



EkoSonic[®] Control Unit

Instructions for Use

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

Intended Use

The EKOS[®] EkoSonic Control Unit is intended exclusively for use with the EkoSonic Endovascular Device and the EkoSonic MACH4 Endovascular Device.¹

Contraindications

- This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition.

Warnings

- Do not operate the EkoSonic Control Unit in the presence of flammable anesthetics.
- Do not remove EkoSonic Control Unit main covers. The only user serviceable part is the air filter, which is on the bottom of the unit. (Refer to Filter Replacement later in this document). There are no other user-serviceable parts. Only the manufacturer's qualified personnel should service the EkoSonic Control Unit.
- The EkoSonic Control Unit is intended for use with the EkoSonic Endovascular Device. Do not connect any other electronic devices to the EkoSonic Control Unit.
- Do not connect any cabling or external devices to the port on the back of the EkoSonic Control Unit during operation.
- Avoid placing liquids on or near the EkoSonic Control Unit such that spillage would contact system components or connectors.
- Do not use spray cleaners while the unit is operating.
- Connect system cables only to their proper connectors as marked. Assure that all connections are secure.
- Connect the EkoSonic Control Unit only to a properly grounded hospital-grade outlet or EKOS[®] provided battery, 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.
- Never transmit ultrasound energy by pushing the green Start Therapy button on the EkoSonic Control Unit with the EkoSonic Endovascular Device in the air.
- Never transmit ultrasound energy to the EkoSonic Endovascular Device unless it is placed within the patient anatomy, solution is running through the drug lumen and coolant is flowing through the coolant lumen. **ALWAYS TURN OFF THE ULTRASOUND BEFORE REMOVING THE MICROSONIC DEVICE FROM THE INTELLIGENT DRUG DELIVERY CATHETER.** Otherwise, overheating of the MicroSonic Device may occur, potentially causing damage to the MicroSonic Device and/or interrupting therapy. **IF A MICROSONIC DEVICE IS DAMAGED IN THIS MANNER AND THEN USED TO CONTINUE THERAPY, VASCULAR INJURY COULD OCCUR.**
- During normal use, ultrasound energy may cause a temperature rise in the treatment zone. There are temperature sensors in the EkoSonic Endovascular Device. The EkoSonic Control Unit monitors and controls the device temperature to limit the device temperature to a maximum of 43° C.
- Make sure that the EkoSonic 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.

¹ The EkoSonic MACH4 Endovascular Device and EkoSonic Endovascular Device are differentiated by the rapid pulse modulation software. For convenience and clarity in this Instructions for Use, both devices are referred to as the EkoSonic Endovascular Device.

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.
- 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 EkoSonic Endovascular Device.
- Use caution when moving the EkoSonic Control Unit so as not to pull the CIC and EkoSonic Endovascular Device.
- Avoid the contact of strong solvents and abrasive cleaners with control unit components.
- Store the EkoSonic 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 BS EN 60601-1-2:2002. These limits are designed to provide reasonable protection against harmful electromagnetic interference in a typical medical installation.

This equipment generates, uses and can radiate 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 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, solution 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 Control System generates ultrasonic energy waves at the treatment zone through the piezoelectric transduction of radio-frequency (RF) energy generated by the EkoSonic Control Unit. The ultrasound emanates radially from the treatment zone into and through blood, thrombus, or tissue surrounding the treatment zone, within the patient's vasculature. The ultrasound acts locally to increase the dispersion of the delivered solutions into the treatment region.

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

EkoSonic Control System Description

The EkoSonic Control System consists of two main components (see Figure 1):

- A single-use sterile EkoSonic Endovascular Device, consisting of an Intelligent Drug Delivery Catheter (IDDC) and a MicroSonic Device (MSD).
- A reusable EkoSonic Control Unit which provides the ultrasound energy source and the user interface. The EkoSonic Control Unit (or PT-3B) includes a Connector Interface Cable (CIC).

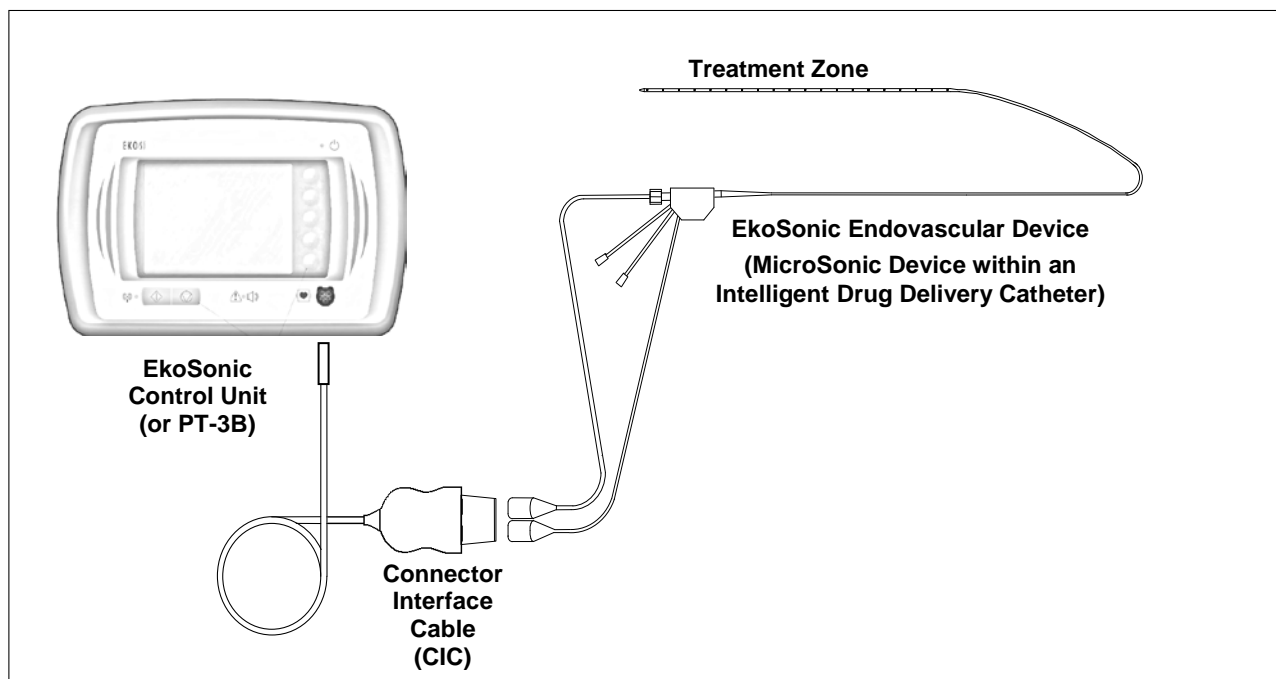


Figure 1. EkoSonic Control System

EkoSonic Endovascular Device Description

The EkoSonic Endovascular Device consists of two major components: an Intelligent Drug Delivery Catheter (IDDC) and a MicroSonic Device (MSD). The IDDC delivers the solutions to the treatment region while the coaxial MSD simultaneously delivers ultrasound energy along the treatment zone.

Both the IDDC and the MSD are connected to the CIC during operation. For further information, refer to the EkoSonic Endovascular Device Instructions for Use.

EkoSonic Control Unit Description

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

Directions for Use for the EkoSonic Control System

See the Instructions for Use for the EkoSonic Endovascular Device for preparation, placement and usage instructions.

1. Connect the Control Unit power cord to an appropriate outlet or ensure it is connected to the battery. Connect the round end of the Connector Interface Cable (CIC) to the front panel connector of the Control Unit.
2. Following selection, preparation and placement of the EkoSonic Endovascular Device, connect the IDDC and MSD electrical connectors to the appropriate connectors at the distal end of the CIC. Make sure the connectors are properly seated in the CIC. Push the MSD and IDDC electrical connectors into the CIC Clip to secure the electrical connectors in the CIC (see **Figure 2**).

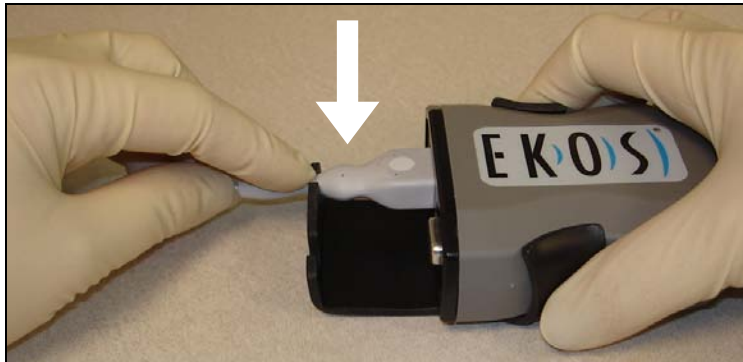


Figure 2. IDDC being secured into CIC Clip.

- **Warning:** 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 EkoSonic Endovascular Device.

Operation

Operation to Provide Therapy

1. If connected to the battery, turn the battery on using the power switch on the upper left of the battery front panel. 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 3 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 3. Initial EkoSonic Control Unit screens during self-testing.

- When the Control Unit successfully completes the self-test, the software will transition to the Schematic Screen. See Figure 4 for an example of the Schematic Screen.

