Aliya™ System

User Manual

Model GTI-00025

℞ *Only*

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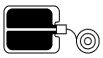
List of Symbols

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

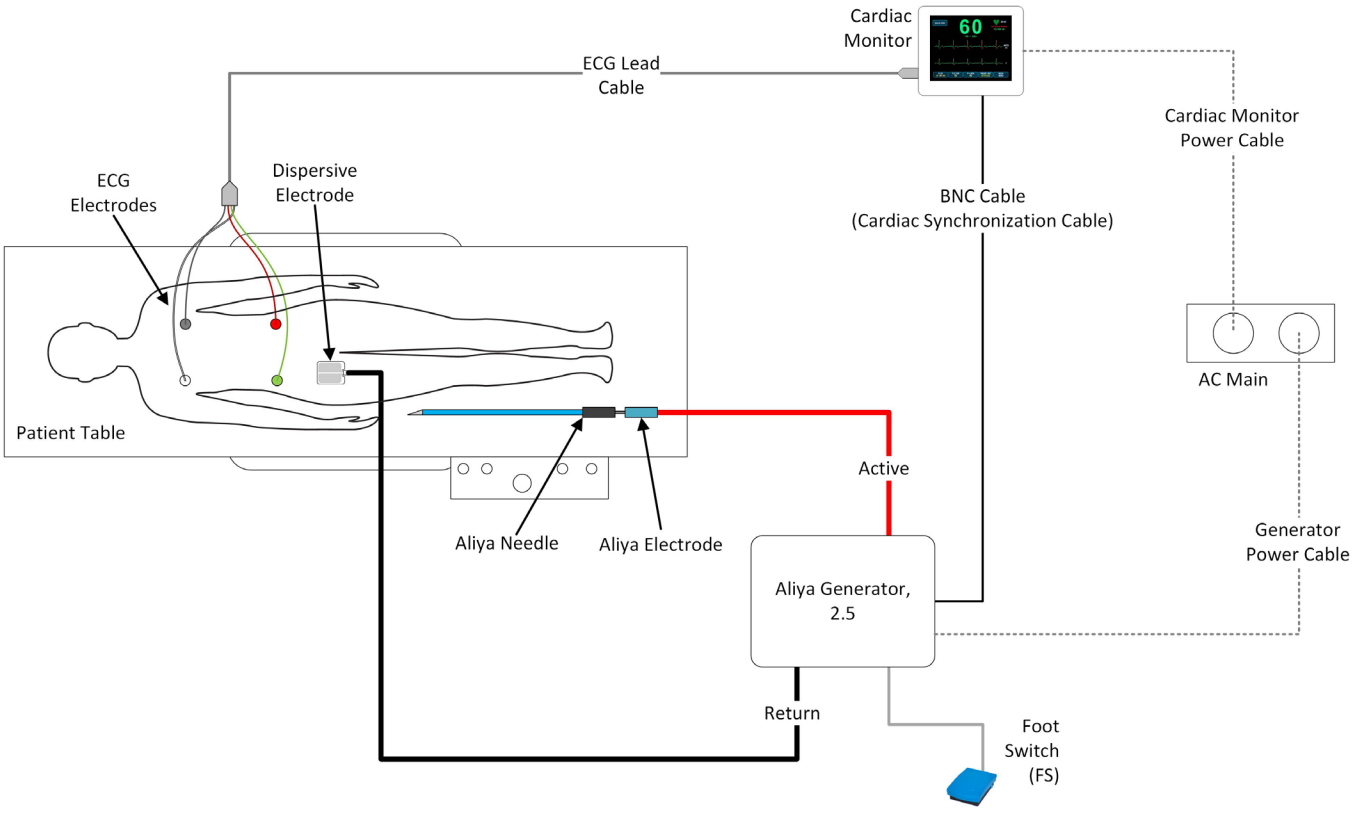
	Catalogue number		Defibrillator proof type CF applied part
	Serial number		Electric shock hazard
	Follow instructions for use		Dispersive electrode
	Manufacturer		Floating dispersive electrode connection for isolated patient circuit
	Date of manufacture		Foot switch
	Alternating current		Input signal
	Power On (Connect to AC mains)		Output signal
	Power Off (Disconnect from AC mains)		DO NOT use if packaging is damaged
	Potential equalization terminal		Keep dry during shipping
	Fuse information		Humidity limits during shipping
	Caution		Temperature limits during shipping
	Warning		Atmospheric pressure limits during shipping
	WEEE compliant		Prescription only
	Quantity		Not compatible with MRI

1. Introduction

1.1. System Overview

The Aliya™ System is an electrosurgical system that delivers controlled non-thermal energy via pulsed electric fields (PEF) to an electrode placed in the targeted tissue. The Aliya System is intended to be used in an Operating Room by healthcare professionals. The Aliya System consists of an Aliya Generator (Generator), an Aliya™ Ablation Device and a cardiac monitor.

The Generator is used outside the sterile field and connects to the supplied foot switch. The user controls energy delivery to the Electrode by pressing and releasing the foot switch. The Aliya Ablation Device comprises two components, the Aliya™ Needle, and the Aliya™ Electrode, which are provided as sterile, single-use devices. See the Aliya Ablation Device Instructions for Use for more details on these single-use components. See Section 4 for further description of the Aliya Generator.



2. Indication for Use

2.1. Indication for Use

The Aliya System is indicated for surgical ablation of soft tissue.

3. Safety Information

Warnings are safety instructions that, if not heeded, might lead to serious injury to patient or user or others in the use environment.

Precautions are safety instructions that, if not heeded, might lead to minor or moderate injury to patient or user or others in the use environment.

3.1. ⚠ Warnings

- Before using the Aliya System read this user manual and the Aliya Ablation Device instructions for use. Failure to follow instructions or failure to heed warnings or precautions may result in harm to patient.
- The Aliya System is for use only by qualified medical personnel trained in the use of electrosurgical devices.
- Use only Galvanize electrodes that are compatible with the Aliya Generator. Non-compatible electrodes may cause patient injury or fail to function properly.
- DO NOT use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.
- DO NOT use the Aliya System if there are any signs of damage to any of its components. Visually inspect all components and verify cables are not damaged.
- DO NOT obstruct vents on the equipment, as they are important for ventilation to prevent overheating.
- DO NOT substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by Galvanize Therapeutics. Doing so could potentially damage the system or cause injury.
- Only use the cardiac monitor supplied with the Aliya System. Use of other cardiac monitors may result in patient injury.
- DO NOT connect a signal source other than the Galvanize Therapeutics-supplied cardiac monitor to the Generator. Use of other signal sources in lieu of the Galvanize supplied cardiac monitor may result in patient injury.
- DO NOT connect the Aliya Ablation Device to the Generator when powering on and preparing the Generator for use. This could result in injury to the operator or the patient.
- 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.
- DO NOT wrap cables around metal instruments. The current running through them can pass into the metal instrument and may result in harm to the patient and/or operator.
- DO NOT deliver energy if the dispersive electrode is not securely affixed on the patient in accordance with 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 trigger an auditory alarm.
- AVOID placing the dispersive electrode on the skin near any metal implants. If a patient has any metal implants, place the dispersive electrode on the skin away from the implant.

