



OMNI

QUICK REFERENCE GUIDE

CONTENTS

1	PREPARATION	4
1.1	Power on and off	4
1.2	Setup	6
1.2.1	Setting Up Heparin	6
1.2.2	Setting Up Citrate	20

2	STARTING THERAPY	34
2.1	Starting Therapy - Heparin	34
2.2	Starting Therapy - Citrate	35
2.3	Troubleshooting	36

3	DURING THERAPY	38
3.1	During Therapy - Heparin	38
3.2	During Therapy - Citrate	42
3.3	Troubleshooting	47
3.3.1	Common Troubleshooting during Therapy	47
3.3.2	Temporary Disconnection and Recirculation	53

4	ENDING THERAPY	54
4.1	Ending Therapy - Heparin	54
4.2	Ending Therapy - Citrate	59

5	UNLOADING DISPOSABLES	64
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1. PREPARATION

1.1 POWER ON AND OFF

ALWAYS KEEP PLUGGED IN

If the OMNI does not switch on, it is likely to have run out of charge. Plug in and allow to charge before trying again.

TO TURN ON – BRIEF PRESS

TO TURN OFF – PRESS AND HOLD

To switch the OMNI on, the green power button should only be pressed once for a short time. Do not press and hold, as this will power the machine on and then off. To switch off the OMNI, press and hold the green button.

FULL CHARGE = 30 MINUTES

The OMNI has a battery capacity of 30 minutes. Therapy stops when the machine is unplugged. Please ensure the OMNI is plugged in at all times and keep the brakes on the machine on when in use.

Press Treatment **1** to be taken to the preparation stage for treatment

All information required is provided on the screen. Follow each step. The hourglass on screen will change to a check mark once the action is completed correctly. If no check appears, repeat the action.

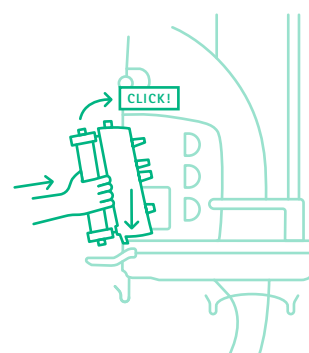
Press the **i** symbol to view the step-by-step instructions from the user guidance



1.2 SETUP

1.2.1 SETTING HEPARIN

- 1 **SCAN KIT**
Scan the barcode on the kit bag using the barcode scanner lit up at the bottom right of the OMNI, lining the cross (red light shining from scanner) onto the barcode. If the barcode is damaged on the packet, the user can input the data manually.
- 2 **SELECT THERAPY**
Ensure the correct therapy, dilution and anticoagulation required are chosen, as prescribed by the physician.
- 3 **SELF-TESTS**
The machine will work through some self-tests. Leave it to do this. The alarm will sound and the light will flash once complete.
- 4 **INSTALL KIT**
 - 4.1 Take the kit out of the bag and place it onto a cart or flat surface. Check the connections, ensuring the priming waste bag is connected securely to the blue (venous) line.
 - 4.2 Open the blood and fluid doors on the right and left sides of the machine.
 - 4.3 Hold the kit with the red filter cap at the top. Insert the lower part of the kit first into the slots above the lower front handle. Now fix the kit onto the front of the machine using the latch at the top, clicking the top part of the filter into place.
 - 4.4 Make sure that no lines are stuck between the kit and the side of the machine. Press the disposable kit sides firmly into the white locks until you hear the locking mechanism click at the top and bottom. Make sure that both the upper and lower locks are engaged. Close the blood and fluid side doors.

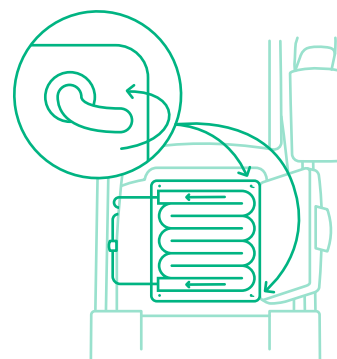


4.5

LOAD THE WARMER BAG

Open the warmer door (at the back of the OMNI).

Put the warmer bag on the two hooks on the door hinge first and then stretch the warmer bag and fix it to the two pins. Lock the warmer door, ensuring it is fully closed (hearing a loud click). Once it is closed firmly, do not open this door again.



4.6

CONNECTING THE PRESSURE LINES

This action does not get an hourglass or a check on screen at this stage; however, this step needs to be completed (a check will appear once loaded). Remove the colored caps from the pressure lines. Connect the pressure lines to the corresponding colored pressure sensor connectors. Make sure all lines are firmly connected.

4.7

INSERTING THE SYRINGE

In therapies with heparin anticoagulation, the syringe is used to infuse heparin. If no anticoagulation is being used, then no syringe is inserted and this step is not shown on screen.

4.7.1

Connect the heparin line to the heparin syringe.

4.7.2

Open the unlocking lever and the syringe holder by pushing the gray clip upwards and pulling the holder outwards.

4.7.3

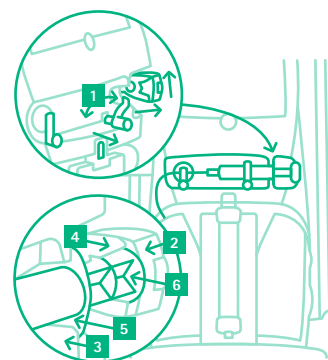
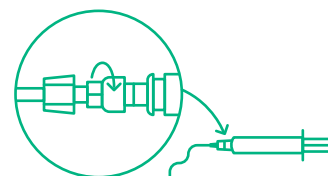
Insert the syringe end into the clip and the wings into the gripping plate in the slot.

4.7.4

Close the unlocking lever.

4.7.5

Make sure the clamp on the syringe line is open. If the syringe insertion does not get a check, try again until the check appears.



4.8

SETTING SYRINGE PARAMETERS

Select the syringe type from the drop-down menu and set the correct volume.

- 1 Unlocking lever
- 2 Syringe holder
- 3 Slot – for gripping plate
- 4 Clip – for piston plate
- 5 Gripping plate
- 6 Piston plate

4.9

LOAD

Once complete, press LOAD on screen. Make sure, once loaded, that the tube segments are installed correctly (visual check the pumps by opening the blood and fluid side doors). If the loading is unsuccessful, press LOAD again. Once completed, press NEXT.

5

INSTALL FLUID BAGS

Depending on the selected therapy type, different fluid bags are required for the load cells.

