

GETTING STARTED & DISPOSABLES SET UP

SUPPLIES REQUIRED:

- VitaSmart™ Machine Perfusion System (VS)
- VS disposable set: kit and oxygenator (do not open until graft validity is verified)
- Cold Belzer MPS® UW Machine Perfusion Solution (2 or 3 L depending on the type of graft)
- Sterile surgical bowl (should hold the graft, preservation solution and ice)
- Sterile crushed ice (3 x 500 ml bags of NaCl 0.9% or equivalent)
- Access to an oxygen source (O_2 +/- O_2 flowmeter)

- 1** Turn on VitaSmart™ (VS) and wait until this screen is displayed.



- 2** Insert the oxygenator in its holder.



Ensure the green cap is at the top and the text orientated correctly.

- 3** Locate the RFID card (inside the lid of the disposables box) and insert it into the card holder.

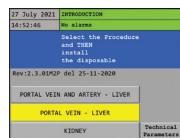


NOTE: Date and time settings cannot be adjusted once the protocol is selected. To make changes, select **Technical Parameter**. In the next screen, adjust the necessary parameters. To return to the initial screen, select **Page Back**.

- 4** Highlight the desired protocol and confirm it by pressing the selector knob.



Selector knob



- 5** Prepare the perfusion bowl: add sterile ice and cover with one of the sterile bowl liners.

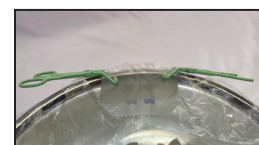


- 6** Add cold preservation solution (Belzer MPS® UW Machine Perfusion Solution recommended).

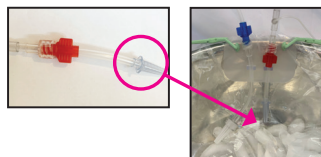


NOTE: the outside of the inner bag is not sterile. Drain it using an infusion set or equivalent.

- 7** Attach the plastic tubing support holder to the perfusion bowl using two green/light blue holder clamps.



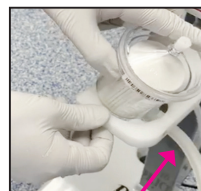
- 8** Remove the cap from the delivery port and insert the line into the tubing support holder; Make sure it points into the bowl and is not occluded.



- 9** Insert the withdrawal port (conical filter) into the holder; Ensure that it is fully submerged and not occluded.



- 10** Insert the filter into the filter support; the tube at the bottom of the filter (flow outlet) will face towards the oxygenator.



- 11** Insert the dampening chamber into its holder by placing it through the top (the air inlet with the white clamp and luer cap are at the top).



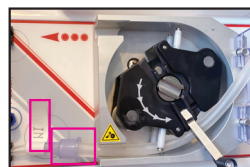
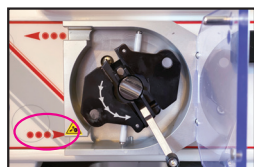
- 12** Insert the delivery line tubing into air detector; Keeping it taut, press or slide it into position.



- 13** Open the pump cover 1 and lift to release the pump 1 rotor lever.



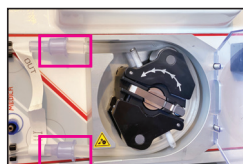
- 14** Place the pump line segment connectors (labelled IN) against the outside of the pump housing at the bottom of the pump (red arrow point IN).



- 15** Following the direction of the arrows, use the lever to turn the rotor (counterclockwise). Continue rotating the handle to guide the tubing into place allowing the white roller pump cradles to guide the tubing.



- 16** Close the rotor lever, verifying that the pump segment line connectors remain outside the pump housing. Close the pump 1 cover.



- 17** Connect the green oxygen tubing to the dedicated oxygenator port (green to green). Connect the other end to the oxygen supply. Connect the pre-oxygenator line to the oxygenator inflow line (red to red). Connect the post-oxygenator line to the outflow line (blue to blue).



- 18** Connect the withdrawal pressure transducer line (identified with the blue cap) to the BLUE withdrawal pressure connector. Ensure the connection is straight on and the BLUE luer cap on the VitaSmart™ is screwed on tight.



- 19** Connect the delivery pressure transducer line (identified with the red cap) to the RED delivery pressure transducer connector. Ensure the connection is straight on and the RED luer cap on the VitaSmart™ is screwed on tight.