- DO NOT reuse, reprocess, or re-sterilize the Aliya Ablation Device, patient dispersive electrode, or ECG electrodes. The Aliya Ablation Device, patient dispersive electrode, and ECG electrodes are intended for single-use only. Any reuse, reprocessing, or re-sterilization could result in device failure causing patient or user injury. Reuse, reprocessing, or re-sterilization could cause contamination of the device, which may result in patient infection.
- To avoid the risk of electric shock, the Aliya System must only be plugged into an AC mains supply outlet with a protective earth ground connection.
- DO NOT disassemble the Generator or any of its components. Modification of this equipment could result in injury to the operator or damage to the unit equipment.
- Electric shock hazard. DO NOT remove or modify 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.
- Ensure the patient does not come into contact with the Aliya Generator or metal parts that are earth grounded or have an appreciable capacitance to earth ground (for example operating table supports, etc.). Failure to do so could lead to unintended ablative effects where contact is made. The use of antistatic sheeting is recommended.
- Skin-to-skin contact (for example between the arms and body of the patient) should be avoided as it can lead to unintended ablative effects where contact is made. Use dry gauze to prevent skin-to-skin contact.
- Monitoring electrodes of any physiological monitoring equipment used on the patient should be placed as far as possible away from the intended treatment location. Needle monitoring electrodes are not recommended. Physiological monitoring equipment incorporating high frequency current limiting devices is recommended to prevent damage to equipment.
- Position the connection cables of the Aliya Ablation Device 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. Failure to do so could lead to patient injury.
- DO NOT allow fluids to pool in the body depressions and cavities before and during energy delivery. Aspirate fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.
- DO NOT touch the dispersive electrode (also known as neutral electrode, return electrode, or grounding pad) during energy delivery. Doing so may lead to injury.
- Patient injury resulting from neuromuscular stimulation is possible during energy delivery. The Aliya System has been designed to minimize the possibility of neuromuscular stimulation.
- DO NOT start the procedure if external defibrillator is not readily available as unintended cardiac arrhythmia may occur.
- DO NOT use in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.

- DO NOT place the Aliya Ablation Device near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.
- When not using the Aliya Ablation Device, place it in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- DO NOT connect adaptors to the generator during energy delivery. Doing so may result in an injury or electrical shock to the patient or operating room personnel.
- DO NOT activate the Aliya Ablation Device when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.

3.2. ⚠ Precautions

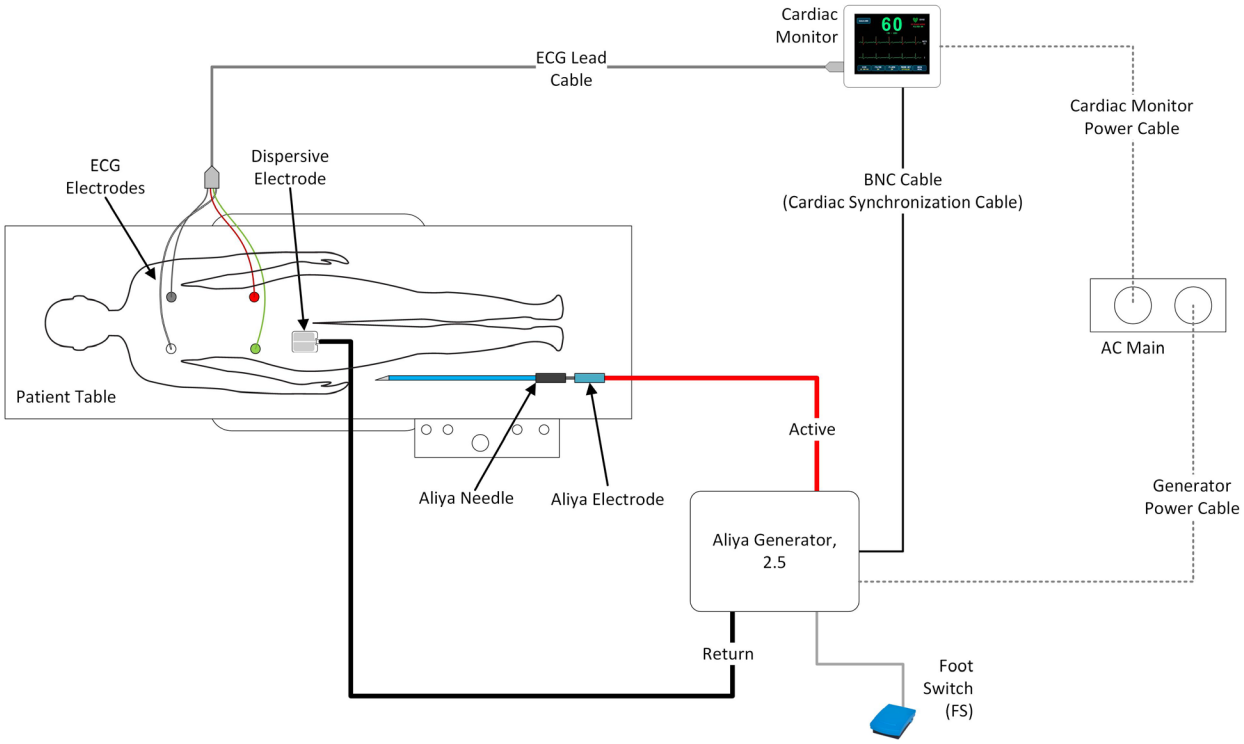
- Use caution when transporting the components of the Aliya System. Some components may be heavy for some users. Dropping a component may result in harm to the user or the component.
- Use caution when walking around the foot switch and foot switch cable to avoid injury.
- Use of the device adjacent 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.
- The Aliya 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 Aliya 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.
- A failure of the Generator could result in an unintended increase of output power.
- Use of devices and cables other than those specified and provided by Galvanize Therapeutics could result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and result in improper operation.
- Equipment connected to the external connections must comply with applicable standards. Anyone connecting such cables or devices to the Aliya Generator may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.
- Interference produced by the operation of the Aliya System may adversely influence the operation of other electronic equipment. See the Technical Specifications section for Warnings related to Electromagnetic Compatibility.
- 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.

