EkoSonic SV™ Control System

Instructions for Use

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Caution: Federal (U.S.) law restricts this device to use by or on the order of a physician.

CE 0197

Intended Use

The EKOS® EkoSonic SV™ Control System is intended exclusively for use with the EKOS® MicroSonic SV™ Endovascular Device.

Contraindications

- This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition.
- This system is not intended for use in neonatal or pediatric applications.

Warnings

- Do not operate the EkoSonic SV Control Unit in the presence of flammable anesthetics.
- Do not remove EkoSonic SV Control Unit main covers. The only user serviceable part is the air filter, which is on the bottom of the unit. (Refer to Filter Cleaning later in this document). There are no other user-serviceable parts. Only the manufacturer's qualified personnel should service the EkoSonic SV Control Unit.
- The EkoSonic SV Control Unit is intended for use with the MicroSonic SV Endovascular Device. Do not connect any other electronic devices to the EkoSonic SV Control Unit.
- Do not connect any cabling or external device to the port on the back of the EkoSonic SV Control Unit during operation.
- Avoid placing liquids on or near the EkoSonic SV Control Unit such that spillage would contact system components or connectors.
- Do not use spray cleaners while the unit is operating.
- Connect the EkoSonic SV Control Unit only to a properly grounded hospital-grade outlet, using the appropriate power cord for the outlet. Assure that power cords are out of the way and do not cause a potential for tripping or other interference.
- Do not turn on ultrasound energy to the MicroSonic SV Endovascular Device while the device tip is in air. Only transmit ultrasound energy to the MicroSonic SV Endovascular Device after it is placed within the patient anatomy and fluid agent is flowing through the central lumen. Otherwise, overheating may occur, causing damage to the ultrasound element.

Precautions

- Carefully read all Instructions for Use prior to use. Observe all warnings and precautions noted throughout these instructions. Failure to do so may result in complications.
- Only trained physicians who have a thorough understanding of percutaneous intravascular techniques and procedures should use the MicroSonic SV Endovascular Device and EkoSonic SV Control Unit.
- Continuous application of ultrasound energy should be limited to 120 minutes.
- All agents used with the EkoSonic SV Control Unit and the MicroSonic SV Endovascular Device should be fully prepared and used according to the instructions for use for the specific agent.
- Connect system cables only to their proper connectors as marked. Assure that all connections are secure.
- The reusable Connector Interface Cable (CIC) is NOT STERILE. Use caution to maintain a sterile operating field after the CIC has been connected to the MicroSonic SV Endovascular Device.
- Use caution when moving the EkoSonic SV Control Unit so as not to pull the CIC and MicroSonic SV Endovascular Device.

- Make sure that the EkoSonic SV Control Unit is securely placed on a table or cart near the patient, but out of the sterile field. The surface of the table must be flat and not block the air intake located under the unit.
- Avoid the contact of strong solvents and abrasive cleaners with EkoSonic SV Control Unit components.
- Store the EkoSonic SV Control Unit under conditions as specified in an area of good ventilation. (See System Specification section).
- This equipment has been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2001. These limits are designed to provide reasonable protection against harmful electromagnetic interference in a typical medical installation.

  This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning this equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

  - Reorient or relocate the receiving device.
  - Increase the separation between the equipment.
  - Connect this equipment into an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer or field service technician for help.

  This equipment also complies with requirements for safe operation when subjected to adverse power line conditions. In the event of extreme surges in electrical line voltage, the Control Unit may enter a protective mode and suspend active delivery of ultrasound energy. If this occurs, drug delivery will continue and the operator will be presented with an error indication on the display. Clearing the error and restarting ultrasound energy will resume normal operation. See the Troubleshooting section of this document for further information about clearing error indicators.

Principles of Operation

The EkoSonic SV System employs ultrasound energy to facilitate the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the patient's peripheral vasculature and contrast material into the neurovasculature. The system generates ultrasound waves near the tip of the device through the piezoelectric conversion of radio frequency (RF) energy generated by the EkoSonic SV Control Unit. The ultrasound emanates radially from the device tip to improve the dispersion of infused fluids within the patient's vasculature.

In addition to generating the prescribed ultrasound energy profile, the EkoSonic SV Control Unit continually monitors output power and temperature of the device tip. The system has safeguard circuits to prevent deviation of these parameters from preset ranges.

Device Description

The EkoSonic SV System (see Figure 1) consists of two main components:
(1) a single-use sterile MicroSonic SV EndoVascular Device, consisting of an end-hole infusion lumen with an ultrasound element at the distal tip, and (2) a reusable EkoSonic SV Control System which provides the ultrasound energy source and the user interface. The EkoSonic SV Control System is comprised of two components: an EkoSonic SV Control Unit and a Connector Interface Cable (CIC).

MicroSonic SV™ Endovascular Device Description

The body of the disposable MicroSonic SV Endovascular Device tapers from 3 French (F) (1 mm) at the proximal end to 2.8 F (0.93mm) at the distal end [the treatment zone is 3.0F (1.0 mm)], with a 150 cm working length and is a single central lumen end-hole design. The central lumen accommodates a 0.014 in. guidewire. Once the MicroSonic SV Endovascular Device is in position, the guidewire must be removed because during operation the central lumen is used as the fluid infusion lumen. The proximal end of the MicroSonic SV Endovascular Device contains a luer port. This port connects to a hemostasis valve, through which the guidewire passes. The hemostasis valve has a port for connecting to the infusion device.

The MicroSonic SV Endovascular Device incorporates one piezoelectric ultrasound element, positioned at the distal end of the MicroSonic SV Endovascular Device. It emits ultrasound energy in a 360° radial pattern perpendicular to the long axis of MicroSonic SV Endovascular Device to disperse infused physician-specified fluids. A thermocouple acts as a temperature sensor and continuously samples temperature, which is monitored by the EkoSonic SV Control Unit to assure operation within safe limits. An electrical connector at the proximal end of the MicroSonic SV Endovascular Device couples to a Connector Interface Cable (CIC) that in turn plugs into the front panel of the Control Unit.