PRIMING PROCEDURE

- 20** Occlude the delivery line after the air bubble detector using a plastic hemostat.



- 21** Remove the luer cap from the top of the filter.



- 22** Remove the luer cap from the top of the dampening chamber and ensure the white clamp on top of the chamber is open.



- 23** Verify all the clamps on the tubing set (red, blue and white) are open before starting the priming procedure.

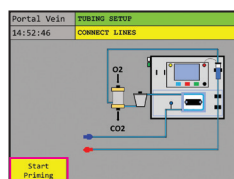


TIMEOUT

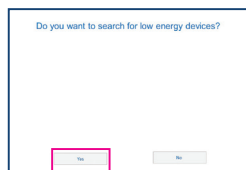
Before pressing Start Priming, complete the **PRIMING PROCEDURE** verifications listed in the VitaSmart™ Checklist or verify the following:

- The perfusion bowl contains at least 2 L of cold machine perfusion solution.
- The cap in the delivery port has been removed (step 8).
- The withdrawal port (conical filter) is fully immersed in the perfusion solution (step 9).
- The delivery line is correctly inserted into the air detector (step 12).
- The delivery line has been occluded with a haemostatic clamp immediately after the air bubble detector (step 20).
- The luer caps on the top of the filter and dampening chamber have been removed (step 21 and 22).
- All clamps are open (step 22 and 23).

- 24** Select and confirm the **START PRIMING** command to open the PRIMING screen.



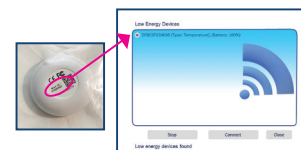
- 25** When priming starts, this screen is displayed on the console. Press **YES** to search.



- 26** Leave the temp probe in the sterile packaging. Using the thumb and index finger, press and release the centre of the sensor.

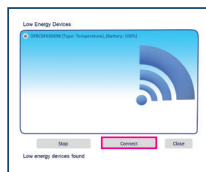


- 27** Verify that the ID code on the temperature sensor matches the ID code on the screen.

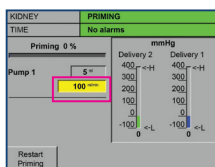


- 28** Select the correct ID code and press **CONNECT** to continue.

Using aseptic technique, open the sterile packaging and drop the sensor into the perfusion bowl.



- 29** Use the selector knob to highlight the flow rate (ml/min) and press it so the field turns from yellow to blue. Then, rotate the selector knob until you reach **100 ml/min** and press it again to confirm (this will change the field from blue to yellow).



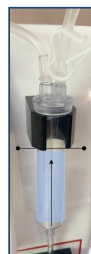
- 30** When the filter is primed to the top, press the green **START/STOP** button to stop the pump.

Replace the luer cap on top of the filter and press the **START/STOP** button to re-start the pump and continue priming.



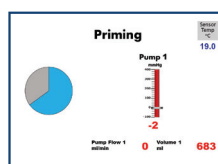
NOTE: Increasing the flow rate too high before the circuit has completely filled with perfusate can lead to the formation of micro-air-bubbles and its accumulation in the tubing that can trigger the "Air in Delivery Line" alarm during perfusion

- 31** When the dampening chamber is primed to 2/3 full and press the green **START/STOP** button to stop the pump.



Replace the luer cap on the dampening chamber air inlet and close the white clamp. Remove the plastic haemostat from the delivery line and press the **START/STOP** to restart the pump and continue the priming.

- 32** Once the circuit is fully primed (approx. after 400 mls), the flow rate can be increased to **250 ml/min** until priming is completed. Meanwhile, verify that the oxygenator bypass line and filter bypass line (**shunt lines**) are both primed and free of air and close both **WHITE** clamps.



During the priming phase, the external console will display the priming screen. The pie diagram is a visual representation of the percentage of completion.

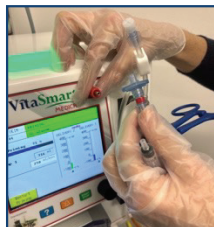
Pump Flow, Total Volume Circulated, Perfusate Temperature and Delivery Pressure are also displayed.

- 33** Prime the delivery pressure transducer line to prevent air entry during perfusion. Without stopping the pump, clamp the delivery pressure transducer line with a blue hemostat next to the red-band filter.