3.3. Potential Adverse Effects

Refer to the Aliya Ablation Device instructions for use for the potential adverse effects related to use of the Aliya System.

4. System Description

4.1. System Diagram

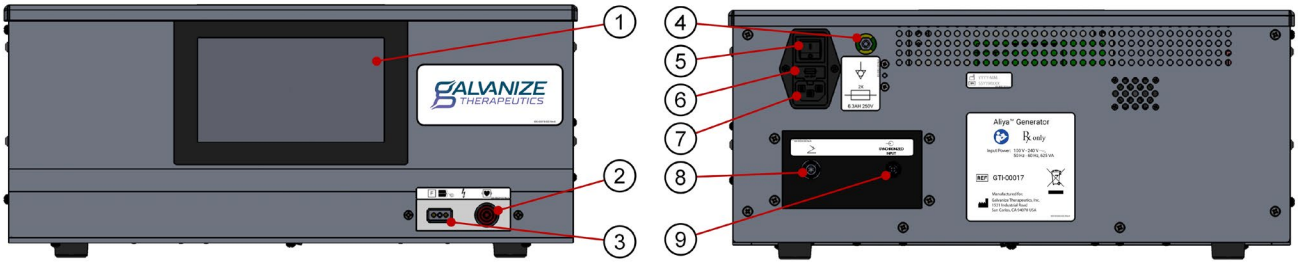


4.2. Aliya Generator

Generator

Foot Switch

Generator Power Cable



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

2. **Output (Type CF Applied Part)**: The Aliya Ablation Device cable connects to this receptacle for delivery of PEF energy to the applied part.

3. **Dispersive Electrode (Applied Part)**: The dispersive electrode connects to this receptacle and provides a return path to the generator for the PEF energy delivered to the applied part.

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. **Foot switch**: Receptacle for connecting the foot switch signal to the Aliya Connect.

9. **Synchronized Input**: Connection to the Synchronized Output signal of the cardiac monitor.

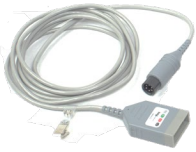
4.3. Cardiac Monitor

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

The Generator utilizes a cardiac monitor for synchronizing the delivery of energy with the patient's cardiac cycle. The Generator is designed to only be used with the Ivy Biomedical Model 7600 Cardiac Monitor (Cardiac Monitor), which is provided with the Aliya 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 output to the patient.

The Generator software includes an algorithm that interprets trigger signals from the Cardiac Monitor. The algorithm will only allow the initiation and delivery of energy output when the patient's heart rate is within acceptable limits. The following items are supplied with the Cardiac Monitor.

Cardiac Monitor



Patient Cable

Cardiac Leads

BNC Cable (Cardiac Synchronization)

Cardiac Monitor Power Cable

Refer to the user manual provided with the Cardiac Monitor for a more detailed description of each component.

4.4. Devices Sold Separately

WARNING: DO NOT substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by Galvanize Therapeutics. Doing so could potentially damage the system or cause injury.

The Aliya System is designed to work with the devices listed in the following tables. These devices are suitable for use within the patient environment.

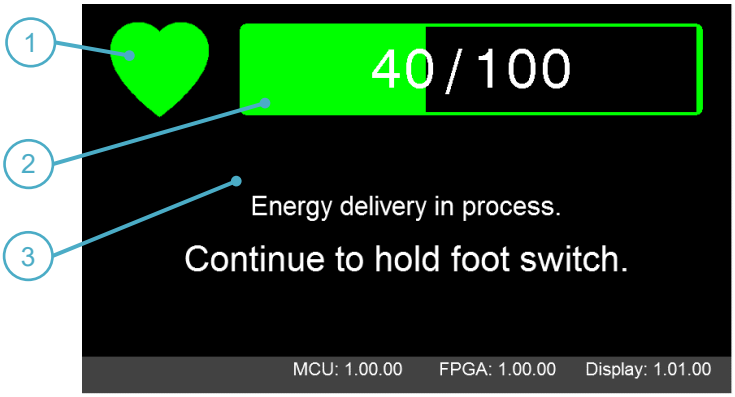
Aliya Ablation Device	Manufacturer	Manufacturer Reference
Aliya Needle	Galvanize Therapeutics	GTI-00023
Aliya Electrode	Galvanize Therapeutics	GTI-00024

Other Devices Sold Separately	Manufacturer	Manufacturer Reference
Patient Dispersive Electrode	3M	Model 9165
Set of 4 ECG Electrodes	Ivy Biomedical System, Inc.	590436 (discontinued) 590494

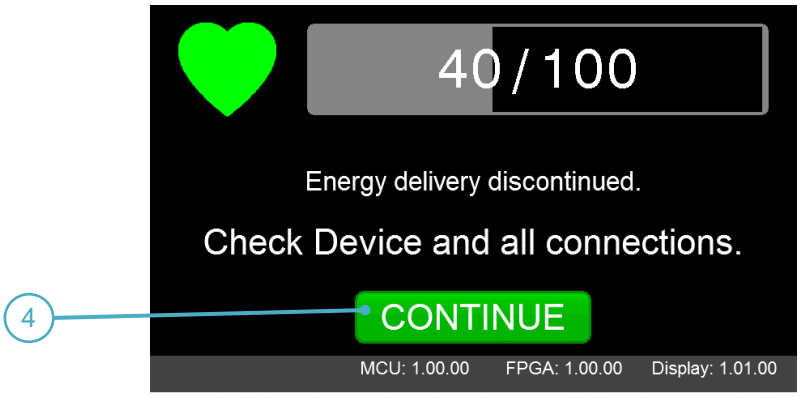
5. Touchscreen Interface

5.1. Treatment Delivery Screen

The Treatment Delivery Screen provides instructions and information for energy delivery. When the foot switch is depressed, the Generator synchronizes the delivery of short duration bursts of energy (“packets”) with the cardiac cycle of the patient.



Example of interface during energy delivery.



