DownStream® System (Model DS-2)
Operators Manual

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DownStream® System (Model DS-2)

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

- Read all instructions and warnings prior to use.
- The DownStream® System equipment may be used only by trained personnel under the supervision of physicians trained in angiography and percutaneous coronary intervention (PCI).
- Do not re-sterilize or reuse the DownStream® Cartridge, SSO_2 Catheter, or disposable accessories; these devices are for single use only.
- Only TherOx personnel or authorized representatives may ship, install and service the DownStream System Console "Console".

CLASSIFICATION PER IEC-60601-1

Classification type	Rating
Type of Protection against electric shock	Class I Equipment
Degree of Protection against electric shock	Type CF Applied Part Defibrillation-Proof Applied Part
Enclosure protection against liquid ingress	IPX0
Degree of Safety – Flammable Anesthetic	Not suitable for use in the presence of flammable anesthetics
Mode of Operation	Continuous Operation

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Indications for Use

The TherOx DownStream System is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy (SSO_2 Therapy) to targeted ischemic regions perfused by the patient's left anterior descending coronary artery immediately following revascularization by means of percutaneous coronary intervention (PCI) with stenting that has been completed within 6 hours after the onset of anterior acute myocardial infarction (AMI) symptoms caused by a left anterior descending artery infarct lesion.

Contraindications

- Ipsilateral insertion of a second sheath in a single femoral artery for SuperSaturated Oxygen Therapy is strictly contraindicated.
- Presence of an intra-aortic balloon pump.
- Proximal coronary stenosis that restricts flow with the SSO_2 Catheter in place.
- Presence of a post-intervention non-stented coronary dissection or perforation.
- Cardiac valvular stenosis or insufficiency, pericardial disease or non-ischemic cardiomyopathy.
- Pregnant or nursing women.
- Cardiogenic shock.
- Patients contraindicated for anticoagulation therapy.
- Subjects with ventricular pseudoaneurysm, VSD, or severe mitral valve regurgitation (with or without papillary muscle rupture).
- Hemoglobin < 10 g/dL.
- Gastrointestinal or genitourinary bleeding within the last two months, or any major surgery (including CABG) within six weeks of procedure.

Summary of Warnings

- Only physicians who have received appropriate training in the use of the DownStream System should perform SuperSaturated Oxygen Therapy (SSO_2 Therapy).
- SuperSaturated Oxygen Therapy must be performed in the cardiac catheterization laboratory (cath lab). The patient must not be moved while the catheter is in place.
- Under no circumstances should the extracorporeal circuit be disconnected and restarted outside the cath lab.
- Do not use any type of catheter for SSO_2 Therapy other than the SSO_2 Catheter. Inspect the SSO_2 Catheter and packaging for damage and kinking prior to use; do not use if the catheter or packaging is damaged.
- Use caution near RF sources. It is good practice to keep the DS-2 Console away from other equipment, such as hand-held transmitters, cellular phones, diathermy, lithotripsy, electrocautery or other electrosurgical equipment, RFID, electromagnetic anti-theft systems, metal detectors, and electrosurgical equipment that may generate strong radio frequency interference (RFI).

- The DownStream System may not be operated concomitantly with magnetic resonance imaging.
- Use aseptic technique throughout procedure.
- Provide adequate anticoagulation prior to and during therapy per clinical practice standards.
- Inspect the cartridge and packaging for damage prior to use; do not use if the cartridge or packaging is damaged.
- Use only 0.9% Normal saline (Isotonic solution).
- Verify that all connections are secure and tight prior to initiating prime.
- Verify that the return line of the cartridge is not connected to the SSO_2 Catheter prior to initiating prime.
- The bubble detector is disabled during prime. Ensure that return line is fully blood primed with no presence of air or bubbles in the line prior to making wet-to-wet connection to the SSO_2 Catheter.
- Do not disconnect return line from SSO_2 Catheter or draw line from sheath when therapy is in progress. Procedure must be stopped before disconnection.
- Do not exceed the SSO_2 Therapy duration of 60 minutes.
- Do not re-use the single-use cartridge and SSO_2 Catheter. Re-use of the cartridge and SSO_2 Catheter may result in patient infection. In addition, the cartridge is programmed for single use only and attempted re-use will result in failure to provide treatment.
- Dispose of used cartridges and SSO_2 Catheters using standard hospital procedures to eliminate hazardous waste.
- Only qualified personnel trained in oxygen safety and handling should change the oxygen bottle.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- No modification of this equipment is allowed.

Summary of Precautions

- The index PCI procedure may be done using femoral or radial access; the SSO_2 Therapy blood draw requires a femoral arterial access site.
- If the recommended 7F Merit Medical Custom Sheath Introducer is not used, or less than an 8F introducer sheath (coaxial approach) or 5F introducer sheath (dual site approach) is used for femoral access, SSO_2 Therapy may stop due to inadequate flow rate.
- Do not use the console if the oxygen bottle pressure is less than 800 psig (54.4 bar).
- Do not expose electrical connections, including the transducer port, to fluid contact.
- Do not stretch the return line while loading into the flow probe.
- Ensure that the return line is fully seated in the flow probe slot before latching to prevent the flow probe door from pinching the line.

- Ensure fluoroscopic contrast agents delivered through the SSO_2 Catheter have been flushed prior to priming circuit; these viscous solutions may result in a flow stoppage after connection to the cartridge return line is made.
- Ensure that draw and return lines are not kinked or restricted prior to starting prime or at any other time during use.
- Do not unplug the transducer once the cartridge has been prepped.
- After placement, inspect the SSO_2 Catheter under fluoroscopic visualization to ensure that it is seated correctly in the LMCA and does not restrict blood flow.
- If the SYSTEM BATTERY POWER LOW message is displayed, plug the console into an electrical outlet.
- Position the console as necessary to provide access to the AC power cable and the Potential Equalization Terminal located on the instrument's back panel. Potential equalization can be managed in accordance with IEC 60601-1.

Potential Adverse Events

Potential adverse events include risks associated with interventional cardiology procedures. Complications from these events may necessitate emergency CABG or intra-aortic balloon pump placement, or re-catheterization.

- Death
- Acute Myocardial Infarction (AMI)
- Stent Thrombosis
- Revascularization (CABG or PCI)
- Congestive Heart Failure
- Hemorrhage
- Abrupt vessel closure/spasm
- Allergic reactions
- Aneurysm
- Anxiety/Dizziness
- Arrhythmias
- Arteriovenous Fistula/Pseudoaneurysm
- Blood loss/damage
- Cardiogenic Shock
- Chest pain/angina
- Coronary Artery Occlusion
- Embolism (including air emboli and thromboemboli)
- Hematoma
- Hemolysis
- Hypertension/Hypotension
- Infection

- Myocardial Rupture
- Nausea/Vomiting
- Neck/back/groin pain
- Pericardial effusion
- Pulmonary Edema
- Renal complications
- Respiratory complications
- Restenosis
- Stroke/TIA
- Tamponade
- Thrombosis
- Vascular damage (dissection, perforation, rupture, or other mechanical injury)

Device Description

SuperSaturated Oxygen (SSO_2) Therapy is an adjunctive cardiac catheterization laboratory initiated procedure targeted at the left main coronary artery (LMCA) of an acute myocardial infarction (AMI) patient after successful percutaneous intervention (PCI) with stenting has been performed of the left anterior descending coronary artery. The equipment necessary for SSO_2 Therapy is comprised of three components: the DownStream® System Console ("console"), the DownStream® Cartridge ("cartridge"), and the SSO_2 Catheter. The console and cartridge function together to create a highly oxygen-enriched saline solution called SuperSaturated Oxygen ("SSO_2") solution. A small amount of autologous blood is mixed with the SSO_2 solution producing oxygen-enriched hyperoxemic blood which is then delivered to the targeted major epicardial artery via the SSO_2 Catheter. The duration of SSO_2 Therapy is 60 minutes.

DownStream Console

The console is the electromechanical device that controls the cartridge and monitors performance and safety during administration of SSO_2 Therapy. The console has safety features that continuously monitor system parameters such as the blood flow rate and pressure and detect potentially unsafe conditions such as the presence of air-in-line. A display screen guides the health care professional through setup and clinical operation. The console is non-sterile and has no direct contact with the patient or the blood flow path. The console is intended to be mains-operated (AC-powered) and stationary during use but is equipped with battery backup power. The console is designed for operation in a cardiac catheterization laboratory and must be operated and monitored by trained personnel when providing SSO_2 Therapy.

DownStream Cartridge

The cartridge is a single-use disposable device that is loaded into the console by a trained healthcare professional. The cartridge has a three-chambered body that creates SSO_2 solution from inputs of hospital-supplied oxygen and physiologic saline and mixes the SSO_2 solution with arterial blood within the cartridge blood path. The cartridge has a tube set that draws the patient's arterial blood through the draw line and returns oxygen-enriched hyperoxemic blood through the return line to the SSO_2 Catheter. The cartridge draw line connects to an arterial sheath. Sheath placement may be coaxial (single arterial access site) or contralateral (two arterial access sites) at the physician's discretion. A physician makes two line connections during the initiation of SSO_2 Therapy: the cartridge draw line is attached to the arterial sheath before priming the blood flow path, and the return line is attached to the SSO_2 Catheter after the blood flow path is successfully primed. The priming volume of the cartridge is approximately 60 ml.