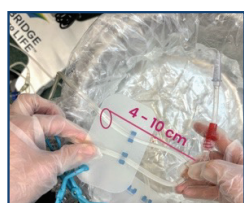


PRIMING PROCEDURE

- 34** Disconnect the delivery pressure transducer line from the RED delivery pressure transducer connector.



- 37** Confirm the delivery pressure transducer line has a column of fluid of 4 to 10 cms from its base (connection point to the delivery line).



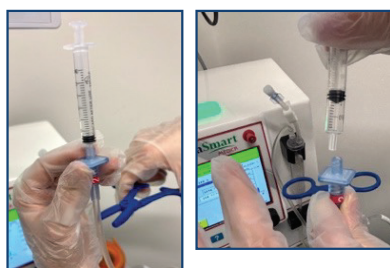
- 40** Using the tubing support clamp, secure the delivery pressure transducer line ensuring it is parallel to the delivery line.



- 35** Attach a syringe (1 ml to 5 ml preferable) to the filter and remove the blue hemostat.



- 38** Reapply the blue hemostat next to the red-band filter before removing the syringe.



- 41** Check the tubing set for any leaks or air bubbles, ensuring that all connections are correctly fastened.

If not done yet, open the O₂ flowmeter to 1 to 2 LPM.

- 36** Withdraw approximately 1 ml of air to draw perfusate into the delivery pressure transducer line.



- 39** Reconnect the delivery pressure transducer line to the RED delivery pressure transducer connector and remove the blue hemostat.



- 42** After circulating 1000 mL of solution, the **BEGIN Perfusion** option appears on the lower right corner of the LCD. Priming – recirculation of the perfusate – will continue until **BEGIN Perfusion** is selected.

KIDNEY		PRIMING	
TIME		No alarms	
Priming 100 %		mmHg	
Pump 1	1000	Delivery 2	Delivery 1
	100	400 <-H	400 <-H
		300	300
		200	200
		100	100
		0	0
		<-L	<-L
		0	0
Restart Priming		BEGIN Perfusion	

NOTE: If the external console does not display the sensor temperature value, press **SENSOR TEMP °C** in the upper right corner of the LCD display, press **SEARCH** and then follow the instructions described in steps 27 and 28 to reconnect it.

PERFUSION PHASE

TIMEOUT

Before pressing **BEGIN PERFUSION**, complete the **PERFUSION PHASE** verifications listed in the VitaSmart™ Checklist or verify the following:

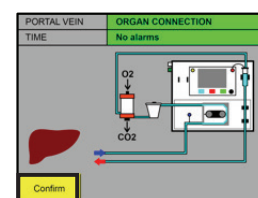
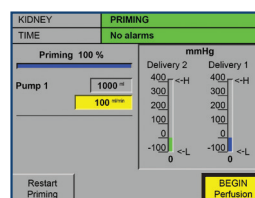
- The luer cap on the dampening chamber is on and the white clamp close (step 31).
- The white clamps on the oxygenator and filter bypass lines (shunt lines) are closed and free of air (step 32).
- The circuit is free of leaks, air bubbles and all connections are correctly tightened (step 32).
- O₂ supply is turned on at 1 to 2 LPM.
- The external console displays the temperature of the perfusate.
- It is **RECOMMENDED** to thoroughly flush the graft in the back-table bowl until the preservation solution is clear (before transferring to the perfusion bowl).
- The graft has been cannulated using either: 1) an appropriate cannula; 2) the delivery line port (for liver); 3) the cannula adaptor (for kidney).

- 43** Transfer the organ to the perfusion bowl. Prime the cannula, which should already be attached to the organ and attach it to the delivery line.



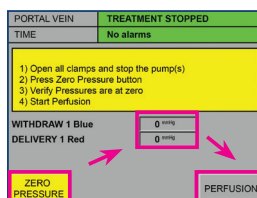
Sample of grafts cannulated using cannula, delivery port (liver) & cannula adaptor (kidney).

- 44** Select and press **BEGIN PERFUSION**. In the next screen, select and press **CONFIRM**.



NOTE: If a cannula is used to perfuse the graft, the diameter and length of the cannula may affect the resistance, pressure and subsequently the perfusion flow.

- 45** Select **ZERO PRESSURE** and press the selector knob to zero values. Verify that both pressures show zero on the display. Then, select and press **PERFUSION** and when prompted press **CONFIRM**.