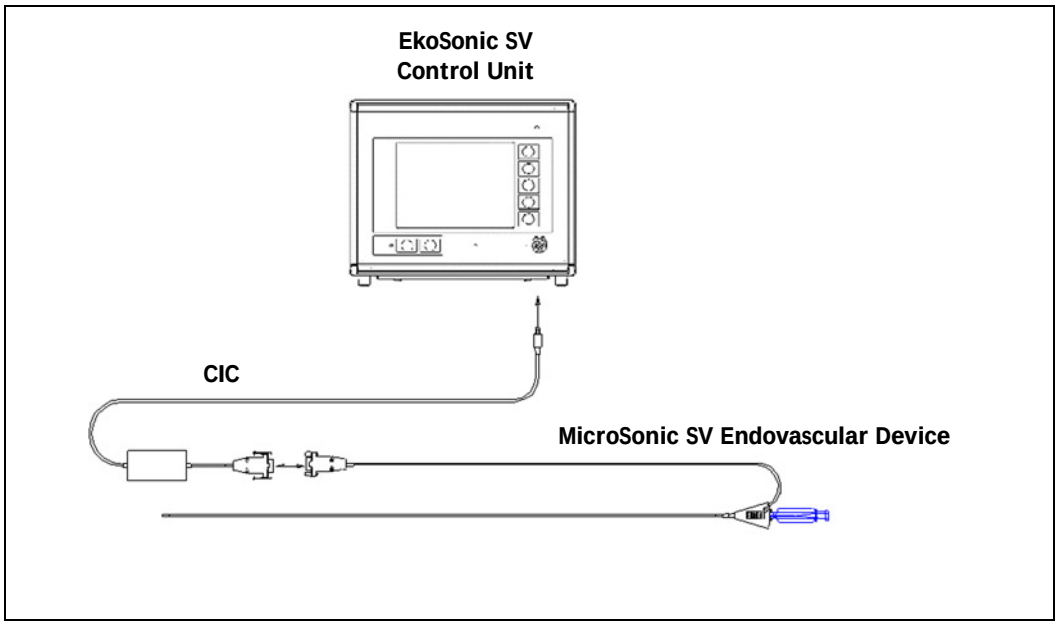


Figure 1. EkoSonic SV System

EkoSonic SV™ Control Unit Description

The EkoSonic SV Control System consists of an EkoSonic SV Control Unit and a Connector Interface Cable (CIC). The EkoSonic SV Control Unit provides electrical power to the piezoelectric elements at the tip of the MicroSonic SV Endovascular Device and monitors operating parameters during operation via the CIC. The EkoSonic SV Control Unit also provides the user interface through the front panel display and keypad. Additionally, the EkoSonic SV Control Unit allows the user to select a secondary interface which displays a history of the average power delivered to the attached MicroSonic SV Endovascular Device.

Directions for Use for the EkoSonic SV Control System

See the Instructions for Use for the EKOS® MicroSonic SV Endovascular Device for preparation, placement and usage instructions.

1. Connect the EkoSonic SV Control Unit power cord to an appropriate outlet. Connect the round end of the Connector Interface Cable (CIC) to the front panel connector of the EkoSonic SV Control Unit.

2. Following selection, preparation and placement of the MicroSonic SV Endovascular Device, connect the electrical connector to the appropriate connector at the distal end of the Connector Interface Cable (CIC). Make sure the connector is properly seated.

- **Warning:** The reusable CIC is NOT STERILE. Use caution to maintain a sterile operating field after the CIC has been connected to the MicroSonic SV Endovascular Device.

Operation

1. Turn the Control Unit on using the power on/off switch located on the rear panel near the power plug connection. The embedded software will automatically perform an initial self-test of the Control Unit function. While the self-test is being performed the screens in Figure 2 will be displayed. The rainbow striped screen is displayed during the hardware test and is followed by the EKOS logo screen during the software test.

Figure 2. Initial EkoSonic SV Control Unit screens during self-testing.

2. When the Control Unit successfully completes the self-test, the software will transition to the Ready Screen. See Figure 3 for an example of the Ready Screen.

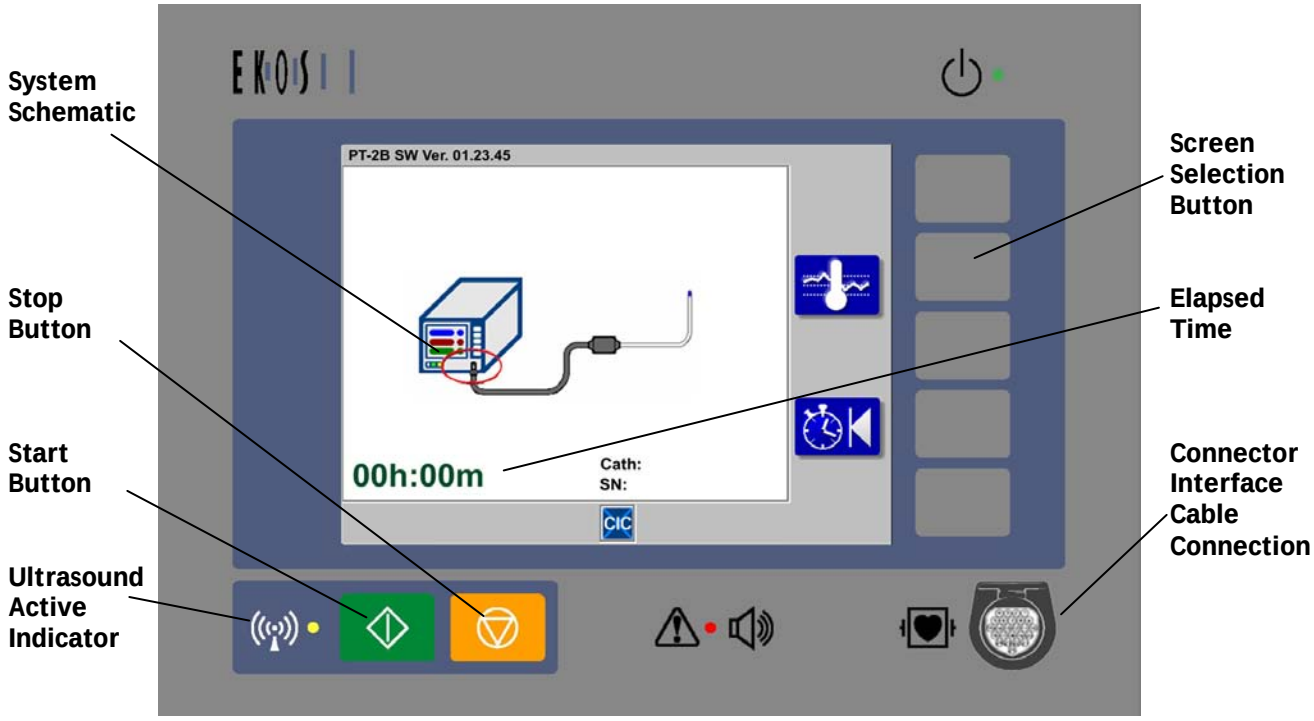


Figure 3. EkoSonic SV Control Unit front display in Ready Screen.

3. Figure 3 specifically shows that the Connector Interface Cable (CIC) has not been plugged into the Control Unit. The red circle around the front panel plug in the system schematic indicates where the CIC must be attached to the Control Unit. Ultrasound output will not be allowed unless the CIC is attached and the device is properly connected to the CIC. If the Control Unit detects any condition that prevents proper operation, it will identify the issue by displaying a combination of screen icons, circles and/or Xs on the system schematic. These icons and symbols are explained in the Troubleshooting section of this document.

4. After attaching the CIC and the MicroSonic SV Endovascular Device to the Control Unit, a screen similar to Figure 4 will be displayed. In the lower part of the screen the device model and serial number will be displayed.

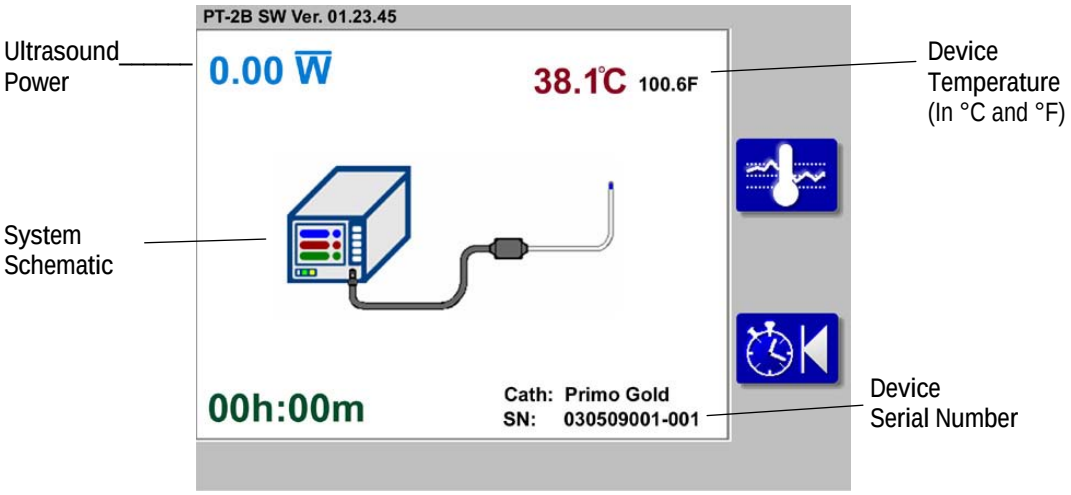


Figure 4. EkoSonic SV Control Unit indicating that CIC and device have been connected.

