Boston Scientific

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EKOS™ Endovascular System

CU 4.0 In-Service

Topics

- EKOS System Components
- EKOS Device Overview, Preparation, & Procedure
- Control Unit 4.0 Overview & Workflow
- Patient Transport & Device Removal
- Control Unit 4.0 Troubleshooting & Support
- OPTALYSE Protocol

Indications

FDA clearance

The EkoSonic™ Endovascular System is indicated for:

- Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature
- Infusion of solutions into the pulmonary arteries
- The ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism

Product availability varies by country. Caution: Federal (US) law restricts this device to sale by or on the order of a physician. Prior to use, please refer to the applicable Instructions for Use (IFU) for complete product indications, contraindications, warnings, and precautions

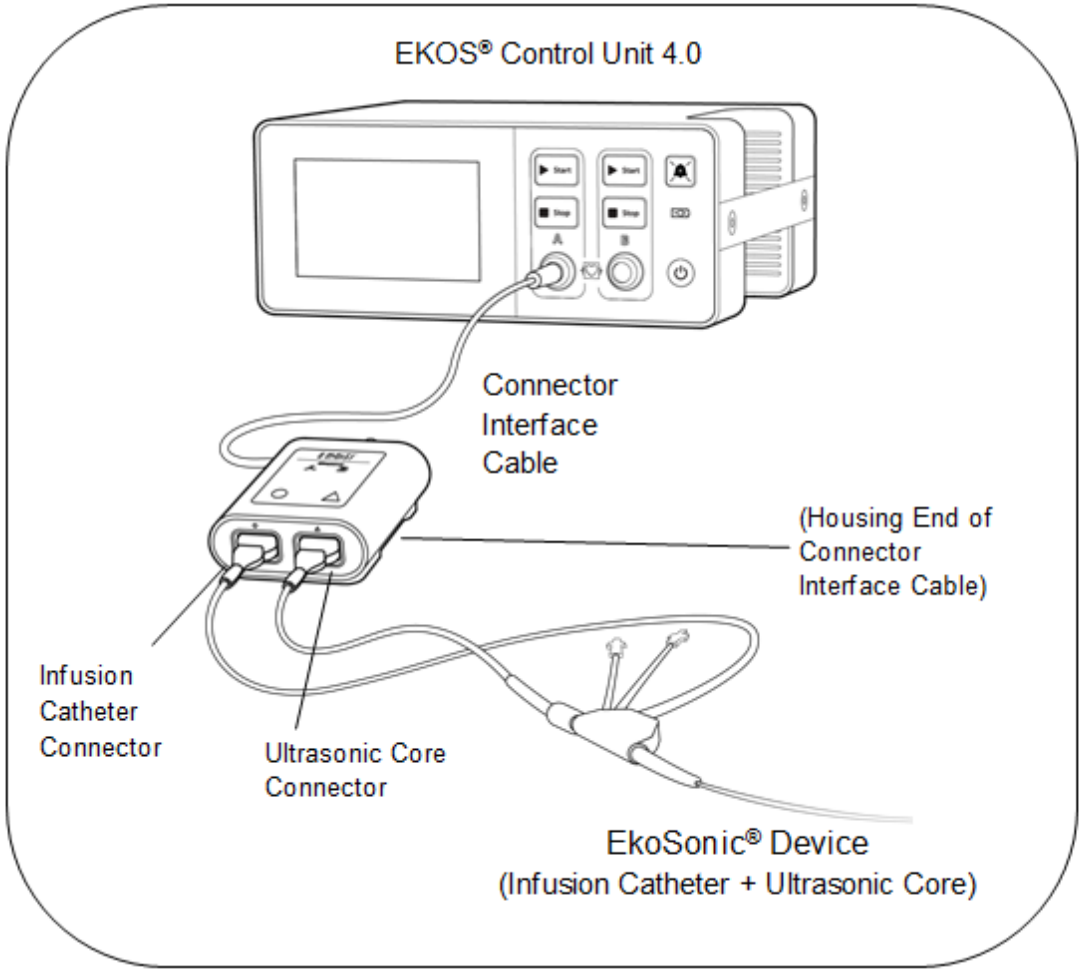
EKOS System Components

EKOS System Components

EKOS Device:
Infusion Catheter + Ultrasonic Core

System:
Control Unit 4.0 **+** Connector Interface Cables

EKOS System As a Whole



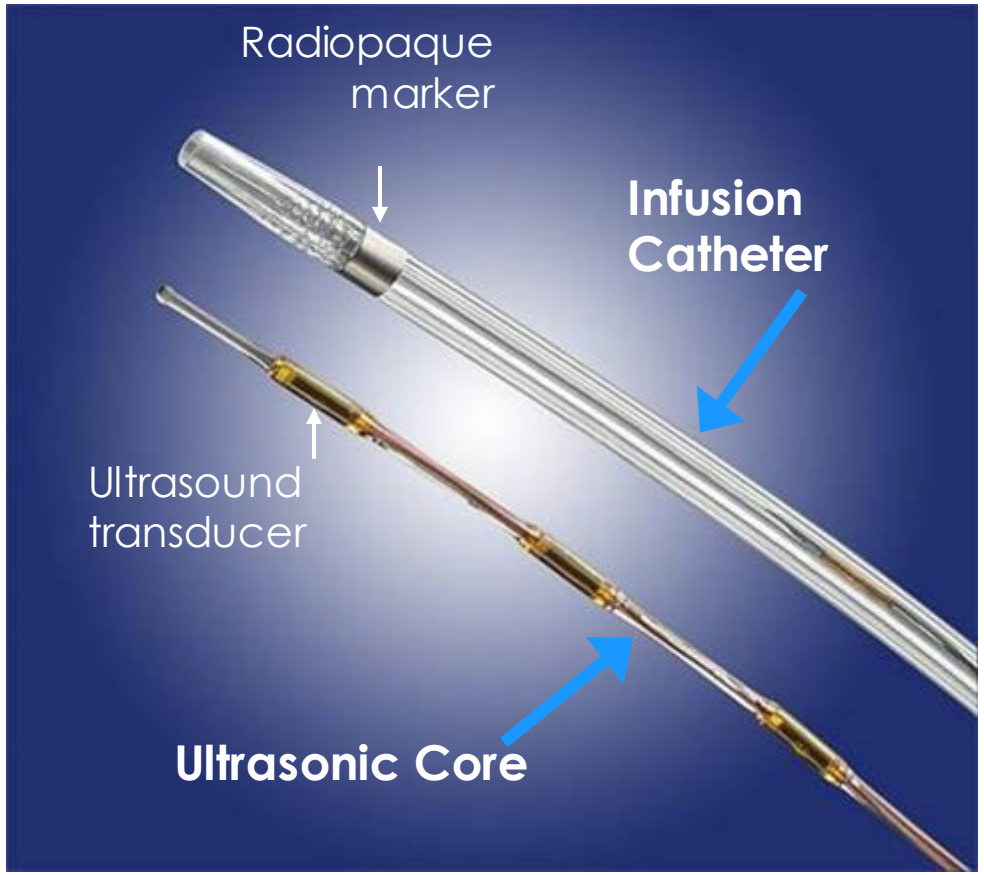
Other Supplies

(2) 3-way stopcocks or flow switches:
- (1) COOLANT port
- (1) DRUG port

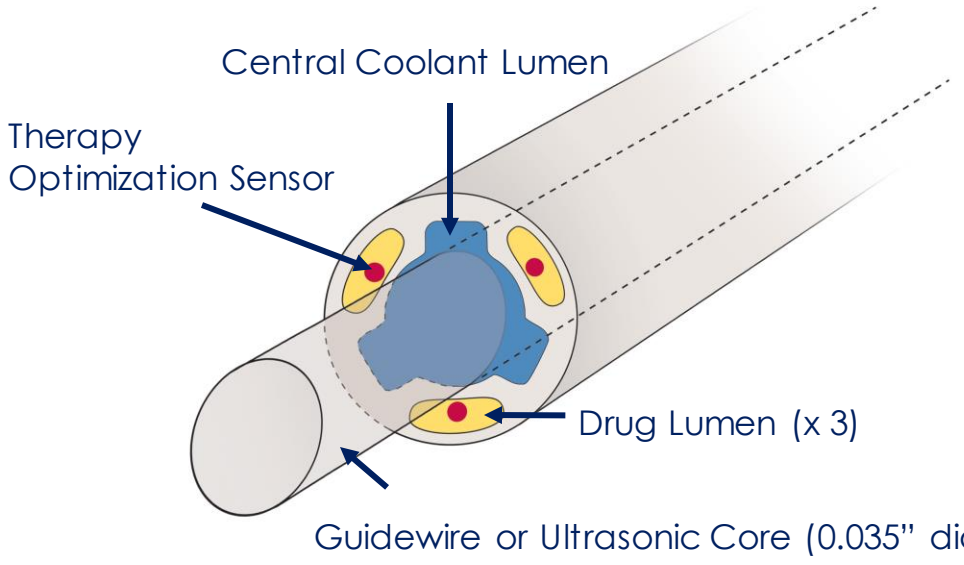
(1) 3 or 5 cc syringe to flush the DRUG lumen

EKOS Device Overview, Preparation, & Procedure

EKOS Device Detail



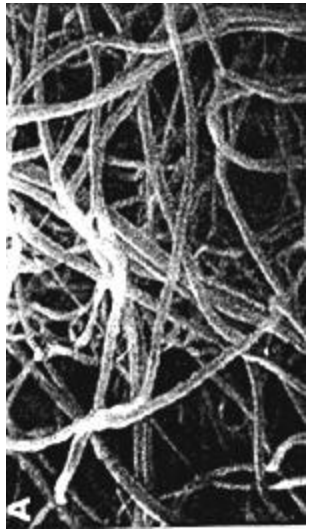
Infusion Catheter cross-section



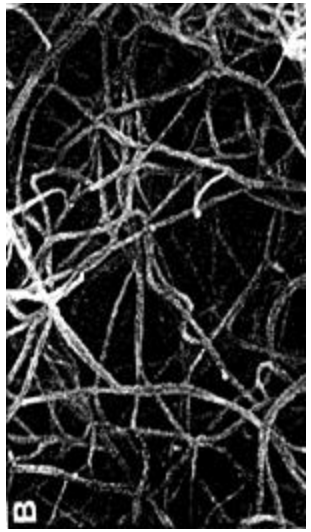
