6. Plasma Therapy

6.1 PEX

6.1.1 DISPOSABLE KIT SETTING UP

The disposable kit components must be installed and connected following the sequence described in the pictures of the next pages.

N.B. The lines are colour-coded.

The operator is asked to install and connect the disposable components

1. bags, plasmafilter

2. arterial line (red)

3. venous line (blue)

4. plasma outlet line (orange)

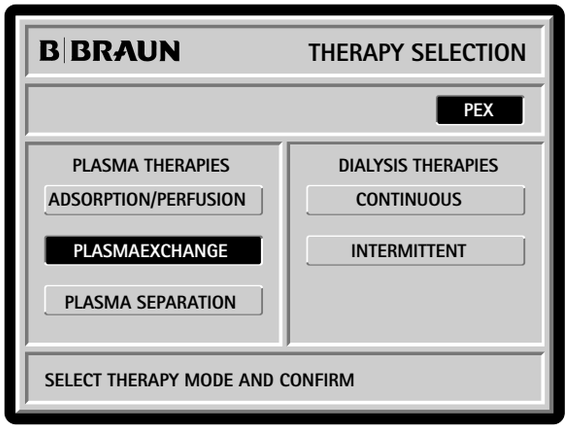
5. substitution line (green)

The setting up procedure can be started only after the unit has been switched on and the following controls have been performed:

- software CRC
- characters on the display
- empty load cell value (see General Operations, chp. 3)

SWITCHING ON

Make sure no bags are hooked to the holder of the weighing system. Answer the questions displayed on the screen by pushing EQ push-button. If the characters and the load cell calibration are OK, the therapy selection menu lis displayed (see chp. 3), then follow the instructions on the screen.



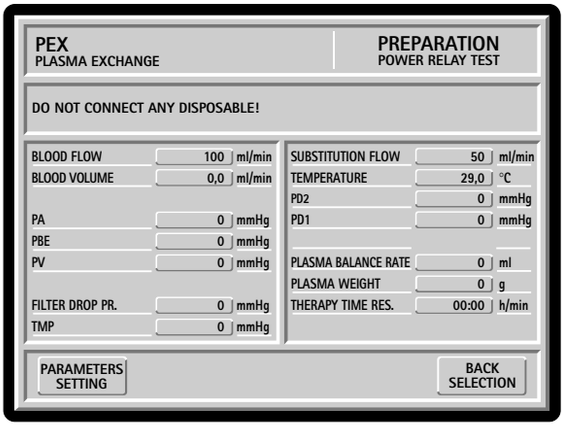
6.1.2 Therapy Selection

Select PLASMAEXCHANGE (PEX)

In Therapy Selection, after activating the appropriate therapy, a blinking inverse string appears at the supervisor position for a few seconds and the EQ key lights up.

If the user does not press the EQ key, the blinking string disappears (the light of EQ key goes out) and the machine remains in Therapy Selection status.

If the user presses the EQ key while the blinking string is on the Preparation phase will be started. The status line changes to PREPARATION.



6.1.3 Preparation

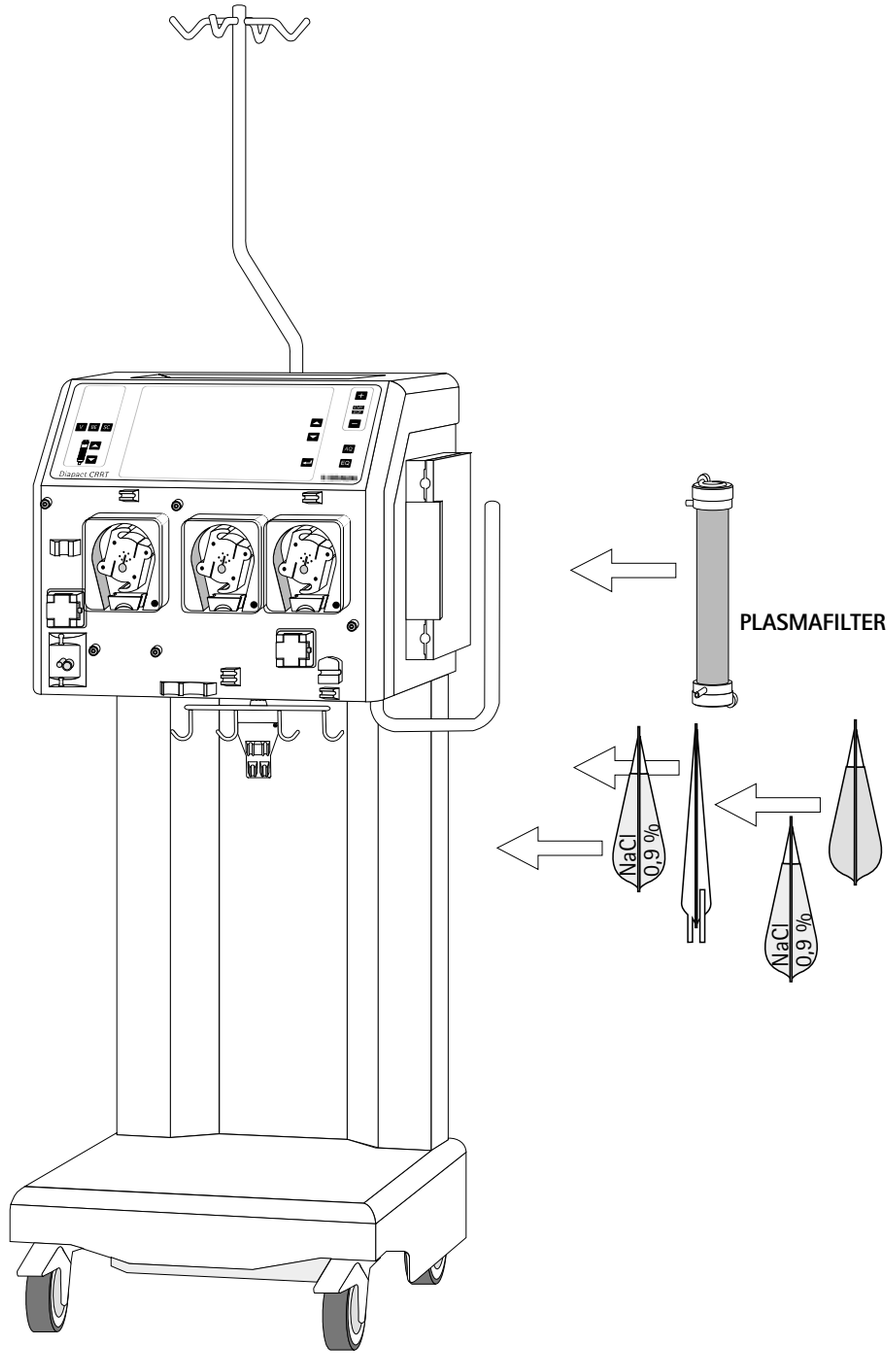
After the second step of Therapy Selection, the system displays the main screen of the PREPARATION phase, then starts the hardware test.

Bags and Plasmafilter Setting Up

Hook the following components to the holder of the weighing system:

- 2 saline bags
- 1 plasma collecting bag
- 1 substitution fluid bag

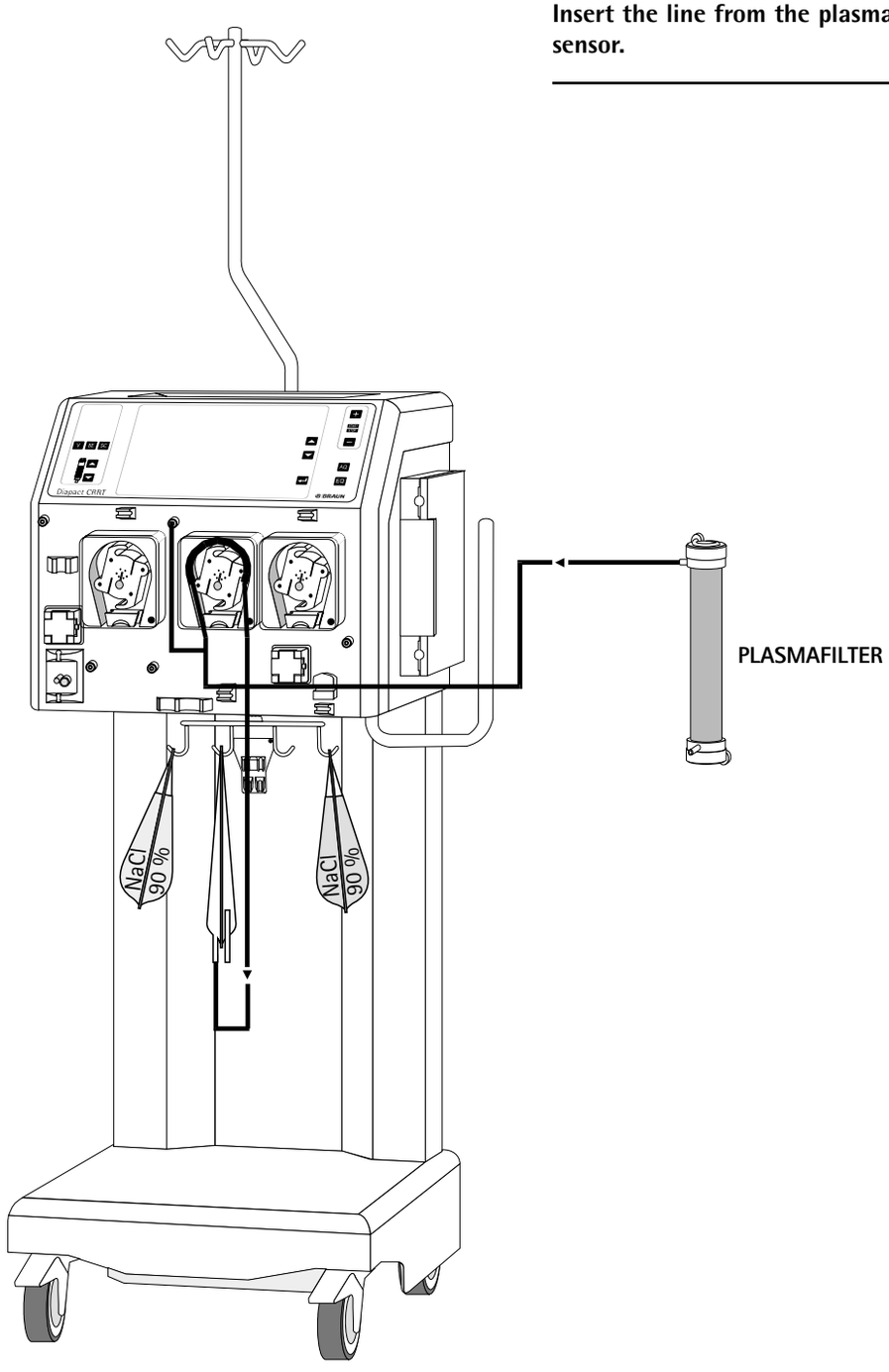
Place the filter on its holder.



