



OUR VISION

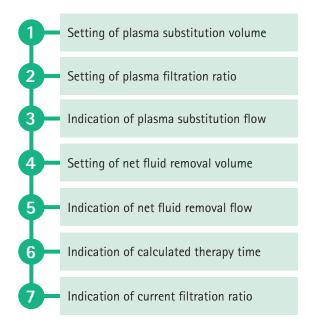
We PROTECT and IMPROVE the HEALTH of people

around the world

CONTENT

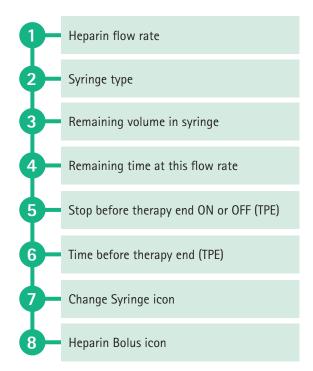
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1. Parameters in TPE





Anticoagulation



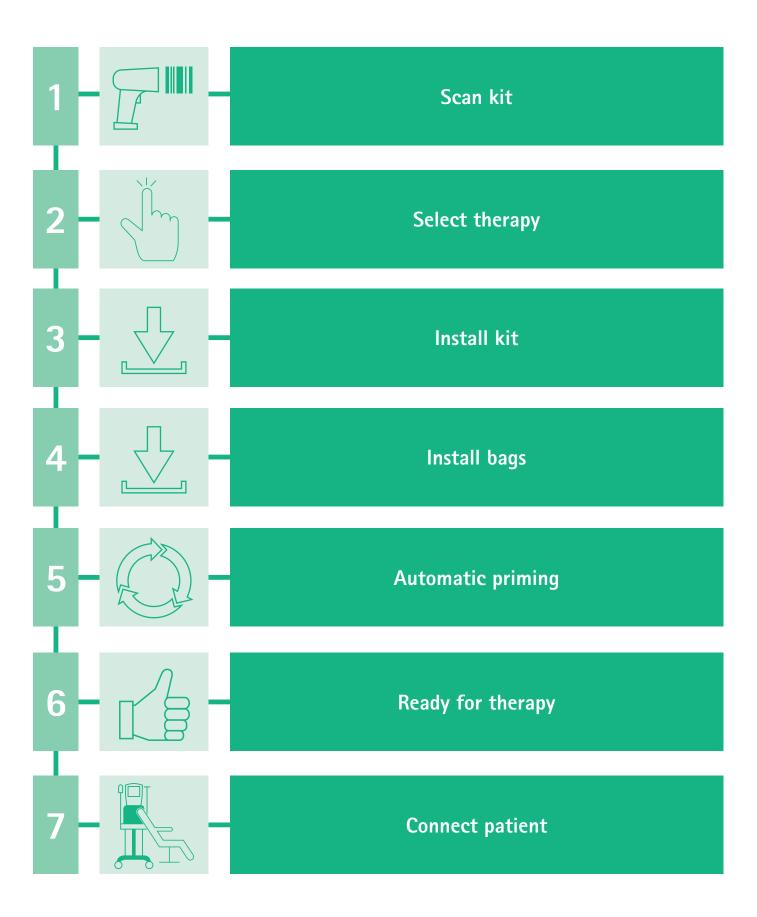


Parameters in TPE therapies

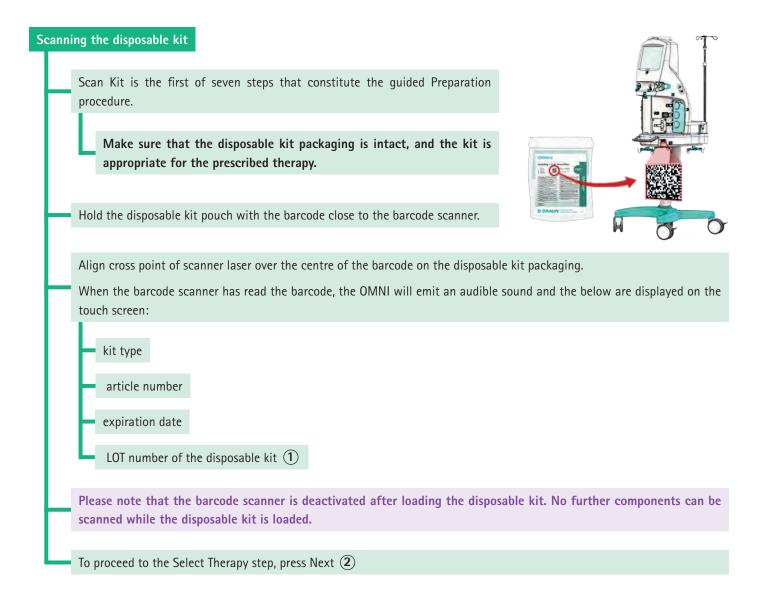
The following parameters can be adjusted in the anticoagulation screen:

- Heparin flow rate
- Remaining volume in syringe

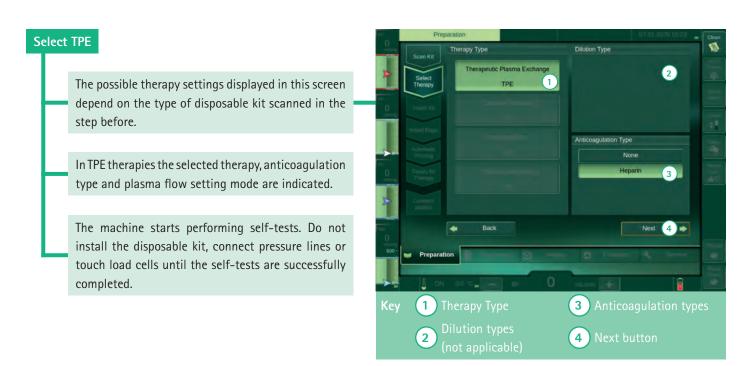
- Stop before therapy end ON or OFF
- Time before therapy end



2.1 Scan kit

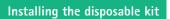


2.2 Selecting the therapy



2.3 Installing the disposable kit

The following tasks must be completed in this step:



Unpacking the disposable kit and attaching the protective cover



Unpacking the Disposable Kit and Attaching the Protective Cover.



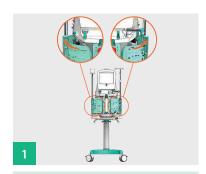
Carefully remove, then dispose of kit packaging.



Attach the protective cover on the disposable kit.

2.3 Installing the disposable kit

