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GALAXY
MEDICAL

CENTAURI™ Generator
Model GTI-00021-01

User Manual

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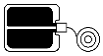
List of Symbols

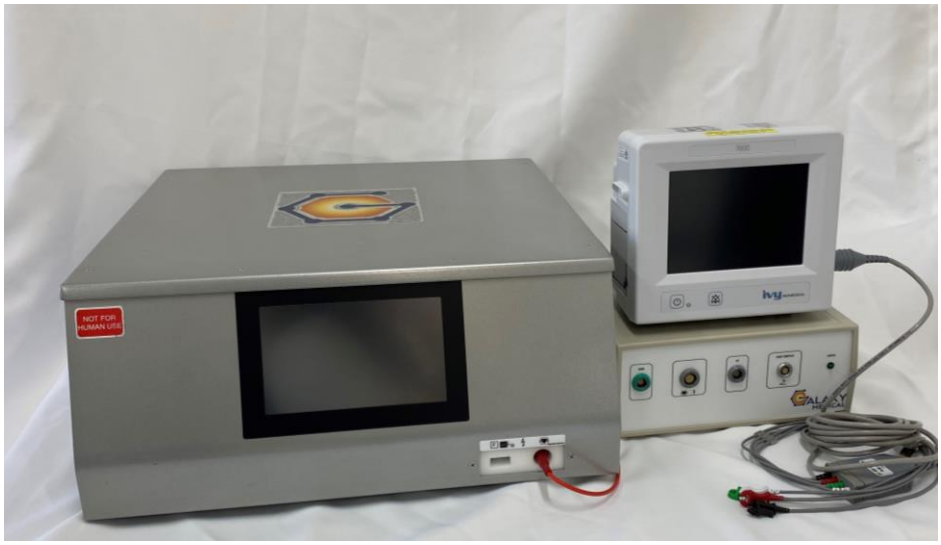
The following is a list of symbols used on the CENTAURI System and throughout this user manual.

	Catalogue number		Defibrillator proof type CF applied part
	Serial number		Electric shock hazard
	Follow instructions for use		Dispersive electrode
	Manufacturer		Floating dispersive electrode connection for isolated patient circuit
	Date of manufacture		Foot switch
	Alternating current		Synchronization signal input
	Power On (Connect to AC mains)		Synchronization signal output
	Power Off (Disconnect from AC mains)		Digital signal cable connection
	Potential equalization terminal		Do not use if packaging is damaged
	Fuse information		Keep dry during shipping
	Caution		Humidity limits during transportation
	Warning		Temperature limits during transportation
	WEEE compliant		Atmospheric pressure limits during transportation
	Authorized representative in the European Community		CE marking with notified body identifying number
	Medical device		Importer
	Swiss authorized representative		

1. Introduction

System Overview

The CENTAURI™ System is an electrosurgical system used in conjunction with cardiac ablation catheters to deliver radiofrequency pulsed electric field WAVE1™ energy to cardiac tissue. The CENTAURI System is comprised of the CENTAURI Generator (“Generator”), the CENTAURI Connect, and IVY Cardiac Monitor. This user manual describes the use of the CENTAURI Generator (GTI-00021-01). For information and instructions on the CENTAURI Connect, see the CENTAURI Connect User Manual. For information and instructions on the IVY Cardiac Monitor, see the IVY Cardiac Monitor User Manual.



Application Specification Summary

The CENTAURI System is intended to be used by a healthcare professional within an Electrophysiology (EP) Laboratory to treat patients in need of conventional cardiac ablation procedures. A cardiac ablation catheter is connected to the CENTAURI System and positioned at the target ablation site within the heart. The user presses and holds the foot switch to deliver energy to the target tissue resulting in tissue ablation. The user then repositions the catheter at subsequent target ablation sites and the process is repeated until all targeted tissue is treated.

CENTAURI Generator (GTI-00021-01)

The CENTAURI Generator (“Generator”) provides controlled delivery of energy to a catheter. The energy delivery settings of the Generator are adjusted using a touchscreen interface. The user controls when energy is delivered by pressing, holding, and releasing the supplied foot switch. The Generator is not intended to come in contact with the patient and therefore is not provided sterile.

CENTAURI Connect (GTI-00022)

CENTAURI Connect is used to connect a catheter to the Generator as well as to an electroanatomic mapping (EAM) system and EP recording system amplifiers. For information and instructions on the CENTAURI Connect, see the CENTAURI Connect User Manual.

Cardiac Monitor (Ivy Biomedical, Model 7600EP)

WARNING: Only use the cardiac monitor supplied with the CENTAURI System. Use of other cardiac monitors may result in patient injury.

The Generator utilizes a cardiac monitor for synchronizing the delivery of energy to the patient's cardiac cycle. The Generator is designed to only be used with the Ivy Biomedical Model 7600EP cardiac monitor ("Cardiac Monitor") provided with the CENTAURI System. The Cardiac Monitor uses a 4-lead configuration, which detects the R-wave of the electrocardiogram (ECG) signal and sends a trigger signal to the Generator upon detection of the R-wave for precise synchronization of energy delivery to the patient. The Cardiac Monitor is not intended to come in contact with the patient and therefore is not provided sterile.

Interconnect power and instrumentation cables

The Generator is provided with a power cord and foot switch. The foot switch, interconnect power and instrumentation cables have been specified and tested for use with the CENTAURI System and should not be substituted with any non-GALAXY Medical specified cables.

Other Devices Used with the CENTAURI Generator

WARNING: Do not substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by GALAXY Medical. Doing so could potentially damage the system or cause injury.

The Generator is designed to work with the devices listed in the following table.

Device	**Manufacturer**	**Manufacturer Reference**
Patient Dispersive Electrode	3M	Model 9165E
Set of 4 ECG Electrodes	Ivy Biomedical Systems, Inc.	590494 (or equivalent)
Cardiac Ablation Catheter	Abbott[1]	TactiCath™ A-TCSE[1]

[1] Refer to the CENTAURI Connect User Manual for a full list of compatible devices that connect directly to the CENTAURI Connect.

2. Intended Purpose, Training, and Contraindications

Intended Purpose

The CENTAURI System is an electrosurgical system used in conjunction with commercially available cardiac ablation catheters to deliver radiofrequency pulsed electric field energy to cardiac tissue. The CENTAURI System is intended to treat adult patients undergoing intracardiac ablation procedures for the treatment of paroxysmal atrial fibrillation.

Refer to the CENTAURI Connect User Manual for a list of compatible ablation catheters (e.g., TactiCath Ablation Catheter, SE) and the instructions for use (IFU) supplied with the cardiac ablation catheter to be used with the CENTAURI System.

Training

The setup of the CENTAURI System shall be performed by qualified GALAXY Medical personnel. No formal training in the use of the CENTAURI System is required; the CENTAURI System may be used only by medical personnel trained and experienced in the techniques of electrophysiology. Before using the CENTAURI System, review this User Manual thoroughly and completely. For further information, please contact GALAXY Medical.

Contraindications

The CENTAURI System shall not be used in patients with active systemic infection.

Refer to the CENTAURI Connect User Manual for the list of the compatible ablation catheters and to the contraindications listed in the IFU supplied with the compatible cardiac ablation catheter.

3. Warnings and Precautions

Warnings and Precautions

THIS USER MANUAL SHOULD BE READ IN CONJUNCTION WITH THE IFU OF A COMPATIBLE CATHETER BEFORE USING THE CENTAURI SYSTEM. FAILURE TO FOLLOW INSTRUCTIONS OR FAILURE TO HEED WARNINGS OR PRECAUTIONS MAY RESULT IN HARM TO THE PATIENT.

1. Hazardous electrical output. The CENTAURI System is for use only by qualified medical personnel trained in the use of this equipment.
2. Do not use the CENTAURI System if there are any signs of damage to any of its components. Visually inspect all components and verify cables are not damaged.
3. Use caution when transporting the components of the CENTAURI System. Some components may be heavy for some users. Dropping a component may result in harm to the user or the component.
4. Do not substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by GALAXY Medical. Doing so could potentially damage the system or cause injury.
5. Only use the cardiac monitor supplied with the CENTAURI System. Use of other cardiac monitors may result in patient injury.
6. Do not connect a signal source other than the GALAXY Medical-supplied Cardiac Monitor to the CENTAURI System.
7. Power on the Generator and allow completion of self-test prior to preparing the patient for the ablation procedure. If the Generator does not perform as expected during the power on sequence, do not use the Generator and contact a GALAXY Medical representative.
8. Do NOT connect the catheter to the front panel of the CENTAURI Connect when powering on the Generator and preparing it for use. If the catheter is connected to the CENTAURI Connect while preparing the device for use, injury to the operator or the patient could happen.
9. Do not use sharp towel clips or metal instruments to attach cables to drapes. Sharp metal clips can damage electrical cables or provide an unwanted point of contact with the patient's skin. Overlapping electrical wire around a metal clip creates an electrical transformer that can cause a hazard and may ignite drapes.
10. Cables should never be wrapped around metal instruments, as the current running through them can pass into the metal instrument and may result in harm to the patient and/or operator.
11. Use caution when walking around the foot switch and foot switch cable to avoid injury.