Plasma Outlet Line Setting (orange)

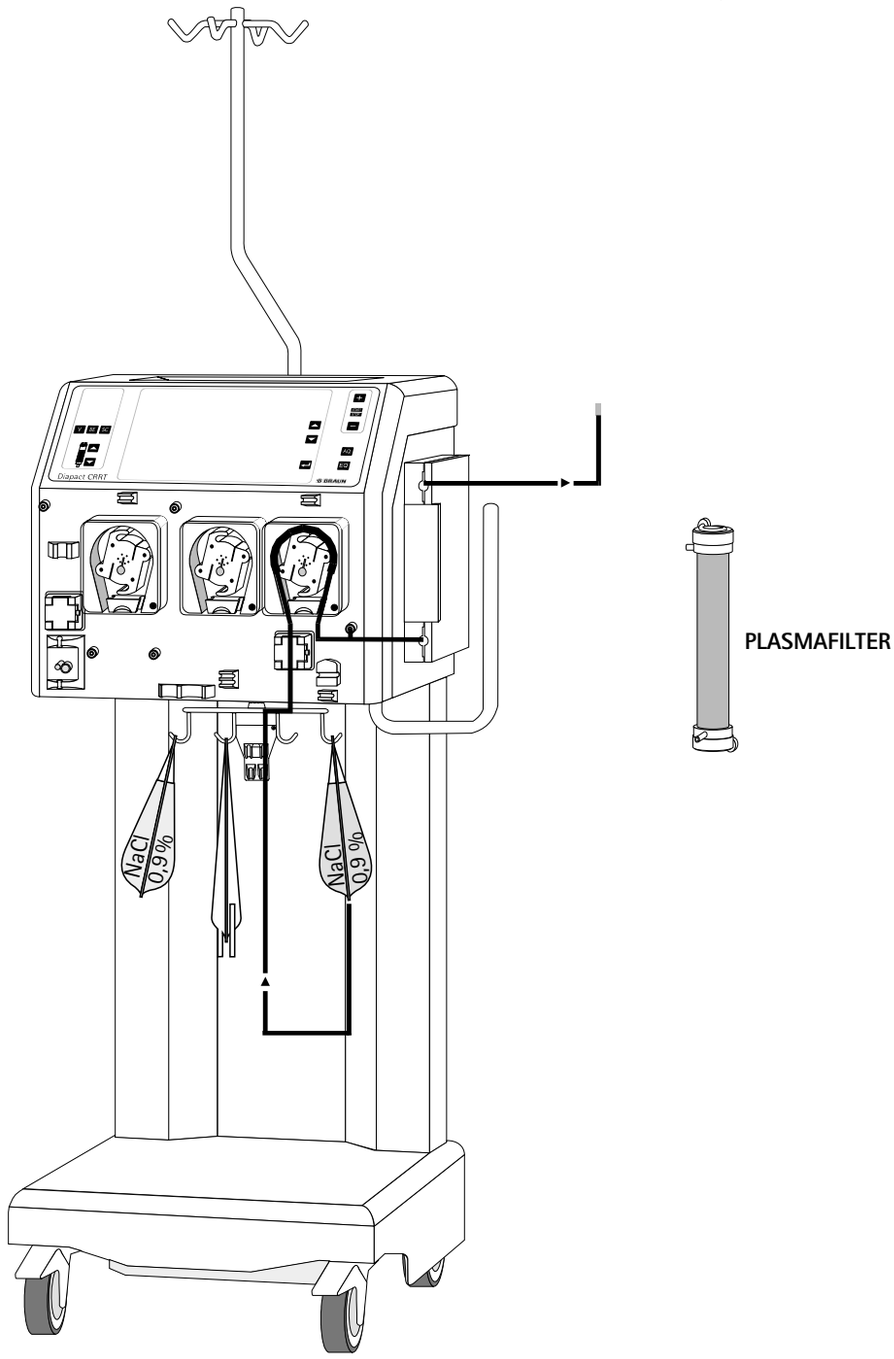
1. Mount the pump segment on the plasma pump.
2. Connect the pre-pump transducer protector to PD2 pressure measurement connector.
3. Connect the line end adapter with red Luer-lock connector to the collecting bag.
4. Connect the line end adapter with Hansen connector (or Luer-lock, according to the filter type) to the plasma port beside the venous blood port of the filter.

Insert the line from the plasma port into the Blood Leak sensor.



Plasma Substitution Line Settinh Up (green)

1. Mount the pump segment on the substitution pump.
2. Insert the pump inlet tube into the Air Detector below.
3. Connect the pre-pump end adapter to the saline bag and fix the line without stressing at the bag holder.
4. Connect the terminal with transducer protector to PD1 pressure measurement connector.
5. Insert the warmer bag into the plate warmer, then close carefully to get the lock system to the right position.
6. Connect the plasma substitution line end adapter (plate warmer outlet) to the venous line.



Arterial Line Setting Up (red)

1. Mount the pump segment on the blood pump.

WARNING!
The pump segment shall be mounted clockwise! (follow directing arrows).

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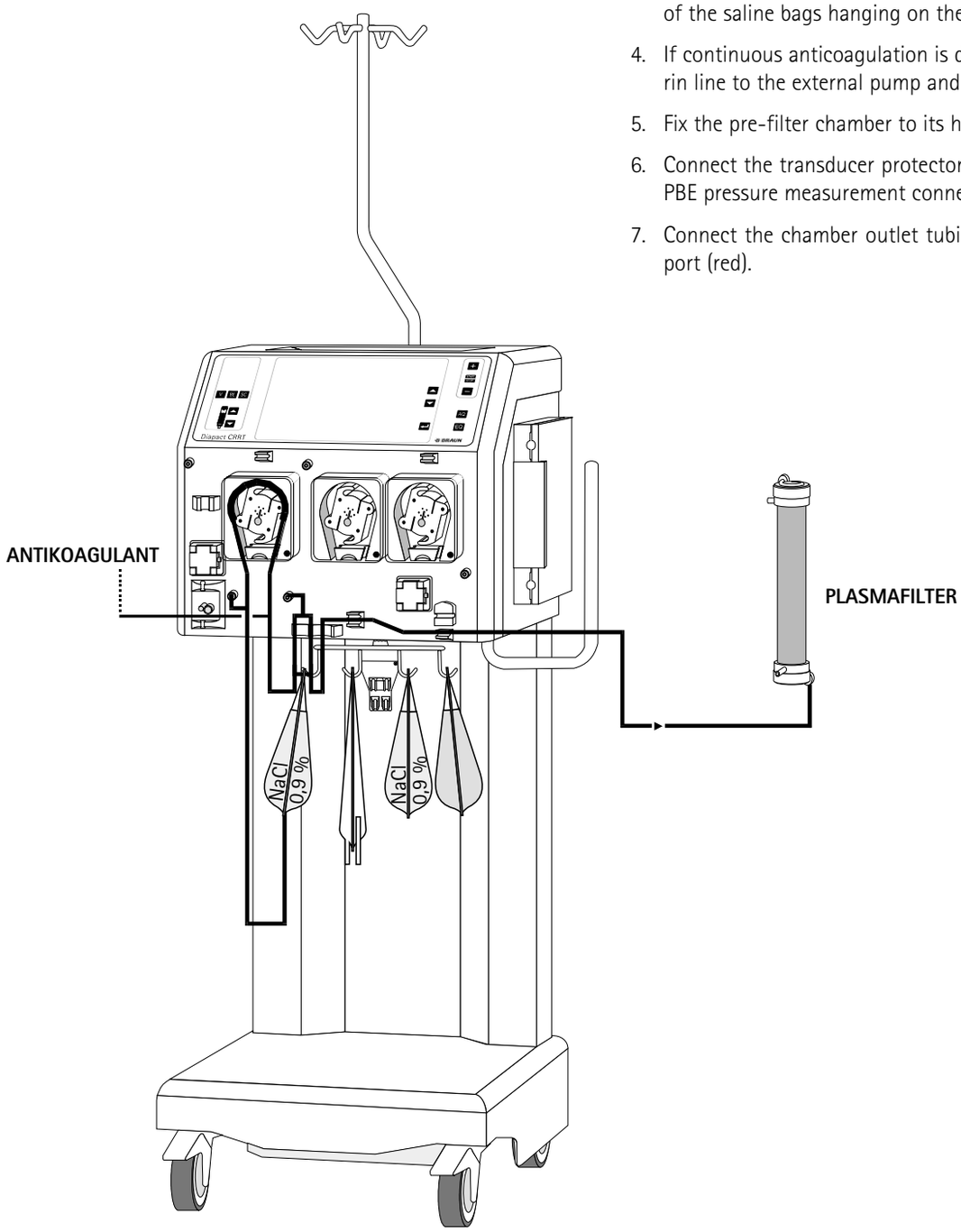
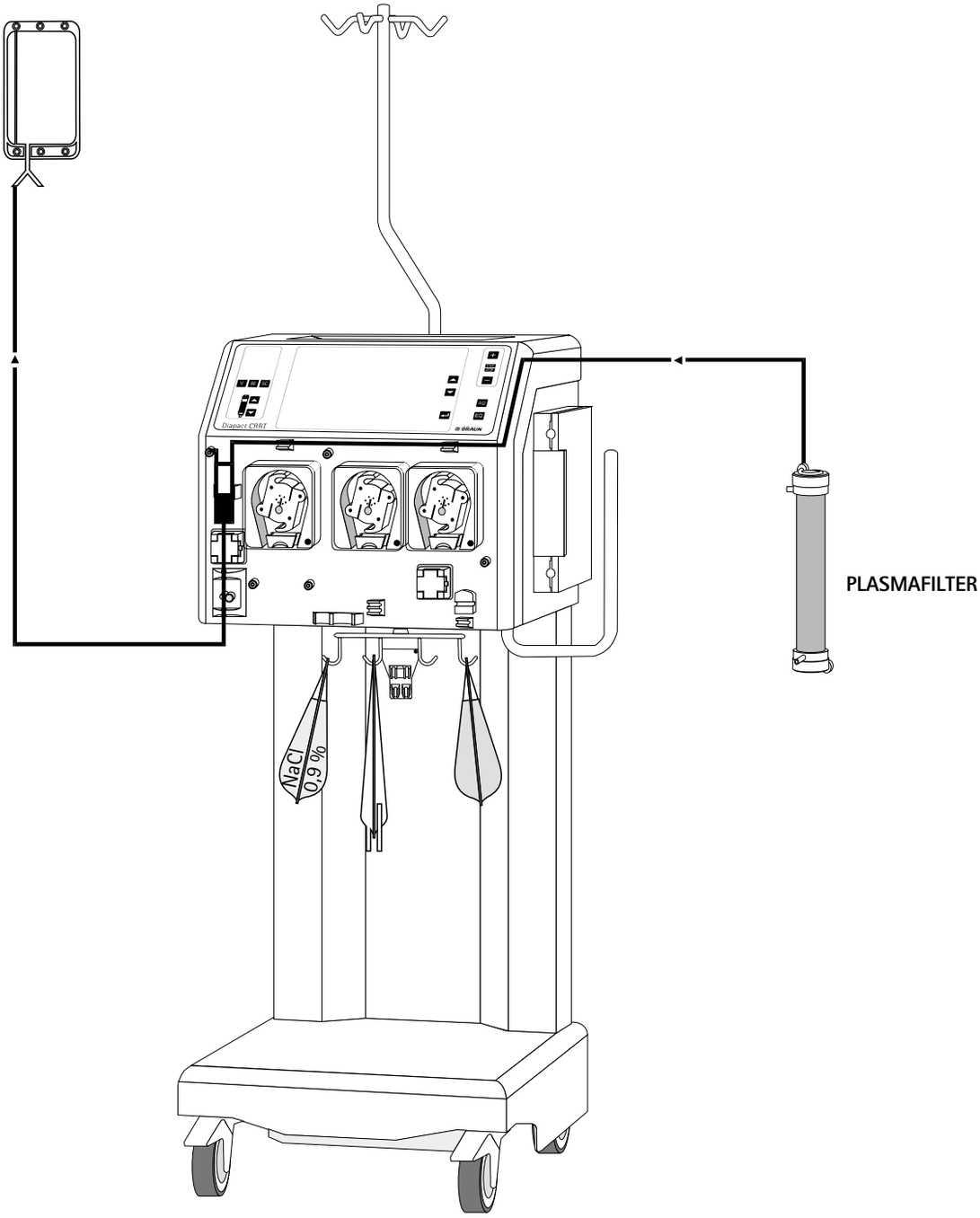
2. Connect the pre-pump transducer protector to PA pressure measurement connector.
3. Connect the tubing line end with spike or luer-lock to one of the saline bags hanging on the weighing system.
4. If continuous anticoagulation is desired, connect the heparin line to the external pump and fill it manually.
5. Fix the pre-filter chamber to its holder.
6. Connect the transducer protector of the above chamber to PBE pressure measurement connector.
7. Connect the chamber outlet tubing line to the filter blood port (red).