Loading the disposable kit



Open the blood and fluid side doors.



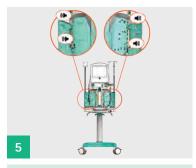
Hold the kit with the red filter cap on the top. Insert the lower part of the kit into the slots above the front handle.



Fix the kit onto the front of the machine using the latch at the top.



Make sure that no lines are stuck between the kit and the machine. Press disposable kit sides firmly into the locks until you hear the locking mechanism click.



Make sure that both upper and lower locks are engaged.

Closing blood and fluid side doors

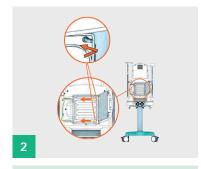


Close the blood and fluid side doors.

Loading the warmer bag



Open the warmer door at the back of the machine.



Put the warmer bag on the two hooks at the door hinge and the shorter line to the top position.



Stretch the warmer bag and fix it on the two positioning pins close to the outlets. Make sure that the warmer bag is not kinked or folded.



Insert the line into the tube holders.

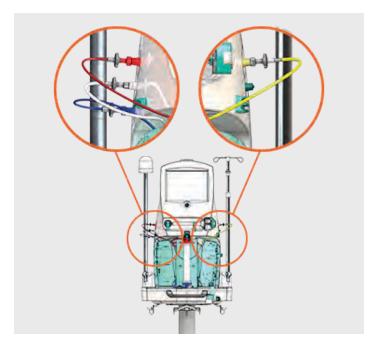


Lock the warmer door.