SSO_2 Catheter

The SSO_2 Catheter is a 5F (O.D.) over-the-wire catheter that is equipped with a standard luer fitting at the proximal end for attachment to the return line of the cartridge. The SSO_2 Catheter has a length of 100 cm and is shaped to facilitate placement in the left main coronary ostium using the PCI arterial access site. The SSO_2 Catheter is placed in the ostium of the LMCA using a guidewire by the trained physician and is connected to the cartridge after blood priming.

Only the SSO_2 Catheter that is supplied with the TherOx DownStream System may be used to deliver the SSO_2 therapy.

The DownStream® System Console, DownStream® Cartridge and SSO_2 Catheter Set-Up are shown in **Figures 1 through 4:**

Figure 1. TherOx® DownStream® System Console

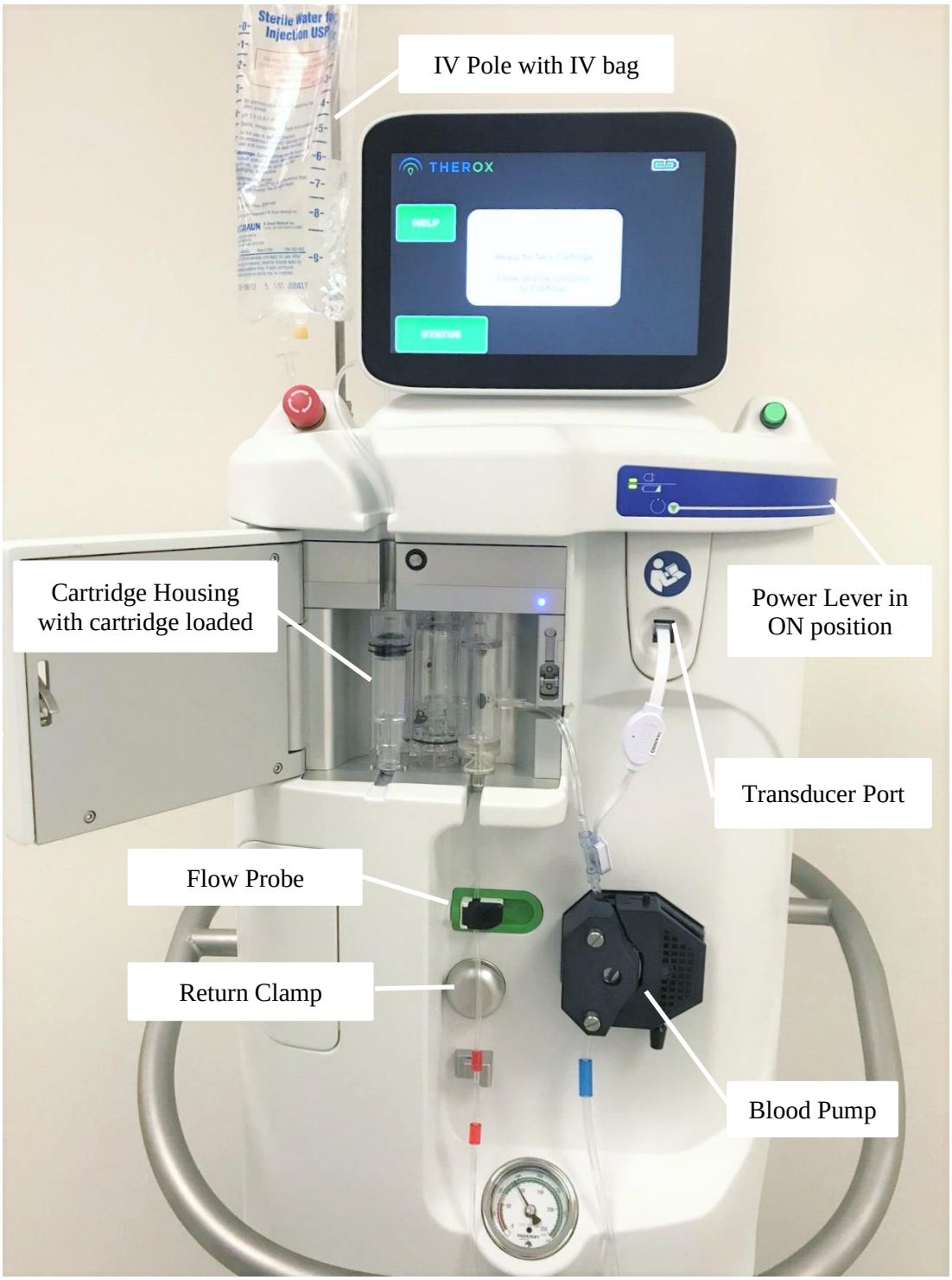


Figure 2. Close-up of DownStream® System Console Components

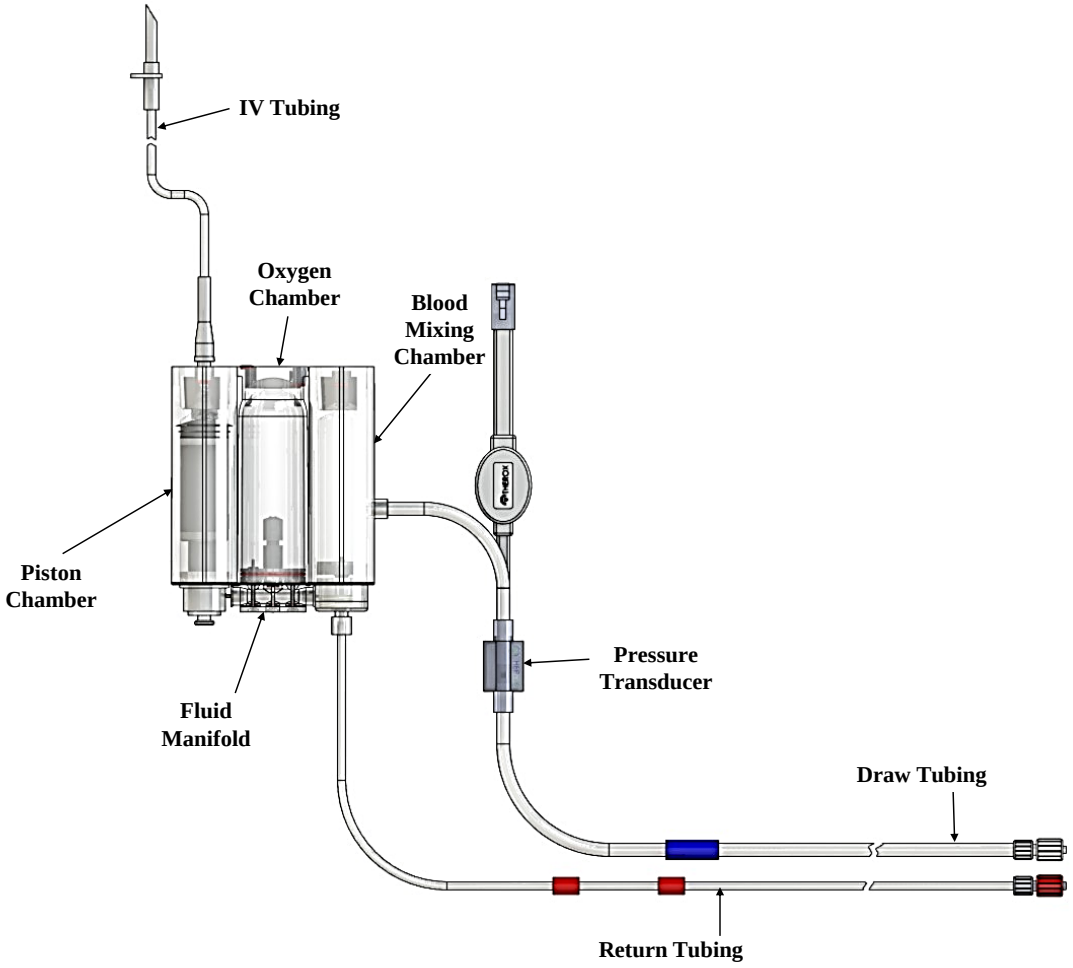


Figure 3. TherOx® DownStream® Cartridge

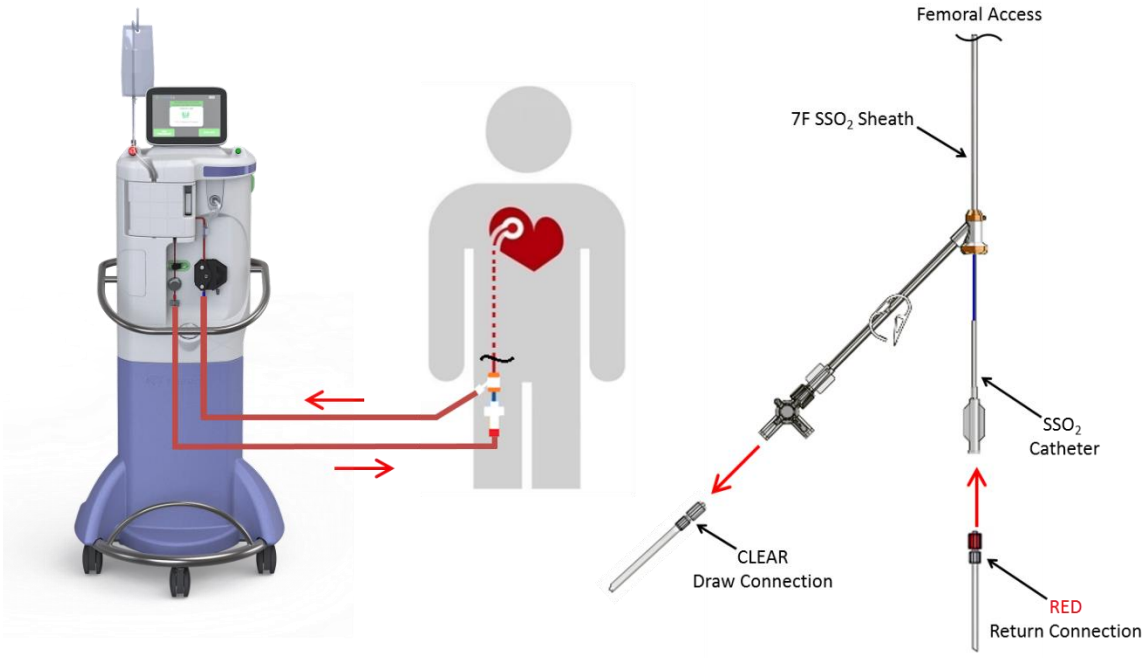


Figure 4.a. SSO_2 Catheter Set-Up (Coaxial Femoral Access Site Approach)

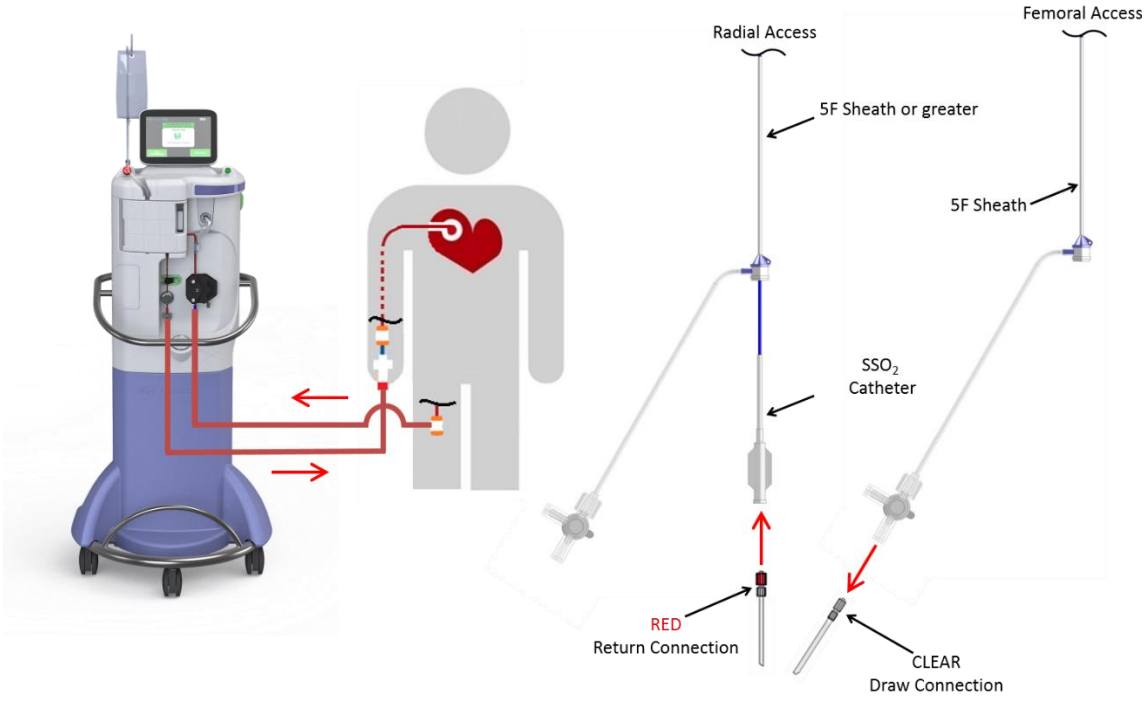


Figure 4.b. SSO_2 Catheter Set-Up (Radial Delivery Femoral Draw Approach)

Patient Selection Criteria

- Patient must be ≥ 18 years and < 80 years of age.
- Within 6 hours from symptom onset to successful reperfusion by means of PCI with stenting of left anterior descending coronary artery ST-elevation AMI.
- Successful revascularization by means of PCI with stenting as documented by < 50% diameter residual stenosis and ≥ TIMI flow grade II in the target vessel.
- Systemic arterial pO_2 greater than or equal to 10.7 kPa or 80 mmHg with supplemental oxygen.

Equipment Requirements

Quantity	Equipment
1	DownStream System Console– Model DS-2
1	DownStream Cartridge – Model DSC-2
1	SSO_2 Catheter
1 liter	Physician-prescribed, sterile physiologic 0.9% normal saline
1	"E" cylinder, or equivalent size of in-hospital, medical-grade oxygen with at least 800 psig (54.4 bar) pressure.
1	Guidewire, maximum OD 0.038 inch (0.97mm)
1	Coaxial approach: 7F** Merit Medical Custom Sheath Introducer Kit (K15-00147) or 8F introducer sheath with sidearm- or - Contralateral approach: 5F (minimum) introducer sheath
7-8	3 ml syringes
1-2	5 ml syringes

** 7F Merit Medical Custom Sheath Introducer Kit has a larger diameter sidearm to allow for required high flow blood draw. No other 7F sheath can be used.

Directions For Use

Patient Anticoagulation

WARNING: Provide adequate anticoagulation prior to and during therapy per clinical practice standards.

