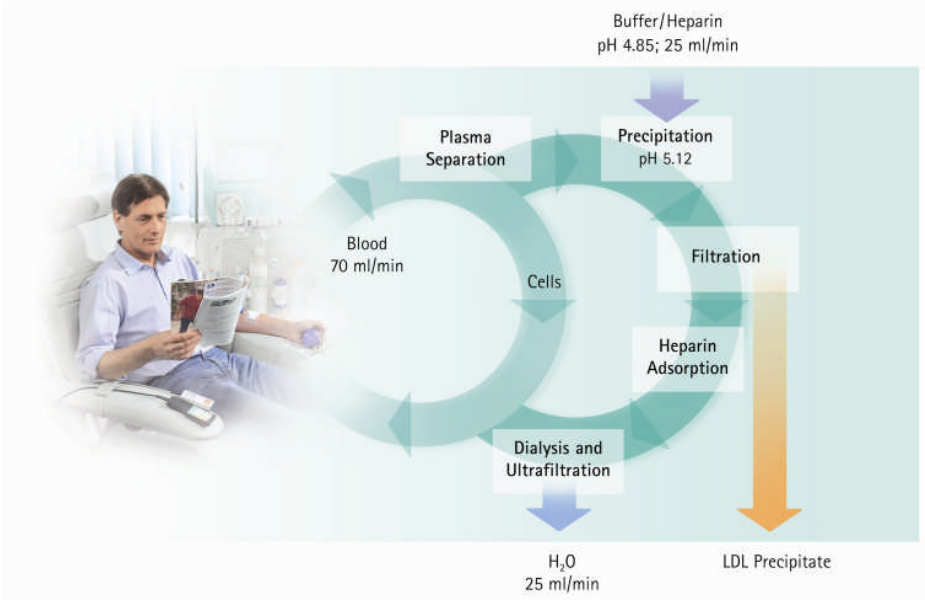
Brief Instructions Plasmat® Futura
Software Version 2.6.01



Heparin induced **E**xtracorporeal **L**DL **P**recipitation

Filters and Lines

- 1 **H.E.L.P. Futura Set** consisting of:
  - 1 H.E.L.P. Futura Kit
    Base plate with attached venous line, plasma-buffer line, filtrate line, connection line, dialysate drainage line, filter venting line and reinfusion line as well as 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 x 5 l empty bag for rinse solution
  - 1 arterial line
  - 1 dialysate line
  - 3 x 7 l empty bags for dialysate

Solutions

- 1 x 3 l H.E.L.P. acetate buffer (pH 4.85)
- 3 x 10 ml H.E.L.P. heparin sodium (300.000 IU)
- 2 x 3 l H.E.L.P. 0.9 % NaCl saline solution
- 3 x 5 l H.E.L.P. BicEl bicarbonate solution for plasma dialysis
- 1 x 2 l H.E.L.P. 0.9 % NaCl saline solution in double-chamber bag

Miscellaneous

- Perfusor syringe 30 ml (Omnifix®) for heparin solution
- Heparin 5000 IU/ml
- Puncture needles, cannulas, swabs
- Syringes for blood samples
- Laboratory test tubings, possibly adapters
- Tourniquets, clamps
- Skin disinfectant, gloves

These Brief Instructions are no substitute for the Operating Manual !

PREPARATION

Machine

- Switch on the machine (main switch on the rear)

An automatic self-test is performed. During this period, neither the pressure transducers nor the load cell may be loaded. The piston pusher of the heparin syringe pump must be lightly pulled back and the clasp must be latched

- Make sure that you hear the **four different alarm signals** during the self-test, that you see **three rows of figures from 0 to 9**, and that the **LEDs** alongside the screen flash.
- Check the three rows of figures which are shown on the monitor after the end of the self-test. The rows of figures must be displayed completely in the sequence from 0 to 9 and in three different fonts. If the rows of figures are correct, select <**End**>, if not, select <**Retest**> to repeat the self-test.
- Press the  key to go to the Start screen.

Rinse bags

- Each of the **3 l 0.9 % H.E.L.P. NaCl bags** must be mixed with **7500 IU heparin**.