Venous Line Setting Up (blue)

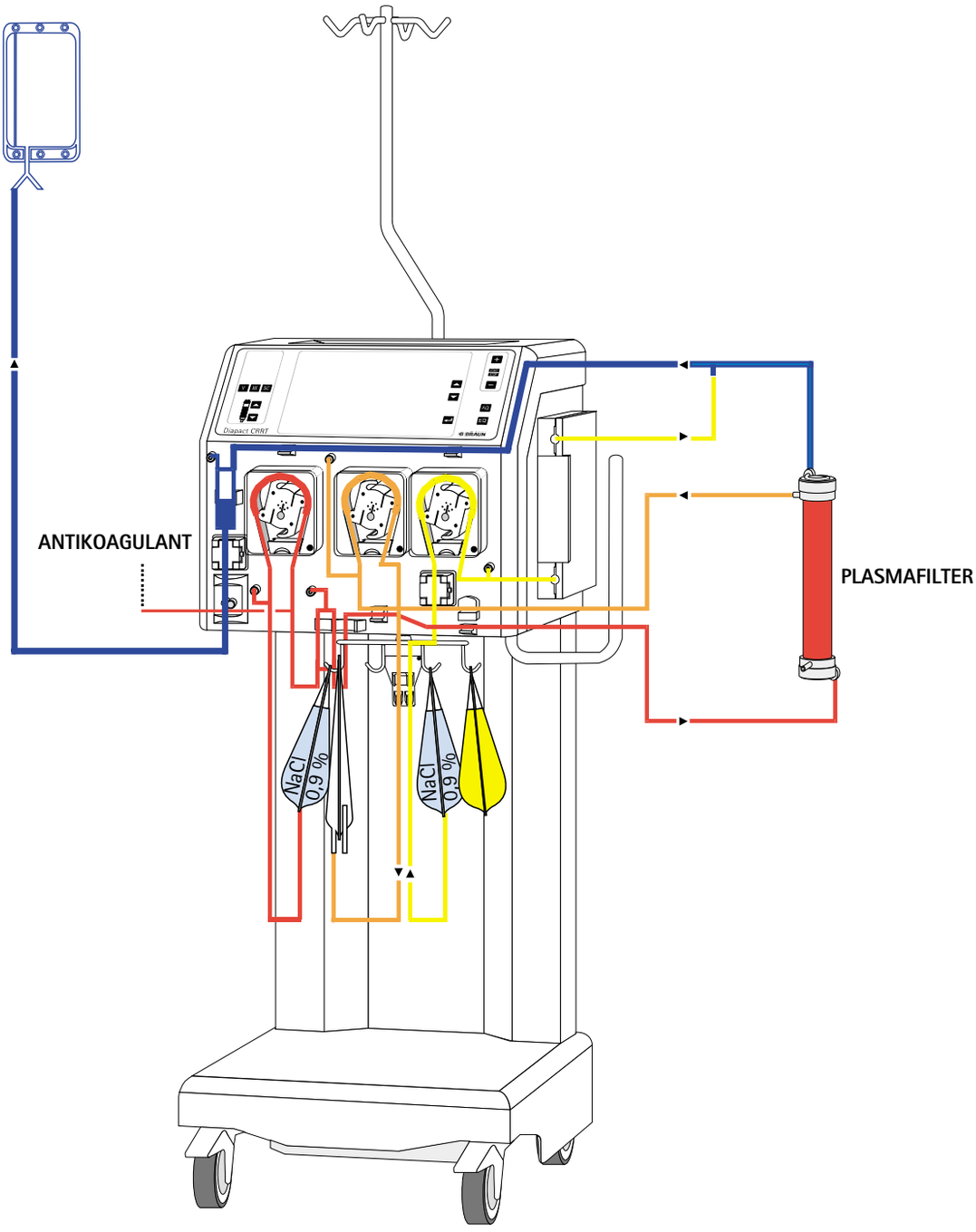
1. Fix the venous chamber to its holder and the tube below into the Safety Air Detector and the safety clamp underneath.
2. Mount the two tubing lines on top of the chamber as follows:
   - connect the short tubing with transducer protector to the PV pressure measurement connector
   - connect the long tubing to the filter blood port (blue).
3. Connect the venous line outlet to the rinsing solution collecting bag and hang the bag to the IV pole.

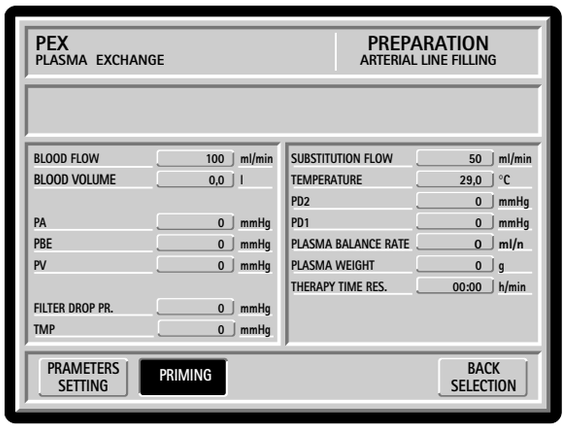


Set Up / Priming Overview

Once the tube mounting and connection have been completed, make sure that all the clamps are open.

Then, the Priming-Rinsing phase can be started.



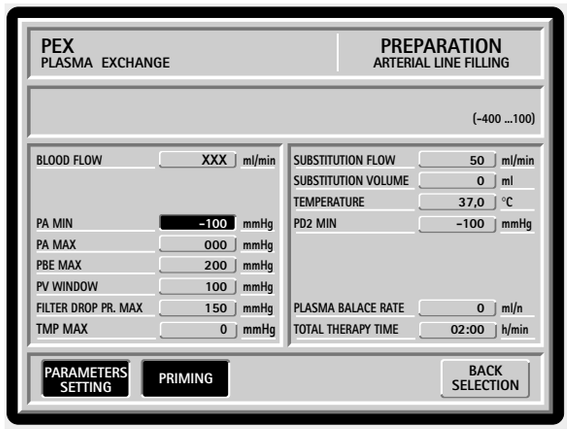


PRIMING/TEST

Once the disposable setting up is completed and the connections have been checked, activate the START-STOP PRIMING function, and then the START-STOP blood pump key. The priming phase runs automatically.

Priming and selftest phases are described in the following table:

time (min : sek)	blood pump (ml/min)	Plasma pump (ml/h)	Substit. pump (ml/h)	Line filling Chamber level Rinsing	Self-tests
0 : 00	100	0	0	Blood line filling Prefilter chamber level	Load cell test Arterial pressure test
2 : 40	30	0	100	Plasma line filling	Air detector test
2 : 50	30	0	100		Substitution pump test
4 : 00	0/30	0	0/100		Heater test
4 : 40	30...110	100	0		Plasma pump test
5 : 20	110	100	0		BLD Calibration and Test
6 : 00	200	0	0	Venous chamber level	
6 : 10	100/50/0	0	0		Venous pressure test Disposable leakage tet
7 : 00	0	0	0		Level adjustment test
7 : 10	200	100	100	Rinsing	
8 : 10				End of priming/rinsing	

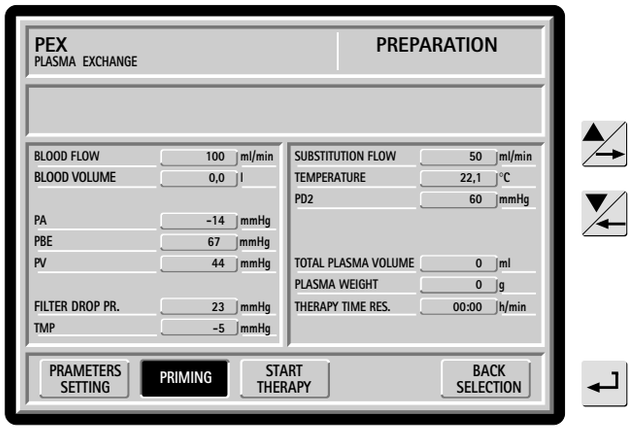


PARAMETER SETTING

During the Priming phase the operator can set the parameter values specific to PEX therapy by activating the PARAMETER SETTING function. The screen displays only the parameters that can be set.

The user can therefore set the followings:

Parameter	Default	Min	Max	Steps	Unit
Blood flow	50	10	500	5	ml/min
PA min.	-100	-400	80	10	mmHg
PA max.	80	-100	100	10	mmH
PBE max.	200	0	500	10	mmHg
PV window	100	60	160	10	mmHg
filter drop pressure max	150	100	350	10	mmHg
	-	-	-	-	-
Substitution flow	20	5	60	2	ml/min
Substitution volume	-	-	-	-	l
temperature	37	30	39	0.1	°C
PD2 min.	-100	-250	250	10	mmHg
TMP max.	80	20	150	10	mmHg
Plasma volume	3000	100	12000	100	ml/Cyc.
Bilanz Rate	0	-500	+200	10	ml/h
Cycle time	-	-	-	-	-