For a table of required fluid bags depending on therapy chosen, please see the OMNI IFU SW 1.75, page 166. The bags discussed below correspond with CVVHD, CVVHDF AND CVVH PRE-POST DILUTION therapies with heparin or without anticoagulation; if using an alternative therapy, please see the table in the IFU for correct bag placement.

When looking at the screen, work clockwise from the IV pole to ensure no stages are missed. The color of the bag on screen correlates to the line to be used. Make sure that the bags and lines hang freely and do not rest on the base.



5.1

INSTALLING WASTE BAG FOR PRIMING (IV POLE)

Hang the priming waste bag attached to the venous line (blue) on the IV pole. Close the clamp (red) on the priming waste bag T-piece.

5.2

INSTALLING THE DIALYSATE / SUBSTITUTION BAG (RIGHT LOAD CELL)

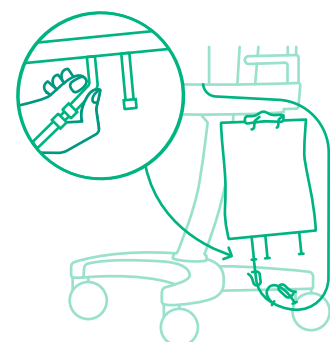
Ensure the correct fluid bag as prescribed is chosen. Consult the instructions for use of the fluid bag. Duosol (or equivalent) is used with heparin or no anticoagulation. Calcium-free bicarbonate solution is for Regional Citrate Anticoagulation use only; do not use calcium-free solution for heparin or no anticoagulation.

5.2.1

Hang one or two fluid bags on the right load cell (two is recommended to avoid frequent changes).

5.2.2

Remove the cap(s) and connect the dialysate line (green) to the fluid bags (one green line Y-piece to one fluid bag).



5.2.3 Break the frangible pin in the bag outlet, snapping it right and left/forward and back.

5.2.4 Make sure that the line clamps are open on all the lines being utilized.

5.3 INSTALLING THE EFFLUENT BAG (CENTER LOAD CELL)

Hang one or two effluent bags on the center load cell. Make sure that the inlet is on the right side of the bag. Remove the cap(s) (green connector) and connect the effluent line (yellow) to the effluent bag(s). Close the drain outlet. Make sure the clamp is open on the effluent line. On the touch screen, select the number of connected effluent bags from the drop-down list.

5.4 INSTALLING A SALINE BAG FOR PRIMING (CENTER LOAD CELL)

Hang a saline bag (minimum 1,000 ml but not more than 2,000 ml) on the center load cell directly on top of the effluent bag(s). Connect the arterial line (red) with the spike to the saline bag. This priming bag sits in front of the effluent bag (on the same scale), as can be seen in the picture and on screen.

5.5 INSTALLING THE LEFT LOAD CELL BAG

The left load cell is the substitution scale (purple).

5.5.1 For CVVHD: The scale is not used in this therapy; however, the purple lines need to be primed. Hang one bag of saline (minimum 500 ml) and attach the purple line (a spike may be required; only one bag of fluid is needed for this purpose). Ensure the purple Y-piece line that is not being used is clamped. This bag remains here for the entirety of the therapy (unless a change of therapy is initiated).

5.5.1 For CVVH pre-post dilution and CVVHDF: Hang one or two substitution bags on the left load cell as prescribed. Connect the purple line(s), one purple line to one fluid bag, and break the frangible pin in the bag outlet. Ensure the lines in use are unclamped.

5.6 CITRATE LOAD CELL

This scale (on the left-hand side on the top of the OMNI, with the black circle) is only for use with citrate anticoagulation. When using heparin or no anticoagulation, this scale is not used and nothing should be placed here.

6

AUTOMATIC PRIMING

During priming, all lines are filled with fluid in order to remove air.

6.1

Make sure that all the clamps in use are open and all those not in use are closed. This includes closing clamps on all syringe lines not in use, along with the clamp at the end of the calcium line next to the venous (blue) line.

6.2

Press Automatic Priming (1) (press and hold until it turns light green, then release). The machine primes and rinses the disposable kit.

6.3

To pause priming, press the Automatic Priming button to stop it. To resume priming, press Automatic Priming again. If an alarm sounds, diagnose the problem and press Reset Alarm. The priming will then continue automatically.

6.4

Wait until automatic priming is completed and make sure to check the blood lines for air prior to commencing the next step.

6.5

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

7

READY FOR THERAPY

7.1

OPTIONAL RINSING

The machine rinses the disposable kit with a specified amount of additional fluid. This function can be used, for example, for additional rinsing with saline following a heparin prime. This step is not necessary if not required.

7.2

OPTIONAL RECIRCULATION

This function can be used to keep the system on standby until the patient can be connected.



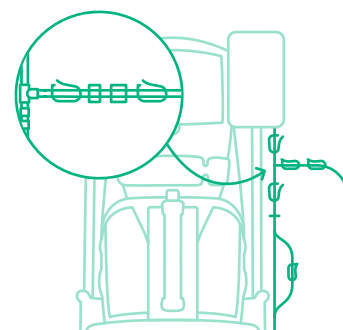
7.2.1 The arterial (red) line is removed from the saline priming bag and connected to the red T-piece on the priming waste bag where the venous (blue) line is on the IV pole. Dispose of the saline bag previously attached to the arterial (red) line.

7.2.2 Make sure to close the white clamp on the priming waste bag for recirculation to prevent sterilization chemicals being recirculated.

7.2.3 Open the clamps on the arterial line (red) and the venous line (blue). Please see the picture to the right for optional recirculation.

7.2.4 To start recirculation, press the Recirculation button, and similarly to stop it, press Recirculation again.

7.2.5 To proceed, press Next.



8

CONFIRM THERAPY PARAMETERS

8.1 To complete preparation, the Confirm Therapy Parameters screen shows all the mandatory fields that need to be filled highlighted in orange. Ensure all parameters are filled as per the protocol used.

8.2 If starting with no fluid removal, "zero" must be input into the net fluid removal field. Otherwise input a volume, remembering it is the volume removed in ml/hr.

8.3 When complete, press Confirm to move to the next step.

9

CONNECT PATIENT

The patient's access should be checked and prepared as per hospital guidelines prior to connecting to the OMNI. Keep the patient access securely clamped until the arterial (red) and venous (blue) lines from the OMNI are securely connected and ready to start therapy.

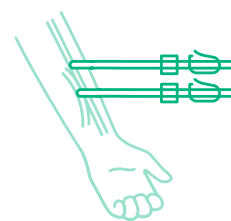
Ensure all lines are clamped when disconnecting from the priming waste bag. Follow all the steps on screen.

Two different connection procedures are supported. The physician is responsible for choosing the appropriate patient connection method.