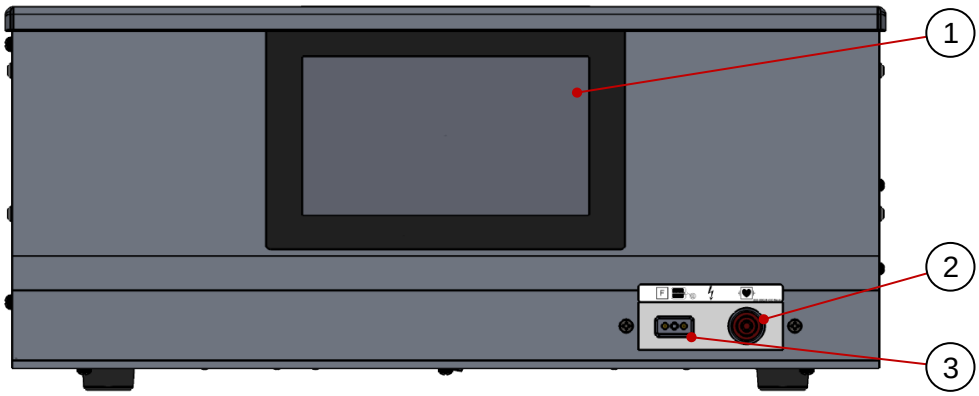
12. For optimum safety, ensure the patient is not wearing any jewelry to avoid complications from possible current leakage.
13. Do not deliver energy if the dispersive electrode (also known as neutral electrode, return electrode, or grounding pad) is not securely affixed on the patient in accordance with the manufacturer's instructions. Do not apply the dispersive electrode where fluid may pool. A loosely or improperly connected dispersive electrode may result in harm to the patient and/or operator. Loss of safe contact between the dispersive electrode and the patient will not result in an auditory alarm.
14. If a patient has any metal implants, place the dispersive electrode on the skin away from any metal orthopedic implant.
15. Do not adhere the dispersive electrode in contact with sensitive electronic equipment (e.g., EAM electrodes, patches or magnetic sensors). The electrical output of the Generator may interfere with the readings / measurements of the equipment.
16. The selected energy delivery settings should be as low as possible for the intended purpose.
17. The catheter, patient dispersive electrode, and ECG electrodes are intended for single-use only. Do not attempt to sterilize and reuse.
18. Do not use steam or heat sterilization to clean any system component. Do not soak any component in disinfectants or fluids. Do not allow liquid to enter into any of the electrical connections or the interior of any component.
19. To avoid the risk of electric shock, the CENTAURI System must only be connected directly to AC supply mains with protective earth.
20. Do not disassemble the Generator or any of its components. Modification of this equipment is not permitted as serious injury to the operator or damage to the unit may result.
21. Electric shock hazard. Do not remove the cover of any equipment or any components from the equipment. Refer servicing to qualified personnel. There are no user-serviceable parts inside the Generator or any of the components of the Generator.
22. Ensure the patient does not come into contact with the CENTAURI System or metal parts that are grounded or have an appreciable capacitance to ground (for example operating table supports, etc.). The use of antistatic sheeting is recommended.
23. Skin-to-skin contact (for example between the arms and body of the patient) should be avoided. Use dry gauze to prevent skin-to-skin contact.
24. Monitoring electrodes of any patient monitoring equipment should be placed as far as possible away from the intended treatment location. Needle monitoring electrodes are not recommended. Patient monitoring equipment incorporating high frequency current limiting devices is recommended.
25. Position the connection cables of the ablation catheter and dispersive electrode in such a way that they do not touch either the patient or other cables. Keep active electrodes that are temporarily not in use at a safe distance from the patient.
26. Do not allow fluids to pool in the body depressions and cavities before and during energy delivery.
27. Do not touch the dispersive electrode while the generator is delivering energy.

28. Interference produced by the operation of the CENTAURI System may adversely influence the operation of other electronic equipment.
29. The CENTAURI System can be used in patients who have implanted electronic devices (e.g., pacemakers, implantable cardioverter defibrillators (ICDs), neurostimulators). Follow the manufacturer instructions to deactivate sensing capabilities and/or device therapy.
30. Make sure that the active electrode of the ablation catheter is not in contact with another catheter or with another metallic conductor, such as an implanted pacemaker lead. This could lead to uncontrolled conduction of the energy to other parts of the body, or to an uncontrolled increase in the elective size of the active electrode.
31. A failure of the Generator could result in an unintended increase of output power.
32. Patient injury resulting from neuromuscular stimulation is possible during energy delivery. The CENTAURI System has been designed to minimize the possibility of neuromuscular stimulation.
33. Do not start the procedure if an external defibrillator is not readily available as unintended cardiac arrhythmia may occur.
34. The CENTAURI System is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.
35. The CENTAURI System has not been tested on pregnant women, or children.

***Note**: Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*

4. System Connections and Receptacles

CENTAURI Generator

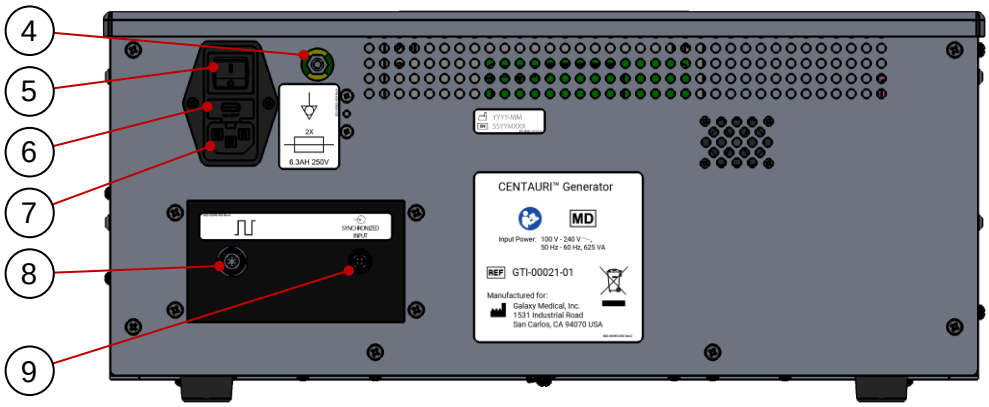


Front

1. **Touchscreen Display**: A liquid crystal display (LCD) used to provide information to the user and allow the user to acknowledge messages.

2. **PEF Output (Type CF Applied Part)**: The high voltage PEF cable connects to this receptacle to deliver PEF energy to CENTAURI Connect and ultimately the ablation catheter.

3. **Dispersive Electrode (Applied Part)**: The dispersive electrode connects to this receptacle and provides a path for the applied electric current to return to the Generator.



Rear

4. ⏚ **Potential Equalization Terminal**: Connection that provides a common electrical ground for other electronic devices used during the procedure

5. **Power Switch**: Switch for turning the Generator on and off

6. ⊟ **Fuse Access Panel**: Provides access to replaceable fuses

7. **Power Cable**: Receptacle to connect the Generator to an AC mains power outlet

8. ⎍ **Digital Signal Connection**: Receptacle for connecting the digital signal cable between the Generator and CENTAURI Connect.

9. ⊖→ **Synchronized Input**: Connection to the Synchronized Output signal of the CENTAURI Connect.

CENTAURI Connect

Refer to the user manual provided with the CENTAURI Connect for a description of receptacles and connections.

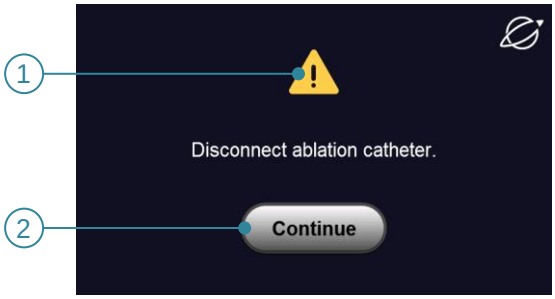
Cardiac Monitor

Refer to the user manual provided with the Cardiac Monitor for a description of receptacles and connections.

