The screen changes to the Therapy screen.

### Display Area of Therapy Screen


Blood flow in ml/min


Heparin flow in ml/h

Heparin bolus in ml

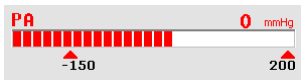
Autostop heparin in min


Plasma flow in ml/min

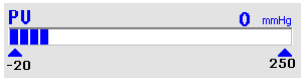

Therapy time [Actual/Rest] in hh:mm


Plasma volume [Actual/Rest] in ml


Balance in g




Arterial pressure in mmHg




Venous pressure in mmHg


Prefilter pressure in mmHg


Plasma pressure in mmHg


- Select <**Start Therapy**> in the menu bar. The following message is displayed in the Warning window: <**W15: Connect buffer – seal and clamp opened?**>
- Exchange the saline bag on the load cell with the prepared acetate buffer bag.
- Remove the venous line from the empty bag on the IV-pole and screw it to the second connection of the saline bag on the IV-pole (next to the arterial line).
- Remove the empty bag from the IV-pole.
- Remove the clamps from the bag and the buffer line and make sure that all bag break seals are open.
- At this point at the latest, enter the parameters required for the therapy, such as plasma volume, heparin flow, heparin bolus, etc. (see chapter 4.2).

Confirm the message in the Warning window with the OK key.

The machine is now ready for the therapy and can be connected to the patient.

### Starting the Blood Circuit

- Disconnect the arterial line from the physiological saline bag on the IV-pole.
- Connect the line to the patient access for drawing blood.
- The green and red LEDs above the Start Stop key blink alternately. Start the blood pump with the Start Stop

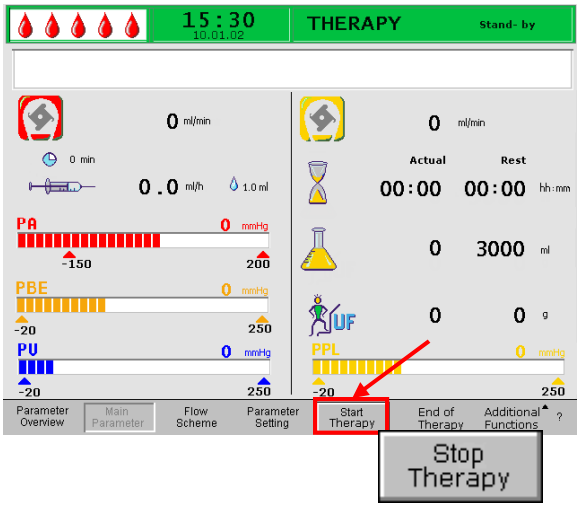
key. The default setting of the blood flow is 40 ml/min.

If desired, adapt the blood flow with the key or the key to the existing pressure situation.

- When the first traces of blood reach the saline bag on the IV-pole, stop the blood pump with the Start Stop key.
- Connect the venous line to the patient access for blood return.
- Start the blood pump with the Start Stop key and adapt the blood flow to the existing pressure conditions and the tolerance of the patient. Observe the pressure limits which are displayed on the monitor!

The patient can also be connected venovenous without phlebotomy but with volume substitution. Connect the patient's arterial line as well as the venous line to the patient's accesses for drawing blood and blood return, respectively. Fill the blood-side line system by pressing the Start Stop key.

**Starting the Plasma Circuit**




- Allow the blood to circulate for a short period (approx. two minutes) until a spontaneous yellow coloring occurs in the proximal part of the plasma filter.
- Start the therapy by selecting the <**Start Therapy**> menu item. Confirm with the key. Plasma treatment begins.
- The text of the softkey <**Start Therapy**> changes to <**Stop Therapy**>.
- The treatment is automatically monitored and terminated when the desired plasma volume has been reached.
- The treatment can be interrupted at any time with the <**Stop Therapy**> menu item and switching to the reinfusion phase.

The therapy period is timed only while the plasma circuit is running.

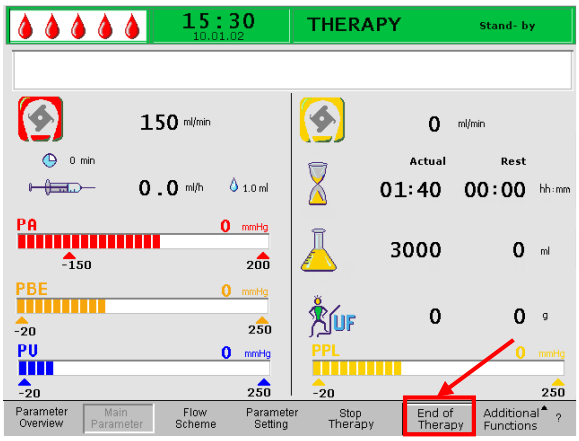

**Risk to patient due to haemolysis because of a high shear stress.**

- **Gradually increase first the blood flow rate to reach the desired target value after 5 minutes.**
- **Subsequently, gradually increase the plasma flow rate to achieve the appropriate value after another 10 minutes.**


**Risk to patient due to insufficient dialysis after restart because of spontaneous ultrafiltration occuring in the therapy stand-by mode.**

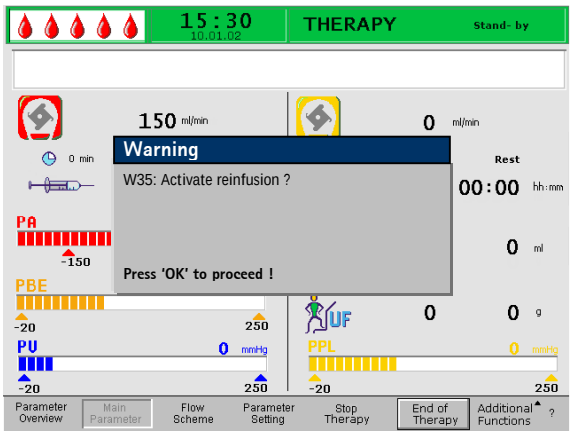
- **Place a clamp on the dialysate drainage line behind the dialyzer.**

## 5.2 Terminating the Therapy




When the treated plasma volume is achieved, the machine switches to the stand-by mode. The blood circuit continues to circulate with the most recent blood flow rate selected.

- The cursor automatically points to the <**End of Therapy**> command in the menu bar. Confirm with the ↵ key.



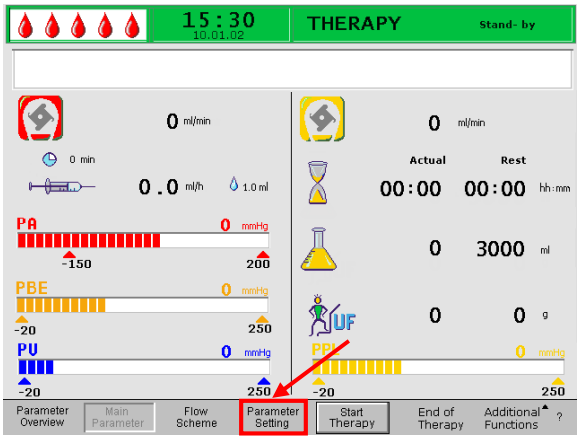

- Confirm the message <**W35: Activate reinfusion? Press 'OK' to proceed!**> in the Warning window by pressing the OK key to change to the reinfusion phase.

> **CAUTION**
>
> **Risk to patient due to blood and/or plasma loss and subsequent blood pressure drop in case of a premature termination of the therapy without reinfusion of the plasma and/or blood volume.**
>
> - **Volume substitution, application of an albumin solution as prescribed by the handling physician.**
> - **Request the patient to drink more liquids than usual.**

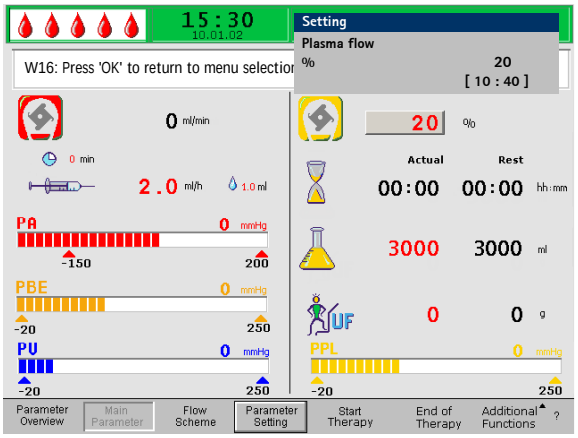
Status 2005-10-26

## 5.3 PARAMETER SETTING

### 5.3.1 Parameter Setting in the <Main Parameter> Screen




To set the parameters, select the <**Parameter Setting**> menu item with the cursor in the <**Main Parameter**> screen and activate it with the ↵ key.




All parameters which can be changed are displayed in red. The currently selected parameter has a gray background. The Setting window displays the allowable range. Using the rotary knob, select the individual parameters.

The following parameters can be set in the therapy phase:

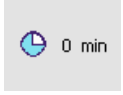

Plasma flow rate (%)


Plasma volume (ml)

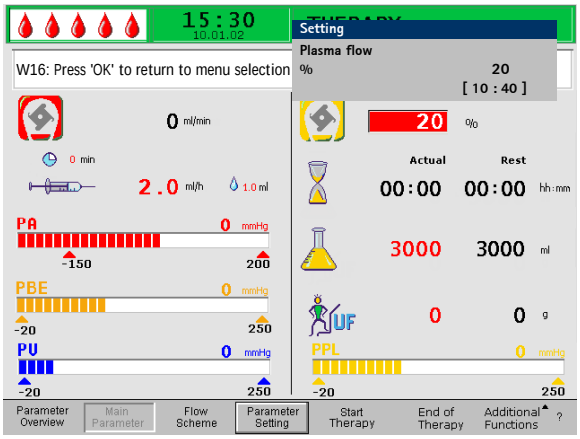
Balance (g)


Heparin flow rate (ml/min)

Heparin bolus (ml)



Autostop heparin (min)




Press the ↵ key to select the parameter to be changed. The field is shown with a red background and white labeling. Perform the desired change using the rotary knob and confirm with the ↵ key. The changing of the following parameters must be confirmed with the OK key since they are relevant to patient safety:

- Plasma flow rate %
- Plasma volume
- Balance
- Heparin bolus
- Heparin flow rate

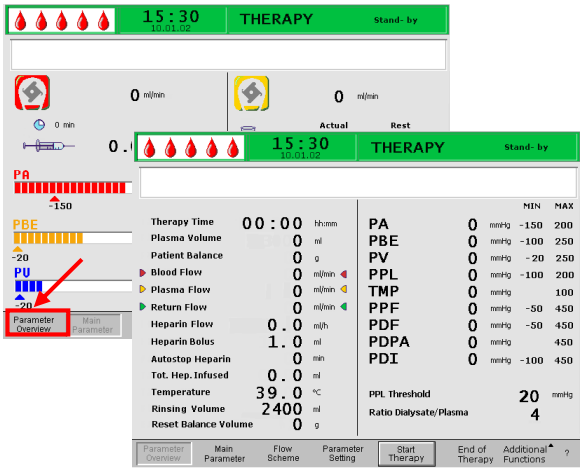
If a parameter is relevant to patient safety, the currently set value is shown in the Setting window above the setting range. In addition, the LEDs above the OK key blink.

To quit the screen for setting the parameters, press the OK key. The cursor changes back to the menu bar and the menu item <**Start Therapy**> of the Parameter Overview screen.

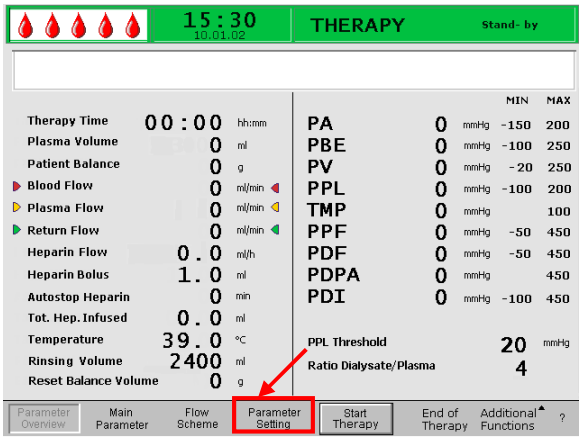
If no settings are changed for more than 15 seconds, the screen automatically changes back to the previously set screen.

For more details, see chapter 4.2.1

### 5.3.2 Parameter Setting in the <Parameter Overview> Screen




Using the rotary knob and the ↵ key, change to the <**Parameter Overview**> screen.

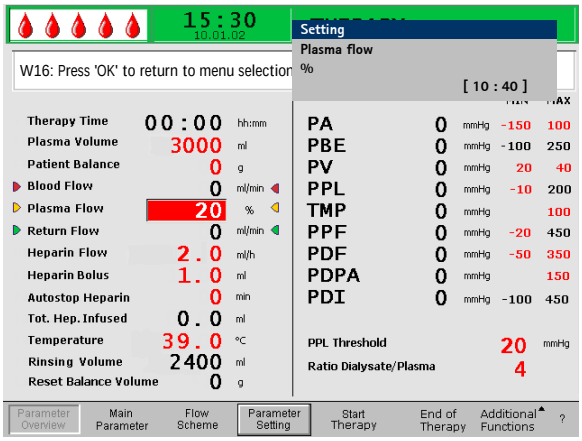



To set parameters, select the <**Parameter Setting**> menu item and activate it with the  key.


All parameters which can be changed are displayed in red. The currently selected parameter has a gray background. The Setting window displays the allowable range. Using the rotary knob, you can select the individual parameters.

The following parameters can be set in the therapy phase:

- Plasma volume (ml)
- Balance (g)
- Plasma flow (%)
- Heparin flow (ml/h)
- Heparin bolus (ml)
- Autostop heparin (min)
- Temperature (°C)
- PA min (mmHg)
- PA max (mmHg)
- PV MIN window (mmHg)
- PV MAX window (mmHg)
- PPL min (mmHg)
- TMP max (mmHg)
- PPF min (mmHg)
- PDF min (mmHg)
- PDF max (mmHg)
- PDPA max (mmHg)
- PPL Threshold (mmHg)
- Ratio Dialysate/Plasma




Press the ↵ key to select the parameter to be changed. The field is shown with a red background and white labeling. Perform the desired change using the rotary knob and confirm it with the ↵ key. The changing of the following parameters must be confirmed with the OK key since they are relevant to patient safety:

- Plasma flow rate
- Plasma volume
- Balance
- Heparin flow rate
- Heparin bolus
- PA min
- PA max
- PV MIN window (mmHg)
- PV MAX window (mmHg)
- Ratio Dialysate/Plasma

If a parameter is relevant to patient safety, the currently set value is shown in the Setting window above the setting range. In addition, the LEDs above the OK key blink.

WARNING

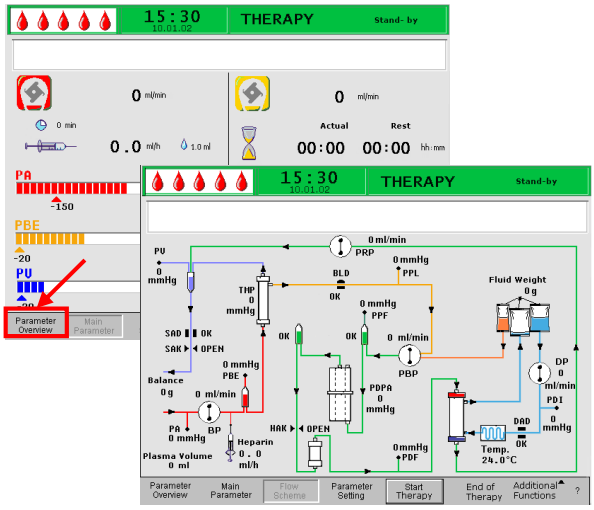
**Risk to patient due to blood loss since increasing the PV MIN window elevates the likelihood of an unrecognised removal of the venous access.**

- ➢ **Do not cover the venous access.**
- ➢ **Keep the patient under continuous surveillance.**

To quit the screen for setting the parameters, press the OK key. The cursor changes back to the menu bar and the menu item <**Start Therapy**> of the Main Parameter screen.

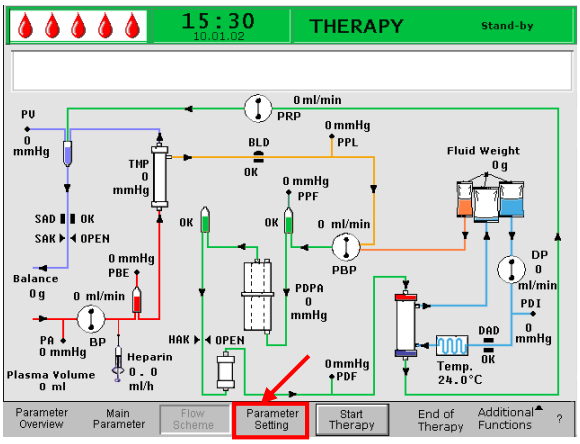
If no settings are changed for more than 15 seconds, the screen automatically changes back to the previously set screen.

For more details, see chapter 4.2.2.

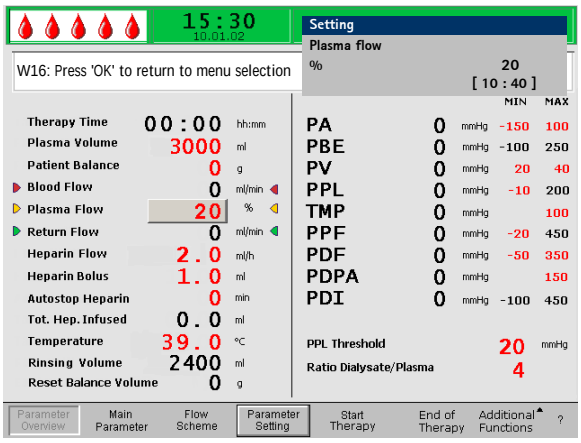



## 5.3.3 Parameter Setting in the <Flow Scheme> Screen

Using the rotary knob and the ↵ key, change to the <**Flow Scheme**> screen.



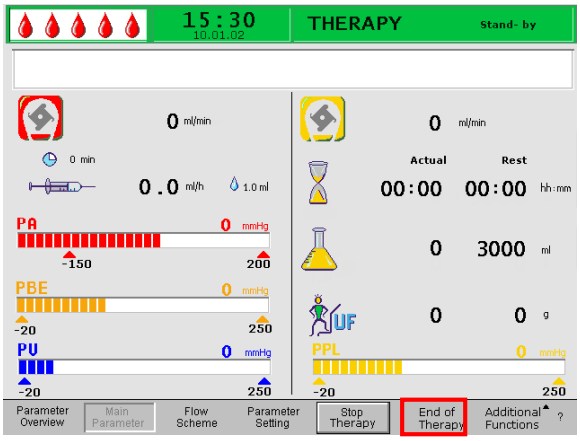

To set the parameters, select the <**Parameter Setting**> menu item with the cursor in the <**Flow Scheme**> screen and activate it with the ↵ key.




The screen changes to the Setting screen of the Parameter Overview and the settings may be changed as described in chapters 5.3.2 and 4.2.2.

## 5.3.4 Additional Functions

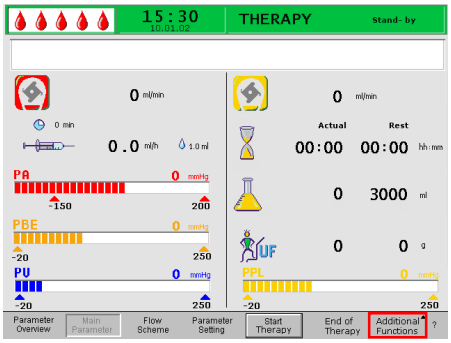
### Premature Termination of Therapy



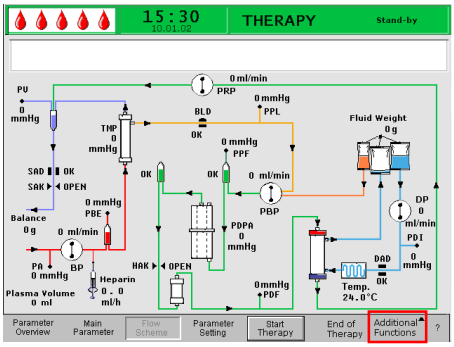

The therapy can be terminated prematurely at any time by selecting <**End of Therapy**> in the menu bar and activated by pressing the ↵ key.

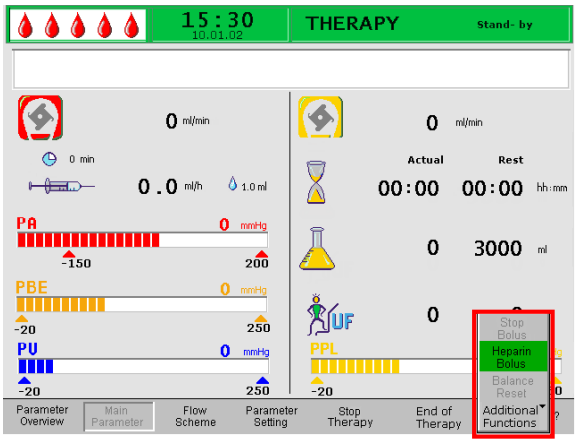

If the therapy is prematurely terminated, the Warning window with the following message is first displayed <**W35: Activate reinfusion ?**> and must be confirmed with the OK key.
The next procedure is described in chapter 6 - Reinfusion.

### Additional Functions




From the <**Main Parameter**>, <**Parameter Overview**>, and <**Flow Scheme**> screens, the <**Additional Functions**> menu item can be selected and activated by pressing the ↵ key.

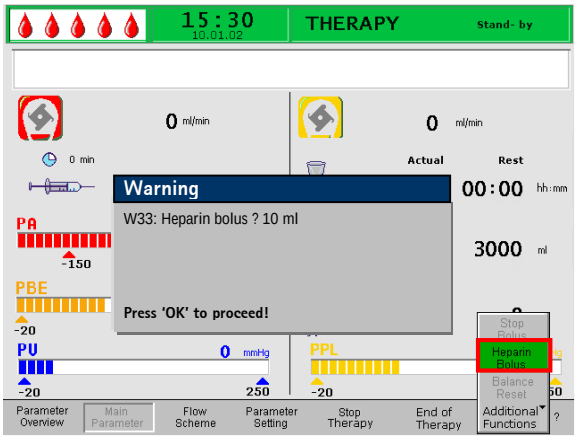




When <**Additional Functions**> is selected, a submenu with the following selections is opened:

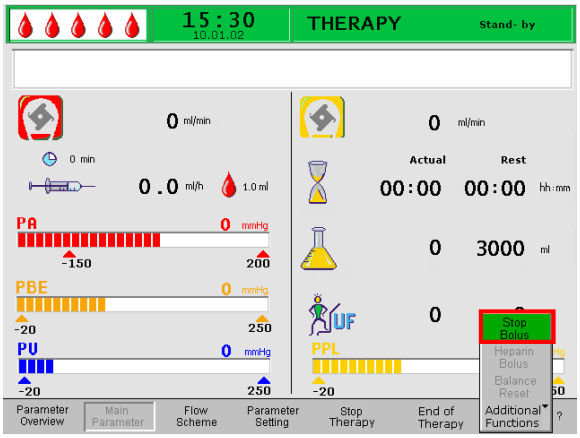
- Stop bolus – active only while the heparin bolus is administered
- Heparin bolus – active during the therapy
- Balance reset – active only for improper balancing > 200 g (for a more detailed description, see Problem Correction).

The active menu items are shown in black labeling, and the inactive items in gray labeling. The selected active field has a green background.