EKOS Mechanism of Action

Fibrin separation

Ultrasound unwinds fibrin without fragmentation of emboli



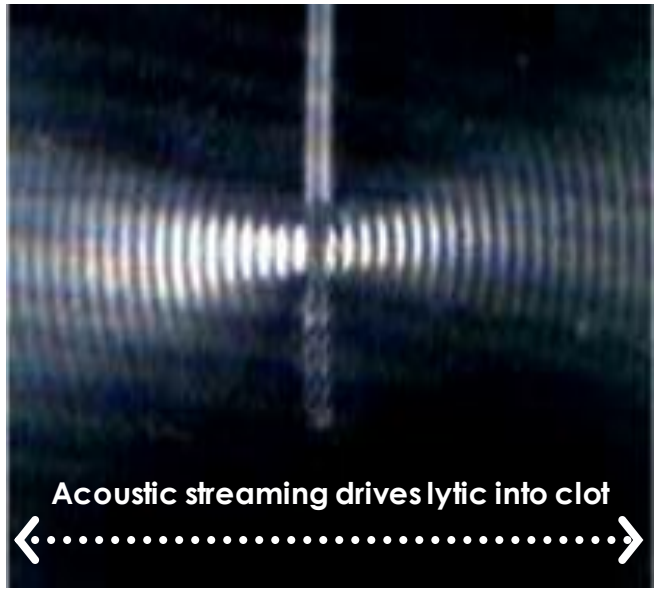
Fibrin without ultrasound



Fibrin with ultrasound

Active drug delivery

Drug is actively driven into clot by "Acoustic Streaming"



EKOS treatment is a minimally invasive system for accelerating thrombus dissolution

1.Braaten JV et al. Ultrasound reversibly disaggregates fibrin fibers.Thromb Haemost 1997;78:1063-8
2.Francis CW et al. Ultrasound accelerates transport of recombinant tissue plasminogen activator into clots. Ultrasound in Medicine and Biology,1995;21(5):419-24
3.Siddiqi F et al. Ultrasound increases flow through fibrin gels. Thromb Haemost 1995; 73(3) 495-8

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Device Preparation

- **Obtain access per standard endovascular techniques**
  - 6 Fr introducer sheath is preferred
  - Use a long supportive sheath for contralateral approach

- **Select the proper treatment zone length based on the clot length**
  - **106 cm working length**
    - 6, 12, 18, 24, 30, 40, 50 cm treatment zones
  - **135 cm working length**
    - 12, 30, 40, 50 cm treatment zones

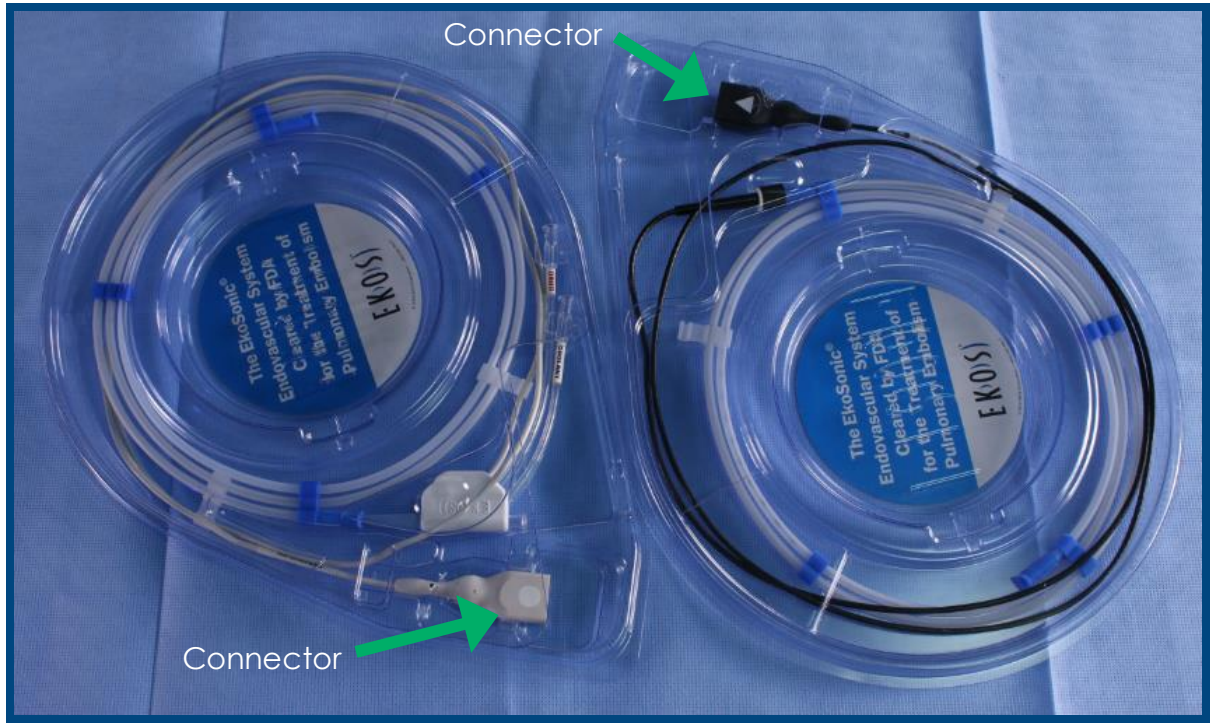
! Do not use an introducer sheath with a rotating hemostasis valve to introduce the EkoSonic® MACH4 Endovascular Device. Insertion or removal through a rotating hemostasis valve may result in removal of the radiographic marker bands, stretching, or other damage to the catheter.