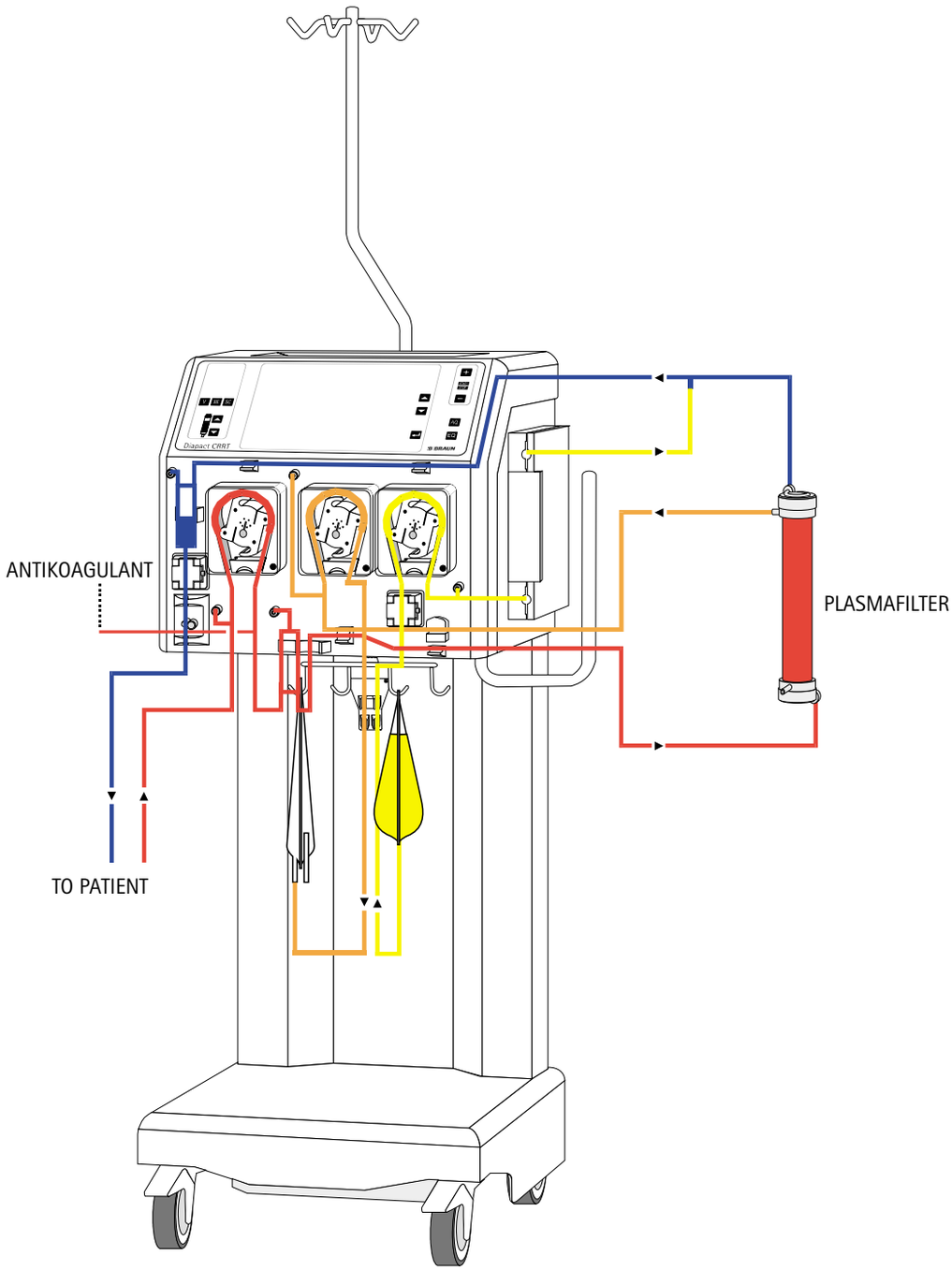
When the Preparation phase is over, the system gives out an acoustic signal and displays START THERAPY function at the bottom line.

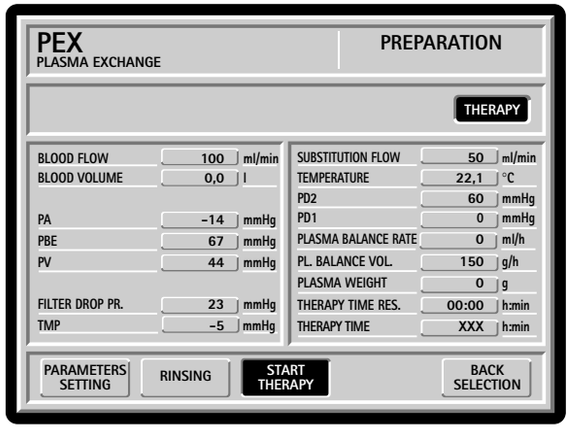
If necessary the operator can choose to continue rinsing by pressing START-STOP RINSING.

Treatment Overview

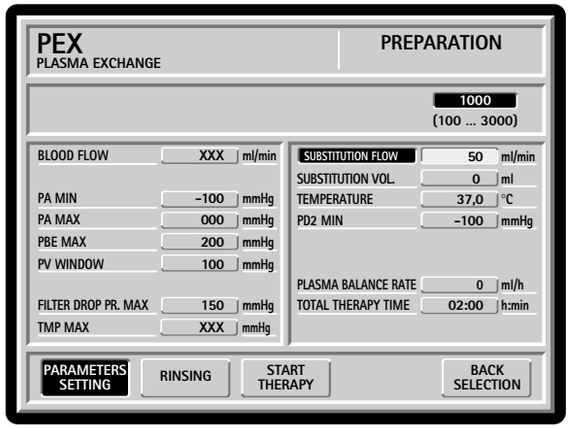
Once the Priming phase is over and the self-tests have been completed, the system can be connected to the patient and the therapy started.

The disposable configuration shall be according to the scheme below.



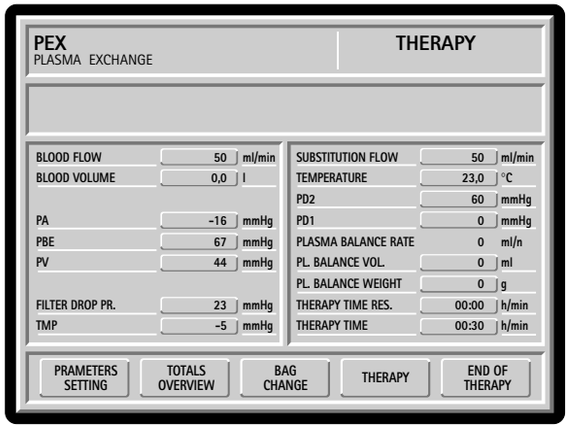


In order to switch from PREPARATION to THERAPY, the user must select START THERAPY, then press the EQ key while the string THERAPY is blinking at the supervisor position (safety procedure).



Then the operator must confirm the Plasma Volume and Substitution Flow preset values (safety data), if these parameters have neither been changed nor confirmed during PARAMETER SETTING procedure.

The value of each parameter displayed at the Supervisor area must coincide with the set values.



6.1.4 Therapy

STAND-BY

– Diapact® CRRT is now in THERAPY STAND-BY status, ready for the next step: the connection to the patient.

CONNECTING THE PATIENT

1. Connect the withdrawal line to the patient's catheter or arterial fistula needle or venous access.
2. Switch on the blood pump and set the flow rate (50-60 ml/min.) by using + and - push-buttons.
3. Check that the withdrawal pressure value (Arterial Pressure - PA) is within the range.
4. When the venous line is ready to be connected to the catheter or to the fistula needle, stop the blood pump and make the connection.
5. Switch on the blood pump again and then slowly adjust the blood flow to the right value,

RUNNING

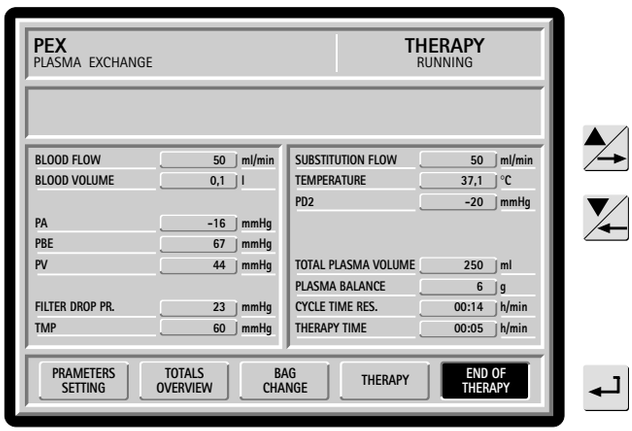
- After the blood has been circulating for 2/3 min. and no alarms have occurred the therapy may be started by activating the START-STOP THERAPY function.
- Now the treatment is running and the parameter overview is displayed.

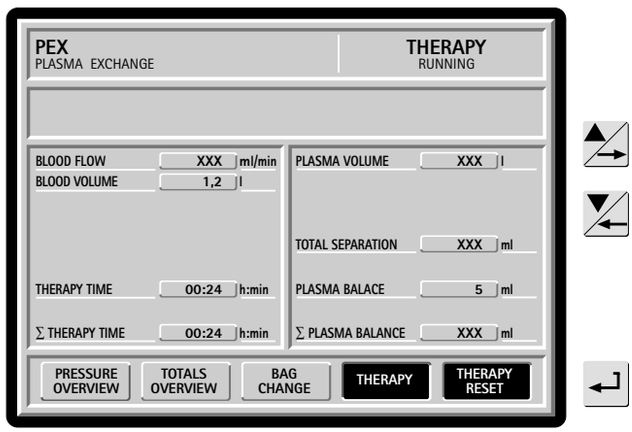
At therapy start as well as after each blood pump stop the fluid side start with reduced speed.

Automatical substitution flow reduction

In case the filtrate flow cannot be reached following control mechanism for the filtrate pressure PD2 starts:

If the PD2 reaches a pressure 20 mmHg below the adjusted PD2 min, the substitution flow is automatically reduced depending on the filter factor. The filter factor is continuously calculated by the unit. If the PD2 reduces by further 50 mmHg the unit will switch into alarm mode.

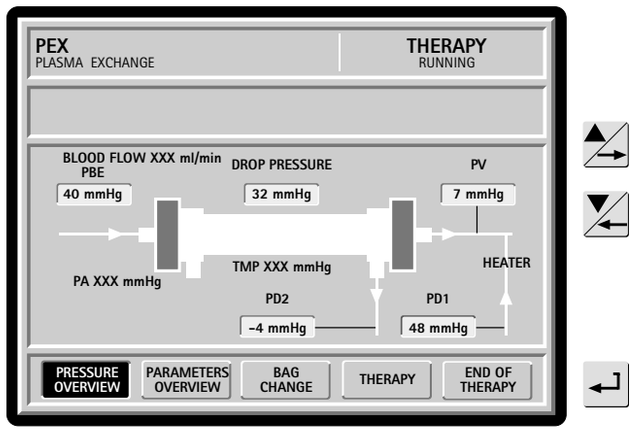




TOTAL OVERVIEW

The TOTALS OVERVIEW function displays the actual total values of some parameters since the beginning of the therapy.

If necessary, "Therapy Time" and "UF Rate" can be reset by striking THERAPY RESET button.



PRESSURE OVERVIEW

The PRESSURE OVERVIEW function can be activated by means of the function selection at the bottom line.

- Select TOTAL OVERVIEW; now the PRESSURE OVERVIEW function is displayed in the function area.
- Select PRESSURE OVERVIEW.

Pressure condition in both blood and filtrate compartments of the plasmafilter are displayed.

In this phase it is important to control the pressure drop value.

PARAMETER SETTING

The PARAMETERS SETTING function can be selected at any time during Therapy Running. Therefore, the values can be changed as in the Preparation phase.

ALARM CONDITION

If an alarm occurs, the therapy stops. The blood pump stops also if the alarm involves the extracorporeal circulation. The system warns the operator by means of an acoustic signal, a message displayed on the video explaining the kind of alarm and the lighting on of the AQ button.

ALARM REMOVAL

The acoustic signal can be stopped by pushing AQ button once. When the cause of the alarm has been detected and eliminated, the therapy starts again if AQ button is pushed once more.

When the preset cycle time is over, PEX therapy is usually completed. If required, a new cycle can be started after replacing both full and empty bags.

No parameter modifications are required.

BAG CHANGE

For a bag change please activate the function "BAG CHANGE". The bags then can be changed without alarm giving and at stopped balancing pumps. After finishing the change of the bag please activate again "THERAPY". The change bag function is automatically deactivated.

END OF THERAPY

The END OF THERAPY function can be selected at the bottom line at any time or at the end of each cycle. The operator must follow the safety procedure.

As soon as the END OF THERAPY phase is activated, the Substitution and Plasma pumps do not operate, whereas the Blood pump runs at reduced speed (50 ml/min.). If necessary, the operator can return to the therapy by selecting BACK TO THERAPY.