WHITE CONNECTION

Double connection. The patient is connected to both the arterial (red) and venous (blue) lines prior to commencing. Blood lines can be filled at this stage using the Fill Blood Lines icon.

- 9.1 Follow the steps on screen to connect the patient, again pressing the ⓘ on screen or referring to the IFU for more information. Make sure to check the patient's access prior to connection as per hospital policy.
- 9.2 Only unclamp the arterial (red) and venous (blue) lines when the patient is securely connected.
- 9.3 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 and the venous pressure is stable, press the Enter Therapy button. The machine enters therapy with the blood pump running. The machine does not automatically stop the blood pump in White Connection.
- 9.4 Once the patient is connected to the red and blue lines and it is safe to do so, please remove and dispose of all unused bags, including the priming waste bag.



1.2 SETUP

1.2.2 SETTING UP CITRATE

1

SCAN KIT

Choose the correct set. OMNIset L (96 hours) and OMNIset Pro (72 hours) can be used with CVVHD citrate anticoagulation. OMNIset L and OMNIset Pro 1.6 m² can be used for CVVHDF citrate anticoagulation. Scan the barcode on the kit bag using the barcode scanner lit up at the bottom right of the OMNI, lining the cross (red light shining from scanner) onto the barcode. If the barcode is damaged on the packet, the user can input the data manually.

2

SELECT THERAPY

Make sure to choose the correct therapy, dilution and anticoagulation required, as prescribed by the physician. CVVHD or CVVHDF therapy can be chosen for use with citrate anticoagulation.

3

SELF-TESTS

The machine will work through the self-tests. Leave it to do this. The alarm will sound and the light will flash.

4

INSTALL KIT

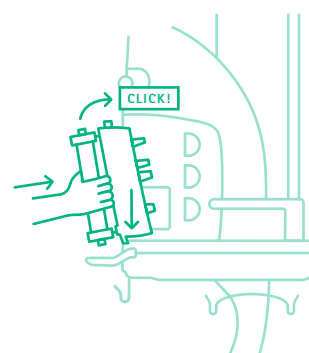
4.1 Take the kit out of the bag and place it onto a cart or flat surface. Check the connections, ensuring the priming waste bag is connected securely to the blue (venous) line.

4.2 Open the blood and fluid doors on the right and left sides of the machine.

4.3 Hold the kit with the red filter cap at the top. Insert the lower (blue) part of the kit first into the slots above the lower front handle. Now fix the kit onto the front of the machine using the latch at the top, clicking the top (red) part of the filter into place.

4.4 Make sure that no lines are stuck between the kit and the side of the machine. Press the disposable kit sides firmly into the white locks until you hear the locking mechanism click at the top and bottom (this needs to be a firm push, holding onto the machine with one arm while pushing with the other). Make sure that both the upper and lower locks are engaged. Close the blood and fluid side doors.

⋮



4.5

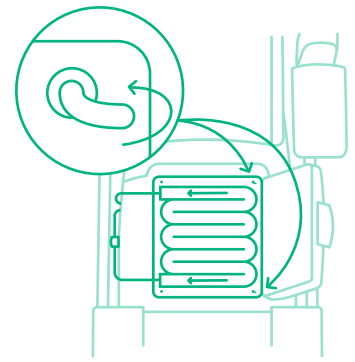
LOAD THE WARMER BAG

Open the warmer door (at the back of the OMNI). Put the warmer bag on the two hooks on the door hinge first and then stretch the warmer bag and fix it to the two pins. Lock the warmer door, ensuring it is fully closed (hearing a loud click). Once it is closed firmly, do not open this door again.

4.6

CONNECTING THE PRESSURE LINES

This action does not get an hourglass or a check on screen at this stage; however, the step needs to be completed (a check will appear once loaded). Remove the colored caps from the pressure lines. Connect the pressure lines to the corresponding colored pressure sensor connector.



4.7

INSERTING THE SYRINGE

Follow the steps below. In therapies with regional citrate anticoagulation, the syringe is used to infuse the calcium. Make sure to choose the correct syringe line; the calcium syringe connects to the calcium line (the line with "calcium" written on it). Ensure there are no air bubbles present in the syringe. The shorter line with a clamp on the calcium line is for air removal during therapy.

4.7.1

Connect the calcium syringe to the calcium line.

4.7.2

Open the unlocking lever, the tube holder and the syringe holder, by pushing the gray clip upwards and pulling the holder outwards.

4.7.3

Insert the syringe end into the clip and the wings into the gripping plate in the slot. The gray clip should automatically come down on its own when the syringe is inserted.

4.7.4

Insert the calcium line into the calcium safety air detector. The calcium line must go through here.

4.7.5

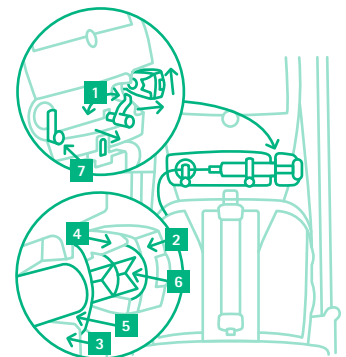
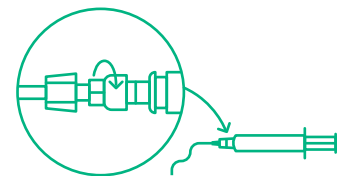
Close the unlocking lever and the tube holder.

4.7.6

Make sure the clamp on the syringe line is open and the clamp on the small air removal line is closed.

The calcium line must go through the calcium air detector (7) as the calcium infuses directly back to the patient.

If the syringe insertion does not get a check, try again until the check appears.



- 1 Unlocking lever
- 2 Syringe holder
- 3 Slot – for gripping plate
- 4 Clip – for piston plate
- 5 Gripping plate
- 6 Piston plate
- 7 Calcium air detector and tube holder

4.8

SETTING SYRINGE PARAMETERS

Ensure the correct calcium concentration is set here on screen to that prescribed. Select the syringe type from the drop-down menu and set the correct volume.

4.9

LOAD

Once complete, press LOAD on screen. Make sure, once loaded, that the tube segments are installed correctly (visual check the pumps by opening the blood and fluid side doors). If the loading is unsuccessful, press LOAD again. Once completed, press NEXT.

5

INSTALL BAGS

Depending on the disposable kit type and selected therapy type, different fluid bags are required for the load cells.

For a table of required fluid bags depending on therapy chosen, please see the OMNI IFU SW 1.75, page 166. The bags discussed below correspond with CVVHD and CVVHDF (post dilution) CITRATE therapy only.