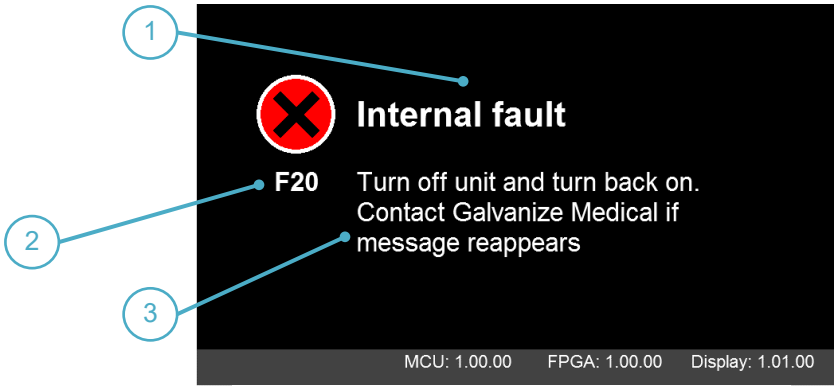
Example of interface displaying an alert message.

Tag	Symbol	Description
1	Cardiac synchronization indicator	The color and shape of the Cardiac Synchronization Indicator displays 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 irregular R-wave trigger signals from the cardiac monitor or the detected heart rate of the patient is outside of the acceptable range of 45 to 120 beats per minute. The Generator will NOT ouput packets when there is an irregular cardiac cycle or when the heart rate is out of range.  The Generator is receiving regular R-wave trigger signals from the cardiac monitor within the acceptable heart rate range (45 to 120 beats per minute). The Generator will synchronize packet delivery to the cardiac cycle when the foot switch is pressed.
2	Packet output indicator	The Packet Output Indicator is a progress bar that shows the number of packets delivered relative to the specified number of packets to be delivered. The color of the Packet Output Indicator changes when energy is being output from the Generator.  The Generator is in a standby state and it is NOT outputing energy until the user presses the foot switch.  The Generator is deliverying energy synchronized to the patient's cardiac cycle. The numbers in the progress bar indicate the number of packets that have been delivered relative to the specified number of packets to be delivered.  The Generator has discontinued energy output. The numbers in the progress bar indicate the number of packets that were delivered before output from the Generator was stopped.
3	Messaging area	Provides information and instructions to the user.

Tag	Symbol	Description
4	Continue button	The CONTINUE button is displayed on the touchscreen when the Generator cannot complete the output of the expected number of packets due to a detected operating condition. The user will not be able to activate energy output using the foot switch until the message is acknowledged by pressing the button.

5.2. Fault Screen

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



Example of interface during energy delivery.

Tag	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.

5.3. 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. See Section 8 for Troubleshooting information.

Displayed Message	Audio Tones	Scenario and User Action
Galvanize Therapeutics logo	3 audio tones increasing in pitch	The Generator is in the process of booting up. **Action:** Wait for boot-up process to complete.
Ensure device cable is NOT connected	None	The Generator has successfully completed the boot-up process. The generator is waiting for the user to confirm that the Aliya Ablation Device is NOT connected to the receptacle on the front panel. **Action:** Ensure the Aliya Electrode is not connected to the front panel of the Generator. Disconnect the Aliya Electrode if it has already been connected. Then press the CONTINUE button on the Generator touchscreen.
Cardiac monitor not linked. Press 'GALA LINK' on the cardiac monitor	None	The Generator is waiting for a signal from the Cardiac Monitor to link the two pieces of equipment. **Action:** Press the GALA LINK touchscreen button on Cardiac Monitor.
Check cardiac monitor	None	The Cardiac Monitor is not sending R-wave trigger signals to the Generator when the R-wave is detected on the patient ECG. **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.
Waiting for synchronization	None	The Generator is receiving an out-of-range R-wave trigger signal from the Cardiac Monitor. **Action:** Wait for the heart rate to come within acceptable range.
Press and hold foot switch to deliver energy	None	The Generator is receiving an R-wave trigger signal from the Cardiac Monitor indicating a heart rate that is within the acceptable limits. **Action:** After the Aliya Ablation Device is in position, 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:** Remove foot from the foot switch.

Displayed Message	Audio Tones	Scenario and User Action
Preparing to deliver energy. Continue to hold foot switch	Steady / constant tone	The Generator is charging the internal circuitry in preparation for delivering energy. **Action:** Continue to hold the foot switch. The Generator will automatically start delivery of energy when the Generator internal circuitry is charged.
Energy delivery in process. Continue to hold foot switch	Beeping	The Generator is delivering energy. **Action:** Continue to hold the foot switch. The Generator will automatically stop energy delivery after the expected number of packets have been delivered.
Waiting for synchronization. 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 outside the acceptable limits during energy delivery. The generator has temporarily paused energy delivery and is waiting for the heart to be within the acceptable limits. **Action:** Continue to hold the foot switch. The Generator will automatically resume energy delivery when the heart rate is within the acceptable limits
Energy delivery complete	Activation completed tone	The Generator has delivered the expected number of packets and has automatically stopped the energy output. **Action:** Release the foot switch. Follow the Aliya Ablation Device IFU to perform additional system activations as necessary.
Unable to initiate energy delivery. Check cardiac monitor	Activation terminated tone	The Generator did NOT deliver energy because it detected an out-of-range R-wave trigger signal from the Cardiac Monitor. **Action:** Ensure patient's ECG signal is displayed on Cardiac Monitor and is 45 to 120 beats per minute. 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.
Unable to initiate energy delivery. Check device and all connections	Activation terminated tone	The Generator did NOT deliver energy because it detected an issue with the patient connections (i.e., Aliya Ablation Device or Dispersive Electrode) on the front panel of the Generator. **Action:** Check that all connections between the front panel of the Generator and the Aliya Ablation Device are secure. Check that the connection between the front panel of the Generator and the Dispersive Electrode are secure. 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 User Action
Energy delivery discontinued by user	Activation terminated tone	The Generator stopped energy delivery when the operator released foot switch. **Action:** Press CONTINUE button to acknowledge message and proceed with additional energy delivery. Complete the ablation by delivering the remaining number of packets to reach 100 packets
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 120 beats per minute. 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. Complete the ablation by delivering the remaining number of packets to reach 100 packets.
Energy delivery discontinued. Check device and all connections	Activation terminated tone	The Generator discontinued energy delivery because an issue was detected with one of the patient connections (i.e., the Aliya Ablation Device or Dispersive Electrode) on the front panel of the Generator. **Action:** Check that all connections between the front panel of the Generator and the Aliya Ablation Device are secure. Check that the connection between the front panel of the Generator and the Dispersive Electrode are secure. Press CONTINUE button to acknowledge message and proceed with additional system activations. Complete the ablation by delivering the remaining number of packets to reach 100 packets. Refer to **Troubleshooting** section if this message appears repeatedly.
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:** Follow instructions within the Fault Screen displayed on the Generator. Refer to the **Troubleshooting** section for diagnosing Fault conditions.
Data write error. Contact Galvanize Therapeutics. Press Continue to proceed without data log capability	None	The Generator has checked the status on internal memory that logs general generator status and found an issue. Continuing will not affect the therapeutic function of the Generator. **Action:** Press CONTINUE button to acknowledge message and proceed with energy delivery. Contact Galvanize Therapeutics to report the error.