DISCONNECTING THE PATIENT

The operator can disconnect the withdrawal arterial line from the patient and connect it to the saline bag (usual amount). Once the extracorporeal blood volume has been returned to the patient, the operator can switch the blood pump off and then disconnect the venous line from the patient.

DISCONNECTING WITH AIR

WARNING!
The operator is reminded of the hazards involved in disconnecting with air.

When the necessary amount of saline solution has been drawn in, stop the supply.

The fluid level in the venous chamber and in SAD sensor lowers till the alarm is activated. In this condition the SAD EXCLUSION functio is activated.

SAD EXCLUSION

The SAD (Safety Air Detector) can be excluded to reinfuse the residual volume of blood. A safe procedure must be carefully followed.

In order to activate the return of the residual blood volume, it is necessary to acknowledge the alarm "Air in blood return line" and start the blood pump with START command.

When all the procedures for the disconnection of the patient are over, all the disposables can be removed from the unit. Then it will be possible to select a new therapy or switch the unit off.

IMPORTANT!
All materials, disposables and fluids removed from the unit must be disposed of in accordance with local regulation.

6.2 PAP

6.2.1 Disposable Kit Setting Up

The disposable kit components must be installed and connected following the sequence described in the pictures of the next pages.

N.B. The lines are colour-coded.

The operator is asked to install and connect the disposable components

1. bags, plasmafilter and cartridge

2. arterial line (red)

3. venous line (blue)

4. plasma outlet line (orange)

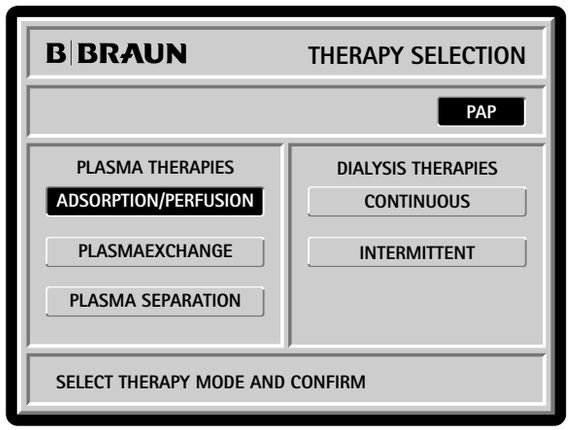
5. reinfusion line (green)

The setting up procedure can be started only after the unit has been switched on and the following controls have been performed:

- software CRC
- characters on the display
- empty load cell value (see General Operations, chp. 3)

SWITCHING ON

Make sure no bags are hooked to the holder of the weighing system. Answer the questions displayed on the screen by pushing EQ push-button. If the characters and the load cell calibration are OK, the therapy selection menu is displayed (see chp. 3.2), then follow the instructions on the screen.



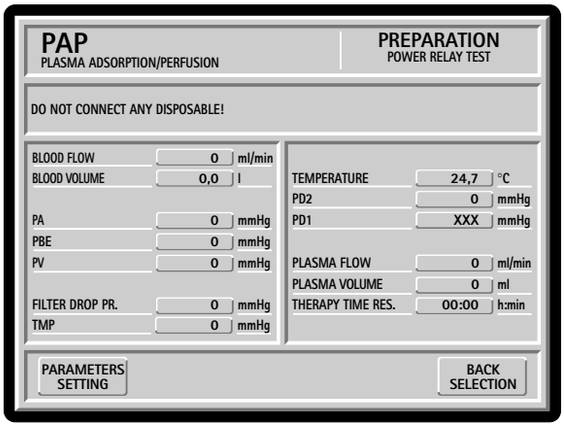
6.2.2 Therapy Selection

Select ADSORPTION/PERFUSION (PAP) therapy.

In Therapy Selection, after activating the appropriate therapy, a blinking inverse string appears at the supervisor position for a few seconds and the EQ key lights up.

If the user does not press the EQ key, the blinking string disappears (the lights of EQ key go out) and the machine remains in Therapy Selection status.

If the user presses the EQ key while the blinking string is on the Preparation phase will be started. The status line change to PREPARATION.

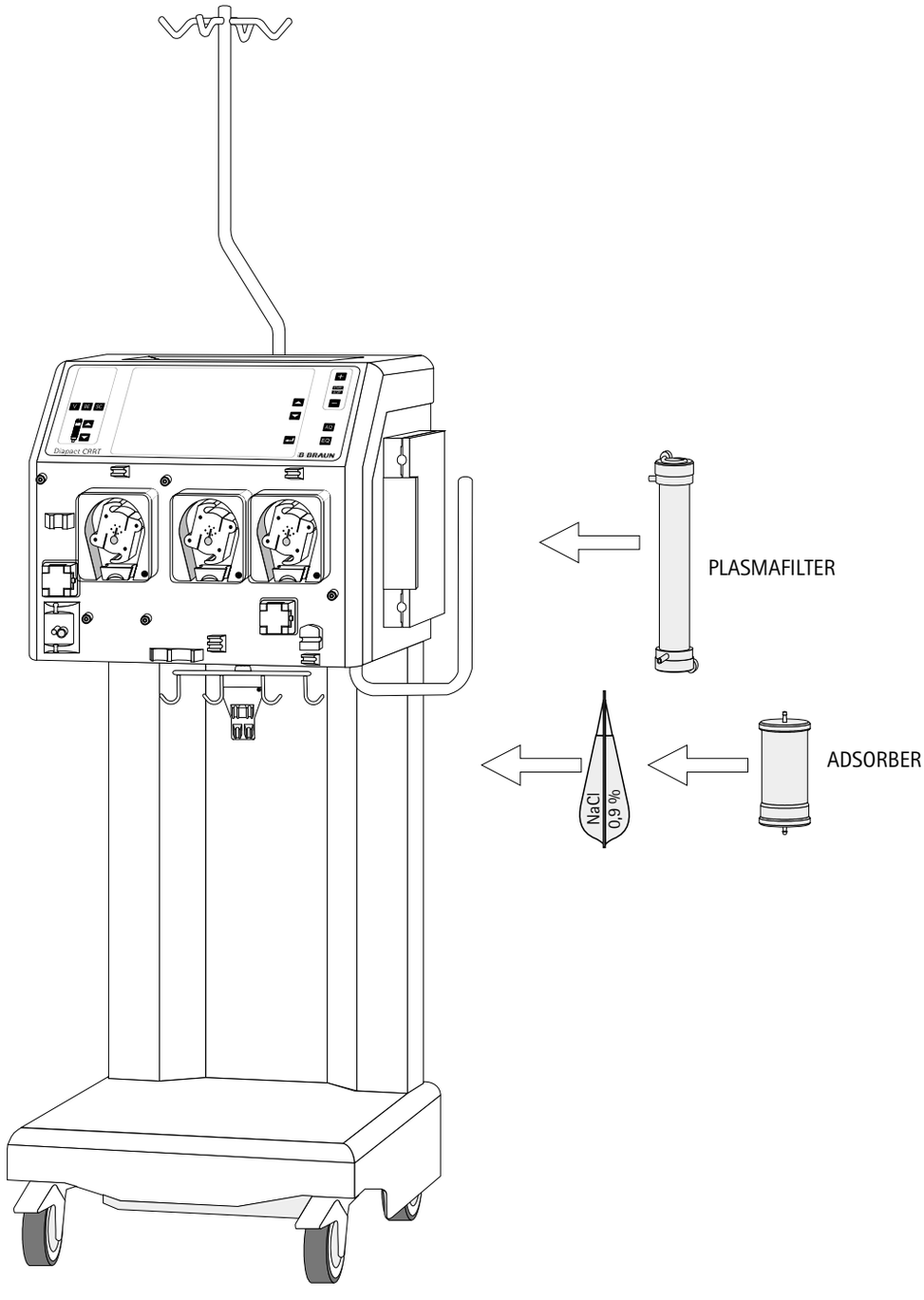


6.2.3 Preparation

After the second step of Therapy Selection, the system displays the main screen of the PREPARATION phase, then starts the hardware test.

Disposable Setting Up

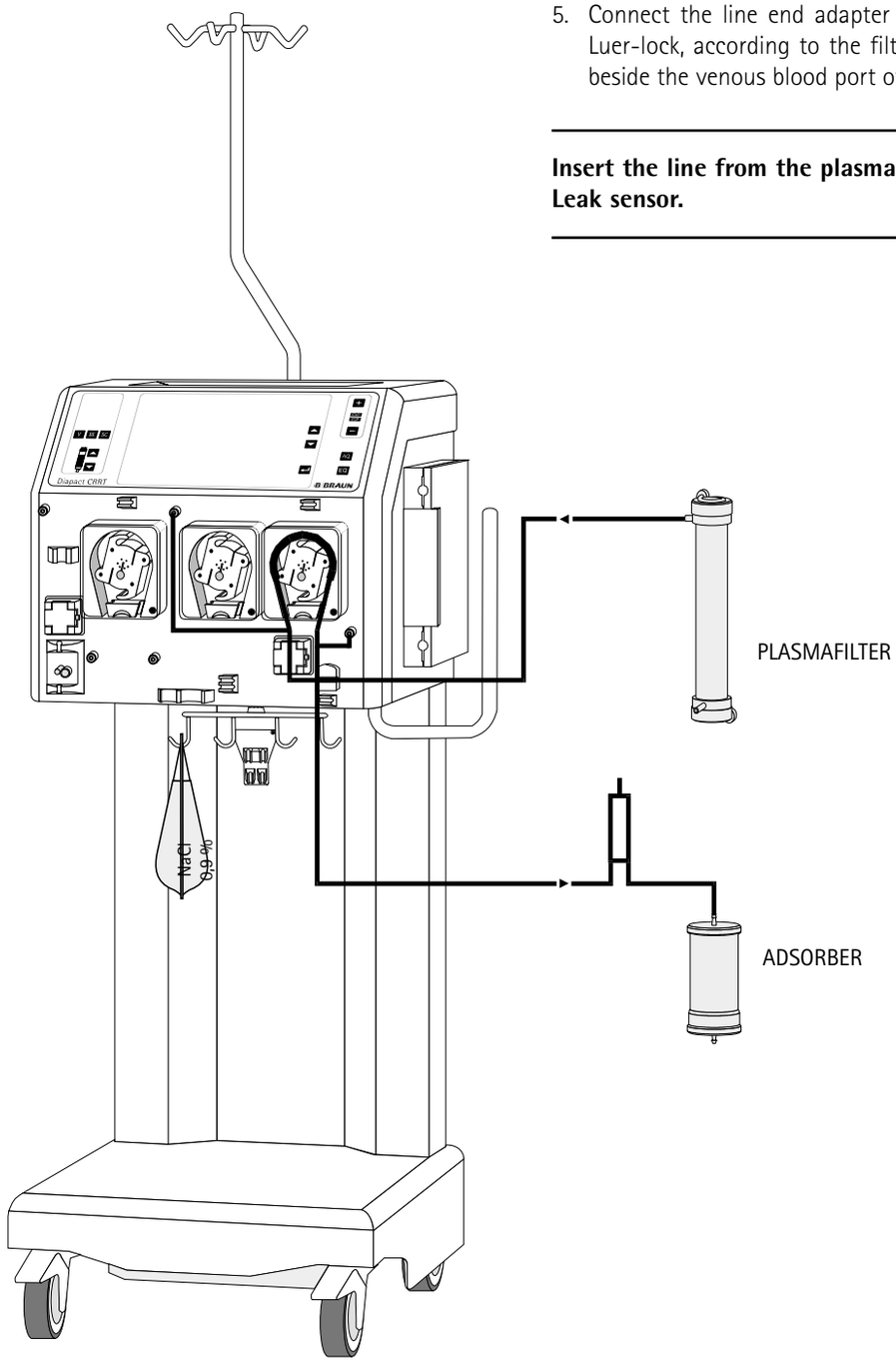
1. Hook the saline bag to the holder of the weighing system.
2. Install the plasmafilter and the cartridge to the proper holders.,