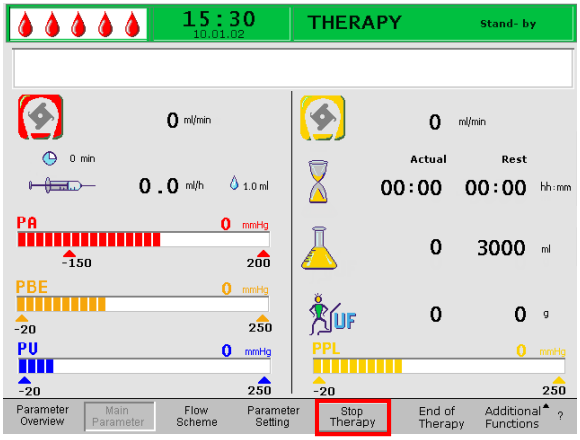



## Heparin bolus

- To administer a heparin bolus during the therapy, select the <**Heparin Bolus**> menu item and confirm the input with the  key.
- The Warning window is displayed with the following message: <**W33: Heparin bolus?**>
- Confirm the message with the  key if you wish to administer the heparin bolus.
- If you do not wish to administer the heparin bolus, wait for the Warning window to disappear after 5 seconds.



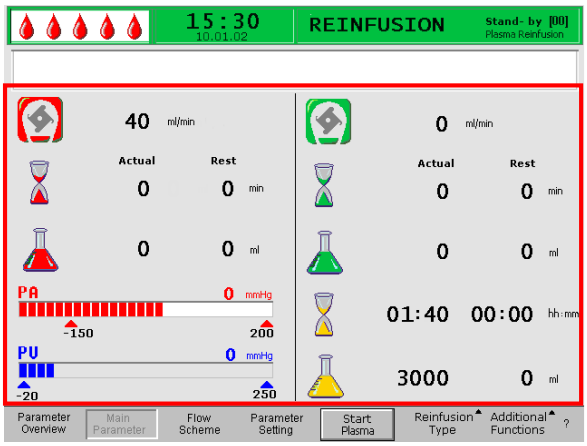

- While the heparin bolus is administered, the <**Stop Bolus**> menu item in the submenu is active. The heparin bolus can be interrupted at any time by pressing the ↵ key.
- During heparin administration, the symbol of heparin bolus (drop) alternates between a large red drop and a small blue drop.




- After heparin administration, the softkey <**Stop Therapy**> is automatically selected.

# 6. REINFUSION

## 6.1 PLASMA REINFUSION




After terminating the therapy as described in chapter 5.2, the screen display changes to the Reinfusion screen.

### Display Area of the Reinfusion Screen


Blood flow in ml/min


Blood reinfusion time in min


Blood reinfusion volume in ml

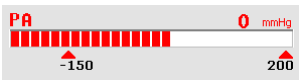

Reinfusion flow in ml/min


Reinfusion time in min


Reinfusion volume in ml


Therapy time [Actual/Rest] in hh:mm

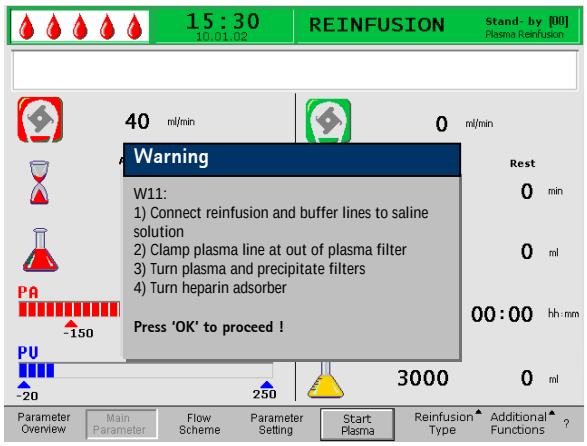

Plasma volume [Actual/Rest] in ml



Arterial pressure in mmHg

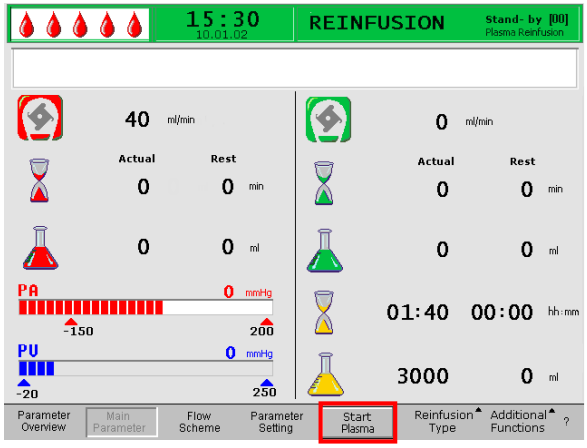
Venous pressure in mmHg

After the change to the reinfusion phase, the blood flow is not stopped but set automatically to 40 ml/min.
The default setting of the plasma reinfusion volume is 400 ml.




The next steps for preparing the reinfusion are summarized in the Warning window.

- Check that the double-chamber bag with the physiological saline solution is hanging on the IV-pole.
- Check whether the reinfusion line is connected to the 1500 ml compartment of the saline bag.
- Break the seal of the saline bag and open the clamps of the reinfusion line.
- Take the buffer bag from the load cell. Remove the buffer line from the buffer bag and connect the buffer line to the 1500 ml compartment of the saline bag.
- Open the break seal of the saline bag and open the clamp on the buffer line.
- Close the clamp on the plasma line directly after the plasma filter.
- Turn over the plasma filter, the precipitate filter and the heparin adsorber.
- After performing all steps, confirm with the OK key.



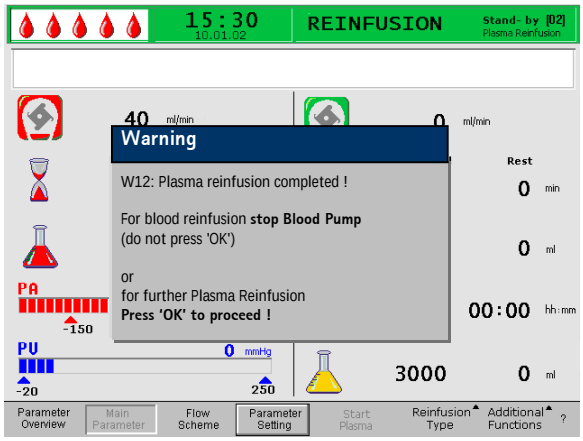

Start plasma reinfusion by selecting the <**Start Plasma**> menu item in the menu bar and pressing the key.

| | |
|---|---|
| ! | If the precipitate filter pressure rises during the plasma reinfusion because of the high filter saturation, the reinfusion flow should be reduced. |

CAUTION

**Risk to patient due to an excessively fast plasma reinfusion. Some patients experience flushing on the arm used for reinfusion and in the throat area, nausea and/or headaches.**

- **Reduce the plasma reinfusion flow to approx. 20 ml/min and increase the blood flow as much as possible (approx. 80 ml/min), so that flows similar to those during therapy are achieved.**




When the reinfusion volume is reached, all pumps except the blood pump stop. The blood flow is maintained. The default setting of the plasma reinfusion volume is 400 ml.

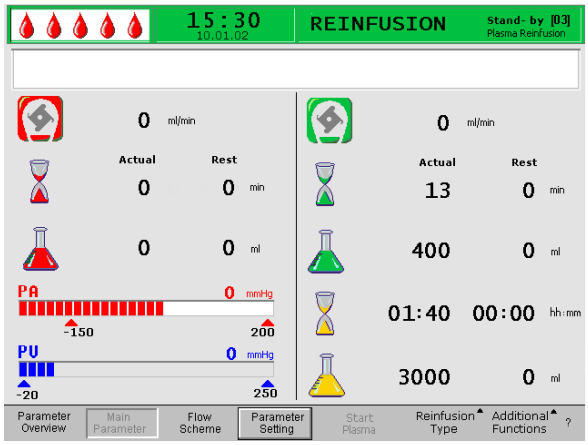
The Warning window on the display explains the next procedure choices:

- Stop blood pump to pass to blood reinfusion

OR

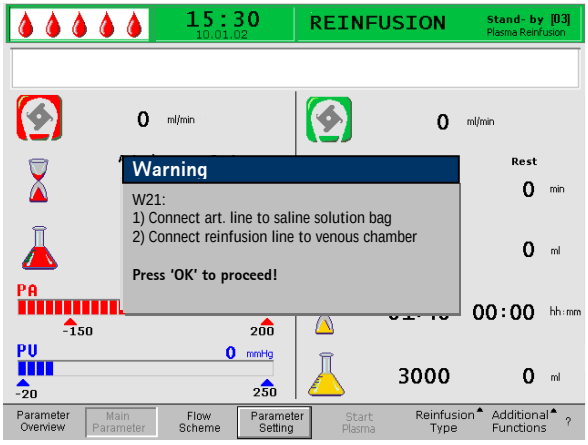
- PRESS the OK key to continue plasma reinfusion.

## 6.2 BLOOD REINFUSION




- Stop the blood pump with the Start Stop key.

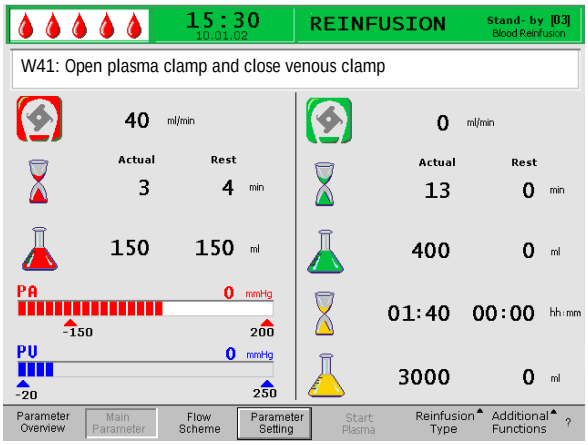
As long as the blood pump is running, the blood reinfusion will not start !




The next steps are summarized in a Warning window.

- Remove the arterial line from the patient's arterial access and connect the line to the 500 ml compartment of the saline bag on the IV-pole.
- Close the clamp of the reinfusion line.
- Take the reinfusion line from the saline bag and screw it to the port of the venous chamber.
- Open the clamps of the reinfusion line and the port.
- Confirm the Warning window with the OK key.
- Start the blood pump with the Start Stop key

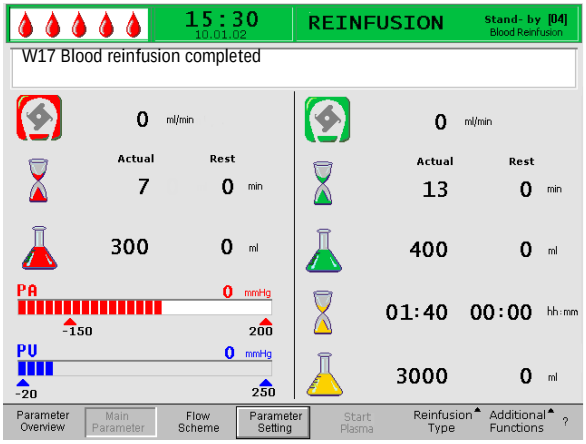
The default setting of the blood reinfusion volume is 300 ml.




When a blood reinfusion volume of 150 ml has been reached warning W41 appears:

- open the clamp of the plasma line after the plasma filter.
- close the clamp on the venous line to the venous chamber.

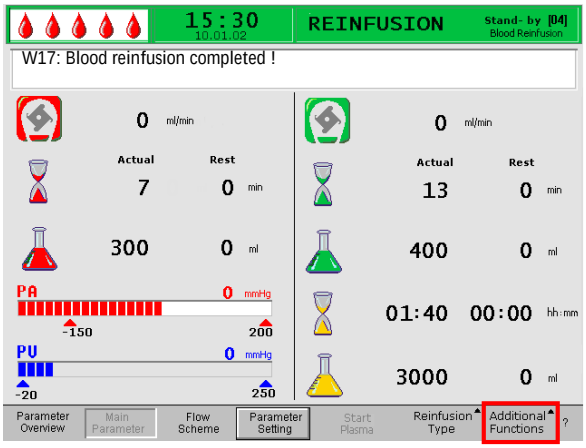
The saline solution is now pumped through the membrane of the plasma filter to the plasma side of the filter. In this manner, the plasma from the plasma filter is also reinfused.



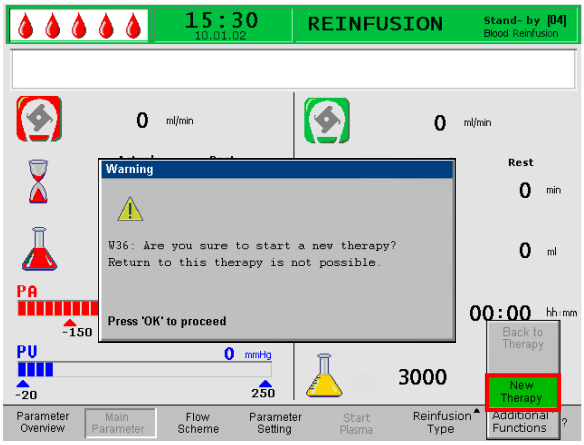

The blood pump stops automatically when the set blood reinfusion volume is reached.

- Remove the venous line from the patient's venous access. For the patient, the treatment is now completed.

## 6.3 TERMINATING THE TREATMENT



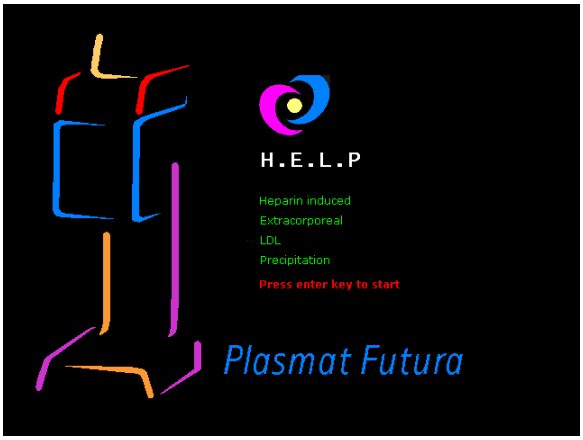

- Make a note of all necessary treatment data of the patient.
- Select the <**Additional Functions**> menu item in the menu bar and open the submenu by pressing the ↵ key.




- Select the <**New Therapy**> menu item.
- Confirm the selection by pressing the OK key.
- Confirm the message in the Warning window <**W36: Are you sure to start a new therapy ? Return to this therapy is not possible**> with the OK key to return to the Start screen.

| | |
|---|---|
| ! | Please note that all data of the treatment just performed are deleted when you quit the reinfusion phase by pressing the OK key. |

- Remove all disposable material from the machine and dispose of it accordingly.

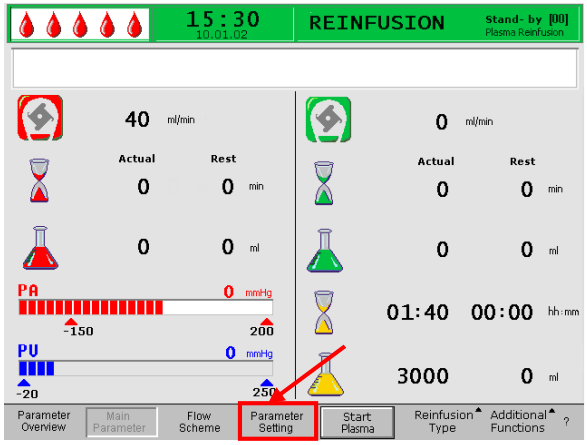



The display returns to the Start screen and you can now:

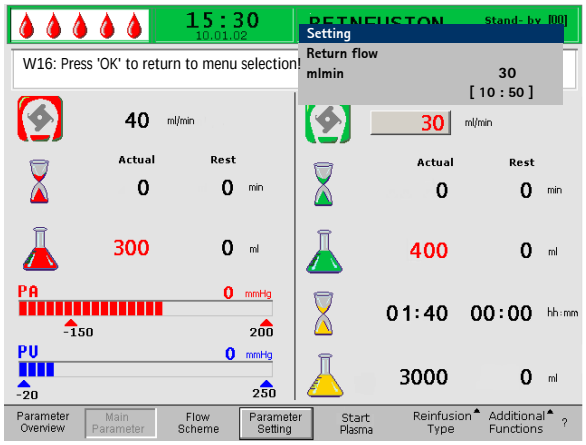
- Prepare the machine for another treatment.
- Switch off the machine.

## 6.4 PARAMETER SETTING

### 6.4.1 Parameter Setting in the <Main Parameter> Screen




To set the parameters, select the <**Parameter Setting**> menu item with the cursor in the <**Main Parameter**> screen and activate it with the ↵ key.



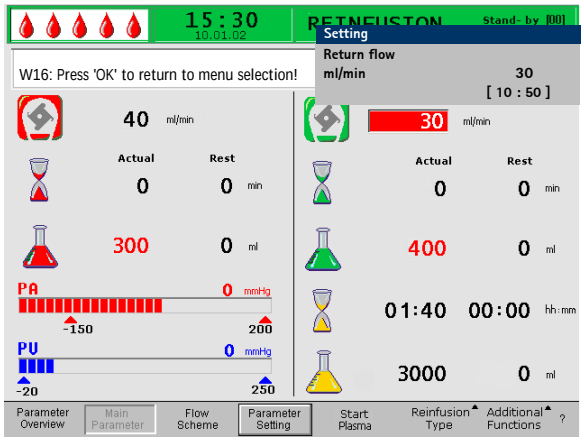

All parameters which can be changed are displayed in red. The currently selected parameter has a gray background. The Setting window displays the allowable range. Using the rotary knob, select the individual parameters.

The following parameters can be set in the reinfusion phase:

**Reinfusion flow**
Default setting: 30 ml/min
Range: 10 ÷ 50 ml/min
Step size: 5 ml/min

**Plasma reinfusion volume**
Default setting: 400 ml
Range: 400 ÷ 1000 ml
Step size: 50 ml

**Blood reinfusion volume**
Default setting: 300 ml
Range: 100 ÷ 600 ml
Step size: 50 ml




Press the ↵ key to select the parameter to be changed. The field is shown with a red background and white labeling. Perform the desired change using the rotary knob and confirm it with the ↵ key.
The changing of the following parameters must be confirmed with the OK key since they are relevant to patient safety:

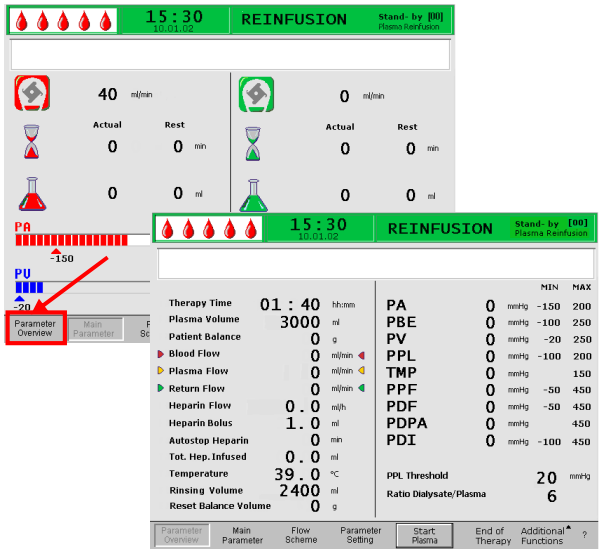
- Reinfusion flow
- Blood reinfusion volume

Which parameters are relevant to patient safety can be seen in the Setting window. The currently set value is shown above the setting area. In addition, the LEDs above the OK key blink.

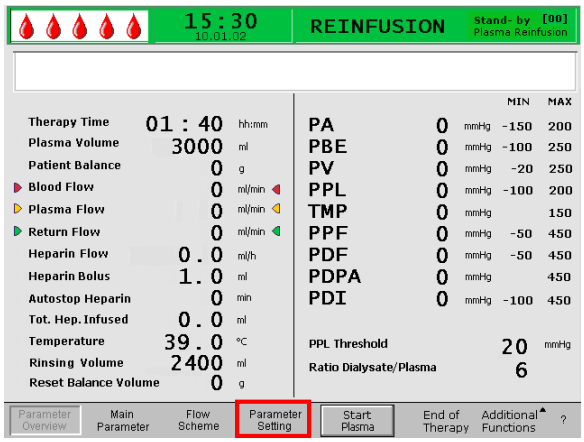
To quit the screen for setting the parameters, press the OK key. The cursor changes back to menu item **<Start Plasma>** of the menu bar of the Parameter Overview screen.

If no settings are changed for more than 15 seconds, the screen automatically changes back to the previously set screen.

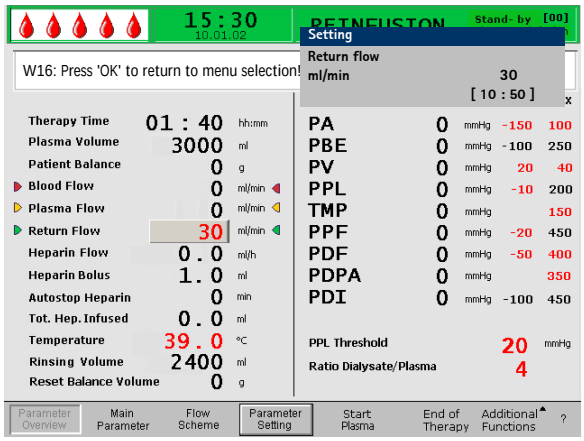
### 6.4.2 Parameter Setting in the <Parameter Overview> Screen




Using the rotary knob and the ↵ key, change to the **<Parameter Overview>** screen.



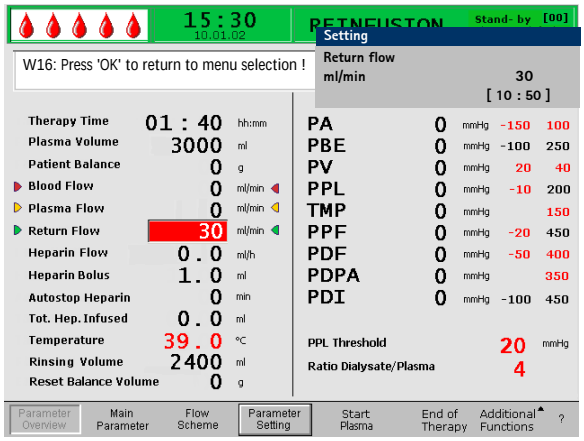

To set the parameters, select the <**Parameter Setting**> menu item with the cursor in the <**Parameter Overview**> screen and activate it with the  key.




All parameters which can be changed are displayed in red. The currently selected parameter has a gray background. The Setting window displays the allowable range. Using the rotary knob, you can select the individual parameters.