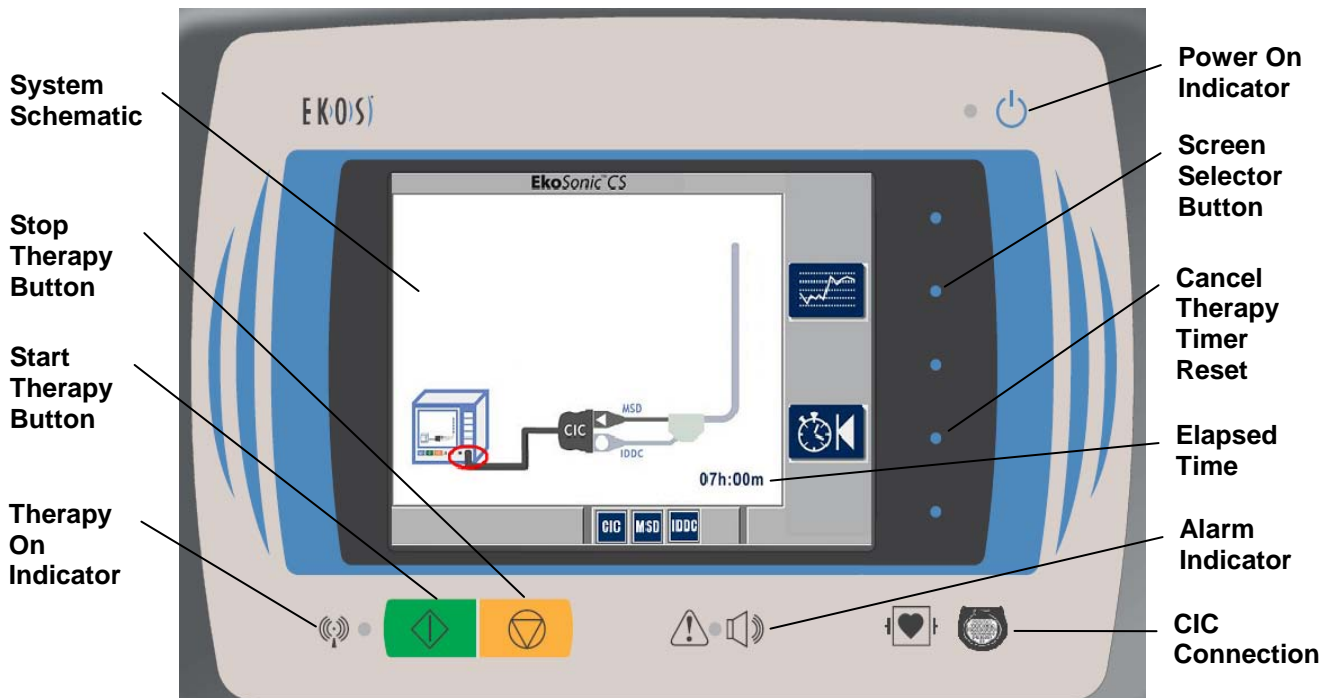


Figure 4. EkoSonic Control Unit in Schematic Screen

- Figure 4 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 Schematic Screen indicates where the CIC must be attached to the Control Unit. Ultrasound output will not be allowed unless the CIC, IDDC, and MSD are properly connected to the CIC. To help avoid un-intentional disconnects, insure that the MSD and IDDC are secured into the CIC Clip.

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 Schematic Screen. These icons and symbols are explained in the Troubleshooting section of this document.

- After attaching the CIC, IDDC, and MSD to the Control Unit, a screen similar to the screen shown in Figure 5 will be displayed.

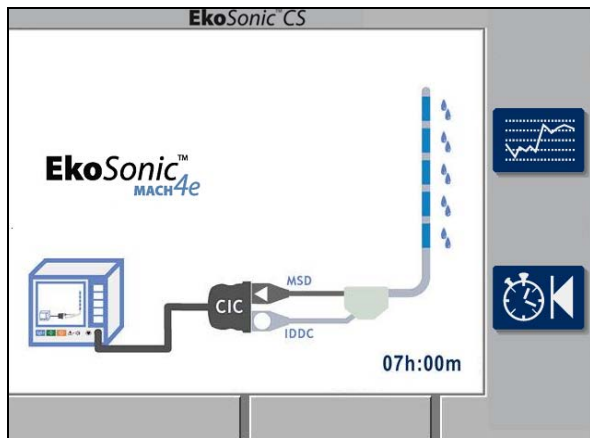


Figure 5a. 30cm IDDC and MSD attached

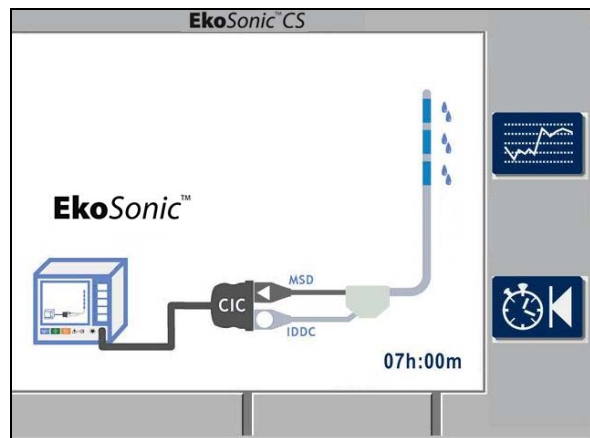


Figure 5b. 18cm IDDC and MSD attached



Figure 5. Typical Schematic Screens

- When the CIC, IDDC, and MSD have been connected and are functional, the EkoSonic icon will be displayed. The EkoSonic MACH4e icon indicates the system is using Rapid Pulse Modulation (RPM) ultrasound.

The number of transducer groups and the length of the drug delivery treatment area will vary depending on the particular IDDC and MSD attached to the Control Unit. **The length of the IDDC drug delivery treatment area is indicated on the screen by the water drops next to the groups in the MSD.**

Figure 5a is an example of the EkoSonic Endovascular System Schematic Screen displaying a MSD with 5 transducer groups and the corresponding drug delivery treatment area in the IDDC is 30 cm long thus giving a total treatment zone of 30 cm.

Figure 5b is an example of the EkoSonic Endovascular System Schematic Screen displaying a MSD with 3 transducer groups and the corresponding drug delivery treatment area in the IDDC is 18 cm long thus giving a total treatment zone of 18 cm.

- Before starting ultrasound transmission, be sure the IDDC and MSD are placed in the patient properly and begin infusion of solutions and coolant fluid through the IDDC infusion ports.
- Press the green Start Therapy button  to begin ultrasound transmission. The yellow light next to the Therapy On Indicator  will begin to flash. During therapy, the Schematic Screen indicates which groups are on at any time and if therapy is being delivered.

When the animated EKOS logo is displayed, the system is delivering therapy. At the bottom of the screen there is the display of the elapsed therapy time in hours and minutes. See Figure 6.

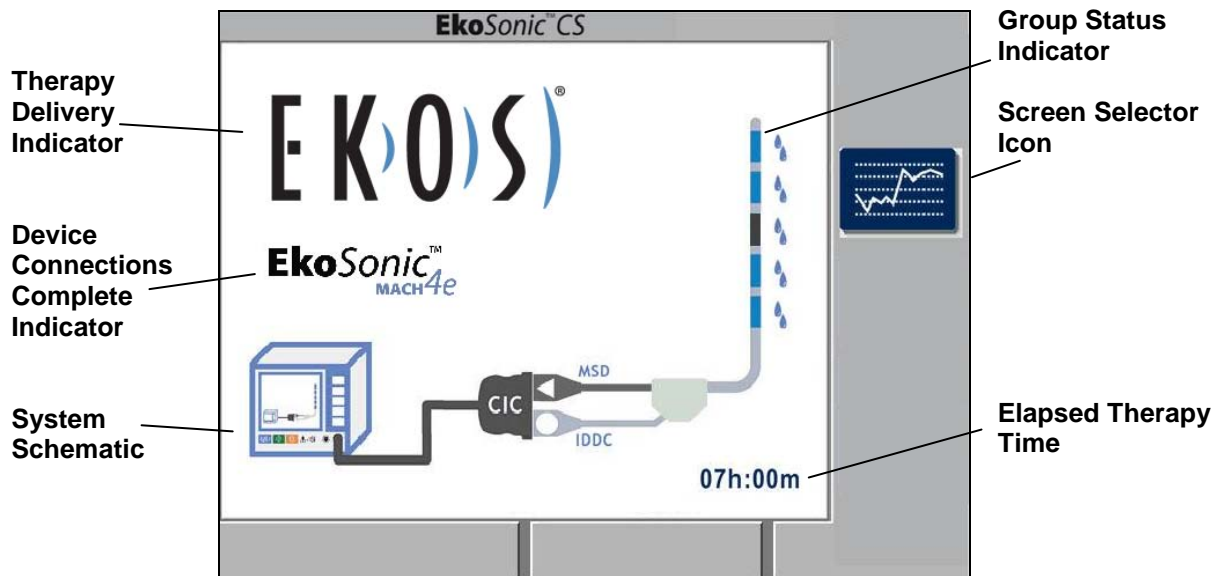
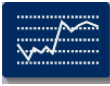



Figure 6. Typical Schematic Screen

Pressing the Screen Selector button next to the Screen Selector icon  will select one of several display screens. Ultrasound energy may be delivered in any of the selected screens. See “Alternate Screen Selection.”

- The Control Unit continuously monitors the temperature of each treatment zone with thermocouples in the IDDC at the distal end of each transducer group. If the temperature of any thermocouple begins to approach the preset maximum temperature (43°C), the system will automatically turn off the output power to the adjacent transducer groups to prevent the device from exceeding the maximum temperature.

- Upon completion of the therapy, press the **Stop** Therapy button  to stop ultrasound transmission.

Never transmit ultrasound energy to the EkoSonic Endovascular Device unless it is placed within the patient anatomy, solution is running through the drug lumen and coolant is flowing through the coolant lumen. **ALWAYS TURN OFF THE ULTRASOUND BEFORE REMOVING THE MICROSONIC DEVICE FROM THE INTELLIGENT DRUG DELIVERY CATHETER.** Otherwise, overheating of the MicroSonic Device may occur, potentially causing damage to the MicroSonic Device and/or interrupting therapy. **IF A MICROSONIC DEVICE IS DAMAGED IN THIS MANNER AND THEN USED TO CONTINUE THERAPY, VASCULAR INJURY COULD OCCUR.**

- Turn the 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 Control Unit will not retain the average power and therapy duration information that is displayed on the screen.


- Discontinue the infusion of all fluids into the IDDC.

Note: Control of the infusion pumps is independent of the EkoSonic Control Unit.

- Disconnect the IDDC and MSD from the CIC.


- Remove the IDDC and MSD from the patient using standard angiographic procedures, observing the removal under fluoroscopy.

Alternate Screen Selection

Pressing the Screen Selector button, located to the right of the Screen Selection icon  will change the screen from the default Schematic Screen to the History Graph Screen. See Figure 7.

The total average power as a percent of maximum group power (up to 100% max) is displayed below the graph. The elapsed time display indicates elapsed therapy time in hours and minutes.

Power data is displayed in blue with the power scale values on the right side of the graph.

Pressing the orange Stop Therapy button  will stop ultrasound transmission and place a yellow Pause Indicator (■) on the screen at the point where ultrasound was stopped.

Any auto-stop of therapy will place a red Auto-Stop Indicator (●) on the screen at the point where ultrasound was stopped.