6. System Setup

Prior to initial use of the Aliya System, complete the setup steps listed in this section to ensure the system is operating properly when initially put into service or if it has been moved between facilities.

WARNING: DO NOT use the Aliya System if there are any signs of damage to any of its components. Visually inspect all components and verify cables are not damaged prior to each use, especially the insulation of the Aliya Ablation Device. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.

WARNING: DO NOT substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by Galvanize Therapeutics. Doing so could potentially damage the system or cause injury

WARNING: DO NOT obstruct vents on the equipment, as they are important for ventilation to prevent overheating.

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

WARNING: DO NOT connect a signal source other than the Galvanize Therapeutics-supplied Cardiac Monitor to the Generator. Use of other signal sources in lieu of the Galvanize supplied cardiac monitor may result in patient injury.

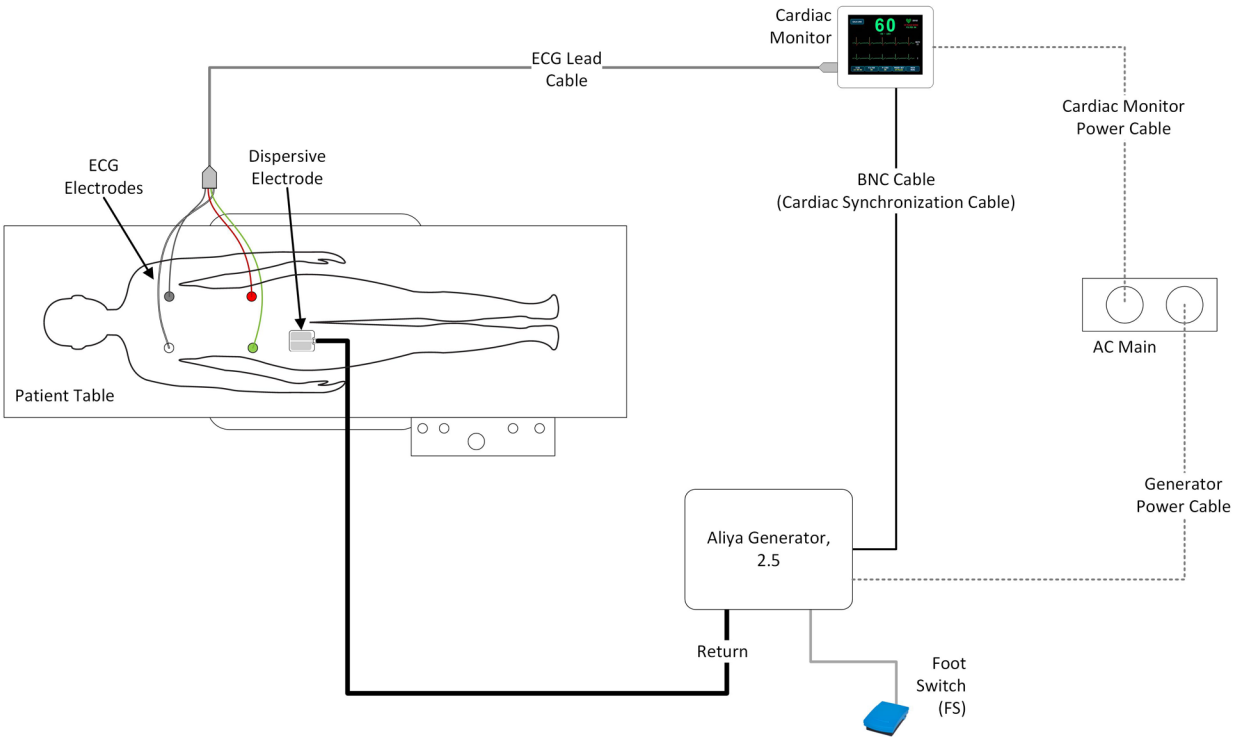
6.1. Unpacking and Setup

Note: As applicable, follow any site-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.

1. Unpack all components of the Aliya System except for the Aliya Ablation Device.

2. Contact a Galvanize Therapeutics representative for a replacement if the user manual is damaged, not legible, or becomes lost.

3. Connect the Aliya System components according to the connection diagram below. Be careful to avoid trip hazard when making connections from the system to the patient.



4. Complete the Pre-Procedure Power-On Sequence as specified in the System Operation section on the following page to confirm the system has been set up correctly.

7. System Operation

7.1. Pre-Procedure Power-On Sequence

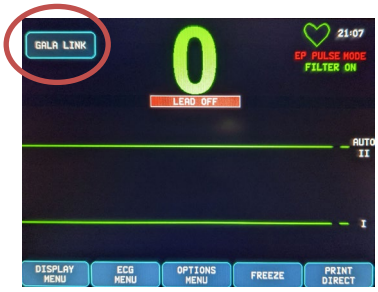
Complete the following steps prior to preparing the patient for procedure and any time the Generator is turned off during a procedure.

⚠ CAUTION: 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 Galvanize Therapeutics representative.

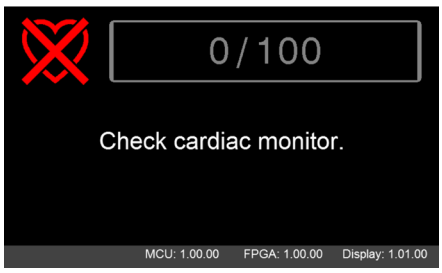
⚠ WARNING: When powering on Generator and preparing it for use, do NOT make connections to the Aliya Ablation Device connector on the front panel of Generator. If connections are made to the Aliya Ablation Device connector on the front panel of the Generator while preparing the Aliya Ablation Device for use, injury to the operator or the patient could happen.