Bicarbonate bag

- **Prepare** all 3 bags with **H.E.L.P. BicEl bicarbonate solution** by transferring the fluid from the small to the large chamber. Thoroughly mix the solution.

Heparin solution

- Prepare the **heparin solution** for the 30 ml Perfusor syringe 30 ml (Omnifix®) e.g. for 20 ml heparin solution with 1000 IU/ml
  ➔ Mix 4 ml heparin (1ml = 5000 IU) + 16 ml 0.9% NaCl solution.

IV-pole

- IV-pole with
  - 5 l empty bag (connection to the top)
  - 1 heparinized 3 l NaCl bag
  - Load the 2 l NaCl double-chamber bag.

Load cell

- Load cell with
  - 3 empty bags
  - 1 heparinized 3 l NaCl bag
  - Load 3 bicarbonate solution bags.

H.E.L.P. Futura Set

Attach the **H.E.L.P. Futura Kit**. Place the plastic plate onto the bottom support. Press the plate against the front and secure the top seat with the upper holder. From the top to the bottom:

- **Insert the pump segments** into the upper pumps (buffer/plasma segment individually)
- **Insert** the two **air chambers** (filtrate and precipitation chambers) into the level monitoring devices **and secure them**.

PREPARATION

- **Screw on** both **pressure transducers** of the plasma and connection line.
- Firmly insert the **filtrate line to the heparin adsorber** into the heparin adsorber clamp (**HAK**).
- **Insert the venous line** in the safety air detector (**SAD**) and in the safety air clamp (**SAK**); **screw on** the pressure transducer (**PV**); **connect the venous line** to the **empty bag** on the IV-pole.
- **Connect the buffer line** to the saline bag on the load cell.
- **Connect the dialysate line** (3-piece) to the 3 drain bags on the load cell.
- **Connect** the **reinfusion line** to the connection of the 1.5 l compartment of the **NaCl double-chamber bag** and fill the line manually. Afterwards close the **clamp**.

Arterial line

- **Screw** the patient-side connection of the **arterial line** to the **3 l NaCl bag** on the IV-pole**.**
- **Insert the pump segment** into the blood pump.
- **Insert the air chamber** into the holder.
- **Screw** the **pressure transducer** in front of the pump segment (**PA**) to the connector in front of the blood pump.
- **Screw** the **pressure transducer** behind the pump segment (**PBE**) to the connector behind the blood pump.
- **Screw on the feeder of the arterial line to the plasma filter**.

Heparin syringe

- **Screw** the prepared **heparin syringe** onto the heparin line. **Vent** the line **by hand** up to the T-piece and **insert** it into the **heparin syringe pump**.

The safety brace of the heparin pump must latch in!
Avoid a tilted position of the syringe!

Dialysate line

- **Insert the warming bag** of the dialysate line with the **blue Hansen connector** pointing **upward** into the **plate warmer**.

The bag must be placed flat on the heating element. The cover of the heating plate must be completely closed with the safety lock!

- **Connect** the blue **Hansen connector** to the upper end of the **dialyzer**.
- **Connect** the connections of the **dialysate line** with the **bicarbonate bags**.
- **Open the seals** of the **bicarbonate bags**.
- Follow the line and **insert** the **pump segment** into the dialysate pump.
- **Screw** the pressure transducer (**PDI**) to the connector.
- **Insert** the feed **line to the heating plate** into the air detector (**DAD**).

PRIMING

Priming

Check again whether all connections are tight and the seals of all bags are open.

- Press the ↵ key to change to the **priming mode**.
- The message <**W18: Break seals and open all clamps !**> is displayed on the monitor. Confirm with the OK key.
- Press the ↵ key to **start** the automatic **priming and rinsing**.
- The message <**W01: Plasma pump starts after pressurization blood side**> is displayed.

Filling the dialyzer

- When the message <**W04: "Turn dialyzer (blue side down) !"** is displayed, turn the dialyzer and press the OK key.

Always ensure that the hose lines are not kinked!

Other preparations

- While the machine rinses fully automatically and performs various tests, the following can be prepared:
  - Add 300,000 IU H.E.L.P. heparin sodium to the buffer bag and mix thoroughly.
  - Complete the treatment protocol.
  - Take blood samples (e.g. cholesterol and coagulation status before and after the treatment)
  - Prepare puncture instruments and initial heparin
  - If required, set therapy parameters.