5. Before starting ultrasound transmission, be sure the MicroSonic SV Endovascular Device is placed in the patient properly and begin infusion through the device infusion port.

6. Press the green Start button  to begin ultrasound transmission. The yellow "Ultrasound Active" indicator on the lower part of the front panel next to the ultrasound indicator icon  will begin to flash and the display mode will switch to a 15 minute power and temperature graph. The average power is indicated in Watts just above the graph. The temperature of the device tip is displayed in both degrees Celsius and degrees Fahrenheit in the upper right corner. The elapsed time in hours and minutes is displayed in the lower left corner. See Figure 5.

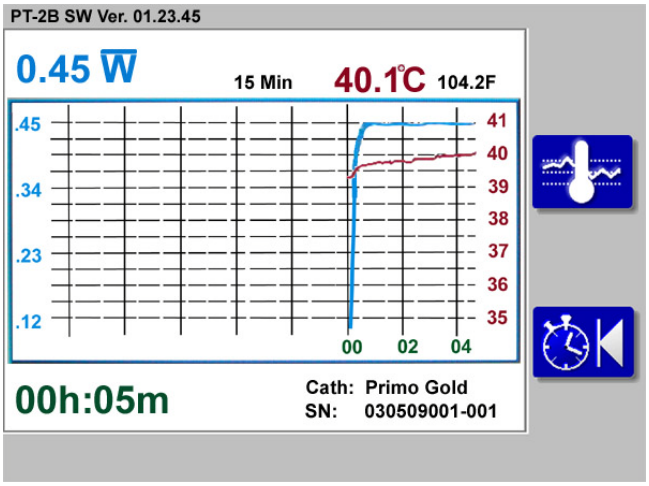


Figure 5: EkoSonic SV Control Unit display during initial delivery of therapy. This is the 15 minute Run Screen. Other run screens are available. See "Alternate Screen Selection."

Pressing the  button on the right side of the display screen will select one of several display screen modes. Ultrasound energy may be delivered in any of the selected screens. See "Alternate Screen Selection."

7. The EkoSonic SV Control Unit continuously monitors the temperature of the device with the thermocouple at the distal tip. If the temperature of the thermocouple begins to approach the preset maximum temperature (43°C), the system will automatically reduce output power to prevent the device from exceeding the maximum temperature.

8. The average power graph is updated every 30 seconds. Power data is displayed in blue with the power scale values on the left side of the graph. Pressing the yellow Stop button  will stop ultrasound transmission and place a pause indicator on the screen at the point where ultrasound was stopped.

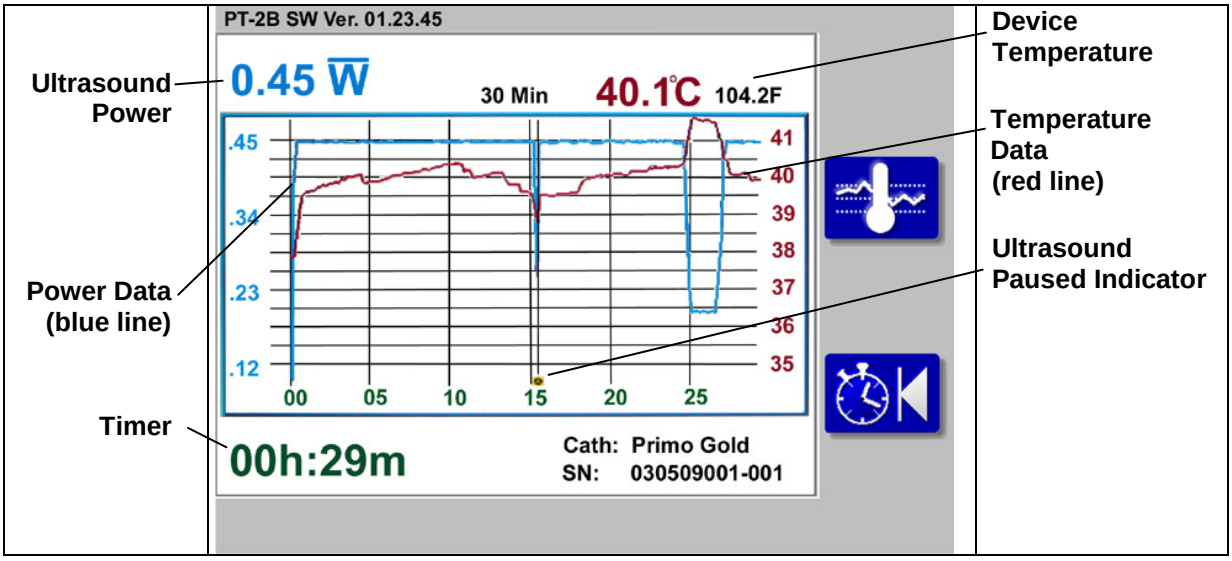


Figure 6: This screen demonstrates an average power decrease in response to increased temperature. Also in this example, an interruption in therapy occurred at 15 minutes and was recorded on the timeline as a yellow stop symbol.

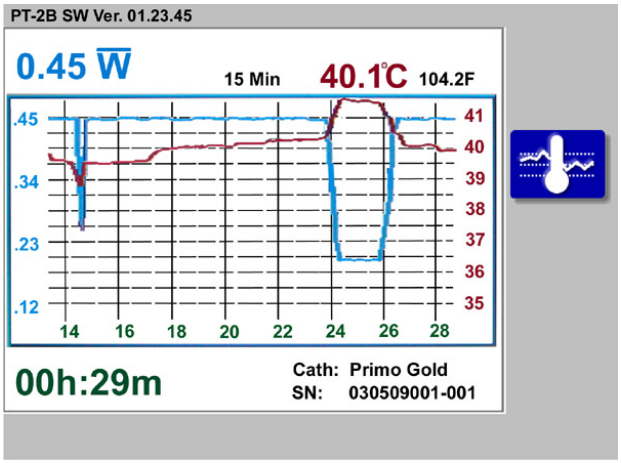
9. Upon completion of the therapy, press the **Stop** button  to stop ultrasound transmission.
10. Discontinue the infusion into the device.

    Note: Control of the infusion pumps is independent of the EkoSonic SV Control Unit.
11. Disconnect the device from the Connector Interface Cable (CIC).
12. Remove the device from the patient using standard angiographic procedures, observing the removal under fluoroscopy.
13. Turn the EkoSonic SV Control Unit off using the power on/off switch located on the rear panel near the power plug connection.

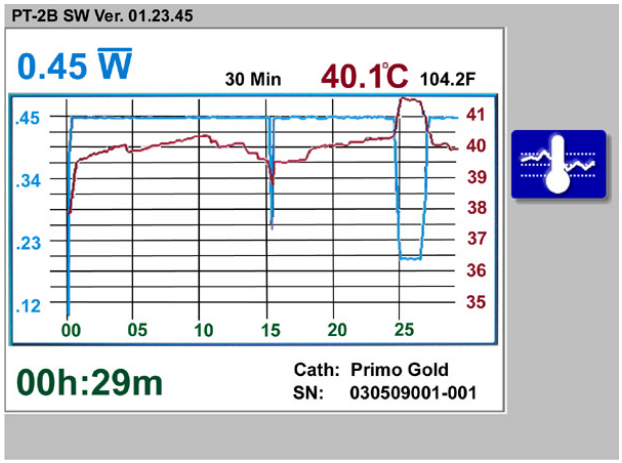
    Note: When power is turned off the EkoSonic SV Control Unit will lose the power and therapy duration information that is displayed on the screen.