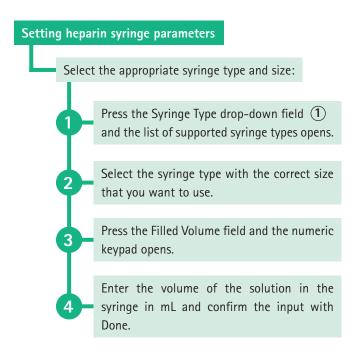
Connecting pressure lines

Remove caps from the pressure lines.

Connect them to the following pressure sensor connectors and make sure that all lines are firmly connected.



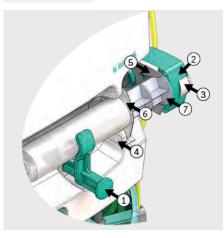
2.3 Installing the disposable kit





Loading the heparin syringe

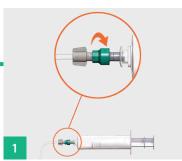
Syringe pump:



- 1 Unlocking lever
- 2 Syringe holder
- 3 Clasp nut
- 4 Slot for gripping plate

Key

- 5 Clip for piston plate
- 6 Gripping plate
- 7 Piston plate



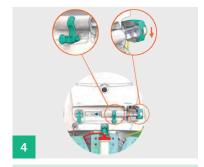
Remove cap from the heparin line and connect it to the heparin syringe.



Open the unlocking lever and the syringe holder by flipping the clasp nut. Keep the clasp nut open while adjusting the rod to the desired position.



Insert the syringe piston plate into the clip and the gripping plate into the slot - the clasp nut should close automatically.



Close the syringe holder and make sure that the clasp nut has been closed.



Make sure the clamp on the heparin line is open.

Completing kit installation

Press the Load button ② and wait until the machine confirms that all tasks have been successfully completed.

Proceed to the Install Bags step, press Next ③

2.4 Installing the bags in tpe therapies

Installing the bags in tpe therapies

The bags with the required fluids must be provided in this step. With a TPE therapy described here, the following bags must be installed:

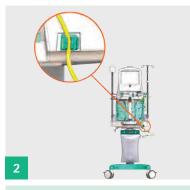
Therapy	Bags	Load cell
TPE	Effluent bag and saline bag	Center
	-	Left
	Plasma substitution bag	Right
	Waste bag	IV pole



Installing the effluent bag (centre load cell)



Hang an effluent bag on the center load cell. Make sure that the inlet is on the right side of the bag.



Insert the effluent line (yellow) into the tube holder.



Remove cap and connect the effluent line (yellow) to the effluent bag.



Close drain outlet. the effluent line.



Make sure that clamp is open on

Installing a saline bag for priming



Hang a saline bag (minimum 1000 mL but not more than 2000 mL) on the center load cell next to the effluent bag.



Remove cap and connect the arterial line (red) to the saline bag. If necessary, break the frangible pin in the bag outlet.

Make sure that the bags and lines hang freely and do not rest on the base or hooks.

2.4 Installing the bags in tpe therapies

Installing the plasma substitution bag (right load cell)

Prepare a plasma bag or bags filled with at least 10 mL but not more than 6000 mL of plasma substitution fluid for the treatment.



Hang some plasma substitution/ priming solution bag(s) on the right load cell.



Slide the plasma substitution line (green) into the tube holder.



Remove cap(s) and connect the plasma substitution line (green) to the plasma substitution bag or priming solution bags.



Clamp the unused plasma substitution line and open all clamps on the used lines.

Make sure that the bags and lines hang freely and do not rest on the base or hooks.

Make sure that the line clamps are closed on all lines not being utilised.

Set the total net volume of the plasma bags. The net volume of all plasma substitution bags on the right load cell must be entered in order to enable the software to calculate when the plasma substitution bags are empty:

Press the Volume input field.