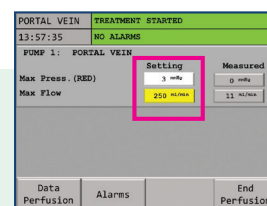


- 46** When the **Treatment** screen appears, set the pressure and flow parameters.

Max. Press. (RED) – Delivery Pump 1 pressure: Maximum pressure in mmHg on the delivery line. It can be set from 3 to 60 mmHg with 1 mmHg increments.

Max Flow – Maximum Delivery Flow of Pump 1: Maximum flow in ml/min.

It can be set from 5 to 250 mL/min with 1 mL/min increments.



NOTE: The flow rate will adjust automatically if the measured pressure is higher than the set maximum pressure.

RECOMMENDED PRESSURE AND FLOW RATE PARAMETERS

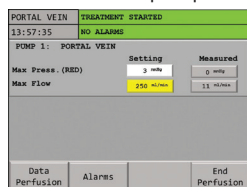
Hepatic perfusion via portal vein:

- Max pressure (RED): **3 mmHg**
- Max flow rate: **250 ml/min**

Renal perfusion via the renal artery:

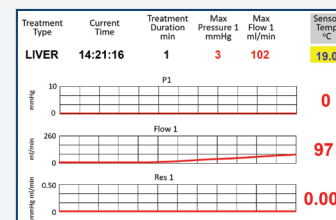
- Max pressure (RED): **25 mmHg**
- Max flow rate: **80 to 250 ml/min***

- 47** Press **START/STOP** to begin the perfusion and visually check that the pump is running.



NOTE: The user can stop and restart the pump as needed throughout the perfusion by pressing the green **START/STOP** button. The first line of the control panel will display if the treatment is stopped or started.

During the perfusion, the external console will display measured data and treatment duration.



HOPE

MONITORING DURING THE PERFUSION

Temperature:

- Continuously monitor the temperature of the solution
- Keep the temperature between **4 and 12°C**; if the temperature exceeds 12°C, the temp field will flash yellow
- Replenish the ice if necessary to prevent it from exceeding 12°C
- During the preparation phase the temperature reading might be below 4°C as usually the temperature probe is deposited on top of ice
- If the preparation phase prolongs and the perfusate temperature rises whilst recirculating, replenish the ice before connecting the graft

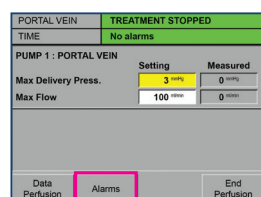
Oxygen:

- Take a sample of the perfusate from the delivery sample port (post-oxygenator), 10 to 15 min after starting of perfusion to analyse PO₂
- Maintain the PO₂ between **450 and 600 mmHg** or **60 to 80 kPa**
- If PO₂ is below 450 mmHg, check that the flowmeter is open; the green oxygen tubing is properly connected and not occluded; and the white clamps on the filter and oxygenator shunt lines are closed. If all is correct, increase the O₂ flow and repeat PO₂ after 15 min
- If the flow of O₂ is changed, repeat the PO₂ analysis after 15 min of the change to ensure that the PO₂ level is kept above 450 mmHg

PERFUSION PHASE (CONTINUED)

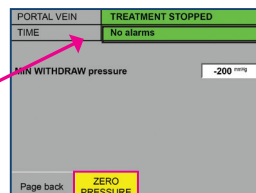
RE-ZEROING PRESSURES

Stop the pump, if not done yet, by pressing the **START/STOP** button. Select and press **ALARMS**.

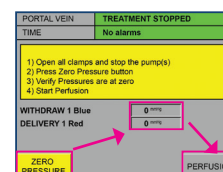


In the next screen, select & press **ZERO PRESSURE**.

NOTE: Ensure the pump shows "Treatment Stopped".

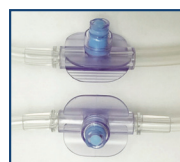
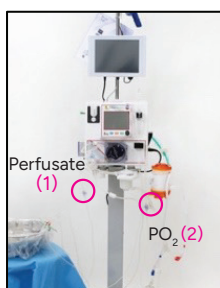


Select and press **ZERO PRESSURE**, ensure that the pressure values display zero and then, select and press **PERFUSION** and **CONFIRM** to return to the treatment screen.