EKOS Device – Infusion Catheter & Ultrasonic Core

Box contains two packages

- (1) Infusion Catheter
- (1) Ultrasonic Core

Isolate the electrical connectors prior to flushing to ensure they stay dry.



Infusion Catheter Ultrasonic Core

! IF THE CONNECTORS GET WET, THE DEVICE WILL NOT FUNCTION PROPERLY.

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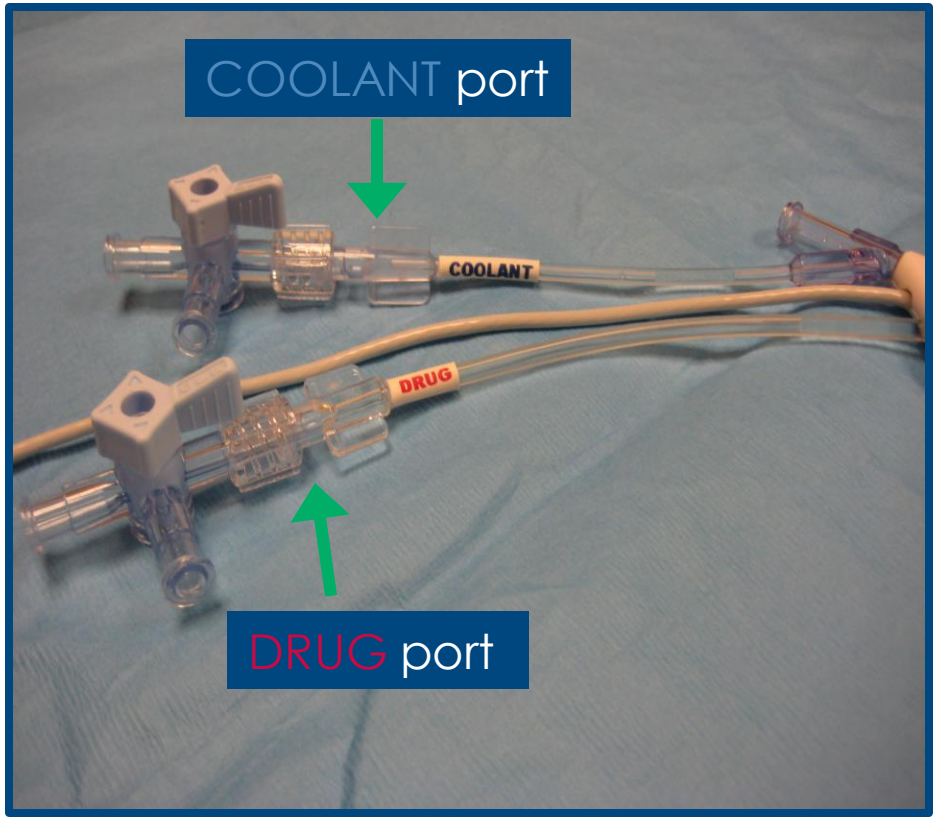
Infusion Catheter Preparation

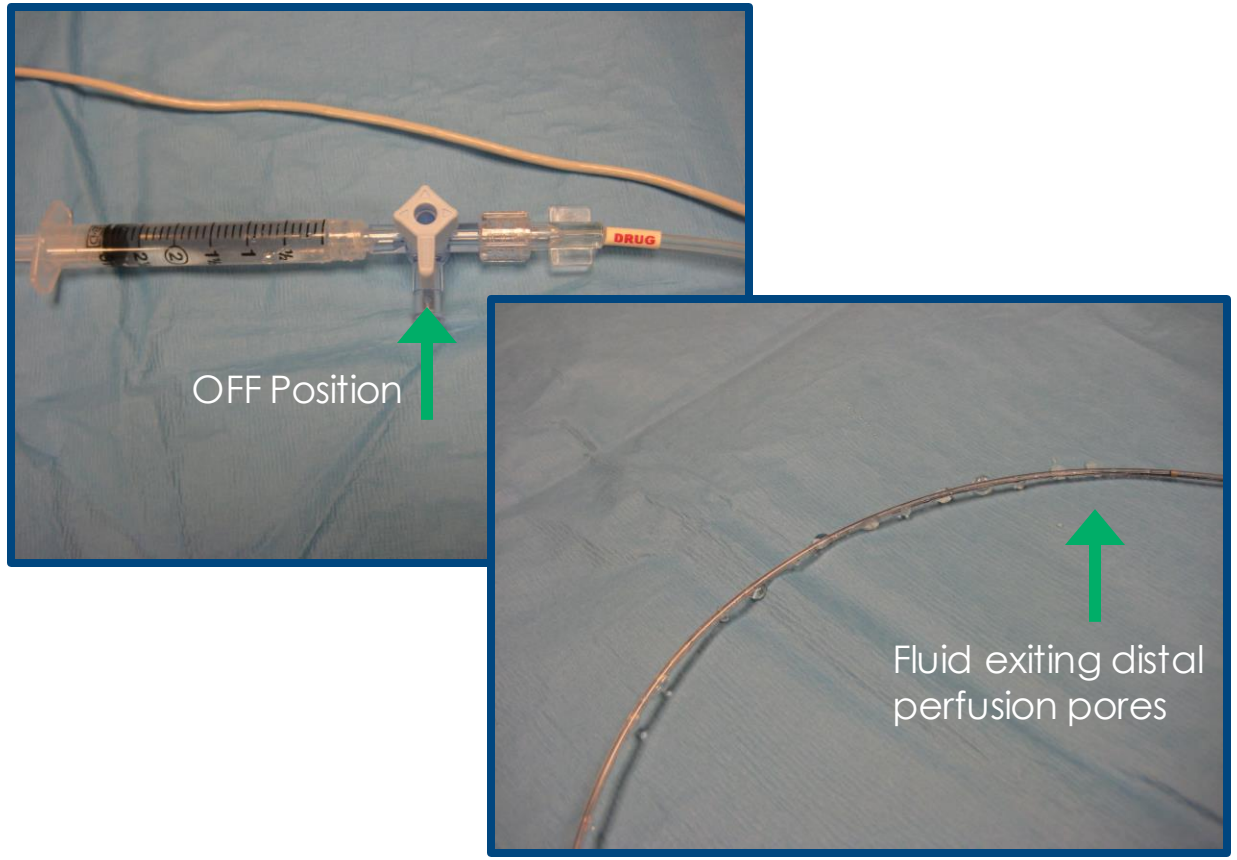
- Remove Infusion Catheter from the tray
- Isolate the gray electrical connector
- Place one stopcock or flow switch on the DRUG port and one on the COOLANT port.