The numeric keypad opens.

Enter the total net volume in mL and confirm with Done.

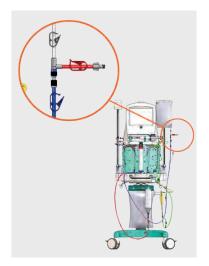
Installing a waste bag for priming (IV pole)

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Hang the priming waste bag attached to the venous line (blue) on the IV pole.

2

Close clamp (red) on priming waste bag T-piece.



Press the $\ensuremath{\mathfrak{J}}$ symbol to view the step by step instructions of the user guidance

For a TPE therapy described here, the following bags must be installed:

Therapy	Bags	Load cell
TPE	Effluent bag and saline bag	Center
	-	Left
	Plasma substitution bag	Right
	Waste bag	IV pole



2.5 Automatic priming



During priming all lines are filled with fluid in order to remove air and any remaining particles.

Press the (i) symbol to view the step-by-step instructions of the user guidance. Make sure that all used clamps are open and all unused are closed.

Press automatic priming 1.

- The machine primes and rinses the disposable kit.
- The progress of priming is indicated on the screen as well as how much time remains until it is finished.

Do not touch the bags and the disposable set on the machine and wait until automatic priming is finished

To interrupt priming, press the Automatic Priming button. To resume priming, press Automatic Priming again.

To proceed to the Ready for Therapy step, press Next (2)



2.6 Ready for therapy

Ready for Therapy is the sixth of seven steps that constitute the guided Preparation procedure.

You may either directly proceed to the next step and complete preparation or choose one of the following two options:

Optional rinsing

The machine rinses the disposable kit with a specified amount of additional fluid. This function can be used e.g., to compensate for intolerances of the patient in terms of residual substances in the system.

Optional recirculation

Venous and arterial line are connected to a saline bag. Saline solution is circulated through the blood lines. This function can be used in order to keep the system on standby until the patient can be connected.

2.7 Confirming therapy parameters

Confirming therapy parameters

To return to the previous step, press the green arrow (1).

To proceed to the next step and connect the patient, press Confirm (2).



Parameters to be set in TPE therapies:

Press the Plasma Substitution Volume field and enter the total volume of plasma substitution fluid to be infused into the extracorporeal circuit.

In flow mode: Press the Plasma Substitution Flow field and enter the volume of plasma substitution fluid to be hourly infused into the extracorporeal circuit.

In ratio mode: Press the Plasma Filtration Ratio field and enter a percentage value to be applied for calculating the plasma substitution flow in proportion to the blood flow.

Press the Net Fluid Removal Volume field and enter the total volume of plasma to be removed from the patient blood but not replaced by plasma substitution fluid.

Press the Heparin Flow Rate field and enter the volume of anticoagulant to be hourly infused into the arterial line. The formulas of the calculated therapy parameters are specified in **chapter 9.14 Formulas (530).** Before confirming therapy parameters, make sure all parameters are according to prescription and appropriate fluids are used. It is only possible to complete preparation and continue to the next step, when all mandatory fields are filled in:

1 To return to the previous step, press the green arrow ①.

To proceed to the next step and connect the patient, press Confirm ②.

In TPE therapies not only the substitution flow but also the net fluid removal flow is automatically decreased, and the therapy time is increased in order to meet the target volumes.

When the flow rate of either pump falls below 50 mL/h, the machine stops treatment and emits a low-priority alarm.

When the effluent pressure returns to a normal pressure range, the system compensates for the missing fluid volume by increasing the substitution fluid flow.

During compensation in TPE therapies, not only the substitution flow but also the net fluid removal flow is automatically increased, and the therapy time is decreased in order to meet the target volumes.

3. Rinsing in TPE therapies

Rinsing in TPE therapies



Select the Optional Rinsing option ① on the touch screen. Press the ② symbol to view the step by step instructions of the user guidance.



Connect the arterial line (red) to the saline bag on the center load cell.