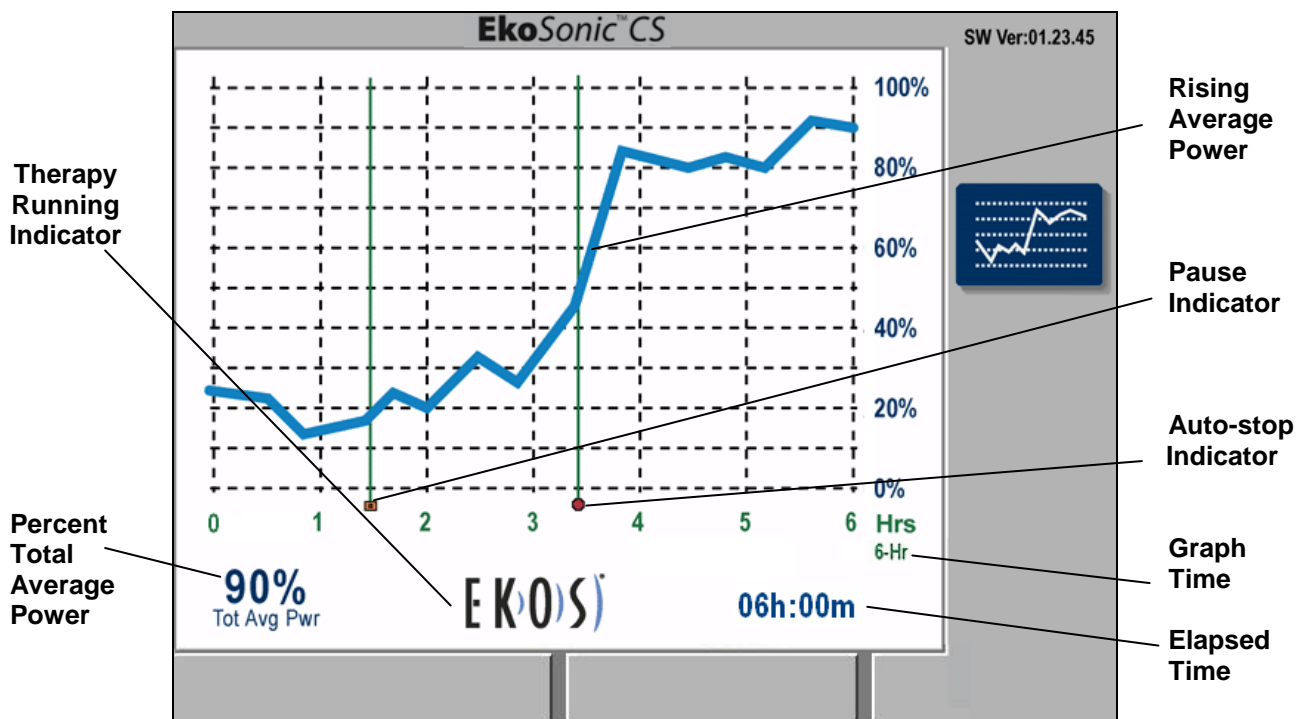


Figure 7. This example 6 Hour History Graph Screen demonstrates an average power increase over the course of treatment. Also in this example, a pause in therapy occurred at 2 1/2 hours when the user pressed the Stop Therapy button and was recorded on the timeline as a yellow Pause Indicator (■). In addition, an auto-stop in therapy occurred at 4 1/2 hours due to an alarm and was recorded on the timeline as a red Auto-Stop Indicator (●).

Based on the Elapsed Time, the History Graph Screen graph will auto scale and be shown on either a 6, 12, or 24 Hour graph. Reference Figure 8a and 8b for example 12 and 24 Hour History Graph Screens.

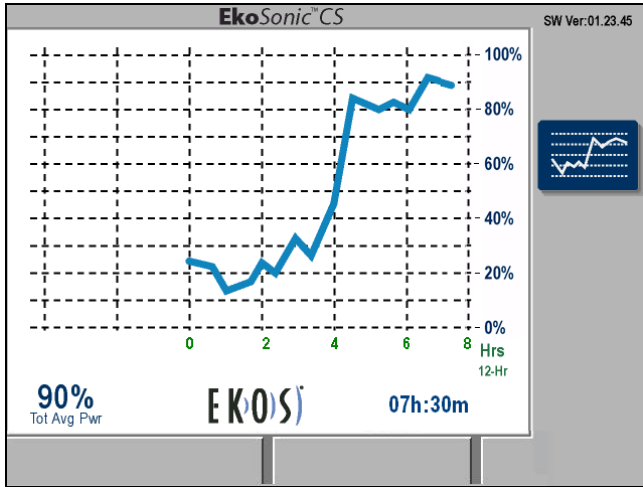


Figure 8a. Example 12 Hour History Graph Screen

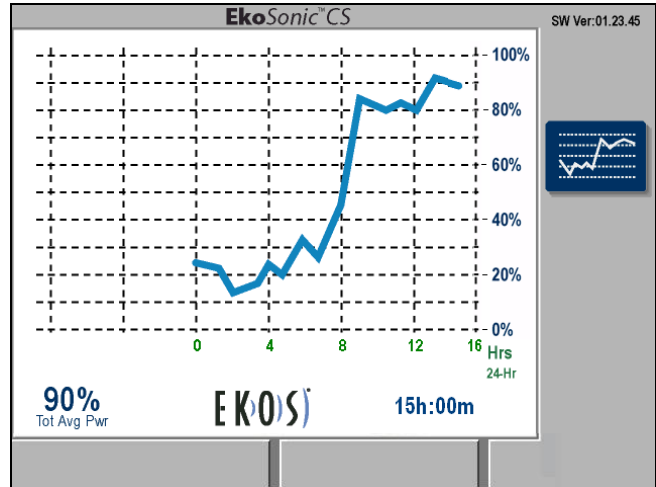




Figure 8b. Example 24 Hour History Graph Screen

Figure 8. Example 12 and 24 Hour History Graph Screens

Pressing the Screen Selector button again, located to the right of the Screen Selection icon  , returns the display to the Schematic Screen.

Timer Reset

When therapy has been stopped, the therapy timer may be reset to zero by pressing the Therapy Timer

Reset button next to the Therapy Timer Reset icon . When the Therapy Timer Reset button is pressed, a cancel option will be provided on the lowest button. If the user presses the Cancel Therapy Timer Reset button, the therapy timer will remain unchanged. If the user presses the Therapy Timer Reset button a second time the therapy timer will be reset to zero. Figure 9 shows the Control Unit waiting for the user to either confirm or cancel the therapy timer reset.

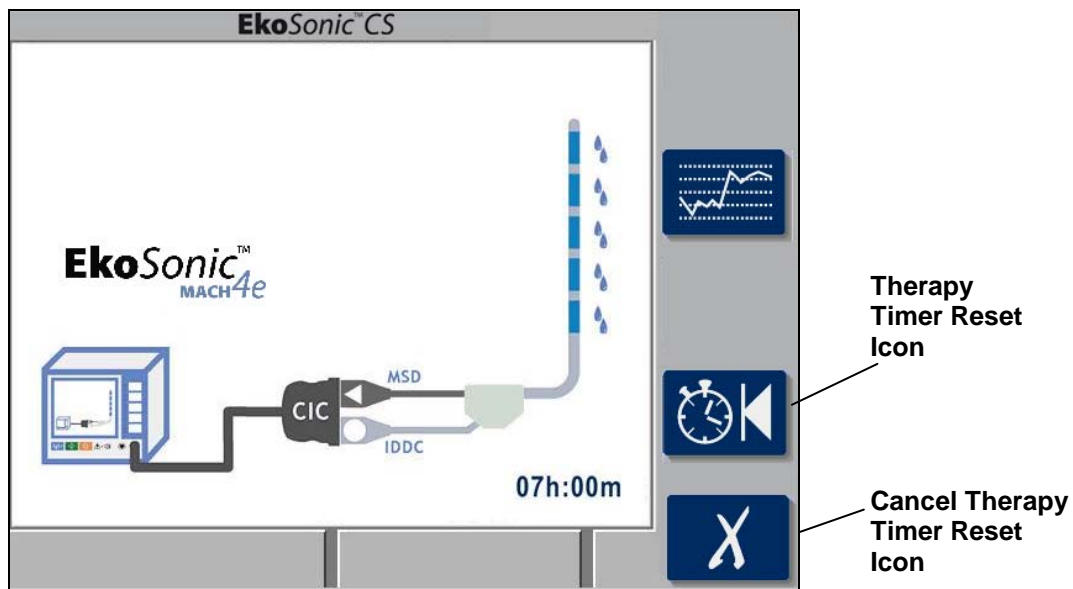
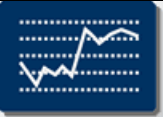







Figure 9. Schematic Screen showing the Control Unit waiting for the user to either confirm or cancel the therapy timer reset.

System Status Icons and Indicators:










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

Table 1. Button Icons for the EkoSonic Control Unit

Normal	Activated	Description
		Screen Selector Icon Located on the right side of the screen. Pressing the button next to the icon will change the screen.
		Therapy Timer Reset Icon Located on the right side of the 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 Therapy Timer Reset Icon This appears on the right side of the screen if the Therapy Timer Reset button has been pressed. Pressing the button next to this icon cancels the Therapy Timer Reset activity.

The icons listed in Table 2 may be displayed by the Control Unit during normal operation. Each icon is listed with a brief description. These status icons typically do not require a user action.

Table 2. Normal running System Status Icons

Icon	Description
	<p>Drug Delivery Section</p> <p>This symbol indicates a drug delivery section in the treatment zone.</p>
	<p>MSD Group Operational</p> <p>This indicates ultrasound power is being delivered to a specific group if therapy is running. If therapy is not running, this means that this group is capable of delivering therapy.</p>
	<p>MSD Group Not Present</p> <p>The indicated group is not considered present.</p>
	<p>MSD Group Disabled</p> <p>This indicates the specified group has been disabled. If therapy is running, no ultrasound power is being delivered to the group.</p>
	<p>Therapy is On</p> <p>This animated symbol on the Schematic Screen or any History Graph Screen indicates therapy is being delivered.</p>
	<p>Therapy Paused</p> <p>This is shown on a History Graph Screen to indicate that therapy was stopped by the operator.</p>
	<p>Therapy Auto-stop</p> <p>This is shown on a History Graph Screen to indicate that therapy was stopped due to an alarm condition.</p>
	<p>Device Connections Complete</p> <p>This icon is displayed when the CIC, MSD and IDDC are connected and functional.</p>
	<p>Device Connections Complete (RPM Capable)</p> <p>This icon is displayed when the CIC, MSD and IDDC are connected and functional and the system is using Rapid Pulse Modulation (RPM) ultrasound.</p>

Disabled Groups

The Control Unit will disable any MSD group in which it has detected a problem in the ultrasound elements or in the thermocouples. When this occurs, the group is shown in dark gray. Figure 10 shows the third group disabled because of a problematic ultrasound group in the MSD or the corresponding IDDC thermocouple is not functioning.

