RheOx™ Model GTI-00007

User Manual

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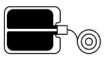
List of Symbols

The following is a list of symbols used on RheOx 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
	Authorized representative in the European Community		CE marking with notified body identifying number
	WEEE compliant		

1. Introduction

System Overview

RheOx with the RheOx™ Catheter (“Catheter”) is an electrosurgical device designed to deliver energy to airway tissue. RheOx is comprised of the RheOx™ Generator (“Generator”), a cardiac monitor and accessories.

Application Specification Summary

RheOx is intended to be used by a healthcare professional within a Bronchoscopy Suite or Operating Room. The user places the RheOx Catheter into the airway using standard bronchoscopy techniques. Upon Catheter placement at the target tissue location, the user presses the RheOx footswitch to initiate energy delivery to the target airway tissue resulting in tissue ablation. The user then repositions the Catheter adjacent to the last location and the procedure is repeated until all target tissue has been treated.

Generator and Accessories

Energy from the Generator is delivered to the RheOx Catheter through the catheter cable attached to the catheter handle. The Generator settings are predetermined and are not adjustable by the user. The user controls energy delivery by pressing the supplied foot switch. The Generator is not intended to come in contact with the patient and therefore is not provided sterile. The following items are supplied with the Generator:

- **Foot switch:** The foot switch is used to start and stop the delivery of energy. The Generator is designed to only be used with the foot switch provided by Gala.
- **Power cord:** The power cord is localized to the country where the Generator is used. The power cord has been specified and tested for use with the Generator and should not be substituted with any other power cord.
- **User manual:** The user manual provides reference information for using RheOx.

Cardiac Monitor and Accessories (Ivy Biomedical, Model 7600)

WARNING: Only use the cardiac monitor supplied with RheOx. 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 7600 cardiac monitor ("Cardiac Monitor") provided with RheOx. 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 a proprietary algorithm that detects and interprets trigger signals from the Cardiac Monitor. The algorithm will only allow the initiation and delivery of energy output when a stable (i.e., regular or steady) cardiac rhythm is detected. If an irregular rhythm is detected or if the patient's heart rate is not within acceptable limits, the algorithm prohibits energy output until a series of stable cardiac cycles are detected.

The following items are supplied with the Cardiac Monitor.

- **ECG patient cable:** The ECG patient cable connects the Cardiac Monitor to the ECG lead wires. This component is suitable for use within the patient environment.
- **ECG lead wires:** A set of 4 wires that connect to ECG electrodes applied to the patient's skin. Each lead wire connects to the ECG patient cable. This component is suitable for use within the patient environment.
- **Interconnect cable:** The interconnect cable is coaxial cable used to send trigger signals from the Cardiac Monitor to the Generator. The Cardiac Monitor sends a signal through the cable to the Generator each time an R-wave is detected in the patient's electrocardiogram.
- **Power cord:** The power cord is localized to the country where the Cardiac Monitor is used. The power cord has been specified and tested for use with the Cardiac Monitor and may not be substituted with any other power cord.
- **User Manual:** The Cardiac Monitor user manual contains additional reference information for configuring and using the Ivy Biomedical Cardiac Monitor Model 7600. All information required to use the Cardiac Monitor as a component of RheOx is provided in this user manual.

Components Not Provided With RheOx

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

WARNING: Use only RheOx Catheters (Models GTI-00005-01 and GTI-00005-02) with RheOx.

RheOx is designed to work with the components listed in the following table. These components are suitable for use within the patient environment.

Component	Manufacturer	Manufacturer Reference
RheOx Catheter (disposable) 	Gala Therapeutics, Inc	GTI-00005-01 GTI-00005-02
Catheter Cable (reusable) 	Kirwan	30-3003
Patient Dispersive Electrode (disposable) 	3M	Model 9165
Set of 4 ECG Electrodes (disposable) 	Ivy Biomedical Systems, Inc.	590436 (discontinued) or 590494

2. Indication for Use / Contraindications

Training

Gala Therapeutics provides user training prior to use to ensure safe and effective use of the primary operating functions of RheOx.

Indication for Use

RheOx is only intended to be used with the RheOx Catheter. Refer to the RheOx Catheter Instructions for Use (IFU) for the indication for use of RheOx with the RheOx Catheter.