1. If the Generator is not already powered on, switch the power toggle on the rear panel of the Generator to the On | position. Confirm the touchscreen illuminates and speaker plays audio tones for approximately 3 seconds.

2. When instructed by the Generator display, ensure the Aliya Ablation Device is not connected to the front of the Generator before pressing the CONTINUE button on Generator touchscreen. Confirm no faults occur and Generator displays a message indicating the “Cardiac monitor is not linked.”
3. 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).
4. Press the GALA LINK button on the upper left corner of the Cardiac Monitor touchscreen. The Generator should display the following, which indicates the cardiac monitor was successfully linked with the Generator (an R-wave trigger signal has not been detected from the Cardiac Monitor).



“Gala Link” on Cardiac Monitor



Generator screen after successful link

7.2. Pre-Procedure Preparation

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

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: DO NOT wrap cables around metal instruments. 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.

WARNING: DO NOT deliver energy if the dispersive electrode is not securely affixed on the patient in accordance with 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 away from the implant.

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

Refer to the IFU of the Aliya Needle and the Aliya Electrode, which together make up the Aliya Ablation Device, for clinical procedure steps necessary to prepare, insert, and place the Aliya Ablation Device for energy delivery.

Refer to the IFU of the dispersive electrode for steps necessary to prepare and place the dispersive electrode prior to energy delivery.

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

2. Place the dispersive electrode on the patient's thigh (shave if necessary for good contact).

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 to the appropriate ECG electrode.

6. Connect the Aliya Ablation Device cable to the front panel of the Generator.

7.3. Delivering Energy

This section describes the sequence of operations for delivering energy.

⚠ WARNING: Connect adaptors to the generator only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

⚠ WARNING: DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.

The diagram on page 28 depicts only the typical messages displayed on the Generator screen during energy delivery. Refer to the **Messages and Audio Alerts** table in the **Touchscreen Interface** section of this user manual for a description of other informational messages that may be displayed during energy delivery.

The activation of the Aliya generator delivers a monopolar biphasic non-adjustable (factory pre-set) treatment at 3 kV and 400 kHz. The Aliya generator delivers a pre-set number of cycles in a packet. The duration of a single treatment is dependent on the patient's heart rate, due to cardiac synchronization. A single treatment for a patient with a 60 BPM heart rate will be approximately 6 minutes. Note: 100 energy packets are recommended for each activation. If energy delivery is discontinued before 100 packets are delivered (by either the user or the Generator), the count will restart at 0 packets when energy delivery is reinitiated by the user. The user should provide the remaining number of energy packets to reach 100 total packets. When the remainder of packets is delivered to reach a total of 100 packets for that treatment, release the foot switch.

1. Confirm that the cardiac synchronization indicator is flashing green, indicating the Generator is in standby.

2. Press and hold the foot switch to begin energy delivery. The Generator will automatically charge the internal circuitry, followed by the delivery of energy in discrete packets.

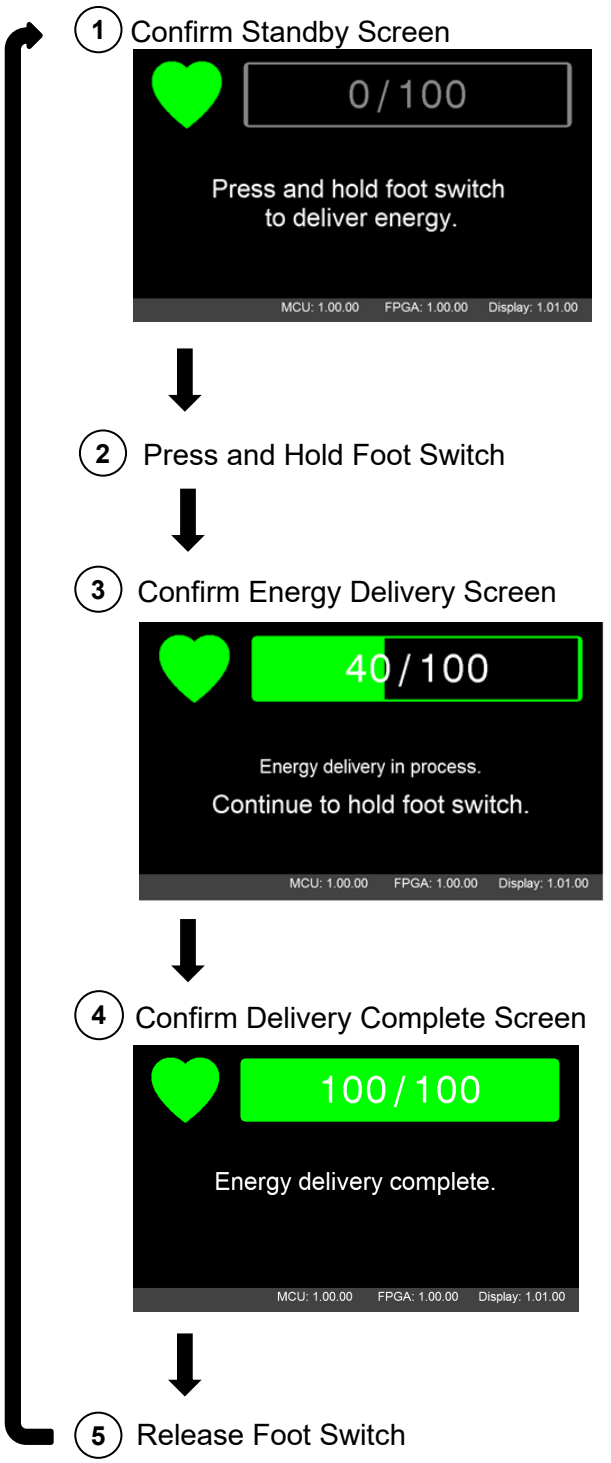
3. Hold the foot switch and wait for energy delivery to complete after approximately 6 minutes. Monitor the packet count on the green bar to track energy delivery progress. Energy delivery is complete and will automatically stop when 100 packets have been delivered.

   To abort energy delivery at any time, release the foot switch and follow the instructions for Discontinued Energy Delivery on the following page.