The following parameters can be set in the reinfusion phase:

- Reinfusion flow (ml/min)
- Temperature (°C)
- PA min (mmHg)
- PA max (mmHg)
- PV MIN window (mmHg)
- PV MAX window (mmHg)
- PPL min (mmHg)
- TMP max (mmHg)
- PPF min (mmHg)
- PDF min (mmHg)
- PDF max (mmHg)
- PDPA max (mmHg)
- PPL Threshold (mmHg)
- Ratio Dialysate/Plasma



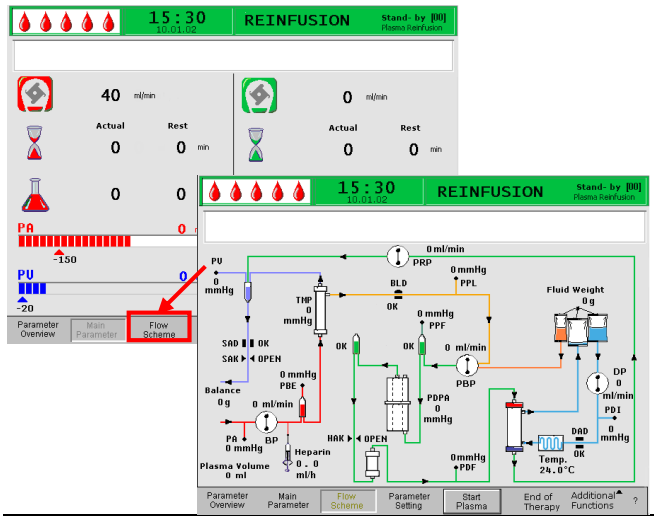

Press the ↵ key to select the parameter to be changed. The field is shown with a red background and white labeling. Perform the desired change using the rotary knob and confirm it with the ↵ key.
The changing of the following parameter must be confirmed with the OK key since it is relevant to patient safety:

- Reinfusion flow in ml/min
- PA min in mmHg
- PA max in mmHg
- PV MIN window (mmHg)
- PV MAX window (mmHg)
- Ratio Dialysate/Plasma

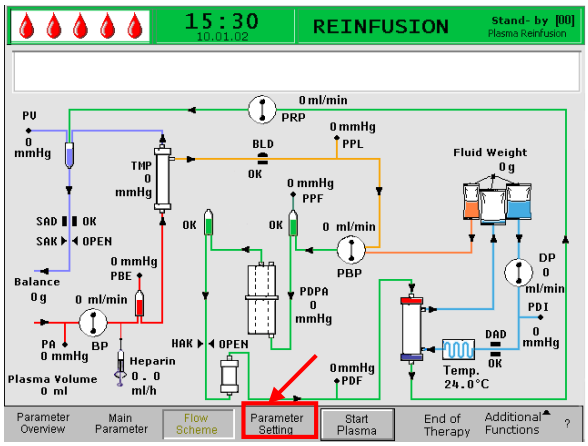
Plasma and blood reinfusion volume can be set only in the <**Main Parameter**> screen.
Parameters relevant to patient safety can be seen in the Setting window. The currently set value is shown above the setting area. In addition, the LEDs above the OK key blink.

To quit the screen for setting the parameters, press the OK key. The cursor changes back to the menu item <**Start Plasma**> of the menu bar of the Parameter Overview screen.
If no settings are changed for more than 15 seconds, the screen automatically changes back to the previously set screen.

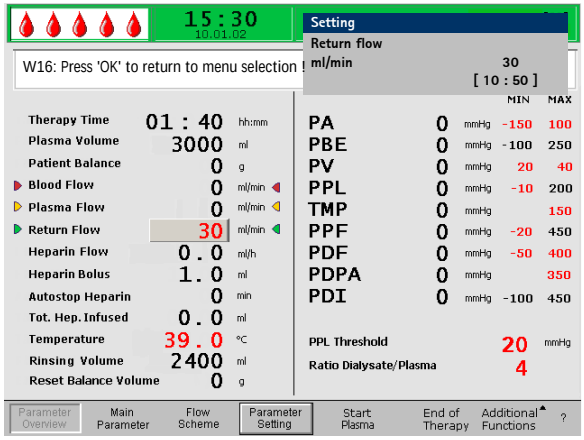
### 6.4.3 Parameter Setting in the <Flow Scheme> Screen




Using the rotary knob and the ↵ key, change to the <**Flow Scheme**> screen.

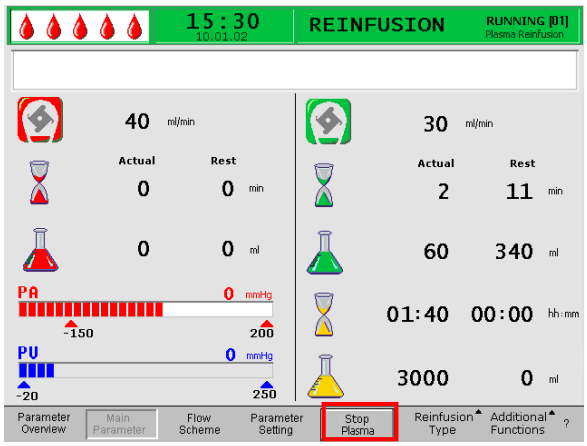



To set the parameters, select the <**Parameter Setting**> menu item with the cursor in the <**Flow Scheme**> screen and activate it with the  key.

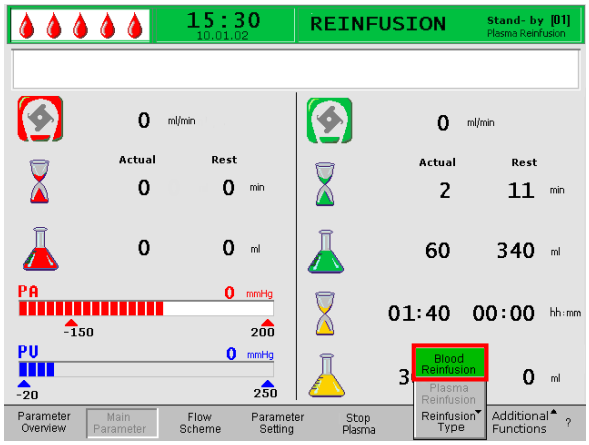



The screen changes to the Setting screen of the Parameter Overview and you can perform here all settings as described in chapter 6.4.2.

### 6.4.4 Additional Functions



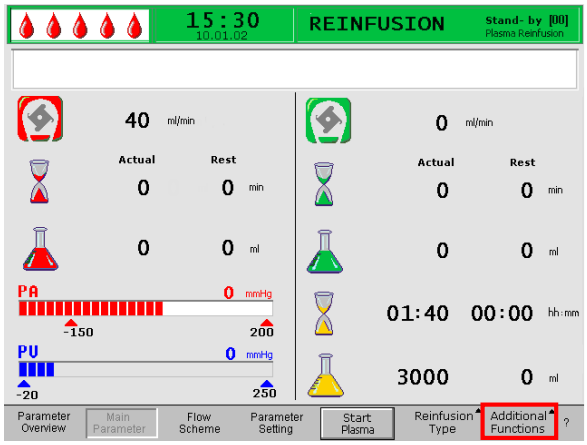

At any time during Plasma Reinfusion, you can prematurely terminate the Plasma Reinfusion by selecting <**Stop Plasma**> in the menu bar and activating it with the ↵ key.



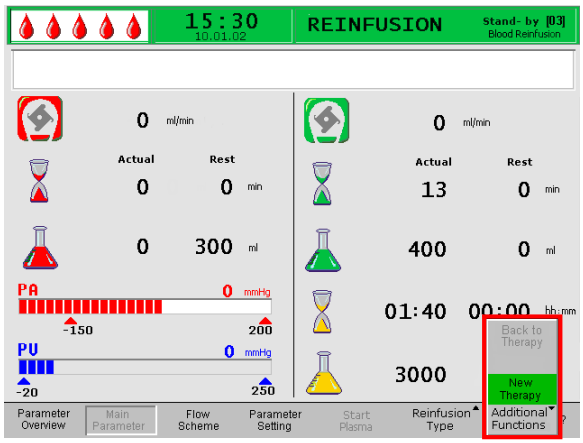

To move on to Blood Reinfusion, stop the blood pump with the Start Stop key. Select the <**Reinfusion Type**> menu item and press the ↵ key. The respective submenu is opened. Select the <**Blood Reinfusion**> menu item in this submenu and confirm it with the ↵ key.

The sub menu <**Blood Reinfusion**> is active only if the blood pump is stopped.

After selection of <**Blood Reinfusion** a Warning Window appears:
**<W21: 1) Connect art. line to saline solution bag 2) Connect reinfusion line to venous chamber>**
which must be confirmed with the OK key.
The next procedure is described in section 6.2 Blood Reinfusion.



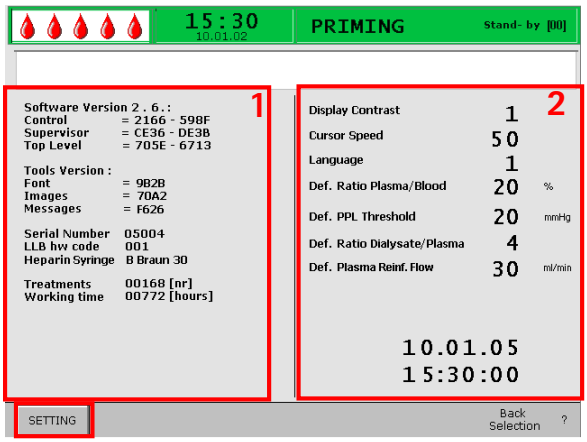

Under the <**Additional Functions**> menu item you can select more functions.



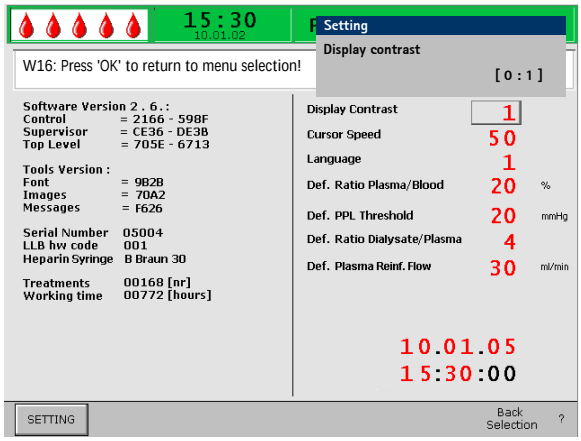

- The <**New Therapy**> menu item is active only during blood reinfusion. It allows for complete termination of the treatment and a return to the Start screen (see chapter 6.3).
- The <**Back to Therapy**> menu item is active only during plasma reinfusion and allows return to therapy.

# 7. BASIC AND DEFAULT SETTINGS

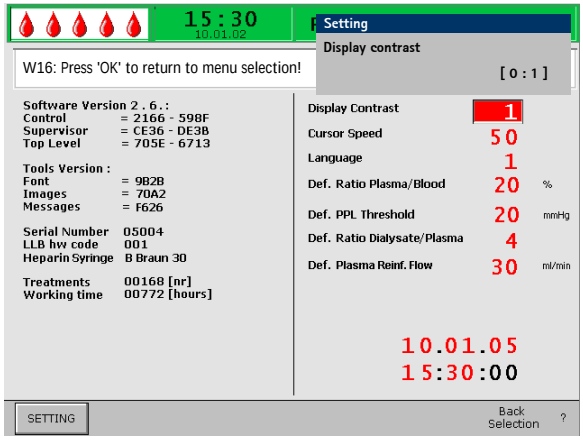
## 7. BASIC AND DEFAULT SETTINGS




By simultaneously pressing the OK key and the key you can go to the Service screen from any screen after the self-test.
Technical information is displayed on the left side of the screen **(1)**.
The parameters set by default are displayed on the right side of the screen **(2)**.
To change the parameters, select the <**SETTING**> menu item and confirm by pressing the key.




All parameters that can be changed are displayed in red. The currently selected parameter has a gray background. The Setting window displays the allowable range. Using the rotary knob, select the individual parameters.




Press the key to activate the parameter to be changed. The field is shown with a red background and white labeling. Perform the desired change using the rotary knob and confirm it with the key.

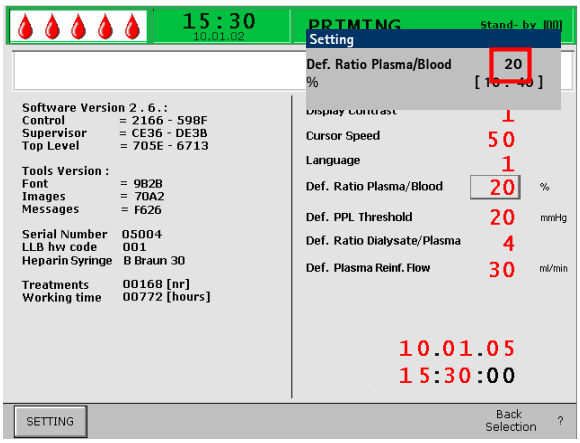
The following parameters can be changed in the Service screen:

- **Display contrast**
  Two settings are available to adjust the display contrast:
  0 = dark, 1 = bright
- **Cursor speed**
  The speed with which the cursor moves over the screen can be adjusted in steps of 10 in the range from 50 (fast) to 200 (fast).
- **Language**
  Italian (0), English (1) and German (2) can be selected for screen display.

- **Def. Ratio Plasma/Blood**
  This parameter sets the percentage share of plasma flow to blood flow during the separation of plasma. The setting is performed in steps of 1% in the range from 10% to 40%. The default setting is 20 %.
  The plasma/blood ratio is relevant to patient safety, therefore confirmation of its change is required.
- **Def. PPL Threshold**
  This parameter sets the limiting value for the automatic plasma flow adaptation during therapy. The setting is performed in steps of 5 mmHg in the range from -20 to 120 mmHg. The default setting is 20 mmHg.
- **Def. Ratio Dialysate/Plasma:**
  This parameter sets the ratio of the dialysate flow in relationship to the plasma flow during the therapy and reinfusion. The setting is performed in steps of 1 in the range from 4 to 12. The default setting is 4.
  The ratio of dialysate/plasma is a parameter relevant to patient safety, therefore confirmation of its change is required.
- **Def. Plasma Reinfusion Flow**
  This parameter sets the Plasma Reinfusion Flow default value on the Default screen: in the range of 10-50 ml/min (First default: 30 ml/min). In every therapy the Reinfusion Flow is set to this default value after a new therapy selection.
- **Date**
  Date, month and year are set successively.
- **Time**
  Hours and minutes are set successively.

The modification of the following parameters must be confirmed with the OK key since they are relevant to patient safety:

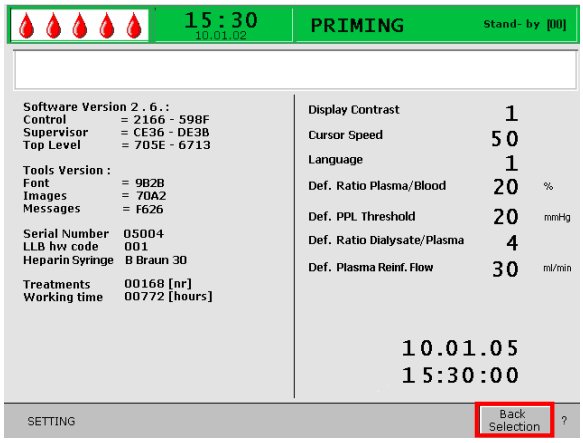
- Def. Ratio Plasma/Blood
- Def. Ratio Dialysate/Plasma.




If a parameter is relevant to patient safety, the currently set value is shown in the Setting window above the setting range. In addition, the LEDs above the OK key blink.

To quit the screen for setting the parameters, press the OK key. The cursor changes back to the menu bar of the Service screen.

If no settings are changed for more than 15 seconds, the screen automatically reverts back to the previously set screen.

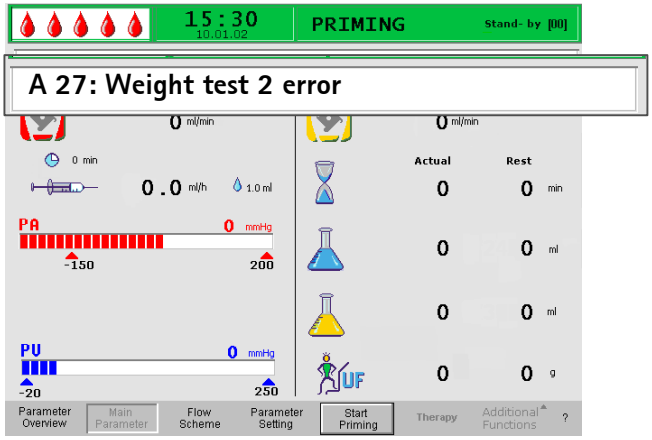



In the menu bar, select <**Back Selection**>, confirm this input with the key and return to the Start screen.

# 8. ALARMS AND PROBLEM CORRECTION

## 8. 1 ALARMS

### 8.1.1 Alarm Concept




An alarm situation always requires special attention and immediate processing by the user.

Alarms are displayed in the alarm/note line and accompanied by an acoustic alarm tone.


Alarm key with LEDs

An active alarm is also indicated by the red LEDs lighting above the key.

When an alarm occurs, the screen display automatically changes to the flow scheme showing the position (e.g. blinking number for pressure alarms) affected by the alarm. After correction of the alarm, the display automatically changes back to the initial screen. If the same alarm occurs again within 30 s, the initial screen display is maintained.

An alarm is normally corrected in two steps:

- Suppression of the alarm tone by pressing the key once.
- Elimination of the cause of the alarm and subsequent acknowledgment of the alarm by pressing the key again.

| | |
|---|---|
| ! | Alarms which are caused by open pump covers (A 59, A 60, A 61, A 62) are self-regulating alarms. These alarms are corrected by closing the respective pump cover. |

