

TherOx |

SSO₂ Therapy Quick Set-Up Guide

1 Prepare the Console for Use:

- Verify patient pO₂ is ≥ 80 mmHg to proceed with SSO₂ Therapy
- Turn power lever to “ON” position and confirm the oxygen bottle contains > 800 psi
- Hang a one-liter bag of sterile physiologic 0.9% normal saline on the console IV pole
- Ensure patient has anticoagulation regimen during administration:
 - heparin: ACT 200-250s with GP IIb/IIIa inhibitor
 - bivalirudin: 0.75 mg/kg IV bolus Pre-PCI then 1.75 mg/kg/hr continued 2-4 hrs post-PCI

2 Load the DownStream Cartridge:

- Open the cartridge compartment and insert the DownStream Cartridge
- Close the compartment door
- Spike the IV bag
- Plug the transducer cable into the transducer jack
- Select “PREP” to ready the cartridge for use

3 Install Tubing Through Blood Pump and Flow/Bubble Detector:

- Insert draw-side tubing into the Blood Pump (position tubing in Blood Pump “V” guides with blue collar below pump)
- Insert the return-side tubing through the Flow/Bubble Detector and Return Clamp (red collars above and below the return guide)

4 Insert the SSO₂ Catheter:

- Remove all interventional devices after successful completion of the PCI procedure
- Select and place the sheath
- Position the 5F SSO₂ Catheter at ostium of the LMCA under fluoroscopic guidance

5 Make Patient Connections:

- Flush the sheath sidearm with heparinized saline
- Attach the clear draw tubing connector to the sidearm of the sheath
- Press and hold the green “PRIME” button to blood prime the circuit
- When the return tubing is primed, make a “wet-to-wet” connection with the red return tubing connector and the SSO₂ Catheter hub

6 Start and Monitor SSO₂ Therapy:

- After circuit is connected to the catheter, press “SSO₂ ON” to initiate SSO₂ Therapy

7 End SSO₂ Therapy:

- After 60 minutes of treatment, the console will indicate that therapy is complete
- Press the “END PROCEDURE” button twice to prepare the cartridge for removal
- Immediately remove the SSO₂ Catheter from patient, disconnect tubing, and remove the cartridge from the console
- Discard used disposable devices per standard procedures
- Turn off the console and plug it in during storage

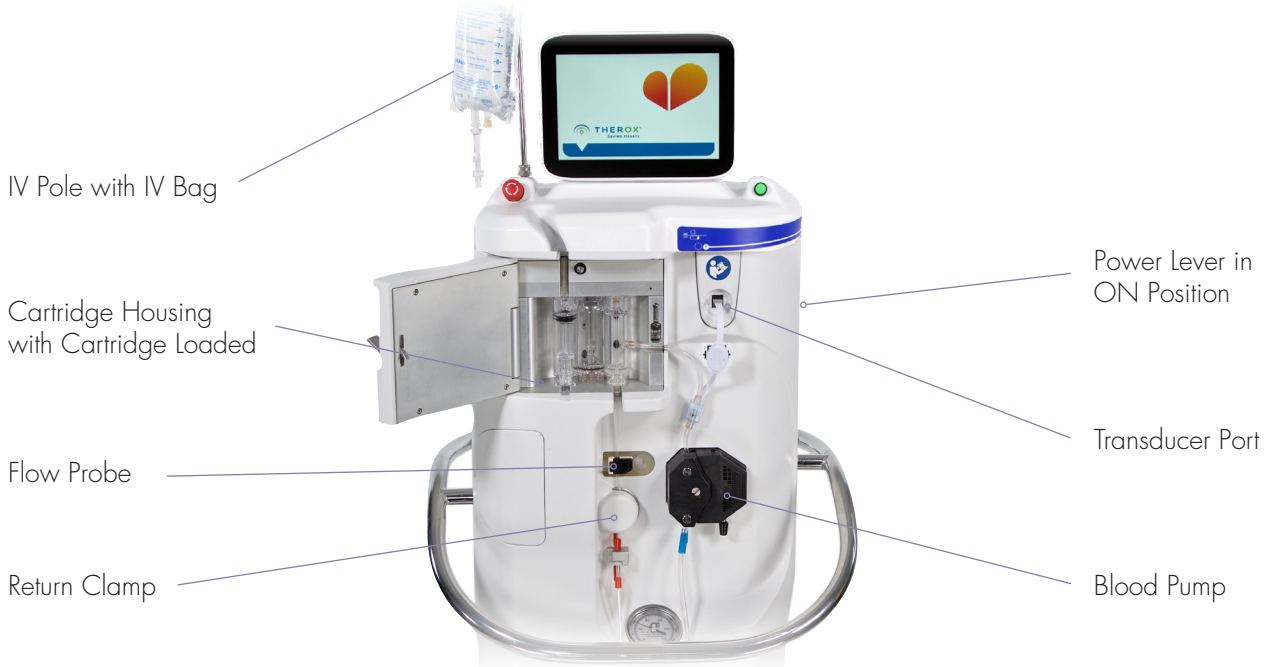
For additional support, please contact our Technical Support Line:

1-800-699-4361. For Live Case Support, Press 1.

Please refer to the Instructions for Use package insert for detailed instructions and a complete list of all contraindications, warnings, and precautions.

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1 Turn console on (using green lever)



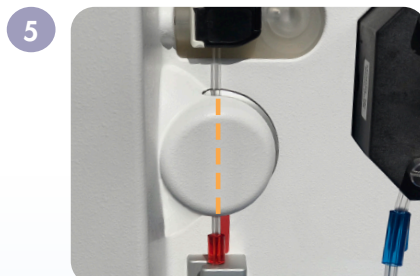
2 Load cartridge, spike IV bag, plug in transducer cable, select "PREP" to ready cartridge for use



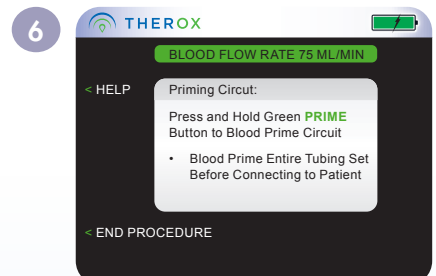
3 Load tubing in Blood Pump



4 Load tubing in Flow Probe (seat tubing)



5 Load tubing in Return Clamp (tubing passes through vertically)



6 PRIME circuit, then make wet-to-wet connection to SSO₂ Catheter

Caution: Federal (USA) Law restricts this device to the sale by or on the order of a physician.

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