When looking at the screen, work clockwise from the IV pole to ensure no stages are missed. The color of the bag on screen correlates to the line to be used. Make sure that the bags and lines hang freely and do not rest on the base.

5.1

INSTALLING WASTE BAG FOR PRIMING (IV POLE)

Hang the priming waste bag attached to the venous line (blue) on the IV pole. Close the clamp (red) on the priming waste bag T-piece.

5.2

INSTALLING THE DIALYSATE BAG (RIGHT LOAD CELL)

Make sure to choose the correct dialysate bag as prescribed. CALCIUM-FREE SOLUTION must always be used as the DIALYSATE bag with citrate anticoagulation. Consult the instructions for use of the dialysate bag.

5.2.1

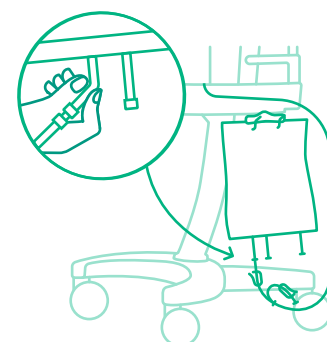
Hang one or two dialysate bags on the right load cell (two is recommended to avoid frequent changes).

5.2.2

Remove the cap(s) and connect the dialysate line (green) to the dialysate bags (one green line Y-piece to one dialysate bag).

5.2.3

Break the frangible pin in the bag outlet (snapping it right, left, forward and back).



5.2.4 Make sure that the line clamps are open on all the lines being utilized.

5.3 INSTALLING THE EFFLUENT BAG (CENTER LOAD CELL)

Hang one or two effluent bags on the center load cell. Make sure that the inlet is on the right side of the bag. Remove the cap(s) (green connector) and connect the effluent line (yellow) to the effluent bag(s). Close the drain outlet. Make sure the clamp is open on the effluent line. On the touch screen, select the number of connected effluent bags from the drop-down list.

5.4 INSTALLING A SALINE BAG FOR PRIMING (CENTER LOAD CELL)

Hang a saline bag (minimum 1,000 ml but not more than 2,000 ml) on the center load cell on top of the effluent bag(s). Connect the arterial line (red) with the spike to the saline bag. This priming bag sits in front of the effluent bag (on the same scale), as can be seen on screen.

5.5 INSTALLING THE LEFT LOAD CELL BAG

The left load cell is the substitution scale (purple).

5.5.1 CVVHD

CVVHD the substitution scale/left load cell will not be used. However, one bag of saline (minimum 500 ml) must be attached to this side to allow for priming of the purple line (a spike may be required; only one bag of fluid is needed for this purpose). This bag remains here for the entirety of the therapy. Ensure the purple Y-piece line that is not being used is clamped.

5.5.2 FOR CVVHDF

The left load cell is for post dilution in this therapy. Hang one or two substitution bags to this load cell as prescribed, carefully following the citrate anticoagulation protocol and prescription. Make sure to check the calcium concentration of the substitution bag on screen corresponds to that prescribed prior to use. Connect the purple line(s), one purple line to one fluid bag, and break the frangible pin in the bag outlet. Ensure the lines in use are unclamped.

5.6 INSTALLING THE CITRATE BAG (CITRATE LOAD CELL)

Please make sure to check the citrate concentration on screen corresponds to that prescribed prior to use. Hang the citrate bag on the citrate load cell. Connect the citrate bag to the citrate line (line with "citrate" written on it). Open the clamp on the citrate line. Break the frangible pin in the bag outlet (snapping it back, forward, left and right).



WARNING Risk of patient death or injury due to incorrect treatment. Make sure that the solutions used are according to prescription. Make sure that the line clamps are closed on all lines not being utilized. Make sure that the line clamps are open on all lines being utilized. Make sure that each bag has been put on the correct load cell and is connected to the correct line. Do not hang anything other than the fluid bags intended for the therapy on the load cells.

6

AUTOMATIC PRIMING

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

6.1

Make sure that all the clamps in use are open and all those not in use are closed, including closing clamps on the syringe lines not in use.

6.2

Press Automatic Priming (1) (press and hold until it turns light green, then release). The machine primes and rinses the disposable kit.

6.3

To pause priming, press the Automatic Priming button to stop it. To resume priming, press Automatic Priming again. If an alarm sounds, diagnose the problem and press Reset Alarm. The priming will then continue automatically without use of the Automatic Priming button.

6.4

Wait until automatic priming is completed and make sure to check the blood lines for air prior to commencing the next step.

6.5

To proceed to the Ready for Therapy step, press Next (3).

7

READY FOR THERAPY

7.1

OPTIONAL RINSING

The machine rinses the disposable kit with a specified amount of additional fluid, used, for example, if additional rinsing is required. Follow the instructions on screen, pressing the ⓘ for more information or referring to the IFU. This step is not necessary if not required.

7.2

OPTIONAL RECIRCULATION

This function can be used to keep the system on standby until the patient can be connected. Follow the steps on screen, pressing the ⓘ for more information or referring to the IFU.

7.2.1

The arterial (red) line is removed from the saline priming bag and connected to the red T-piece on the priming waste bag where the venous (blue) line is on the IV pole. Dispose of the saline bag previously attached to the arterial (red) line.

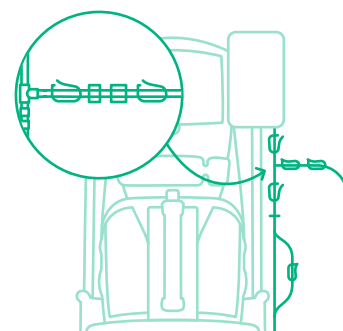


7.2.2 Make sure to close the white clamp on the priming waste bag for recirculation to prevent sterilization chemicals from the kit being recirculated.

7.2.3 Open the clamps on the arterial line (red) and the venous line (blue). Please see the picture to the right for optional recirculation.

7.2.4 To start recirculation, press the Recirculation button, and similarly to stop it, press Recirculation again.

7.2.5 To proceed, press Next.



8 CONFIRM THERAPY PARAMETERS

8.1 To complete preparation, the Confirm Therapy Parameters screen shows all the mandatory fields that need to be filled highlighted in orange. Make sure to fill all parameters as per the protocol used.

8.2 If starting with no fluid removal, "zero" must be entered into the net fluid removal field. Otherwise input a volume, remembering it is the volume removed in ml/hr.

8.3 When complete, press Confirm to move to the next step.

Make sure to carefully fill in the parameters closely following the citrate protocol. The machine works out the rate of citrate and calcium to deliver based on the anticoagulation parameters input into the machine.