Alternate Screen Selection

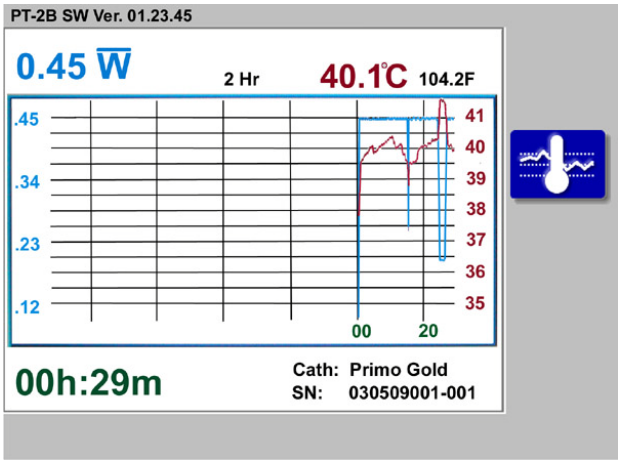
Pressing the  button, located on the right side of the display screen will change the display screen from the default 15 minute graph to a 30 minute graph. A second push will display a two hour graph. Pressing the button again returns the display to the original system schematic. Subsequent pushes repeat the cycle beginning with the 15 minute graph. As seen in Figure 7a, if enough time has elapsed only the most recent 15, 30 or 120 minutes will be displayed.



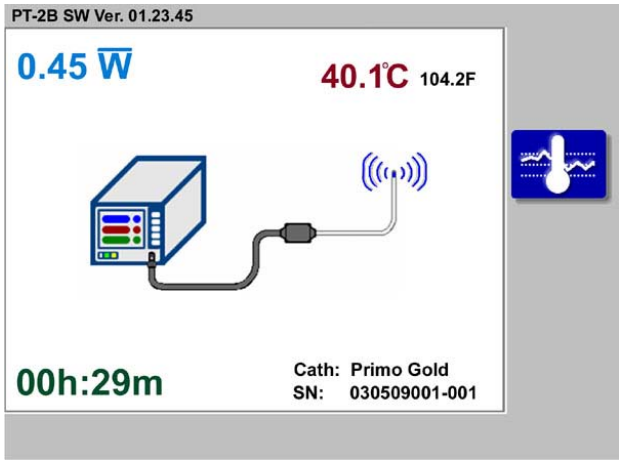
a) 15 minute display graph



b) 30 minute display graph



c) 2 hour display graph



d) Schematic screen

Figure 7. The four alternate screens

Timer Reset

When therapy is stopped, the timer may be reset to zero by pressing the Timer Reset button. When the timer reset button is pressed, a cancel option appears at the lowest button. If the user presses the cancel button, the therapy timer will remain unchanged. If the user presses the timer reset button a second time the therapy timer will be reset to zero. Figure 8 shows the Control Unit waiting for the user to either confirm or cancel the therapy timer reset.

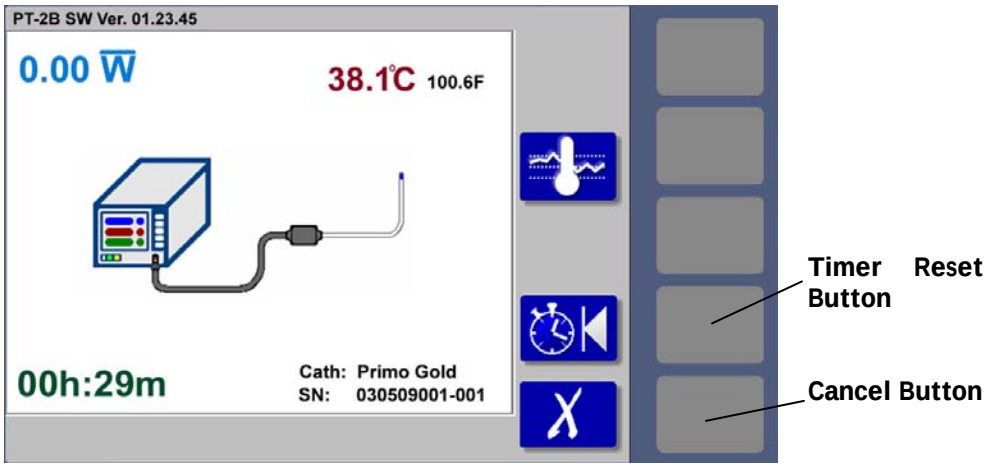
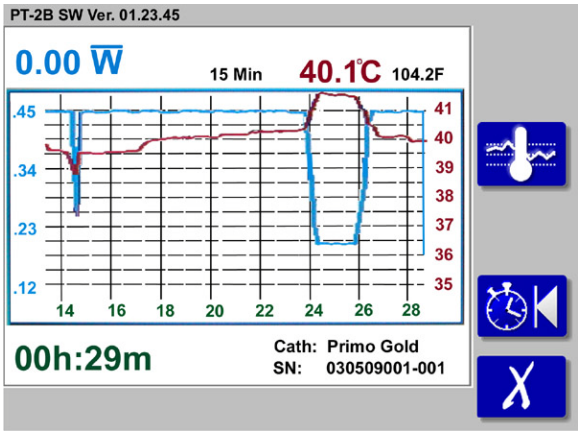


Figure 8: Showing the Control Unit waiting for the user to either confirm or cancel the therapy timer reset.



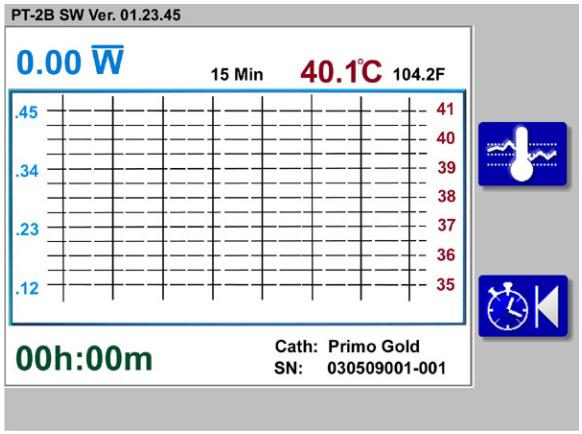
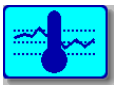


Figure 9a and 9b: Showing a 15 minute run screen before and after the therapy timer reset.

System Status Icons and Indicators:

During normal operation of the EkoSonic SV Control Unit, various icons and indicators may be displayed on the screen. Table 1 lists button icons with a brief description and the expected user action.

Table 1 Button indications for the EkoSonic SV Control Unit

Normal	Activated	
		**Screen Selector** Located on the right side of the display. Pressing the button next to the icon will change the screen.
		**Timer Reset** Located on the right side of the Ready Screen. Pressing the button next to this icon brings up the Cancel icon below. The user can then either push the button again to re-set the elapsed time to zero or press the cancel button to retain the elapsed time information.
		**Cancel** This appears on the right side of the display if the Timer Reset button has been pressed. Pressing the button next to this icon cancels the Timer Reset activity.

The icon described in Table 2 may be displayed by the EkoSonic SV Control Unit during normal operation. This status icon does not require a user response.