Patient anticoagulation throughout the SSO_2 Therapy procedure is aligned with current practice in STEMI patients treated with primary PCI as outlined below. Bivalirudin is recommended for this study, but patient anticoagulation must consist of one of the following regimens:

- Bivalirudin and cangrelor, with provisional (bail-out) use of GP IIb/IIIa inhibitors allowed
- Bivalirudin, with provisional (bail-out) use of GP IIb/IIIa inhibitors allowed
- Heparin and cangrelor, with provisional (bail-out) use of GP IIb/IIIa inhibitors allowed
- Heparin and routine use of GP IIb/IIIa inhibitors

Procedural anticoagulation must consist of either bivalirudin with or without the addition of cangrelor (in which case GPIIb/IIIa inhibition is not recommended unless required for refractory procedural thrombotic complications) or heparin with either cangrelor or with routine use of a GP IIb/IIIa inhibitor. If a GP IIb/IIIa inhibitor is used, it should be continued during the SSO_2 infusion and for a total of at least 12 hours post procedure, as per standard of care. Intravenous cangrelor may also be used according to label per physician discretion, administered as a bolus plus infusion, with the infusion continued for 2-4 hours post-PCI.

If unfractionated heparin is selected, local dosing regimens may be used, although it is recommended that an initial bolus of 60 IU/kg is administered, followed by titration to the ACT of 200-250 seconds in patients receiving a GP IIb/IIIa inhibitor.

If bivalirudin is selected as the procedural anticoagulant, it should be administered as a bolus of 0.75 mg/kg IV prior to PCI, followed by an infusion of 1.75 mg/kg/h initiated as soon as possible. Intravenous cangrelor may also be used according to label per physician discretion, administered as a bolus plus infusion, with the infusion continued for 2-4 hours post-PCI.

SSO_2 Therapy Preparation (Post-PCI)

WARNING: Use aseptic technique throughout procedure.

WARNING: Use caution near RF sources. It is good practice to keep the DS-2 Console away from other equipment, such as hand-held transmitters, cellular phones, diathermy, lithotripsy, electrocautery or other electrosurgical equipment, RFID, electromagnetic anti-theft systems, metal detectors, and electrosurgical equipment that may generate strong radio frequency interference (RFI).

Only physicians who have received appropriate training in the use of the DownStream System should perform SuperSaturated Oxygen Therapy (SSO_2 Therapy).

SSO_2 Therapy must be performed in the cardiac catheterization laboratory (cath lab). The patient must not be moved while the catheter is in place.

The DownStream System may not be operated concomitantly with magnetic resonance imaging.