5. Touchscreen Interface

Self-Test Interface

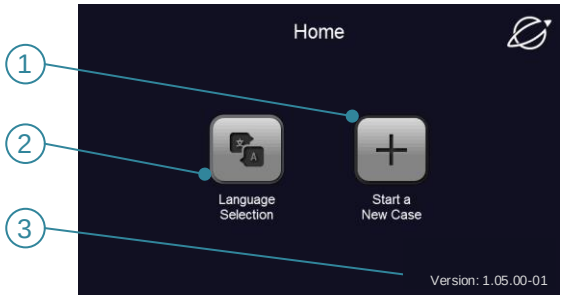
The Self-Test Interface is displayed when the Generator is powered on. When the Continue button is pressed, the Generator will perform a test of internal circuitry followed by display of the Cardiac Monitor Linking Interface.



Symbol	Description
1. ⚠ Warning Icon	An indication to the user to follow the instructions on the screen to prevent injury to the patient or user.
2. Continue Continue Button	The Continue button should only be pressed if the catheter is disconnected from the receptacle in the front panel of the CENTAURI Connect.

Home Interface

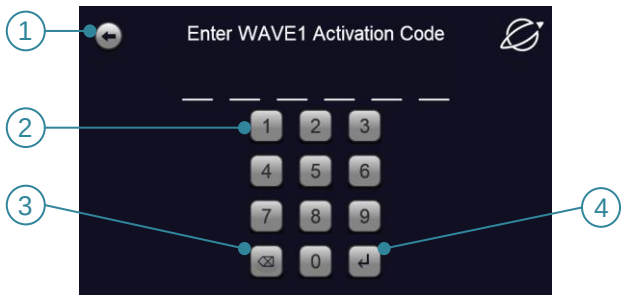
The Home Interface provides the option to start a new case or to update the language setting of the Generator interface.

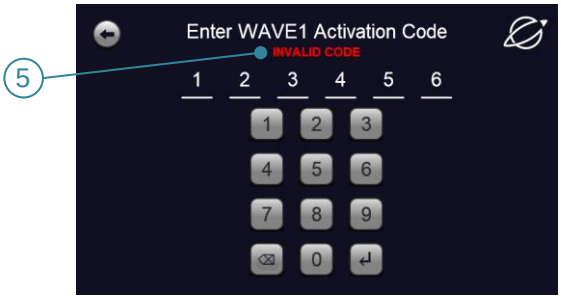


Symbol	Description
1. Start a New Case Button	Select this button to begin a new procedure.
2. Language Selection Button	Select this button to change the language of the Generator interface.
3. Version	Display of the Generator software version.

WAVE1 Activation Code Interface

The WAVE1 Activation Code interface is used to enter the WAVE1 Activation Code, provided by Galaxy Medical. The WAVE1 Activation Code is required at the start of each case.

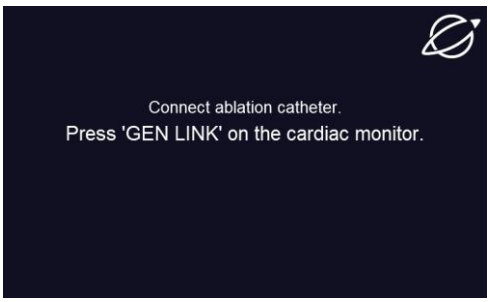


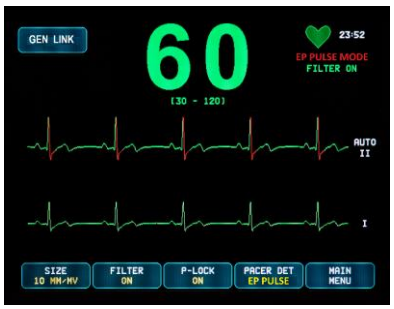


Symbol	Description
1. Back Button	Select this button to go back to the previous screen (Home) .
2. Pin Pad	Enter the WAVE1 Activation Code with the numbers provided.
3. Delete Button	Select this button to delete the previous number entered.
4. Enter Button	Select this button to enter the WAVE1 Activation Code.
5. Message Area	Provides information to the user.

Cardiac Monitor Linking Interface

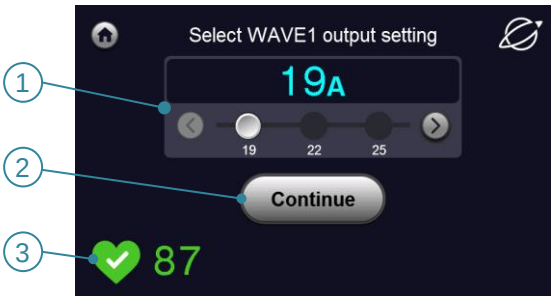
The Cardiac Monitor Linking Screen provides instructions for linking the cardiac monitor and the Generator. Pressing the GEN LINK button on the Cardiac Monitor touchscreen initiates the linking process. The Generator interface will automatically change to the **Energy Setting Selection Interface** when the linking process is complete.





Energy Setting Selection Interface

The Energy Setting Selection Interface is used to specify the energy that is delivered when the generator output is activated. Select between the following energy settings: 19A, 22A, or 25A. The Generator energy delivery cannot be activated from the Energy Setting Selection Screen. The Continue button must be pressed to proceed to the Treatment Delivery Interface before the Generator energy can be activated.

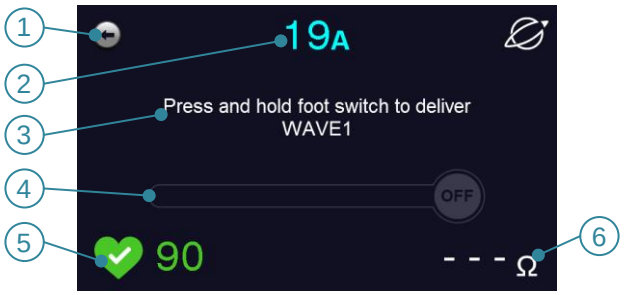


Symbol	Description
1. Energy Setting Selector	Use the arrow buttons or slider to select the energy delivery setting of the Generator. **Energy Setting** / **Complete energy delivery duration @60 bpm** 19 Amps / 4 seconds 22 Amps / 7 seconds 25 Amps / 10 seconds
2. Continue Button	Select the Continue button to proceed to the Treatment Delivery Interface.

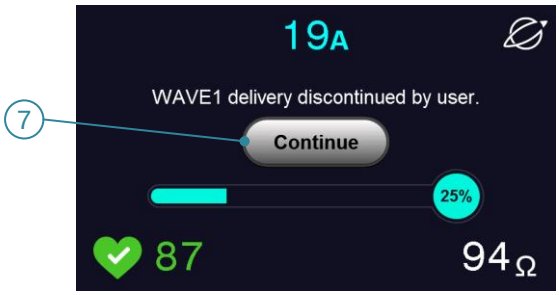
Symbol	Description
3. Cardiac synchronization and heart rate indicator	The color and shape of the Cardiac Synchronization Indicator display the state of R-wave triggers being received by the Generator.  The Generator is NOT receiving R-wave trigger signals from the Cardiac Monitor.  The Generator is receiving R-wave trigger signals from the cardiac monitor outside of the acceptable range of **45 to 150 beats per minute (bpm)**. The Generator will NOT be able to ouput energy when the heart rate is out of range.  The Generator is receiving R-wave trigger signals from the Cardiac Monitor within the acceptable heart rate range. The Generator will be able to synchronize energy delivery to the cardiac cycle when the foot switch is pressed.

Treatment Delivery Interface

The Treatment Delivery Interface provides instructions and information for energy delivery (output current). When the foot switch is pressed, the Generator initiates energy delivery that is synchronized to the QRS of the patient's cardiac cycle.