Table 2: Normal running System Status Icons

	**Device Calibration in Progress** The temperature measurement channel is being re-calibrated. Ultrasound output is reduced during re-calibration. This occurs at regular intervals.

Trouble Shooting

1. System Schematic Indicators

When connecting the MicroSonic SV Endovascular Device and CIC, the Control Unit will indicate which devices are connected and which devices are not detected or appear to be non-functional. The Control Unit indicates this connection status by placing red ellipses or a red 'X' over various parts of the schematic. Figure 10 shows the control unit indicating that either the CIC is not connected or the device is not connected.

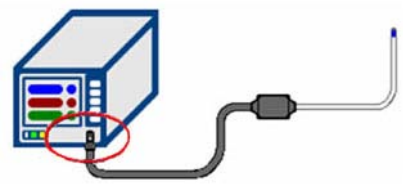


Figure 10A

Indication: **CIC not connected.**

User Response: **Connect CIC to the Control Unit.**

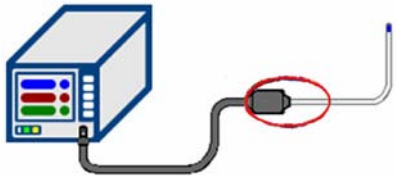


Figure 10B

Indication: **Device not connected.**

User Response: **Connect device to the CIC.**

Figure 10: Status indications using the System Schematic and suggested user responses.

2. Temperature Indicators

During operation, the temperature of the device tip is monitored by a thermocouple. If the device is not positioned inside the patient but is at room temperature (< 32° C) the control unit will display a small blue thermometer icon below the schematic. See Figure 11A. If the thermocouple in the device tip reads less than 32°C, the control unit will not allow ultrasound therapy to begin. Once the device is placed inside the vasculature of the patient, the control unit will indicate that the device is at proper operating temperature by removing the blue thermometer icon and then allowing ultrasound therapy to start.

If the control unit senses the thermocouple at a temperature above the maximum temperature of 43°C before therapy is started, it will indicate this by displaying a red thermometer icon below the schematic and will not allow ultrasound therapy to start. Figure 11B shows how this will appear on the screen.

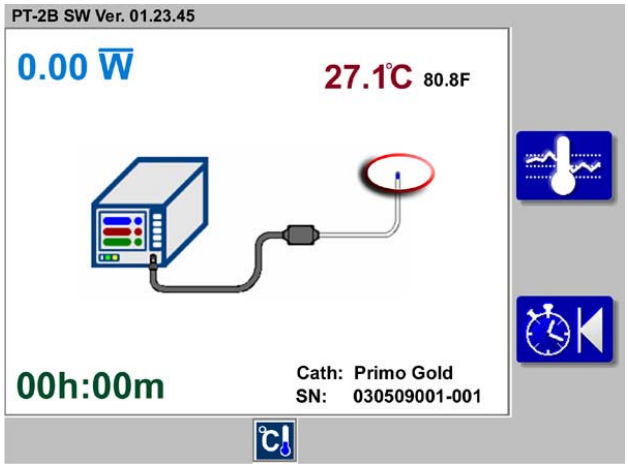


Figure 11A

Indication: **Ultrasound operation will not begin because the device thermocouple is less than 32°C.**

User Response: **Verify that the device is properly positioned and/or reduce the coolant in small increments**

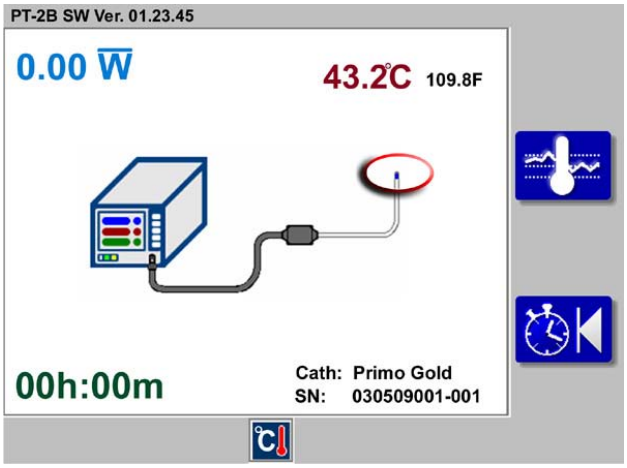


Figure 11B

Indication: **Ultrasound operation will not begin because the device thermocouple is more than 43°C.**

User Response: **Verify that the device is properly positioned and/or increase the coolant in small increments**

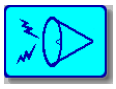
Figure 11: Examples of the Control Unit preventing the start of ultrasound operation because thermocouple readings are either too cold or too hot.

3. Interruption of Therapy

If a condition occurs that interrupts therapy and the Control Unit returns to the Ready Screen, the alarm will beep and an Alarm icon will appear on the right side  of the display.

A red indicator will light on the lower center of the front panel between the  and  symbols.
The alarm will beep repeatedly until silenced by pressing the button to the right of the alarm icon. Correcting the condition that caused the alarm also will silence the alarm.
The Control Unit may indicate with a 'O' or an 'X' on the system schematic where the user should check to correct the condition. Additionally, during an alarm condition, any of the indicators in Table 3 may be displayed to indicate to the user why the therapy was interrupted.

Table 3: Alarm Code Icons

Normal	Activated	
		**Alarm** When the alarm is heard, this symbol appears on the right side of the display next to a button. Pressing the button will silence the alarm.

4. Incorrect Information Indicators

If the Control Unit can not read correct data from the device or CIC, it will display one of the symbols shown in Figure 12. If this screen appears, the user should disconnect the device and then reconnect it to be sure that the connection is properly seated. If the Control Unit still can not read the data correctly, exchange the device or CIC for another device.

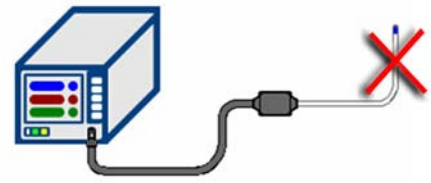


Figure 12A
Indication: Device not functional.
User Response: Replace the device and contact EKOS.

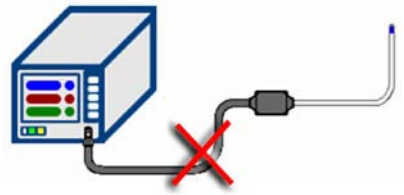


Figure 12B
Indication: CIC not functional
User Response: Replace the CIC and contact EKOS.

Figure 12: Status indications showing defective equipment and suggested user responses

5. Alarm Code Icons:

If an alarm condition occurs during operation of the Control Unit, an icon may be displayed along the bottom of the screen suggesting the cause of the alarm. Figure 13 is an example where the device has exceeded the temperature limit. The Control Unit has sounded the alarm, turned off all ultrasound power, switched to the schematic to indicate excessive temperature and is displaying the alarm code icon for "Device Temperature Too High".

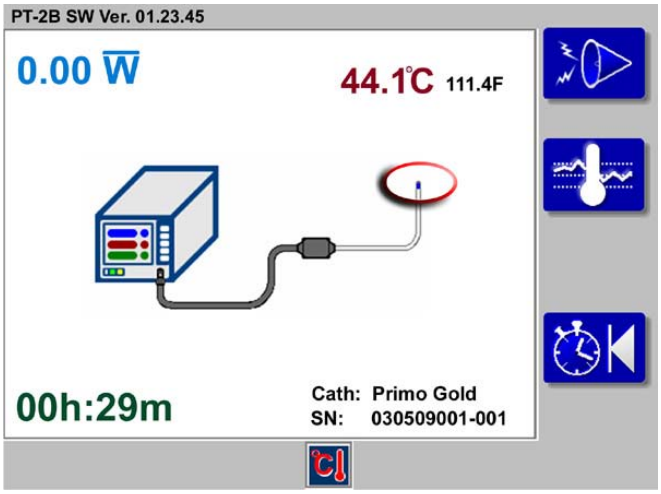


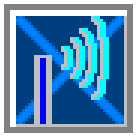
Figure 13: Example of alarm code icon showing that the device temperature has exceeded the limit and the Control Unit has shut off ultrasound power.