The following devices and conditions should be in place prior to starting SSO_2 Therapy:

- Use recommended guidewire to place SSO_2 Catheter.
- For a coaxial (single access site) femoral approach (**Figure 4.a.**), place the 7F Merit Medical Custom Sheath Introducer or an 8F introducer sheath with sidearm in the femoral artery.
- For a dual femoral access site, a 5F introducer sheath placed in the contralateral femoral artery is required for blood withdrawal.
- For radial access site approach (**Figure 4.b.**), place SSO_2 Catheter through radial sheath introducer. An additional 5F introducer sheath in femoral artery is required for blood withdrawal.

WARNING: Ipsilateral insertion of a second sheath in a single femoral artery for SuperSaturated Oxygen Therapy is strictly contraindicated.

Precaution: The index PCI procedure may be done using femoral or radial access; the SSO_2 Therapy blood draw requires a femoral arterial access site.

Precaution: If the recommended 7F Merit Medical Custom Sheath Introducer is not used, or less than an 8F introducer sheath (coaxial approach) or 5F introducer sheath (dual site approach) is used for femoral access, SSO2 Therapy may stop due to inadequate flow rate.

- Post PCI, draw an arterial blood sample and analyze pO_2. Systemic arterial pO_2 must be greater than or equal to 10.7 kPa or 80 mmHg to proceed with SSO_2 Therapy.

Prepare the Console for Use

1. Position the console and immobilize the wheels by pressing down on and securing the wheel locks. Ensure that the console is plugged into an electrical outlet.

2. Locate the IV pole on the top of the console. Loosen the nut of the IV Pole and slowly raise it to the desired height or until it stops. Tighten the nut to keep it in position. Hang a one-liter bag of sterile physiologic 0.9% normal saline on the console IV pole.

3. To energize the console, rotate the green power lever handle from the Standby position until it latches into the ON position (see **Figure 5**). Engaging the power lever will simultaneously open the oxygen bottle located at the back of the console.

Figure 5. Energizing the DownStream® System Console

4. Confirm that the oxygen bottle contains at least 800 psig (54.4 bar) of oxygen.

   Precaution: Do not use the console if the oxygen bottle pressure is less than 800 psig (54.4 bar).

   After the console is turned on, the console will start the display. When completed (this may take up to one minute), the display will change to a splash screen (**Figure 6**), indicating the console is ready for use.

Figure 6. Splash Screen

After approximately 15 seconds the screen shown in **Figure 7** appears:

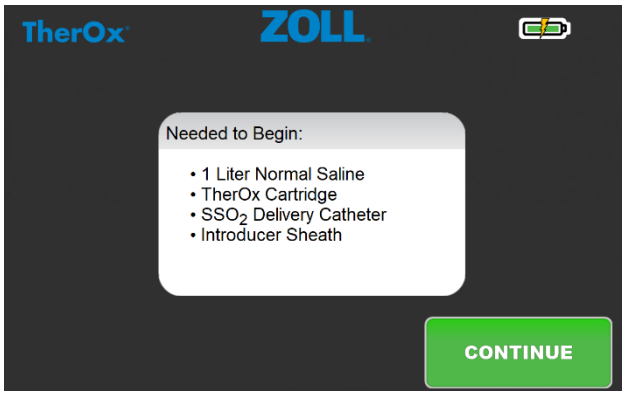


Figure 7. Screen Displays Items Required to Begin Therapy

Load the Cartridge

WARNING: Inspect the DownStream Cartridge and packaging for damage prior to use. Do not use if the cartridge or packaging is damaged.

Prior to use, all packaging, cartridge and lines should be examined for damage. Do not use any defective equipment. Contact TherOx Customer Service for replacement.

1. Open the package. Pass the cartridge tray with the tube set to the sterile field.

2. A user in the sterile field removes the cartridge from the tray, keeps the sterile pouch with tube set and passes cartridge to non-sterile field.

3. Press the button identified as 'CONTINUE' on the display to continue to the next screen and begin the loading process. Once the "CONTINUE' button is pressed the screen shown in **Figure 8** appears:

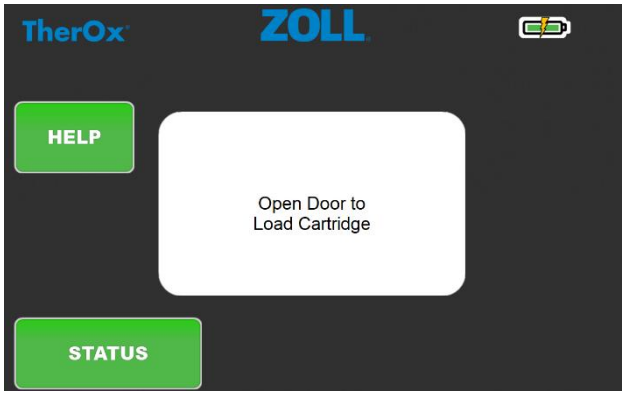


Figure 8. Screen Displays Prompt to Load Cartridge

4. Open the cartridge compartment door. A small BLUE flashing light in the compartment door indicates the lever for opening the door. When the door is opened, the screen will display the message, “Ready for New Cartridge”.

Figure 9. DownStream Cartridge Compartment

5. Align the IV line in the open groove above the cartridge compartment (see **Figure 9**). Ensure the draw and return lines are placed through open grooves in the cartridge compartment.

6. Insert the cartridge, ensuring proper alignment, then close and latch the compartment door. Verify IV tube is not restricted when door is closed. Once the cartridge has been loaded and the door closed, the screen shown in **Figure 10** appears:

   Note: The blue light stops flashing.

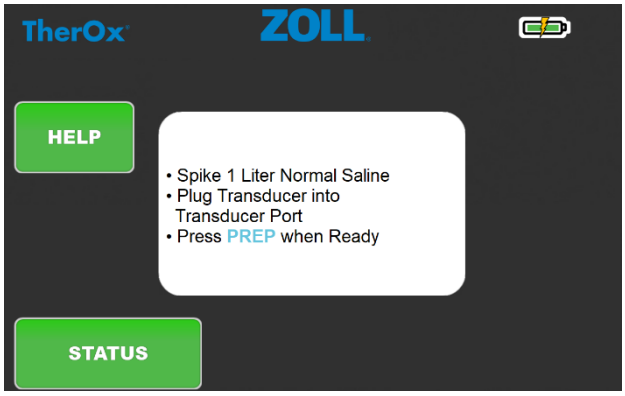


Figure 10. Prep Screen

7. Insert the IV spike into the bag of sterile physiologic 0.9% normal saline.

   WARNING: Use only 0.9% Normal saline (Isotonic solution).

8. Plug the transducer cable into the transducer port.

Precaution: Do not expose electrical connections, including the transducer port, to fluid contact.

9. Press the button identified as 'PREP' on the display to continue to the next screen and begin the cartridge prepping process. Once the 'PREP' button is pressed the screen shown in **Figure 11** appears:

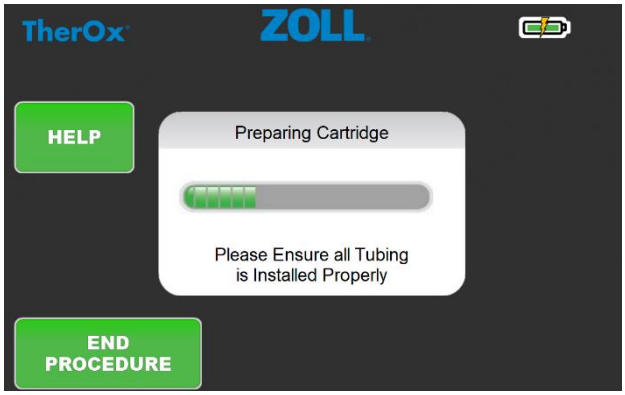


Figure 11. Prep Screen

10. Install the lines through the blood pump, flow probe, return safety clamp, and return line guide while the console is in PREP (see **Figures 12** and **13**).

    a. Open the blood pump by rotating the blood pump lever upward.

    b. Insert the draw line into the blood pump, aligning it with the tubing guides (V slots). After achieving proper alignment of the draw line, rotate the blood pump lever downward to close the blood pump.

    Note: The blue collar on the draw line must be positioned below the pump head.

    c. Press the release button for the flow probe door. The flow probe door will spring open. Insert the return line in the flow probe slot.

    Precaution: Do not stretch the return line while loading into the flow probe.

    Precaution: Ensure that the return line is fully seated in the flow probe slot before closing to prevent the flow probe door from pinching the line.

    d. Close the flow probe door.

    e. Insert the return line through both the return safety clamp and the return line guide.

    Note: The red collars should be above and below the return line guide when properly loaded. (**Figure 13**).