Example of interface during typical use



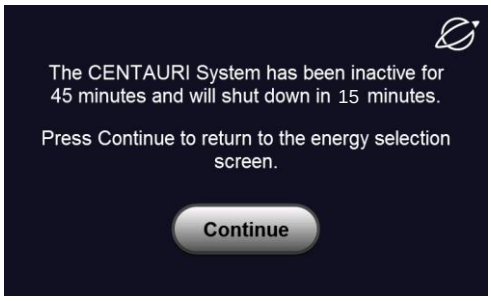
Example of interface displaying an alert message

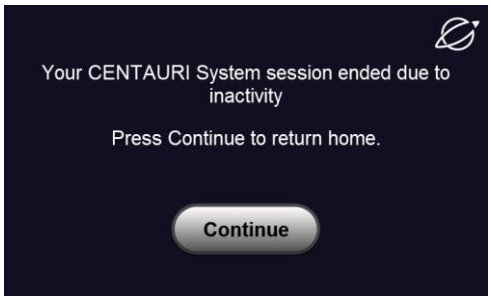
Symbol	Description
1. Back button	Select the Back Button to proceed to the Energy Setting Selection Interface to change the output setting.
2. Energy setting	Displays the selected generator energy delivery setting.
3. Message area	Provides information and instructions to the user.

Symbol	Description
4. Energy Progress Bar	The Energy Progress Bar shows the status of the energy delivered. The Energy Progress Bar may be shown in the following states:  The Generator is in a standby state and it is NOT delivering energy until the user presses the foot switch.  The Generator is delivering energy synchronized to the patient's cardiac cycle. The numbers in the progress bar indicate the relative energy delivered as compared to the specified energy to be delivered. The generator automatically discontinues the delivery of energy when Energy Progress Bar displays 100%.
5. Cardiac synchronization and heart rate indicator	Refer to the description in the Energy Setting Selection Interface.
6. Impedance	Displays the impedance measured by the Generator while delivering energy. The Generator will only measure impedance during energy delivery. This measurement will NOT be updated when the Generator is in standby. The measurement may be shown in the following states during energy delivery:  The impedance is within the acceptable range and energy delivery can still occur.  The impedance is high, but energy delivery can still occur.  The impedance is outside of the acceptable range for the Generator to deliver energy, and the Generator has terminated energy delivery. The Generator will terminate energy delivery when the impedance is outside the range of 50 Ohms to 200 Ohms.
7. Continue button	The Continue button is displayed on the touchscreen when the Generator cannot complete the energy delivery due to a detected operating condition. The user will not be able to deliver energy using the foot switch until the message is acknowledged by pressing the button.

Timeout Warning Interface

The Timeout Warning Interface notifies the user that the Generator has been inactive for at least 45 minutes. Selecting Continue will return the Generator to the Energy Setting Selection Screen. After 60 minutes of inactivity, the Generator will notify the user that the session has ended. Selecting Continue will return the Generator to the Home Interface.





Language Selection Interface

The Language Selection Interface allows for selection of the language displayed on the Generator interface.

Symbol	Description
1. Back button	Select the Back Button to go back to the Home Interface without saving the new language setting.
2. Language Selection	Displays all available languages. Select the preferred language.
3. Save Button	Selects and saves the highlighted language, and proceeds back to the Home Interface.

Fault Interface

The Generator will display the Fault Interface when it detects a fault condition. Refer to the **Troubleshooting** section for details on possible fault conditions.

Example of Fault Screen Formatting

Symbol	Descriptions
1. Fault description	Brief description of the detected fault condition
2. Fault code	A code unique to the detected fault condition
3. Recommended action	Instructions for resolving the fault condition

Messages and Audio Alerts

The Generator touchscreen displays messages in conjunction with audio alerts to communicate information to the user. The information conveyed to the user by these methods is summarized in the table below.

Displayed Message	Audio Tones	Scenario and Action
GALAXY MEDICAL CENTAURI	3 different audio tones	The Generator is in the process of booting up. **Action:** Wait for boot-up process to complete
Disconnect ablation catheter	None	The Generator has successfully completed the boot-up process. The Generator is waiting for the user to confirm that the ablation catheter is NOT connected to the system. **Action:** Ensure the catheter is not connected to the CENTAURI Connect. Disconnect the catheter output if it has already been connected. Then press the Continue button on the Generator touchscreen.
Connect ablation catheter. Then press GEN LINK on the Cardiac Monitor	None	The Generator has successfully completed internal tests. The ablation catheter can now be connected to CENTAURI Connect. Additionally, the Generator is waiting for a signal from the Cardiac Monitor to link the two pieces of equipment. **Action:** Connect the ablation catheter to CENTAURI Connect. Press the GEN LINK touchscreen button on Cardiac Monitor.
Select WAVE1 output setting.	None	The Generator is waiting for the user to select the energy delivery setting via the touchscreen interface. **Action:** Select the appropriate energy setting. Press Continue to proceed to the Treatment Delivery Interface

Displayed Message	Audio Tones	Scenario and Action
Low heart rate (<45 bpm). Check Cardiac Monitor.	None	The patient heart rate is slower than the acceptable range for energy delivery. **Action:** Ensure the patient's ECG signal is displayed on the Cardiac Monitor. If not, check that all ECG leads are securely attached to an ECG electrode on the patient's skin and that the ECG patient cable is connected to the Cardiac Monitor.
High heart rate (>150 bpm). Check cardiac monitor.	None	The patient heart rate is faster than the acceptable range for energy delivery. **Action:** Wait for the patient heart rate to decrease below 150 bpm before pressing the foot switch to activate the Generator energy.
Press and hold foot switch to deliver WAVE1.	None	The Generator is ready to deliver energy when the foot switch is pressed. **Action:** After the catheter is positioned in the heart, press and hold the foot switch to deliver energy to the target tissue.
Release foot switch.	None	The foot switch has not been released since the last energy activation. **Action:** Stop pressing the foot switch.
Preparing to deliver WAVE1. Continue to hold foot switch	Steady/constant tone	The Generator is charging the internal circuitry in preparation of delivering energy. **Action:** Continue to hold the foot switch. The Generator will automatically start delivery of energy when the internal circuitry of the Generator is charged.
WAVE1 delivery in process. Continue to hold foot switch	Beeping	The Generator is in the process of delivering energy. **Action:** Continue to hold the foot switch. The Generator will automatically stop the delivery of energy after the expected energy has been delivered.
Low heart rate (<45 bpm). Continue to hold foot switch	Beeping	The Generator is receiving an R-wave trigger signal from the Cardiac Monitor with a heart rate that is lower than the acceptable range during the delivery of energy. The Generator has temporarily paused energy delivery and is waiting for the heart rate to be within the acceptable range. **Action:** Continue to hold the foot switch. The Generator will automatically resume energy delivery when the heart rate is within the acceptable range.

Displayed Message	Audio Tones	Scenario and Action
High heart rate (>150 bpm). Continue to hold foot switch	Beeping	The Generator is receiving an R-wave trigger signal from the cardiac monitor with a heart rate that is higher than the acceptable range during the delivery of energy. The Generator has temporarily paused energy delivery and is waiting for the heart rate to be within the acceptable range. **Action:** Continue to hold the foot switch. The Generator will automatically resume energy delivery when the heart rate is within the acceptable range.
WAVE1 delivery complete.	Activation completed tone	The Generator has completed delivery of energy and has automatically stopped the energy output. **Action:** Release the foot switch. Follow the catheter IFU to perform additional system activations, as necessary.
No cardiac trigger detected. Check Cardiac Monitor.	Activation terminated tone	The Generator did NOT deliver energy because it is not receiving synchronization trigger signals from the cardiac monitor. **Action:** Ensure patient's ECG signal is displayed on Cardiac Monitor. If ECG signal is not displayed, check that all ECG leads are securely attached to an ECG electrode on the patient's skin and that the ECG patient cable is connected to the Cardiac Monitor. Press Continue button to acknowledge message and proceed with additional system activations.
Low Impedance (<50 Ohms)	Activation terminated tone	The Generator has stopped the delivery of energy because a low impedance environment was detected**.** **Action:** Visually inspect all cables for damage and replace any damaged cables. Ensure the catheter cable and dispersive electrode cable are not in contact. Press Continue button to acknowledge message and proceed with additional system activations. Refer to **Troubleshooting** section if this message appears repeatedly.