! REMINDER: DO NOT GET THE CONNECTORS WET

Flush the DRUG Lumen

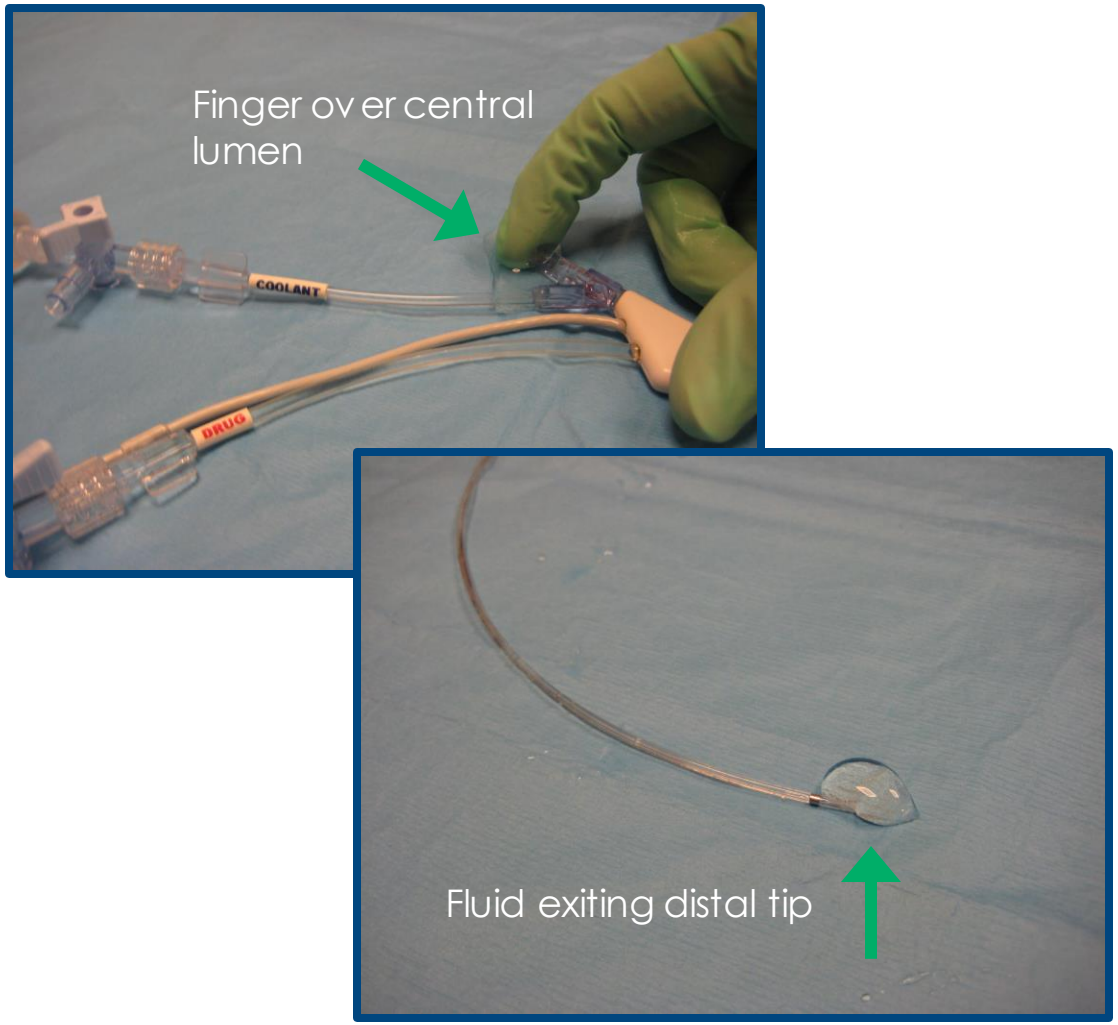
- Attach a 3 or 5 cc syringe to the DRUG port. Flush the DRUG lumen with heparin until fluid exits the most distal perfusion pores.
- Turn stopcock **OFF** to the Infusion Catheter to keep air from being introduced into the vasculature.



NEVER DRAW BACK BLOOD INTO THE DRUG LUMEN OR INFUSE ANYTHING BUT HEPARIN, SALINE, OR THROMBOLYITIC DRUG THROUGH THE DRUG LUMEN. IF THE LUMEN MICRO-PORES BECOME BLOCKED, THE INFUSION CATHETER MUST BE REPLACED.

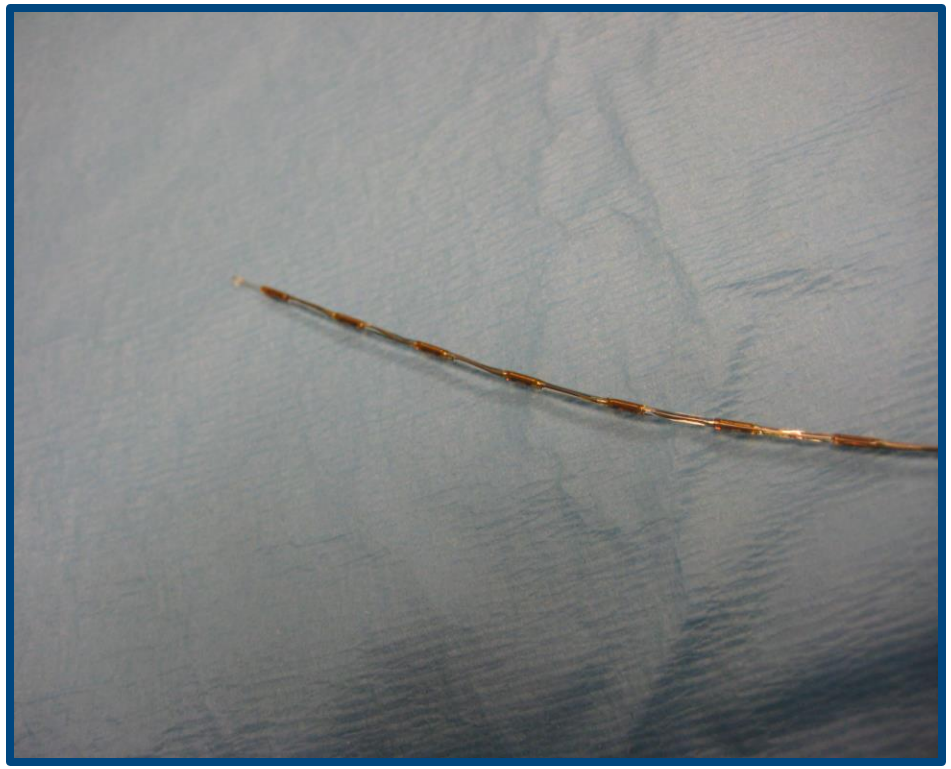
Flush the Coolant Lumen

- Attach a 10 cc syringe to the **COOLANT** port. Flush **COOLANT** lumen with heparinized saline.
- Fluid will exit the central guidewire lumen. Place your finger over the central lumen and continue to flush until you see fluid exit the distal tip of the Infusion Catheter.
- Turn stopcock **OFF** to the Infusion Catheter to keep air from being introduced into the vasculature.