9 CONNECT PATIENT

The patient's access should be checked and prepared as per hospital guidelines prior to connecting to the OMNI. Keep the patient access clamped until the arterial (red) and venous (blue) lines from the OMNI are securely connected and ready to start therapy.

Make sure to clamp all lines when disconnecting from the priming waste bag. Follow all the steps on screen.

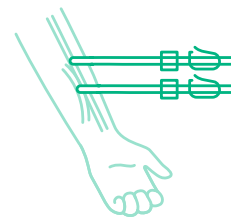
Two different connection procedures are supported. The physician is responsible for choosing the appropriate patient connection method. White connection is discussed here; if requiring red connection (single connection), please see the OMNI IFU SW 1.75.

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

WHITE CONNECTION

Blood lines can be filled at this stage using the Fill Blood Lines icon. Double connection. The patient is connected to the arterial (red) line and venous (blue) lines prior to commencing.

- 9.1 Follow the steps on screen to connect the patient, again pressing the ⓘ on screen or referring to the IFU for more information. Make sure to check the patient's access prior to connection as per hospital policy.
- 9.2 Only unclamp the arterial (red) and venous (blue) lines when the patient is securely connected.
- 9.3 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 and the venous pressure is stable, press the Enter Therapy button. The machine enters therapy with the blood pump running. The machine does not automatically stop the blood pump in White Connection.
- 9.4 Once the patient is connected to the red and blue lines and it is safe to do so, please remove and dispose of all unused bags, including the priming waste bag.



2. STARTING THERAPY

2.1 STARTING THERAPY - HEPARIN

Starting the therapy (once the patient is connected)

- 1 If the blood lines are not already filled, press (and hold) the blinking Blood Pump icon (1). The blood pump is started and the red line begins to move around the icon. The blood begins to enter the kit from the patient and the syringe pump commences administering the heparin automatically.
- 2 Increase the blood flow rate by pressing number (2) in the middle of the screen to the flow rate as per protocol at a rate based on the patient's stability.
- 3 Once the patient is stable and the blood is returning to the patient at blood flow target, commence the therapy by pressing the Therapy icon (3). This initiates the substitution, dialysate and effluent pumps. The OMNI is now running.



WARNING Risk of blood loss due to improper connection of blood lines to patient. After starting the blood pump and specifying the blood flow rate, check the arterial line, venous line, patient access and hemofilter for leaks.



2. STARTING THERAPY

2.2 STARTING THERAPY - CITRATE

Starting the therapy (once the patient is connected)

- 1 If the blood lines are not already filled, press (and hold) the blinking Blood Pump icon (1). The blood pump is started, the red line begins to move around the icon and blood begins to enter the kit from the patient.
- 2 Increase the blood flow rate by pressing number (2) in the middle of the screen to the flow rate as per protocol at a rate based on the patient's stability.
- 3 Once the patient is stable and the blood is returning to the patient at blood flow target, commence the therapy by pressing the Therapy icon (3). This initiates the fluid side pumps. The OMNI is now running. Refer to the citrate protocol for the next steps relating to citrate and calcium monitoring.



WARNING Risk of blood loss due to improper connection of blood lines to patient. After starting the blood pump and specifying the blood flow rate, check the arterial line, venous line, patient access and hemofilter for leaks.



2. STARTING THERAPY

2.3 TROUBLESHOOTING

When Enter Therapy is pressed, please start the blood pump and increase the blood flow to the protocol target blood flow at a rate based on the patient's stability.

LOW VENOUS ALARM

If this alarm appears, please double check your connections, as this can happen when the lines become disconnected. However, if the blood lines have not been filled during the patient connection phase, this alarm appears while the blood is making its way around the set from the patient. This can be due to the saline being returned to the patient at present (from priming) being less viscous than blood and triggering the low venous alarm. If the connection is secure, try to raise the height of the bed, which can increase the venous pressure, and press Reset Alarm. Once the blood is returning to the patient, the problem should be resolved.

Once you have started the blood pump and therapy using the red and blue buttons in the bottom corner, please avoid pressing these unless required to stop the blood pump or therapy. During therapy, if the machine needs to stop them, it will, and it will similarly restart them itself. For example, during a bag change, the therapy will stop, and when the "Bag Change/Weight Reset" button is pressed, the therapy will restart itself.

3. DURING THERAPY

3.1 DURING THERAPY - HEPARIN

STOPPING AND STARTING BLOOD PUMP, THERAPY AND ANTICOAGULATION

- Pressing the Blood Pump icon during therapy pauses the operation of all pumps. Pressing the Blood Pump icon again resumes the operation of all the paused pumps.
- Pressing the Therapy icon during therapy pauses 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 pauses operation of the syringe pump. Pressing the Heparin icon again resumes operation of the syringe pump.
- Please be careful not to 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 resume automatically.

DIAGNOSING AND RESOLVING ALARMS

- When an alarm initially sounds, press Audio Pause to silence it.
- When an alarm is triggered, a banner is shown in the bottom corner of the screen. Pressing on the banner expands it, with the ⓘ symbol giving advice and possible workarounds for the alarm.
- When the issue is resolved, press Reset Alarm.

BAG CHANGES

- The bags can be changed at any time during therapy.
- To start the bag change procedure, either press the Bags icon on screen or select Functions > Change Bag on the menu bar.
- Make sure to always press the Bags icon when doing a bag change. Do not lift any bags off their scale without doing so.
- The machine automatically determines the number of installed bags by weight when they are installed. The user has to select the correct number of effluent bags only. Confirm the bag change by pressing the Bag Change/Weight Reset icon.
- The therapy will stop when bag change is pressed. When the Bag Change/Weight Reset icon is pressed, the therapy will resume automatically once again.

HOW TO CHANGE THE HEPARIN SYRINGE

- 1 Press Functions or Parameters > Anticoagulation on the menu bar.
- 2 Press the Change Syringe icon.
 - 2.1 The Syringe Change screen pops up.
 - 2.2 Simultaneously, the syringe pump is stopped while the blood pump and fluid side pumps continue running.

Disconnect and dispose of the syringe and install a new syringe (as per prescription), as done previously.

Enter the syringe type and the correct filled volume on screen. Press Confirm. The heparin syringe will commence dispensing once again.

PATIENT CARE

- The machine can be set to patient care mode to provide nursing care to the patient without triggering any alarms.
- Setting the machine to patient care mode causes the fluid side pumps to stop.

The blood flow rate is reduced to 50 ml/min. The alarm parameters are widened to avoid triggering alarms during this time.

- An alarm is triggered when patient care mode has been active for a period of time.
- Press the Patient Care icon to activate this feature, and once complete, press Patient Care to return to normal therapy.