This example will not cause an alarm. Ultrasound power would continue to be delivered to the remaining MSD groups.



Figure 10. Example of MSD group 3 turned off

When a MSD group has been disabled, no power will be sent to that MSD group. The user may attempt to re-enable the disabled MSD group by stopping therapy, checking the connections, and then re-starting ultrasound output. If the Control Unit is still not able to drive a MSD group correctly or the IDDC thermocouple for the MSD group is detected as not functioning properly, the MSD group will again be disabled.

A MSD group that has been disabled because of a broken IDDC thermocouple cannot be restarted until the Control Unit detects that the thermocouple problem has been resolved. When a MSD group is disabled, the Control Unit will continue to drive the remaining enabled MSD groups.

Refer to Section 8 **Additional Trouble Shooting** on page 24 for more information.

Groups Present

The Control Unit will show as not present any group which does not have a thermocouple in the IDDC. Figure 11 shows the fourth and fifth groups not present because a) the connected MSD has more groups than the IDDC and b) the connected IDDC has more thermocouples than the MSD.

IDDC lengths of 6, 12, 18, 24 and 30 cm can be operated with MSD lengths of 6, 12, 18, 24 and 30 cm, however, only ultrasound groups that have a corresponding drug delivery section will operate.

MSD lengths of 40 and 50 cm will only operate with IDDC lengths of 40 and 50 cm respectively. If a 40 cm MSD is connected to the Control Unit with an IDDC of any length other than 40 cm, no groups in the MSD will be enabled for operation. Attempting to deliver ultrasound power in this condition will result in an alarm.

Refer to Section 8 **Additional Trouble Shooting** on page 24 for more information.

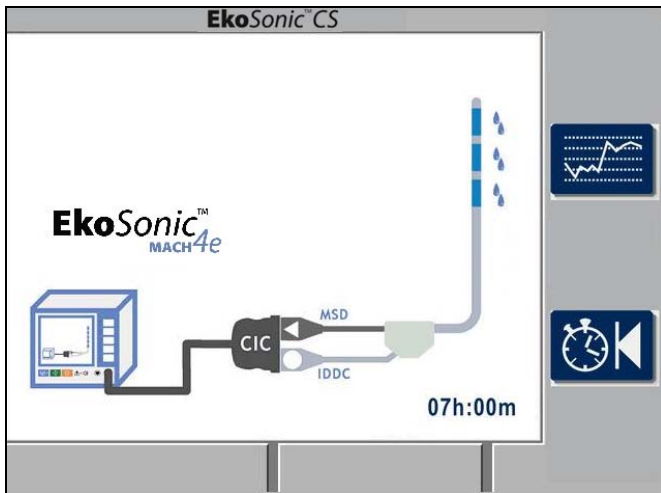


Figure 11a
Indication: Two groups not present because the MSD has 5 groups and the IDDC only has 3 thermocouples
User Action: OK to use three groups

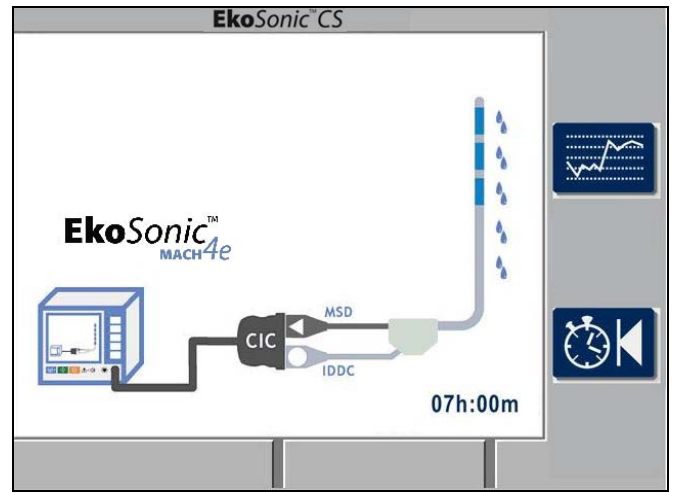


Figure 11b
Indication: Two groups not present because the IDDC has 5 thermocouples and the MSD only has 3 groups
User Action: OK to use three groups

Figure 11. Examples of groups 4 & 5 unused because the MSD is a different length than the IDDC.

Trouble Shooting

1. Schematic Screen Connection Indications:

When connecting the CIC, IDDC and MSD, 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 red 'X's over various parts of the schematic. Figure 12 lists the indications and their meanings and what the user should do when these indications are shown on the screen.

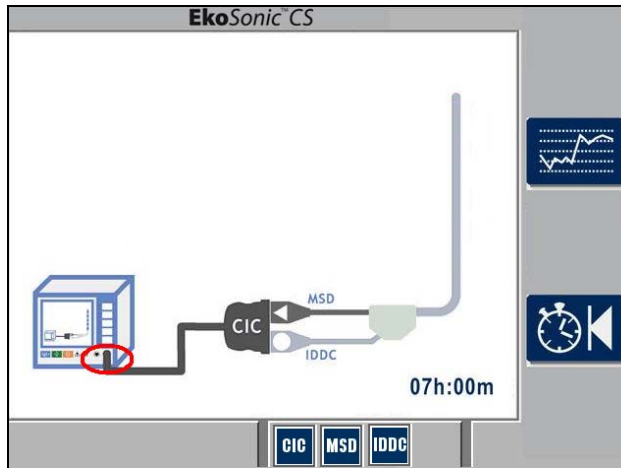


Figure 12a
Indication: CIC not connected
User Action: Connect CIC to the Control Unit

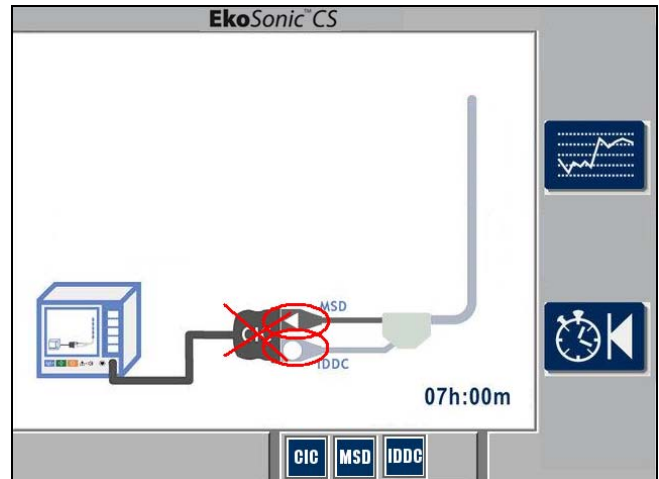


Figure 12b
Indication: CIC not functional and MSD and IDDC not connected
User Action: Replace the CIC and contact EKOS

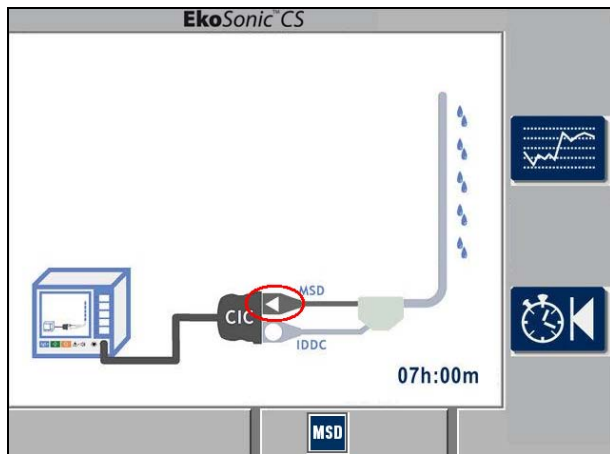


Figure 12c
Indication: MSD not connected
User Action: Connect MSD to the CIC

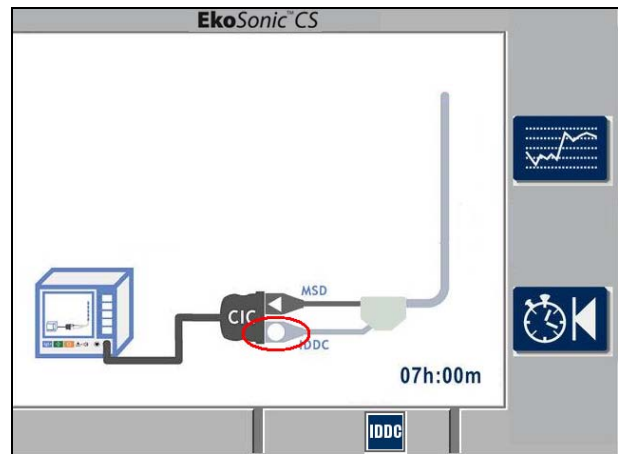


Figure 12d
Indication: IDDC not connected
User Action: Connect IDDC to the CIC

Figure 12. Status indications using the Schematic Screen and suggested user actions (more than one circle or X may appear simultaneously).