Ultrasonic Core Preparation

- Isolate the black electrical connector of the Ultrasonic Core.
- Flush protective coil with heparinized saline to moisten the Ultrasonic Core until ready for use, or wipe with a wet 4 x 4 prior to inserting into the Infusion Catheter.



! REMINDER: DO NOT GET THE CONNECTORS WET

Device Placement – Infusion Catheter

- Place Infusion Catheter through a 6 Fr sheath over an 0.035" exchange length guidewire
- Position the distal marker on the Infusion Catheter 1 cm beyond the clot
- Remove 0.035" guidewire
- Flush the guidewire lumen

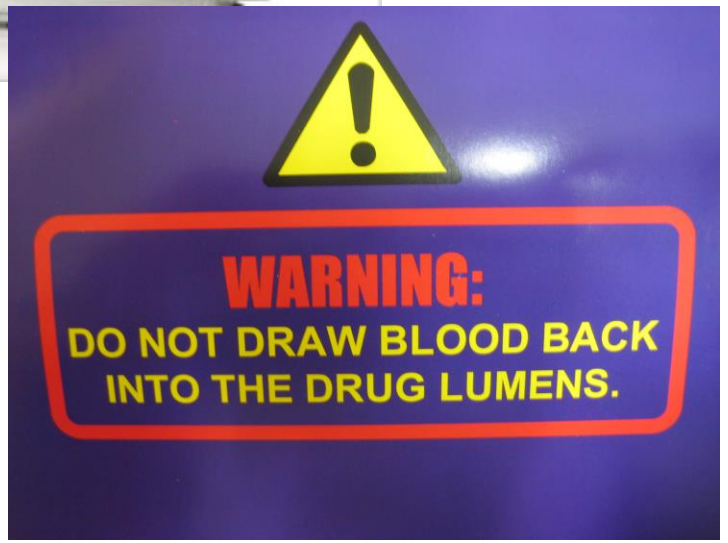
Device Placement – Ultrasonic Core

- Insert Ultrasonic Core into the guidewire lumen in 1 cm increments to prevent kinking or bending
- Luer lock Ultrasonic Core into the manifold of the Infusion Catheter

! IF AN INFUSION CATHETER OR ULTRASONIC CORE BECOME KINKED OR OTHERWISE DAMAGED DURING USE, DISCONTINUE USE AND REPLACE

Infusions Set-Up

- Consider using sterile extension tubing to begin infusions before breaking down the sterile field.
- Flush forward to purge any air out of side port of the stopcocks attached to the **DRUG** and **COOLANT** ports. Turn stopcocks on to the device, set the rate, begin infusion.
- Infuse heparinized saline or normal saline through the **COOLANT** port at 35 ml/hr (Max 120 ml/hr).
- Infuse lytic through the **DRUG** port at a prescribed dose with a flow rate range from 5 ml to 35 ml/hr.
- Sheath maintenance is at physician discretion.



Control Unit 4.0 Overview & Workflow

EKOS Control System 4.0

Components

- EKOS Control Unit 4.0 (CU4.0)
- Connector Interface Cables (CICs)

Features

- Manages two EKOS devices simultaneously.
- Touchscreen displays clear instructions and color coded screens for easy set-up, operation & troubleshooting.
- Controls & monitors output power and temperature of the ultrasound transducers.

EKOS® Control Unit 4.0 with built-in battery and mounting bracket

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Control Unit 4.0 Set-Up

- Locate the power switch on the lower right front of the Control Unit
- Turn on the Control Unit
- Wait for the boot screen to appear followed by the EKOS logo

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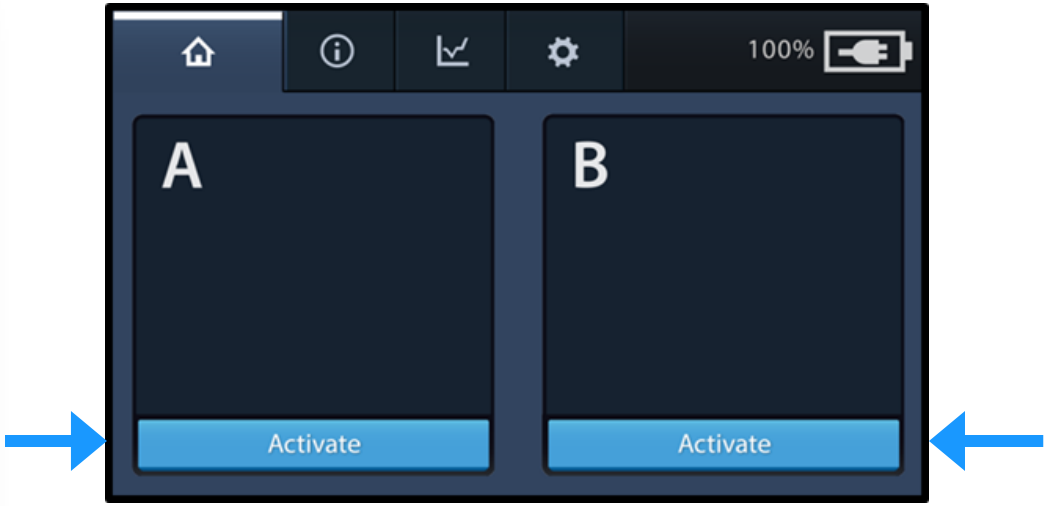
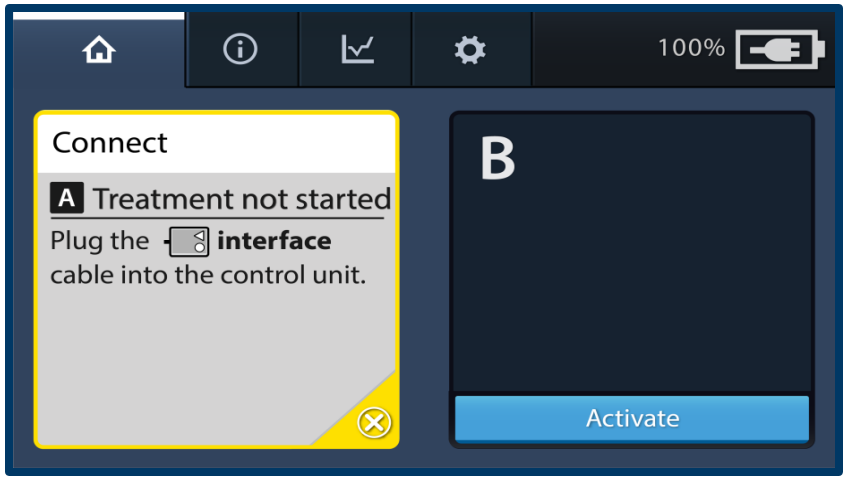
Step-by-Step Guide for Set-Up