Figure 12. Line Installation

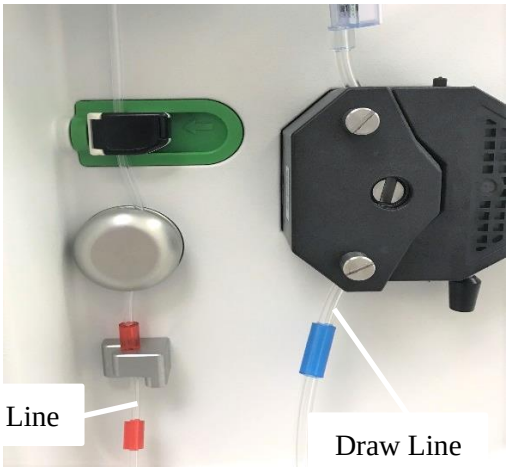


Figure 13. Line Installation – Close-up View

11. After the cartridge has been successfully prepped the screen shown in **Figure 14** appears prompting the operator to confirm the correct setup. If user message prompts to spike saline bag, ensure IV spike is fully inserted into saline bag, then press 'CONTINUE' to complete Prep.

    Precaution: Do not unplug the transducer once the cartridge has been prepped.

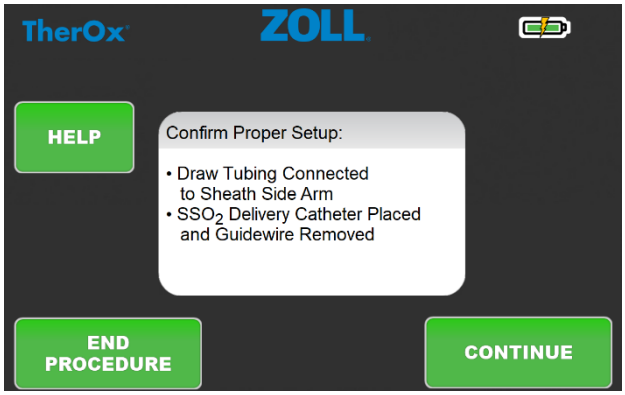


Figure 14. Proper Setup Confirmation Screen

12. After the set up has been confirmed, press the button identified as 'CONTINUE' on the display to continue to the next screen and begin the circuit priming process.

Making Patient Connections

WARNING: Do not use any type of catheter for SSO_2 Therapy other than SSO_2 catheter. Inspect the SSO_2 Catheter and packaging for damage and kinking prior to use. Do not use if the catheter or packaging is damaged.

SSO_2 Catheter Preparation

Prior to use, all packaging and devices should be examined for damage. Do not use any defective equipment. Contact TherOx Customer Service for replacement.

1. Transfer the sterile SSO_2 Catheter on to the sterile field.

2. Place the SSO_2 Catheter into the ostium of the LMCA per standard cardiac catheterization laboratory practice.

3. Remove the guidewire after satisfactory placement of SSO_2 Catheter.

Precaution: After placement, inspect the **SSO_2 C**atheter under fluoroscopic visualization to ensure that it is seated correctly in the LMCA and does not restrict blood flow.

4. Maintain a heparinized saline flush or lock through the SSO_2 Catheter until connection to the cartridge has been made and the end of the priming sequence.

Precaution: Ensure fluoroscopic contrast agents delivered through the SSO_2 Catheter have been flushed prior to priming circuit; these viscous solutions may result in a flow stoppage after connection to the cartridge return line is made.

Cartridge Line Connections

Coaxial Femoral Approach – refer to **Figure 4.a.**

1. Release the ends of the sterile cartridge lines from the pouch on to the sterile field.

2. Attach the draw connector to the sidearm of the arterial sheath, keeping the stopcock on the sidearm closed until ready to prime the circuit with blood.

3. When ready to begin the Prime sequence, open the stopcock on the sidearm of the sheath to allow blood flow into the draw line.

Radial-Femoral Approach – refer to **Figure 4.b.**

1. Release the ends of the sterile cartridge lines from the pouch on to the sterile field.

2. Attach the draw line connector to the sidearm of the femoral sheath, keeping the stopcock on the sidearm closed until ready to prime the circuit with blood.

3. When ready to begin the Prime sequence, open the stopcock on the sidearm of the sheath to allow blood flow into the draw line.

Priming the Blood Path

WARNING: Verify that all connections are secure and tight prior to initiating prime.

Verify that the return line of the cartridge is NOT CONNECTED to the SSO_2 Catheter prior to initiating prime.

Precaution: Ensure that draw and return lines are not kinked or restricted prior to starting prime or at any other time during use.

1. Press and continuously hold the green PRIME button located on the console display to blood prime the circuit. As the green PRIME button is held, blood will begin to flow through the circuit and out of the return line.

2. As the console pump begins to operate, a message appears on the screen indicating that the circuit is priming (see **Figure 15**). The blood pump will slow down to facilitate priming the return line.

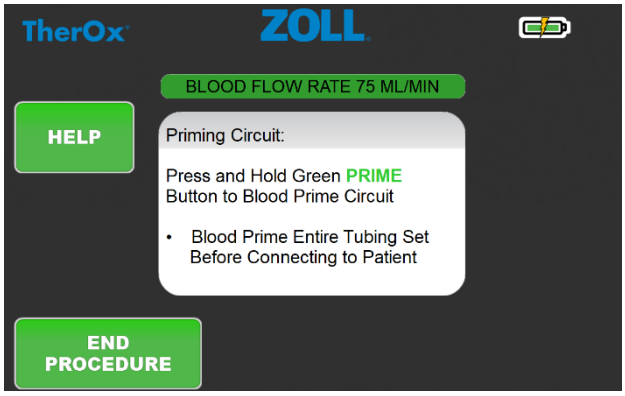


Figure 15. Prompt to Press and Hold PRIME Button

3. When the return line is blood primed and bubble free, the physician makes a wet-to-wet connection with the red return line connector to the SSO_2 Catheter hub.

   WARNING: The bubble detector is disabled during prime. Ensure that return line is fully blood primed with no presence of air or bubbles in the line prior to making wet-to-wet connection to the SSO_2 Catheter.

4. Keep pressing the green PRIME button until the screen gives notice that the console pressure is stabilizing (see **Figure 16**) and allows the release of the green PRIME button.

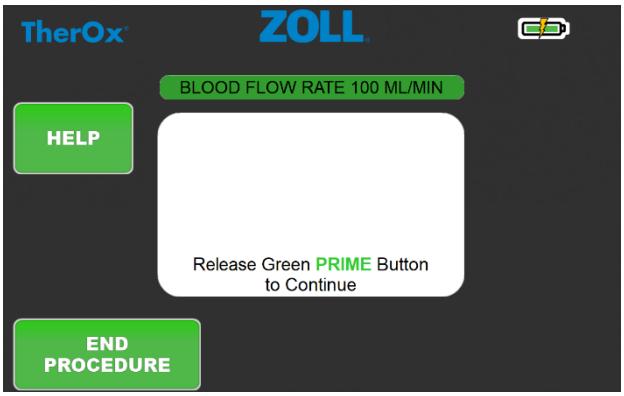


Figure 16. Prompt to Release PRIME Button

5. At the completion of prime, visually inspect that all line connections are leak free.

WARNING: **Do not disconnect return line from SSO_2 Catheter or draw line from sheath when therapy is in progress. Procedure must be stopped before disconnection.**

Start and Monitor SSO_2 Therapy

Note: SSO_2 Therapy is performed in the cardiac catheterization laboratory.

1. At completion of Prime, the following screen will appear (**Figure 17**):

Figure 17. Screen Display for Entering SSO_2 ON

2. Press the button on the display identified as "SSO_2 ON" to begin SSO_2 Therapy.

3. SSO_2 Therapy will continue for 60 minutes. The screen shown in **Figure 18** will be displayed during therapy.

Figure 18. Screen Display During SSO_2 Therapy

Terminate SSO_2 Therapy and Blood Flow

After 60 minutes of treatment, SSO_2 Therapy will stop and the console will indicate (on the display) that the infusion is complete. The blood pump will continue to circulate normoxic arterial blood through the cartridge; the blood will not be mixed with SSO_2 solution (see **Figure 19**).

Figure 19. Screen Display after SSO_2 Therapy Complete

1. Press the button identified as 'END PROCEDURE' on the display.

2. The yellow message area on the screen will display a prompt to confirm the user request to end the procedure.

3. Press the button 'END PROCEDURE' again to indicate procedure completion and to stop flow through the cartridge.

4. The display will change to a screen that prompts the operator to disconnect from the patient and to press the 'CONTINUE' button when finished. See **Figure 20.**

Note: Decompression in the cartridge chamber will be accompanied by an audible hissing sound. Do not attempt to open the cartridge compartment door until prompted.

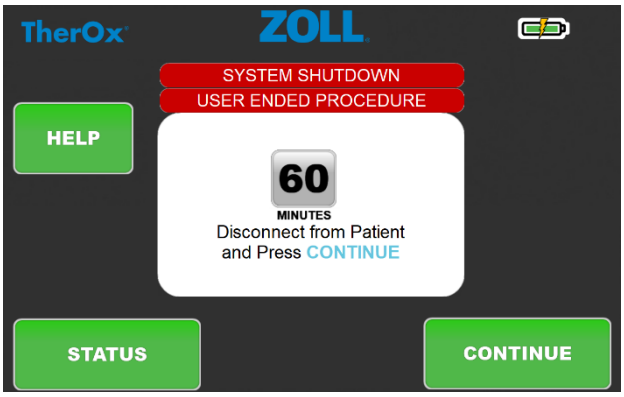


Figure 20. Screen Display Continue Button

5. Once the blood pump has stopped, close the stopcock on the sheath sidearm.

6. Detach the SSO_2 Catheter from the cartridge return line by disconnecting the red return connector from the SSO_2 Catheter hub.