Each alarm code icon is listed in Table 4 below with a brief description of what it means, and a suggestion for the possible cause and user response.

Table 4: Alarm Code Icons

CIC	**Defective Connector Interface Cable (CIC)**	
	Either the CIC is not connected securely or it is defective.	(1) Check that the cable connection is properly seated. (2) Turn the power off and back on. (3) Replace the CIC if available. (4) Call EKOS®
CATH	**Defective Device**	
	Either the Device is not connected securely or it is defective.	(1) Check that the cable connection is properly seated. (2) Turn the power off and back on. (3) Replace the device if available. (4) Call EKOS®
℃	**Invalid Device Temperature**	
	Either the Device is not connected securely or it is defective.	(1) Check that the cable connection is properly seated. (2) Turn the power off and back on. (3) Replace the device if available. (4) Call EKOS®
℃	**Device Temperature Too High**	
	The Control Unit is preventing ultrasound output because the device temperature is too high.	(1) Cancel The Alarm. (2) Check that excessive temperature is no longer indicated. (3) Increase coolant flow in 10ml increments. (4) Re-start ultrasound output.

Table 4 (continued): Alarm Code Icons

	**Device Temperature Too Low**	
	The device tip temperature is less than 32ºC. The Control Unit assumes the device is not placed in the patient.	(1) Check for placement of the device in the patient. (2) Briefly turn off flow in the introducer sheath. (3) Replace the CIC if available (4) Replace the Control Unit if available. (5) Call EKOS®
	**Hardware Thermal Shutoff**	
	The Control Unit has turned off ultrasound output and returned to the Ready Screen because it has detected an invalid temperature (broken thermocouple) or an excessive instantaneous temperature in the device.	(1) Cancel the alarm. (2) Check connections (3) Re-start ultrasound output. (4) Replace the device.
	**Excessive Pulse Power**	
	The Control Unit has turned off ultrasound output and returned to the Ready Screen because it has detected an excessive instantaneous pulse power output in the device.	(1) Cancel the alarm. (2) Check connections. (3) Re-start ultrasound output. (4) Replace the device.
	**Excessive Average Power**	
	The Control Unit has turned off ultrasound output and returned to the Ready Screen because it has detected an excessive instantaneous average power output in the device.	(1) Cancel the alarm. (2) Check connections. (3) Re-start ultrasound output. (4) Replace the device.
	**Excessive Phase**	
	The Control Unit has turned off ultrasound output and returned to the Ready Screen because the device is operating outside established limits. The ultrasound transducer element may be damaged or the connections may be intermittent.	(1) Check the device connections and restart ultrasound output. (2) Replace the CIC if available. (3) Replace the device.
	**Bad power output**	
	The Control Unit has turned off ultrasound output and returned to the Ready Screen because the device could not be driven within parameters of operation. The ultrasound transducer element may be damaged or the connections may be intermittent.	(1) Check the device connections and restart ultrasound output. (2) Replace the CIC if available. (3) Replace the device.

6. Idle Screen Indicators:

If the Control Unit is not successful in performing the initial self-test or detects a condition preventing proper performance, an "Idle Screen" will be displayed. An Idle Screen may be displayed any time during operation if a triggering condition is detected. Idle screens are accompanied by a double-beeping alarm which can only be silenced by turning the power to the Control Unit off. Figure 18 shows an example of an Idle Screen.

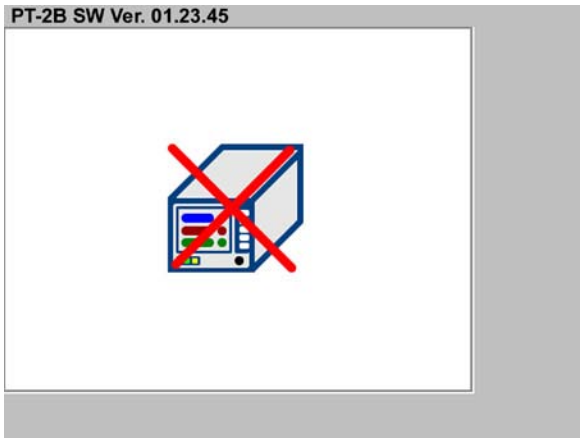
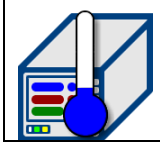


Figure 14: Typical Idle Screen

Potential Idle Screen icons are shown in Table 4. Each icon is listed with a brief description of what it means and a suggestion for the possible cause and user response.

Table 5: Idle Screen Icons

Icon	Possible Cause	User Action
	**Control Unit Failure**	
	The Control Unit has detected a hardware malfunction.	Turn the power off and back on. If this icon reappears, do not attempt to use the Control Unit. Contact EKOS® Corporation for assistance.
	**Control Unit temperature too high**	
	The Control Unit is warmer than its specified operating temperature.	Check to ensure the cooling air intake under the unit or air exhaust at the back of the unit are not blocked. Turn the unit off and allow it to cool down. When the unit cools down, turn the unit back on.
	**Control Unit temperature too low**	
	The Control Unit is colder than its specified operating temperature.	Turn the unit off and let it adjust to room temperature. When the unit has warmed up, turn the power back on.

7. Additional Trouble Shooting

If error conditions prevent or stop ultrasound, momentarily disconnect the device and CIC and then reconnect them. Be sure that all connectors are properly and completely seated. Restart ultrasound by pressing the green START button,

If a condition is persistent and will not allow the delivery of ultrasound energy even after all troubleshooting attempts, infusion may be performed without ultrasound. Contact EKOS® at telephone **1-425-415-3100** or toll free (in the U.S.) at **1-888-356-7435.**

Preventive Maintenance

Cleaning

The EkoSonic SV Control Unit should be cleaned after each use. Clean the Control Unit and Connector Interface Cable (CIC) by wiping with a soft cloth moistened with either distilled water, mild soap solution, isopropyl alcohol, or disinfectant. When cleaning the unit, follow these guidelines.

- Unplug the system before cleaning.
- Do not spill or spray any fluid on any part of the system.
- Do not submerse the unit in any fluid.
- Do not use excessive amounts of fluid.
- Do not sterilize the EkoSonic SV Control Unit or CIC.
- After cleaning the system components, be sure to dry them with a soft cloth to remove any cleaning residues.

Filter Cleaning

The air intake filter located on the bottom of the EkoSonic SV Control Unit should be cleaned every six months. To clean the filter, remove the four screws that hold the filter cover in place. Remove the filter cover and clean with a soft cloth moistened with either distilled water, mild soap solution, isopropyl alcohol, or disinfectant. Remove the filter and wash in water using a mild soap. Allow the filter to dry before replacing.

If the filter is damaged or is unable to be easily cleaned, new replacement filters may be purchased from EKOS® Corporation. Only use approved filter material with the EkoSonic SV Control Unit.

After cleaning, replace the filter over the air intake vents on the bottom of the EkoSonic SV Control Unit. Replace the filter cover over the filter and attach in place with four screws.