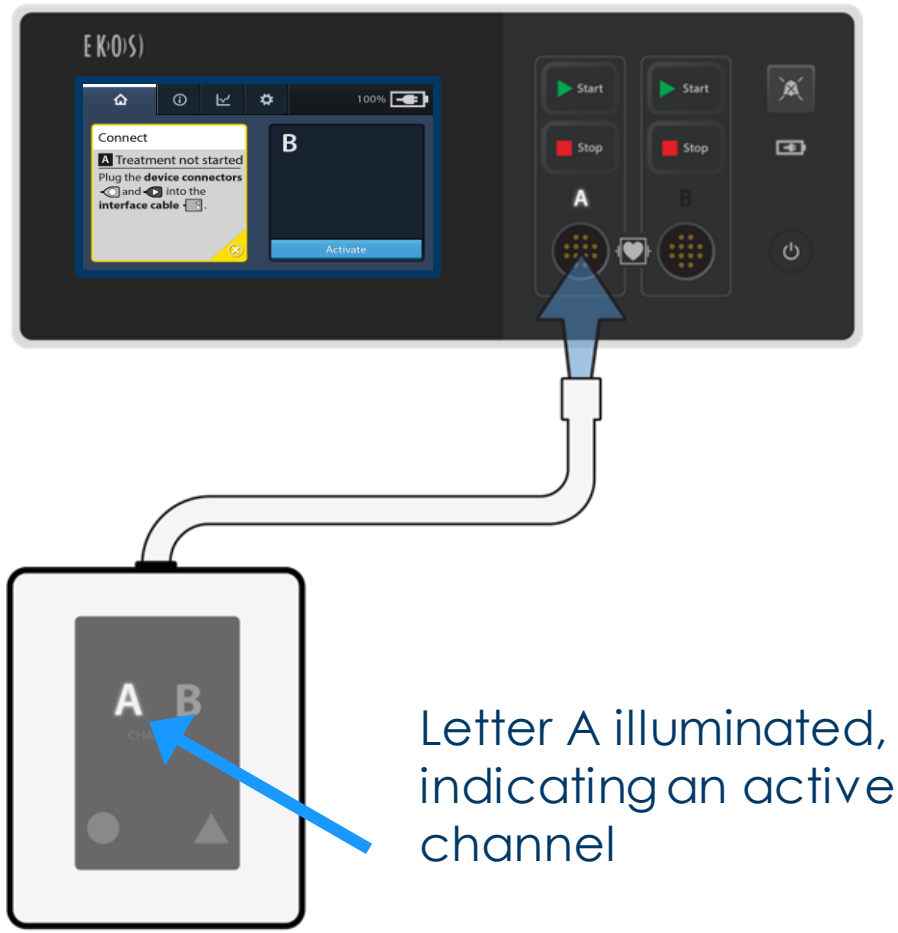
- After start-up completes, if the Connector Interface Cable (CIC) is not connected, both channels (A and B) are available to Activate.
- Press the Activate button for either channel A or B. The unit will display a message to plug in the CIC.
- Use both channels for bilateral treatment.





Connect CIC to Control Unit

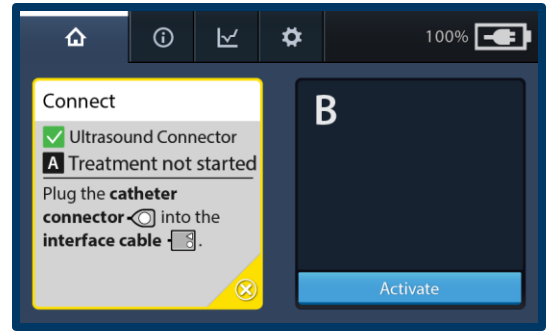
- Plug in Connector Interface Cable (CIC) to Control Unit.
- A message displays indicating to connect device connectors to CIC.
- A or B illuminates on the CIC housing when CIC is connected to Control Unit. The letter indicates the channel to which the cable is connected.

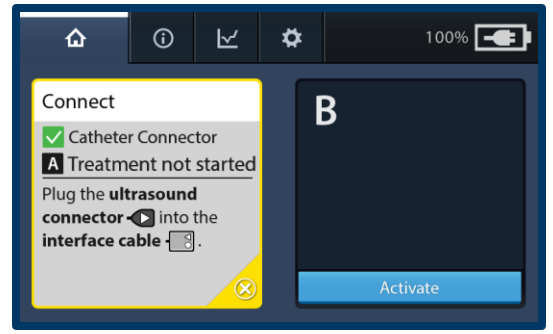


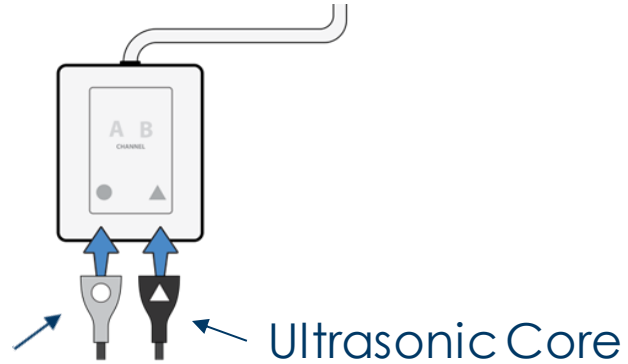
Connect Device Cables to CIC

- Ensure proper connections
  - **Black** to **Black** and Δ to Δ
  - **Gray** to **Gray** and O to O

- If using both channels, make sure both cables from each device are connected to a single CIC.



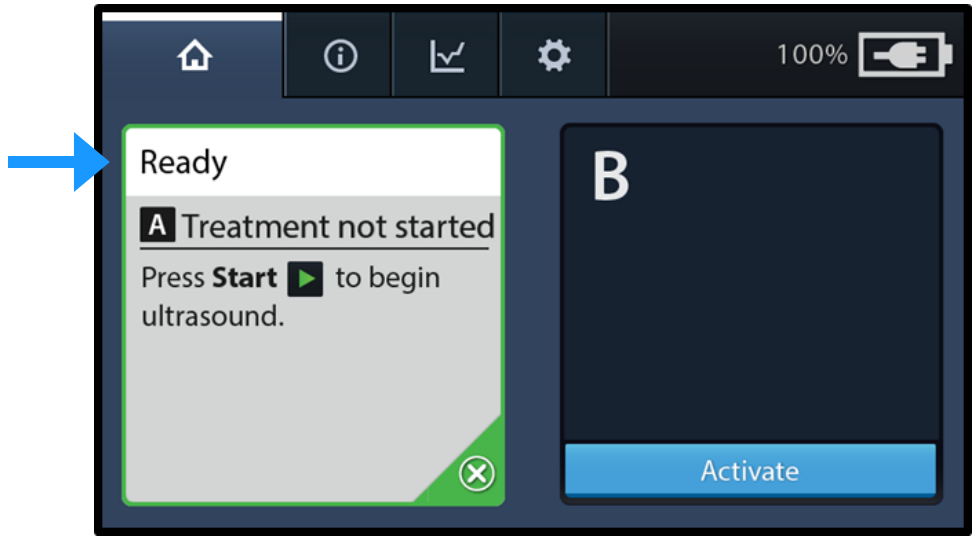




! CROSS CONNECTING AN ULTRASONIC CORE AND INFUSION CATHETER FROM TWO DIFFERENT PAIRS COULD RESULT IN PATIENT INJURY.

Starting Ultrasound

- When the device is properly connected, a **Ready** message displays indicating the Control Unit is ready.
  - If the device is not properly connected, a **Connect** message displays indicating the specific device cable that needs to be connected.
- Confirm fluids are infusing.
- Press the **Start**  button for the appropriate channel on Control Unit when prompted.

