

EkoSonic® Endovascular System with Control Unit PT-3B Intensive Care Protocol

Terms and Abbreviations

Control Unit	CU
Connector Interface Cable	CIC
EkoSonic® Endovascular Device	Infusion Catheter (IDDC) and Ultrasonic Core (MSD)

Indications for use	<p>The EkoSonic® Endovascular System is indicated for the:</p> <ul style="list-style-type: none"> • 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.
System Components	<p>The EkoSonic® Control System consists of two main components:</p> <ul style="list-style-type: none"> • A single-use sterile EkoSonic® Endovascular Device, consisting of an Infusion Catheter (labeled IDDC) and an Ultrasonic Core (labeled MSD). • A reusable EkoSonic® Control Unit which provides power to the device and the user interface for operator control. The EkoSonic® Control Unit (or PT-3B) also includes a Connector Interface Cable (CIC).
Mechanism of action	<p>EKOS® technology is called Acoustic Pulse Thrombolysis™ treatment. It uses ultrasound in combination with a thrombolytic drug to quickly, safely and effectively dissolve thrombus. The ultrasound thins the clot fibrin to allow the drug to penetrate the clot more rapidly and completely. The system automatically monitors and controls the ultrasound delivery.</p>

When patient arrives in the ICU

- a. Plug the UPS/battery supporting the EkoSonic® CU into a hospital grade outlet as soon as possible upon arrival into the unit.

Note: The CU should be plugged into the UPS/battery on the bottom of the cart and the UPS/battery turned ON. The UPS/battery should be plugged into a hospital grade outlet when not transporting the equipment. If unplugged, the UPS/battery will alarm. The alarm may be silenced by pressing and holding the “MUTE” button on the front of the UPS/battery. The UPS/battery will operate the CU for 60 minutes when it is fully charged. If the UPS/battery discharges to a critical point, it will beep incessantly and cannot be silenced unless it is plugged into a hospital grade outlet.

- b. Confirm that drug and coolant are infusing at physician specified rates.
 - a. Check that heparinized saline or normal saline is infusing through the COOLANT port of the Infusion Catheter. It should run between a minimum of 35 mL/hr and maximum of 120 mL/hr.
 - b. Check that the lytic is infusing through the DRUG port of the Infusion Catheter; minimum 5 mL/hr to maximum 35 mL/hr.

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This checklist is intended as an example to demonstrate the type of checklist you may wish to implement in your clinical practice. Any checklist you implement should reflect your actual clinical practice at your facility. EKOS® makes no recommendations or representations about the content of this sample checklist. The responsibility for such a checklist rests with the clinical practice.

- c. Confirm that ultrasound is running. Proper functioning of the EkoSonic® CU is confirmed by a flashing yellow light below the display and immediately to the left of the green START button.
- d. If the yellow light is not blinking:
 - Check that the CIC is connected to the front of the CU.
 - Check that the CIC is connected to the electrical cables of the Ultrasonic Core (MSD – black wire) and the Infusion Catheter (IDDC- gray wire).
- Red circles on the Control Unit schematic screen will denote any areas of a loose or missing connection.
- Check to see if the lytic drug and coolant infusions are flowing. If both infusions are flowing, press the green START button on the front of the EkoSonic® Control Unit. confirm the yellow light at the bottom left begins to flash.
- **Never** aspirate from the drug lumen as this will occlude the micro-pores in the Infusion Catheter with blood.
- **Never** infuse any medicines via COOLANT or DRUG port other than heparinized saline, normal saline, and/or therapeutic agent.
- The EkoSonic® Endovascular System does not control the infusions. The DRUG and COOLANT are infused through hospital infusion pumps.
- To ensure proper infusion and reduce the potential for infusion pump alarms, the infusion pressure setting on the pumps should be set to the highest value allowed by hospital policy. A minimum of 10 PSI or 500 mmHg will reduce the potential of downstream occlusion alarm.

During EKOS® therapy

- a. The RN will request that the physician complete the routine thrombolytic orders.
- b. Whenever checking on the patient, look at the CU to ensure the yellow light is flashing. If the yellow light is flashing, the CU is functioning properly and no interaction with the unit is required. If the yellow light is not flashing, see point “d” above.
- Follow the physician orders for thrombolytics regarding lab tests, sedation, IV/IA site management, sheath maintenance, vitals and neuro checks, etc.
- If thrombolytic drug must be discontinued for any reason, run NS KVO through the DRUG and COOLANT ports. Do not completely stop infusing through the DRUG and COOLANT ports. Turn ultrasound OFF by pressing the orange STOP button on the Control Unit and disconnect the black and gray cables from the CIC. Confirm KVO orders with the interventionalist when thrombolytic drug is stopped. This will help maintain patency of the catheter if the thrombolytic drug and ultrasound can be restarted.
- Push the orange STOP button when performing Doppler checks or Echocardiograms. An alarm will occur after 5 minutes as a reminder to restart the ultrasound. Pushing the Alarm Silence button will reset the 5 minute timer. Resume ultrasound after the Doppler or Echo is finished by pressing the green START button.

Troubleshooting

- a. If a CU alarm sounds it can be muted by pushing the upper right hand soft key beside the Alarm Silence Icon.
- b. Confirm that the CU Display does not show any red circles indicating a disconnected cable. Reconnect any cable showing a circle and confirm that it goes away. Push the green START button.
- c. If the alarm condition persists then identify the troubleshooting icon that is flashing at the bottom of the CU display between the two gray bars.
- d. Call EKOS® Help Line at 888-356-7435 (24/7/365). The Help Line number is located on top of the EkoSonic® CU.
- e. If unable to resume ultrasound therapy after contacting EKOS®, contact the interventional physician.

Process for transporting a patient:

- a. Unplug UPS/battery from AC outlet (battery will last for 60 minutes).
- b. When UPS/battery is unplugged, an alarm will sound.

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- c. Silence the alarm by pressing and holding the "MUTE" button located on the front of the battery for 2 seconds.
- d. Transport patient to new location.
- e. Plug UPS/battery into AC outlet.

Removal of the device at bedside:

- a. Turn off ultrasound by pressing the orange STOP button - disengage black connector clip, and disconnect the gray and black connectors from the CIC.
- b. Turn stopcocks off to the DRUG and COOLANT ports to prevent air from being introduced into the vasculature.
- c. Discontinue infusions and disconnect infusion tubing from the stopcocks.
- d. Don PPE and place the patient flat.
- e. Have the patient exhale and hold breath if able.
- f. Stabilize the introducer sheath with one hand and then pull the Infusion Catheter out in a steady motion. Verify there is a marker band near the distal tip of the Infusion Catheter. NOTE: If resistance is felt, stop and notify physician.
- g. If sheaths are to be discontinued, follow the hospital policy.

Name: _____ **Date:** _____

Reviewer: _____