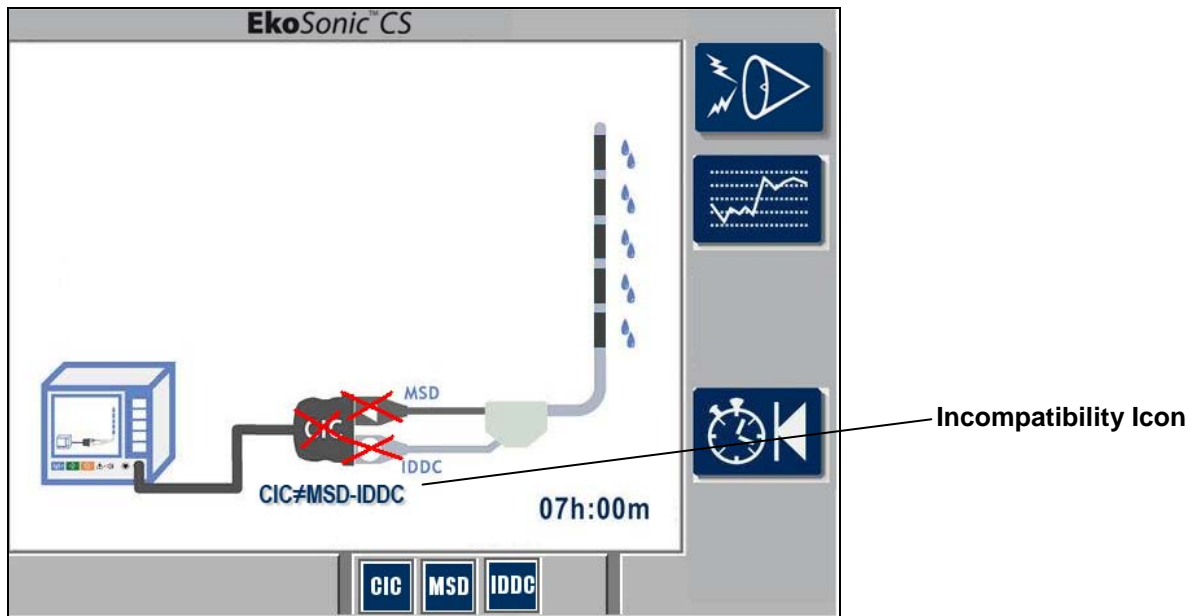


Figure 12e

Indication: CIC not compatible with MSD/IDDC/Both
User Action: Replace the CIC if a replacement is available.
 Otherwise, perform infusion only

Figure 12 (cont.): Status indications using the Schematic Screen and suggested user actions.

2. Device Information Indicators:

If the Control Unit can not read correct data from the IDDC or MSD, it will display the screen shown in Figure 13. If this screen appears, the user should disconnect the IDDC or MSD with the defective data 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 IDDC or MSD for another device.

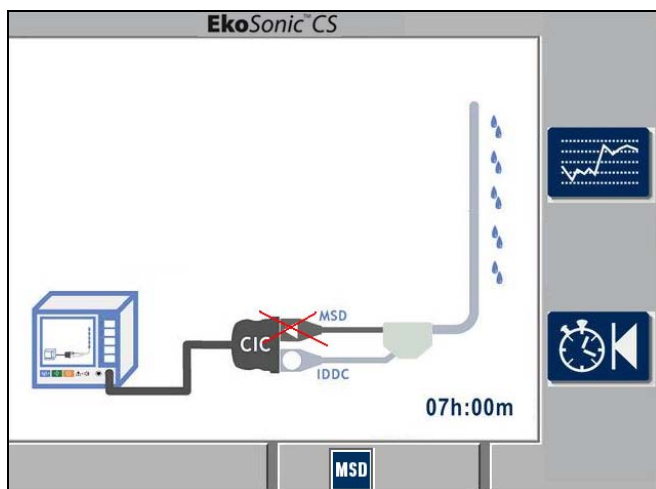


Figure 13a

Indication: MSD not functional.
User Action: Replace the MSD

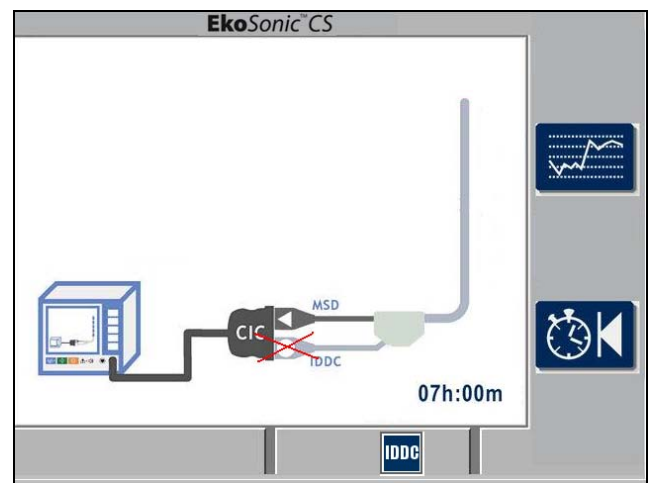





Figure 13b

Indication: IDDC not functional
User Action: Replace the IDDC

Figure 13. Status indications showing defective device and suggested user actions



3. Interruption of Therapy

If a condition occurs that interrupts therapy, the Control Unit will display the Schematic Screen. The alarm will beep and the Alarm Silence icon will appear on the right side  of the screen. The EKOS® logo will be removed from the screen.

The Alarm Indicator (a red LED) 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 Silence icon.

The Control Unit may indicate with a 'O' or an 'X' on the Schematic Screen where the user should check to correct the condition should this be a device or CIC connection problem. Additionally, during an alarm condition, any of the indicators in Table 4 may be displayed to indicate to the user why the therapy was interrupted.

Table 3. Button Icon for the EkoSonic Control Unit

Normal	Activated	Description
		Alarm Silence When the alarm is heard, this symbol appears on the right side of the screen next to a button. Pressing the Alarm Silence button next to this icon will silence the alarm. In addition, pressing the Stop Therapy button will also silence the alarm.

4. 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 14 is an example where a thermocouple of the device has exceeded the temperature limit for more than 25 seconds.

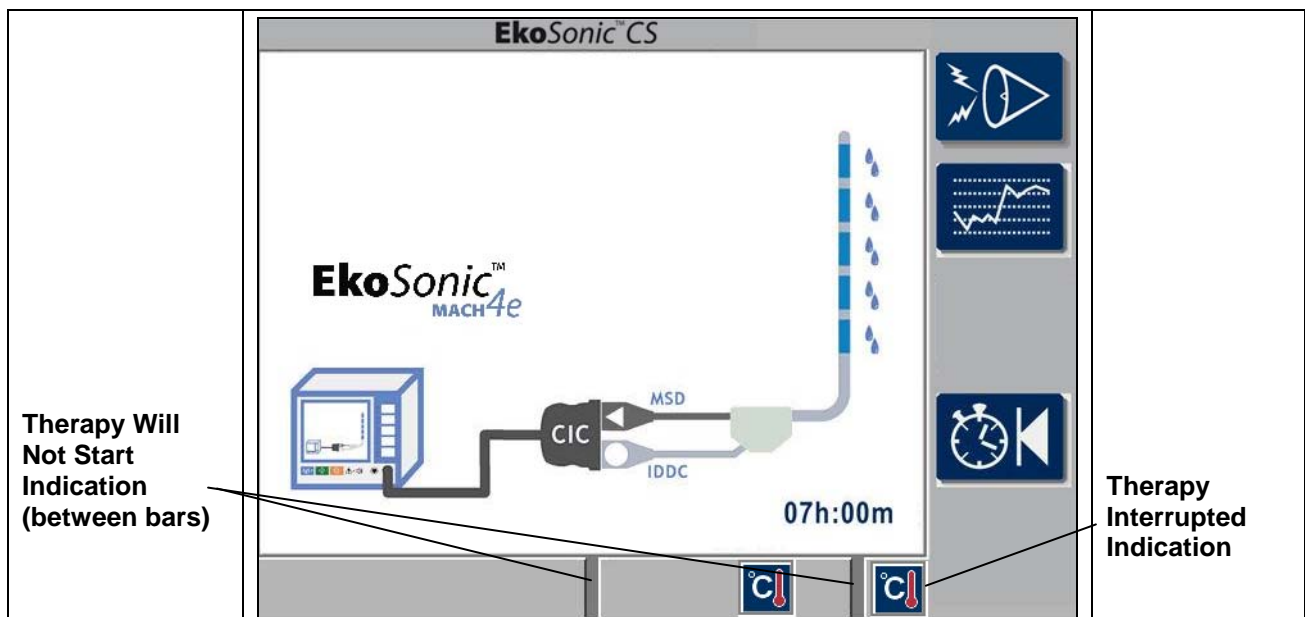


Figure 14. Example of alarm code icon showing Device Temperature Too High

The Control Unit has sounded the alarm, turned off all ultrasound power, switched to the Schematic Screen, if needed, and removed the EKOS logo. The Schematic Screen is always used to show there is an alarm condition.

In this case, the Schematic Screen displays the therapy interrupted alarm code icon for “Device Temperature Too High” on the bottom right hand side of the screen. Since the temperature is initially still too high after therapy is stopped, the “Device Temperature Too High” icon will also be shown as a therapy will not start indication between the bottom gray bars.

When the thermocouple has cooled sufficiently the icon on the left will be removed. However, the icon on the right will remain on the screen until the Start Therapy button is pressed.

Each alarm code icon is listed in Table 4 and Table 5 below with a brief description of what it means, and a suggestion for the possible cause and user action.