System Specifications

Models	EKOS® EkoSonic SV™ System consisting of: (A) EkoSonic SV™ Control Unit (1) Power cable (1) Connector Interface Cable (B) MicroSonic SV™ Endovascular Device
Classification	Complies with IEC 601-1 with Amendments 1&2, C22.2 No. 601.1-M90, with exception of Clause #42, (maximum temperature specification) Class I, Grounded Equipment Type CF Patient Applied Parts, Defibrillation proof Mode of Operation – Continuous, with automatic shut-off features EkoSonic SV Control Unit water ingress rating: IPX1
Ultrasound Transducer Composition	PZT (Lead Zirconate Titanate)
Maximum Device Temperature Limit	43°C
Power Requirements	100 – 240V, 50/60Hz, 1.6A maximum

Environmental Conditions:

Storage Temperature	-20°C to +60°C
Operating Temperature	+15°C to +40°C
Humidity	30% to 75%, non-condensing
Operating Atmospheric Pressure	73 kPa – 111 kPa

Ordering Information:

Product	Catalog Number
EkoSonic SV Control Unit	600-10202
EkoSonic SV Replacement Filter	700-20201
EkoSonic SV CIC	700-10203
Power Cord (North American)	700-51101

Symbols and Indicators

This section lists all symbols and icons appearing on the Control Unit and CIC. Some of these symbols may have already been described in the Normal Operation and in Troubleshooting. Refer to those sections for detailed description of those symbols.

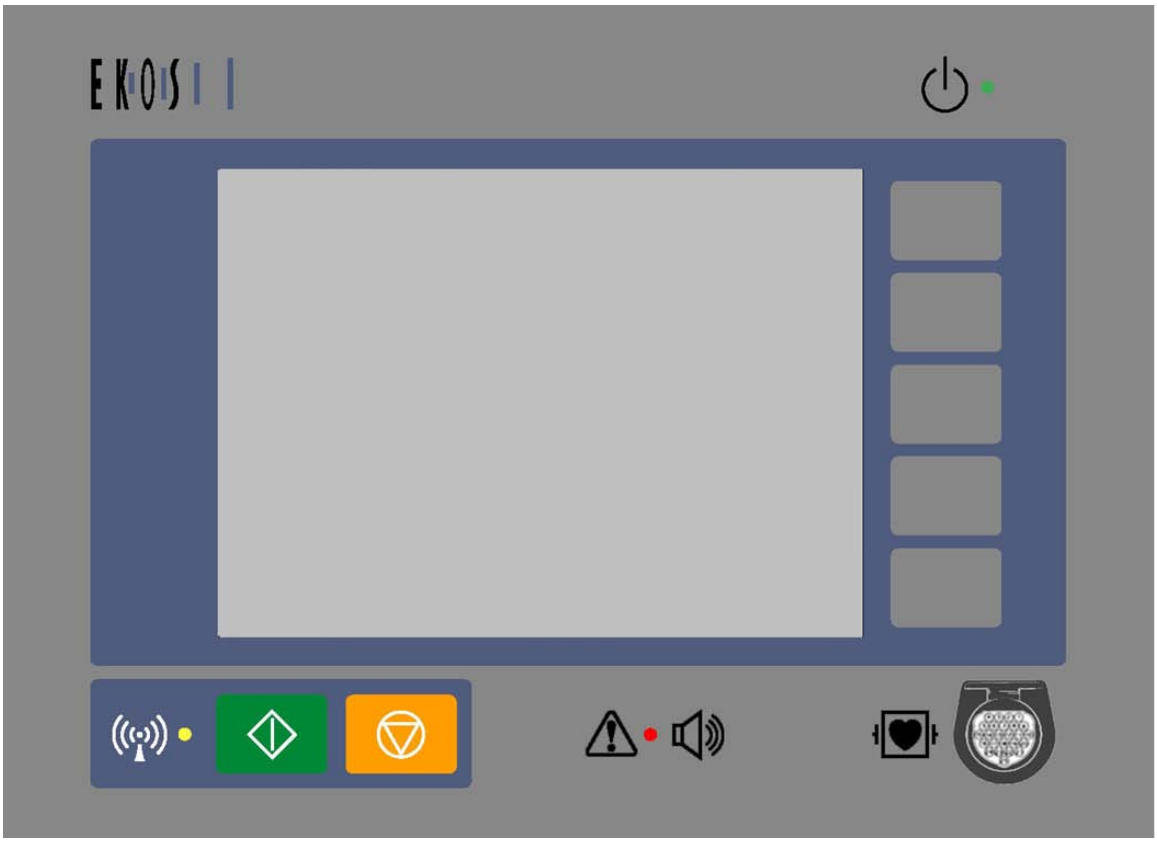


Figure 15. Front Panel of EkoSonic SV Control Unit

1. Front Panel Symbols: Table 6

These symbols are permanently displayed on the front panel of the Control Unit.

	**Power Indicator:** The green light next to this symbol on the upper right corner of the front panel illuminates when power has been applied to the Control Unit.
	**Attention Symbol/Indicator Light:** Read the accompanying documentation before operating this equipment. A red light next to this symbol in the lower front of the console indicates a system failure or malfunction.
	**Audible Alarm Symbol:** This symbol is in the center of the lower part of the front panel.
	**Start Symbol:** It has a green background and appears on the lower left of the front panel. This symbol identifies the Start button. Press this button to begin therapy.

	**Stop Symbol:** This has an orange background and appears on the lower center of the front panel. This symbol identifies the Stop button. Press this button to halt therapy.
	**Ultrasound Indicator Light:** This symbol has a blue background and appears on the lower left of the front panel. The yellow light next to this symbol blinks when ultrasound therapy is being delivered to the patient. The symbol stands for Non-Ionizing Radiation.
	**Symbol for Defibrillator - Proof CF Equipment:** This equipment provides a degree of protection against electrical shock to Type CF as defined in IEC 601-1. This equipment has F type applied part capable of withstanding the effects of defibrillator discharge, and the C designation implies it meets the leakage requirements for cardiac intervention.

Table 6 (continued): Front Panel symbols

2. Other Symbols Appearing on the System: **Table 7**

These symbols are also permanently displayed on of the Control Unit or on the CIC.

I O	**Power On/Off Switch:** This toggle switch located on the rear of the Control Unit turns the power On (I) and Off (O). When the switch is in the "On" position, a green light will illuminate in the upper right corner on the front of the unit.
	**Symbol for Electro-static Discharge (ESD) sensitive equipment:** This equipment is resistant to ESD as required by IEC 601-1-2. However, parts marked with this symbol could be damaged by direct application of electrical discharge.
IPX1	**Ingress Protection Rating:** This equipment is protected against dripping liquids as required by IEC 601-1.
	**Manufactured on:** This equipment was manufactured during the listed year.
	**Protective Earth:** The terminal marked with this symbol is the protective earth connection for the EkoSonic SV Control Unit. This label is inside the unit. It is not visibly marked on the outside.

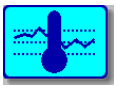
3. System Status Icons: Table 8

These symbols may appear on the Control Unit's display during normal operation.
Refer to the Operation section for more detailed discussion of the meaning of each symbol.

	**Device Calibration in Progress** The temperature measurement channel is being re-calibrated.
	**Ultrasound Paused Indicator** Displayed on the history graph when ultrasound power has been stopped by the user.
	**Ultrasound Stopped Due to Error Indicator** Displayed on the history graph when ultrasound power has been stopped due to an error condition.

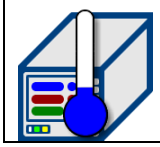
4. Button Indicators: Table 9

These button labels may appear on the Control Unit's display during normal operation.
Refer to the Operation section for more detailed discussion.