CHANGING FLOW RATES AND PARAMETERS

- Net fluid removal (mls/hr), dialysate, substitution 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.

HISTORY AND VOLUMES

- To navigate to the fluid balance information, press History > Volumes > Totals (totals being on the top right side of the page).
- This will show the net fluid removed during therapy, which can be shown as hourly for charting on the fluid balance chart.

3. DURING THERAPY

3.2 DURING THERAPY – CITRATE

STOPPING AND STARTING BLOOD PUMP, THERAPY AND ANTICOAGULATION

- Pressing the Blood Pump icon during therapy pauses operation of all pumps. Pressing the Blood Pump icon again resumes operation of all the paused pumps.
- Pressing the Therapy icon during therapy pauses operation of the fluid side pumps and the citrate and calcium delivery. The blood pump will continue running. Pressing the Therapy icon again resumes operation of the fluid side pumps and the administration of citrate and calcium.
- Please be careful not to 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 itself and resume automatically when the bag change is complete.

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 it.

- When an alarm is triggered, a banner is shown in the bottom corner of the screen. Pressing on the banner expands it, with the ⓘ symbol giving advice and possible workarounds for the alarm.
- When the issue is resolved, press Reset Alarm.

BAG CHANGES

- The bags can be changed at any time during therapy.
- To start the bag change procedure, either press the Bags icon on screen or select Functions > Change Bag on the menu bar. Make sure to always press the Bags icon when doing a bag change. Do not lift any bags off their scale without doing so.
- The machine automatically determines the number of installed bags by weight when they are installed. The user has to select the correct number of effluent bags only. Confirm the bag change by pressing the Bag Change/Weight Reset icon.
- The therapy will stop when Bag Change is pressed. When the Bag Change/Weight Reset icon is pressed, the therapy will resume automatically once again.

HOW TO CHANGE THE CALCIUM SYRINGE

- 1 Press Functions or Parameters > Anticoagulation on the menu bar.
- 2 Press the Change Syringe icon on the Functions or Anticoagulation screen.
 - 2.1 The Syringe Change screen pops up.
 - 2.2 Simultaneously, the citrate and syringe pumps are stopped while the blood pump and fluid side pumps continue running.
- 3 Disconnect and dispose of the syringe and install a new syringe (as per prescription), as done previously.
- 4 Enter the syringe type and the correct filled volume on screen. Press Confirm to return to Therapy. The pumps will restart automatically.

NOTE: Anticoagulation is off during the syringe change; therefore, the more time taken, the more likely the blood is to clot. Make sure to have the next calcium syringe prepared prior to commencing the change of syringe.

PATIENT CARE

- The machine can be set to patient care mode to provide nursing care to the patient without triggering any alarms.
- Setting the machine to patient care mode causes the fluid side pumps to stop. The blood flow rate is reduced to 50 ml/min. The alarm parameters are widened to avoid triggering alarms during this time.
- An alarm is triggered when patient care mode has been active for a period of time.
- Press the Patient Care icon to activate this feature, and once complete, press Patient Care again to return to normal therapy. The therapy will then resume automatically. Do not press the THERAPY icon.

CHANGING FLOW RATES AND PARAMETERS

- Net fluid removal (mls/hr), dialysate 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.
- Please remember to refer to the consultant and the protocol when adjusting any parameters or settings. Changing the blood flow in citrate anticoagulation will alter the amount of citrate being given.

HISTORY AND VOLUMES

- To navigate to the fluid balance information, press History > Volumes > Totals (Totals being on the top right side of the page).
- This will show Net Fluid Removed during therapy, which can be shown as hourly for charting on the fluid balance chart.

3.3 TROUBLESHOOTING

3.3.1 COMMON TROUBLESHOOTING DURING THERAPY

BAG CHANGES

ALWAYS press the Bags button when changing any fluid bag. If a bag is changed and the button is not pressed, it will trigger an alarm and could cause a "safety check error" message to show and a possible inability to continue treatment. If this alarm shows and you cannot reset it, you may need to cause a power failure on the machine (turning it off and then on), which should resolve the alarm. The OMNI will take approximately three minutes to switch back on and will return to its last state after it restarts. Always press the Bags button to ensure this does not occur.

LONG ANTICOAGULATION STOP

This alarm happens when anticoagulation has been stopped for approximately five minutes. Anticoagulation stops during a bag or syringe change. Always make sure to preempt bag or syringe changes to ensure the set does not clot.

AIR IN CALCIUM SYRINGE

Make sure to use a small syringe and slowly pull the air out; it should only be a small volume that needs to be removed. Keep the calcium line clamp open when doing this to be able to pull the air out. Do not pull too hard or there will be blood returned in the calcium line from the venous line.

BLOOD LEAK DETECTOR ALARM

- 1 There is visible blood in the effluent might caused by a rupture of the membranes.
- 2 This alarm can also trigger when there is a discoloration of the effluent (for example from high bilirubin levels). If you are satisfied that this is the reason, you can press "temporary override," causing a small box to appear in the left-hand bottom corner of the screen.
- 3 Additionally, if there is bright light shining on the blood leak detector (underneath the effluent chamber), this can trigger the alarm. Remove the light source and press No Override.
- 4 Finally, if the effluent chamber is empty, this can trigger the alarm. Go to the Levels button on the screen and VERY SLOWLY fill the effluent chamber using the up arrow until the chamber is filled halfway only. Do not do this too fast or fill the chamber

too full as this can cause a change of pressure within the set and possible subsequent alarms. Once the chamber is filled halfway, press No Override on the blood leak detector and this should resolve the problem.

If the blood leak detector is put into override, please consider testing the effluent for blood using the small line on the fluid side of the machine to draw out some effluent.

BLOOD IN THE ARTERIAL (RED) PRESSURE LINE

This is due to the blood pump stopping/low blood flow, causing a backflow of blood from the arterial/access line. When blood is seen in the arterial pressure line, try to resolve this by:

- 1 Pressing the Patient Care button
- 2 Clamping the access/arterial line at patient access
- 3 Disconnect the arterial pressure line from the arterial pressure port

⋮



4 Checking to see if the blood has returned to the chamber from the pressure line



5 Reconnect the arterial pressure line to the pressure port



6 Release the clamp at arterial line at patient access



7 Deactivate patient care mode by pressing the Patient Care button again

As long as the blood pump is running, this will cause the blood to move out of the line and return to the chamber. If there is an arterial pressure alarm during this procedure as a result of the access/arterial line being clamped, the blood pump will stop; make sure to reset the alarm to allow the blood pump to run for enough time for the blood to be removed from the line and continue with the steps detailed above. Make sure to always reattach the pressure line before unclamping the arterial/access line. If the blood is already clotted in the pressure line, DO NOT reconnect it to the machine. Leave it as it is, as you do not want to return clots to the chamber. If blood reaches the pressure measurement sensor at the top of the pressure line, this may trigger an arterial pressure measurement failure alarm. Attempt to remove the blood if not clotted following the steps above, and reset the alarm. If the alarm does not reset, the kit may need to be changed.