Displayed Message	Audio Tones	Scenario and Action
High Impedance (>200 Ohms)	Activation terminated tone	The Generator has stopped the delivery of energy because a high impedance environment was detected**.** **Action:** Ensure the catheter has been advanced to the target ablation area and the dispersive electrode is well adhered to the patient. Also, ensure all catheter and dispersive electrode connections are secure. Press Continue button to acknowledge message and proceed with additional system activations. Refer to **Troubleshooting** section if this message appears repeatedly.
WAVE1 delivery discontinued by user	Activation terminated tone	The Generator stopped energy delivery when the user released the foot switch. **Action:** Press Continue button to acknowledge message and proceed with additional energy delivery.
Not able to synchronize. Check Cardiac Monitor	Activation terminated tone	The Generator stopped energy delivery because of an out-of-range R-wave trigger signal from the Cardiac Monitor that did NOT resolve within 20 seconds. **Action:** Ensure patient's ECG signal is displayed on the Cardiac Monitor and is 45 to 150 bpm. If ECG signal is not displayed, check that all ECG leads are securely attached to the ECG electrodes on the patient's skin and that the ECG patient cable is connected to the Cardiac Monitor. Press Continue button to acknowledge message and proceed with additional system activations.
The CENTAURI System has been inactive for 45 minutes and will shut down in 15 minutes. Press Continue to return to the Energy Setting Selection Screen.	Timeout warning tone	The Generator has been inactive for at least 45 minutes. **Action:** Press Continue button to return to the Energy Setting Selection Screen and continue the procedure.
The CENTAURI System session ended due to inactivity. Press Continue to return to the Home Interface.	Timeout warning tone	The Generator has been inactive for 60 minutes. **Action:** Press Continue button to return to the Home Interface.
Fault	Steady/constant tone lasting 10 seconds	The Generator has detected an internal issue and is not operable. The Generator will show the Fault message indefinitely. **Action:** Refer to the **Troubleshooting** section for diagnosing Fault conditions.

6. System Setup

Prior to initial use of the CENTAURI System, the system should be unpacked and setup by qualified GALAXY Medical personnel according to the typical setup as shown in the System Connection Diagram.

WARNING: Do not use the CENTAURI System if there are any signs of damage to any of its components. Visually inspect all components and verify cables are not damaged.

WARNING: Do not substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by GALAXY Medical. Doing so could potentially damage the system or cause injury

WARNING: Only use the cardiac monitor supplied with the CENTAURI System. Use of other cardiac monitors may result in patient injury.

WARNING: Do not connect a signal source other than the GALAXY Medical-supplied Cardiac Monitor to the Generator.

System Connection Diagram

See the CENTAURI Connect User Manual for a full system diagram.

System Power-on Self-test

1. Complete the **Pre-Procedure Power-On Sequence** as specified in the **System Operation** section to confirm the system has been set up correctly.

Electrical Safety Inspection

As applicable, follow any site and / or country specific requirements for equipment qualification for use within the facility prior to use. See the **Electrical Safety Inspection** section for recommended guidance and testing specific to on-site electrical safety testing.

7. System Operation

Pre-Procedure Power-On Sequence

Complete the following steps prior to preparing the patient for the cardiac ablation procedure and any time the Generator is turned off during a procedure.

WARNING: Power on Generator and allow completion of self-test prior to preparing the patient for the ablation procedure. If the Generator does not perform as expected during the power on sequence, do not use the Generator and contact a GALAXY Medical representative.

WARNING: When powering on the Generator and preparing it for use, do NOT connect the catheter to the CENTAURI Connect. If the catheter is connected to the Generator while preparing the device for use, injury to the operator or the patient could happen.

1. If the Generator is not already powered on, turn the power switch on the rear panel of the Generator to the On | position. Confirm the touchscreen illuminates and the speaker plays audio tones for approximately 3 seconds.
2. Ensure the catheter is not connected to the CENTAURI Connect before pressing the Continue button on the Generator touchscreen.
3. The Generator will then display the message indicating the “Cardiac monitor is not linked.”
4. Press the Power On/Standby switch on the front of the Cardiac Monitor. The patient’s ECG signal should appear on the display (signal will not be present if patient is not connected).
5. Press the GEN LINK button on the upper left corner of the Cardiac Monitor touchscreen. The Generator display should change to the Energy Setting Selection Interface, which indicates the Cardiac Monitor was successfully linked with the Generator (an R-wave trigger signal has not been detected from the Cardiac Monitor as yet).

Pre-Procedure Preparation

Perform the following steps to prepare the patient prior to activating energy delivery. When connecting cables to the Generator, avoid draping cables over the patient or other leads.

WARNING: For optimum safety, ensure the patient is not wearing any jewelry to avoid complications from possible current leakage.

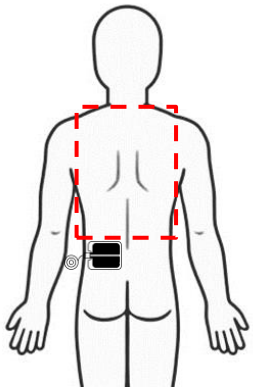
WARNING: Do not use sharp towel clips or metal instruments to attach cables to drapes. Sharp metal clips can damage electrical cables or provide an unwanted point of contact with the patient's skin. Overlapping electrical wire around a metal clip creates an electrical transformer that can cause a hazard and may ignite drapes.

WARNING: Cables should never be wrapped around metal instruments, as the current running through them can pass into the metal instrument and may result in harm to the patient and/or operator.

1. Place the foot switch in an area on the floor such that the operator can press the foot switch when ready to deliver energy.

WARNING: Use caution when walking around the foot switch and foot switch cable to avoid injury.

2. Place the dispersive electrode on the patient’s lower back, outside of the EAM system’s magnetic field frame (if applicable, shown with a red, dashed line below) and away from any EAM system magnetic sensor patches, as best as possible. If necessary, shave area for good contact.



WARNING: Do not adhere the dispersive electrode in contact with sensitive electronic equipment (e.g., EAM electrodes, patches, or magnetic sensors). The electrical output of the Generator may interfere with the readings/measurements of the equipment.

WARNING: Do not deliver energy if the dispersive electrode is not securely affixed on the patient in accordance with the manufacturer’s instructions. Do not apply the dispersive electrode where fluid may pool. A loosely or improperly connected dispersive electrode may result in harm to the patient and/or operator. Loss of safe contact between the dispersive electrode and the patient will not result in an auditory alarm.

WARNING: If a patient has any metal implants, place the dispersive electrode on the skin away from any metal orthopedic implant.

WARNING: Do not touch the dispersive electrode while the generator is delivering energy.

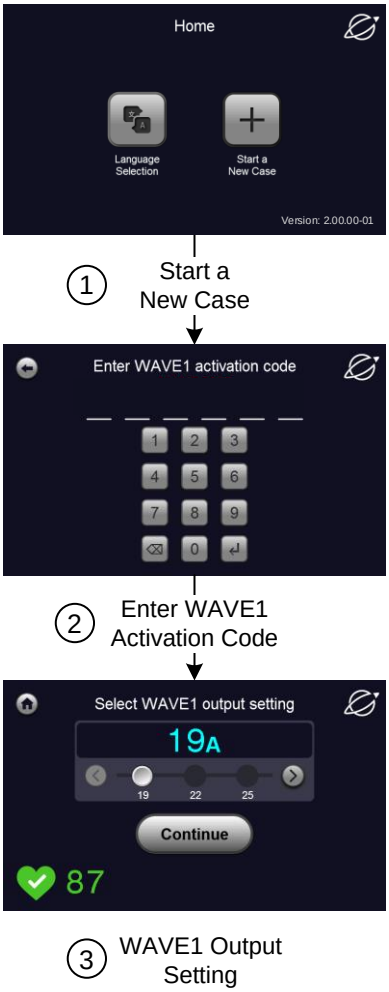
3. Plug the dispersive electrode into the appropriate receptacle on the front panel of the Generator.
4. Prepare each ECG electrode site and apply the ECG electrodes to the patient using standard technique.
5. Attach each ECG lead from the Cardiac Monitor to the appropriate ECG electrode.

Setup the CENTAURI Connect per the CENTAURI Connect User Manual.

Delivering Energy

Refer to the IFU of the cardiac ablation catheter for clinical procedure steps necessary to prepare, insert, and place the catheter for energy delivery. A constant low flow rate is required for irrigated catheters. See the table below for more information.

This section describes the sequence of operations for delivering energy. Refer to the **Messages and Audio Alerts** section of this user manual for a description of other informational messages that may be displayed during energy delivery.