Rinsing

- When the **minimum rinsing volume** of **2400 ml** is reached after **fully automatic rinsing**, all pumps stop.
- Confirm the message <**W14: Rinsing completed. Set new value to continue rinsing**> with the OK key.
- The <**Therapy**> function is active in the menu selection (black labeling).
- Confirm the message <**W32: Activate therapy mode ?**> with the OK key.

Buffer bag

- Hang the **buffer bag** onto the load cell and **connect** the **buffer line**.
- Remove the **NaCl bag** from the load cell.

Venous line

- **Connect** the **venous line** to the 3 l NaCl bag on the IV-pole.
- **Remove** the **empty bag** with the rinse fluid from the IV-pole.

Connecting the patient

- Take the weight and blood pressure of the patient.
- **Puncture with the arterial needle**, check for correct seating, fix it in place, take blood samples, rinse.
- **Puncture with the venous needle**, check for correct seating, fix it in place, administer the initial heparin, rinse.
- Confirm the message <**W15: Connect buffer – seal and clamps opened ?**> with the OK key.
- **Connect the arterial line** to the patient**.**
- **Start the blood pump** (preset value is 40 ml / min)

Monitor the arterial pressure (PA) as well as the inlet pressure of the blood into the plasma filter (PBE)!

- When the **blood circuit** has been **filled with blood, stop the blood pump**.
- **Connect the venous line** to the patient. **Start the blood pump**.

Monitor the venous pressure (PV)!
The pressure should be within the range 20 - 60 mmHg.

Circulate the blood for about 2 minutes in the plasma filter. In doing so adjust the blood flow step by step monitoring PA, PBE and PV.

Performing the therapy

- Start the therapy with <**Start Therapy**> and enter the time.
- **Adjust the plasma flow** step by step monitoring PV and PPL.

RULES:
The plasma flow should be approximately 30% of the blood flow but should not exceed 35 ml/min.
Changes of PPL and TMP must be taken into account when adjusting the plasma flow !
This ensures that the separation of plasma is performed spontaneously.

- **Record the values in the log**, repeat the recording during the therapy every 30 minutes.

The anticoagulation (heparinization) should be controlled with coagulation checks (ACT or PTT)!
The testing should be done every 30 minutes.
The sample can be taken from the port of the arterial line.

- At the **end of the therapy,** the machine switches **automatically** to the **bypass mode.**
- Record the time, the treated plasma amount and the therapy time in the log.
- Confirm the message <**W06: Therapy completed !**> with the OK key and change to the **reinfusion mode**.
- Press the OK button to confirm when asked <**W32: Do you want to switch to the reinfusion phase?**>

REINFUSION AND TERMINATION

Preparation

- The message <**W11: 1) Connect reinfusion and buffer lines to saline solution 2) Clamp plasma line at out of plasma filter 3) Turn plasma and precipitate filters 4) Turn heparin adsorber**> is displayed.
- Confirm the performance of the individual steps with the OK key.

The blood pump continues to run with 40 ml/min. All other pumps have stopped.

Plasma reinfusion

Start the **plasma reinfusion** by selecting the <**Start Plasma**> menu item in the menu bar and pressing the key.
The default setting of the reinfusion pump is 30 ml/min.

If a pressure rise of the PPF and/or PDF occurs, the reinfusion flow has to be reduced.
The blood pump speed can be adjusted independent of the reinfusion flow.

- The machine stops the plasma-side pumps when a **reinfusion volume** of **400 ml** (default setting) has been reached.
- The following message is displayed: <**W12: Plasma Reinfusion completed ! For Blood Reinfusion stop Blood Pump (do not press 'OK') or for further Plasma Reinfusion press 'OK' to proceed.**>.

The reinfusion volume can be manually increased up to 1000 ml, if necessary.

Blood reinfusion Part 1

- **Stop the blood pump** (as long as the blood pump is running the blood reinfusion is not active).
- Under **reinfusion type,** select <**blood reinfusion**> and confirm by pressing the return button.
- The message <**W21: Connect art. line to saline solution bag. Connect reinfusion line to venous chamber**> is displayed.
- After having performed these handling steps confirm with the OK key.
- **Take blood samples**.
- **Start the blood pump**.