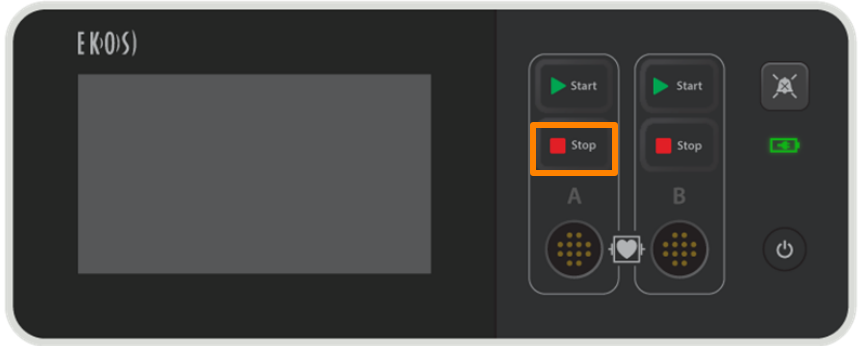


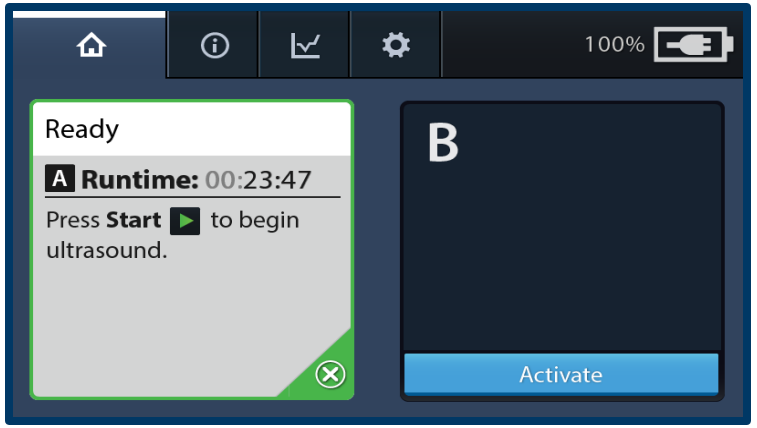
Monitoring Ultrasound

- When ultrasound is running, white bands animate, a green "Running" indication is displayed, and a runtime clock counts up.
- Monitor the timer to determine how long the device has delivered ultrasound therapy. The time is shown in Hours:Minutes:Seconds.
- If using both channels, the running status is displayed independently for each channel or device.

Stopping or Pausing the Ultrasound

- To stop or pause the ultrasound, press the **Stop** Stop button on the Control Unit for the appropriate channel.
- When the Stop button is pressed, the ready to start instruction and total elapsed runtime is displayed.
- If therapy is not resumed within 5 minutes, the **Start** reminder activates.
- Press the Audio Pause button on the Control Unit to silence the reminder for an additional 5 minutes.





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Control Unit Home Tab

Shows cable connection status, instructions, and ultrasound runtime information

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Control Unit System Information Tab

Displays system information including Control Unit model number, software version, serial numbers, device information, and EKOS Helpline phone number

Control Unit Graph Tab

Displays the amount of power delivered for each channel

Control Unit Settings Tab

Displays a menu for adjusting audible alert volume, screen brightness, and language

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Patient Transport & Device Removal

Preparation for Patient Transport

- Secure device with Tegaderm™, Steri-Strips™, or tape
- Refrain from coiling the catheter too severely
- Move patient onto a bed or stretcher
- Inform patient that they will be on bed rest and will have to keep the affected extremity straight at the insertion site and treatment zone

Patient Transport

- Unplug AC power cord from wall outlet.
- Control Unit will automatically switch to battery power to continue providing ultrasound therapy. A fully charged battery provides power for ~1 hour if two channels are running & ~2 hours if one channel is running.
- Secure the housing end of the CIC near patient to prevent the device from dislodging.
- Secure the power cord.
- Use the carrying handle, EKOS® custom cart, or infusion stand to transport the Control Unit with patient.
- When transport is complete, place Control Unit on table, or use EKOS® custom cart or infusion stand.
- Plug the Control Unit into hospital-grade outlet.
  - If not already turned ON, press the **Power** button.
  - Press the **Start** button if ultrasound stopped or was paused during transport.

Device Removal – Endovascular Lab or Beside

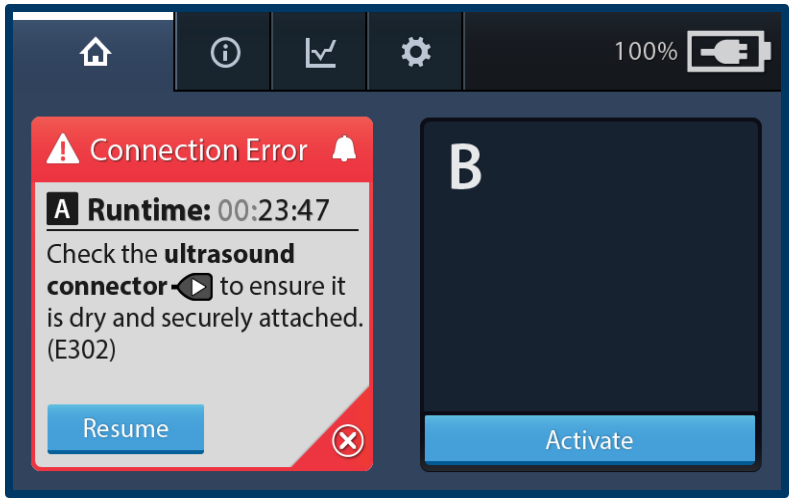
1. ALWAYS turn off the ultrasound by pressing the **Stop** button on the Control Unit for the appropriate channel before removing the Ultrasonic Core from the Infusion Catheter.
   - If the Ultrasonic Core is removed while running, it will turn off automatically, but in the few seconds it takes to turn off, it can become very hot.
2. Turn off the Control Unit by pressing and holding the **Power** button for 3 seconds.
3. Disconnect the Ultrasonic Core and Infusion Catheter from the CIC. Store the CIC with the Control Unit.
4. Turn stopcocks off to the **DRUG** and **COOLANT** ports so no air is introduced into the catheter. Discontinue infusions.
5. [*Endovascular lab only*] Decontaminate the exposed portions of the device and drape in a sterile fashion. Angiography may be performed at this time to assess the treatment site.