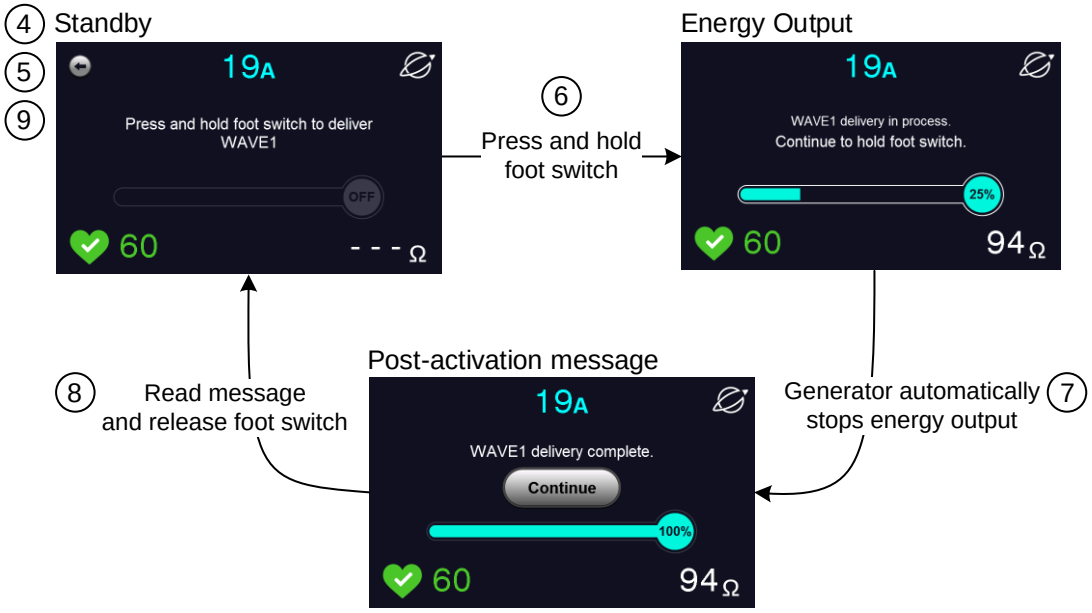
1. From the Home Interface, select Start a New Case.
2. Enter the WAVE1 Activation Code provided by Galaxy Medical.
   Note: *Each WAVE1 Activation Code expires after 60 minutes of Generator inactivity. See Timeout Warning Interface Section.*

WARNING: The selected energy delivery setting should be as low as possible for the intended purpose.

3. Select the energy delivery setting on the Generator touchscreen. The following table describes the available settings.

Energy setting	Energy delivery duration	Typical application duration @60 bpm*	Irrigation flow rate for procedure
19A	1.4ms	4 seconds	≥4ml/min
22A	2.4ms	7 seconds	≥4ml/min
25A	3.4ms	10 seconds	≥4ml/min

*The cardiac synchronization function of the CENTAURI System may affect the typical application duration required to complete PEF delivery at each energy setting. These functions may include patient heart rate, heart rate variability, and synchronization detection. The total energy delivered is not affected by these factors.



4. Prior to delivering energy, the Generator is in Standby state. The cardiac synchronization icon (bottom left of screen) should be flashing green.

5. Ensure the catheter is in position and ready for energy delivery.

WARNING: Do not deliver energy if the dispersive electrode is not securely affixed on the patient in accordance with the manufacturer's instructions. Do not apply the dispersive electrode where fluid may pool. A loosely or improperly connected dispersive electrode may result in harm to the patient and/or operator. Loss of safe contact between the dispersive electrode and the patient will not result in an auditory alarm.

6. Press and hold the foot switch to deliver energy. The Generator will automatically charge the internal circuitry, followed by the delivery of energy.

7. Wait for the Generator to automatically terminate energy delivery once the pre-specified amount of energy has been delivered, then release the foot switch.

   ***Note**: The user can also terminate energy delivery, by releasing the foot switch, at any time during the delivery of energy.*

8. Read and acknowledge any messages shown on the Generator display after the completion of the system activation. Some messages may require the user to press the Continue button on the Generator touchscreen.
9. Following the message acknowledgement, the Generator is in Standby state and the steps listed above can be repeated as necessary to deliver energy to additional treatment sites.

Post Procedure

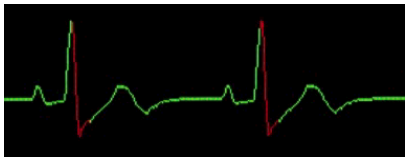
Perform the following steps after the procedure is complete.

1. Disconnect the dispersive electrode from the front panel receptacle of the Generator.
2. Remove the dispersive electrode from the patient.
3. Disconnect the ECG leads from the ECG electrodes.
4. Remove the ECG electrodes from the patient.
5. Press the Power On/Standby ⏻ switch on the front of the Cardiac Monitor to power off the Cardiac Monitor.
6. Switch the power toggle on the rear of the Generator to the Off ◯ position.
7. Refer to the **Cleaning and Maintenance** section for cleaning of the CENTAURI System components.

8. Troubleshooting

The following table provides a list of problems which may occur during routine operation. If a problem is encountered that is not listed here or cannot be addressed with the suggested actions, contact a GALAXY Medical representative.

Problem	Troubleshooting Steps
The Generator display does not illuminate when the power switch is turned on.	• Ensure Generator is connected to a working electrical outlet. • Unplug the power cord and check the fuses within the power switch module on the rear panel. If the fuse is blown, refer to **Maintenance** section for information on replacing fuses.
No audio tones are heard when the Generator powers on.	• Ensure the Generator is connected to a working electrical outlet. • Unplug the power cord and check the fuses within the power switch module on the rear panel. If fuse is blown, refer to **Maintenance** section for information on replacing fuses.
The Generator is stuck on the screen that states “Connect ablation catheter. Press GEN LINK on the cardiac monitor.”	• Ensure the R-wave trigger interconnect cable is connected between the Cardiac Monitor and the Generator. • Press the “GEN LINK” button on the Cardiac Monitor touchscreen.
Generator does not respond to the foot switch press.	• Ensure the foot switch is securely connected to the CENTAURI Connect. • Ensure the digital signal interconnect cable is connected between CENTAURI Connect and the Generator (ref **the CENTAURI Connect User Manual for full connection details**).
A red heart is displayed on the Generator touchscreen.	• Ensure the patient’s ECG signal is displayed on the Cardiac Monitor. If not, check that all ECG leads are securely attached to the ECG electrodes on the patient’s skin and that the ECG patient cable is connected to the Cardiac Monitor. • Ensure the R-wave trigger interconnect cable is connected between the Cardiac Monitor and the Generator.

Problem	Troubleshooting Steps
A yellow flashing heart is displayed.	• Ensure the heart rate displayed on the cardiac monitor is between 45bpm and 150 bpm. • Ensure the Cardiac Monitor is providing output triggers as indicated by a red tracing on the ECG signal as shown below. If a trigger event (red tracing) is not displayed during each QRS of the cardiac cycle, select a different lead and check if the triggering on the cardiac monitor becomes more regular.  • Ensure all ECG electrode pads are well adhered to the patient's skin. If not, follow the ECG electrode IFU to apply new electrodes.
Generator repeatedly displaying "High impedance (>200 Ohms)." message	• Ensure the catheter output is connected between the Generator and CENTAURI Connect. • Ensure the catheter is connected to CENTAURI Connect. • Ensure the dispersive electrode is connected to the front panel of the Generator. • Ensure the dispersive electrode is well adhered to the patient's skin. If not, apply a new dispersive electrode. • Ensure the catheter has been advanced to the target ablation area and the distal tip electrode has exited the sheath.
Activating the Generator (i.e., pressing the foot switch to deliver energy) causes a critical error message or mapping issues on the EAM system	• Ensure the dispersive electrode is not in contact with any of the mapping electrodes adhered to the patient. • Move the dispersive electrode further from mapping electrodes or mapping magnets. • Reset EAM amplifier and system, if required
The WAVE1 Activation Code is not accepted.	• Ensure the correct WAVE1 Activation Code has been entered into the Generator. • Ensure the WAVE1 Activation Code has not been previously entered for another procedure. • If the error persists, use a new WAVE1 Activation Code and contact GALAXY Medical.
Generator consistently displays a FAULT message.	• See following section of User Manual for troubleshooting FAULT conditions.

Fault Conditions

A fault condition occurs when the Generator detects an incorrect connection or setting, a self-test failure, or an internal circuitry failure. When a fault condition is detected, the Generator will stop energy delivery if the Generator is in the process of delivering energy and display a message describing the fault and any additional information needed by the user to address the condition.

The following table provides a description of all fault conditions and suggested actions for addressing the condition. Fault conditions can only be reset by turning off power. Prior to turning off power, record the fault code number and software version. If a fault condition persists, contact GALAXY Medical.

