EkoSonic® Endovascular System with CU 4.0 Control Unit
Intensive Care Protocol

Terms and Abbreviations

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

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.
System Components	The EkoSonic® Control System consists of two main components: • A single-use sterile EkoSonic® Endovascular Device, consisting of an Infusion Catheter (IC) and an Ultrasonic Core (USC). • A reusable EkoSonic® Control Unit which provides power to one or two devices and a user interface for operator control. The EkoSonic® CU 4.0 Control Unit also includes two Connector Interface Cables (CIC).
Mechanism of action	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.

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.

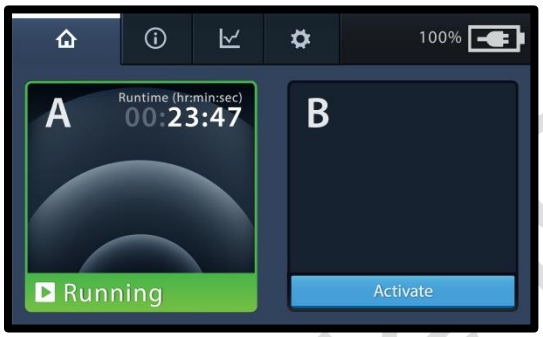
When patient arrives in the ICU

a. Plug the CU 4.0 or CU 4.0 cart supporting the EkoSonic® CU into a hospital grade outlet as soon as possible upon arrival into the unit.

   Note: The CU 4.0 should be plugged into the EKOS integrated power strip located on the EKOS® cart. The cart should be plugged into a hospital grade outlet when not transporting the equipment. If unplugged, the control unit will power one device for two hours or two devices for one hour. An audible alert will notify staff when the battery charge is below 30%.

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(s). The rate should be 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(s); minimum 5 mL/hr to maximum 35 mL/hr.

c. Confirm that ultrasound is running. Proper functioning of the EkoSonic® CU 4.0 is confirmed by the green "Running" indicator with white bands animating for each channel in use.



d. If the running indicator is not visible:

   - Ensure you are on the Home screen. Select the HOME tab.
   - Check that the CIC is connected to the electrical cables of the Ultrasonic Core (USC -black wire) and the Infusion Catheter (IC - gray wire).
   - Ensure the fluids are infusing and press START for the appropriate channel(s).

e. **Never** aspirate from the drug lumen as this will occlude the micro-pores in the Infusion Catheter with blood.
f. **Never** infuse any medicines via COOLANT or DRUG port other than heparinized saline, normal saline, and/or therapeutic agent.
g. The EkoSonic® Endovascular System does not control the infusions. The DRUG and COOLANT are infused through hospital infusion pumps.
h. 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.

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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 channel displays the "Running" indicator. If the running indicator with the white bands animating is displayed the CU is functioning properly and no interaction with the unit is required. If the "Running" indicator is not displayed, refer to the above, section d.

c. Follow the physician orders for thrombolytics regarding lab tests, sedation, IV/IA site management, sheath maintenance, vitals, and neuro checks, etc.

d. If thrombolytic drug must be discontinued for any reason, request a physician order to infuse Normal Saline KVO through the DRUG and COOLANT ports. Do not completely stop infusing through the DRUG and COOLANT ports. This will help maintain patency of the catheter if the thrombolytic drug and ultrasound needs to be restarted. Turn ultrasound OFF by pressing and holding the power button ⏻ for at least 3 seconds on the Control Unit and disconnect the black and gray cables from the CIC.

e. Push the red STOP button for each channel when performing Doppler checks or Echocardiograms. An audible alert will occur after 5 minutes as a reminder to restart the ultrasound. Pushing the audio pause button will reset the 5-minute timer. Resume ultrasound after the Doppler or Echo is finished by pressing the green START button(s) for each channel.

Troubleshooting

a. If a CU generates and audible alert, press the audio silence button  to silence the alert for 5 minutes.
b. Follow the onscreen instructions and note the error code in parenthesis (E###) at the end of the message.
c. If the audible alert persists, call the EKOS® Helpline at 888-356-7435 (24/7/365). Please have the error code ready to give the Clinical Specialist on call.
d. Call the EKOS® Helpline for any issues with the Control Unit, Cart, Device, or Infusions.
e. If unable to resume ultrasound therapy after contacting EKOS®, contact the interventional physician.

Process for transporting a patient:

a. Unplug the EKOS® Cart from the AC outlet (battery will last for 1 to 2 hours).
b. Transport patient to new location.
c. Plug EKOS® Cart into a red AC outlet.

Removal of the device at bedside:

a. Turn off ultrasound by pressing the red STOP button for each channel.
b. Disconnect the black and gray cables of the device from the CIC(s).
c. Turn off control unit by pressing and holding the power button on the front of the control unit.
d. Turn stopcocks off to the DRUG and COOLANT ports to prevent air from being introduced into the vasculature.
e. Discontinue infusions and disconnect infusion tubing from the stopcocks.
f. Don PPE and place the patient flat.
g. Have the patient exhale and hold breath if able.
h. 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.
i. If sheath(s) are to be discontinued, follow the hospital policy.

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EKOS Brief Summary

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.

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