NEVER connect Infusion Catheter to a power injector

Control Unit 4.0 Troubleshooting & Support

Control Unit Troubleshooting Tips

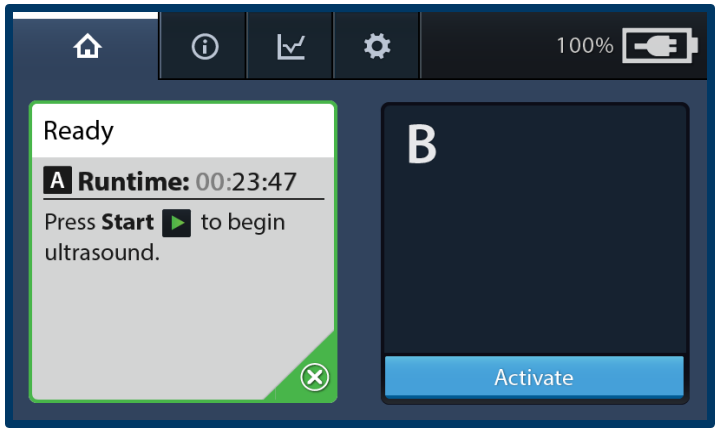
- The Control Unit continuously performs extensive self-tests to ensure that your patient safely receives optimal therapy
- Occasionally, the Control Unit will alert you to a problem
- If an error occurs, an error message with an alert icon displays and an audible tone sounds
  - Press the **Audio Pause** button on the Control Unit to silence the alert tone for 5 minutes
  - Read the error message and follow the instructions to correct the error

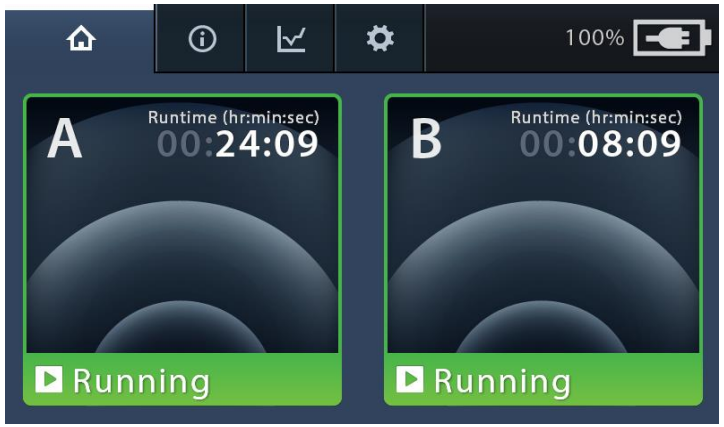


Channel A Connection Error Example: A channel error affects one specific channel and stops ultrasound therapy to the device associated with that channel.

Control Unit Troubleshooting Tips

- When the error is corrected, the alert icon disappears. The Ready to start instruction is displayed, showing the total elapsed runtime for the ultrasound therapy.
- To restart the ultrasound, press the **Start** ▶ Start button for the appropriate channel on the Control Unit. The runtime will resume counting.
- Confirm therapy is running. When ultrasound is running, white bands animate, a green "Running" indication is displayed, and a runtime clock counts up.





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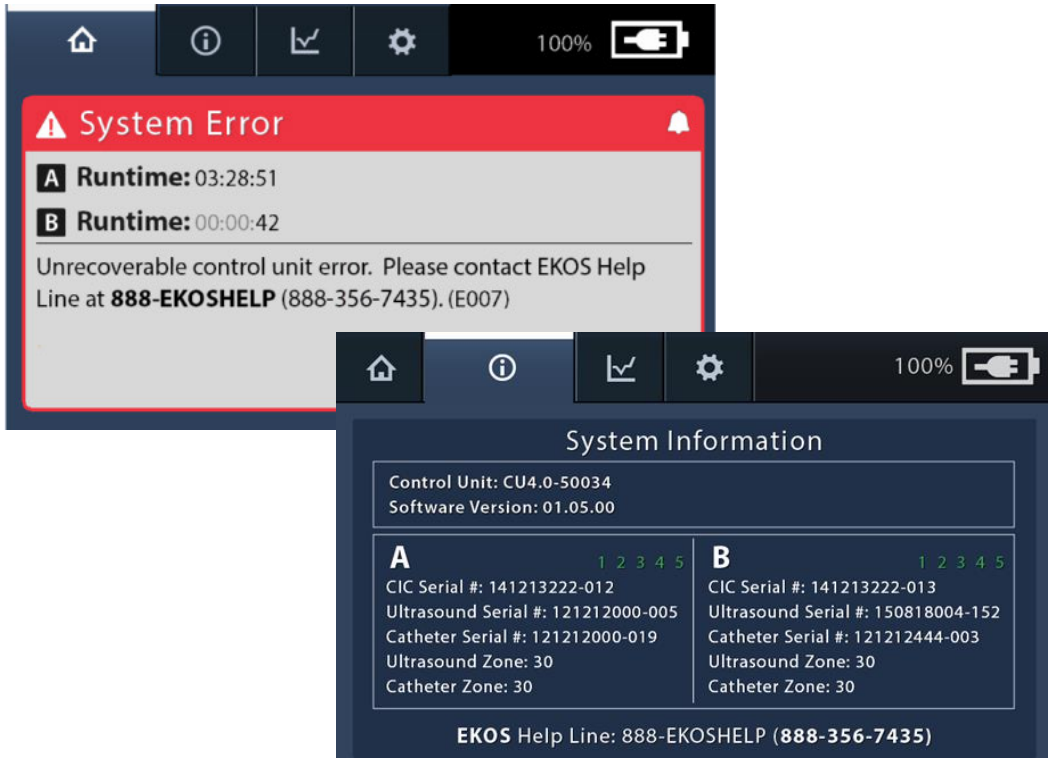
EKOS Help Line 24/7/365

- Some error messages will prompt calling the EKOS® Help line.
- Note the error code in parentheses at the end of the message and call 888-356-7435.
- The Help line is staffed by customer service experts and clinical specialists 24/7/365.
- The Help line number is listed in the System Information tab.



System Error Message Example: A system error affects both channels and stops ultrasound therapy on both channels.

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OPTALYSE Protocol

OPTALYSE Protocol

Group	Cohort 1	Cohort 2	Cohort 3	Cohort 4
# Patients	27**	27	28	18
Procedure Length	2 (h) EKOS	4 (h) EKOS	6 (h) EKOS	6 (h) EKOS
Total mg r-tPA	4/8 mgr-tPA*	4/8 mgr-tPA*	6/12 mgr-tPA*	12/24 mgr-tPA*
RV/LV Ratio at 48 hours compared to baseline	24% reduction	23% reduction	26% reduction	26% reduction

*Total mg r-tPA: one/two catheters for unilateral or bilateral
**One of the original 28 patients in this arm did not receive EKOS treatment

Tapson V et al. A randomized trial of the optimum duration of acoustic pulse thrombolysis procedure in acute intermediate-risk pulmonary embolism. JACC: Cardiovascular Interventions 2018; 11(14):1401-1410.

Product Information

EKOS Acoustic Pulse Thrombolysis Treatment

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INDICATIONS FOR USE: The EkoSonic Endovascular System is indicated for the: Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism. • Infusion of solutions into the pulmonary arteries. • Controlled and selective infusion of physician specified fluids, including thrombolytics, into the peripheral vasculature. All therapeutic agents utilized with the EkoSonic Endovascular System should be fully prepared and used according to the instruction for use of the specific therapeutic agent. CONTRAINDICATIONS: Not designed for peripheral vasculature dilation purposes. • This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition.

POTENTIAL COMPLICATIONS: Vessel perforation or rupture • Distal embolization of blood clots • Vessel spasm • Hemorrhage • Hematoma • Pain and tenderness • Sepsis/Infection • Thrombophlebitis • Tricuspid and pulmonic valve damage • Pulmonary infarct due to tip migration and spontaneous wedging, air embolism, and/or thromboembolism • Right bundle branch block and complete heart block • Intimal disruption • Arterial dissection • Vascular thrombosis • Drug reactions • Allergic reaction to contrast medium • Arteriovenous fistula • Thromboembolic episodes • Amputation • Pneumothorax • Perforation of the pulmonary artery. • Cardiac Arrhythmias – most frequently occurring during placement, removal or following displacement into the right ventricle. PI-726201-AA