Table 4. “Therapy Will Not Start” Alarm Code Icons












Icon	Possible Cause	User Action
	Defective Connector Interface Cable	
	Either the Connector Interface Cable 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) Contact EKOS
	Defective Intelligent Drug Delivery Catheter	
	Either the IDDC is not connected securely or it is defective.	(1) Check that the IDDC connection is properly seated (2) Replace the IDDC if available (3) Contact EKOS
	Defective MicroSonic Device	
	Either the MSD is not connected securely or it is defective.	(1) Check that the MSD connection is properly seated (2) Replace the MSD if available (3) Contact EKOS
	Device Temperature Too High	
	The EkoSonic Device temperature is greater than 43° C	(1) Cancel the alarm. (2) Increase coolant flow in 10ml increments. (3) Start ultrasound output.
	Device Temperature Too Low	
	The EkoSonic Device temperature is less than the low temperature limit. The Control Unit assumes the EkoSonic Device is not placed in the patient.	(1) Check for placement of the device in the patient. (2) Turn off all flow in the IDDC coolant port for 5-15 minutes (3) Start ultrasound output. (4) Contact EKOS

Table 5. “Therapy Interrupted” Alarm Code Icons

Icon	Possible Cause	User Action
	<p>Device Temperature Too High</p>	<p>(1) Cancel the alarm. (2) Increase coolant flow in 10ml increments. (3) Start ultrasound output.</p>
	<p>The Control Unit has turned off ultrasound output due to excessive temperature in one or more thermocouples for more than 25-seconds.</p>	
	<p>Hardware Thermal Shutoff</p>	<p>(1) Cancel the alarm. (2) Check MSD & IDDC connections. (3) Re-start ultrasound output.</p>
	<p>The Control Unit has turned off ultrasound output and returned to the Schematic Screen because it has detected excessive instantaneous temperature in one or more thermocouples.</p>	
	<p>High Instantaneous Voltage Shutoff</p>	<p>(1) Cancel the alarm. (2) Check MSD connections. (3) Re-start ultrasound output. (4) Contact EKOS (5) Replace MSD.</p>
	<p>The Control Unit has turned off ultrasound output and returned to the Schematic Screen because it has detected an excessive instantaneous voltage output in one or more groups.</p>	
	<p>High Instantaneous Pulse Power Shutoff</p>	<p>(1) Cancel the alarm. (2) Check MSD connections. (3) Re-start ultrasound output. (4) Contact EKOS (5) Replace MSD.</p>
	<p>The Control Unit has turned off ultrasound output and returned to the Schematic Screen because it has detected an excessive instantaneous pulse power output in one or more groups.</p>	
	<p>High Instantaneous Average Power Shutoff</p>	<p>(1) Cancel the alarm. (2) Check MSD connections. (3) Re-start ultrasound output. (4) Contact EKOS (5) Replace MSD.</p>
	<p>The Control Unit has turned off ultrasound output and returned to the Schematic Screen because it has detected an excessive instantaneous average power output.</p>	
	<p>Excessive Average Power Shutoff</p>	<p>(1) Cancel the alarm. (2) Check MSD connections. (3) Re-start ultrasound output. (4) Contact EKOS (5) Replace MSD.</p>
<p>The Control Unit has turned off ultrasound output and returned to the Schematic Screen because it has detected excessive average power output.</p>		

5. Disabled Groups

As discussed in the Operation section, the Control Unit will disable groups with problematic ultrasound elements. Similarly, the Control Unit will disable a group if it does not have a corresponding working thermocouple in the IDDC.

As long as there is at least one group enabled, therapy will continue. If all groups become disabled, the Control Unit will sound an alarm and remove the EKOS logo.

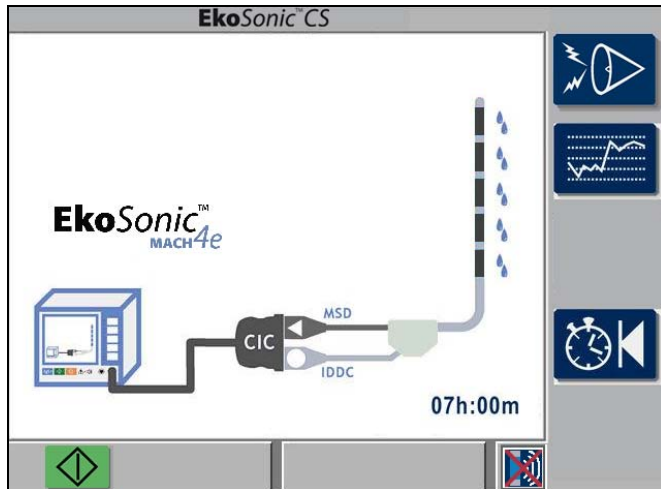


Figure 15a

Indication: All MSD groups turned off
User Action: Check the MSD connection
 Attempt to restart.
 Contact EKOS

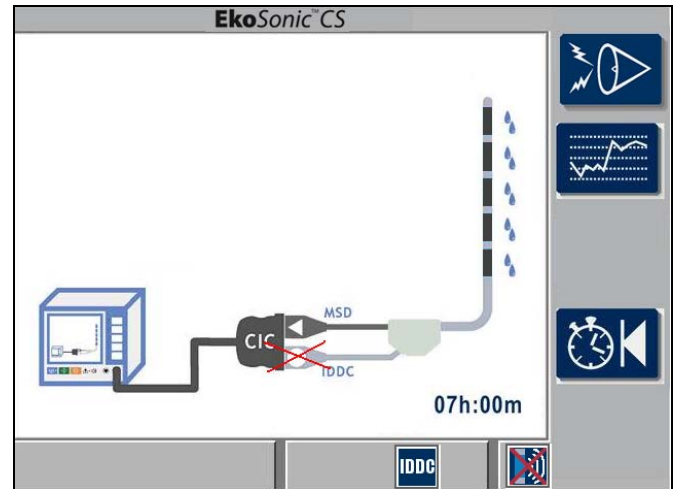



Figure 15b

Indication: All IDDC thermocouples turned off
User Action: Check the IDDC connection
 Attempt to restart
 Contact EKOS

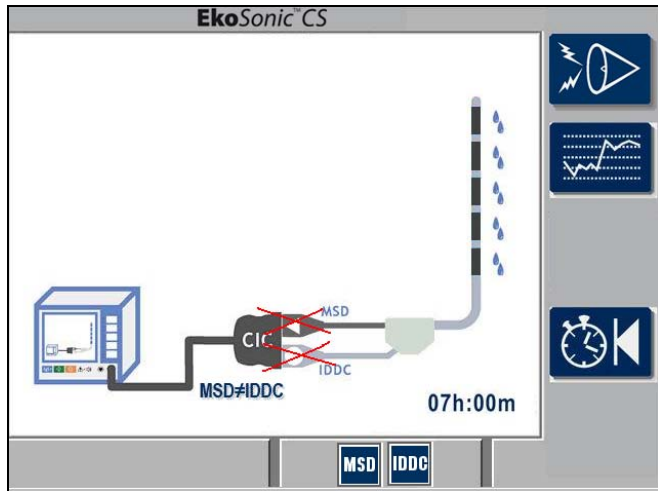
Figure 15. Examples of all groups disabled because of a problematic elements in the MSD or because of a broken thermocouples in the IDDC.

The example shown in Figure 15a also displays the restart prompt. The Start Therapy icon  appearing on the screen and flashing indicates that the user can press the Start Therapy button to restart therapy. This is additionally highlighted by the lack of icons in the “therapy will not start” area on the screen.

The example shown in Figure 15b shows a problem with the IDDC. The restart prompt will not be shown until the IDDC icon is removed from the “therapy will not start” area on the screen.

The Control Unit will disable any group without a matching valid IDDC thermocouple. In this example all thermocouples are invalid so all groups are disabled and the control unit indicates there is a problem with the IDDC. If one or more thermocouples become usable, the IDDC icons will be removed allowing therapy to be restarted.

Figure 16 shows a MSD with an IDDC that are not compatible with each other. No ultrasound groups in the MSD are enabled.



Indication: Operation not allowed because the MSD is not compatible with the IDDC

User Action: Replace the MSD with a model that is compatible with the IDDC

Figure 16. Example of an incompatible MSD and IDDC connected to the Control Unit. Operation is not allowed with this mismatch.

6. Temperature Indicators

During the use of the EkoSonic Endovascular Device, the temperature of each group is monitored by a thermocouple in the IDDC.

If the IDDC is not positioned inside the patient or the IDDC has been placed inside the patient but in an area of the patient that is exhibiting a low temperature, the Control Unit will display this fact by displaying a “Device Temperature Too Low” icon. Figure 17a shows this icon. If all of the thermocouples are less than the low temperature limit, the Control Unit will not allow ultrasound therapy to begin. This is shown by the icon being displayed in the “therapy will not start” area of the screen.

Once the IDDC is placed inside the vasculature of the patient and is above the low temperature limit, the thermocouples will indicate that the device is at proper operating temperature by removing the “Device Temperature Too Low” icon and will then allow ultrasound therapy to start.

Once ultrasound therapy is successfully underway, the “Device Temperature Too Low” icon will not be displayed and the condition will not interrupt operation.

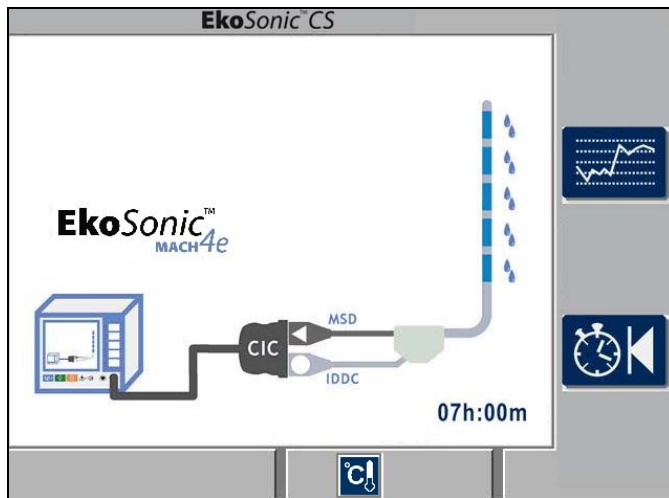


Figure 17a

Indication: Ultrasound operation will not begin because the IDDC thermocouples are reading less than 28°C

User Action: Verify that the IDDC is properly positioned and/or turn off the coolant for 5-15 minutes

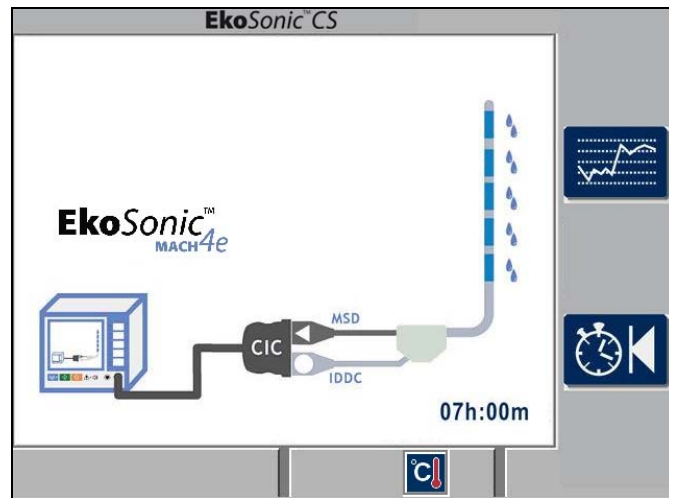


Figure 17b

Indication: Ultrasound operation will not begin because an IDDC thermocouple is reading more than 43°C

User Action: Verify that the IDDC is properly positioned and/or increase the coolant in small increments

Figure 17. Examples of the Control Unit preventing the start of ultrasound operation because thermocouple readings are either too cold or too hot.