Code	Fault Description	Recommended Action
F1	Watchdog timer fault	Turn off unit and turn back on. Contact GALAXY Medical if message reappears.
F2	RAM test fault	
F3	SW image corrupt	
F4	Discharge fault	
F5	Charge fault	
F6	Internal fault	
F7	Internal fault	
F8	Internal fault	
F9	Internal fault	
F10	Stuck foot switch	Ensure foot switch is not pressed. Turn off unit and turn back on. Contact a GALAXY Medical representative if message reappears.
F11	Calibration data corrupt	Turn off unit and turn back on. Contact a GALAXY Medical if message reappears.
F12	Self-test fault	
F13	Flash driver fault	
F14	Measurement packet fault	
F15	Therapy packet fault	
F16	Internal fault	
F17	Internal fault	
F18	Internal fault	
F19	Internal fault	
F20	Internal fault	
F21	Internal fault	
F22	Data Write Error	
F23	Internal fault	
F24	Internal fault	
F25	Internal fault	
F26	Internal fault	

9. Cleaning and Maintenance

Cleaning

Clean components of the CENTAURI System per the instructions below.

CAUTION: Do not use steam or heat sterilization to clean any system component. Do not soak any component in disinfectants or fluids. Do not allow liquid to enter into any of the electrical connections or the interior of any component.

Generator and Cardiac Monitor

1. Disconnect the unit from the wall outlet before cleaning.
2. Wipe the exterior surface of the unit with 70 % to 90 % isopropyl alcohol or an equivalent alcohol-based wipe.
3. Allow all surfaces and connections to dry before reconnecting the Generator.

Foot Switch

1. Wipe the exterior surface with 70 % to 90 % isopropyl alcohol or an equivalent alcohol-based wipe.
2. Care should be taken not to allow fluid inside the foot switch connector.

Cables

1. Disconnect all cables from the system components.
2. Wipe down all cables with 70 % to 90% isopropyl alcohol or an equivalent alcohol-based wipe.
3. Allow cables to dry before reconnecting.

Maintenance

Do not perform maintenance or service when the CENTAURI System is in use with a patient.

Routine Maintenance

The CENTAURI System does not require routine maintenance or servicing.

Electrical Safety Inspection: EN 62353

Follow test instructions in the appropriate area of the standard. The acceptable limits (normal condition) for the CENTAURI System can be found in Table 1 of Appendix A.

Fuse Replacement

The Generator has a fuse that can be replaced in the field by qualified personnel. Replace the fuse with the same value fuse (see table below). Replacing with incorrect fuse rating could damage the Generator or create a fire hazard. To replace the fuse, open the fuse access panel on the back of the Generator, remove fuse housing with fuse, and replace the fuse. Reinstall the fuse housing and close the fuse access panel.

Component	Replacement Fuses
CENTAURI Generator	6.3A H 250V

Refer to Cardiac Monitor user manual for fuse replacement.

Service and Returns

Should service or repair be necessary, contact a GALAXY Medical representative.

End of Life Disposition

Do not dispose of CENTAURI System components in the unsorted municipal waste stream. Follow local regulations for proper disposal.

10. Technical Specifications

Energy Output	33A maximum
Impedance Range	50 ohms – 200 ohms (±5%), 1 ohm resolution
Heart Rate	0 bpm – 220 bpm (±5%), 1 bpm resolution
Input Power	100 V - 240 V ~, 50 Hz - 60 Hz universal power supply, 625 VA input power rating. The power cord is used for removing AC mains power from the unit.
Dimensions	45.7cm wide x 21.6cm high x 49.5cm deep
Weight	13.7kg
Rear Controls	Line Power On/Off
Display	Front panel, touch screen display capable of displaying graphics, messages, activation information and receiving touch screen input from the operator.
Connections	AC Line power, foot switch, synchronization input, catheter connector, dispersive electrode connections, and electrogram output
Classifications	Class 1, Defibrillator Proof - Type CF, IPX0. The CENTAURI System is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Applicable general test and electrical safety requirements for Class 1 protection of ANSI AAMI ES60601-1, EN 60601-1, and CAN/CSA C22.2 No. 60601-1. Safety requirements of high-frequency surgical equipment of ANSI AAMI IEC 60601-2-2 and EN 60601-2-2. Electromagnetic compatibility (EMC) requirements of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.

Environmental Conditions

	Transport or Storage	**Operating**
Temperature	-29 °C to +60 °C	15 °C to 40 °C
Humidity (non-condensing)	30 % to 85 %	30 % to 70 %
Atm. Pressure	600 hPa to 1060 hPa	700 hPa to 1060 hPa

Replacement Part Numbers

WARNING: Do not substitute cables, equipment, or disposables with other cables, equipment, or disposables not provided by GALAXY Medical. Doing so could potentially damage the system or cause injury.

Component	Part Number
CENTAURI Generator	GTI-00021-01
Cardiac Monitor	GTI-00026

Essential Performance Characteristics

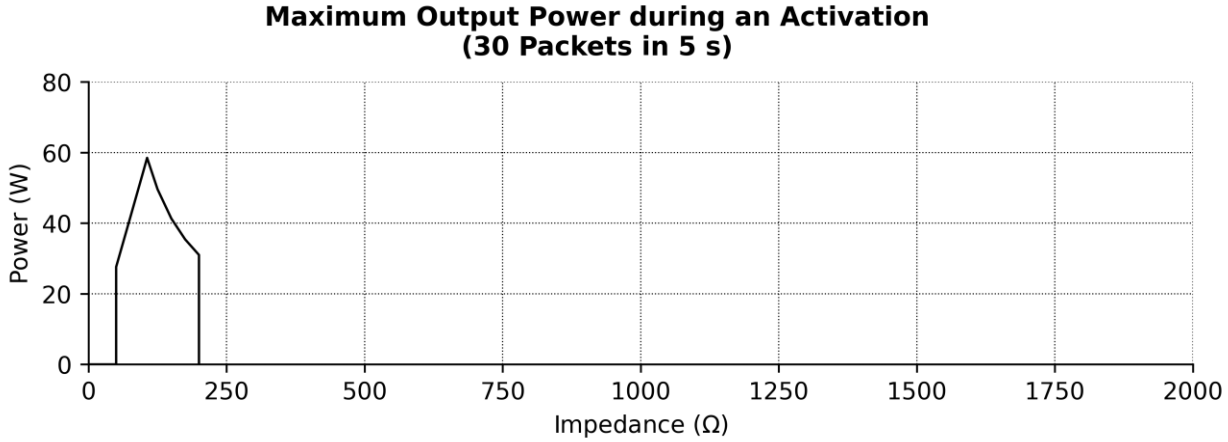
The characteristics related to safety (i.e., Essential Performance) of the CENTAURI System include the following:

- The software must correctly deliver energy per the defined energy output scheme.*
- The Generator hardware must function safely, properly and prevent the user from altering the software. This includes proper function of:
    - hardware-related and software POST activities & fault recognition;
    - LCD touch screen functionality and foot switch controls;
    - the Generator watchdog timer;
    - audio alerts;
    - treatment parameter information on the display is used for treatment determination – transient loss of display readability or the display of unintended characters outside of the treatment parameter fields (e.g., due to interference) would not impact the safety of the procedure; permanent loss of display could result in a terminated procedure but would not result in unacceptable risk to the patient;
    - safety features associated with minimizing the risk of shock to the user and patient.

* “software must correctly deliver energy per the defined energy output scheme” means that the attributes of the high-frequency pulsed energy output meet the defined performance criteria of the system.

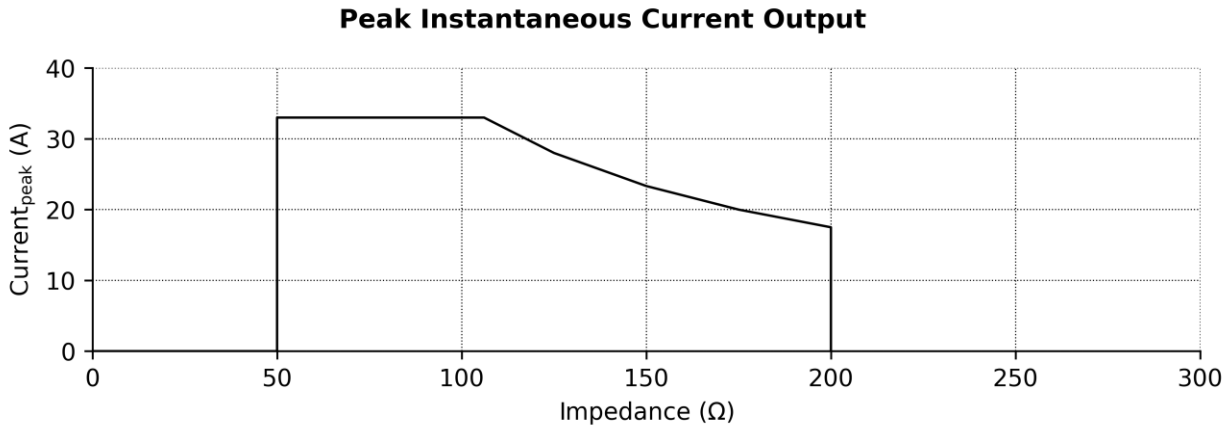
Power Output Diagram

The figure below displays the maximum possible power delivery of the Generator over the specified range of impedance. The maximum possible power delivery is defined as an output of 30 packets synchronized to a 90bpm (i.e., 1.5 Hz trigger signal), which equates to an output of 30 packets in 5 seconds.