SAMPLE COLLECTION

The VitaSmart system has two sampling ports:



1. **Withdrawal sample port** (before the withdrawal pressure transducer line), perfusate samples for analysis on request of the institution
2. **Delivery sample port** (after the dampening chamber in the delivery line), samples for PO₂ analysis per HOPE protocol

Using aseptic technique, attach a luer syringe to the desired sample port, aspirate the solution and test the sampled perfusate using a blood gas analyser or according to your institutional policy.

REMOVAL OF AIR FROM FILTER & DAMPENING CHAMBER

If during the priming or perfusion air accumulates in the filter or the dampening chamber:

- **Filter:** open the luer cap from the top of the filter while the pump is on to remove the air and close once it is refilled with perfusate.
- **Dampening chamber:** stop the pump, place a plastic haemostat after the air bubble detector, open the white clamp on top of the dampening chamber and remove the luer cap from its top. Restart the pump until the chamber is primed to 2/3 full and then stop it again. Replace the luer cap, close the white clamp and remove the haemostat before restarting the pump. If the dampening chamber is too full, open the white clamp and remove the luer cap from its top to allow the perfusate level to fall by gravity.

RECOMMENDATIONS IF BENCHING WHILST PERFUSING

NOTE: The graft is floating in perfusate, and it will move more than in standard bench surgery. The pressure and flow may fluctuate during the back-table.

For hepatic graft:

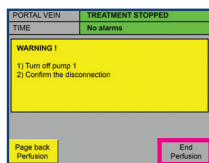
- Using a cannula (25F short or similar) may cause less fluctuation of the delivery pressure as there is less bending/twist.
- Try to minimise turning / flipping the liver once connected as this can lead to pressure to rise which can reduce / stop the flow.
- Flush the graft with cold preservation solution (Belzer MPS® UW Machine Perfusion Solution recommended) until the solution runs clear and before transferring the graft to the perfusion bowl. Cannulation and connection should be done as described in this guide.
- When possible, someone should monitor the pressure and flow while the benching is in progress and the graft is being manipulated and should notify the surgeons if the delivery pressure increases and the delivery line / cannula needs to be repositioned (to avoid the flow from stopping completely).
- **Ensure the withdrawal port (with conical filter) remains fully submerged throughout the procedure.**
- If the delivery pressure rises but does not drop below the maximum set pressure, stop the pump, re-zero (as described in this guide) and continue the perfusion.
- At the end of the bench, perform the zero again and cover the tray with the sterile bowl liner provided in the disposables.

*NOTE: If the VitaSmart™ is switched off or disconnected from the power supply at any point during its operation, it will revert to the pre-existing situation upon restart. The user will need to press the green **START/STOP** button to resume the pump operation (if it occurs during the priming and/or treatment phase). Ensure the **green light** at the top of the pump head is **on**.*

END OF PERFUSION

To end the treatment, select and confirm **END PERFUSION**; the perfusion will finish and the VS will return to the main menu.

To return the system to the Perfusion Phase, select **PAGE BACK PERFUSION**.



NOTE: Once the treatment has ended, the RFID card will be cancelled and cannot longer be used to continue or restart the perfusion.

CLEANING THE VITASMART™

Remove the withdrawal and delivery ports from the circuit at the luer connections; Connect both lines together to get a closed circuit. Discard the disposables as per your institutional policy.

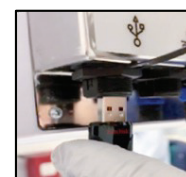
Before cleaning the VS, verify the power cable is disconnected. Use a soft cloth dampened with water to wipe the VS. If the dirt is hard to clean, we recommend using a neutral detergent that does not contain aggressive chemical agents.

For more information see the VitaSmart™ User Manual.

DATA DOWNLOAD

Remove the temperature monitoring antenna cable from the USB port.

Insert a USB flash drive into the USB port and follow the on-screen directions.



NOTE: Treatment's data is stored on the VS console. When downloaded, the name of the files will correspond to the date and time of the treatment.