Connect the venous line (blue) to the priming waste bag on the IV pole.



Open the clamps on the arterial line (red) and the venous line (blue).

Setting the rinsing parameters

1 To change the pre-set blood side rinsing volume, press the number in the Volume (Blood Side) field.

The numeric keypad opens.

Type in a new value and confirm with Done.

- 2 If necessary, switch on fluid side rinsing by pressing the ON button.
- 3 To start rinsing, press the Rinsing button.
- 4 To interrupt rinsing, press the Rinsing button. To resume rinsing, press Rinsing again.
- 5 To continue rinsing after the set rinsing volume has been reached, set a new blood side rinsing volume.
- 6 To proceed to the Confirm Therapy Parameters step, press Next 3.

Recirculation in TPE

- 1 Select the Optional Recirculation option ② on the touch screen.
- 2 Connect the arterial line (red) to the waste bag:



Close the clamp (white) on the waste bag.



Connect the arterial line (red) to the venous line using the T-connector at the waste bag. Make sure that the priming waste bag is placed on the IV pole. Make sure that the venous line (blue) is also connected to the priming waste bag.

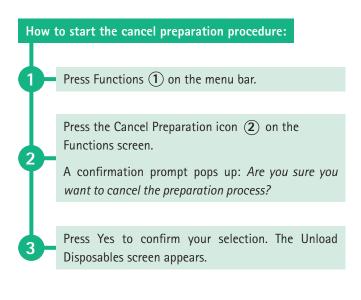
- 3 Make sure that the white clamp on the waste bag is closed.
- 4 Open the clamps on the arterial line (red) and the venous line (blue).
- 5 To start recirculation, press Recirculation.

The blood pump starts recirculating the fluid through the lines of the disposable kit.

The period of time the machine is in recirculation is timed and displayed in the Elapsed Time field.

- 6 To interrupt recirculation, press the Recirculation button. To resume recirculation, press Recirculation again.
- 7 To proceed to the Confirm Therapy Parameters step, press Next ③.

4. Cancelling preparation





5. Connecting the patient

Connect Patient is used to fill the blood lines and subsequently start the therapy.

White connection

The patient is connected to the arterial line and venous line. The blood lines and the haemofilter/plasma filter are filled with blood from the arterial line. The fluid in the disposable kit is infused into the venous access of the patient.

Red connection

The patient is connected to the arterial line. The blood lines and the haemofilter/plasma filter are filled with blood from the arterial access. The fluid in the disposable kit is collected in the priming waste bag on the IV pole. The venous line is connected to the patient only after the blood lines are filled. The blood lines are filled at a default.

5. Connecting the patient

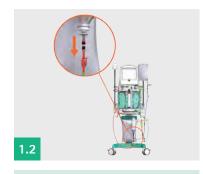
White connection in TPE therapies

Select the White Connection option (1) on the touch screen.

1. Connect the arterial (red) and 2. venous (blue) lines to the patient:



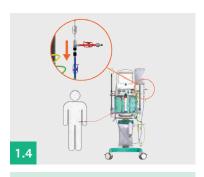
Clamp the arterial (red) and venous (blue) lines and the corresponding bags.



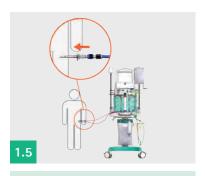
Disconnect the arterial line (red) from the saline bag.



Connect the arterial line (red) to the arterial access of the patient.



Disconnect the venous line (blue) from the saline or priming waste bag.



Connect the venous line (blue) to the venous access of the patient.



Open clamps on the arterial (red) and venous (blue) lines and on the patient access.

1.7 Remove waste bag from IV pole and discard it.

Remove all non-used bags:

To start filling the blood lines, press the Fill blood lines button. The volume of blood being delivered is indicated on the screen.

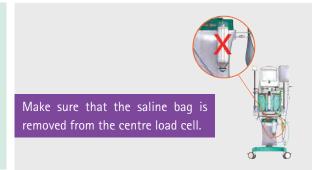
When the blood lines are filled, press the Enter Therapy button.