SOLUTION FLOW / PUMP FAILURE / FLOW PROBLEM

Make sure to diagnose and rectify as soon as possible to avoid a fluid balance management error. Often these alarms can be triggered by unbroken pins. Always ensure pins are broken. At times they can seem broken; however, if they are not fully open, the machine is unable to pull the fluid at the desired rate and therefore an alarm is triggered, which will then trigger subsequent alarms. Make sure to double check pins/clamps if any of these alarms are triggered to ensure this is not the problem.

CIRCUIT CLOTTING

This can happen for various reasons, around 50% of these being access issues – please speak to medical staff regarding any access problems. The OMNI cannot run successfully if the access is poor. Several blood pump or therapy interruptions will cause the Circuit to clot. Make sure not to press the BLOOD PUMP or THERAPY buttons on and off when in therapy. Ensure anticoagulation is appropriate.

SELF-TEST

The machine carries out tests every 24 hours during therapy. It will alarm and flash; leave it to go through this process. If another alarm triggers during this time, it may cause the tests to fail. Press Reset Alarm and allow the tests to continue; this should resolve this issue. Please note that pressing the Blood Pump icon to turn it off can block the 24-hour self-test.

SOLUTION CHAMBER REGULATION FAILURE

The most common reason for this alarm is a pin not being broken properly on the dialysate bag or a clamp being left on, causing a level regulation problem in the solution chamber. Check the pin and clamps and reset the alarm. It can take two or three alarm resets for the dialysate fluid level to resolve, giving it time to flow through the warmer bag to the solution chamber. If the alarm does not reset after two or three attempts, it may be necessary to release the green solution pressure line for a second by disconnecting it from the green pressure port at the side of the machine and connecting it securely back into the green solution pressure port and then resetting the alarm.

Additionally, if there is no problem with a pin or a clamp, the alarm could be due to condensation within the solution chamber. If condensation is noted, go to the Levels page, where you will see the four chambers. Going to the solution chamber, keeping it in auto regulation, slowly increase the level in the chamber to get rid of the bubbles. The machine should bring the level back down automatically, clearing the bubbles and resolving the issue. Press Reset Alarm, and allow the machine to continue with therapy automatically.

3.3 TROUBLESHOOTING

3.3.2 TEMPORARY DISCONNECTION AND RECIRCULATION

This is for when the patient will be off the OMNI for a short period.

Only press Temporarily Disconnect Patient when ready to return the blood, with the equipment and sterile field prepared. Once this is pressed, the blood pump stops and the blood will begin to clot.

Return the blood as instructed on the screen, making sure to follow all steps in turn.

Put into recirculation once the blood has been returned, connecting the blue and red lines to the three-way tap.

Once ready to reconnect to the patient, ensure there are no clots within the set. If there are, a new set may be required, as we cannot risk returning blood clots to the patient.

Follow the steps on screen and reconnect the patient.

If recirculation following temporary disconnection has been ongoing for longer than the recommended recirculation time, then you must change to a new set.

4. ENDING THERAPY

4.1 ENDING THERAPY - HEPARIN

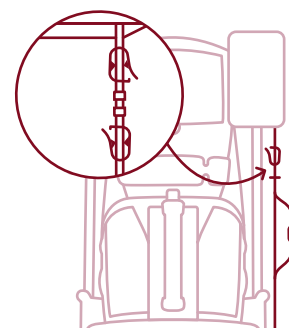
- A running therapy can be terminated at any time.
- Use End Therapy when the therapy is over and the patient is not to be connected to the machine again.
- Use Temporarily Disconnect Patient when the therapy is not over and the patient is to be reconnected to the machine after a short period of time.
- Change Kit is used to take the current kit off and replace it with a new kit right away (e.g., if there is a kit issue or you have reached kit expiry time).
- Navigate to Functions to see this screen:

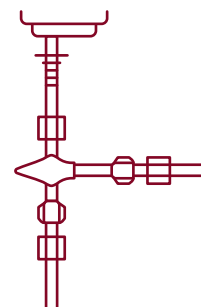


HOW TO START THE TEMPORARILY DISCONNECT PROCEDURE

During recirculation, the venous (blue) and arterial (red) lines are connected to a saline bag in order to keep the machine on standby until reconnection of the patient is required. A saline bag (250 or 500 ml) and three-way tap are required for this procedure, along with blood return equipment. The blood is returned to the patient prior to recirculation.

- 1 Press Functions (1) on the menu bar.
- 2 Ensure all the blood return equipment is prepared and ready (as the blood pump will stop once the disconnection process is commenced, causing the blood to begin to clot). Hang the saline bag on the IV pole.
- 3 Press the Temporarily Disconnect Patient icon on the Functions screen, as above, and press Yes to confirm your selection.
- 4 The Return Blood screen appears:
 - 4.1 Return the blood as detailed on screen, following each step in turn. Remove the arterial (red) line from the patient and connect it to the saline bag on the IV pole. Make sure to secure the patient access and clamp all clamps before disconnecting from the patient.
 - 4.2 Press Return Blood when ready to return the blood, after unclamping the arterial (red) line at the saline bag and only when satisfied all connections are secure. Make sure to monitor the patient and the lines closely throughout.





4.3 The OMNI automatically returns the volume within the set. 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 icon. If blood remains in the set, the user can press the Return +50 ml icon to return more blood to the patient. Ensure there is enough saline left in the saline bag to do this.

4.4 Once the blood has been returned, disconnect the venous line (blue) from the patient and connect it to the three-way tap on the IV pole for recirculation.

4.5 Make sure to clamp lines and patient access prior to disconnection. The patient should now be fully disconnected from the machine with access securely clamped.

HOW TO START THE TEMPORARILY DISCONNECT PROCEDURE

5 Press Next to proceed to the recirculation step. Open the clamps on the arterial (red) and venous (blue) lines when on the three-way tap connected to the saline bag.

6 To start recirculation, press Recirculation. The blood pump starts recirculating the fluid through the lines of the disposable kit. The machine is now recirculating and can be left until the user is ready to reconnect the patient. The time period the machine is in recir-

ulation for is displayed. Do not reconnect if over the recommended recirculation time. Do not reconnect to the patient if there are clots in the set; a new kit is required. To stop recirculation, press the Recirculation button.