After a reinfusion volume of 150 ml, the warning <W41: Open plasma clamp and close venous clamp.> will be displayed.

Blood reinfusion Part 2

When a blood reinfusion volume of 150 ml has been reached the warning W41 appears: **<W41: Open plasma clamp and close venous clamp!>**

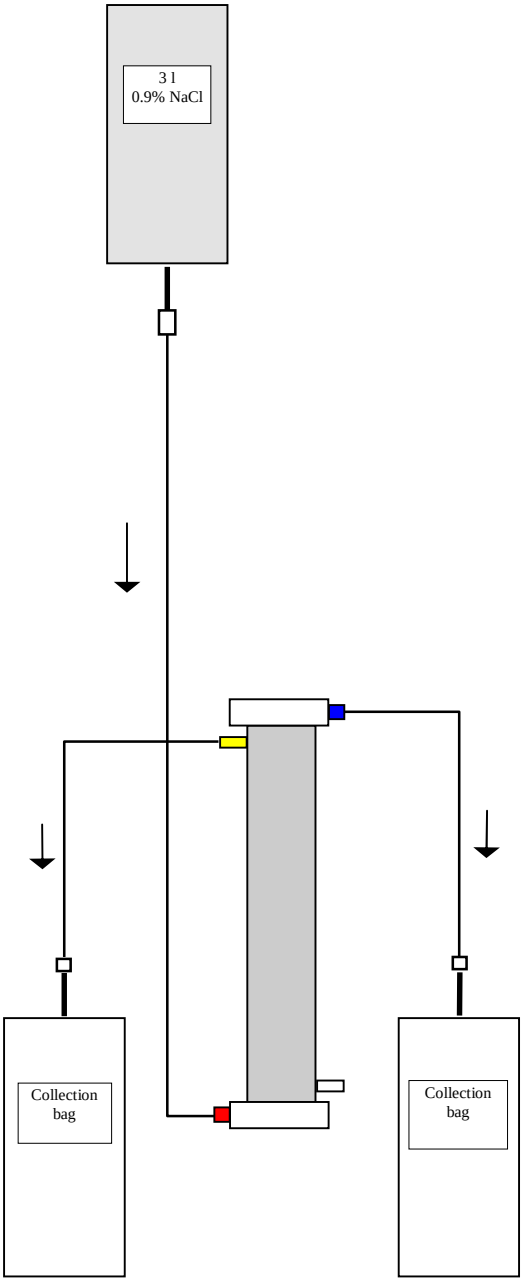
- **Open** the **clamp** of the **plasma line behind the plasma filter** and **close** the **clamp** on the **venous line behind the plasma filter**.

The saline is now pressed through the membrane = plasma-side rinsing of the plasma filter.

- When a **blood reinfusion volume of 300 ml** (default setting) has been reached, the **blood pumps stop**.
- **Remove the venous line** from the patient.
- Take the weight and blood pressure of the patient.
- Change to the Start screen by selecting <**New Therapy**> in the <**Additional Functions**> menu and confirmation with the OK key. The machine can now be used for the next therapy or it can be switched off.