⚠ Contraindications

RheOx is only intended to be used with the RheOx Catheter. Refer to the RheOx Catheter IFU for the contraindications of RheOx with the RheOx Catheter.

3. Warnings and Precautions

Warnings and Precautions

THIS USER MANUAL SHOULD BE READ IN CONJUNCTION WITH THE RHEOX CATHETER (MODELS GTI-00005-01 and GTI-00005-02) IFU BEFORE USING RHEOX. FAILURE TO FOLLOW INSTRUCTIONS OR FAILURE TO HEED WARNINGS OR PRECAUTIONS MAY RESULT IN HARM TO PATIENT.

1. Use only RheOx Catheters (Models GTI-00005-01 and GTI-00005-02) with RheOx.
2. Hazardous electrical output. RheOx is for use only by qualified medical personnel trained in the use of this equipment.
3. Do not use RheOx in the presence of flammable agents, explosive gases, bio-intestinal gases, or in oxygen-enriched environments.
4. Only use the cardiac monitor supplied with RheOx. Use of other cardiac monitors may result in patient injury.
5. Power on the Generator and allow the device to complete system self-test prior to patient prep / accessing the patient's airway. If the Generator does not perform as expected during the power on sequence, do not use the device and contact a Gala representative.
6. Do NOT connect the catheter cable to the front panel of the Generator when powering on the system and preparing it for use. If the catheter cable is connected to the Generator while preparing the device for use, injury to the operator or the patient could result.
7. Electric shock hazard. Do not remove the cover of the Generator or any components of the Generator. Refer servicing to qualified personnel. There are no user-serviceable parts inside the Generator or any of the components of the Generator.
8. To avoid the risk of electric shock, the Generator must only be connected directly to AC supply mains with protective earth. Do not use a multiple socket-outlet or extension cord to connect the Generator to AC supply mains.
9. 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.
10. Do not use RheOx if there are any signs of damage to any of its components. Contact a Gala representative if there are any signs of damage.
11. 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.

12. Do not allow fluids to pool in the body depressions and cavities before and during energy delivery.
13. Do not allow flammable liquids to pool in the body depressions and cavities before and during energy delivery.
14. Do not use sharp towel clips or metal instruments to attach the 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.
15. Ensure the patient does not come into contact with RheOx 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.
16. 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.
17. Patient injury resulting from neuromuscular stimulation is possible during energy delivery. RheOx has been designed to minimize the possibility of neuromuscular stimulation.
18. Needle monitoring electrodes for use with any physiological monitoring equipment used on the patient is not recommended. Physiological monitoring equipment incorporating high-frequency current limiting devices is recommended.
19. Do not connect any cables or equipment to RheOx that are not specified by Gala. Doing so could potentially damage the system or cause injury.
20. Do not connect a signal source other than the Gala supplied Cardiac Monitor to the Generator.
21. Do not substitute cables, equipment, or disposables with any cables, equipment, or disposables not supplied or specified by Gala. Doing so could potentially damage the system or cause injury.
22. Use caution when walking around the foot switch and foot switch cable to avoid injury.
23. The RheOx Catheter, patient dispersive electrode, and ECG electrodes are intended for single-use only. Do not attempt to sterilize and reuse.
24. Once used, the RheOx Catheter, patient dispersive electrode, and ECG electrodes are considered biohazardous material; dispose in accordance with hospital policies, local governing ordinances and recycling plans.
25. Use caution when transporting the Generator, which may be heavy for some users. Dropping the Generator may result in harm to the user or the Generator.
26. Do not use steam or heat sterilization to clean any RheOx component. Do not soak any component of the Generator system in disinfectants or fluids. Do not allow liquid to enter into any of the electrical connections or the interior of any component of the Generator system.
27. A failure of the Generator could result in an unintended increase of output power.
28. Interference produced by the operation of the Generator may adversely influence the operation of other electronic equipment. See the **Technical Specifications** section for Warnings related to Electromagnetic Compatibility.

4. Generator Controls and Receptacles

Front Panel

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

2. **Catheter (Type CF Applied Part)**: The catheter cable connects to this receptacle and provides electric current to the RheOx 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.