7. Disconnect the draw connector from the sheath sidearm.

8. Immediately remove the SSO_2 Catheter from the patient.

   Note: It is not recommended to return the blood in the cartridge to the patient. It is recommended to leave the blood (approximately 60 ml) in the cartridge for disposal (using standard hospital procedures to eliminate hazardous waste).

Unload the Cartridge

1. Press the button on the display identified as 'CONTINUE' to unload the cartridge. The display will change to a screen that notifies the operator that the console is preparing to unload the cartridge (see **Figure 21**).

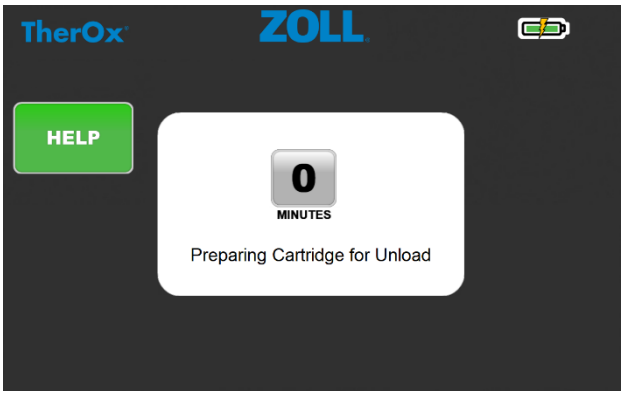


Figure 21. Preparing Cartridge for Unload

2. Slide the blood pump lever up toward the top of the console and remove the draw line.

3. Open the flow probe door by pressing the flow probe door release button and remove the return line.

4. Remove the return line first from the return safety clamp and then from the return line guide.

5. When the screen displays the "Open Door and Unload Cartridge" prompt (**Figure 22**), open the cartridge compartment door, unplug the transducer cable from the transducer port, and then remove the cartridge.

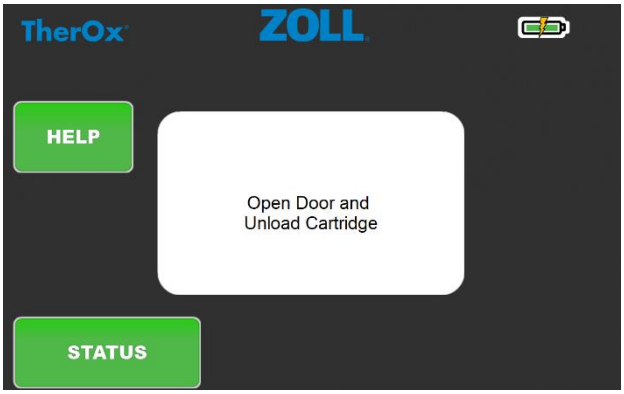


Figure 22. Prompt to Unload Cartridge

6. After the cartridge has been removed, close and secure the compartment door.

7. Dispose of the single-use cartridge and sterile physiologic 0.9% normal saline bag per standard hospital procedure.

WARNING: Do not re-use the single-use cartridge and SSO_2 Catheter.

Dispose of used cartridges and SSO_2 Catheters using standard hospital procedures to eliminate hazardous waste.

Shut Down the Console

Move the green power lever handle from the ON position to the Standby position. This will also close the oxygen bottle located at the back of the console.

Emergency Stop

Press the large red Emergency Stop switch on the front panel, at any time, to immediately stop console operation (See **Figure 23**). To resume console use, release the Emergency Stop switch by turning it clockwise.

Note: The cartridge must be replaced to resume treatment after an Emergency Stop.

WARNING: Under no circumstances should the extracorporeal circuit be disconnected and restarted outside the cath lab.

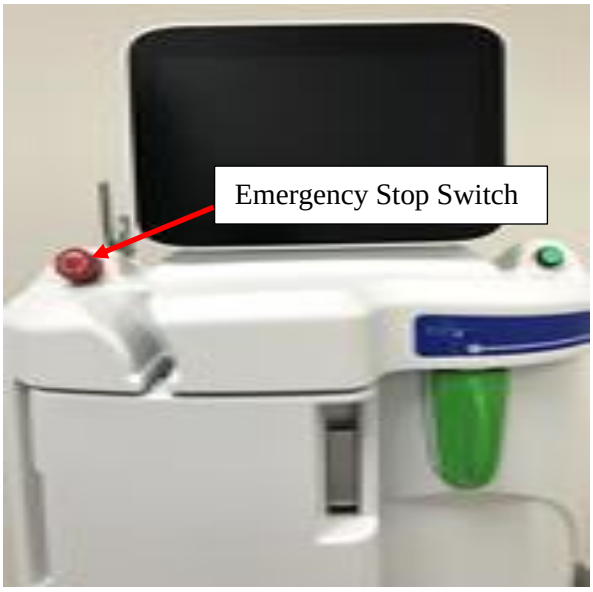


Figure 23. Emergency Stop Switch

Responding To Error Messages

Under certain conditions, an error message may appear in the message area in the center of the display screen. If the error message appears in yellow, follow the recovery procedures indicated on the screen. If the error message appears in red, the console is stopped. Follow the instructions displayed in the message area on the display.

Help Screen

The Help screen provides user information specific to the current step in the operating sequence. The Help screen also displays the TherOx Technical Support telephone number.

Equipment Maintenance - DownStream System Console

WARNING: Only qualified personnel trained in oxygen safety and handling should change the oxygen bottle.

- As needed, wipe the console cabinet and the interior of the cartridge compartment with an approved hospital bactericidal agent. Avoid fluid contact with the transducer port.
- To maintain batteries in fully charged condition, the console must be powered from an electrical outlet when not in use.
- After a low battery warning, allow at least six hours to fully recharge the batteries before the next use.
- Expected battery life is 200 cycles or up to four years.

- Consoles that have been in storage (un-powered) should be charged for at least 12 hours before use.

- In normal use, a full oxygen bottle should provide over 50 uses. When the oxygen bottle contains less than 800 psig (54.4 bar), it should be replaced by qualified personnel per standard hospital procedures.

- The console contains no hospital serviceable parts.

Setup, Maintenance and Service Requirements

Only TherOx personnel or representatives are authorized to setup and service the DownStream Console. To ensure safe operation of the TherOx console, preventive maintenance including a comprehensive technical inspection and electrical safety test, is required annually. Contact your local sales representative for information on preventive maintenance pricing and complete service packages available in your region.

WARNING. No user-serviceable parts inside the console. Only TherOx-authorized personnel may service and repair the console

Troubleshooting

This section describes potential error conditions, including causes and recovery procedures.

Warning Messages

If a warning condition occurs, the console will display the warning on the screen in yellow.

Warning Message	Cause	Corrective Action
System On Battery Power	Console not plugged in to AC outlet	If the console is not connected to AC power, plug console into an AC outlet.
System Battery Power Low	Low battery voltage due to discharged or defective battery	Plug console into an AC outlet and verify warning message is cleared. If warning persists, contact TherOx Technical Support.
Green Power Lever Disengaged	Power lever not fully latched in ON position by operator	Ensure power lever is rotated beyond red latch.
Oxygen Pressure Low	Low oxygen pressure	Occurs only during PREP. Verify oxygen valve is open. Check oxygen gage. If it indicates less than 800 psig (54.4 bar), replace oxygen bottle.
Blood Pump Stopped	Check user message	Read user message. Press Prime when indicated to start pump.
Occlusion Detected	Draw or return line restriction	Inspect draw and return lines for restrictions. Press Prime to restart flow.
Not Infusing SSO_2 Solution	SSO_2 ON not pressed or other warning	Read user message for corrective action required. If SSO_2 on button is visible, therapy can be initiated.
SSO_2 Therapy Complete	Therapy is complete, console is no longer infusing SSO_2	Press End Procedure, disconnect from patient and remove cartridge.
To Confirm, Press End Procedure	End Procedure Pressed Once	To End Procedure, Press End Procedure twice within 10 seconds.
Temperature Low	Environment too cold	Room should be above 15° C when operating the console.
Temperature High	Environment too warm	Room should be below 35° C when operating the console.
Cartridge Not Removed	Cartridge in console when power lever disengaged	Remove cartridge and close door before moving power lever to stand-by position.

Shutdown Error Messages

If this type of error occurs, the display will transition to the Shutdown screen and prompt the user to press 'CONTINUE'. The error code will be displayed on the Status page. Press the 'CONTINUE' button, unload the cartridge, and load a new cartridge to continue. If the error cannot be corrected and cleared, call TherOx Technical Support.