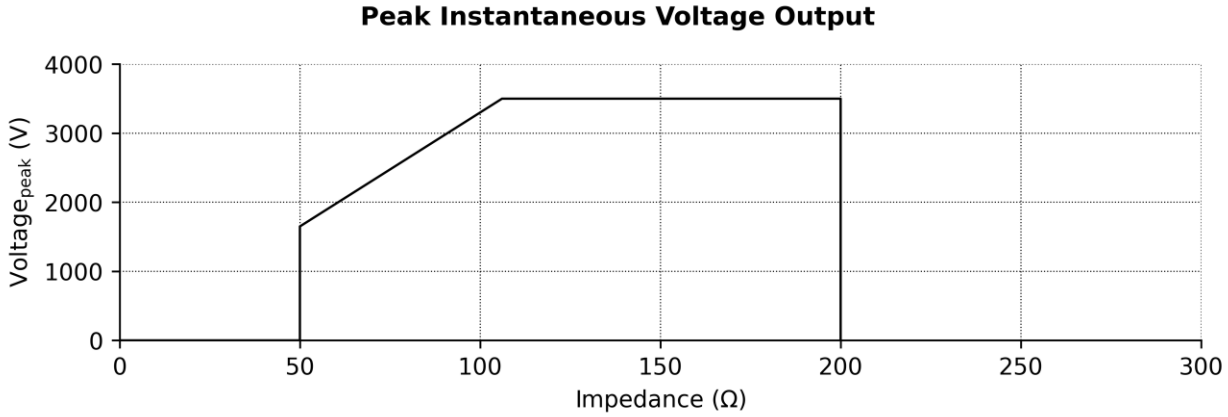
Current Output Diagram

The figure below displays the maximum instantaneous current output from the Generator over the specified range of impedance.



Voltage Output Diagram

The figure below displays the maximum instantaneous voltage output from the Generator over the specified range of impedance.



Electromagnetic Compatibility (EMC)

The CENTAURI System has been verified to the electromagnetic compatibility requirements of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.

This equipment uses non-ionizing radiation for treatment. Interference produced by the operation of high-frequency surgical equipment, such as the Generator, may adversely influence the operation of other electronic medical equipment such as monitors and imaging systems and special precautions should be taken. Portable and mobile RF communications equipment (e.g., cellular phones) can affect electronic medical equipment. The CENTAURI System should be setup and put into service according to the EMC information provided in this section.

The CENTAURI System is suitable for use in all establishments other than domestic (i.e., residential) and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

***Note**: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.*

If any of the essential performance characteristics are lost or degraded due to electromagnetic disturbances, the user may see any of the following conditions:

- Distortion and / or lock-up of the generator front panel display screen
- Distortion and / or lock-up of the cardiac synchronization monitor

Warnings

- The CENTAURI System is intended for use by healthcare professionals only. This device may cause radio interference and disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the CENTAURI System or shielding the location. Interference with electronic medical equipment such as monitors and imaging systems is usually resolved or minimized by rearranging the cables such that the unit cables do not overlap with the cables from the monitoring equipment.
- Use of the device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to confirm that they are operating properly.
- Use of components and cables other than those specified and provided by GALAXY Medical could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the device including cables specified by the manufacturer. Otherwise, degradation of the performance of the device could result.

CENTAURI Generator Cables

Cable	Maximum Length
AC Power Cable	2.5 m

Guidance and Manufacturer's declaration – Electromagnetic Emissions

The CENTAURI System is suitable for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11 (EN55011)	Group 1	When Generator is in the STANDBY state, radio frequency [RF] energy is only used for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment. When Generator is delivering energy, the device must emit electromagnetic energy to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11 (EN55011)	Class A	The CENTAURI System is suitable for use in all establishments other than domestic (i.e., residential) and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions EN 61000-3-2	Class A	
Voltage fluctuations / flicker emissions EN 61000-3-3	Complies	

Guidance and Manufacturer's declaration – Electromagnetic Immunity

The information provided within this section is applicable to the CENTAURI System.

The CENTAURI System has been verified and found to be in compliance with the immunity standards at the test levels specified below. It is suitable for use in the electromagnetic environment specified below. For maintaining the Essential Performance of the device with regards to electromagnetic disturbances, the user must ensure it is used in such an environment.			
Immunity test	**Level Required**	**Level Tested**	**Electromagnetic environment – guidance**
EN 61000-4-2 Electrostatic discharge (ESD)	±8 kV contact ±15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
EN 61000-4-3 Radiated, radio-frequency, electromagnetic field immunity	80 MHz - 2700 MHz, 3 V/m, 80 % 1 kHz AM Various per Table 9 of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.	80 MHz - 2700 MHz, 3 V/m*, 80 % 1 kHz AM As per Table 9 of ANSI AAMI IEC 60601-1-2 and EN 60601-1-2.	Radio frequency and electromagnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
EN 61000-4-4 Electrical fast Transient/burst	For AC / DC power ports: ±2 kV ±1 kV for signal ports	±2 kV for AC power ports Equipment does not have DC power ports therefore no test. Equipment does not have cables > 3 m connected to signal ports	Mains power quality should be that of a typical commercial or hospital environment.

EN 61000-4-5 Surge	For AC / DC power ports: ±1 kV differential mode ±2 kV common mode 1.2/50 µs	For AC power port: ±1 kV differential mode ±2 kV common mode 1.2/50 µs Equipment does not have DC power ports therefore no test.	Mains power quality should be that of a typical commercial or hospital environment.
EN 61000-4-6 Conducted, radio-frequency immunity	For AC / DC power ports, signal ports, and patient ports: 0.15 MHz - 80 MHz, 3 V_{rms}, 80 % 1 kHz AM, 6 V_{rms} in ISM/Amateur bands	For AC power, signal, and patient ports: 0.15 MHz - 80 MHz, 3 V_{rms}*, 80 % 1 kHz AM, 6 V_{rms} in ISM/Amateur bands Equipment does not have DC power ports therefore no test.	Radio frequency and electromagnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
EN 61000-4-8 Power frequency magnetic field	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
EN 61000-4-11 Voltage dips, short interruptions, and voltage variations on power supply input lines, U_T = AC 230V/50Hz	>95 % dip in U_T for 0.5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles >95 % dip in U_T for 250 cycles	>95 % dip in U_T for 0.5 cycle 60 % dip in U_T for 5 cycles 30 % dip in U_T for 25 cycles >95 % dip in U_T for 250 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CENTAURI System requires continued operation during mains power interruptions, it is recommended that the CENTAURI System is powered from an uninterruptible power supply.

* The level tested exceeds the test level required by the standard. Testing was performed at a higher severity level to meet the requirements of other tests.

Appendix A

Electrical Safety Tests (Optional)

Only qualified individuals should perform electrical safety testing. Measurements should be made per local electrical safety standards.

Note: *These tests are not required for planned preventative maintenance*

Table 1. Acceptable Safety Test Limits (normal condition) per EN 62353

Measurement	Limit
Protective earth resistance (resistance between Mains Plug protective earth connector and protectively earthed accessible conductive parts)	0.3 ohm
Earth (or Equipment) leakage current (NFPA99/120VAC operation)*	0.3 mA (300 µA)
Earth (or Equipment) leakage current (all other AC operating voltages)**	0.5 mA (500 µA)
Enclosure (or Touch) leakage current	0.1 mA (100 µA)
Patient (or Applied Part) leakage current	0.01 mA (10 µA)

* Applicable only for United States.

** Applicable for all geographies outside of the United States.

GALAXY MEDICAL

CE 0459

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