The machine enters therapy with a running blood pump.

The machine does not automatically stop the blood pump in White Connection.

Make sure that the saline bag is removed from the centre load cell.

Closely monitor patient connections during blood line filling. The machine may not detect separation of the venous line.



6. During therapy

6.1 Stopping and starting blood pump, therapy and anticoagulation

Stopping and starting blood pump, therapy and anticoagulation

Pressing the blood pump icon during therapy interrupts the operation of all pumps. Pressing the blood pump icon again resumes the operation of all interrupted pumps.

Pressing the therapy icon during therapy interrupts the operation of the fluid side pumps. The blood pump and the heparin syringe continue running. Pressing the therapy icon again resumes operation of the fluid side pumps.

Pressing the heparin icon during therapy interrupts operation of the syringe pump. Pressing the heparin icon again resumes operation of the syringe pump.

Please be careful to not stop the blood pump, therapy or anticoagulation without cause, to avoid interruptions in treatment and possible clotting of blood. The OMNI stops and starts these functions as required, for example during a bag change, the therapy will stop and start automatically.

6.2 Changing bags in TPE therapies

The bags can be changed during therapy.

Depending on the disposable kit type and selected therapy type, the following bags can be changed in TPE therapies:

Effluent bag on the center load cell (when full).

Plasma substitution bag on the right load cell (when empty) To start the bag change procedure, either press the Bags icon (1) or select Functions > Change Bag on the menu bar.

The machine automatically determines the remaining volume of the bags based on the total volume entered by the user and the measured weight of the bag.

The user must confirm the input by pressing the Bag change/ Weight reset button.

If during a TPE therapy a bag is changed because a Plasma substitution bag empty alarm has occurred, the system performs a warmer degassing procedure after bag change has finished in order to ensure that no air remains in the warmer bag.

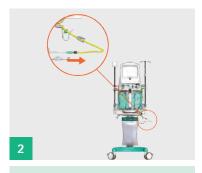
To remove the air the device switches to bypass mode, rotates the substitution pump at high speed for a while and performs solution chamber level regulation several times.



Changing the effluent bag (center load cell)



Clamp the effluent line (yellow) and the effluent bag(s) if needed.



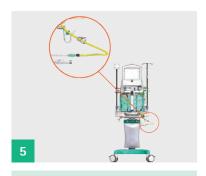
Disconnect effluent bag from the effluent line (yellow).



Unload full effluent bag from the center load cell.



Hang a new effluent bag on the center load cell. Make sure that the inlet is on the right side of the bag.



Remove cap and connect the effluent line (yellow) to the effluent bag.



Close drain outlet.



Open clamp on effluent line (yellow).

Make sure that the bags and lines hang freely and do not rest on the base

6. During therapy

6.2 Changing bags in TPE therapies

Changing the plasma substitution bag (right load cell)

Prepare a plasma bag or bags filled with at least 10 mL but not more than 6000 mL of plasma substitution fluid for the treatment.



Clamp the plasma substitution bag(s) and the plasma substitution line(s) (green).



Disconnect plasma substitution bag(s) from the plasma substitution line(s) (green).



Unload empty plasma substitution bag(s) from the right load cell.



Hang some new plasma substitution bags on the right load cell.



Remove cap and connect the plasma substitution line(s) (green) to the plasma substitution bag(s). Break the frangible pin in the bag outlet if needed.



Open clamp on the plasma substitution line(s).

Make sure that the bags and lines hang freely and do not rest on the base.

Make sure that the line clamps are closed on all lines not being utilised.

Set the total net volume of the plasma bags. The net volume of all plasma substitution bags on the right load cell must be entered in order to enable the software to calculate when the plasma substitution bags are empty:

Press the Volume input field.

The numeric keypad opens.

Enter the total net volume in mL and confirm with Done.