ERR Code	Fault Condition	Cause	Corrective Action
9	Emergency stop engaged	Emergency stop switch pressed	Release the Emergency stop switch. Press continue, remove cartridge and load a new cartridge.
10	Temperature high	Console temperature out of range - high	The recommended room temperature is above 15° C and below 35° C. Once temperature is in range, continue with a new cartridge.
11	Temperature low	Console temperature out of range - low	The recommended room temperature is above 15° C and below 35° C. Once temperature is in range, continue with a new cartridge.
13	Piston pressure high	Piston pressure high	Press continue, remove cartridge and load a new cartridge.
14	Return pressure high	Return pressure high	Press continue, remove cartridge and load a new cartridge.
15	Battery low fault	Console battery voltage below 11 Volts	Plug console into AC outlet and charge until charge indicator is green.
16	Cartridge lost saline prime	Cartridge leak	Press continue, remove cartridge and load a new cartridge.
17	Blood level high	Cartridge leak (BMC vent leak).	Press continue, remove cartridge and load a new cartridge.
18	System not ready	Console not properly shutdown	Press continue. Console will prepare to load a new cartridge.
19	Green Power Lever disengaged	Power Lever rotated off during operation	Engage power lever, press continue, remove cartridge and load a new cartridge.
20	SSO_2 low flow	Cartridge flow is restricted	Press continue, remove cartridge and load a new cartridge.
21	Oxygen pressure low	Cartridge leak (oxygen chamber)	Press continue, remove cartridge and load a new cartridge.

ERR Code	Fault Condition	Cause	Corrective Action
23	Piston at top of stroke	Cartridge leak (piston) or IV Bag empty	Press continue, remove cartridge and load a new cartridge.
24	User Ended Procedure	End procedure pressed twice	Press continue, unload cartridge. Turn Console off if complete.
26	Cartridge could not be prepped	Cartridge leak	Press continue, remove cartridge and load a new cartridge.
27	No BMC pressure decay	BMC Vent valve failed to open to enable priming	Press continue, remove cartridge and load a new cartridge.
33	Return Pressure Low	Return line leak or Pressure transducer failed	Press continue, remove cartridge and load a new cartridge.
34	Flow Probe signal lost	Tubing stretched or bubble detector opened in use	Press continue, remove cartridge and load a new cartridge. Ensure line is loaded correctly in flow probe and tube restraints.
35	Bubble volume exceeded	Bubbles detected in return line	Press continue, remove cartridge and load a new cartridge.
42	SSO_2 solution Flow Out of Range	Cartridge is damaged	Press continue, remove cartridge and load a new cartridge.
45	Blood Flow Rate out of range	Blood flow probe not properly loaded (or console error)	Press continue, remove cartridge and load a new cartridge. Ensure line is correctly loaded in flow probe.
48	Can't maintain oxygen pressure	Cartridge leak (oxygen chamber or low tank pressure)	Press continue, remove cartridge and load a new cartridge. Verify oxygen tank has at least 800 psig (54.4 bar).
50	Cartridge Valve Check Failure	Cartridge valves not functioning properly	Press continue, remove cartridge and load a new cartridge.
51	Blood timer expired	Blood timer expired before blood pump restart was attempted	Press continue, remove cartridge and load a new cartridge.
63	3-hour prime timer expired	Cartridge Prepped but not primed within 3-hours	Press continue, remove cartridge and load a new cartridge.

ERR Code	Fault Condition	Cause	Corrective Action
202	Piston stalled	Piston stall detected	Press continue, remove cartridge and load a new cartridge.
234	7-day timer expired	Console left on for 7 days	Turn console off or restart console.
240	SSO_2 solution level low	SSO_2 solution level not detected after end of Fill Cycle	Press continue, remove cartridge and load a new cartridge.
241	Cartridge PROM error	Can't read or write to cartridge PROM	Press continue, remove cartridge and load a new cartridge.
245	Cartridge blood level low	Air introduced in draw line	Press continue, remove cartridge and load a new cartridge. Ensure all draw side connections are tight.
246	Transducer unplugged	Cartridge transducer unplugged during therapy	Press continue, remove cartridge and load a new cartridge. Ensure transducer cable remains plugged into transducer port for entire procedure.

System Error Messages

When a system error is detected, the Console display will change to a "CALL SERVICE" message. If this occurs, terminate case and contact TherOx Technical Support. The only response to a system error is to unload the cartridge (if possible) and turn the console off.

ERR Code	Fault condition	Cause	Corrective Action
1	Cartridge control software failure	CC Software Watchdog Timer Failure	Console failure. Terminate case and contact TherOx Technical Support.
2	Cartridge control cal CRC failure	Console calibration values lost or corrupted - CRC Error	Console failure. Terminate case and contact TherOx Technical Support.
3	System Cal data range failure	Console calibration values out of range	Console failure. Terminate case and contact TherOx Technical Support.
4	Bubble detector software failure	Bubble detector software fails to initialize (boot)	Console failure. Terminate case and contact TherOx Technical Support.
6	Display failure	General display failure – Language Files not properly loaded	Console failure. Terminate case and contact TherOx Technical Support.
7	Power off 24V status	Cannot disable 24 V	Console failure. Terminate case and contact TherOx Technical Support.
8	Power on 24V status	Cannot enable 24 V	Console failure. Terminate case and contact TherOx Technical Support.
12	Oxygen pressure high limit	Oxygen valve or sensor failure	Console failure. Terminate case and contact TherOx Technical Support.
22	Pump speed error	Blood pump control failure	Console failure. Terminate case and contact TherOx Technical Support.
28	Safety Interlock config. error	FPGA Safety Interlock configuration not properly set	Console failure. Terminate case and contact TherOx Technical Support.
36	FPGA failure	FPGA clocking failure	Console failure. Terminate case and contact TherOx Technical Support.
40	Blood Pump head opened	Pump head lever lock or sensor failed in procedure	Console failure. Terminate case and contact TherOx Technical Support.
41	Door Opened	Door lock or door sensor failure	Console failure. Terminate case and contact TherOx Technical Support.

ERR Code	Fault condition	Cause	Corrective Action
44	Bubble detector cal CRC failure	BD Calibration values lost or corrupted - CRC error	Console failure. Terminate case and contact TherOx Technical Support.
46	CI software comm. error	Cartridge Interface software communication failure	Console failure. Terminate case and contact TherOx Technical Support.
47	Console calibration error	Calibration not complete (cal flags not set in mfg)	Console failure. Terminate case and contact TherOx Technical Support.
52	Display software comm. error	Display software failed to establish or maintain communication	Console failure. Terminate case and contact TherOx Technical Support.
160	Console software version error	Incorrect software versions installed on console	Console failure. Terminate case and contact TherOx Technical Support.
200	Temperature sensor fault	Primary and redundant temperature sensor failure	Console failure. Terminate case and contact TherOx Technical Support.
201	Blood pump encoder fault	Blood pump stalled or encoder failure	Console failure. Terminate case and contact TherOx Technical Support.
203	Safety clamp solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.
204	Door lock solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.
205	Oxygen flow solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.
206	BMC vent solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.
207	Oxygen vent solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.
208	SSO_2 flow solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.
209	Flush valve solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.
210	Fill valve solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.

ERR Code	Fault condition	Cause	Corrective Action
211	Pump lock solenoid fault	Solenoid driver fault or solenoid disconnected	Console failure. Terminate case and contact TherOx Technical Support.
212	Piston sensor fault	Top or bottom sensor failure	Console failure. Terminate case and contact TherOx Technical Support.
213	Blood Pump motor fault	Blood pump motor failure	Console failure. Terminate case and contact TherOx Technical Support.
214	Bubble detector software failure	BD software failure (watchdog fault detected)	Console failure. Terminate case and contact TherOx Technical Support.
215	Fan failure	Fan 1 and Fan 2 failure	Console failure. Terminate case and contact TherOx Technical Support.
218	5V failure	5V out of range (comparator)	Console failure. Terminate case and contact TherOx Technical Support.
219	12V failure	12V out of range (comparator)	Console failure. Terminate case and contact TherOx Technical Support.
220	24V failure	24V out of range (comparator)	Console failure. Terminate case and contact TherOx Technical Support.
221	-12V failure	-12V out of range (comparator)	Console failure. Terminate case and contact TherOx Technical Support.
235	Cartridge control software failure	Cartridge Control invalid state / step failure	Console failure. Terminate case and contact TherOx Technical Support.
236	FPGA failure	FPGA watchdog failure	Console failure. Terminate case and contact TherOx Technical Support.
244	BD software comm. failure	Bubble detector software communication error	Console failure. Terminate case and contact TherOx Technical Support.
249	FPGA timer expired	FPGA Timer expired (rolls over after 46 days)	Console failure. Terminate case and contact TherOx Technical Support.
251	BD program CRC failure	Bubble detector software program CRC invalid	Console failure. Terminate case and contact TherOx Technical Support.