### 8.1.2 List of Alarms

| | |
|---|---|
| ! | If an alarm cannot be corrected with the measures described, if it occurs frequently and you cannot determine its cause or if a machine defect exists, please inform technical service. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| **A 01** | Supervisor system not working properly | Hardware problem | • Acknowledge the alarm (twice). If the alarm is repeated switch the machine off and on again to eliminate a possible transient failure.<br>• If the problem cannot be solved, close the treatment immediately and inform technical service. |
| **A 02** | Deviation between controller and supervisor state | Hardware problem | • Acknowledge the alarm (twice). If it is not possible switch the machine off and on again.<br>• If the problem cannot be solved, restart the machine completely or close the treatment immediately.<br>• If the problem cannot be solved with a machine restart inform technical service. |
| **A 03** | Deviation of arterial pressure between controller and supervisor | Calibration or hardware problems | • Acknowledge the alarm (twice).<br>• If the problem cannot be solved, inform technical service. |
| **A 04** | Deviation of venous pressure between controller and supervisor | Calibration or hardware problems | • Acknowledge the alarm (twice).<br>• If the problem cannot be solved, inform technical service. |
| **A 05** | Deviation of weight fluid between controller and supervisor | Calibration or hardware problems | • Acknowledge the alarm (twice).<br>• If the problem cannot be solved, inform technical service. |
| **A 06** | Deviation of temperature between controller and supervisor | Calibration or hardware problems | • Acknowledge the alarm (twice).<br>• If the problem cannot be solved, inform technical service. |
| **A 07** | Blood leak detector (BLD) test failed | Hardware problem | • Acknowledge the alarm (twice). If the alarm is repeated switch the machine off and on again.<br>• If the problem cannot be solved, stop the treatment as soon as possible while visually inspecting for a possible blood leak in the plasma line.<br>• Inform technical service. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| A 08 | Safety air detector (SAD) test failed | Hardware problem | • Acknowledge the alarm (twice). If the alarm is repeated switch the machine off and on again.<br>• If the problem cannot be solved, stop the treatment immediately taking care to visually inspect for air bubbles in the venous return line.<br>• Then inform technical service. |
| A 09 | Weight system test failed | Hardware problem | • Acknowledge the alarm (twice). If the alarm is repeated switch the machine off and on again.<br>• If the problem cannot be solved, stop the therapy immediately then close the treatment with reinfusion.<br>• Inform technical service. |
| A 10 | User interface not communicating | Hardware problem | • Acknowledge the alarm (twice). If the alarm is repeated switch the machine off and on again to eliminate a possible transient failure.<br>• If the problem cannot be solved, stop the treatment immediately and inform technical service. |
| A 13 | Arterial pressure (PA) not zero | Consumables already or still mounted | • Remove all consumables from the machine. |
| A 14 | Prefilter pressure (PBE) not zero | Consumables already or still mounted | • Remove all consumables from the machine. |
| A 15 | Venous pressure (PV) not zero | Consumables already or still mounted | • Remove all consumables from the machine. |
| A 16 | Load cell not empty or load cell error | Consumables already or still mounted | • Remove all consumables from the machine. |
| A 17 | Line in SAD not empty or SAD error | Consumables already or still mounted | • Remove all consumables from the machine. |
| A 18 | Chamber in PCLD not empty or PCLD error | Consumables already or still mounted | • Remove all consumables from the machine. |
| A 19 | Chamber in HCLD not empty or HCLD error | Consumables already or still mounted | • Remove all consumables from the machine. |
| A 20 | Line in DAD not empty or DAD error | Consumables already or still mounted | • Remove all consumables from the machine. |
| A 21 | Power relay test failed | Defective hardware | • Switch the machine off and on again and restart the machine. |
| A 22 | Heater relay test failed | Defective hardware | • Switch the machine off and on again and restart the machine. |
| A 25 | Check correct insertion return line | In the priming and rinsing phase, a test is performed to determine whether the pump segment of the plasma/buffer pump is correctly inserted. This test failed. | • Ensure that:<br>▪ The pump segment is correctly inserted in the plasma/ buffer pump. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| **A 26** | Weight test 1 error - Is PCLD chamber full ? | It was determined with weight test 1 that the plasma/buffer pump does not deliver correctly.<br>• Malfunction of the plasma/buffer pump<br>• Malfunction of the load cell | • Ensure that:<br>▪ The seal on the saline bag is open.<br>▪ The clamp on the buffer line is open.<br>▪ The buffer line is not kinked or clamped.<br>▪ The plasma/buffer pump segment is not inserted crosswise and in the correct direction.<br>• After eliminating the the cause of the alarm and acknowledging the alarm, the test is automatically repeated. |
| **A 27** | Weight test 2 error | It was determined with the weight test 2 that the dialysate pump does not deliver correctly.<br>• Dialysate flow obstructed<br>• Malfunction of the load cell | • Ensure that:<br>▪ The seals of the dialysate bags are open.<br>▪ The clamps of the dialysate lines are open.<br>▪ The dialysate line is not kinked or clamped.<br>▪ The bags are hanging motionless on the load cell.<br>• After eliminating the the cause of the alarm and acknowledging the alarm, the test is automatically repeated. |
| **A 28** | DAD test failed | An error occurred during the DAD check.<br>• Malfunction of DAD | • Ensure that:<br>▪ The dialysate line is inserted in the air detector for the dialysate (DAD).<br>▪ The clamps on the dialysate line are open.<br>▪ The seals of the dialysate bags are open.<br>▪ The connections between the dialysate bags and the dialysate line are firmly seated.<br>• After eliminating the the cause of the alarm and acknowledging the alarm, the test is automatically repeated. |
| **A 29** | Pressure test failed | Pressure build-up and pressure holding test failed | • Ensure that:<br>▪ The PBE pressure transducer is screwed on correctly.<br>▪ The venous line was inserted in the safety air clamp (SAK).<br>▪ All lines were installed according to instruction.<br>▪ The venous pressure transducer (PV) is correctly screwed on. |
| **A 30** | Leak test failure / venous lead inserted in SAK ? | An error occurred during the check of the safety air clamp (SAK) and the line leakage test. | • Ensure that:<br>▪ The venous line is inserted in the safety air clamp (SAK).<br>▪ The connections between the lines and the filters are firmly seated.<br>▪ The venous pressure transducer (PV) is correctly screwed on.<br>• After eliminating the the cause of the alarm and acknowledging the alarm, the test is automatically repeated. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| A31 | Venous pressure test failed | An error occurred during the calibration of the venous pressure (PV) and the inlet pressure on the plasma filter (PBE). | • Ensure that:<br>▪ The pressure transducer for the PV is correctly screwed on.<br>▪ The pressure transducer for the PBE is correctly screwed on.<br>▪ The pump segment is inserted in the reinfusion pump.<br>• After eliminating the the cause of the alarm and acknowledging the alarm, the test is automatically repeated. |
| A 32 | Heater test failed | Malfunction of heater | • Inform technical service. |
| A 33 | HAK test failed, check insertion line? | Line not correctly inserted in HAK clamp | • Ensure that:<br>▪ The filtrate line is inserted correctly in the HAK clamp. |
| A 34 | 2 ml air infused | SAD has detected a total of > 2 ml air | • Ensure that:<br>▪ The lines have no leaks. When leaks are found, replace the respective line.<br>▪ All components have been connected firmly and properly.<br>▪ The venous chamber is sufficiently filled. If required, fill the venous chamber manually. |
| A 35 | Blood leak detector (BLD) calibration failed | Malfunction of blood leak detector | • Inform technical service. |
| A 36 | Blood leakage from plasma filter | The BLD detects a blood leak or larger air bubbles in the line | • Perform a visual inspection of the line after the plasma filter. Replace the plasma filter when a blood leak is found (see 8.3.4).<br>• If air bubbles are found, check the connections for firm seating and the lines for possible damage. |
| A 37 | Air in venous line, set PV to -50 mmHg and acknowledge alarm | Air found in venous line | • Clamp shut the venous line with the clamp between the plasma filter (venous outlet) and the venous chamber.<br>• Using the level adjustment button of the venous air chamber, adjust the PV to – 50 mmHg.<br>The safety air clamp (SAK) opens automatically and the air is removed from the venous line into the venous chamber.<br>• Open the clamp on the venous line.<br>• Acknowledge the alarm.<br>• Continue the treatment.<br>• Using the level adjustment button, manually adjust the level in the venous air chamber again. |
| A 38 | Minimum arterial pressure (PA) | Arterial pressure too low | • Ensure that:<br>▪ The arterial access is free and properly connected.<br>• If necessary, reduce the blood flow. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| **A 39** | Maximum arterial pressure (PA) | Arterial pressure too high | • Ensure that:<br>▪ The arterial access is free and properly connected.<br>• If necessary, increase the blood flow. |
| **A 40** | Minimum prefilter pressure (PBE) | Prefilter pressure too low | • Ensure that:<br>▪ The venous access is free and properly connected. |
| **A 41** | Maximum prefilter pressure (PBE) | Prefilter pressure too high | • Ensure that:<br>▪ The venous access is free and properly connected.<br>▪ The venous line is not kinked or clamped. |
| **A 42** | Minimum venous pressure (PV) | Venous pressure too low | • Ensure that:<br>▪ The arterial access is free and properly connected.<br>▪ The buffer line is not kinked or clamped. |
| **A 43** | Maximum venous pressure (PV) | Venous pressure too high | • Ensure that:<br>▪ The venous access is free and properly connected.<br>▪ The venous line is not kinked or clamped. |
| **A 44** | Minimum plasma pressure (PPL) | Plasma pressure too low, plasma flow too high | • Ensure that:<br>▪ The blood flow/plasma flow ratio is approximately 1:3.<br>▪ The plasma filter is unobstructed and functional. Replace the plasma filter if it is obstructed (see 8.3.4).<br>• If necessary, reduce the plasma flow. |
| **A 45** | Maximum plasma pressure (PPL) | Plasma pressure too high<br>Defective PPL pressure transducer<br>Defective pressure sensor | • Check the plasma line and replace it if you find a defect. |
| **A 46** | Low PPF. Check high chamber level, protector or buffer bag empty. | Precipitate filter pressure too low | • Ensure that:<br>▪ The clamp on the buffer line is open.<br>▪ The seal of the acetate buffer bag is open.<br>▪ The acetate buffer bag is not empty.<br>▪ The level in the PPF chamber is not high and especially the PPF protector is not wet. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| A 47 | Maximum precipitate filter pressure (PPF) | Precipitate filter pressure too high<br>Defective level detector | • Ensure that:<br>▪ The lines after the precipitate chamber are not kinked or clamped.<br>▪ The pump segment of the reinfusion pump is correctly inserted.<br>▪ The precipitate filter is not saturated. If the precipitate filter is saturated, a rise of the PDPA occurs in parallel. Replace the filter in this case (see 8.3.5).<br>▪ The heparin adsorber is permeable. If this is not the case, replace the heparin adsorber (see 8.3.6).<br>▪ The dialyzer is permeable. If this is not the case, replace the dialyzer (see 8.3.7).<br>• If necessary, reduce the plasma flow or the reinfusion flow. |
| A 48 | Minimum dialysis filter pressure (PDF) | Dialyzer pressure too low (< -50 mmHg)<br>Plasma flow too low | • Ensure that:<br>▪ There is no dialyzer leakage. If this is the case, replace the dialyzer (see 8.3.7).<br>• If necessary, increase the plasma flow. |
| A 49 | Maximum dialysis filter pressure (PDF) | Dialyzer pressure too high | • Ensure that:<br>▪ The lines after the dialyzer are not kinked or clamped.<br>▪ The pump segment is correctly inserted in the reinfusion pump.<br>▪ The dialysate drain line is not kinked or clamped.<br>▪ The clamps on the dialysate drain are open. |
| A 50 | Minimum dialysate inlet pressure (PDI) | Dialysate inlet pressure too low<br>Defective dialysate pump | • Ensure that:<br>▪ The clamps on the dialysate line are open.<br>▪ The seals of the dialysate bags are open. |
| A 51 | Maximum dialysate inlet pressure (PDI) | Dialysate inlet pressure too high | • Ensure that:<br>▪ The warming bag is inserted correctly and without kinks.<br>▪ The line between the dialyzer and the plate warmer is not kinked or clamped. |
| A 53 | Maximum transmembrane pressure (TMP) | Transmembrane pressure too high<br>Defective pressure sensors for PV, PPL or PBE | • Ensure that:<br>▪ The venous pressure (PV) is not too high.<br>▪ The plasma prefilter pressure (PBE) is not too high.<br>▪ The plasma filter is not clogged. If this is the case, replace the filter (see 8.3.4).<br>▪ The blood flow/plasma flow ratio is approximately 1:3.<br>▪ The pressure transducers for PV, PPL and PPE are correctly seated and are dry.<br>• If necessary, increase the blood flow.<br>• If necessary, reduce the blood flow. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| **A 54** | Maximum precipitate filter/adsorber pressure drop (PDPA) | Pressure drop between precipitate filter and adsorber too high | • Ensure that:<br>▪ The precipitate filter is not saturated. If this is the case, replace the filter (see 8.3.5).<br>▪ The lines between the precipitate filter and the adsorber are not kinked or clamped. |
| **A 55** | Low PPF chamber level. Check air bubbles in chamber and locking. | PPF chamber level sensor detects air | • Ensure that:<br>▪ The buffer line is not kinked or clamped.<br>▪ The seal of the acetate buffer bag is open.<br>▪ The acetate buffer bag is not empty.<br>▪ The PPF chamber is positioned and the level sensor is locked properly.<br>▪ No air bubble is attached to the inner chamber wall. |
| **A 56** | Air in heparin adsorber chamber | HCLD detects air<br>Defect of automatic level adjustment | • Check whether the precipitate filter is saturated. If this is the case, replace the filter (see 8.3.5). |
| **A 57** | Air in dialysate line | DAD detects air | • Ensure that:<br>▪ The dialysate bags are full.<br>▪ The clamps of the dialysate lines are open.<br>▪ The seals of the dialysate bags are open.<br>▪ The dialysate line is not damaged and the connections to the bags are tight. Replace the line if it is damaged. |
| **A 58** | Stop of blood pump too long ! | Blood pump stop > 120 s | • Start the blood pump to eliminate the alarm and to acknowledge the error. |
| **A 59** | Blood pump cover open | Blood pump cover open, magnetic sensor of pump defective | • Close the pump cover. |
| **A 60** | Plasma/ buffer pump cover open | Plasma/buffer pump cover open<br>Magnetic sensor of pump defective | • Close the pump cover. |
| **A 61** | Plasma return pump cover open | Reinfusion pump cover open<br>Magnetic sensor of pump defective | • Close the pump cover. |
| **A 62** | Dialysate pump cover open | Cover of dialysate pump open<br>Magnetic sensor of pump defective | • Close the pump cover. |
| **A 63** | Blood pump speed error | Wrong speed of blood pump<br>Defective blood pump | • Ensure that:<br>▪ The pump segment is correctly inserted in the blood pump. |
| **A 64** | Plasma/buffer pump speed error | Wrong speed of plasma/buffer pumps<br>Pump defective | • Ensure that:<br>▪ The pump segment is correctly inserted in the plasma/ buffer pump |
| **A 65** | Plasma return pump speed error | Wrong speed of reinfusion pump<br>Reinfusion pump defective | • Ensure that:<br>▪ The pump segment is correctly inserted in the reinfusion pump. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| A 66 | Dialysate pump speed error | Wrong speed of dialysate pump<br>Defective dialysate pump | • Ensure that:<br>▪ The pump segment is correctly inserted in the dialysate pump. |
| A 67 | Dialysate temperature out of limits | Dialysate too warm (> 41.5°C for > 10 s)<br>Defective heating element | • Close the cover of the plate warmer. |
| A 68 | Excessive weight change, check bags and lines ! | Weight variation between 50 and 200 g for more than 5 s or weight variation > 200 g | • Ensure that:<br>▪ The bags are hanging motionless on the load cell.<br>▪ The lines are hanging free and do not pull on the bags on the load cell.<br>▪ The bags do not move too much.<br>• This alarm is also activated if a bag has been removed from or added to the load cell. In this case, please correct the error. |
| A 69 | Balance error | Balance error > 200 g<br>Defect of plasma/buffer pump, of reinfusion pump or of load cell | • Ensure that:<br>▪ The seals of the saline bags and of the dialysate bags are open.<br>▪ The lines are not kinked or clamped.<br>▪ The clamps on the buffer line and on the dialysate line are open.<br>▪ The dialysate line is inserted into the support on the load cell.<br>▪ The pump segments are correctly inserted. |
| A 70 | Weight too high or load cell empty | Weight > 24500 g or weight < 50 g | • Reduce the weight on the load cell.<br>• Place the bags back to the load cell. |
| A 73 | High PPF chamber level | PPF chamber level is too high, PPF protector is wet.<br>No PPF pressure increase in case of closed HAK clamp. | • Ensure that:<br>▪ The PPF chamber level is not too high and PPF protector is not wet.<br>▪ The PPF protector is connected properly.<br>▪ The PPF chamber is positioned and the level sensor is locked properly.<br>▪ No air bubble is attached to the inner chamber wall. |
| A 74 | PPF protector is not connected | No pressure change on PPF. | • Ensure that:<br>▪ The PPF protector is connected properly. |

**!** Alarms marked with (S) (A 80 – A 104) are alarms which are generated by the supervisor. If these alarms are active, it is possible that the controller does not operate correctly. If an alarm cannot be corrected with the actions suggested below or if it occurs frequently, inform technical service.

| | | | |
|---|---|---|---|
| A 80 | (S) SAD clock error, switch off and on | It was not possible to synchronize the SAD status between the controller and the supervisor. | • Switch the machine off and on. |

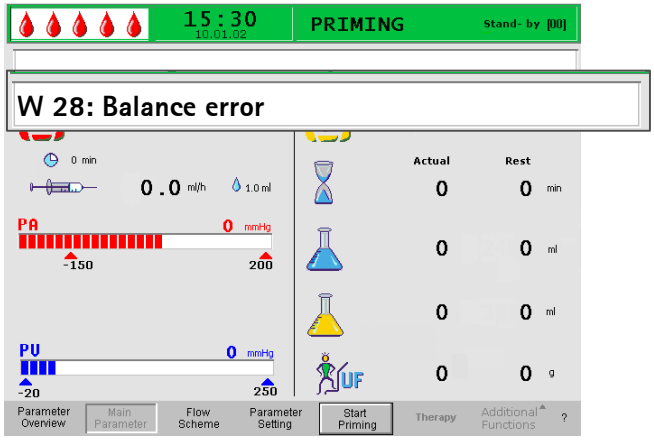
| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| **A 81** | (S) Blood pump speed error | Wrong speed of blood pump<br>Defective blood pump | • Ensure that:<br>▪ The pump segment is correctly inserted in the blood pump. |
| **A 82** | (S) Plasma/buffer pump speed error | Wrong speed of plasma/buffer pump<br>Defective plasma/buffer pump | • Ensure that:<br>▪ The pump segment is correctly inserted in the plasma/ buffer pump. |
| **A 83** | (S) Plasma return pump speed error | Wrong speed of reinfusion pump<br>Reinfusion pump defective | • Ensure that:<br>▪ The pump segment is correctly inserted in the reinfusion pump. |
| **A 84** | (S) Dialysate pump speed error | Wrong speed of dialysate pump<br>Defective dialysate pump | • Ensure that:<br>▪ The pump segment is correctly inserted in the dialysate pump. |
| **A 85** | Heparin pump problem. Check pump or syringe. | Syringe empty or<br>Current position of heparin pump wrong | • Ensure that:<br>▪ The syringe is not empty.<br>▪ The lock on the heparin pump support is closed.<br>▪ The guide of the heparin pump is no longer in the maximum upper position. |
| **A 86** | (S) Blood pump stop for too long ! | Blood pump stop<br>> 150 sec | • Start the blood pump to eliminate the alarm and to acknowledge the error. |
| **A 87** | (S) Dialysate temperature above maximum limit ! | Temperature of dialysate too high (> 42°C for > 20 s)<br>Defective heating element | • Inform technical service. |
| **A 88** | (S) Venous pressure (PV) out of limits | Venous pressure too high or too low | • Ensure that:<br>▪ The venous access is free and properly connected.<br>▪ The venous line is not kinked, clamped or damaged. |
| **A 89** | (S) Arterial pressure out of limits | Arterial pressure too high or too low | • Ensure that:<br>▪ The arterial access is free and properly connected.<br>▪ The arterial line is not kinked or clamped.<br>• If required, reduce the blood flow if the arterial pressure (PA) is too low.<br>• If required, increase the blood flow if the arterial pressure is too high. |
| **A 90** | (S) Safety air detector (SAD) test failed ! | Calibration or hardware problems | • Switch the machine off and on again. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| **A 91** | (S) Air in venous line | Air found in venous line | • Clamp the venous line with the clamp between the plasma filter (venous outlet) and the venous chamber.<br>• Connect a syringe to the venous chamber and manually suck out the air from the venous line.<br>• Open the clamp on the venous line.<br>• Acknowledge the alarm.<br>• Continue the treatment.<br>• Using the level adjustment button of the venous air chamber, readjust the level in the venous air chamber. |
| **A 92** | (S) 3 ml air infused | SAD has detected a total of > 3 ml air | • Ensure that:<br>▪ The lines have no leaks. When leaks are found, replace the respective line.<br>▪ All components have been connected firmly and properly.<br>▪ The venous chamber is sufficiently filled. If required, fill the venous chamber manually. |
| **A 93** | (S) Heparin pump test failed ! | Heparin pump slider in false position during the test | • The heparin pump slider may not be fully inserted. Place the heparin pump slider into a different position. |
| **A 94** | (S) SAD reference test error ! | Calibration or hardware problems | • Switch the machine off and on again. |
| **A 95** | (S) Line in SAD not empty or SAD error | Consumables already or still mounted | • Remove all consumables from the machine. |
| **A 96** | (S) Load cell not empty or load cell error | Consumables already or still mounted | • Remove all consumables from the machine. |
| **A 97** | (S) Venous pressure (PV) not zero ! | Consumables already or still mounted | • Remove all consumables from the machine. |
| **A 98** | (S) Arterial pressure (PA) not zero ! | Consumables already or still mounted | • Remove all consumables from the machine. |
| **A 99** | (S) Control system not working properly ! | Erroneous controller or user interface function | • Acknowledge the alarm (twice). If it is not possible switch the machine off and on again to eliminate a possible transient failure.<br>• If the problem cannot be solved, close the treatment immediately and inform technical service. |
| **A 100** | (S) SAD clock test failed. Switch off and on | Erroneous SAD clock function | • Switch the machine off and on.<br>• If alarm remains after power off, call service. |
| **A 103** | (S) Balance error | Balance error > 500 g<br>Defect of plasma/buffer pump, of reinfusion pump or of load cell | • Ensure that:<br>▪ The seals of the saline bags and of the dialysate bags are open.<br>▪ The lines are not kinked or clamped.<br>▪ The clamps on the buffer line and on the dialysate line are open.<br>▪ The dialysate line is inserted into the support on the load cell.<br>▪ The pump segments are correctly inserted. |

| Code | Alarm Text | Alarm Cause | Corrective Action |
|---|---|---|---|
| A 104 | (S) Plasma volume error | Count error of Plasma treated volume | • Ensure that:<br>▪ The plasma lines are not kinked or clamped.<br>▪ The pump segments are correctly inserted. |

## 8. 2 WARNINGS

### 8.2.1 Warning Concept

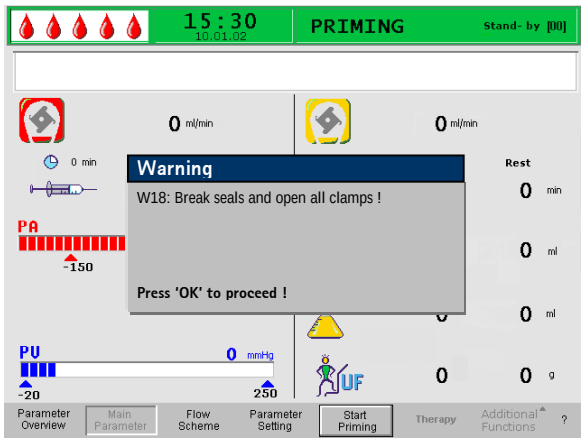



Warnings are given when:

- The user should perform a certain action.
- A certain state must be pointed out to the user.

Warnings are always accompanied by acoustic warning tones.

Warnings which serve to point out a situation are displayed in the **Alarm / Note field**.




Warnings requiring an action are displayed in a Warning window, they must be acknowledged with the OK key (<Press 'OK' to proceed>) to continue in the respective phase.


**OK key for acknowledging a warning**

This kind of warnings are also indicated by the yellow LEDs lighting above the OK key.

### 8.2.2 List of Warnings

**M = display in the Message box, T = display in the Alarm/Note line**

| Code | Warning Text | Reason for Warning | Corrective Action | |
|---|---|---|---|---|
| **W 01** | Plasma pump starts after pressurization blood side | Indication that the arterial line is filled and the filling phase is continuing. | | **T** |
| **W 03** | Press 'OK' to confirm safety data | Safety query when parameters with safety relevance have been changed | • The changed parameters have safety relevance. Check the setting thoroughly and confirm with the OK key. | **M** |
| **W 04** | Turn dialyzer (blue side down) ! | In the filling phase, the next handling step is indicated. | • Turn over the dialyzer and confirm with the OK key | **M** |
| **W 05** | Therapy stop for too long ! | Therapy interrupted for more than 5 minutes | • Continue the therapy.<br>• Select the <**Start Therapy**> command and confirm with the ↵ key. | T |
| **W 06** | Therapy completed ! | The end of the therapy is indicated. | • Press the OK key to change to the reinfusion phase. | **M** |
| **W 08** | Reinfusion stop for too long ! | Reinfusion interrupted for more than 5 minutes | • Continue the reinfusion.<br>• Select the <**Start Reinfusion**> command and confirm with the ↵ key. | **T** |
| **W 09** | Check lines and bags ! | Deviation of total weight on the load cell in bypass | • Check the bags and lines and perform the necessary corrections.<br>• Press the OK key to continue. | **M** |
| **W 10** | Plasma vol. > 3 l.<br>Change buffer bag and check dialysate bags | Solution volume not sufficient for continuation of the treatment. | • Remove the buffer bag and hang on a new one.<br>• If necessary, remove the full drain bags and hang on new dialysate bags.<br>• Press the OK key to continue.<br>• For changing the solution bags, see chapter 8.3.3. | **M** |
| **W 11** | 1) Connect reinfusion and buffer lines to saline solution<br>2) Clamp plasma line at out of plasma filter<br>3) Turn plasma and precipitate filters<br>4) Turn heparin adsorber | Information for preparing the plasma reinfusion | • Follow the instructions on the monitor and then press the OK key to continue. | **M** |

| Code | Warning Text | Reason for Warning | Corrective Action | |
|---|---|---|---|---|
| W 12 | Plasma reinfusion completed !<br>For Blood Reinfusion Stop Blood Pump<br>(do not press 'OK')<br>or<br>for further Plasma Reinfusion<br>Press 'OK' to proceed ! | Plasma reinfusion completed, information concerning the preparation for blood reinfusion | • Follow the instructions on the monitor to change to the blood reinfusion or press the OK key to continue plasma reinfusion. | M |
| W 14 | Compulsory rinsing completed. Set new value to continue rinsing. | The minimum rinsing volume of 2400 ml has been reached. | • Confirm the warning with the OK key.<br>• Change to the therapy mode when you consider the rinsing volume to be sufficient.<br>• Increase the rinsing volume (see chapter 4) and therefore extend the rinsing phase, if required (e.g. when replacing a filter during the rinsing phase). | M |
| W 15 | Connect buffer – seal and clamp opened ? | Confirmation before the start of the therapy. | • Check the positions given on the monitor and confirm with the OK key to continue. | M |
| W 16 | Press 'OK' to return to menu selection ! | Information for quitting the screen when adjusting the parameters | • Press the OK key to return from <**Parameter Setting**> to the menu bar. | T |
| W 17 | Blood reinfusion completed ! | Information that blood reinfusion is completed. | • Remove the venous line from the patient and terminate the treatment.<br>• Increase the blood reinfusion volume (see chapter 6) and continue reinfusion if you consider it necessary. | T |
| W 18 | Break seals and open all clamps ! | Confirmation at the start of priming and rinsing | • Follow the instructions on the monitor and confirm with the OK key to continue. | M |
| W 19 | Press 'OK' to exclude BLD alarms ! | Is offered as an option after three BLD alarms | • Press the OK key to override the BLD alarm. | M |
| W 20 | BLD alarms excluded ! | Information when the BLD alarm has been overridden by accepting the W19 option. | | T |
| W 21 | 1) Connect art. line to saline solution bag<br>2) Connect reinfusion line to venous chamber | Confirmation before the blood reinfusion. | • Check the positions given on the monitor and confirm with the OK key to continue. | M |

| Code | Warning Text | Reason for Warning | Corrective Action | |
|---|---|---|---|---|
| **W 22** | Arterial pressure (PA) does not change by blood flow | The machine does not register a change of the PA while the blood pump is running. | • Ensure that:<br>▪ The arterial pressure transducer (PA) is correctly connected and dry.<br>• If the error cannot be corrected, the pressure transducer or the pressure sensor is defective. | **T** |
| **W 23** | Low dialysate inlet pressure (PDI) | Information when the inlet pressure of the dialysate is too low. | • Ensure that:<br>▪ The clamps on the dialysate line are open.<br>• Increase the plasma flow. | **T** |
| **W 24** | Balance error > 300 g<br>Check lines and bags ! | Balancing error of more than 300 g | • Ensure that:<br>▪ Bags and lines are hanging free.<br>▪ There is no leakage on bags and lines.<br>▪ The bags are hanging motionless. | **M** |
| **W 25** | Balance error > 400 g<br>Check lines and bags !<br>**END OF THERAPY IS RECOMMENDED** | Balancing error of more than 400 g | • Ensure that:<br>▪ Bags and lines are hanging free.<br>▪ There is no leakage on bags and lines.<br>▪ The bags are hanging motionless.<br>• If none of the errors listed above exists, stop the therapy or perform a balance reset (see 8.3.1). | **M** |