TABLE OF PLASMAT FUTURA PRESSURE VALUES			
	Work Range[1] mmHg	Limits[2] mmHg	* Function: • Cause of Alarm
Blood-Side Pressures			
PA Arterial pressure	-60 - +10	-150 ÷ +100 (m = -250/+200)	* Monitors the arterial needle • When ↓↓: Hypotension? Needle? In v.v. treatment congestion, muscle pump, local warmth? If necessary, reduction of blood flow
PBE Plasma filter pre-pressure	+90 - +140	PBEref-40 ÷ PBEref+80	* Monitors the plasma filter • When ↑↑: VP? Coagulation? If necessary, reduction of blood and/or plasma flow, rinse plasma filter, change plasma filter • When↓↓ (rare): VP? Hypotension?
PV Venous pressure	+20 - +50	PVref-20 ÷ PVref+40 (m = window)	* Monitors the venous needle * Should not exceed 60 mmHg • When↑↑: Needle? Coagulation? Coagulation in ven. chamber? • When ↓↓: Hypotension? Disconnection?
Plasma-Side Pressures			
PPL Plasma pressure	+20 - +50	-10 ÷ +200 (m = -20)	* Regulates the plasma flow: If the pressure sinks below the set PPL threshold, the plasma flow will be reduced. • When ↓↓: Coagulation? Reduce plasma flow, rinse plasma filter, change plasma filter
TMP Transmembrane pressure	+20 - +60	-450 ÷ +100 (m = +200)	* TMP=(PBE+PV)/2-PPL applies * Monitors the plasma filter * Should not exceed 100 mmHg • When ↑↑: Coagulation? If necessary, reduction of blood and/or plasma flow, rinse plasma filter, change plasma filter
PPF[3] Precipitate filter pressure	+150 - +300	-20 ÷ +450 (m = -50)	* Monitors the precipitate filter * Monitors the buffer bag and line • When ↑↑: Air filter of precipitate filter? Precipitate filter ? PDF↑? Dialyzer? • When ↓↓: Buffer bag? Buffer line?
PDF[3] Dialyzer pressure	+120 - +270	-50 ÷ +350 (m = +350)	* Monitors the dialyzer • When ↑↑: Plasma flow? Dialyzer? If necessary, reduce plasma flow, change dialyzer. • When ↓↓ (rare): Plasma flow? Dialyzer leak ?
PDPA Prec./adsorber pressure drop	+20 - +50	-450 ÷ +150 (m = 200)	* PDPA=PPF-PDF applies * Monitors the precipitate filter and the heparin adsorber • When ↑↑: Precipitate filter? Heparin adsorber ?
PDI Dialysate pressure	+60 - +80	-50 ÷ +200	* Monitors the dialysate flow • When ↑↑: Warming bag? Dialysate line? Empty bag ? • When ↓↓ (rare): Bicarbonate bag?

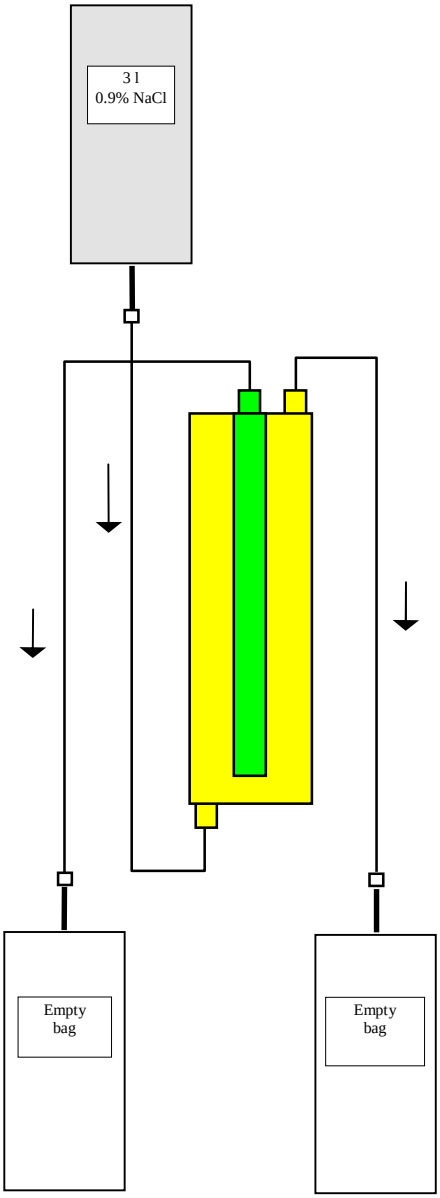
[1] These pressure values are valid for a normal hematocrit, blood flow 60-120 ml/min and plasma flow 20-35 ml/min
[2] Above the limits, the max. system pressure is still at 450 mmHg
[3] PDF and following PPF can vary in a large range due to inconstant flow between plasma and reinfusion pump
m= these parameters can still be set individually by the user.