4. Confirm energy delivery is complete as indicated by the energy delivery complete screen.

5. Release the foot switch. The Generator will return to standby.

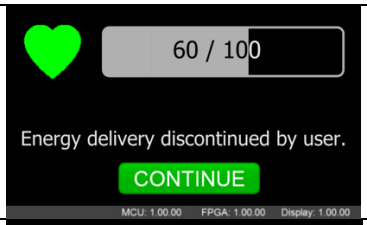
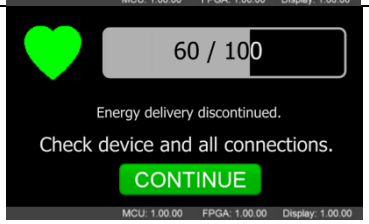
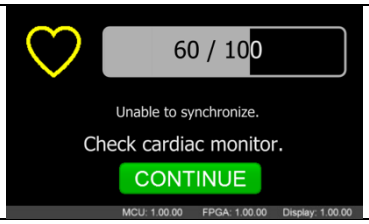
6. If necessary, re-position the Aliya Ablation Device and repeat steps 1-5 until the desired ablation volume is achieved. Refer to the Aliya Ablation Device IFU for treatment volume dimensions and device positioning instructions.



Typical messages displayed on the Generator screen during energy delivery.

7.4. Discontinued Energy Delivery

1. If energy delivery is discontinued before 100 packets have been delivered (by either the user or the Generator), the count will restart at 0 packets when energy delivery is reinitiated by the user. Perform the recommended action from Section 5.3 based on the Displayed Message on the Generator. When reinitiating energy, the user should provide the remaining number of energy **packets to reach 100 total packets.** When the remainder of packets is delivered to reach a total of 100 packets for that treatment, release the foot switch.
2. Energy could be discontinued due to any of the reasons listed within the table below.

Reason Energy May Be Discontinued	Displayed Message	Recommended Action
User lifts foot from foot switch		Refer to Section 5.3 (Row corresponding to the “Energy delivery discontinued by user” Displayed Message)
Generator detected an issue with one of the patient connections		Refer to Section 5.3 (Row corresponding to the “Energy delivery discontinued. Check device and all connections” Displayed Message)
Generator detected an out-of-range R-wave trigger signal from the Cardiac Monitor that did NOT resolve within 20 second		Refer to Section 5.3 (Row corresponding to the “Not able to synchronize. Check cardiac monitor” Displayed Message)

7.5. Post Procedure

Perform the following steps after the procedure is complete.

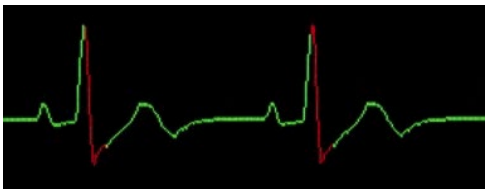
1. Remove the Aliya Ablation Device from the patient.
2. Disconnect the Aliya Ablation Device from the front panel receptacle of the Generator.
3. Disconnect the ECG leads from the ECG electrodes.
4. Remove the dispersive electrode from the patient.
5. Remove the ECG electrodes from the patient.
6. Disconnect the dispersive electrode from the front panel receptacle of the Generator.
7. Press the Power On/Standby ⏻ switch on the front of the Cardiac Monitor to power off the Cardiac Monitor.
8. Switch the power toggle on the rear of the Generator to the Off O position.
9. Refer to the **Cleaning** section for cleaning of Aliya System non-sterile, reusable 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 Galvanize Therapeutics representative.

8.1. General Troubleshooting

Problem	Troubleshooting Steps
The Generator display does not illuminate when the power switch is turned on.	• Ensure Generator is connected to AC Mains. • Unplug 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.
No audio tones are heard when the Generator powers on.	• Ensure Generator is connected to a working electrical outlet. • Unplug 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 "Cardiac monitor not linked. Press 'GALA LINK' on the cardiac monitor."	• Ensure the R-wave trigger interconnect cable is connected between the Cardiac Monitor and the Generator. • Press the "Gala 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 back panel of the Generator.
A red heart is displayed.	• 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. • 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 120bpm. • 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 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 instructions for use to apply new electrodes.
Generator display repeatedly displaying instructions to "Check device and all connections" message.	• Ensure the Aliya Ablation Device is connected to the Generator. • Ensure the Patient Dispersive Electrode is connected to the front panel of the Generator. • Ensure the Patient Dispersive Electrode is well adhered to the patient's skin. If not, apply a new Patient Dispersive Electrode.
Generator consistently displays a FAULT message.	• See following section of User Manual for troubleshooting FAULT conditions.

8.2. 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 will 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.

Code	Fault Description	Recommended Action
F1	Watchdog timer fault	Turn off unit and turn back on. Contact Galvanize Therapeutics if message reappears.
F2	Not used	
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 Galvanize Therapeutics if message reappears.
F11	Calibration data corrupt	Turn off unit and turn back on. Contact Galvanize Therapeutics if message reappears.
F12	Self-test fault	
F13	Flash driver fault	
F14	Measurement packet fault	
F15	Therapy packet fault	

9. Cleaning

Clean non-sterile, reusable components of the Aliya 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 any of the electrical connections or the interior of any component.

9.1. 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.
4. Contact a Galvanize Therapeutics representative if any label becomes non-legible.

9.2. 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.

9.3. 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.

10. Maintenance

DO NOT perform maintenance or service when the Aliya System is in use with a patient.

10.1. Routine Maintenance

The Aliya System does not require routine or preventative maintenance.

10.2. Electrical Safety Inspection: EN 62353

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

10.3. Fuse Replacement

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

Component	Replacement Fuses
Aliya Generator	6.3A H 250V

Refer to Cardiac Monitor user manual for fuse replacement of these system components.

10.4. Service and Returns

Should service or repair be necessary, contact a Galvanize Therapeutics representative.

10.5. Intended Service Life

The intended operational life of the Aliya Generator is 1 year.

10.6. End of Life Disposition

DO NOT dispose of Aliya System components in the unsorted municipal waste stream. Follow local regulations for proper disposal.

11. Technical Specifications

Energy Output	6 Watt average power output per packet (at 50 ohms) 100 packets maximum per activation (i.e. foot switch press) synchronized to a trigger signal of 0.75 Hz – 2.0 Hz (45 beats per minute to 120 beats per minute)	
Impedance Range	50 ohms – 1500 ohms	
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	Aliya Generator: 45.7cm wide x 21.6cm high x 49.5cm deep	
Weight	Generator: 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, Aliya Ablation Device connector and dispersive electrode connections	
Classifications	Class 1, Defibrillator Proof - Type CF, IPX0. The Aliya 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

11.1. Replacement Part Numbers

⚠ WARNING: DO NOT substitute cables, equipment, or disposables with any cables, equipment, or disposables not provided or specified by Galvanize Therapeutics. Doing so could potentially damage the system or cause injury.