ADDITIONAL INSTRUCTIONAL RESOURCES:

VitaSmart™ SETUP Videos:



Bridge to Life Brochures:



ALARMS



RED = Alarm
YELLOW = Warning
GREEN = Normal

The VitaSmart™ device has two categories of alarms (visual and audible):

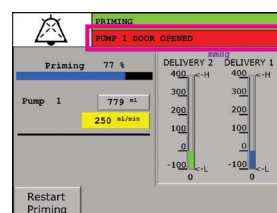
- **MEDIUM Priority:** Yellow, lower frequency
- **HIGH Priority:** Red, higher frequency



High Priority Alarm symbol

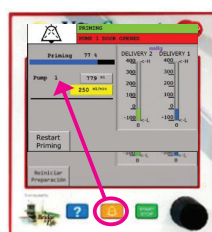
The indicator light at the top of the pump head displays visual alarms (red or yellow).

The second line of the control panel monitor will display the description of the type of alarm.

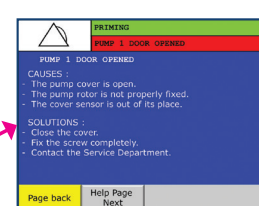
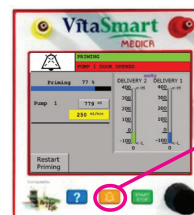


Press the orange **ALARM MUTE** button to silence the alarm during a minute.

If the issue is resolved, press the button a second time to reset the alarm. If unresolved, the alarm sound will reactive after 60 seconds or earlier if a different alarm is triggered.



When alarm occurs, the blue **HELP** button (?), opens the Help screen which provides a list of possible causes that may have triggered the alarm and a series of possible solutions to resolve the issue.



NOTE: The VitaSmart™ can be moved within the hospital or OR when its operating. When disconnected from the mains whilst powered on, the display will turn off and an audible alarm will sound after one second and continue either until reconnected to the mains or until the battery is depleted (approx. 15 min if full).

COMMON ALARMS RESOLUTION

For more detailed information about alarms resolution, check the VitaSmart™ User Manual or contact our technical team

The External Console Does Not Display the Temperature Value, Gives Wrong Values or is Frozen

Possible causes:

- The temperature probe is under the graft or has lost connection

Possible solutions:

- Press **Sensor Temp °C** in the upper right corner of the LCD display. Press **Search** and select the correct ID code on the screen. Select **Connect** to continue

If the temperature value does not reappear:

- Contact the technical support team
- Check if the sensor appears in the "Tempo Plus 2" application, if downloaded

If necessary, replace the temp sensor.

Maximum Delivery Pressure / (Delivery Line Occluded)

Possible causes:

- Delivery port cap not removed (during priming phase)
- Bent delivery line or closed clamp (keep red & blue clamps ALWAYS open; and CLOSE white clamps after priming)

Possible solutions:

- Remove the delivery port cap if still in place, and/or
- Remove any other possible occlusions (haemostat in delivery line or open red & blue clamps if closed)

Pump Not Running / Pump Speed Error

Possible causes:

- Pump stopped for longer than 1 min
- Measured pressure $\geq$ selected max delivery pressure
- Measured pressure $\leq$ selected max delivery pressure but pump remains off (has not restarted)

Possible solutions:

- Check for possible causes of increased delivery pressure (twist or bend at cannula insertion site, graft manipulation, ...) ➔ If nothing is obvious, rezero the pressures and restart perfusion (see instructions in Perfusion Phase page)

AIR IN DELIVERY LINE

(As a safety precaution, the pump will not restart until the alarm is resolved.)

Possible causes:

- Air or presence of micro-air-bubbles in the delivery line placed on the air detector
- Movement of the delivery line near the air detector

Possible solutions:

- Examine the delivery line checking for presence of air or bubbles
 - » **Micro-air-bubbles detected, or NO air detected:** if present, eliminate micro-air-bubbles, reinsert the delivery line on the air detector, and reset the alarm pressing the orange **ALARM MUTE** button
 - » **If AIR is detected: disconnect the graft,** remove air from the delivery line by manually rotating the lever on the pump until the line is free-of-air; refill the dampening chamber manually (follow the instructions from the air removal section); press the orange **ALARM MUTE** button to reset the alarm. **When the delivery line is free of air,** reconnect it to the cannula (manually fill the cannula with perfusate if needed), re-zero the pressure and press **START/STOP** button to continue the perfusion.

BRIDGE TO LIFE offers continuous support (24/7). Contact the technical support if you have questions, need help, or want to report an issue (phone numbers on the contact card on the VitaSmart™). **For additional help or support, contact BRIDGE TO LIFE.**