Plasma Outlet Line Setting Up (orange)

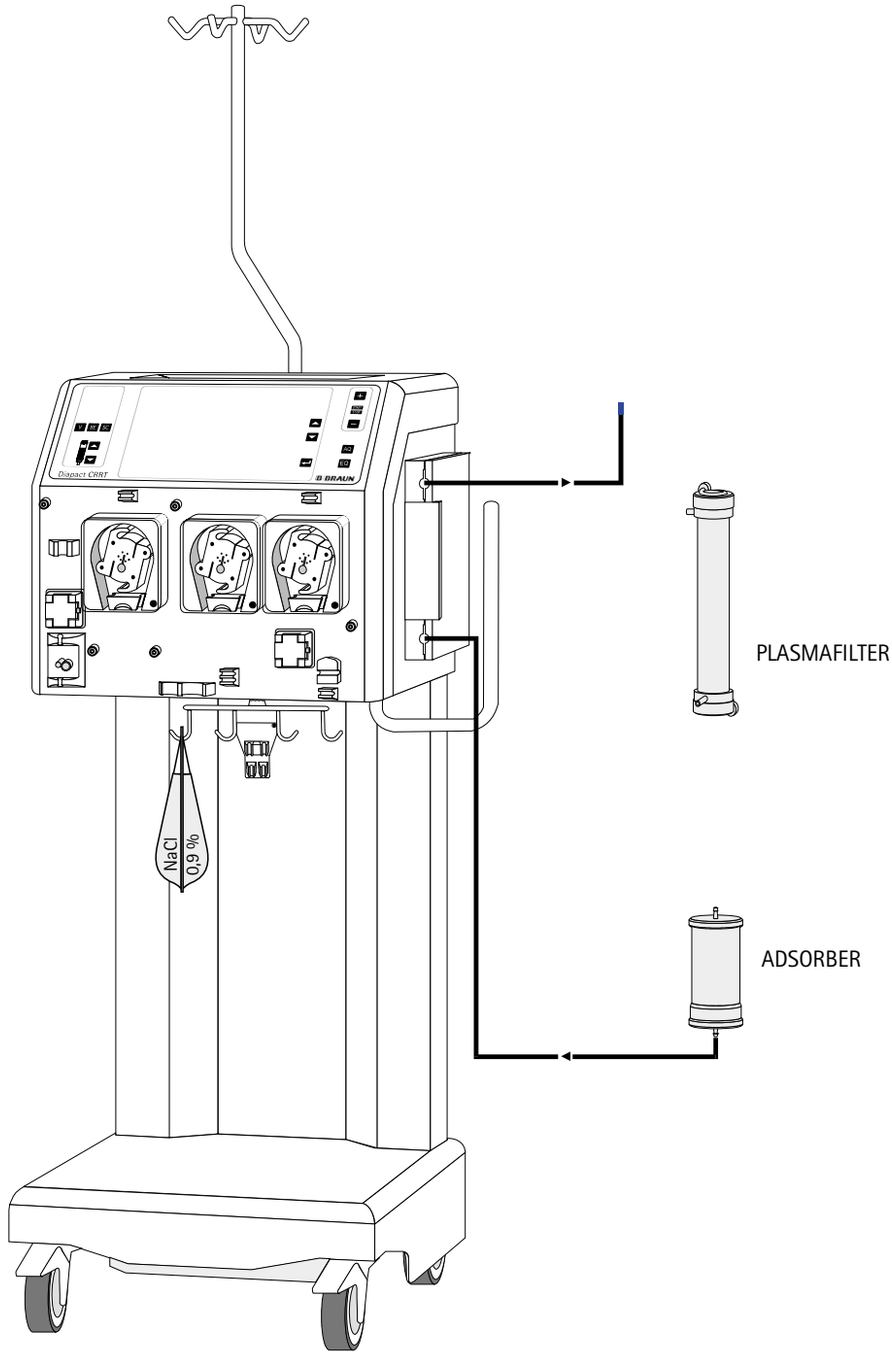
1. Mount the pump segment on the plasma pump.
2. Connect the pre-pump transducer protector to PD2 pressure measurement connector.
3. Connect the post-pump transducer protector to PD1 pressure measurement connector.
4. Connect the line end adapter with red Luer-lock connector to the cartridge and fit the bubble catcher to the proper holder. The bubble catcher prevents the air from passing into the cartridge during Priming/Rinsing phase and Therapy.
5. Connect the line end adapter with Hansen connector (or Luer-lock, according to the filter type) to the plasma port beside the venous blood port of the filter.

Insert the line from the plasma port into the Blood Leak sensor.



Reinfusion Line Setting Up (green)

1. Insert the warming bag into the plate warmer, then close carefully to get the lock system to the right position.
2. Connect the reinfusion line end adapter (plate warmer outlet) to the venous line.
3. Connect the reinfusion line end connector (plate warmer inlet) to the cartridge outlet.

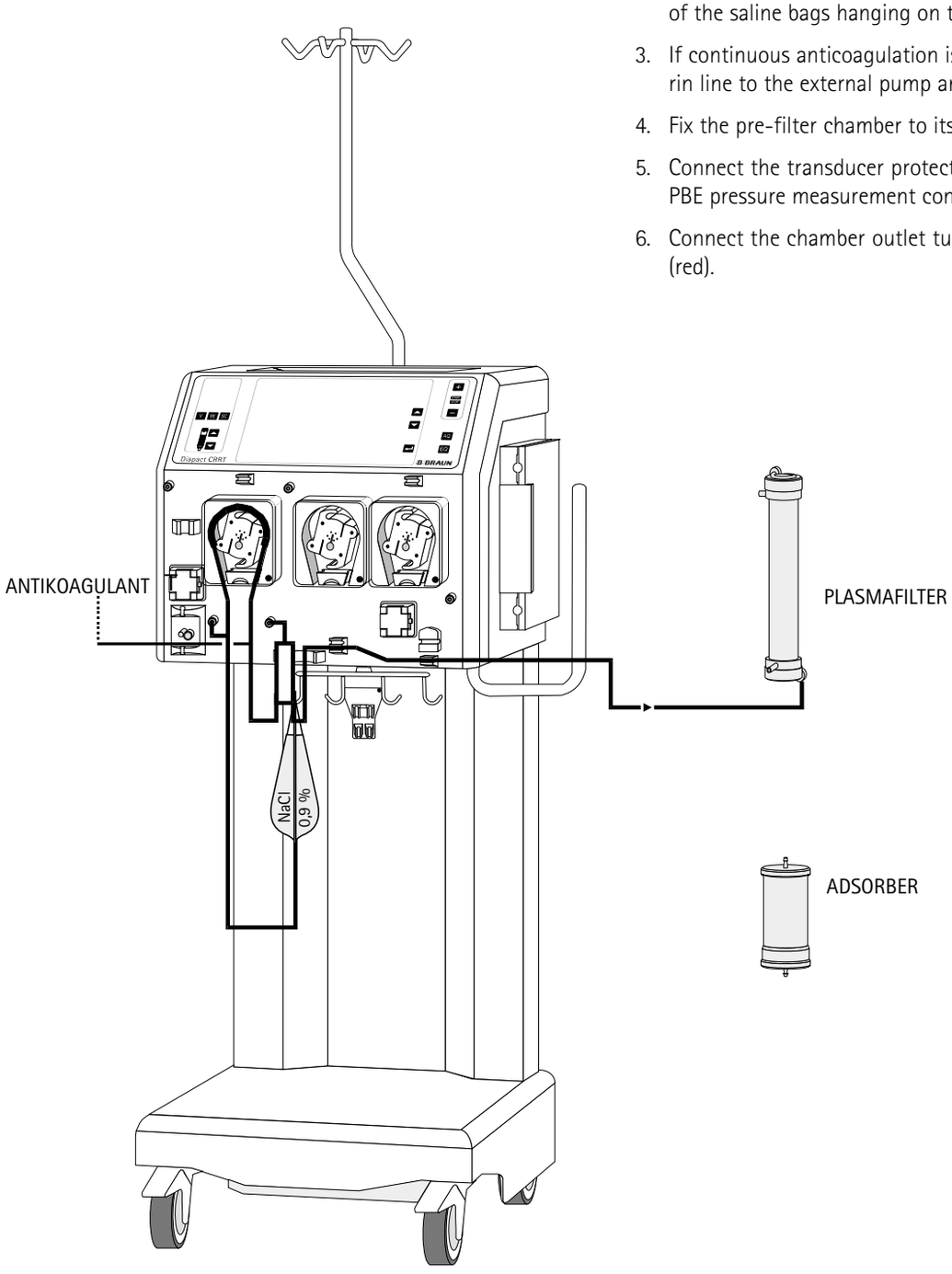


Arterial Line Setting Up (red)

– Mount the pump segment on the blood pump

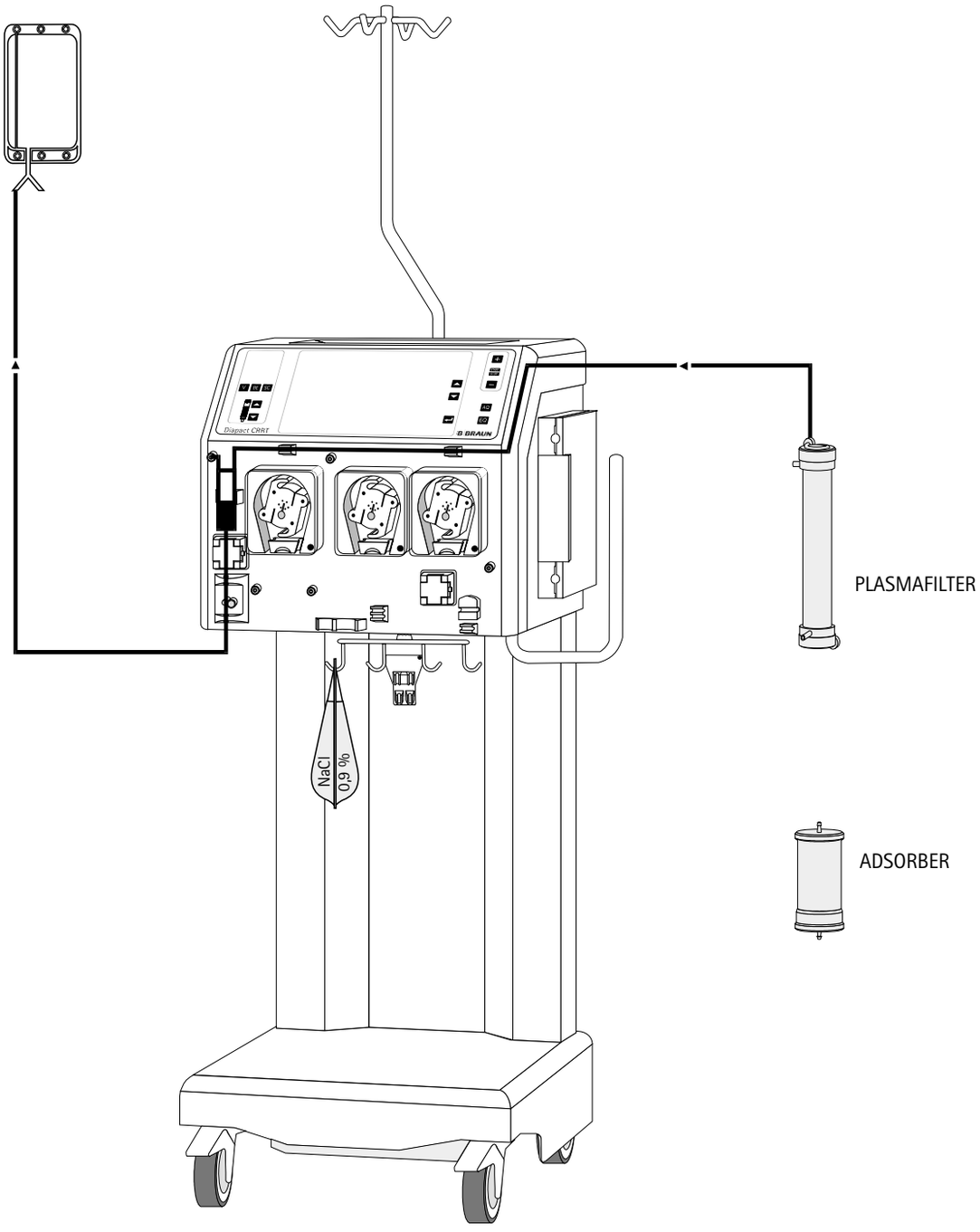
WARNING!
The pump segment shall be mounted clockwise! (follow directing arrows).