CAUTION

**Risk to patient due to impact on the patient's fluid balance.**

➢ **Perform the balance reset only when you are sure that the balancing error does not concern the patient!**

| | | | | |
|---|---|---|---|---|
| **W 26** | Reinfusion volume wrong | The weight variation on load cell differs of \|150g\| from reinfused plasma in plasma reinfusion. | • Ensure that:<br>▪ Buffer line is connected to the saline solution.<br>▪ Bags and lines are hanging free. | **T** |
| **W 28** | Balance error | Balancing error of > 200 g | • Ensure that:<br>▪ Bags and lines are hanging free.<br>▪ There is no leakage on bags and lines.<br>▪ The bags are hanging motionless. | **T** |
| **W 29** | Are you sure to reset patient balance? | Safety query during balance reset | • Confirm with the OK key when you are sure that you wish to perform the balance reset. | **M** |
| **W 30** | Control system not communicating | Controller problem | • Switch the machine off and on again. If the problem cannot be solved, inform technical service. | **T** |
| **W 31** | Supervisor system not communicating | Supervisor problem | • Switch the machine off and on again. If the problem cannot be solved, inform technical service. | **T** |
| **W 32** | Activate therapy mode ? | Prompt for changing to therapy mode | • Confirm with the OK key. | **M** |

| Code | Warning Text | Reason for Warning | Corrective Action | |
|---|---|---|---|---|
| **W 33** | Heparin bolus ... ml. | Safety query before administering the set heparin bolus | • Press the OK key to administer the heparin bolus.<br>• If you do not wish to administer the heparin bolus, wait 5 s for the Warning window to disappear. | **M** |
| **W 35** | Activate reinfusion ? | Prompt for changing to reinfusion mode | • Press the OK key to change to the reinfusion phase. | **M** |
| **W 36** | Are you sure to start a new therapy?<br>Return to this therapy is not possible. | Information before returning to the Start screen. | • Press the OK key if you wish to return to the Start screen. | **M** |

! Note that the data of the currently performed therapy are deleted when you return to the Start screen.

| | | | | |
|---|---|---|---|---|
| **W 37** | Selftests completed, check characters and press ENTER | Confirmation of the successfully performed initial selftest | • Select 'END' softkey and press ↵. | **T** |
| **W 39** | Power fail eliminated !<br>Check lines, filters and parameter setting, restart ! | Information after a power failure | • Press the OK key after verification of the required positions to continue therapy. | **M** |
| **W 41** | Open plasma clamp and close venous clamp! | Confirmation in the middle of blood reinfusion (after 150 ml) | • Press the OK key after opening/closing the respective clamps to continue blood reinfusion. | **M** |
| **W 42** | Set Plasma Flow is too low. Increase Blood or Plasma Flow. | Information that the required Plasma Flow is too low (< 2 ml/min) | • Increase the Blood Flow or increase the Plasma Flow value. | **T** |
| **W 43** | Attention! Precipitate filter rupture possible!<br>Check PPF chamber level, PPF protector and connection<br>Or check air bubbles in chamber and chamber locking. | PPF chamber level is too high, PPF protector is wet. No PPF pressure increase in case of closed HAK clamp.<br>(This warning appears together with alarm A73) | • Ensure that:<br>▪ The PPF chamber level is not too high and PPF protector is not wet.<br>▪ The PPF protector is connected properly.<br>▪ The PPF chamber is positioned and the level sensor is locked properly.<br>▪ No air bubble is attached to the inner chamber wall.<br>• Then press the OK key after examination to continue therapy. | **M** |
| **W 44** | W44: Patient Balance too high or Plasma Flow too low. Please adjust. | The required Patient Balance cannot be reached in the remaining therapy time. Balance error might occur later during the course of the treatment. | • Reduce the Patient Balance value or increase the Plasma Volume value or increase Plasma Flow value. | **T** |

| Code | Warning Text | Reason for Warning | Corrective Action | |
|---|---|---|---|---|
| **W 45** | W45: Dialysate bags nearly empty. Change bags if necessary. | The dialysate bags are nearly empty since the ratio dialysate/plasma is > 1:4 and 15 l of dialysate were used.. | • Remove the full drain bags and the empty dialysate bags and replace them with empty drain bags and new dialysate bags, respectively. | **M** |

## 8. 3 PROBLEM CORRECTION

### 8.3.1 Balance Reset

**Balance error > 200 g**
For a balance error > 200 g, the alarm <**A69: Balance error!**> and the warning <**W28: Balance error**> are displayed. Check whether:

- The bags are hanging correctly on the load cell.
- All seals and clamps are open.
- All lines are free from kinks.

Acknowledge the alarm with the  and the 

keys after you have eliminated the cause of the error. The warning <**W28: Balance error**> is displayed until the balance error has been compensated.

**Balance error > 300 g**
If the balance error remains and exceeds a value of 300 g, the alarm <**A69: Balance error !**> is initiated and the warning <**W24: Balance error > 300 g, check lines and bags !**> displayed.
Check the system as described above. Acknowledge the alarm and the warning with the  and the 

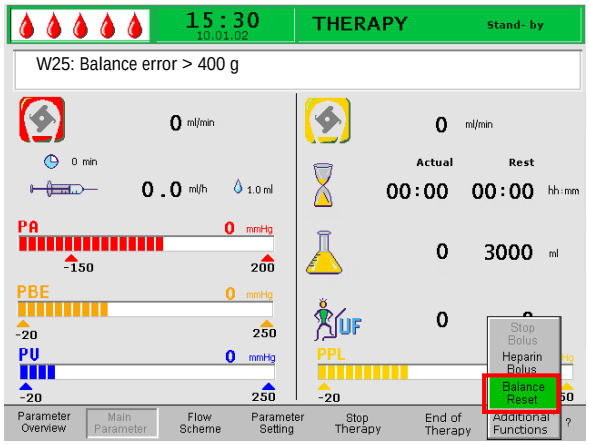
keys after you have eliminated the cause of the error. The warning <**W28: Balance error**> is displayed until the balance error has been compensated.

**Balance error > 400 g**
If it was not possible to correct the balance error with the measures described above and it exceeds a value of 400 g, the alarm <**A69: Balance error !**> is initiated again and the warning <**W25: Balance error > 400 g END OF THERAPY IS RECOMMENDED**> is displayed.
The end of therapy is recommended to exclude a balance error in the fluid balance of the patient. Terminate the therapy as described in chapter 6.

CAUTION

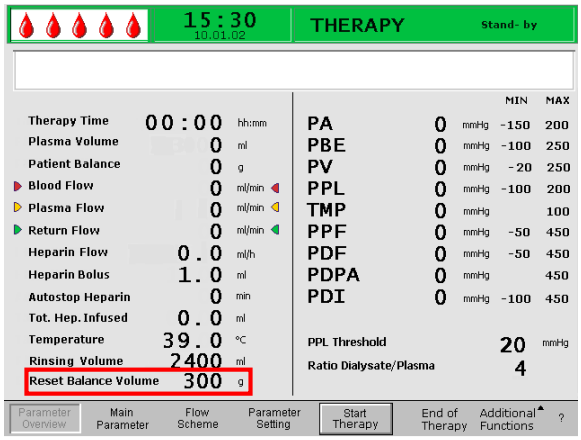
**Risk to patient due to impact on the patient's fluid balance.**

➢ **Perform the balance reset only when you are sure that the balancing error does not concern the patient!**




**Balance Reset**

Starting with a balance error > 200 g, the <**Balance Reset**> menu item under <**Additional Functions**> can be selected by turning the knob and pressing the key. Warning W29: <Are you sure to reset Patient Balance?> is displayed. Press OK to proceed.




During a balance reset, the load cell is newly tared. The data of the balance reset are saved and shown in the Parameter Overview. Every reset performed in the course of the therapy is saved and the values are summated.

### 8.3.2 Deaeration of the Heparin Adsorber

If the fluid level in the heparin adsorber drops during the therapy, it can refilled.

- During the treatment, remove the feed line to the heparin adsorber from the heparin adsorber clamp (HAK).
- Select the <**Stop Therapy**> function to go to the bypass mode (blood pump is turning, plasma-side pumps stand still).
- Place a clamp on the filtrate line behind the precipitate filter and on the line to the PDF pressure transducer.
- Turn over the heparin adsorber by 180°.
- Press the ▲ key of the manual level adjustment of the heparin adsorber air chamber to draw the air out of the heparin adsorber and the line.
- Turn over again the heparin adsorber by 180°.
- Remove the clamps on the filtrate line and on the line to the PDF pressure transducer.
- Rotate the dialysate pump by two revolutions by hand.
- Restart the therapy by selecting the <**Start Therapy**> function.
- Correctly reinsert the feed line to the heparin adsorber into the heparin adsorber clamp (HAK).

| | |
|---|---|
| ! | Perform the refilling of the heparin adsorber without severe intervention on the pressure parameters!<br>If necessary, repeat the operation. |

### 8.3.3 Changing the Solution Bags

**Change as a result of a defective bag**

- Select the <**Stop Therapy**> function to go to the bypass mode (blood pump is turning, plasma-side pumps stand still).
- Attach a clamp to the bag to be exchanged and close the clamp on the feed line.
- Exchange the defective bag for a new bag.
- Break the seal of the new bag.
- Open the clamp of the feed line again.
- Confirm the warning W09 <Check lines and bags> by pressing the OK key.
- Continue the treatment by selecting the <**Start Therapy**> function.

**Change at a treatment volume > 3000 ml**

At a treatment volume > 3010 ml, the Plasmat® Futura automatically switches to bypass. The warning <**W 10: Plasma vol. > 3 l. Change buffer bag and check dialysate bags**> is displayed. Remove the full drain bags and replace them.

- Attach a clamp to the feeding buffer line.
- Remove the empty acetate buffer bag and replace it by a new prepared acetate buffer bag.
- Open the seal of the new acetate buffer bag.
- Reopen the clamp on the buffer line again.
- Check also whether sufficient dialysate is available and replace dialysate bags if necessary.
- Confirm the change by pressing the OK key.
- Continue the therapy by selecting the <**Start Therapy**> function.

**Change of the dialysate bags if they are nearly empty**

If the ratio dialysate/plasma is > 1:4 and the dialysate bags are nearly empty, the Plasmat® Futura automatically switches to bypass. The warning <**W 45: Dialysate bags nearly empty. Change bags if necessary.**> is displayed.

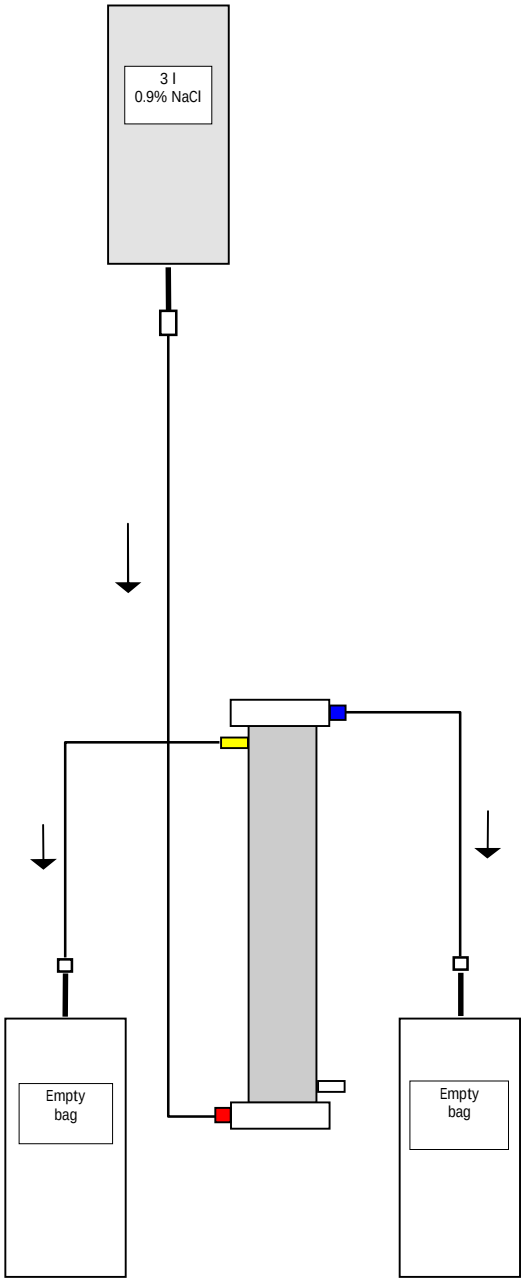
a) Exchange dialysate bags if more dialysate solution is required:
   - Attach a clamp to the feeding dialysate line.
   - Remove the empty dialysate bag and replace it by a newly prepared dialysate bag.
   - Open the seal of the new dialysate bag.
   - Reopen the clamp on the dialysate line again.

- Repeat for the other dialysate bags if necessary.
- Remove the full drain bags and replace them.
- Confirm the subsequent message box < **W 09: Check lines and bags !**> by pressing the OK key.

b) The remaining amount of dialysate is sufficient for termination of the treatment:

- Confirm by pressing the OK key.

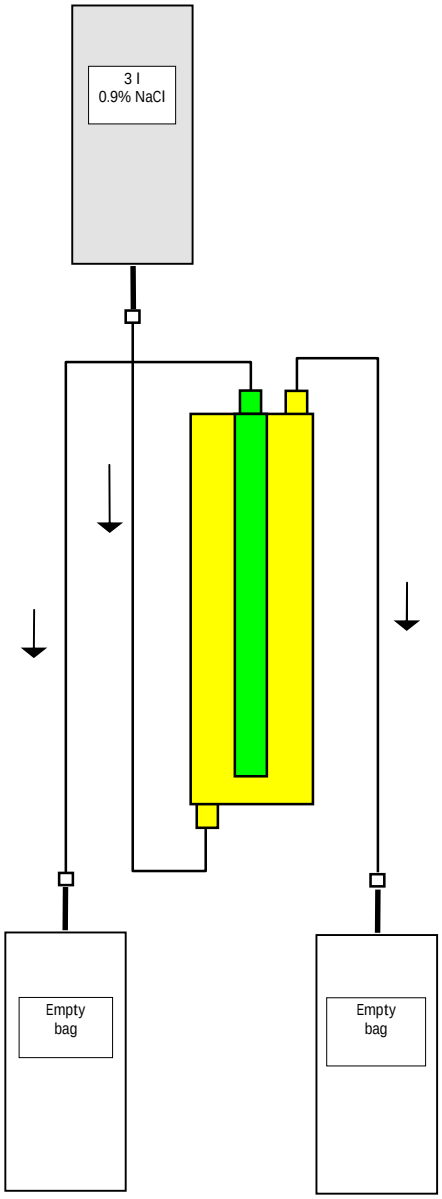
For the required number of dialysate bags please refer to chapter 9.3.8.




### 8.3.4 Changing the Plasma Filter

| Material | Article number |
|---|---|
| Haemoselect M 0.3 m² | 7210694 |
| 2 x collection bags | 7210543 |
| 3 l H.E.L.P. 0.9% NaCl solution | 34 |
| 3 connection lines | 7060130 |
| 3 anti-contamination caps | |
| 2 venting filters | |
| 7500 IU heparin | |

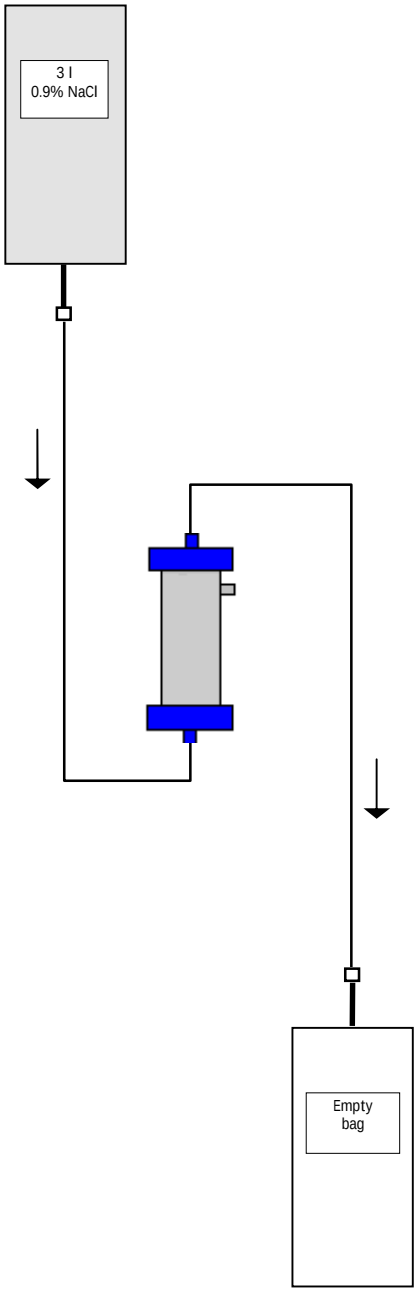
- Mix the H.E.L.P. 0.9% NaCl solution and 7500 IU heparin.
- Attach a connection line with the NaCl solution, fill the line and connect it with the blood-side filter inlet.
- Connect the remaining connection lines and the empty bags as shown in the Figure with the plasma and blood sides of the filter and clamp the line on the plasma side.
- Allow the rinse solution to flow by means of gravity into the blood-side empty bag.
- Hold the filter so that it is filled from the bottom to the top and thoroughly vented in the process.
- Open the plasma-side line when approximately half of the rinse solution has flown into the blood-side empty bag and clamp the blood-side line. Continue to rinse.
- Clamp shut all connection lines when the remaining rinse solution has flown through (be careful that no air enters the filter!) and remove the bags.
- Stop the blood pump, clamp shut the arterial and the venous plasma lines, remove the old filter and connect them with the new plasma filter in the correct orientation. Close the old filter with the anti-contamination caps.
- Reopen the blood and plasma lines and start the blood pump.




### 8.3.5 Changing the H.E.L.P. Precipitate Filter

| Material | Article number |
|---|---|
| H.E.L.P. precipitate filter | 706101A |
| 2 x collection bags | 7210543 |
| 3 l H.E.L.P. 0.9% NaCl solution | 34 |
| 3 connection lines | 7060130 |
| 3 anti-contamination caps | |

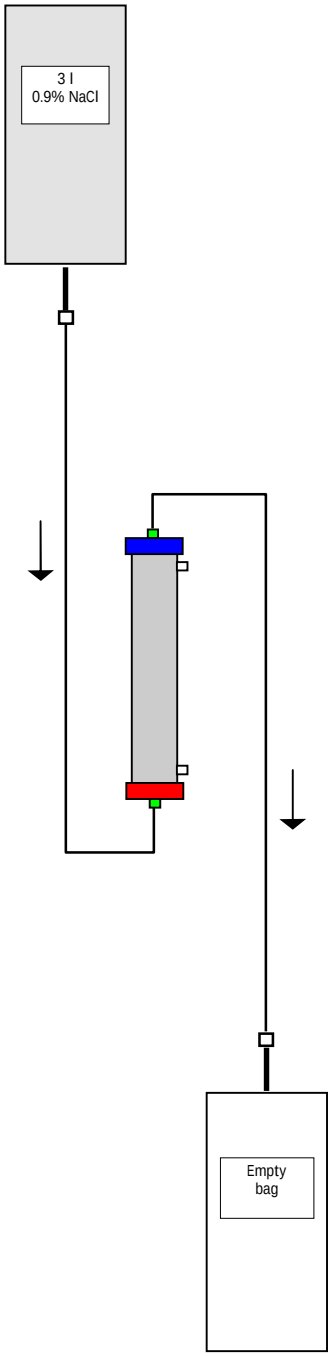
- Attach a connection line with the NaCl solution, fill the line and connect it with the bottom, precipitate-side filter opening.
- Connect the remaining connection lines and the empty bags as shown in the Figure with the upper precipitate and filtrate-side opening of the filter and clamp shut the line on the filtrate side.
- Allow the rinse solution to flow by means of gravity into the precipitate-side collection bag.
- Hold the filter so that it is filled from the bottom to the top and thoroughly vented in the process.
- Open the filtrate-side line when approximately half of the rinse solution has flown into the precipitate-side empty bag and clamp shut the precipitate-side line. Continue to rinse.
- Clamp shut all connection lines when the remaining rinse solution has flown through (be careful that no air enters the filter!) and remove all bags.
- Switch the machine to bypass mode by selecting <**Stop Priming**> or <**Stop Therapy**> in the menu bar and confirm with the  key.
- Clamp shut the filtrate line and the circulation line on both sides of the old precipitate filter, remove the old filter and then connect the new filter in the correct orientation with the lines. Close the old filter with the anti-contamination caps.
- Reopen the circulation and filtrate lines and continue the interrupted phase by selecting <**Start Priming**> or <**Start Therapy**> and confirm with the  key.
- Retain the exchanged filter until the end of the therapy, providing it has no leak. Connect it again in the reinfusion phase and then return the plasma. Increase the reinfusion volume accordingly.




### 8.3.6 Changing the H.E.L.P. Heparin Adsorber

| Material | Article number |
|---|---|
| H.E.L.P. heparin adsorber | 7210688 |
| 1 x collection bags | 7210543 |
| 3 l H.E.L.P. 0.9% NaCl solution | 34 |
| 2 connection lines | 7060130 |

- Attach a connection line with the NaCl solution, fill the line and connect it to the inlet side of the heparin adsorber.
- Attach the second connection line and the collection bag as shown in the Figure to the outlet side of the heparin adsorber.
- Allow the rinse solution to flow by means of gravity into the empty bag.
- Hold the adsorber so that it is filled from the bottom to the top and thoroughly vented in the process.
- Clamp shut all connection lines when the remaining rinse solution has flown through (be careful that no air enters the adsorber!).
- Switch the machine to bypass mode by selecting **<Stop Priming>** or **<Stop Therapy>** in the menu bar and confirm with the key.
- Clamp shut the filtrate and the connection line on the adsorber, remove the old adsorber and connect the new adsorber in the correct orientation with the filtrate and the connection line (Observe the flow direction!). Connect the old adsorber with the connection lines on rinse solution and drain bag.
- Reopen the filtrate and connection lines and continue the interrupted phase by selecting **<Start Priming>** or **<Start Therapy>** and confirm with the key.




### 8.3.7 Changing the H.E.L.P. Ultrafilter

| Accessories | Article number |
|---|---|
| H.E.L.P. Ultrafilter SMC 1,8 | 7203136 |
| 1 x collection bags | 7210543 |
| 3 l H.E.L.P. 0.9% NaCl solution | 34 |
| 2 connection lines | 7060130 |

- Attach a connection line with the NaCl solution, fill the line and connect it with the red, plasma-side filter opening.
- Attach the second connection line and the empty bag as shown in the Figure with the blue, plasma-side filter opening.
- Hold the filter so that it is filled from the bottom to the top and thoroughly vented in the process.
- Clamp shut both connection lines when approx. 1 l rinse solution has flown through (be careful that no air enters the filter!).
- Switch the machine to bypass mode by selecting **<Stop Priming>** or **<Stop Therapy>** in the menu bar and confirm with the key.
- Clamp shut the connection and reinfusion line leading to the dialyzer, remove the old filter and connect the new filter in the correct orientation to the connection and reinfusion lines. Connect the old filter with the connection lines on rinse solution and drain bag.
- Plug the Hansen connectors from the old onto the new filter (hold old filter horizontally!). Observe the color marking. Insert the new filter with the blue end down into the support.
- Fill the dialysate side of the filter by manually rotating the dialysate pump.
- Reopen the connection and reinfusion lines and continue the interrupted phase by selecting **<Start Priming>** or **<Start Therapy>** and confirm with the key.

