OrganOx metra®



Quick Reference Guide

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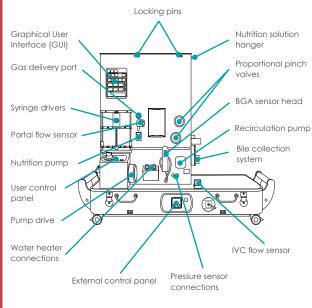
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This Quick Reference Guide provides a summary of the steps required to prepare the OrganOx metra for use. Refer to the Instructions for Use (IFU-001-US) for complete instructions.

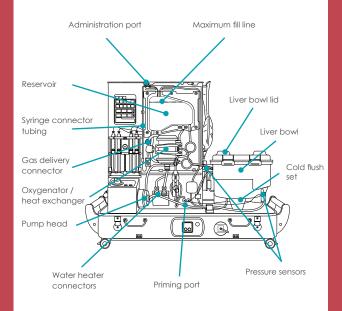
1. Device Overview

See pages 11-13 of the Instructions for Use.

Unloaded Device



Loaded Device

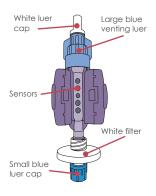


2. BGA Calibration



See pages 16-23 of the Instructions for Use.

- Switch on
 OrganOx metra
- Select option 5 on the Terumo monitor
- Follow the on-screen instructions to calibrate the sensor
- Following calibration, remove the cable-head from the calibrator
- Tighten the large blue venting luer
- Place the Terumo in operate mode and ensure that messages 170 and 190 are absent from the metra screen



3. Medication



For preparation of medication, refer to page 21 of the Instructions for Use.

4. Organ Preparation



WARNING: The liver should be prepared with hemostasis in mind.

IVC

- The suprahepatic IVC should be oversewn / stapled
- Adrenal and phrenic veins should be ligated
- IVC cannula tip should be positioned adjacent to hepatic veins
- IVC cannula should be secured using a purse string and heavy tie or tourniquet

Portal Vein

- Any tributaries should be tied
- Insert cannula 1-2cm and secure with two heavy ties

Artery

- Any tributaries should be tied
- The hepatic artery can be pressure tested for leaks
- Insert cannula 1-2cm and secure with two heavy ties

Bile Duct

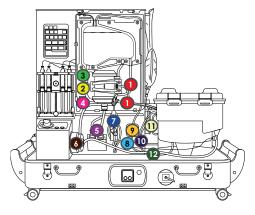
 Ligate cystic duct and tag end of common bile duct with a suture. Following 15 minutes of perfusion, insert cannula and secure with a horizontal mattress stitch, do not use silk.

5. Device Setup



See pages 23-29 of the Instructions for Use.

Secure the liver bowl in the side bracket by engaging the lock pin. Unfold the cartridge tray, secure using two locking pins and complete the 12 connections below:



- Insert tubing in both arterial and portal pinch valves
- Wet portal tubing and insert into flow probe
- Firmly connect gas line
- Insert nutrition tubing, ensuring collars are external amua ot
- Connect both water heater lines
- Engage pump head so white label aligns with clip
- Connect BGA line, ensuring white filter is removed
- Connect both red (arterial) and blue (IVC) pressure sensors
- Place the smaller tubing in the recirculation roller pump
- Wet the larger recirculation tubing and place in sensor
- Fit bile tubing to pinch valve and sensor on rear of device
- Leave IVC tubing out of flow probe until priming



WARNING: Ensure the tubing is free from kinks, in particular the IVC, arterial and recirculation lines.

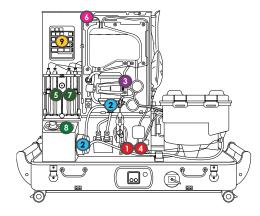
6. Device Priming



See pages 30-39 of the Instructions for Use.



CAUTION: The device operator should wear gloves.



- Connect the administration line to the red 2-way priming port on the IVC line and introduce colloid
- If required, de-air pump head and portal line behind oxygenator. Wet and fit IVC line in flow (2)
- Close the oxygenator bypass line once 500ml colloid has been added to the circuit. Check for leaks at this point
- Add 3 units of donor compatible packed red cells, close red 2-way tap when completed
- Connect 4 infusions (30ml syringes) to the svringe driver
- Add 3 bolus infusions to the reservoir (calcium gluconate, heparin and cerfuroxime) via yellow 3-way tap
- Prime infusion line by rotating the black knob clockwise, then expel remaining air from reservoir
- Press start on the machine and ensure the device enters 'Preparation mode' with a pump speed of 1,500 RPM
- When device displays >36°C add 8.4% sodium bicarbonate to correct pH to ~7.3. Add further boluses as required



WARNING: The device should not display any message codes prior to liver connection. Seek assistance if any codes are present.

7. Stabilization Period



See pages 40-41 of the Instructions for Use.

- Observe good global perfusion
- Confirm absence of twisting or kinking of cannulae/vessels
- Ensure adequate hemostasis

Device Operator

- Confirm device displays 'Liver On-Board'
- Check IVC line for air
- Observe regulated pressures and flows
- Ensure recirculation line is air free

8. Troubleshooting



See pages 61-74 of the Instructions for Use.



Technical Helpline

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