Normal	Activated	
		**Screen Selector** Pressing the button next to the icon will change the screen.
		**Timer Reset** Pressing the button brings up the Cancel icon below. Press the button again to re-set elapsed time to zero or press the cancel button to retain the elapsed time information.
		**Cancel** Press the button next to this icon to cancel the Timer Reset activity.

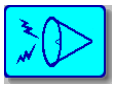
5. Idle Screen Symbols: Table 10

One of these symbols will be displayed if the Control Unit if it detects a condition which prevents normal operation. Refer to the Troubleshooting section for more detailed discussion.

Icon	Possible Cause	User Action
	**Control Unit Failure**	
	The Control Unit has detected a hardware malfunction.	Turn the power off and back on. If this icon reappears, do not attempt to use the Control Unit. Contact EKOS® Corporation for assistance.
	**Control Unit temperature too high**	
	The Control Unit is warmer than its specified operating temperature.	Check to ensure the cooling air intake under the unit or air exhaust at the back of the unit are not blocked. Turn the unit off and allow it to cool down. When the unit cools down, turn the unit back on.
	**Control Unit temperature too low**	
	The Control Unit is colder than its specified operating temperature.	Turn the unit off and let it adjust to room temperature. When the unit has warmed up, turn the power back on.

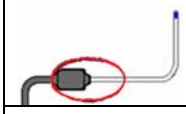
6. Alarm Indicator: Table 11

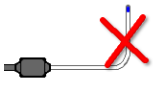
An alarm will sound and this button label will appear on the Control Unit's display if an event occurs that prevents delivery of ultrasound energy. Refer to the Troubleshooting section for more detailed discussion.

Normal	Activated	
		**Alarm** This appears when the audible alarm is active Press the button to silence the alarm.

7. System Status Icons: Table 12

These symbols may appear on the Control Unit's display associated with an alarm. Refer to the Troubleshooting section for more detailed discussion of the meaning of each symbol and how to resolve the alarm condition.

	**Device Not Detected** This may indicate a loose connector.
	**CIC Not Detected** This may indicate a loose connector.
	**Device Temperature Too Low** The device tip temperature is less than 32ºC. The Control Unit assumes the device is not placed in the patient.
	**Device Temperature Too High** The Control Unit has turned off ultrasound output because it has detected excessive temperature for more than 15-seconds.

	**Hardware Thermal Shutoff** The Control Unit has turned off ultrasound output because it has detected a broken thermocouple or an excessive instantaneous temperature.
	**Control Unit does not detect valid device information.** This is displayed when any of the device's information is corrupt or incorrect.
	**Control Unit does not detect valid CIC information.** This is displayed when any of the CIC's information is corrupt or incorrect.
	**Defective CIC** The CIC is either not connected or is defective.

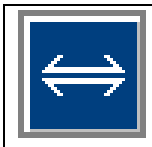
	**Excessive Pulse Power** The Control Unit has turned off ultrasound output because it has detected excessive instantaneous pulse power output.
	**Excessive Average Power** The Control Unit has turned off ultrasound output because it has detected excessive instantaneous average power output.

Table 12 (continued): System Status Icons

8. Control Unit Service Symbols: Table 13

These symbols only appear when EKOS authorized personnel are accessing the communication port to gather case histories or to install new software. Disconnect the cable from the port before attempting to start ultrasound energy.

The communication port is <u>not</u> for clinical use. It is for use under the direction of EKOS® authorized personnel only.

	**External Application is Communicating with Control Unit** A computer is connected to the Control Unit and is running external application software.
	**Control Unit has Lost Communication with an External Application** The Control Unit has unexpectedly lost communication with a computer running external application software.
	**Data Transfer in progress with External Application** The external computer is transferring data through the communication port. Wait until the transfer is complete before disconnecting the cable from the port.

System Component Interconnection

Connect the components as illustrated in Figure 16 and Figure 17.

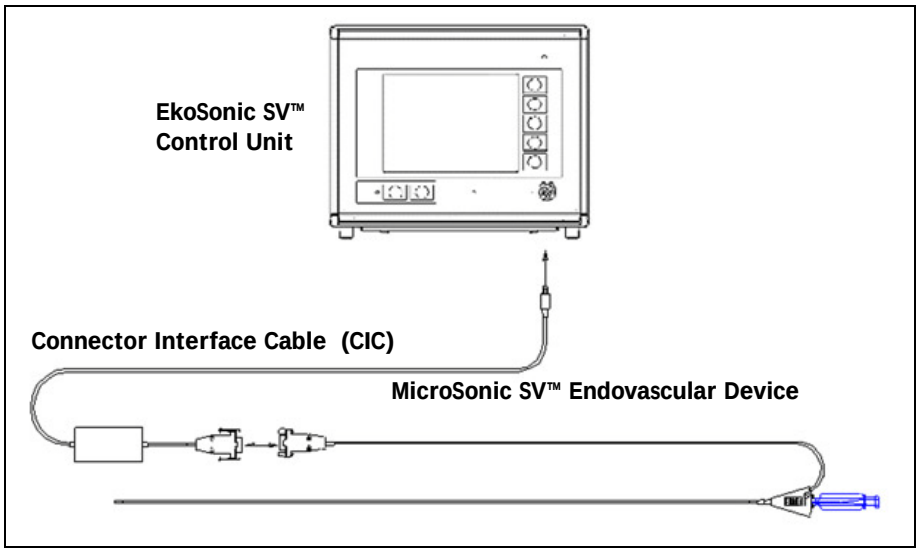


Figure 16. CIC Connection to the Front Panel.
MicroSonic SV Endovascular Device Connection to the CIC.

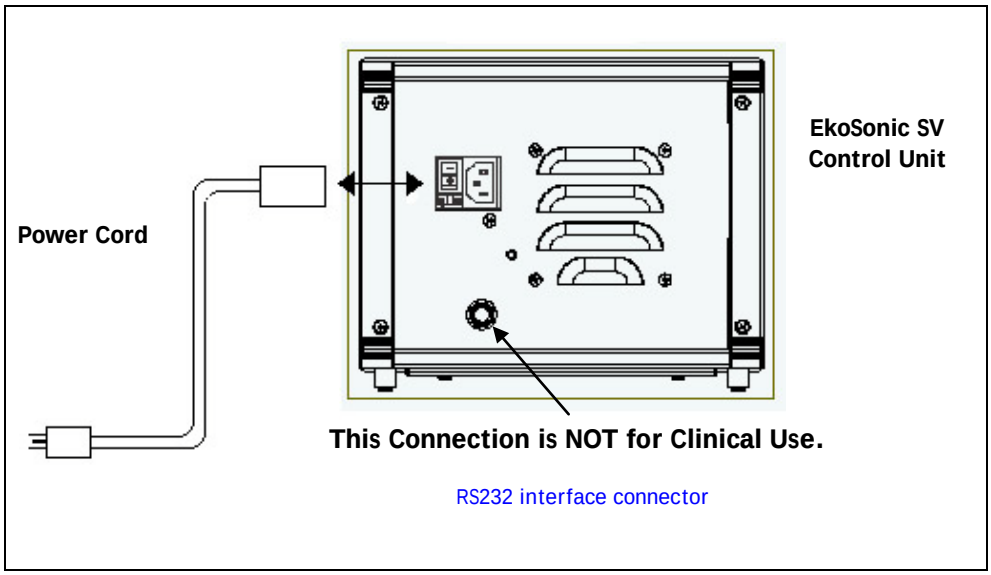


Figure 17. EkoSonic SV Control Unit Rear Panel Interconnection Diagram

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Part number: 5397-003 REV G
Revision date: 03/2009

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Appendix Overleaf