# 9. TECHNICAL INFORMATION

## 9.1 TRANSPORTATION

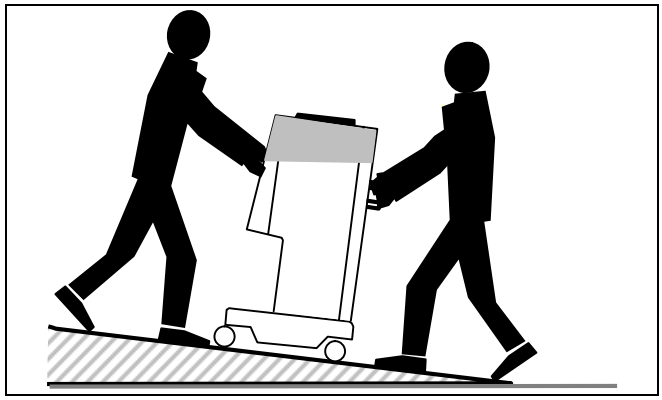
### 9.1.1 Wheeling

CAUTION

**Risk of damage if Plasmat® Futura is tilted by > 5°!**

- **Have 2 or more persons at hand for transporting the machine on stairs and inclined areas.**
- **Do not tilt the Plasmat® Futura by more than 5°.**

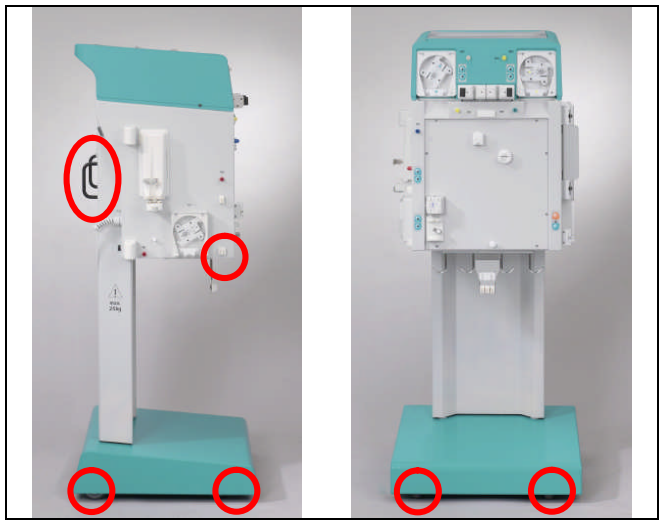
- Press the green brake release button in order to release the brakes.
- Wheel the Plasmat® Futura machine.
- Press the red brake locking button in order to apply the brakes.



Transport on stairs and slopes (2 persons)

### 9.1.2 Carrying

For carrying, the Plasmat® Futura can be held at the base, at the handles at the rear panel and at the protrusion at the front of the machine, as shown in the illustration below.



Holding points for carrying the Plasmat® Futura

CAUTION

**Danger of damage due to incorrect transportation (wrong holding points)!**

- **Do not hold machine on monitor, on the green top of the housing, or on infusion pole when transporting.**

## 9.2 OPERATING CONDITIONS

| | |
|---|---|
| ! | The Plasmat® Futura may be operated only by trained specialist personnel. The instructions in the Operating Manuals for the machine, the disposables and consumables and the intended use must be followed. |

### 9.2.1 Place of Installation

| | |
|---|---|
| ! | Installation must be done only by qualified and adequately trained staff. |

**Ambient conditions**

Observe information about ambient conditions, see chapter 9.3.

**Electrical connection**

The existing mains voltage must correspond with the voltage specified on the type plate.
The electrical installation of the room where the machine is installed must comply with the relevant regulations (VDE 01017/VDE 0100 or IEC provisions). National guidelines specific to each country must be taken into account. If in doubt, consult your in-house technician.

| | |
|---|---|
| ! | The Plasmat® Futura may be operated only when connected to grounding outlets which have been installed according to the regulations.<br>Do not use an adapter or extension cord on the main cable. |

| | |
|---|---|
| ! | No equipment emitting electromagnetic radiation (e.g. mobile telephones) may be switched on or operated in the vicinity of an operating Plasmat® Futura. |

### 9.2.2 Initial Start-up

Installation and initial start-up of the Plasmat® Futura are performed by service personnel who has been authorized by the manufacturer.
Before the initial start-up of the machine, check whether it is complete and undamaged.

| | |
|---|---|
| ! | If damage is found which endangers the safe operation, the machine may not be put into operation. Inform the responsible customer service.<br>Do not switch the machine on until it has reached room temperature.<br>Do not operate the machine in an environment where danger of explosion exists. |

### 9.2.3 Service and Maintenance

| | |
|---|---|
| ! | Repairs and maintenance may be performed only by personnel authorized and trained by the manufacturer. |

No special maintenance by the user is required.
The Technical Safety Inspection is to be performed every twelve months based on the Service Manual and the Operating Manual, subject to technical changes, and to be documented.
The maintenance of the calibration sensors (load cell, temperature, pressures, blood leak detector, SAD etc.) must be performed in accordance with the specifications of the Service Manual and the respective working instructions.
If the exchanging of fuses is required, only the fuses specified by the manufacturer may be used (see Service Manual).

### 9.2.4 Disposables, Consumables and Accessories / Replacement Parts

The machine may be used only in combination with the H.E.L.P. apheresis treatment system.
When using the approved single-usage articles, consumables and accessories, observe the instructions for use of the respective components.
Dispose of the single-usage articles required for the treatment according to the local regulations.
Use only accessories and replacement parts whose suitability with respect to technical safety has been established and certified by an inspection authority. This verification must be carried out by an inspection authority who is authorized to inspect the ready-for-use machine.

### 9.2.5 Cleaning and Disinfection

All modules of the Plasmat® Futura and the screen may be cleaned with ethanol-containing (≤ 70%) or isopropano-containing (≤ 60%) surface disinfectants. Please observe the instruction for use of the respective manufacturer

## 9.3 TECHNICAL DATA

### 9.3.1 Technical Data – General

| | | | |
|---|---|---|---|
| Machine dimensions | Height:<br>Width:<br>Weight: | 1330<br>500<br>520 | mm<br>mm<br>mm |
| Weight | | 55 | kg |
| Electrical connection | Rated voltage<br>Overvoltage category:<br>Rated frequency<br>FI circuit-breaker<br>Class of protection 1, type B, IP 21 | 110 – 240<br>II<br>50/60<br>30 | V AC<br><br>Hz<br>mA |

| | |
|---|---|
| ! | The rated voltage must be identical with the voltage specified on the type plate (e.g. 230 V AC, 50/60 Hz) |

| | | | |
|---|---|---|---|
| Power input | Rated current: | 3.5 | A max. |
| Classification | Type IIb according to Directive 93/42 EEC | | |
| Leakage currents | Ground leakage current:<br>Patient leakage current: | < 500<br>< 100 | µA<br>µA |

| | |
|---|---|
| ! | The allowed leakage currents may increase when several machines are connected. |

| | | | |
|---|---|---|---|
| Operating conditions | Operating temperature;<br>Rel. humidity:<br>Atmospheric pressure:<br>Height:<br>Pollution degree classification: | +15 ÷ +35<br>30 – 90<br>700 – 1060<br>0-3000 m above sea level<br>3 | °C<br>%<br>mbar<br><br> |
| Storage conditions | Storage temperature;<br>Rel. humidity:<br>Atmospheric pressure: | - 20 ÷ +55<br>10 – 90<br>700 – 1060 | °C<br>%<br>mbar |
| Potential equalization | Connection according to DIN 42801 (EN 60-601/1) | | |
| Interface | RS 485 interface for the connection of an external PC by the technical service or for therapy data collection and/or monitoring (option, information on request) | | |

| | |
|---|---|
| ! | The external PC must comply with the ICE 950 standard (or equivalent standards/ directives). |

| | |
|---|---|
| Electromagnetic compatibility | According to EN 60601-1-2 (IEC 601-1-2) |
| Housing material | Corrosion-resistant aluminium<br>Plastics ( polyurethane Baydur ) |

### 9.3.2 Recommended Safe Distances; Acc. to EN 60601-1-2 - Table 206

**Recommended safe distances between portable or mobile HF telecommunication devices and Plasmat® Futura**

The Plasmat Futura is for the use in ambient conditions with controlled High Frequency disturbance variables. The user can avoid electromagnetic disturbances by keeping the distance between Plasmat Futura and FH telecommunication devices, following the values in the table below, in dependency to the output power of those devices.

| Nominal output power P of transmitter in Watt [W] | Safe distance d depending on transmitter frequency in Meter [m] | | |
|---|---|---|---|
| | 150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$ | 80 MHz to 800 MHz $d = 1{,}2\sqrt{P}$ | 800 MHz to 2,5 GHz $d = 2{,}3\sqrt{P}$ |
| 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 with other output power ratings the recommended safe distance d in Meter can be calculated with the above formulas. Heed the max. output power in accordance to the manufacturers information, to use the right formula from above.

REMARK 1: For 80 MHz and 800 MHz use the higher frequency range.

REMARK 2: This guideline may not be practicable in some cases. The propagation of electromagnetic quantity is influenced by absorbtion and reflection of buildings, equipment and humans

Find more informations about EMC, radio disturbance and IEC 60601-1-2:2001 in the service manual or contact the manufacturer.

### 9.3.3 Technical Data - Components

Definition: Acoustic alarm interval is the time period after which an acknowledged alarm is repeated if the cause of the alarm is still present.

Pressure working ranges are defined for normal haematocrit, blood flow rate 60 – 120 ml/min, and plasma flow rate 20 – 35 ml/min.
For details of the pressure limits, please refer to Annex 2.

## 9.3.4 Extracorporeal Blood Circuit

| | |
|---|---|
| **Blood pump (BP)** | Peristaltic roller pump with motor switch-off when the pump cover is open<br><br>Delivery rate: 10 ÷ 150 ml/min<br>Delivery rate tolerance: < ± 10 %<br>Working pressure range: -140 ÷ +500 mmHg<br><br>Protection system:<br>Pump status and rate is monitored via a rotation detector.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |
| **Arterial pressure (PA)** | Electronically measured by a pressure sensor and digitally displayed<br><br>Measurement range: - 500 ÷ +500 mmHg<br>Allowed tolerance ± 10 mmHg<br>Working range: -60 ÷ +10 mmHg<br><br>**During Therapy:**<br>Default alarm limits: -150 ÷ +100 mmHg<br>Adjustable in parameter setting<br><br>Protection system:<br>Double channel pressure monitoring with sensor test during preparation phase.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |
| **Prefilter pressure (PBE)** | Electronically measured by a pressure sensor and digitally displayed<br><br>Measurement range: - 500 ÷ +500 mmHg<br>Allowed tolerance ± 10 mmHg<br>Working range: +90 ÷ +140 mmHg<br><br>**During Therapy:**<br>Alarm limits: -140 ÷ +250 mmHg<br>Default alarm window: Automatic control<br>Lower limit: Reference value - 40 mmHg<br>Upper limit: Reference value + 80 mmHg<br><br>Protection system:<br>Sensor test during preparation phase.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |

| | |
|---|---|
| **Venous pressure (PV)** | Electronically measured by a pressure sensor and digitally displayed<br><br>Measurement range: - 500 ÷ +500 mmHg<br>Allowed tolerance ± 10 mmHg<br>Working range: +20 ÷ +50 mmHg<br><br>**During Therapy:**<br>Alarm limits: -10 ÷ +250 mmHg<br>Default alarm window: Automatic control<br>Lower limit: Reference value - 20 mmHg<br>Upper limit: Reference value + 40 mmHg<br>Adjustable in parameter setting<br><br>The window limiting values are set 10 s after reaching the set Blood Flow. The reference value slowly follows the systematic pressure variation.<br><br>Protection system:<br>Double channel pressure monitoring with sensor test during preparation phase.<br>Alarm override:<br>The absolute alarm limits cannot be overridden.<br>The alarm window can be overridden during Blood Flow change/stop, Therapy start or PV level regulation till the re-stabilization of PV pressure (10 s).<br>Acoustic alarm interval: 120 s |
| **Safety air detector (SAD)** | Ultrasonic sensor on the venous line below the venous air chamber<br><br>Sensitivity: 0.1 ml air bolus or 2.0 ml air*<br>*Calculated integral volume of any air in the form of micro-bubbles, micro-foam or the dropping of the air level in the venous line below the sensor. It is decreased continuously by a natural air removal rate.<br>Protection system:<br>Double channel air monitoring with sensor test during preparation phase and automatic, cyclic test during therapy.<br>Alarm override:<br>The alarm cannot be overridden during the therapy.<br>Acoustic alarm interval: 120 s |
| **Safety air clamp (SAK)** | Electromagnetic clamp behind the safety air detector to close the venous return line<br><br>It is closed in case of a blood side alarm (e.g. by air detection).<br><br>Protection system:<br>Double channel activation with actuator test during preparation phase. |

| | |
|---|---|
| **Heparin pump (HP)** | Syringe pump (calibrated to Perfusor syringe 30 ml Omnifix®)<br><br>Delivery rate: 0 ÷ 10.0 ml/h<br>Delivery rate variation: < 10%<br>Working pressure range: 0 ÷ +250 mmHg<br>Protection system:<br>Pump status and rate is monitored via a rotation detector.<br>Alarm override:<br>Not possible during the therapy |

### 9.3.5 Plasma Circuit

| | |
|---|---|
| **Plasma/buffer pump (PBP) (marked yellow)** | Peristaltic roller pump with motor switch-off when the pump cover is open<br><br>Delivery rate: 2 ÷ 50 ml/min<br>Delivery rate variation: < 10 %<br>Working pressure range: -100 ÷ +450 mmHg<br><br>Protection system:<br>Pump status and rate is monitored via a rotation detector.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |
| **Plasma pressure (PPL)** | Electronically measured by a pressure sensor and digitally displayed<br><br>Measurement range: - 500 ÷ +500 mmHg<br>Allowed tolerance ± 10 mmHg<br>Working range: +20 ÷ +50 mmHg<br><br>**During Therapy:**<br>Default alarm limits: -10 ÷ +200 mmHg<br>Lower limit adjustable in parameter setting<br><br>Protection system:<br>Sensor test during preparation phase.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |
| **Blood leak detector (BLD)** | Photometrical red detector on disposable tubing close to plasma filter outlet<br><br>Sensitivity: 0.25 %<br>(For detecting 0.5 ml of blood in 200 ml of fluid)<br>**Avoid direct light exposure!**<br><br>Reaction time: approx. 20 s<br><br>Protection system:<br>Automatic calibration and self-test during preparation phase and cyclic self-test during therapy.<br>Possibility of repeating the calibration/self-test at alarm during therapy.<br>Alarm override:<br>Possibility for alarm overriding during therapy when the self-test/calibration failed three times. The therapy can be continued with monitoring by the user.<br>**A periodically occurring warning is maintained.**<br>Acoustic alarm interval: 120 s |

| | |
|---|---|
| **Precipitate filter pressure (PPF)** | Electronically measured by a pressure sensor and digitally displayed<br><br>Measurement range: - 500 ÷ +500 mmHg<br>Allowed tolerance ± 10 mmHg<br>Working range: +150 ÷ +300 mmHg<br><br>**During Therapy:**<br>Default alarm limits: -20 ÷ +450 mmHg<br>Lower limit adjustable in parameter setting<br><br>Protection system:<br>Sensor test during preparation phase.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |
| **Dialyzer pressure (PDF)** | Electronically measured by a pressure sensor and digitally displayed<br><br>Measurement range: - 500 ÷ +500 mmHg<br>Allowed tolerance ± 10 mmHg<br>Working range: +120 ÷ +270 mmHg<br><br>**During Therapy:**<br>Default alarm limits: -50 ÷ +350 mmHg<br>Adjustable in parameter setting<br><br>Protection system:<br>Sensor test during preparation phase.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |
| **Reinfusion pump (PRP) marked green** | Peristaltic roller pump with motor switch-off when the pump cover is open<br><br>Delivery rate: 1 ÷ 60 ml/min<br>Controlled by patient balance feedback control system (based on weight measurement by load cell).<br>Allowed tolerance: < 10 %<br>Working pressure range: -100 ÷ +450 mmHg<br><br>Protection system:<br>Pump status and rate is monitored via a rotation detector.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |

| 9.3.6 Dialysing Circuit | |
|---|---|

| | |
|---|---|
| **Dialysate pump (DP)** | Peristaltic roller pump with motor switch-off when the pump cover is open<br><br>Delivery rate: 40 ÷ 400 ml/min<br>Delivery rate tolerance: < ± 10 %<br>Working pressure range: -140 ÷ +500 mmHg<br><br>Protection system:<br>Pump status and rate is monitored via a rotation detector.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |
| **Dialysate inlet pressure (PDI)** | Electronically measured by a pressure sensor and digitally displayed<br><br>Measurement range: - 500 ÷ +500 mmHg<br>Allowed tolerance ± 10 mmHg<br>Working range: +60 ÷ +80 mmHg<br><br>**During Therapy:**<br>Alarm limits: -50 ÷ +450 mmHg<br><br>Protection system:<br>Sensor test during preparation phase.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |
| **Air detector (DAD)** | Ultrasonic sensor on the dialysate line behind the dialysate pump<br><br>Sensitivity: Air for 800 ms<br><br>Protection system:<br>Sensor test during preparation phase.<br>Alarm override: 40 s after alarm<br>Acoustic alarm interval: 120 s |

| | |
|---|---|
| **Plate warmer (H)** | Fluid warming system with temperature sensors based on heat transfer between temperature controlled metal plate and plastic dialysate bag<br><br>Temperature range: 34.0 ÷ 40.0 °C<br>Default in therapy: 39.0 °C<br>Allowed variation: 0.5 °C<br><br>Upper alarm limit: 41.5°C for 10 seconds.<br><br>Protection system:<br>Double channel temperature monitoring with sensor test during preparation phase.<br>Alarm override:<br>Not possible during the therapy<br>Acoustic alarm interval: 120 s |

### 9.3.7 Weight System

| | |
|---|---|
| **Load cell** | Loading capacity: 30 kg<br>Weight resolution: 1 g<br>Linearity: 0.015 %<br>Working range: 0.00 ÷ 25.00 kg<br><br>Overload protection: Electrically at 24.5 kg<br>Mechanically at 26.0 kg<br>Weight change alarm:<br>Weight deviation < 50 g: no alarm<br>Weight deviation 50÷200 g: alarm after 5 seconds if deviation has not been corrected<br>Weight deviation > 200 g: immediate alarm<br><br>Protection system:<br>Sensor test during preparation phase and electric current through load cell bridge monitoring during therapy.<br>Alarm override:<br>Not possible during the therapy.<br>Acoustic alarm interval: 120 s |

| | |
|---|---|
| **Patient balance** | Patient balance feedback control system based on weight measurement by the load cell controlling the reinfusion pump (marked green).<br><br>Patient balance range: - 600 ÷ 0 g<br>Allowed tolerance ± 50 g<br>Working range: - 600 ÷ 0 g<br><br>**During Therapy:**<br>Alarm limits: ± 200 g<br>Patient balance (calculated by the software from weight change) is compared continuously to the momentary theoretical value.<br><br>Protection system:<br>Double channel patient balance monitoring with sensor test during preparation phase.<br>Alarm override:<br>Alarm limit can be increased by 100 g by alarm acknowledge, but reaching the alarm limit ± 400 g override is not possible anymore.<br>Acoustic alarm interval: 120 s |

### 9.3.8 Estimation of Required Number of Dialysate Bags

Based on both the ratio dialysate/plasma and the required plasma volume, the following table shows an estimation of the required number of dialysate bags.

| | Ratio Dialysate/Plasma | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Plasma Volume** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** |
| **3000** | 3 | 4 | 5 | 6 | 6 | 7 | 8 | 9 | 9 |
| **3500** | 4 | 5 | 6 | 6 | 7 | 8 | 9 | 10 | 11 |
| **4000** | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| **4500** | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| **5000** | 5 | 7 | 8 | 9 | 10 | 11 | 12 | 14 | 15 |
| **5500** | 6 | 7 | 8 | 10 | 11 | 12 | 13 | 15 | 16 |
| **6000** | 6 | 8 | 9 | 10 | 12 | 13 | 15 | 16 | 17 |

## 9.4. WARRANTY AND LIABILITY

### 9.4.1 Manufacturer Responsibility

The manufacturer, installation company and check-out or instructor personnel consider themselves responsible for the effects on safety, reliability and performance of the machine only when installation, extensions, new settings, changes or repairs were performed by persons authorized by them, and the electrical installation of the room involved complies with the requirements of VDE 0100/VDE 010/IEC stipulations and the machine is used in accordance with the Operating Manual.

### 9.4.2 Liability and Warranty

For the Plasmat® Futura, B. Braun Avitum AG grants 12 months guarantee as from the initial installation. The guarantee comprises the repair or the replacement of defective parts, providing they have design, production or material defects.
The guarantee becomes void when the owner or third parties have performed modifications or repairs on the machine.
Excluded from the guarantee is the correction of faults which are due to incorrect handling, improper treatment and normal wear.

## Commissioning Record for Plasmat Futura

The **commissioning** (setting into service) according to the specified check list, must be performed and documented before the machine is handed over to the user, with reference to the service manual and operating manual.

**Type:** ..... **Nr.:** .....

**Year of Purchase:** ..... **User:** .....

.....

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

**SW Version:** .....

**Manufacturer:**
B. Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, Germany

**Check List**

| | | | | OK |
|---|---|---|---|---|
| **1.** | **Visual Inspection** | | | |
| 1.1 | Machine: clean/complete; no damages/moisture influences; unit rollers are moveable; electrical brake functions; machine record book present; type plate, labels and inscriptions present and legible | | | ❑ |
| 1.2 | Check tight seat of mains supply (power supply line, strain relief and connectors, boards) | | | ❑ |
| 1.3 | LC Display: no restriction of movement, track knob functions, tight seat of all key membranes/not damaged | | | ❑ |
| 1.4 | Function of the keys, display illumination | | | ❑ |
| 1.5 | Tight seat conductors | | | ❑ |
| **2.** | **Function Inspection (Document Measurement Values)** | | | |
| 2.1 | Arterial Pressure PA:<br>(permissible tolerance ±10 [mmHg]) | - Comparison measurement at: | - 250 = ..... **[mmHg]**<br>0 = ..... **[mmHg]** | ❑<br>❑ |
| 2.2 | Prefilter Pressure PBE:<br>(permissible tolerance ±10 [mmHg]) | - Comparison measurement at: | 0 = ..... **[mmHg]**<br>+ 250 = ..... **[mmHg]** | ❑<br>❑ |
| 2.3 | Venous Pressure PV:<br>(permissible tolerance ±10 [mmHg]) | - Comparison measurement at: | 0 = ..... **[mmHg]**<br>+ 250 = ..... **[mmHg]** | ❑<br>❑ |
| 2.4 | Plasma Pressure PPL:<br>(permissible tolerance ±10 [mmHg]) | - Comparison measurement at: | 0 = ..... **[mmHg]**<br>+ 150 = ..... **[mmHg]** | ❑<br>❑ |
| 2.5 | Precipitate Filter Pressure PPF:<br>(permissible tolerance ±10 [mmHg]) | - Comparison measurement at: | 0 = ..... **[mmHg]**<br>+ 400 = ..... **[mmHg]** | ❑<br>❑ |
| 2.6 | Dialyzer Pressure PDF:<br>(permissible tolerance ±10 [mmHg]) | - Comparison measurement at: | 0 = ..... **[mmHg]**<br>+ 400 = ..... **[mmHg]** | ❑<br>❑ |
| 2.7 | Weight System | | | |
| 2.7.1 | Load cell comparison measurement (with reference weight) at:<br>(permissible tolerance ± 50 g) | | + __.___ g = ..... **[g]**<br>Difference between Reference/Actual Value = _____ **[g]** | ❑ |
| 2.7.2 | Load cell comparison measurement (without reference weight) at:<br>(permissible tolerance ± 50 g) | | 0 g = ..... **[g]**<br>Difference between Set/Actual Value = _____ **[g]** | ❑ |
| 2.8 | Power Fail Function: | - Check function, activate buzzer in power supply (during self-test)<br>Duration of a constant audible alarm > 1 minute | | ❑ |
| **3.** | **Electrical Safety Check According to EN 60601-1/IEC 601-1** | | | |
| 3.1 | Measure mains voltage | | ..... **[V~]** | ❑ |
| 3.2 | Protective Earth Conductor Resistance < 0.2 [Ω]:<br>(Machine incl. power supply cord) | - Potential equalization bolt<br>- Screw connection plate warmer | ..... **[Ω]**<br>..... **[Ω]** | ❑ |
| 3.3 | Earth Leakage Current ≤ 0.5 [mA]: | - During heat-up phase | ..... **[mA]** | ❑ |
| 3.4 | Patient Leakage Current < 0.1 [mA]: | - Under normal conditions | ..... **[mA]** | ❑ |
| **4.** | **Setting into Service with Tubing System according to Description Commissioning with Test Set** | | | |
| 4.1 | Switch on Machine: | - Hardware self-test passed | | ❑ |
| 4.2 | Blood Leak Detector (BLD): | - Test alarm function passed | | ❑ |
| 4.3 | Safety Air Detector (SAD): | - Test alarm function passed | | ❑ |
| 4.4 | Dialysate Air Detector (DAD): | - Test alarm function passed | | ❑ |

**The commissioning was performed and the machine was hand over to the user**

Name Service Technician: .....
Date / Signature

Name of Company: .....