If the Control Unit senses one or more of the thermocouples at a temperature above the maximum temperature of 43°C before therapy is started, it will indicate this by displaying the “Device Temperature Too Warm” icon.

If any of the thermocouples are indicating an elevated temperature above 43° C, the Control Unit will not allow ultrasound therapy to start. This is shown by the icon being displayed in the “therapy will not start” area of the screen. Figure 17b shows how this will appear on the screen.

Pushing the Start Therapy button when the over temperature condition is still present will only result in a double-beep with no change in the screen. Increasing the coolant flow may help resolve the over temperature condition.

7. 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 an audible alarm. Figure 18 shows an example of an Idle Screen.

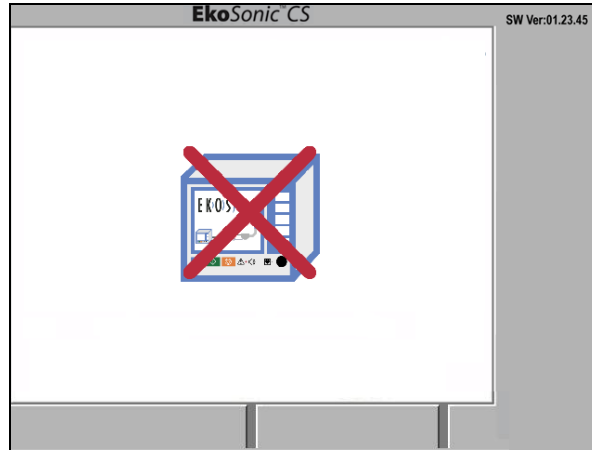





Figure 18. Example Idle Screen

Potential Idle Screen icons are shown in Table 6. Each icon is listed with a brief description of what it means, and a suggestion for the possible cause and user action.

Table 6. Idle Screen Icons

Icon	Possible Cause	User Action
	Control Unit Failure The Control Unit has detected a hardware malfunction.	<ol style="list-style-type: none"> (1) Turn the power off and then back on. (2) If this icon reappears, do not attempt to use the Control Unit. (3) Contact EKOS Corporation for assistance.
	Control Unit temperature too high The Control Unit is warmer than its specified operating temperature.	<ol style="list-style-type: none"> (1) Check to ensure the cooling air intake under the unit or air exhaust at the back of the unit are not blocked. (2) Allow Control Unit to cool down. (3) When it cools down, turn the power off and then back on.
	Control Unit temperature too low The Control Unit is colder than its specified operating temperature.	<ol style="list-style-type: none"> (1) Check to ensure the cooling air intake under the unit or air exhaust at the back of the unit are not blocked. (2) Allow Control Unit to warm up. (3) When it has warmed up, turn the power off and then back on.

8. Additional Trouble Shooting

If error conditions prevent or stop therapy, momentarily disconnect the MSD, IDDC and CIC and then reconnect them. Be sure that all connectors are properly and completely seated. Restart therapy by pressing the green Start Therapy button.

If a condition is persistent and will not allow the delivery of ultrasound energy even after all troubleshooting attempts, infusion may be continued through the Intelligent Drug Delivery Catheter without using the MicroSonic Device, or the EkoSonic Endovascular Device may be removed and therapy provided using a standard method. Contact EKOS at telephone **1-425-415-3100** or toll free (in the U.S.) at **1-888-356-7435**.

EkoSonic Connector Interface Cable (CIC) Clip Installation

The CIC clip is intended as an accessory which prevents inadvertent disconnection of the MSD and IDDC electrical cables from the CIC. Keep the CIC Clip on CIC at all times. CIC Clip may be temporarily removed for cleaning.

CIC Clip Installation Instructions

1. Unplug CIC from the Control Unit.
2. Thread CIC cable through the CIC Clip.



Figure 19

3. Snap the CIC Clip arms around the CIC. Verify the EKOS label on the CIC is still visible.



Figure 20

4. Plug CIC into the Control Unit.



Figure 21

Preventive Maintenance

Cleaning

The EkoSonic Control Unit should be cleaned after each use. Clean the Control Unit and Connector Interface Cable by wiping with a soft cloth moistened with 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 submerge the unit in any fluid.
- Do not use excessive amounts of fluid.
- Do not sterilize the EkoSonic Control Unit or Connector Interface Cable.
- After cleaning the system components, be sure to dry them with a soft cloth to remove any cleaning residues.

Filter Replacement

The air intake filter is the only user-serviceable part in the Control Unit.

The air intake filter is located on the bottom of the EkoSonic Control Unit. It should be inspected annually and replaced if necessary.

To access the filter, remove the four screws that hold the filter cover in place. Remove the filter cover and clean the cover with a soft cloth moistened with: distilled water, mild soap solution, isopropyl alcohol, or disinfectant.

Remove the filter and replace with EKOS catalog number 700-20201. Only use an approved filter with the EkoSonic Control Unit.

Replace the filter over the air intake vents on the bottom of the EkoSonic Control Unit. Replace the dried filter cover over the filter and attach in place with four screws.

System Specifications

Models	EKOS [®] EkoSonic Control System consisting of: (A) EkoSonic Control Unit (1) Power cable (1) Connector Interface Cable (B) EkoSonic Endovascular Device
Classification	Complies with BS EN 60601-1, C22.2 No. 601.1-M90, with exception of Clause #42, (maximum temperature specification) Complies with EN55011 Class A Emissions Limits EkoSonic Endovascular Device complies with ISO 10993-1 biocompatibility safety guidelines for limited contact duration (< 24 hours) external communicating devices in circulating blood. Class I, Grounded Equipment Type CF Patient Applied Parts, Defibrillation proof Mode of Operation – Continuous, with automatic shut-off features EkoSonic Control Unit water ingress rating: IPX1
Device Frequency	2.05 – 2.35 MHz
Ultrasound Transducer Composition	PZT (Lead Zirconate Titanate)
System Output Power	Automatically controlled, 50.0W pulse power maximum 30.0W average device power maximum
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:	
<u>Product</u>	<u>Catalog Number</u>
EkoSonic [®] Control Unit	600-30000
EkoSonic [®] Replacement Filter	700-20201
EkoSonic [®] CIC	700-10302
EkoSonic [®] CIC Clip	700-40000
Power Cord (North American)	700-51102

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 22. Front Panel of EKOS EkoSonic Control Unit









1. Front Panel Symbols: Table 7

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

Icon	Description
	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/Alarm Indicator: 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 Therapy Symbol. It has a green background and appears on the lower left of the front panel. This symbol identifies the Start Therapy button. Press this button to begin therapy.
	Stop Therapy Symbol: This has an orange background and appears on the lower center of the front panel. This symbol identifies the Stop Therapy button. Press this button to halt therapy.
	Therapy On Indicator: This symbol 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.
	Symbol for Defibrillator - Proof CF Equipment: This equipment provides a degree of protection against electrical shock to Type CF as defined in BS EN 60601-1. This equipment has a Type CF applied part capable of withstanding the effects of defibrillator discharge and it meets the leakage requirements for cardiac intervention.










2. Other Symbols Appearing on the System: Table 8

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

Icon	Description
	<p>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.</p>
	<p>Symbol for Electro-static Discharge (ESD) sensitive equipment: This equipment is resistant to ESD as required by BS EN 60601-1-2. However, parts marked with this symbol could be damaged by direct application of electrical discharge.</p>
<p>IPX1</p>	<p>Ingress Protection Rating: This equipment is protected against dripping liquids as required by BS EN 60601-1.</p>
	<p>Manufactured on: This equipment was manufactured during the listed year.</p>
	<p>Manufactured on: This equipment was manufactured during the listed year.</p>
	<p>MicroSonic Device symbol: The MicroSonic Device attaches to this connector on the CIC.</p>
	<p>Intelligent Drug Delivery Catheter symbol: The Intelligent Drug Delivery Catheter attaches to this connector on the CIC.</p>
	<p>Equipotential Terminal The terminal marked with this symbol is the equipotential terminal. It can be connected to the external equipotential line to prevent danger caused by the difference in the potentials between the other devices.</p>
	<p>Equipotential Terminal The terminal marked with this symbol is the equipotential terminal. It can be connected to the external equipotential line to prevent danger caused by the difference in the potentials between the other devices.</p>

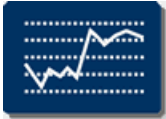





3. System Status Icons: Table 9

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

Icon	Description
	<p>Drug Delivery Section This symbol indicates a drug delivery section of the treatment zone.</p>
	<p>MSD Group Operational This indicates ultrasound power is being delivered to a specific group if therapy is running. If therapy is not running, this means that this group is capable of delivering therapy.</p>
	<p>MSD Group Not Present The indicated group is not considered present.</p>
	<p>MSD Group Disabled This indicates the specified group has been disabled. If therapy is running, no ultrasound power is being delivered to the group.</p>
	<p>Therapy Paused This is shown on a History Graph Screen to indicate that therapy was stopped by the operator.</p>
	<p>Therapy Auto-stop This is shown on a History Graph Screen to indicate that therapy was stopped by an error condition.</p>
	<p>Therapy is On This animated symbol on the Schematic Screen or any History Graph Screen indicates therapy is being delivered.</p>
	<p>Device Connections Complete This icon is displayed when the CIC, MSD and IDDC are connected and functional.</p>
	<p>Device Connections Complete (RPM Capable) This icon is displayed when the CIC, MSD and IDDC are connected and functional and the system is using Rapid Pulse Modulation (RPM) ultrasound.</p>



4. Button Icons: Table 10

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

Normal	Activated	Description
		<p>Screen Selector Icon Pressing the button next to this icon will change the screen.</p>
		<p>Therapy Timer Reset Icon Pressing the button next to this icon 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.</p>
		<p>Therapy Timer Reset Cancel Icon Press the button next to this icon to cancel the Timer Reset activity.</p>




5. Alarm Silence Icon: Table 11

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

Normal	Activated	
		<p>Alarm Silence This appears when the audible alarm is active. Press the button next to the icon to silence the alarm.</p>


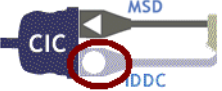








6. Idle Screen Symbols: Table 12









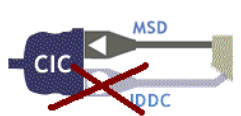
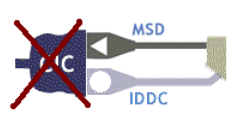
One of these symbols will be displayed if the Control Unit detects a condition which prevents normal operation. Refer to the Troubleshooting section for more detailed discussion.