Confirm and complete the bag change by pressing the Bag change/weight reset button.

6.3 Heparin syringe changes

Syringe changes

Press functions or parameters > anticoagulation on the menu bar.

2 Press the change syringe icon.

The syringe change screen pops up.

ii Simultaneously, the syringe pump is stopped while the blood pump and fluid side pumps continue running.

3 — Disconnect and dispose of syringe and install new syringe (as per prescription) as done previously.

Enter syringe type and correct filled volume on screen. Press confirm, the heparin syringe will commence once again.

6.4 Changning flow rates and parameters

Changing flow rates and parameters

Net fluid removal (mls/hr), Plasma Filtration ratio and anticoagulation flow rates can be changed during therapy if required.

To open the flow rates screen, select parameters on the menu bar and navigate to flow rates or anticoagulation.

6.5 History and volumes

History and volumes

To navigate to fluid balance information, press on history > volumes > totals (totals being at the top right side of the screen).

This will show net fluid removed during therapy, this can be shown as hourly for charting on the fluid balance chart.

6.6 Diagnosing and resolving alarms

Diagnosing and resolving alarms

Please refer to the alarms remedial action booklet for information on diagnosing and resolving alarms.

When an alarm initially sounds press Audio Pause to silence the alarm.

When an alarm is triggered a banner is shown in the bottom corner of the screen. By pressing on the banner it expands with the (i) symbol giving advice and possible work arounds for the alarm

When the issue is resolved press Reset Alarm.

6. During therapy

6.7 Changing disposable kit

Changing the disposable kit during therapy can be necessary, e.g., when the hemofilter or plasmafilter is clogged or defective or when the maximum use time of the disposable kit has been reached. The system supports you in replacing the disposable kit with the Change Kit procedure.

How to start the change kit procedure:

Press Functions ① on the menu bar.

Press the Change Kit icon ② on the Functions screen. A confirmation prompt pops up: *Are you sure you want to change the kit?*

Press Yes to confirm your selection, the Return Blood screen appears. Simultaneously, the fluid side pumps are stopped. When the Change Kit icon is pressed, the system checks if the remaining therapy time is less than the maximum kit use time of a new disposable kit. As in this case the new disposable kit cannot be used for the full use time, the system prompts the user to choose one of three options:

Select Back to continue treatment with the same disposable kit, if the condition of the disposable kit allows it.

Select Change Kit to continue treatment with a new disposable kit for the remaining therapy time. The Change Kit procedure is started.

Select End Therapy to start a new therapy with a new disposable kit for the full kit use time. The End Therapy procedure is started. The Change Kit procedure is designed to guide you step-by-step through all activities needed to replace a disposable kit. It is divided into three main steps: **Return Blood, Unload Disposables and Preparation.**

The purpose of the Return Blood step is to return the blood remaining in the lines of the disposable kit to the patient. The Return Blood step is optional, you may skip this step.

During Unload Disposables all lines and bags are disconnected, and the disposable kit is removed.

Finally, you are redirected to the Preparation procedure in order to install the new disposable kit and reconnect the patient.

7. Blood return/end of therapy

How to start the change kit procedure:



Select the Return blood option.

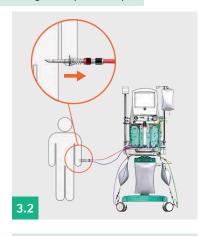


Hang a saline bag on the IV pole.

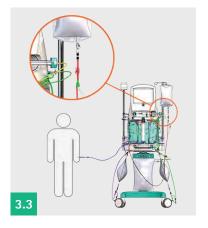
3 Connect arterial line (red) to saline bag and open clamps:



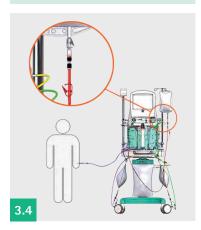
Close clamp on arterial line (red).



Safely remove the arterial line (red) from the patient access.



Connect arterial line (red) to saline bag.



