

EkoSonic® Endovascular Device and EKOS® Control Unit 4.0 Circulator Skills Checklist

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.

Please refer to the Instructions for Use for indications, contraindications, precautions, warnings, and full operational instructions.

Terms and Abbreviations Control Unit	CU
Connector Interface Cable	CIC
EkoSonic® Endovascular Device	device

Skills to Review	Reviewer Initials
<p>1. Steps for initial setup of EkoSonic® Endovascular System:</p> <p>a. Verify that the Control Unit 4.0 has power:</p> <ul style="list-style-type: none"> • CU is plugged into a hospital-grade outlet. • Locate the power button found in the lower right front corner of the CU. Turn CU on and wait for the boot screen followed by the EKOS® logo screen to appear. <p>b. Set up the prescribed solutions via standard hospital infusion pump to the drug and coolant ports of the EKOS® Infusion Catheter. Ensure all air bubbles are purged from the tubing.</p> <ul style="list-style-type: none"> • 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. • Thrombolytic drug via port marked DRUG at prescribed dose. Minimum infusion rate 5 mL/hr, maximum 35 mL/hr. Adjust drug concentration to stay within these flow rates. • Normal saline or heparinized saline via port marked COOLANT at 35 mL/hr, maximum 120 mL/hr. • If applicable, heparinized saline or heparin via side arm of the sheath at prescribed dose. <p>c. Connect infusions after the device has been placed in the patient’s vasculature. Consider attaching sterile extension tubing to the infusion lines so they can be started before breaking the sterile field. Flush forward to purge any air out the side port of the stopcocks attached to the Drug and Coolant ports. Insert infusion tubing into the pump, start the pump, and turn the stopcock on to the Infusion Catheter.</p> <p>d. Ensure that all cables are attached correctly:</p> <ul style="list-style-type: none"> • CIC is attached to CU. • Ultrasonic Core black cable and Infusion Catheter gray cable are connected to the CIC. 	

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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.

<ul style="list-style-type: none"> • Always verify that both electrical connectors from an Ultrasonic Core-Infusion Catheter pair are connected to the same CIC if more than one channel is being used. e. Confirm that drug and coolant are infusing, then begin ultrasound therapy by pressing the green START button. f. Confirm that ultrasound is running. When ultrasound is running, white bands animate in the channel message area, a green Running indication displays, and a runtime clock counts up. The running status is displayed independently for each channel . 	
<p>2. Process for transporting a patient:</p> <ul style="list-style-type: none"> a. Check the battery level prior to transport to ensure it is adequately charged. b. Unplug CU from AC outlet. The CU will automatically switch to battery power and continue to provide ultrasound therapy. The internal battery will provide ultrasound therapy for approximately two hours if one channel is used and approximately one hour if two channels are used. c. Secure the housing end of the CIC near the patient to prevent the device from dislodging. d. Secure the power cord. e. Use carrying handle or an approved infusion stand to transport CU with patient. f. When transport is complete, securely place CU on table, cart, or approved infusion stand near patient. g. Plug CU into a hospital-grade outlet. 	
<p>3. Process for troubleshooting CU alert conditions:</p> <ul style="list-style-type: none"> a. If an alert occurs, press Audio Pause button in top right corner to silence alert for 5 minutes. b. Read the message displayed on the CU screen and follow instructions for corrective action or troubleshooting steps to take. When the error is corrected, the alert icon disappears and the Ready to start instruction is displayed. Push the green Start button to restart ultrasound. c. If the issue cannot be resolved, note the error code in parentheses at the end of the message and call the EKOS® Help Line at 1-888-356-7435 (24/7/365). The Help Line number can also be found in the System Information tab of the CU. d. If unable to resume ultrasound therapy after contacting EKOS®, contact the interventional physician. 	
<p>4. Important guidance for proper operation of the EkoSonic® Endovascular System:</p> <ul style="list-style-type: none"> a. Never aspirate from the DRUG or COOLANT ports. This will clog the lumens with blood and render the catheter inoperable. Never piggyback any solutions on the drug or coolant infusions. b. Infusion rate ranges are: <ul style="list-style-type: none"> • 5-35 mL/hr for the drug lumen • 35-120 mL/hr for the coolant lumen c. Never infuse any medicines via Coolant or Drug port other than heparinized saline, normal saline, and/or therapeutic agent. d. Never transmit ultrasound energy to the Ultrasonic Core-Infusion Catheter pair unless it is placed within the patient anatomy and infusions are running. e. Always turn the ultrasound OFF before removing the Ultrasonic Core from the Infusion Catheter or before removing the device from the patient. 	

<ul style="list-style-type: none">f. Discontinue the infusions before removing the device. Turn stopcocks OFF to both lumens to prevent air from being introduced into the vasculature.g. Never get electrical connectors wet.h. Never connect Infusion Catheter to a power injector.	
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Name: _____ **Date:** _____

Reviewer: _____