Icon	Possible Cause	User Action
	<p>Control Unit Failure</p> <p>The Control Unit has detected a hardware malfunction.</p>	<ol style="list-style-type: none"> (1) Turn the power off and then back on. (2) If this icon reappears, do not attempt to use the Control Unit. (3) Contact EKOS Corporation for assistance.
	<p>Control Unit temperature too high</p> <p>The Control Unit is warmer than its specified operating temperature.</p>	<ol style="list-style-type: none"> (1) Check to ensure the cooling air intake under the unit or air exhaust at the back of the unit are not blocked. (2) Allow Control Unit to cool down. (3) When it cools down, turn the power off and then back on.
	<p>Control Unit temperature too low</p> <p>The Control Unit is colder than its specified operating temperature.</p>	<ol style="list-style-type: none"> (1) Check to ensure the cooling air intake under the unit or air exhaust at the back of the unit are not blocked. (2) Allow Control Unit to warm up. (3) When it has warmed up, turn the power off and then back on.

7. System Status Icons: Table 13

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

Icon	Description
	<p>MSD Not Detected This may indicate a loose connector or a disconnected MSD.</p>
	<p>IDDC Not Detected This may indicate a loose connector or a disconnected IDDC.</p>
	<p>CIC Not Detected This may indicate a loose connector or a disconnected CIC.</p>
	<p>Defective CIC The CIC is either not connected or is defective.</p>
	<p>Defective IDDC The IDDC is either not connected or is defective.</p>
	<p>Defective MSD The MSD is either not connected or is defective.</p>
	<p>MSD Group Disabled This indicates the specified group has been disabled. If therapy is running, no ultrasound power is being delivered to the group.</p>
	<p>Flashing Start Therapy Prompt When the Start Button Icon is flashing on the screen and the alarm is sounding, the system is ready to start but the Start Therapy button has not been pressed. Pressing the Stop Therapy button or the Alarm Silence button will suspend the alarm for 5 minutes after which the alarm will sound again. The Start Therapy button must be pressed to clear the condition.</p>
	<p>Device Temperature Too Low The IDDC temperature is less than the low temperature limit.</p>
	<p>Device Temperature Too High The Control Unit has turned off ultrasound output because it has detected excessive temperature in one or more thermocouples for more than 25-seconds.</p>





Icon	Description
	<p>Hardware Thermal Shutoff</p> <p>The Control Unit has turned off ultrasound output because it has detected a broken thermocouple or an excessive instantaneous temperature in one or more thermocouples.</p>
	<p>MSD withdrawn while functioning.</p> <p>This is displayed when the MSD has been withdrawn from the IDDC while operating. If this icon appears and the MSD has been withdrawn from the IDDC, do not attempt to re-insert the MSD since it may be damaged.</p> <p>If this icon appears and the MSD has not been disconnected and/or removed from the IDDC, press the green Start Therapy button to continue therapy.</p>
	<p>All MSD Groups Disabled</p> <p>This is displayed when all MSD groups have been disabled for any reason. Once all groups are disabled, therapy is stopped, and an alarm sounds.</p>
	<p>High Instantaneous Voltage Shutoff</p> <p>The Control Unit has turned off ultrasound output because it has detected an excessive instantaneous voltage output in one or more groups.</p>
	<p>High Instantaneous Pulse Power Shutoff</p> <p>The Control Unit has turned off ultrasound output because it has detected an excessive instantaneous pulse power output in one or more groups.</p>
	<p>High Instantaneous Average Power Shutoff</p> <p>The Control Unit has turned off ultrasound output because it has detected an excessive instantaneous average power output.</p>
	<p>Excessive Average Power</p> <p>The Control Unit has turned off ultrasound output because it has detected an excessive average power output.</p>
	<p>Control Unit does not detect valid MSD information.</p> <p>This is displayed when any of the MSD information is corrupt or incorrect.</p>
	<p>Control Unit does not detect valid IDDC information.</p> <p>This is displayed when any of the IDDC information is corrupt or incorrect.</p>
	<p>Control Unit does not detect valid CIC information.</p> <p>This is displayed when any of the CIC's information is corrupt or incorrect.</p>
<p>CIC≠IDDC</p>	<p>CIC is not compatible with the IDDC</p> <p>The CIC and IDDC are not configured to work together. Replace the devices.</p>
<p>CIC≠MSD-IDDC</p>	<p>CIC is not compatible with the IDDC and the MSD</p> <p>The CIC, IDDC and MSD are not configured to work together. Replace the devices.</p>

Icon	Description
	CIC is not compatible with the MSD The CIC and MSD are not configured to work together. Replace the devices.
	MSD is not compatible with the IDDC The MSD and the IDDC are not configured to work together. Replace the devices.

8. Control Unit Service Symbols: Table 14

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 therapy.

The communication port is not for clinical use. It is for use under the direction of EKOS authorized personnel only.

Icon	Description
	External Application is Communicating with Control Unit A computer is connected to the Control Unit and is 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.
	Software download in progress The Control Unit is being reprogrammed with a software revision. Wait for the software download to complete. This icon will go away and then the Cycle Power icon will appear.
	Cycle Power to Control Unit This icon appears following installation of a software revision. Turn Control Unit power off and then back on.

System Component Interconnection

Connect the components as illustrated in Figure 23 and Figure 24.

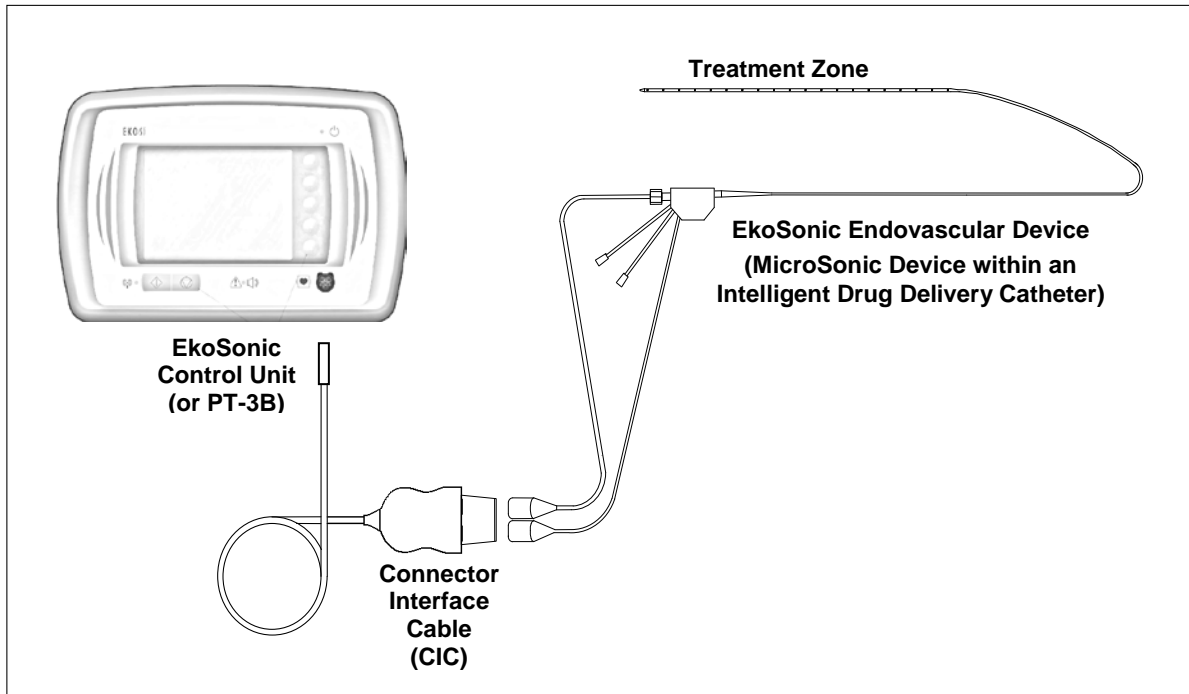


Figure 23. Connector- Interface Cable Connection to the Front Panel. Intelligent Drug Delivery Catheter Connection to the CIC. MicroSonic Device Connection to the CIC.

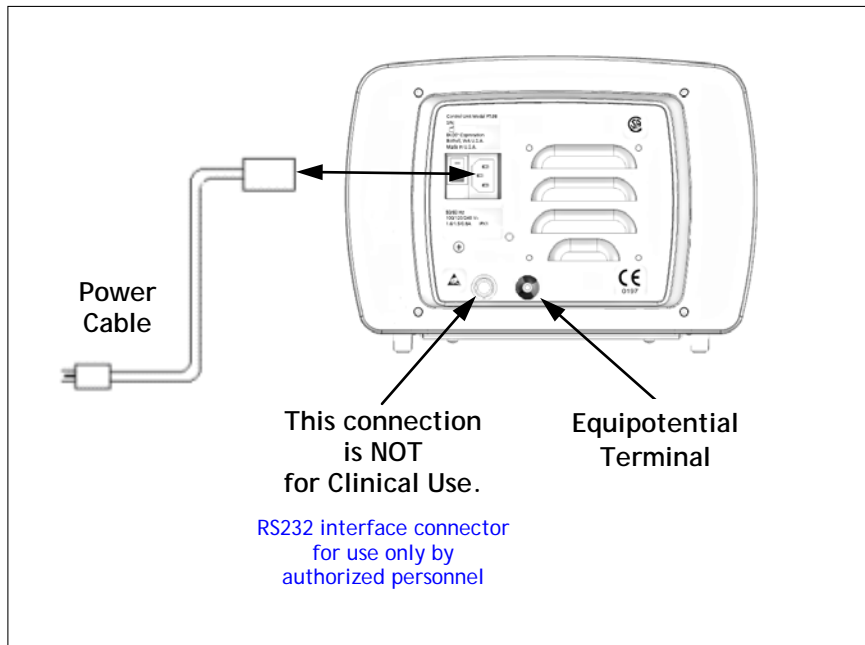


Figure 24. Control Unit Rear Panel Interconnection Diagram



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22041 Hamburg, Germany

This system is covered by and/or manufactured under one or more of the following patents:
U.S. Pat. Nos. 6,979,293 and 6,585,678.
Other U.S. and foreign patents pending.