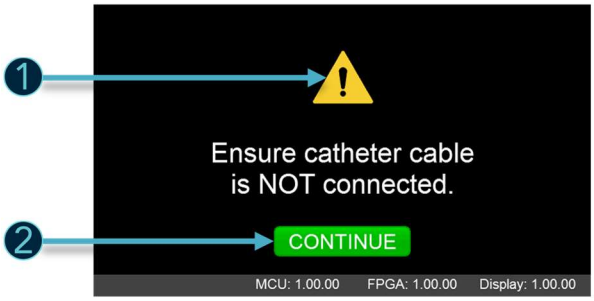
Back Panel

1. **Potential Equalization Terminal**: Connection that provides a common electrical ground for other electronic devices used during the procedure
2. **Power Switch**: Switch for turning the Generator on and off
3. **Fuse Access Panel**: Provides access to replaceable fuses
4. **Power Cable**: Receptacle to connect the Generator to an AC mains power outlet
5. **Foot switch**: Receptacle for connecting the foot switch used to activate and deactivate energy delivery
6. **Synchronized Input**: Connection for the interconnect cable that connects to the cardiac monitor

5. Touchscreen Interface

Self-Test Screen

The Self-Test Screen 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 Screen.



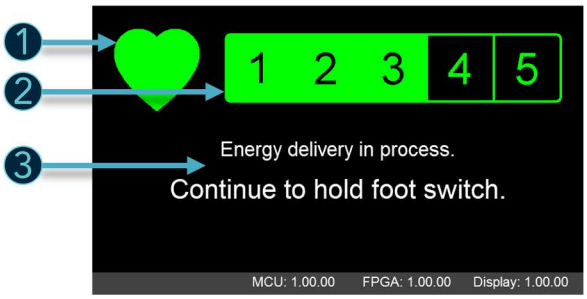
1. ⚠ **Warning Icon**: An indication to the user to follow the instructions on the screen to prevent injury to the patient or user.
2. CONTINUE **Button**: The CONTINUE button should only be pressed if the catheter cable is disconnected from the receptacle in the front panel of the Generator.

Cardiac Monitor Linking Screen

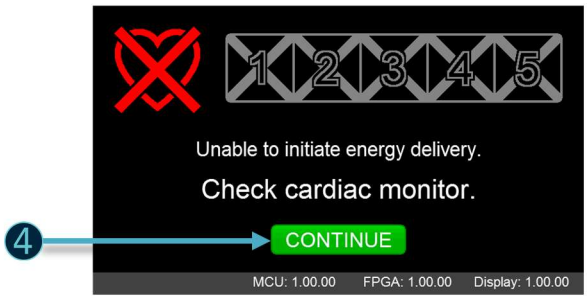
The Cardiac Monitor Linking Screen provides instructions for linking the cardiac monitor and the Generator. Pressing the GALA LINK button on the cardiac monitor touchscreen initiates the linking process. The Generator interface automatically changes to the **Treatment Delivery Screen** when the linking process is complete.

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 5 short duration bursts of energy (“packets”) with the cardiac cycle of the patient.



Example of interface during typical use



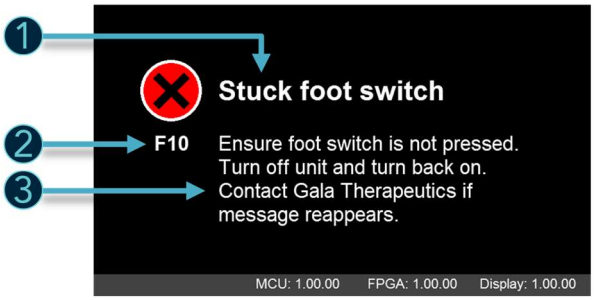
Example of interface displaying an alert message

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 synchronized packets to 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. The Generator will synchronize packet delivery to the cardiac cycle when the foot switch is pressed.
2 Packet output indicator	The packet output indicator shows the progress of energy delivery by changing the color and shape of individual packet delivery icons.  The Generator is in a standby state until the user presses the foot switch.  The Generator is delivering energy synchronized to the patient’s cardiac cycle, but has not yet delivered the packet indicated by number in the icon.  The Generator has delivered the packet indicated by number in the icon.