How Supplied

DownStream® System Console

- Non-sterile, AC-powered electromechanical console.

DownStream® Cartridge

- STERILE NON-PYROGENIC. This device is sterilized with ethylene oxide gas.
- CONTENTS: One DownStream® Cartridge.
- DISPOSAL: Dispose of device in accordance with local hospital regulations.

SSO_2 Catheter

- STERILE NON-PYROGENIC. This device is sterilized with ethylene oxide gas.
- CONTENTS: The qualified SSO_2 Catheter (5F Boston Scientific Impulse® angiographic catheter).
- DISPOSAL: Dispose of device in accordance with local hospital regulations.

SSO_2 Procedural Sheath Introducer Kit

- STERILE NON-PYROGENIC. This device is sterilized with ethylene oxide gas.
- CONTENTS: 7F Merit Medical Custom Sheath Introducer Kit (K15-00147).
- DISPOSAL: Dispose of device in accordance with local hospital regulations.

Device Labeling Symbols

	Model Number
	Read all instructions prior to use
	Batch Code
	Sterilized with ethylene oxide gas
	Use By (yyyy-mm-dd)
	Do Not Reuse
	Storage Temperature
	Store in a cool, dry place
	Cardiovascular floating defibrillation proof
~	A/C Current
A	Amps
V	Volts
	Power is on

Console is in standby mode, and the battery is charging (while plugged into an electrical outlet)

Fusing

Electrostatic sensitive devices

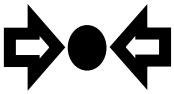
Separate collection for waste electrical and electronic equipment (WEEE)

Refer to instruction manual/booklet

Equipotentiality

Manufacturer

Oxygen Connector



Maximum Oxygen inlet pressure

Maximum Console weight

System Console Technical Description

Device Classification per IEC 60601-1

Classification type	Rating
Type of Protection against electric shock	Class I Equipment
Degree of Protection against electric shock	Type CF Applied Part Defibrillation-Proof Applied Part
Enclosure protection against liquid ingress	IPX0
Degree of Safety – Flammable Anesthetic	Not suitable for use in the presence of flammable anesthetics.
Mode of Operation	Continuous Operation

Physical Description

Item	Description
Model Number	DS-2
Size (D x W x H)	63” high, 27” diameter
Weight	130 lb
Mobile	Intended to be moved from one location to another between periods of use, while supported by its own wheels.

Power Supply Description

Item	Description
Mains Power Requirements	100 - 240V 50/60 HZ, 250VA
Internal Power source	12V Sealed Lead Acid Battery
Typical Operating Time on Battery	One Hour
Minimum Operating Time on Battery	30 minutes
Battery Charge Method	Constant Voltage – Current Limited
Battery Recharge Time	Six hours after battery use.
Battery Mode of Insertion	Batteries are not intended to be changed by the operator.

Displayed Values - Characteristics

Parameter	Range	Accuracy
SSO_2 Run Time	0 – 60 Minutes	$\pm$ 1 %
Return Blood Flow Rate	100 ml/min*	$\pm$ 10 %

* Fixed Set Point

Environmental Requirements

The DownStream System Console is designed to operate and withstand storage under the following conditions:

Condition	Minimum	Maximum
Operating temperature	15° C	30° C
Operating humidity	30 %	75 %
Operating atmospheric pressure	0.7 bar	1.06 bar
Storage temperature	-18° C	60° C
Storage humidity	10%	90%
Storage atmospheric pressure	0.5 bar	1.06 bar

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The TherOx DS-2 Console meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2 (2014) standard for emissions and immunity. It is good practice to keep the DS-2 Console away from other equipment such as hand-held transmitters, cellular phones, diathermy, lithotripsy, electrocautery, RFID, electromagnetic anti-theft systems, metal detectors and electrosurgical equipment that may generate strong radiofrequency interference (RFI). Refer to the Separation Distance section shown below for recommended minimum distances.

The TherOx DownStream System Console Model DS-2 is intended for use in the electromagnetic environment specified below. The customer or user of the DownStream System Console Model DS-2 should assure that it is used in such an environment.

The TherOx DownStream System Console Model DS-2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

The TherOx DownStream System Console Model DS-2 is Class A of CISPR 11 for RF emissions.

The TherOx DownStream System Console Model DS-2 complies with IEC 61000-3-2 class A for harmonic emissions.

The TherOx DownStream System Console Model DS-2 complies with IEC 61000-3-3 class A for voltage fluctuations/flicker emissions.

The TherOx DownStream System Console Model DS-2 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The TherOx DownStream System Console Model DS-2 is intended for use in the electromagnetic environment specified below. The customer or the user of the DownStream® System Console Model DS-2 should assure that it is used in such an environment.

Immunity Test	IEC 60101 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	± 8 kV contact ± 15 kV air	IEC 60601-1-2:2014	Floors should be wood, ceramic or concrete tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4:2012	± 2 kV for power supply lines ± 1 kV for input/output lines	IEC 60601-1-2:2014	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5:2014	+ 1 kV line(s) to line(s) +2 kV line(s) to earth	IEC 60601-1-2:2014	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2004	<5 % U_r (>95 % dip in U_r) for 0.5 cycle 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 s	IEC 60601-1-2:2014	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DownStream® System Console Model DS-2 requires continued operation during power mains interruptions, it is recommended that the DownStream® System Console Model DS-2 be powered from an interruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8:2009	3 A/m	IEC 60601-1-2:2014	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_r is the A.C. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Cont'd)

Immunity Test	IEC 60101 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the [ME EQUIPMENT OR ME SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6:2013	3 Vrms 150 kHz to 80 MHz	3 V rms	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3:2010	3 v/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DownStream® System Console Model DS-2 is used exceeds the applicable RF compliance level above, the DownStream® System Console Model DS-2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DownStream® System Console Model DS-2.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity (Cont'd)

Recommended separation distances between portable and mobile RF communications equipment and the TherOx Downstream System console Model DS-2.

The DownStream® System console Model DS-2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DownStream® System console Model DS-2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DownStream® System console Model DS-2 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter. Where *P* is the maximum output power rating of transmitters in watts (W) according to the transmitter manufacturer.

Warranty

TherOx warrants that its products are free from defects in original workmanship and materials for a period of twelve (12) months from date of purchase or the date the console is first placed in service, whichever date occurs later, not to exceed two (2) years from date of manufacturing, when the console has been properly operated, maintained, and used for its intended purpose. TherOx warrants that sterile products will remain sterile for the period as labeled as long as the original packaging remains intact. The DownStream® Cartridge and SSO_2 Catheter are designed for single use only; they are not designed for re-use. If any TherOx product is proven to be defective in original workmanship or materials, TherOx, in its sole discretion, will repair or replace any such product, or provide a refund of the purchase price less charges for transportation and labor costs incidental to inspection, removal or restocking of product.

During the factory warranty period, if the console requires repair, TherOx at its sole discretion shall repair or replace the defective parts without charge to the purchaser. TherOx reserves the right to make any necessary repair at the facilities of the purchaser, a TherOx manufacturing facility, or at any authorized TherOx repair center

The warranty covers all parts, labor, and shipping costs for the repair of the console. Replacement parts may be new or remanufactured parts. Parts replaced under warranty become the property of TherOx. If TherOx's inspection detects no defects in material or workmanship, TherOx's regular service charges shall apply. Replacement parts are covered during the remainder of the factory warranty period.

This warranty applies only to original factory delivered products that have been used for their normal and intended uses. The warranty shall NOT apply to TherOx products which have been altered, modified or repaired in any way (except by authorized TherOx personnel) or re-sterilized, and shall NOT apply to TherOx products which have been improperly stored or improperly installed, operated or maintained contrary to TherOx's instructions.

THIS WARRANTY IS MADE IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE ARE SPECIFICALLY EXCLUDED. TherOx shall have no liability whatsoever for any improper use or improper repair of the console.

Technical Support and Resources

TherOx provides field- and factory-based technical support for its products. Our service hotline can answer questions, provide guidance, and schedule service for your console.

Limitation of Liability

In any claim or lawsuit for damages arising from alleged breach of contract, negligence, product liability or any other legal or equitable theory, TherOx shall not be liable for damages for loss of profits or revenues, loss of the use of product, loss of facilities or services, any downtime costs, or for claims of buyer's customers for any such damage. TherOx's sole liability for damages will be limited to the cost to buyer of the specified goods sold by TherOx to the buyer that give rise to the claim for liability.

A buyer's use of TherOx product will be deemed acceptance of the terms and conditions of these warranties, exclusions, disclaimers and limitations of liability for money damages.

Patents

TherOx products are covered by one or more of the following U.S. patents as well as related foreign patents:

8,636,952, 8,246,564, 8,192,384, 7,820,102, 7,013,703, 6,974,435, 6,899,847, 6,890,482, 6,849,235, 6,843,099, 6,811,750, 6,622,542, 6,613,280, 6,602,468, 6,582,387, 6,576,191, 6,555,059, 6,533,766, 6,387,324.

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