Changing the Plasma Filter

Material	Article number
Haemoselect M 0.3 m²	7210694
2 x 3 l 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	

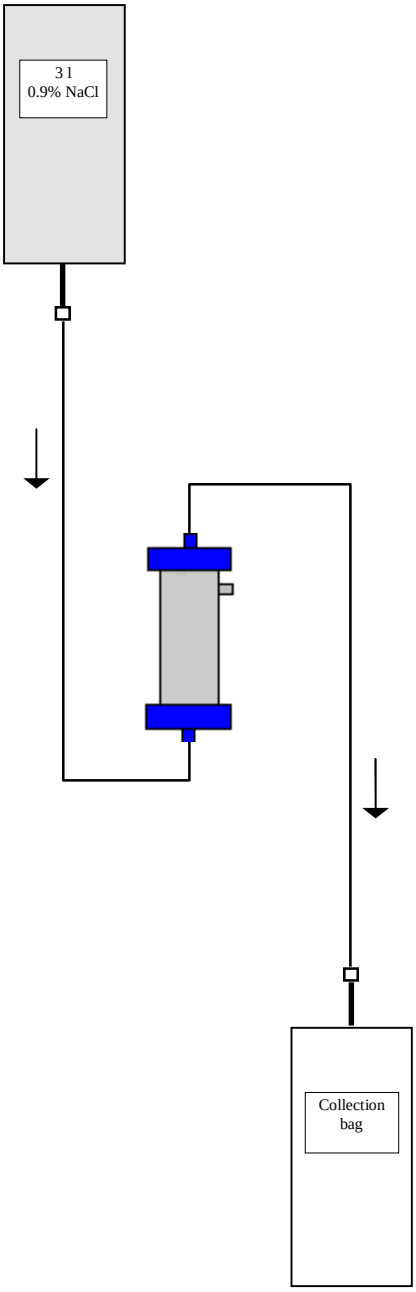
- Mix 7500 IU heparin into the H.E.L.P. 0.9% NaCl solution.
- Attach a connection line to the NaCl solution, fill the line and connect it with the blood-side inlet of the filter.
- Attach the remaining connection lines and the collection bags as shown in the Figure with the plasma and blood side of the filter and clamp shut the line on the plasma side.
- Allow the rinse solution to flow by means of gravity into the blood-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 plasma-side line when approximately half of the rinse solution has flown into the blood-side collection bag and clamp shut 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 line, remove the old filter and connect it 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.



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

Material	Article number
H.E.L.P. precipitate filter	706101A
2 x 3 l collection bags	7210543
3 l 0.9 % H.E.L.P. 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.
- Attach the remaining connection lines and the collection 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 collection bag and clamp 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 the bags.
- Switch the machine to bypass mode by selecting **<Stop Priming>** or **<Stop Therapy>** in the menu bar.
- 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>**.
- 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.



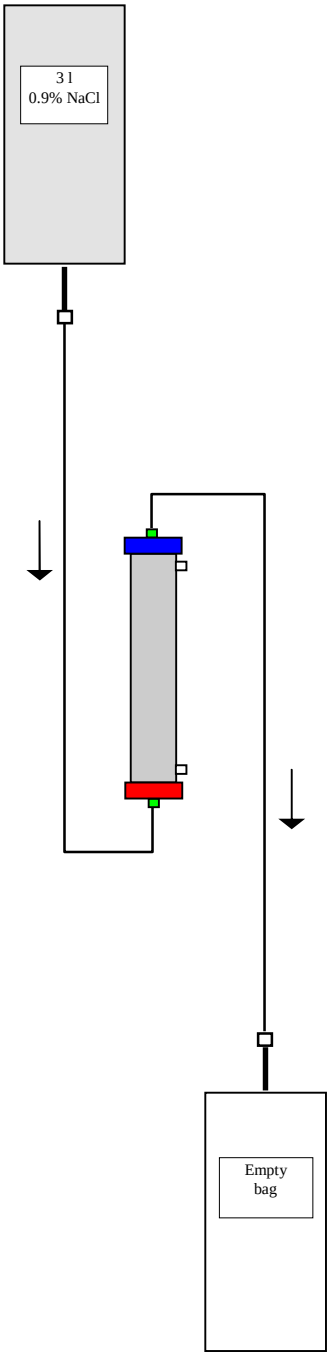
Changing the H.E.L.P. Heparin Adsorber

Material	**Article number**
H.E.L.P. heparin adsorber	7210688
1 x 3 l collection bag	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 inlet side of the heparin adsorber.
- Attach the second connection line and the collection bag as shown in the Figure with outlet side of the heparin adsorber.
- Allow the rinse solution to flow by means of gravity into the collection 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 filter!),
- Switch the machine to bypass mode by selecting **<Stop Priming>** or **<Stop Therapy>** in the menu bar.
- 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 absorber with the connection lines on rinse solution and collection bag.