1. Connect the pre-pump transducer protector to PA pressure measurement connector.
2. Connect the tubing line end with spike or luer-lock to one of the saline bags hanging on the weighing system.
3. If continuous anticoagulation is desired, connect the heparin line to the external pump and fill it manually.
4. Fix the pre-filter chamber to its holder.
5. Connect the transducer protector of the above chamber to PBE pressure measurement connector.
6. Connect the chamber outlet tubing line to filter blood port (red).



Venous Line Setting Up (blue)

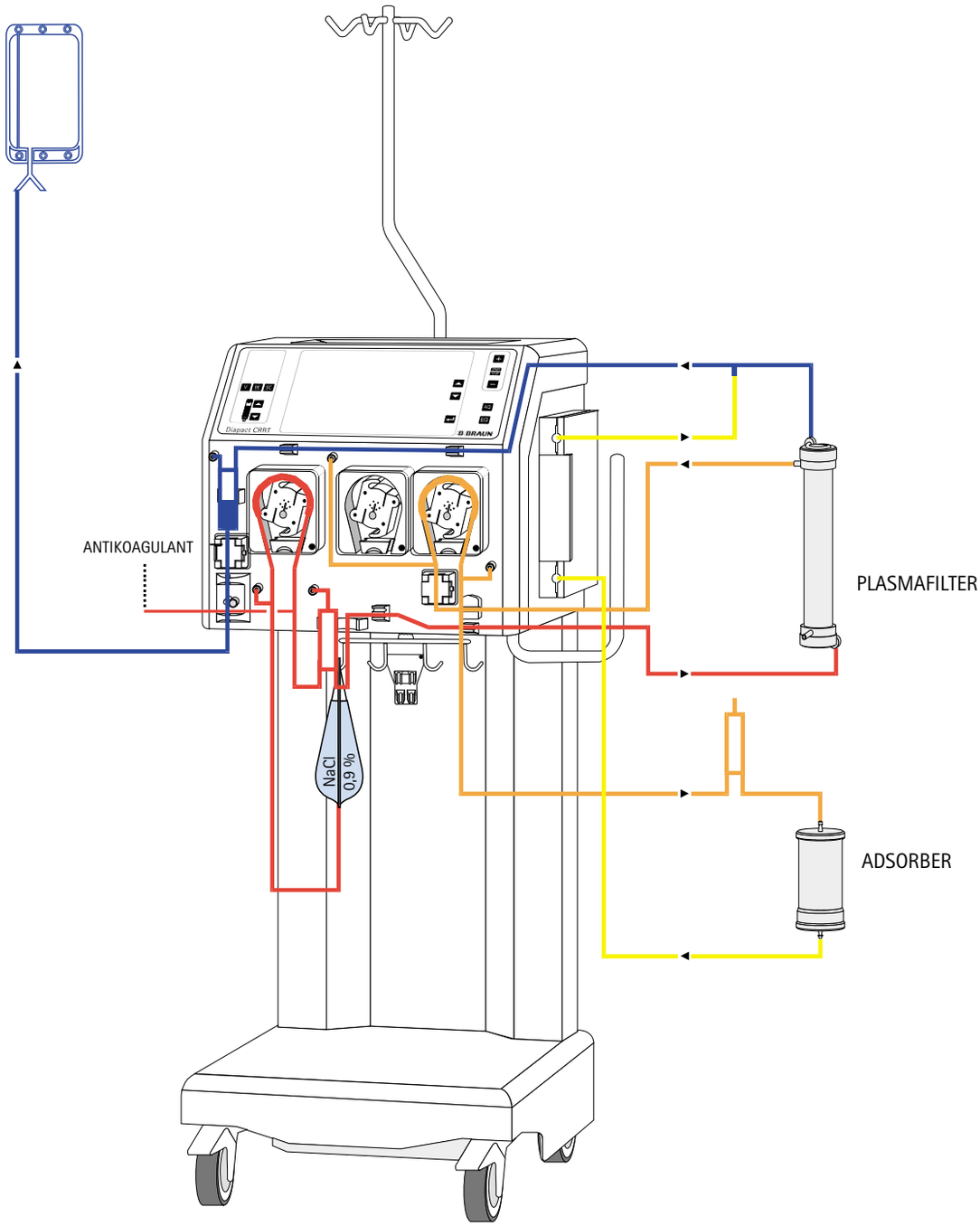
1. Fix the venous chamber to its holder and the tube below into the Safety Air Detector and the safety clamp underneath.
2. Mount the two tubing lines on top of the chamber as follows:
   - connect the short tubing with transducer protector to the PV pressure measurement connector
   - connect the long tubing to the filter blood port (blue).
3. Connect the venous line outlet to the rinsing solution collecting bag and hang the bag to the IV pole.

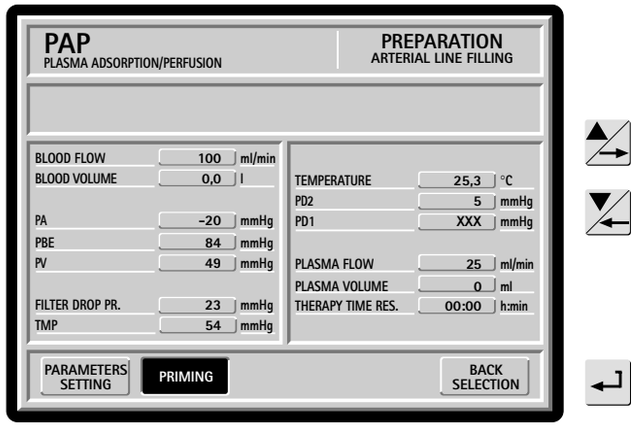


Set Up / Priming Overview

Once the tube mounting and connection have been completed, make sure that all the clamps are open.

Then, the Priming-Rinsing phase can be started.



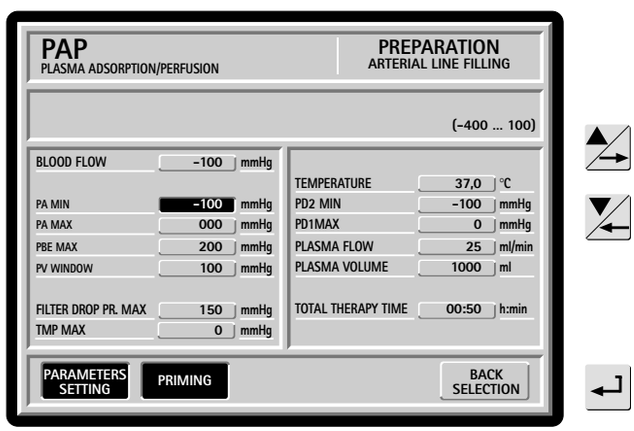


PRIMING/TEST

Once the disposable setting up is completed and the connections have been checked, activate the PRIMING function and then the START/STOP blood pump key. The priming phase runs automatically.

Priming and selftest phases are described in the following table:

time (min : sek)	blood pump (ml/min)	UF pump (ml/h)	Line filling Chamber level Rinsing	Self-test
0 : 00	100	0	Blood line filling Prefilter chamber level	Arterial pressure test
2 : 00	35...100	35...100	Plasma line filling	Air detector test
3 : 00	50...110	50.100		BLD Calibration and Test
3 : 15	0	0		Heater test
4 : 10	200	0	Venous chamber level	Plasma pump test
4 : 40	100/50/0	0		Venous pressure test Disposable leakage test
5 : 00	0	0		Level adjustment test
5 :1 0	200	100	Rinsing	
6 : 10			End of priming/rinsing	

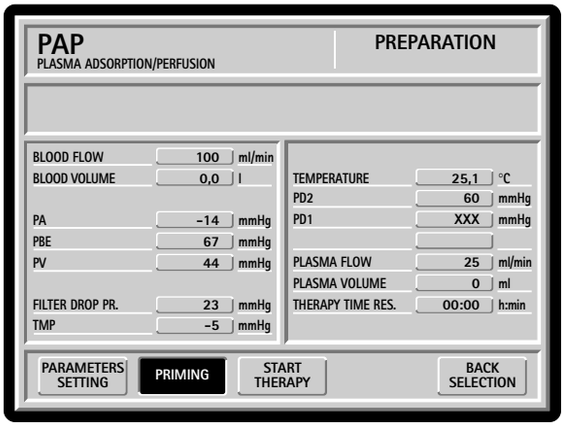


PARAMETER SETTING

During the Priming phase the operator can set the parameter values specific to PAP therapy by activating the PARAMETER SETTING function. The screen displays only the parameters that can be set.