User: .....
Date / Signature

## Technical Safety Inspection and Preventive Maintenance for Plasmat Futura

The technical safety inspection, according to the specified check list, must be performed and documented **every 12 months**, with reference to the service manual and operating manual.
The preventive maintenance with the exchange of wear and tear parts, is recommended **every 12 months** and should be documented, according to the specified check list, with reference to the service manual and operating manual.

**Type:** ..... **Nr.:** .....

**Year of Purchase:** ..... **User:** .....

.....

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

**SW Version:** .....

**Manufacturer:**
B. Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, Germany

**Check List**
**Technical Safety Inspection** ..... ❑
**Technical Safety Inspection with Preventive Maintenance** ..... ❑
S M **S = Technical Safety Inspection Points; M = Preventive Maintenance Points**

| | | | | | No | Yes | OK |
|---|---|---|---|---|---|---|---|
| | | **1.** | **Visual Inspection, Function Inspection (Document Measurement Values and if necessary Calibrate) and Maintenance Procedures** | | | | |
| S | | 1.1 | Machine: clean/complete; no damages/moisture influences; unit rollers are moveable; electrical brake functions; machine record book present; no special incidents; type plate, labels and inscriptions present and legible | | ❑ | ❑ | ❑ |
| | M | 1.1.1 | Clean interior space and exterior surfaces | | ❑ | ❑ | ❑ |
| S | | 1.2 | Check mains supply (power supply line and connectors) | | ❑ | ❑ | ❑ |
| | M | 1.3 | Tight seat of boards and connectors | | ❑ | ❑ | ❑ |
| | M | 1.4 | LC Display: no restriction of movement, track knob functions, tight seat of all key membranes/not damaged | | ❑ | ❑ | ❑ |
| S | | 1.5 | Function of the keys, display illumination | | ❑ | ❑ | ❑ |
| | | 1.5.1 | Alarm signal | | ❑ | ❑ | ❑ |
| | M | 1.6 | Tight seat conductors | | ❑ | ❑ | ❑ |
| | M | 1.7 | Blood Pump (BP): | - Check function, moveability, drive belt, noise rating | ❑ | ❑ | ❑ |
| | | 1.7.1 | Check roller; if necessary grease bearing | | ❑ | ❑ | ❑ |
| S | | 1.7.2 | Alarm cover switch | | ❑ | ❑ | ❑ |
| | | 1.7.3 | One-way bearing | | ❑ | ❑ | ❑ |
| | M | 1.8 | Plasma/Buffer Pump (PBP): | - Check function, moveability, drive belt, noise rating | ❑ | ❑ | ❑ |
| | | 1.8.1 | Check roller; if necessary grease bearing | | ❑ | ❑ | ❑ |
| S | | 1.8.2 | Alarm cover switch | | ❑ | ❑ | ❑ |
| | | 1.8.3 | One-way bearing | | ❑ | ❑ | ❑ |
| | M | 1.9 | Reinfusion Pump (PRP): | - Check function, moveability, drive belt, noise rating | ❑ | ❑ | ❑ |
| | | 1.9.1 | Check roller; if necessary grease bearing | | ❑ | ❑ | ❑ |
| S | | 1.9.2 | Alarm cover switch | | ❑ | ❑ | ❑ |
| | | 1.9.3 | One-way bearing | | ❑ | ❑ | ❑ |
| | M | 1.10 | Dialysate Pump (DP): | - Check function, moveability, drive belt, noise rating | ❑ | ❑ | ❑ |
| | | 1.10.1 | Check roller; if necessary grease bearing | | ❑ | ❑ | ❑ |
| S | | 1.10.2 | Alarm cover switch | | ❑ | ❑ | ❑ |
| | | 1.10.3 | One-way bearing | | ❑ | ❑ | ❑ |
| S | | 1.11 | Venous Tubing Clamp: | - Function and moveability | ❑ | ❑ | ❑ |
| | | 1.11.1 | Gap 1.4 (+0.1 mm) | | ❑ | ❑ | ❑ |
| S | | 1.12 | Heparin Adsorber Tubing Clamp (HAK): | - Function and moveability | ❑ | ❑ | ❑ |
| | | 1.12.1 | 1.1 (+0.1 mm) | | ❑ | ❑ | ❑ |
| S | | 1.13 | Arterial Pressure PA | - Comparison measurement at: - 250 = ..... [mmHg] | | | ❑ |
| | | | (permissible tolerance ±10 [mmHg]) | 0 = ..... [mmHg] | | | ❑ |
| S | | 1.14 | Prefilter Pressure PBE | - Comparison measurement at: 0 = ..... [mmHg] | | | ❑ |
| | | | (permissible tolerance ±10 [mmHg]) | + 250 = ..... [mmHg] | | | ❑ |
| S | | 1.15 | Venous Pressure PV | - Comparison measurement at: 0 = ..... [mmHg] | | | ❑ |
| | | | (permissible tolerance ±10 [mmHg]) | + 250 = ..... [mmHg] | | | ❑ |
| S | | 1.16 | Plasma Pressure PPL | - Comparison measurement at: 0 = ..... [mmHg] | | | ❑ |
| | | | (permissible tolerance ±10 [mmHg]) | + 150 = ..... [mmHg] | | | ❑ |

| S | M | S = Technical Safety Inspection Points; M = Preventive Maintenance Points | | | No | Yes | OK |
|---|---|---|---|---|---|---|---|
| S | | 1.17 Precipitate Filter Pressure PPF<br>(permissible tolerance ±10 [mmHg]) | - Comparison measurement at: | 0 = ..... [mmHg]<br>+ 400 = ..... [mmHg] | | | ❑<br>❑ |
| S | | 1.18 Dialyzer Pressure PDF<br>(permissible tolerance ±10 [mmHg]) | - Comparison measurement at: | 0 = ..... [mmHg]<br>+ 400 = ..... [mmHg] | | | ❑<br>❑ |
| S | | 1.19 Weight System<br>1.19.1 Load cell comparison measurement (with reference weight) at:<br>(permissible tolerance ± 50 g)<br>1.19.2 Load cell comparison measurement (without reference weight) at:<br>(permissible tolerance ± 50 g) | | + __.___ g = ..... [g]<br>Difference between Reference/Actual Value = _____ [g]<br>0 g = ..... [g]<br>Difference between Set/Actual Value = _____ [g] | | | <br>❑<br><br>❑ |
| S | | 1.22.3 Power Fail Function: | - Check function, activate buzzer in power supply (during self-test)<br>Duration of a constant audible alarm > 1 minute | | | | ❑ |
| | | **2. Electrical Safety Check According to EN 60601-1/IEC 601-1** | | | | | |
| S | | 2.1 Measure mains voltage | | ..... [V~] | | | ❑ |
| S | | 2.2 Protective Earth Conductor Resistance < 0.2 [Ω]<br>(Machine incl. power supply cord) | - Potential equalization bolt<br>- Screw connection plate warmer | ..... [Ω]<br>..... [Ω] | | | ❑<br>❑ |
| S | | 2.3 Earth Leakage Current ≤ 0.5 [mA]: | - During heat-up phase | ..... [mA] | | | ❑ |
| S | | 2.4 Patient Leakage Current < 0.1 [mA]: | - Under normal conditions | ..... [mA] | | | ❑ |
| | | **3. Setting into Service According to Description** | | | | | |
| S | | 3.1 Switch on Machine: | - Self-test passed | | ❑ | ❑ | ❑ |
| S | | 3.2 Temperature | - Comparison measurement at 37 °C (-1.5; +0.5) | ..... [°C] | | | ❑ |
| S | | 3.3 Blood Leak Detector (BLD): | - Test alarm function passed | | ❑ | ❑ | ❑ |
| S | | 3.4 Safety Air Detector (SAD): | - Test alarm function passed | | ❑ | ❑ | ❑ |
| S | | 3.5 Dialysate Air Detector (DAD): | - Test alarm function passed | | ❑ | ❑ | ❑ |
| **CHECK RESULTS:** Defects were detected, which could endanger patients, users or third parties. | | | | | ❑ | ❑ | ❑ |
| Applied Accessories/Disposables: | | | | ..... | | | |
| Must actions be taken with reference to maintenance | | | | | ❑ | ❑ | ❑ |
| Note next appointment: | | | | ..... | | | |
| The technical safety inspection or technical safety inspection with preventive maintenance was performed correctly. | | Name of Service Technician:<br>.....<br>.....<br>Date / Signature | | Name of Company:<br>..... | | | |
| | | User:<br>.....<br>Date / Signature | | | | | |

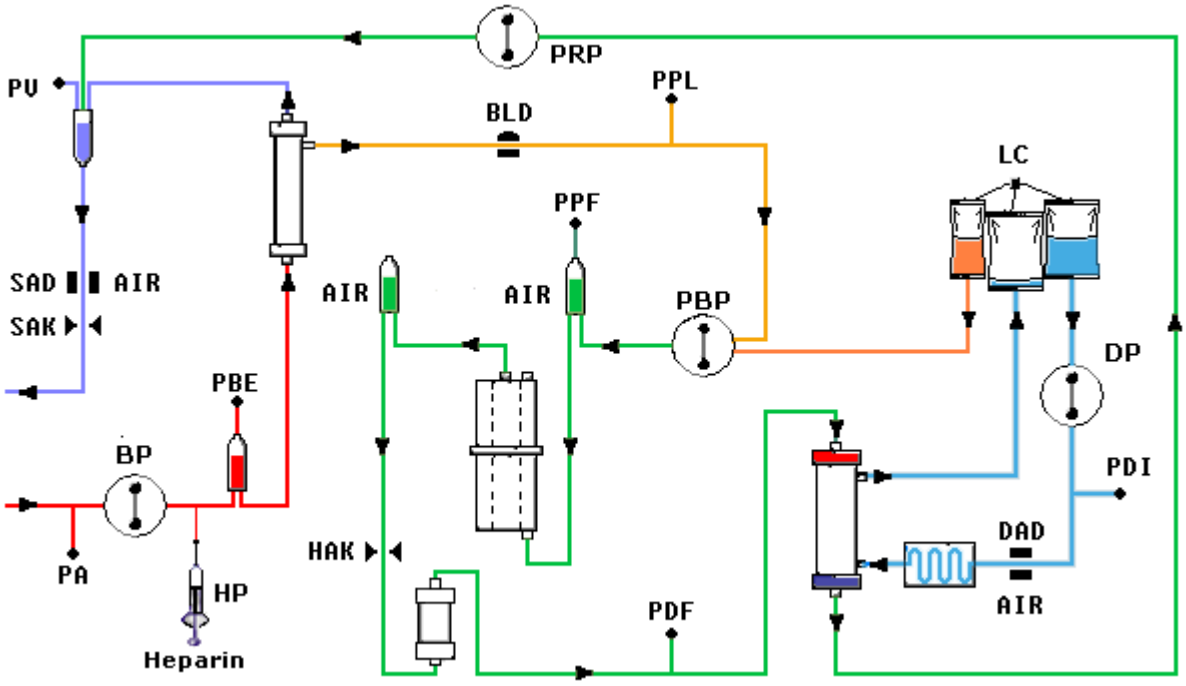
# ANNEX 1 – CONSUMABLES

## List of Articles

| Article Number | Article |
|---|---|
| 7210545a | H.E.L.P. Futura set |
| | **Single parts of the H.E.L.P. Futura set** |
| 7210552 | Venous line |
| 7210553 | Plasma/buffer line |
| 7210554 | Filtrate line |
| 7210555 | Connection line |
| 7210556a | Dialysate drainage line |
| 7210557 | Venting line |
| 7210541 | Arterial line |
| 7210542 | Dialysate line |
| 7210544b | Empty bag for dialysate |
| 7210543 | Empty bag for rinse solution |
| 706101A | H.E.L.P. precipitate filter |
| 7203136 | H.E.L.P. ultrafilter SMC 1,8 |
| 7210694 | Haemoselect M 0.3 $m^2$ plasma filter |
| 7210688 | H.E.L.P. heparin adsorber |
| 34 | 3000 ml H.E.L.P. 0.9 % NaCl sodium chloride solution (2 bags/treatment) |
| 28 | 3000 ml H.E.L.P. acetate buffer (1 bag/treatment) |
| 4376 | 5000 ml H.E.L.P. BicEl bicarbonate solution (3 bags/treatment) |
| 44 | 2000 ml H.E.L.P. 0.9% NaCl sodium chloride solution in double-chamber bag (1 bag/treatment) |
| 706 1188 | 1 x 30 ml H.E.L.P. heparin sodium (300.000 IU) |
| | **Accessories** |
| 7060130 | Empty bag connection line |
| 7210224 | Transducer protector (protector for PA, PBE, PDI, PPF, PV transducer) |
| 7020197 | Transducer protector for tubing 2,5 x 4,1 (protector for PDF and PPL transducer) |
| 4617304F | 30 ml Omnifix® Luer Lock syringe |

# ANNEX 2 – EXPLANATION OF PRESSURES

## Relevant Pressures




**PA** Arterial pressure PA

**PBE** Arterial prefilter pressure

After the blood pump is started and adapted and the automatic level adjustment of the arterial air chamber is activated, the lower and upper PBE limits are set within ten seconds in the therapy and reinfusion phase. The **momentary acquired pressure (PBE Ref)** serves as reference for the calculation of the alarm window.

**Lower limit:**
PBE min = (PBE Ref – 40) mmHg
**Upper limit:**
PBE max = (PBE Ref + 80) mmHg

The lower limit **PBE min** can be a **minimum of –100 mmHg**.
The upper limit **PBE max** can be a **maximum of +250 mmHg**.

**TMP** Transmembrane pressure

The TMP is calculated as follows:

TMP = (PBE+PV) / 2 – PPL

The alarm limits can be set in 10 mmHg steps between 20 and 200 mmHg. The default setting is 100 mmHg.

**PPL** Plasma pressure

**PPF** Precipitate filter pressure

**PDPA** Precipitate filter/adsorber pressure drop

The PDPA is calculated as follows:

PDPA = PPF – PDF

**PDF** Dialyzer pressure

**PDI** Dialysate inlet pressure

**PV** Venous pressure

During therapy and reinfusion phase, 10 sec after start of blood pump or plasma pump, and after change of the blood flow, or after the manual level regulation of the venous or PBE chamber, respectively, the lower and upper PV limits are automatically adjusted. The **momentary acquired venous pressure (PV Ref)** serves as mean value for the calculation of the alarm window.

**Lower limit:**

PV min = (PV Ref – MinW) mmHg when PV Ref > MinW
PV min = 0 mmHg when 5 ≤ PV Ref ≤ MinW
PV min = -10 mmHg when PV Ref < 5
MinW = Minimum PV window (default value = 20 mmHg)

**Upper limit:**

PV max = (PV Ref + MaxW) mmHg
MaxW = Maximum PV window (default value = 40 mmHg)

## Pressure Limits

The following table shows the limiting value ranges of the pressures depending on the current phase of the system.

| Pressure (mmHg) | Priming | Therapy BP RUN | | | Therapy BP STOP | | | Reinfusion BP RUN | | | Reinfusion BP STOP | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Def | Def / Auto | Min | Max | Def | Min | Max | Def / Auto | Min | Max | Def | Min | Max |
| **PA min** | -150 | -150 | -350 | 80 | -150 | -350 | 80 | -150 | -350 | 80 | -150 | -350 | 80 |
| **PA max** | 190 | 100 | 0 | 200 | 200 | - | - | 100 | 0 | 200 | 200 | - | - |
| **PBE min** (2) | -450 | PBE ref–40 | -100 | 210 | -100 | - | - | PBE ref–40 (plasma reinf.) PBE ref–60 (blood reinf.) | -100 | 210 | -100 | - | - |
| **PBE max** (2) | 250 | PBE ref+80 | -20 | 250 | 250 | - | - | PBE ref+80 | -20 | 250 | 250 | - | - |
| **PV min** (3) | -450 | PV ref - MinW | -10/0 | 250 - MinW | -20 | - | - | -20 | - | - | -20 | - | - |
| **PV max** (3) | 250 | PV ref + MaxW | PVmin + MaxW | 250 | 250 | - | - | PV ref + MaxW | PVmin + MaxW | 250 | 250 | - | - |

| Pressure (mmHg) | Priming | Therapy fluid side RUN | | | Therapy fluid side STOP | | | Reinfusion fluid side RUN | | | Reinf. fluid side STOP | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Def | Def | Min | Max | Def | Min | Max | Def | Min | Max | Def | Min | Max |
| **TMP max** | 200 | 100 | 20 | 200 | 100 | 20 | 200 | 150 | 20 | 200 | 150 | 20 | 200 |
| **PPL min** | -20 | -10 | -20 | 10 | -100 | - | - | -100 | - | - | -100 | - | - |
| **PPL max** | 450 | 200 | - | - | 200 | - | - | 200 | - | - | 200 | - | - |
| **PPF min** | -50 | -20 | -50 | 50 | -250 | - | - | -20 | -50 | 50 | -250 | - | - |
| **PPF max** | 450 | 450 | - | - | 450 | - | - | 450 | - | - | 450 | - | - |
| **PDF min** | -50 | -50 | -50 | 0 | -50 | - | - | -50 | -50 | 0 | -50 | - | - |
| **PDF max** | 400 | 350 | 10 | 450 | 450 | - | - | 400 | 10 | 450 | 450 | - | - |
| **PDPA max** (1) | 450 | 150 *450* | 50 - | 350 - | 450 | - | - | 350 *450* | 50 - | 450 - | 450 | - | - |
| **PDI min** | -450 | -50 | - | - | -100 | - | - | -100 | - | - | -100 | - | - |
| **PDI max** | 450 | 450 | - | - | 450 | - | - | 450 | - | - | 450 | - | - |

**Def** = Default value of a parameter settable by user.
**Min** = Minimum settable value or possible value.
**Max** = Maximum settable value or possible value.
**Auto** = Limit is calculated by software and is not settable by user.
**BP** = Blood pump.

(1) PDPA max: 450 mmHg is the limit in the first 20 sec after fluid side pumps start running.

(2) PBE min, max: for more details see above

(3) PV min, max: for more details see above

# ANNEX 3 – LIMITS

## Limits of Adjustable Parameters

| Parameter | Default | min | max | Step Sequence | Unit |
|---|---|---|---|---|---|
| **Blood flow** | 40 | 10 | 150 | 5 | ml/min |
| **Plasma flow** | 20 | 10 | 40 | 1 | % blood flow |
| **Plasma reinfusion volume** | 400 | 400 | 1000 | 50 | ml |
| **Blood reinfusion volume** | 300 | 100 | 600 | 50 | ml |
| **Return flow** | 30 | 10 | 50 | 5 | ml/min |
| **Ratio Dialysate/Plasma** | 4 | 4 | 12 | 1 | |
| **Rinsing volume** | 2400 | 2400 | 20000 | 100 | ml |
| **Plasma volume** | 3000 | 100 | 6000 | 50 | ml |
| **Patient Balance** | 0 | -600 | 0 | 50 | g |
| **Temperature** | 39 | 34 | 40 | 0,5 | °C |
| **Heparin flow** | 2,0 | 0,0 | 10,0 | 0.5 | ml/h |
| **Heparin bolus** | 1,0 | 0 | 10 | 0,5 | ml |
| **Autostop heparin** | 0 | 0 | 60 | 5 | min |
| **PA min** | -150 | -350 | 80 | 10 | mmHg |
| **PA max** | 100 | 0 | 200 | 10 | mmHg |
| **Minimum PV window** | 20 | 10 | 40 | 5 | mmHg |
| **Maximum PV window** | 40 | 20 | 100 | 5 | mmHg |
| **PPL min** | -10 | -20 | 10 | 1 | mmHg |
| **PPL threshold** | 20 | -20 (1) | 120 | 5 | mmHg |
| **TMP max** | 100 | 20 | 200 | 10 | mmHg |
| **PPF min** | -20 | -50 | 50 | 5 | mmHg |
| **PDF min** | -50 | -50 | 0 | 5 | mmHg |
| **PDF max** | 350 | 10 | 450 | 10 | mmHg |
| **PDPA max** | 150 | 50 | 350 | 10 | mmHg |

(1) Default PPL threshold (min): -10 mmHg

# ANNEX 4 – SELF-TESTS

After the machine is switched on, the system initiates a series of hardware self-tests. For these tests, no disposable material (solution bags, lines) must be installed on the machine.

**Numeric Test**
This test displays the numeric strings (0 1 2 3 4 5 6 7 8 9) in the three different fonts which the machine has available. The user has to check whether the sequence is correct.

If one of the self-tests fails, a relevant warning is displayed. In this case, ensure that the machine is in the initial state. Then another self-test can be performed after correction of the cause of the error by selecting the <**Retest**> menu item in the menu bar and pressing the  key.

When the hardware tests and the numeric test have been successfully completed, the Start screen is displayed by selecting the <**End**> menu item in the menu bar and confirming with the  key.

**LED Test**
During the execution of self-tests, the hardware performs self-tests of the LEDs by switching them on intermittently:

-  key
- 

key
- 

key.

The user must make sure that all LEDs operate correctly.

**T0 tests**
The T0 tests are performed continuously and periodically over the complete operating period of the machine.

**Static T1 tests**
The static T1 tests are performed after the machine is switched on. The therapy can be started only when all T1 tests were performed without error.

**Dynamic T1 tests**
Dynamic T1 tests are performed during the priming and rinsing phase to ensure the correct installation of the lines.

The system performs various dynamic self-tests during the priming and rinsing phase to ensure the functionality of the following units:

- Load cell
- Blood leak detector (BLD)
- Dialysate air detector (DAD)
- Venous air detector (SAD)
- Arterial pressure (PA)
- Plasma prefilter pressure (PBE) and venous pressure sensors (PV)
- Pumps
- Heating
- The temperatures of the dialysate measured by the controller and the supervisor, respectively, are compared.