Reopen the filtrate and connection lines and continue the interrupted phase by selecting **<Start Priming>** or **<Start Therapy>**.

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



Accessories	Article number
H.E.L.P. Ultrafilter SMC 1,8	7203136.
1 x 3 l collection bag	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 collection 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 all connection lines when approximately 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.
- 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 line. Connect the old filter with the connection lines to rinse solution and collection bag.
- Plug the Hansen connectors from the old to the new filter (hold old filter horizontally!). Observe the color marking. Insert the new filter with the blue end down into the holder.
- Fill the dialysate side of the filter by manually turning the dialysate pump.
- Reopen the connection and reinfusion lines and continue the interrupted phase by selecting **<Start Priming>** or **<Start Therapy>**.

Observe the necessary hygienic precautions when preparing, performing and terminating the therapy and when changing parts of the treatment unit.

H.E.L.P. Futura

Patient:	
Date:	**Treatment No.:**
Physician in charge:	**Nurse in charge.:**

Set (Lot No.) ..... **BicEl (Lot No.)** .....

Plasma filter (Lot No.) ..... **Heparin Adsorber (Lot No.)** .....

Acetate buffer (Lot No.) ..... **H.E.L.P. Heparin Sodium 30 ml (Lot No.)** .....

Access..... **Initial heparin** ..... **IU** **Heparin rate.** ..... **IU/h**

Parameter Overview							
Therapy Time h:min							
Plasma Volume ml							
Patient Balance g							
Blood Flow ml/min							
Plasma Flow ml/min							
Return Flow ml/min							
ACT/aPTT sec							
Heparin Flow ml/h							
Heparin Bolus ml							
Autostop Heparin min							
Tot. Hep. Infused ml							
Temperature °C							
Rinsing Volume ml							
Reset Balance Volume g							
PA mmHg							
PBE mmHg							
PV mmHg							
PPL mmHg							
TMP mmHg							
PPF mmHg							
PDF mmHg							
PDPA mmHg							
PDI mmHg							
PPL Threshold mmHg							
Ratio Dialysate/Plasma							

Start ..... **h:min**

BP before ..... **mmHg**

BP after ..... **mmHg**

Pulse before .....

Pulse after .....

Temp. before ..... **°C**

Temp. after ..... **°C**

Weight before ..... **kg**

Weight after ..... **kg**

Weight difference ..... **kg**

Fibrinogen after ..... **mg/dl**

Quick % / INR after .....

Plasma quantity ..... **ml**

Therapy time ..... **h:min**

End ..... **h:min**

Complaints after the last therapy .....

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Remarks .....

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H.E.L.P. – Futura

Patient:	
Date	**Treatment No.:**
Physician in charge:	**Nurse in charge.:**

Set (Lot No.) ..... **BicEl (Lot No.)** .....

Plasma filter (Lot No.) ..... **Heparin Adsorber (Lot No.)** .....

Acetate buffer (Lot No.) ..... **H.E.L.P. Heparin Sodium 30 ml (Lot No.)** .....

Access..... **Initial heparin** ..... **IU** **Heparin rate.** ..... **IU/h**

BP before ..... **mmHg** **Pulse before** ..... **Weight before** ..... **kg**

Start .....**h:min**

Main Parameter									
Blood Flow ml/min									
Heparin Flow ml/h									
PA mmHg									
PBE mmHg									
PV mmHg									
Plasma Flow ml/min									
Therapy Time h:min									
Plasma Volume ml									
Patient Balance g									
PPL mmHg									

End ..... **h:min** **Plasma quantity** ..... **ml** **Therapy time** ..... **h:min**

BP after ..... **mmHg** **Pulse after** ..... **Weight after** ..... **kg**

Complaints after the last therapy.....

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Remarks .....

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