7 Once ready to reconnect to the patient, press Reconnect to proceed to the reconnection step. The Confirm Reconnection Parameters dialog appears. The parameter settings entered during preparation are displayed for verification. Keep or change the parameter settings as needed.

8 To proceed to the next step and connect the patient, press Confirm and continue with patient connection as done previously.

HOW TO START THE END OF THERAPY PROCEDURE

- 1 Select Functions (1) on the menu bar, as above.
- 2 Press the End Therapy icon (2) on the Functions screen.
- 3 Once ready with the required equipment for blood return, press Yes to confirm your selection.
 - 3.1 The Return Blood screen appears. Return the blood as detailed on screen and above. Blood return can be skipped here if required.
- 4 Once blood return is complete, disconnect the venous (blue) line from the patient and ensure the patient is fully disconnected from the machine prior to navigating to the unload disposables stage, clamping all clamps and patient access prior to disconnection.

CHANGE OF KIT

Change of kit returns the blood in the same way as above; however, following this will directly move to installing a new kit, as done previously. Follow the steps on screen.

4. ENDING THERAPY

4.2 ENDING THERAPY - CITRATE

- A running therapy can be terminated at any time.
- Use End Therapy when the therapy is over and the patient is not to be connected to the machine again.
- Use Temporarily Disconnect Patient when the therapy is not over and the patient is to be reconnected to the machine after a short period of time.
- Change Kit is used to take the current kit off and replace it with a new kit right away (e.g., if there is a kit issue or you have reached kit expiry time).
- Navigate to Functions to see this screen:

HOW TO START THE TEMPORARILY DISCONNECT PROCEDURE

During recirculation, the venous (blue) and arterial (red) lines are connected to a saline bag in order to keep the machine on standby until reconnection of the patient is required. A saline bag (250 or 500 ml) and three-way tap are required for this procedure, along with blood return equipment. The blood is returned to the patient prior to recirculation.

- 1 Press Functions (1) on the menu bar.



2 Ensure all the blood return equipment is prepared and ready (as the blood pump will stop once the disconnection process is commenced, causing the blood to begin to clot). Hang the saline bag on the IV pole.

3 Press the Temporarily Disconnect Patient icon on the Functions screen, as above, and press Yes to confirm your selection.

4 The Return Blood screen appears:

4.1 Return the blood as detailed on screen, following each step in turn. Remove the arterial (red) line from the patient and connect it to the saline bag on the IV pole. Make sure to secure the patient access and clamp all clamps before disconnecting from the patient.

4.2 Press Return Blood when ready to return the blood, having unclamped the arterial (red) line at the saline bag only when satisfied all connections are secure. Make sure to monitor the patient and the lines closely throughout.

4.3 The OMNI automatically returns the volume within the set. 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 icon. If blood remains in the set, the user can press the Return +50 ml icon to return more blood to the patient. Ensure there is enough saline left in the saline bag to do this.

4.4 Once the blood has been returned, disconnect the venous line (blue) from the patient and connect it to the three-way tap on the IV pole for recirculation.

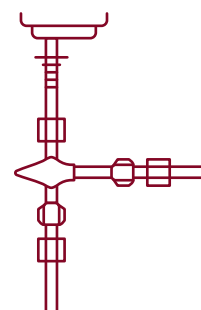
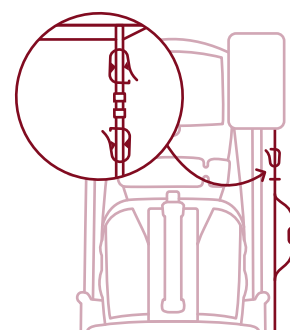
4.5 Make sure to clamp lines and patient access prior to disconnection. The patient should now be fully disconnected from the machine with access securely clamped.

HOW TO START THE TEMPORARILY DISCONNECT PROCEDURE

5 Press Next to proceed to the recirculation step. Open the clamps on the arterial (red) and venous (blue) lines when on the three-way tap connected to the saline bag.

6 To start recirculation, press Recirculation. The blood pump starts recirculating the fluid through the lines of the disposable kit. The machine is now recirculating and can be left until the user is ready to reconnect the patient. The time period the machine is in recirculation for is displayed. Do not reconnect if over the recommended recirculation time. Do not reconnect to the patient if there are clots in the set; a new kit is required. To stop recirculation, press the Recirculation button.

7 Once ready to reconnect the patient, press Reconnect to proceed to the reconnection step. The Confirm Reconnection Parameters dialog appears. The parameter settings



entered during preparation are displayed for verification. Keep or, if needed, change the parameter settings. Please consider the parameters carefully when reconnecting; speak to medical staff and closely follow the protocol for all parameters.

8 To proceed to the next step and connect the patient, press Confirm and continue with patient connection as previously done.

HOW TO START THE END OF THERAPY PROCEDURE

1 Select Functions (1) on the menu bar, as above.

2 Press the End Therapy icon (2) on the Functions screen.

3 Once ready with the required equipment for blood return, press Yes to confirm your selection.

3.1 The Return Blood screen appears. Return the blood as detailed on screen and above. Blood return can be skipped here if required.

4 Once blood return is complete, disconnect the venous (blue) line from the patient and ensure the patient is fully disconnected from the machine prior to navigating to the unload disposables stage, clamping all clamps and patient access prior to disconnection.

CHANGE OF KIT

Change of kit returns the blood in the same way as above; however, following this will directly move to installing a new kit, as done previously. Follow the steps on screen.

5. UNLOADING DISPOSABLES

- Make sure that the patient has been disconnected from the machine.
- Follow all steps in turn on the screen; do not press Unload until all steps are complete. Pressure lines again do not get a check mark until the kit is unloaded; this step needs to be done in turn.
- Press Unload, and the kit will unload. If any alarm triggers during unloading, make sure to resolve the issue and press Reset Alarm to allow the unload process to continue.
- Dispose of all disposables.
- **CAUTION!** Risk of contamination of environment. Dispose of all used bags and the used disposable kit as per facility protocol.
- Navigate to the next stage. Press New Therapy and the start screen will appear.
- Switch the machine off by pressing and holding the green button on the back of the OMNI.
- Ensure the machine remains plugged in when not in use.

B. Braun Avitum AG | Schwarzenberger Weg 73-79 | 34212 Melsungen | Germany
Tel. +49 5661 71-0 | dialysis@bbraun.com | www.bbraun-dialysis.com

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