Component	Part Number
Aliya Generator	GTI-00017
Cardiac Monitor	GTI-00009

11.2. Essential Performance Characteristics

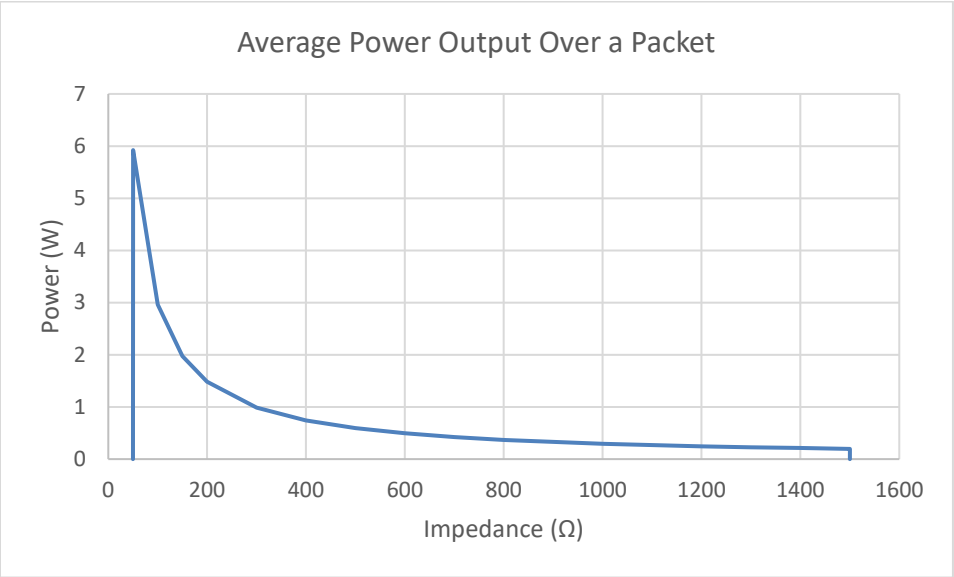
The characteristics related to safety (i.e., Essential Performance) of the Aliya System include the following.

- The software must correctly deliver energy per the defined dosing scheme.[1]
- The Generator hardware must function safely, properly and prevent the user from altering the software.
- Where redundant functions exist, only single fault conditions are considered. 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;
    - safety features associated with minimizing the risk of shock to the user and patient.

[1] "software must correctly deliver energy per the defined dosing scheme" means that the attributes of the high-frequency pulsed energy output meet the defined performance criteria of the system. This includes timing characteristics of the cardiac synchronization function that ensure energy is delivered at the appropriate time during the patient's ECG cycle.

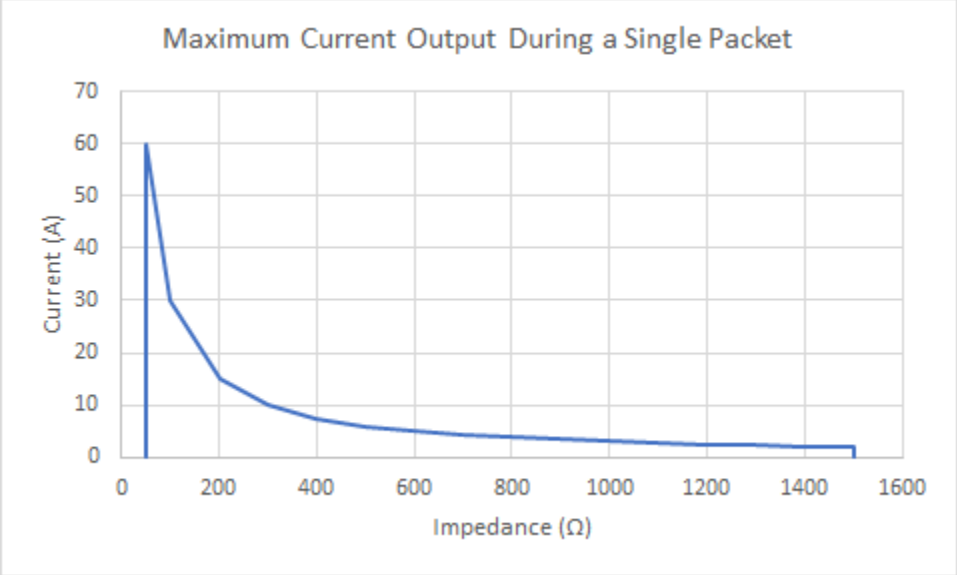
11.3. Power Output Diagram

The figure below displays the average power the Generator can deliver over the specified range of impedance during a 100-packet activation (One energy delivery).



11.4. Current Output Diagrams

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



11.5. Electromagnetic Compatibility (EMC)

The Aliya 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 Aliya System should be setup and put into service according to the EMC information provided in this section.

The Aliya 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

⚠ WARNING:

- The Aliya 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 Aliya 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 devices and cables other than those specified and provided by Galvanize Therapeutics 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.

⚠ CAUTION:

- 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

11.6. Aliya System Cables

Cable	Maximum Length	Reference
AC Power Cable (NEMA 5-15 Plug)	3.0 m	PRT-00020-01
Alternate AC Power Cable (AS/NZS 3112 Plug)	2.5 m	PRT-00020-02
Alternate AC Power Cable (CEE 7/7 Plug)	2.5 m	PRT-00020-03
Alternate AC Power Cable (CEI 23-50 S11 Plug)	2.5 m	PRT-00020-04
Interface Cable, ECG Trigger, BNC-BNC	2.4 m	Ivy Biomedical / 1564-01-01
ECG Patient Cable (Cardiac Monitor to ECG Leads)	3.0 m	Ivy Biomedical / 590432 (discontinued) Ivy Biomedical / 590478
Set of 4 ECG Cable Leads	61 cm	Ivy Biomedical / 590433

11.7. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Aliya 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 Aliya 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	

11.8. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

The Aliya 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, 10 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.

Immunity test	Level Required	Level Tested	Electromagnetic environment – guidance
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 Aliya System requires continued operation during mains power interruptions, it is recommended that the Aliya System is powered from an uninterruptible power supply.

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

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.

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