Open clamp on arterial line (red). If necessary, break the frangible pin in the bag outlet. Check bag connection, clamps and all lines.

7. Blood return/end of therapy

How to start blood return:

Press the Return blood button and monitor the blood lines. The blood pump starts feeding back the blood volume set in the Return volume field. A progress bar indicates the amount of blood being returned.

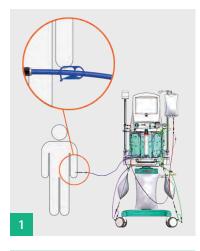
The return volume can be set up to 500 mL when the blood pump is stopped. By default, the return volume is the nominal volume of the disposable kit.

The blood return will automatically stop once the return volume has been reached. Alternatively, it can be manually stopped at any time by releasing the Return blood button.

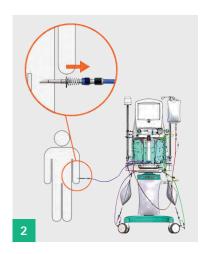
Release the Return blood button when the blood is returned or increase the volume, if necessary.

Return additional volume either by pressing the Return +50 mL button or by adjusting the Return volume parameter and pressing Return blood. Blood return can be manually stopped at any time by releasing the Return +50 mL button or the Return blood button.

Disconnect venous line (blue) from patient:



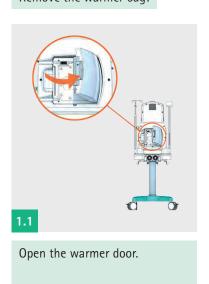
Close clamp on venous line (blue).

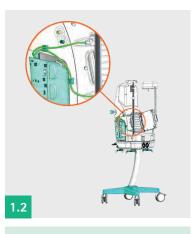


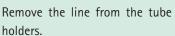
Safely remove the venous line (blue) from the patient access when the blood return is done.

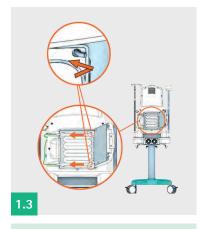
8. Unloading disposables

Unloading disposables Make sure that the patient has been disconnected from the machine. Disconnect all bags: Clamp all lines and bags. Disconnect all lines from bags. Remove the warmer bag:









Remove the warmer bag from the two hooks at the door hinge.

Disconnecting the pressure lines

Red pressure line from (red) arterial connector (AP).

White pressure line from (white) pre-filter connector (FP).

Blue pressure line from (blue) venous connector (VP).

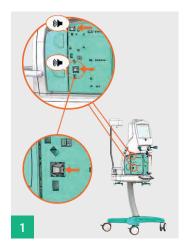
Yellow pressure line from (yellow) effluent connector (EP).

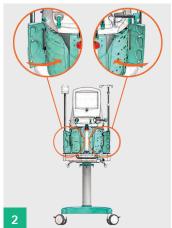


8. Unloading disposables

Removing the disposable kit

Release the locks on the fluid and blood side kit plates:





Press levers on both kit locks on the fluid and blood sides to release the kit.

Then press Unload.

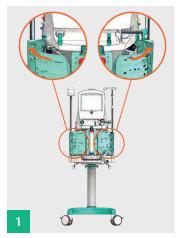
Start automatic unloading of the tube segments by pressing the Unload button.

In case of unsuccessful unloading: Make sure the blood and fluid side doors are closed.

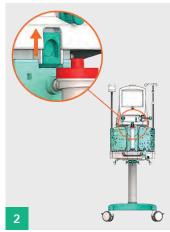
Then press Unload again.

Detaching the disposable kit

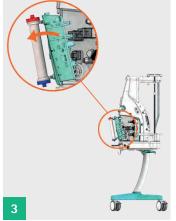
Unload the kit from the machine. Detach the protective cover and save it for later use:



Open fluid and blood side doors.



Release the kit by opening the latch at the top.



Remove the kit from the front of the machine.



Detach the protective cover from the disposable kit, clean it and save it for later use.

9. Post treatment