The user can therefore set the followings:

Parameter	Default	Min	Max	Steps	Unit
Blood flow	50	20	150	5	ml/min
PA min.	-100	-400	80	10	mmHg
PA max.	80	100	100	10	mmHg
PBE max.	200	0	500	10	mmHg
PV window	100	60	160	10	mmHg
filter drop pressure max	150	100	350	10	mmHg
	-	-	-	-	
	-	-	-	-	
Plasma flow	20	5	50	2	ml/min
temperature	37	30	39	0.1	°C
PD2 min.	-100	-250	250	10	mmHg
TMP max.	80	20	150	10	mmHg
Plasma volume	1000	100	6000	100	ml
Bilanz volume	-	-	-	-	-
Cycle time	-	-	-	-	-



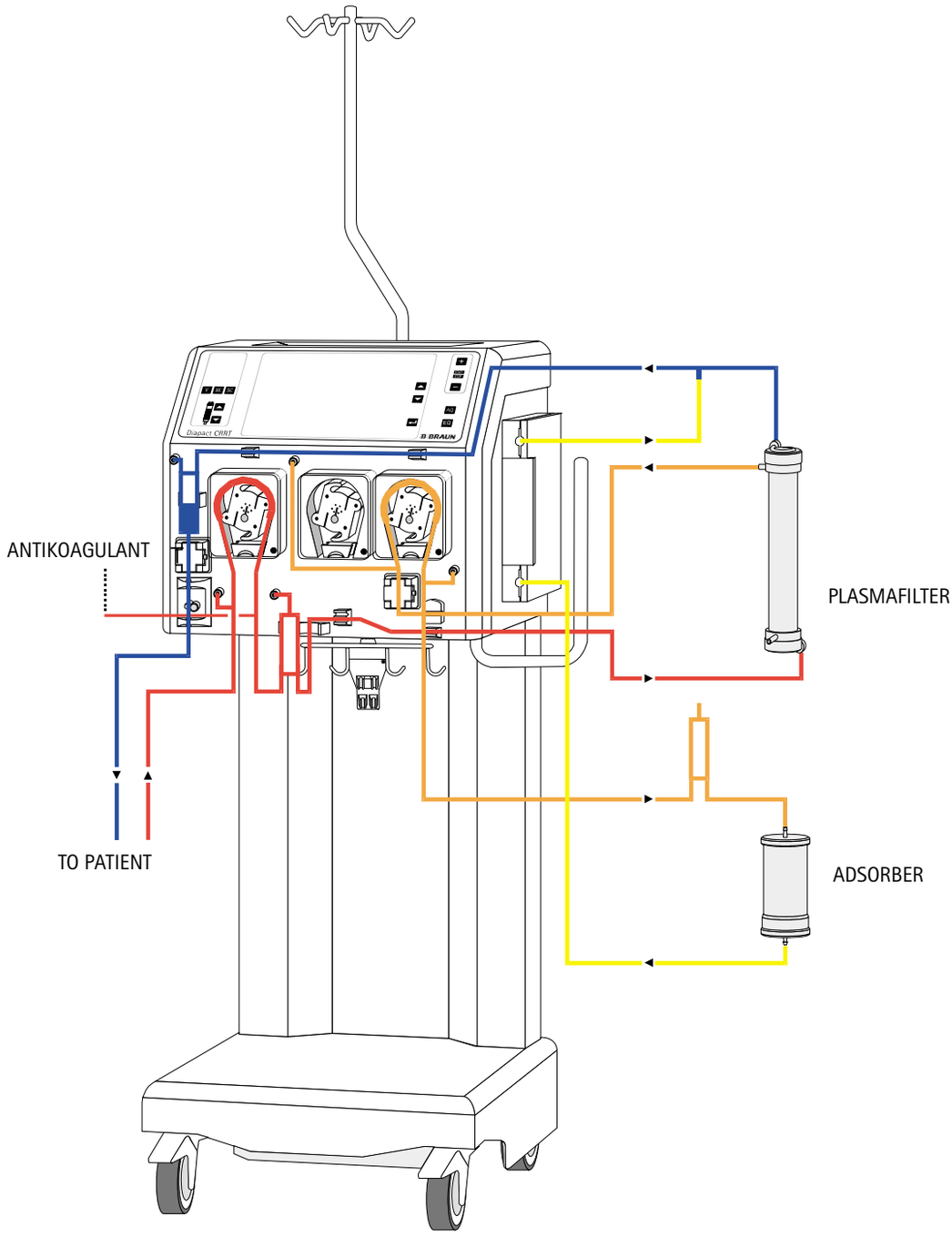
When the Preparation phase is over, the system gives out an acoustic signal and displays START THERAPY function on the bottom line.

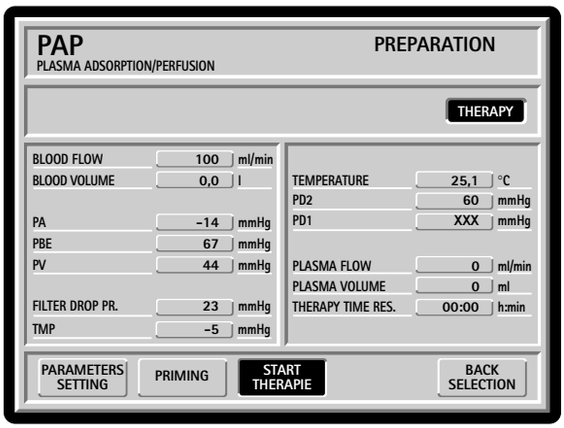
If necessary, the operator can choose to continue the rinsing by pressing RINSING.

Treatment Overview

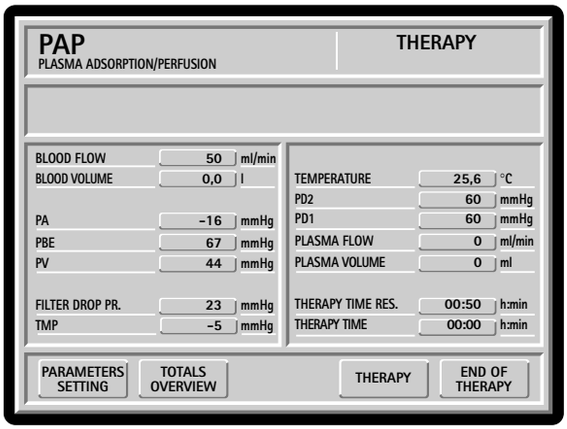
Once the Priming phase is over and the self-tests have been completed, the system can be connected to the patient and the therapy started.

The disposable configuration shall be according to the scheme below.





In order to switch from PREPARATION to THERAPY, the user must select START THERAPY, then press the EQ key while the string THERAPY is blinking at the supervisor position (safety procedure).



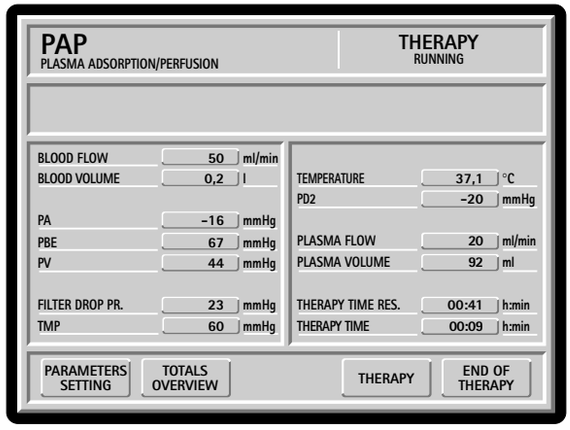
6.2.4 THERAPY

STAND-BY

- Diapact® CRRT is now in THERAPY STAND-BY status, ready for the next step: the connection to the patient. The blood pump runs with rinsing solution at 50 ml/min.

CONNECTING THE PATIENT

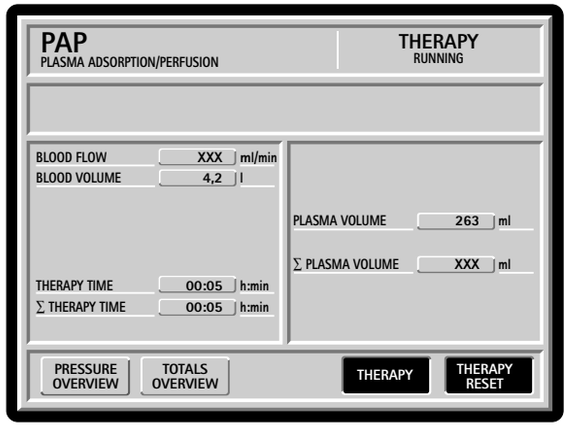
1. Connect the arterial line to the patient's catheter or arterial fistula needle.
2. Switch on the blood pump and set the flow rate (50-60 ml/min.) by using + and - push-buttons.
3. Check that the withdrawal pressure value (Arterial Pressure -PA) is within the range.
4. When the venous line is ready to be connected to the catheter or to the fistula needle, stop the blood pump and make the connection.
5. Switch on the blood pump again and then slowly adjust the blood flow to the right value, according to the patient's condition.
6. Check that the arterial and venous pressure values on the screen are within the normal range.



RUNNING

– After the blood has been circulating for 2/3 min. and no alarms have occurred, the therapy may be started by activating the START-STOP THERAPY function.

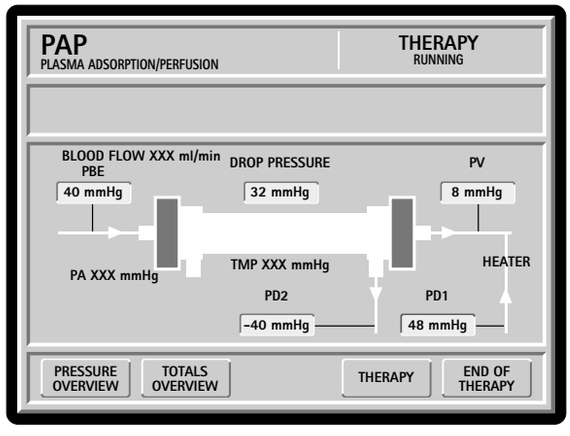
Now the therapy is running and the parameter overview is displayed.



TOTAL OVERVIEW

The TOTALS OVERVIEW function displays the actual total values of some parameters since the beginning of the therapy.

If necessary, "Therapy Time" and "UF Rate" can be reset by striking THERAPY RESET button.



PRESSURE OVERVIEW

The PRESSURE OVERVIEW function can be activated by means of the function selection at the bottom line.

– Select TOTAL OVERVIEW; now the PRESSURE OVERVIEW function is displayed in the function area.

– Select PRESSURE OVERVIEW.

Pressure condition in both blood and filtrate compartments of the hemofilter are displayed.

In this phase, it is important to control the pressure drop value.

PARAMETER SETTING

The PARAMETERS SETTING function can be selected at any time during Therapy Running. Therefore, the values can be changed as in the Preparation phase.

ALARM CONDITION

If an alarm occurs, the therapy stops. The blood pump stops also if the alarm involves the extracorporeal circulation. The system warns the operator by means of an acoustic signal, a message displayed on the video explaining the kind of alarm and the lighting on of the AQ button.

ALARM REMOVAL

The acoustic signal can be stopped by pushing AQ button once. When the cause of the alarm has been detected and eliminated, the therapy starts again if AQ button is pushed once more.

When the preset cycle time is over, a new cycle can be started by setting the new value of TOTAL PLASMA VOLUME.

6.2.5 END OF THERAPY

The END OF THERAPY function can be selected at the bottom line at any time or at the end of each cycle.

The operator must follow the safety procedure.

As soon as the END OF THERAPY phase is activated, the Plasma pump does not operate, whereas the Blood pump runs at reduced speed (50 ml/min.). If necessary, the operator can return to the therapy by selecting BACK TO THERAPY.

DISCONNECTING THE PATIENT

The operator can disconnect the withdrawal arterial line from the patient and connect it to the saline bag (usual amount). Once the extracorporeal blood volume has been returned to the patient, the operator can switch the blood pump off and then disconnect the venous line from the patient.

DISCONNECTING WITH AIR

WARNING!
The operator is reminded of the hazards involved in disconnecting with air.

When the necessary amount of saline solution has been drawn in, stop the supply.

The fluid level in the in the venoua chamber and SAD sensor lowers till the alarm is activated. In trhis condition the SAD EXCLUSION function is activated.

SAD EXCLUSION

The SAD (Safety Air Detector) can be excluded to reinfuse the residual volume of blood. A safe procedure must be carefully followed.

In order to activate the return of the residual blood volume, it is necessary to acknowledge the alarm "Air in blood return line" and start the blood pump with START command.

When all the procedures for the disconnection of the patient are over, all the disposables can be removed from the unit. Then it will be possible to select a new therapy or switch the unit off.

IMPORTANT!
All materials, disposables and fluids removed from the unit must be disposed of in accordance with local regulation.