Various self-tests are performed during the entire therapy in periodic intervals for the safety of the patient. The following parameters are monitored:

- Fluid weight on the load cell
- Blood leak detector (BLD)
- Safety air detector (SAD)

Proceed as follows in the case of a failed test:

1. Suppress the acoustic alarm with the  key
2. Follow the instructions on the monitor and determine which test failed.
3. Determine and correct the displayed cause, if possible.
4. Repeat the test by again pressing the  key.

| Test | Time [seconds] | Alarm Code |
|---|---|---|
| **T0 Tests by the Controller** | | |
| ***Proper Supervisor operation***<br>Periodical life signal is received from Supervisor. | 3 s | A99 |
| ***Functional states of controller and supervisor are identical***<br>Verification whether the controller and the supervisor have the same working state. | 5 s | A02 |
| ***Arterial pressures of controller and supervisor are identical***<br>The arterial pressures (PA) of the controller and the supervisor may deviate by a maximum of ± 30 mmHg (in priming and rinsing only). | 30 s | A03 |
| ***Venous pressures of controller and supervisor are identical***<br>The venous pressures (PV) of the controller and the supervisor may deviate by a maximum of ± 30 mmHg (in priming and rinsing only). | 30 s | A04 |
| ***Weight values of controller and supervisor are identical***<br>The weights determined by the controller and the supervisor on the load cell may deviate by a maximum of ± 250 g (in priming and rinsing only and if plasma side is running). | 30 s | A05 |
| ***Temperatures of controller and supervisor are identical***<br>The temperatures determined by the controller and the supervisor may deviate by a maximum of 2.5 °C (in priming and rinsing only). | 180 s | A06 |
| ***BLD self-test***<br>This test is performed every 5 min during the therapy and reinfusion phase. | 5 min | A07 |

| | | |
|---|---|---|
| ***SAD self-test***<br>The first test verifies whether the sensor detects an air signal. The second test performs a comparison between the voltage threshold and the calibration value. This test is performed every 1.5 s (=time required by an air bubble at maximum blood flow to reach the venous cannula) during priming and rinsing as well as during the therapy and reinfusion phases. | 1.5 s | A08 |
| ***Load cell self-test***<br>The load cell is tested every 3 s. | 5 s | A09 |
| ***Running internal communication***<br>Correct periodical communication is performed with the User Interface. | 4 s | A10 |

| **T0 Tests by the Supervisor** | | |
|---|---|---|
| ***SAD clock test***<br>Time control of the SAD is checked. | 0 s | A80 |
| ***SAD test***<br>No or too many SAD tests are executed by the Controller or fluid is detected during test. | 2 s | A90 |
| ***SAD reference test***<br>Reference voltage of SAD is tested to be within limit. | 1 s | A94 |
| ***Running internal communication***<br>Correct periodical communication is performed with the User Interface and periodical life signal is received from Controller. | 6 s<br>3 s | A99 |

| **Static T1 Tests by the Controller** | | |
|---|---|---|
| ***ROM-RAM***<br>The ROMs and RAMs of the controller are verified with a CRC test. | Self-test | |
| ***Calibration data***<br>The calibration data of the controller are verified with a CRC test. | Self-test | |
| ***Sensor ZERO test***<br>The controller analyses the following target values:<br>• Arterial pressure [within +/- 20 mmHg]<br>• Prefilter pressure [within +/- 20 mmHg]<br>• Venous pressure [within +/- 20 mmHg]<br>• Weight [below 50 g]<br>• SAD in air detection<br>• PCLD in air detection<br>• HCLD in air detection<br>• DAD in air detection<br>Verification of whether the dialysate air detector (DAD), the sensor for the level monitoring of the precipitate air chamber (PCLD) and the sensor for the level monitoring of the heparin adsorber air chamber (HCLD) detect an air signal. | Self-test | A13-A20 |

| | | |
|---|---|---|
| ***Supervisor 24 V relay***<br>The controller checks whether the supervisor can stop all pumps by means of the 24 V relay.<br>• Controller activates the blood pump with a flow rate of 100 ml/min for 5 s.<br>• The supervisor opens the 24 V relay.<br>The test passes when the controller detects that the blood pump is stopped. | Self-test | A21 |
| ***Supervisor heating relay***<br>The controller checks whether the supervisor initiates the switching off of the heating via the heating relay.<br>• The supervisor opens the heating relay.<br>• The controller activates the heater to the maximum temperature for 20 s.<br>The test passes when the temperature deviation is less than 1.0 °C. | Self-test | A22 |
| ***Controller alarm tone buzzer***<br>The test includes the successive activation of all four alarm tones.<br>• Power failure buzzer<br>Long alarm tone<br>The control system initiates the alarm situation of a mains failure for 2 s.<br>• Controller alarm buzzer<br>Continuous alarm tone<br>The control system initiates the buzzer for 2 s.<br>• Supervisor alarm buzzer<br>Continuous alarm tone<br>The supervisor system activates the buzzer for 2 s.<br>• Warning buzzer<br>Three alarm tones in successive short intervals.<br>The monitor system activates the warning buzzer for 2 s. No danger exists for the patient.<br>The user is responsible for checking whether the buzzers function correctly. | Self-test | |

| **Static T1 Tests by the Supervisor** | | |
|---|---|---|
| ***ROM-RAM***<br>The ROMs and RAMs of the supervisor are verified with a CRC test. | Self-test | |
| ***Calibration data***<br>The calibration data of the supervisor are verified with a CRC test. | Self-test | |
| ***Sensor ZERO test***<br>The supervisor analyses the following set values:<br>• Arterial pressure [within +/- 20 mmHg]<br>• Venous pressure [within +/- 20 mmHg]<br>• Weight [below 100 g]<br>• SAD in air detection | Self-test | A95-A98 |
| ***Heparin pump test***<br>The supervisor initiates a heparin bolus and checks the uniform delivery rate of the pump by means of a light barrier.<br>➢ The piston guide should be engaged in the middle position! | Self-test | A93 |

| | | |
|---|---|---|
| ***Supervisor alarm tone buzzer***<br>The test includes the successive activation of all four alarm tones.<br>• Supervisor alarm buzzer<br>Continuous alarm tone<br>The supervisor system activates the buzzer for 2 s.<br>The user is responsible for checking whether the buzzers function correctly. | Self-test | |

| **Dynamic T1 Tests by the Controller** | | |
|---|---|---|
| ***Weight deviation by the plasma/buffer pump***<br>Verification after activation of step 4 of the priming and rinsing phase whether the weight increase on the load cell corresponds to the delivery rate of the plasma/buffer pump (65 ml/min).<br>For a duration of 30 s, the weight increase must be higher than 20 g and less than 40 g, otherwise alarm A26 will be initiated and the test sequence has to be repeated | Step 4<br>Priming and rinsing | A26 |
| ***HAK leakage test***<br>Verification in step 6 of the filling and rinsing phase whether the HAK can be closed and the plasma line is inserted properly into HAK.<br><br>For a duration of 10 s pressure increasing of PDPA must be > 60mmHg with a running Plasma pump (30 ml/min) and closed HAK, otherwise alarm A33 will be initiated. Before the test or before repeating the test the PPF pressure is reduced to below 150 mmHg automatically (if necessary). | Step 6<br>Priming and rinsing | A33 |
| ***DAD Test***<br>Verification at the beginning of step 9 of the filling and rinsing phase whether fluid is recognized at the beginning of dialysate line filling and DAD sensor works properly.<br>The sensor must detect fluid within 20 s after the start of the filling process of the dialysate line running with 200 ml/min flow, otherwise alarm A28 will be initiated. | Step 9<br>Filling and rinsing | A28 |
| ***Weight deviation by the dialysate pump***<br>After a successful DAD test, verification in step 9 of the filling and rinsing phase whether the weight decrease on the load cell corresponds to the delivery rate of the dialysate pump (100 ml/min).<br>For a duration of 20 s the weight decrease must be higher than 20 g and less than 46 g, otherwise alarm A27 will be initiated and the test is performed once again. Afterwards the filling and rinsing phase continues. | Step 9<br>Filling and rinsing | A27 |

| | | |
|---|---|---|
| ***Blood-side pressure build-up test***<br>***Blood-side pressure holding test***<br>***Venous pressure holding test***<br>***Safety Air Clamp (SAK) test***<br>The following leakage tests are performed in step 9 of the filling and rinsing phase:<br>• SAK is closed by the Supervisor while the blood pump is operating.<br>• Within 30 s, the venous pressure must reach 200 mmHg, otherwise alarm A29 will be initiated.<br>• When the venous pressure reaches 200 mmHg, the blood pump is stopped for 5 s and SAK is closed by the Controller.<br>• Then Supervisor opens the SAK (however, SAK is still closed by the Controller).<br>• The venous pressure loss must not be higher than 30 mmHg during the 5 sec period while the blood pump is stopped, otherwise alarm A30 will be initiated.<br>• At the same time, the absolute difference value between the venous pressure PV and the prefilter pressure PBE is determined which may not be higher than 20 mmHg, otherwise alarm A31 will be initiated. | Step 9<br>Filling and rinsing | A29<br>A30<br>A31 |
| ***Heating function test***<br>Verification in step 9 of the filling and rinsing phase whether a correct temperature rise of the dialysate by the heating is performed.<br>The heating is switched on with a set temperature 43.5 °C. Test is successful if the temperature of the heater plate reaches 41.5 °C measured by the Controller and 42.0 °C measured by the Supervisor within 100 sec. Otherwise alarm A32 will be initiated. If the temperature reaches 45.0 °C, alarm A67 is activated. | Step 9<br>Filling and rinsing | A32<br>A67 |
| ***Check correct insertion reinfusion line***<br>Verification in step 9 of the filling and rinsing phase whether the reinfusion line is mounted correctly.<br>Test is successful if PDF variation during pressurization test is < +/-20 mmHg, otherwise alarm A25 will be initiated. | Step 9<br>Filling and rinsing | A25 |

# ANNEX 5 – H.E.L.P. TREATMENT UNIT

CE 0123

**Instructions for use – please read carefully!**

# H.E.L.P. Apheresis

### [1] Product description

The H.E.L.P. apheresis treatment unit is a medical device system for the extracorporeal treatment of plasma.
All components are
- sterile and pyrogen-free.
- intended for single use only.
- only to be used for the H.E.L.P. apheresis treatment.

**A H.E.L.P. apheresis treatment unit consists of:**

1 H.E.L.P. Futura Set consisting of:
1 H.E.L.P. Futura Kit
Support with integrated Venous Line, Plasma-Buffer Line, Filtrate Line, Connection Line, Dialysate Drainage Line, Venting Line, Haemoselect M 0,3 $m^2$ Plasma Filter, H.E.L.P. Precipitate Filter, H.E.L.P. Heparin Adsorber and H.E.L.P. Ultrafilter SMC 1.8.
1 Empty bag for priming
1 Arterial line
1 Dialysing fluid line
3 Drainage bags for dialysate
The H.E.L.P. Futura set is sterilised by ethylene oxide.

| | |
|---|---|
| 1 x 30 ml glass bottle | H.E.L.P. LDL-Apherese Heparin Sodium 10.000 IU/ml |
| 1 x 3000 ml bag | H.E.L.P. LDL-Apherese Sodium Acetate Buffer pH 4,85 |
| 3 x 5000 ml bags | H.E.L.P. BicEl bicarbonate solution |
| 2 x 3000 ml bags | H.E.L.P. NaCl 0,9% solution |
| 1 x 2000 ml double chamber bag | H.E.L.P. NaCl 0,9% DC solution |

All solutions are steam sterilised.

### [1.1] H.E.L.P. Heparin Sodium

Glass bottle with 30 ml of sterile heparin sodium solution
Intended only for extracorporeal application within the frame of the H.E.L.P. apheresis
Sterile and endotoxin free.

**Composition of the sterile heparin sodium solution**

1 ml solution contains:
10.000 IU heparin sodium according to 4$^{th}$ WHO-standard (porcine intestinal mucosae)
Sodium chloride
Water for injection
Benzylic alcohol as preservative
Sodium hydroxide/hydrochloric acid for pH adjustment

### [1.2] Plasma filter Haemoselect M 0.3 $m^2$

Hollow fibre filter for plasma separation

Technical Data

Housing

| | |
|---|---|
| Effective length: | 258 mm |
| Blood priming volume: | 28 ml |
| Plasma priming volume: | 125 ml |
| Blood side connector: | Connector according to EN 1283 / ISO 8637 |
| Plasma side connector: | Connector according to EN 1283 / ISO 8637 |

Membrane

| | |
|---|---|
| Material: | polyethersulfone |
| Effective surface: | 0.3 $m^2$ |
| Inner diameter: | 300 µm |
| Wall thickness: | 100 µm |
| Pore size: | 0.5 µm |
| Maximal inlet pressure: | 250 mmHg |
| Maximal transmembrane pressure: | 100 mmHg |
| Recommended blood flow: | 60 - 180 ml/min (max. 180 ml/min) |
| Recommended plasma flow: | 30% of blood flow |

### [1.3] H.E.L.P. Precipitate filter

Filter for the removal of the precipitate from the plasma buffer mixture within the context of the H.E.L.P. apheresis.

| | |
|---|---|
| Membrane material: | polyethersulfone |
| Effective surface: | 0.45 $m^2$ |
| Priming volume: | 800 ml |

### [1.4] H.E.L.P. Heparin Adsorber

Adsorber for the adsorption of extracorporeal heparin within the context of the H.E.L.P. apheresis

| | |
|---|---|
| Membrane material: | DEA-modified polyamide |
| Heparin adsorption capacity: | ≥ 300,000 IU |
| Priming volume: | 150 ml |

### [1.5] Ultrafilter SMC 1.8

Hollow fibre membrane filter for plasma dialysis within the context of the H.E.L.P. apheresis

| | |
|---|---|
| Material: | synthetically modified cellulose |
| Effective surface: | 1.84 $m^2$ |
| Priming volume: | 117 ml |
| Internal fibre diameter: | 200 µm |
| Wall thickness: | 8.5 µm |
| Maximum transmembrane pressure: | 600 mmHg |
| Ultrafiltration coefficient: | 10.3 ml $mmHg^{-1}h^{-1}$ |

### [2] Intended use

The H.E.L.P. apheresis treatment unit must be used only in connection with the H.E.L.P. apheresis device Plasmat® Futura from B. Braun Avitum AG.
The instructions for use given with Plasmat® Futura and the individual components must be followed.

### [2.1] Field of application

The H.E.L.P. apheresis treatment unit is used in connection with the Plasmat® Futura for the therapeutic removal of LDL- and VLDL-cholesterol, lipoprotein(a) and fibrinogen from plasma and is indicated in the case of:

1. Patients suffering from severe lipometabolic disturbances that cannot be sufficiently controlled through diet or medication, such as
   a. homozygous form of familial hypercholesterolemia;
   b. heterozygous form of familial hypercholesterolemia or secondary hypercholestorolemia, where the plasma LDL cholesterol concentration cannot be sufficiently controlled despite maximum dietary and medicinal therapy, high risk of arteriosclerotic complications or manifest coronary heart disease;
   c. strong increase in plasma lipoprotein(a) concentration (> 60 mg/dl) and a high risk of arteriosclerotic complications or manifest coronary heart disease.

   Dietary and medicinal lipid lowering therapies should be continued in order to achieve optimum success with the H.E.L.P. apheresis therapy.
2. Patients with acute hearing loss (hearing loss ≥ 15 dB in 3 frequency bands in the affected ear in relation to the unaffected ear) if treatment is started within a maximum of 7 days after the occurrence of the event.
3. Patients suffering from acute hyperlipidemia or fibrinogenemia for whom an acute and effective lowering of fibrinogen, LDL cholesterol, VLDL cholesterol or lipoprotein(a) is medically indicated.

Should only be applied following rigorous individual benefit-risk evaluation.

### [2.2] Instructions for use

- Remove the components of the H.E.L.P. treatment unit from the sterile packaging only immediately before use.
- The H.E.L.P. apheresis treatment unit must be set up onto Plasmat® Futura in accordance with the relevant instructions for use.
- The content of the bottle (30 ml) of H.E.L.P. heparin-sodium 10,000 IU/ml must be injected into a bag of sodium acetate buffer pH 4.85 through the injection port immediately before application.
- The patient must be heparinized with a medication suitable for this purpose before every H.E.L.P. apheresis treatment. The dosage should be selected in the same way as described for the haemodialysis. An initial dose of 35 IU of unfractioned heparin/kg BW are administered IV and 1,000-1,500 IU/h is administered continuously during the H.E.L.P. apheresis treatment. The dose must be correspondingly reduced for patients who receive oral anticoagulants, thrombocyte aggregation inhibitors, or other substances that increase the effect of heparin. Depending on the initial situation, it may be necessary to reduce the dose by a third or a half. The heparin administration is stopped approx. 30 minutes before the end of the H.E.L.P. apheresis treatment.
- The H.E.L.P. treatment unit must be fully prepared before the start of the H.E.L.P. apheresis treatment in accord with the instruction for use of the Plasmat® Futura.

### [2.3] Type and duration of use

Unless specified otherwise, the following dosage is recommended:
Disturbances in lipid metabolism: One H.E.L.P. apheresis therapy regularly every 7 – 14 days.
Hearing loss: One H.E.L.P. apheresis therapy within a maximum of 7 days after the occurrence of the acute event.
Acute hyperlipidemia or fibrinogenemia: One H.E.L.P. apheresis treatment every 1 to 3 days, until the normal plasma concentration has been reached.

**[3] Contraindications**

The H.E.L.P. apheresis treatment must not be applied in the case of
- Hemorrhagic diathesis
- Ulcers in the gastrointestinal area
- Haemorrhage
- Coagulation disorder and neoplasm
- Liver diseases
- Severe heart failure and valvular defect
- Condition following apoplexia
- Dementia
- Pregnancy and during lactation
- Children and infants in whose case the extracorporeal volume is a limiting factor.

**[4] Side effects**

Occasionally, the occurrence of
- Angina pectoris

has been observed

In rare cases, there are
- Heart rhythm irregularities and laboured breathing caused by the underlying disease
- Bradycardia
- Vasovagal syncopes
- Circulatory collapse
- Hypotonia
- Nausea/sickness
- Dizziness
- Headache
- Tiredness/exhaustion
- Tension and swelling of arms, hands and face
- Burning eyes
- Prolonged bleeding time
- Dyspnea
- Hypertonia
- Feeling hot, sweating
- Hypersensitivity reactions against the hydrophilic components of the tubing and filter material are generally rare in extracorporeal treatment procedures.

In isolated cases there is
- Iron deficiency anaemia
- Hypertonia and oedema formation in the case of patients with renal function impairment

Benzyl alcohol can cause hypersensitivity reactions in rare cases.

## [5] Precautions

### Before the treatment

- The H.E.L.P. apheresis should be applied and supervised only by physicians with sufficient experience in the execution of extracorporeal procedures for blood purification.
- Clinical reports and laboratory analysis data must be collected for every patient before the commencement and during the course of the therapy. Coagulation parameters and lipoprotein status must be verified and documented.
- A particularly careful benefit-risk evaluation must be carried out before the application of the H.E.L.P. apheresis in the case of patients suffering from C1 esterase inhibitor deficiency or hereditary C3 deficiency.
- Before starting the treatment, the entire H.E.L.P. system, i.e. all plasma carrying filters and lines, must be pre-rinsed with a total of ≥ 2400 ml of heparinized isotonic sodium chloride solution as described in the instruction for use of Plasmat® Futura. Otherwise there is a danger of hemolysis and/or allergic reactions such as, e.g. rise in body temperature, shivering, chilling, burning eyes and itchiness.
- The components of the H.E.L.P. apheresis treatment unit must not be used if the sterile packaging or the component itself is damaged.

### During the treatment

- In order to avoid haemolysis, gradually increase first the blood flow rate to reach the desired target value after 5 minutes. Subsequently, gradually increase the plasma flow rate to achieve the appropriate value after another 10 minutes.
- If it is necessary to replace individual components (filters, heparin adsorber), the component must be fully prepared (filled and rinsed) before being integrated into the H.E.L.P. apheresis treatment unit in accordance with the instruction for use of the component. The procedure for the replacement is described in the instruction for use of Plasmat® Futura.
- During treatment plasma buffer mix shall be clear after the H.E.L.P. precipitate filter.
- Emergency medication for the treatment of shock must be available.
- If disruptions occur within the course of the treatment cycle, the treatment must be stopped immediately and the cause must be detected and corrected.
- If there are indications that the heparin adsorber is not functioning properly (e.g. adsorber is not completely filled with fluid, air bubbles in the adsorber), or if the plasma before the heparin adsorber is cloudy, coagulation parameters should be controlled. If the partial thromboplastin time (aPTT) and/or the thrombin time (Tt) are more than 100 seconds at this point or during the check at the end of the treatment, the measurement must be repeated after one hour for subsequent monitoring. If this still shows increased times, the patient must be monitored in hospital with a regular aPTT, Tt, Quick's test and fibrinogen check until the coagulation values have normalised.

### After the treatment

- In the case of the H.E.L.P. apheresis, parallel medication can be eliminated to differing extents. This means that the level of active substances in a patient who is receiving H.E.L.P. treatment can be lowered up to 60 %. If possible, any medication should be taken after the H.E.L.P. treatment
- The H.E.L.P. apheresis treatment takes between 2 and 3 hours, after which the patient is immediately mobile and can leave the clinic, insofar as the results of aPTT and Tt allow it.
- The components of the H.E.L.P. apheresis treatment unit can be potentially contaminated by the agents of transmittable diseases after treatment. After use the components must be disposed of in accordance with local regulations.

### Recommended laboratory tests

- In the case of long-term therapies, the Hb, vitamin E and C3/C4 plasma levels should be regularly monitored. In the case of patients with low initial values of iron and fibrinogen, it is recommended that the subsequent course of the respective serum concentration is monitored.
- It is advisable to monitor the immunoglobulin level at appropriate intervals.
- In order to monitor the therapy, the partial thromboplastin time (aPTT), the thrombin time (Tt) and fibrinogen or the thrombin time, the Quick's value and fibrinogen must be controlled at the end of each treatment.

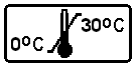
- If the values for the partial thromboplastin time (aPTT) and the thrombin time (Tt) or the thrombin time and the Quick time are above 100 seconds at the end of a treatment, it can be assumed that the heparin adsorber is not functioning sufficiently.

**General notes**

- The components of the H.E.L.P. apheresis treatment unit are intended for single use only. Do not re-use!
- The components of the H.E.L.P. apheresis treatment unit must not be used after the expiration date indicated on the components and the outer packaging.
- Use only if the sterile packaging and the individual components are undamaged.
- The fibrinogen, antithrombin III, plasminogen and some plasma proteins, such as e.g. C3-C4 complement and C1 inhibitor levels are decreased through the heparin treatment of the plasma under the conditions of the H.E.L.P. apheresis. The levels normalise in the case of antithrombin III within 24 hours, in the case of fibrinogen, plasminogen and the plasma proteins within 7 days.
- In the case of patients with low initial fibrinogen levels it must be ensured that the plasma volume that is to be treated is decreased to such an extent that the fibrinogen does not fall below the critical value of 60 mg/dl.
- It is possible that plasma proteins like plasminogen, complement factors C3 and C4, C1 inhibitor, albumin, antithrobin III and ceruloplasmin are co-precipitated during the H.E.L.P. apheresis. HDL is only precipitated in very small quantities. Negative clinical effects through the precipitation reaction do not result because of the short regeneration time.
- Protamin-chloride/-sulphate should only be administered to reverse the heparin effect in the case of life-threatening haemorrhaging, as there is a danger of thrombosis if the heparin is completely neutralised.
- Caution: Federal Law (U.S.) restricts this device for sale by or on order of a physician.
- Waste disposal according to the local regulation.

B. Braun Avitum AG

Schwarzenberger Weg 73-79
D-34212 Melsungen

| | |
|---|---|
|   | Sterilized by ethylene oxide |
|   | Steam sterilized |
|  | See instructions for use |
|  | Do not re-use |
|   | Article number |
|   | Batch number |
|  | Expiry date |
|   | Storage temperature |