Symbol	Description
	 The Generator has discontinued energy output. The packet indicated by the number was NOT delivered to the patient.
3 Messaging area	Provides information and instructions to the user.
4 Continue button	The CONTINUE button is displayed on the touchscreen when the Generator cannot complete the 5 packets of output 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.

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 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
GALA THERAPEUTICS	3 different audio tones	The Generator is in the process of booting up. **Action:** Wait for boot-up process to complete
Ensure catheter 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 Catheter is NOT connected to the receptacle of the front panel. **Action:** Ensure the catheter cable is not connected to the front panel of the generator. Disconnect the catheter cable if it has already been connected. The 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 irregular or out of range R-wave trigger signal from the Cardiac Monitor. **Action:** Wait for the irregular signal to become stable or heart rate to come within acceptable range. If signal does not stabilize, refer to the **Troubleshooting** section.
Press and hold foot switch to deliver energy.	None	The Generator is receiving a stable R-wave trigger signal from the Cardiac Monitor. **Action:** After the Catheter is position in the airway per the RheOx Catheter IFU, press and hold the foot switch to deliver energy to the target tissue.

Displayed Message	Audio Tones	Scenario and Action
Release foot switch.	None	The foot switch has not been released since the last energy activation. **Action:** Remove foot from the foot switch.
Preparing to deliver energy. 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.
Energy 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 5 packets have been delivered.
Waiting to synchronize. Continue to hold foot switch	Beeping	The Generator is receiving an irregular R-wave trigger signal from the cardiac monitor during the delivery of energy. The generator has temporarily paused energy delivery and is waiting for the trigger signal to become stable. **Action:** Continue to hold the foot switch. The Generator will automatically resume energy delivery when a stable trigger signal is detected and will then stop the delivery of energy after 5 packets have been delivered.
Energy delivery complete	Activation completed tone	The Generator has delivered 5 packets and automatically stopped the energy output. **Action:** Release the foot switch. Follow the Catheter 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 irregular or 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. If signal does NOT become stable as indicated by a green flashing heart icon, refer to **Troubleshooting** section.

Displayed Message	Audio Tones	Scenario and Action
Unable to initiate energy delivery. Check Catheter and all connections	Activation terminated tone	The Generator did NOT deliver energy because it detected an issue with the patient connections on the front panel of the Generator. **Action:** Check that all connections on front panel of Generator are secure and that catheter cable is connected to the Catheter. Press CONTINUE button to acknowledge message and proceed with additional system activations. Refer to **Troubleshooting** section if this message appears repeatedly.
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.
Not able to synchronize. Check cardiac monitor	Activation terminated tone	The Generator stopped energy delivery because of an irregular or out of range R-wave trigger signal from the cardiac monitor that did NOT become stable or within range 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. If signal does NOT become stable as indicated by a green flashing heart icon, refer to the **Troubleshooting** section of this user manual.
Energy delivery discontinued. Check catheter and all connections	Activation terminated tone	The Generator discontinued energy delivery because an issue was detected with one of the patient connections on the front panel of the Generator. **Action:** Check that all connections on the front panel of the Generator are secure and that the catheter cable is connected to the Catheter. Press CONTINUE button to acknowledge message and proceed with additional system activations. 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:** Refer to the **Troubleshooting** section for diagnosing Fault conditions.

6. System Installation

Prior to initial use of RheOx, complete the installation steps listed in this section to ensure RheOx is operating properly when initially put into service or if it has been moved between facilities. Installation may be performed by the user and does not need to be performed by a Gala representative.

Generator Unpacking and Inspection

WARNING: Do not use RheOx if there are any signs of damage to any of its components. Contact a Gala representative if there are any signs of damage.

1. Unpack all components of the Generator.
2. Confirm the following components are contained within the shipping package of the Generator.
   - User manual
   - Generator
   - Power cord
   - Foot switch
3. Contact a Gala representative for a replacement if the user manual is damaged, not legible, or becomes lost.
4. Place the Generator on a flat surface. Ensure the rear vents of the Generator are not blocked. Do not position the generator in a way that would cause difficulty disconnecting it from the power source.

Cardiac Monitor Unpacking and Inspection

WARNING: Do not use the Cardiac Monitor if there are any signs of damage. Contact a Gala representative if there are any signs of damage.

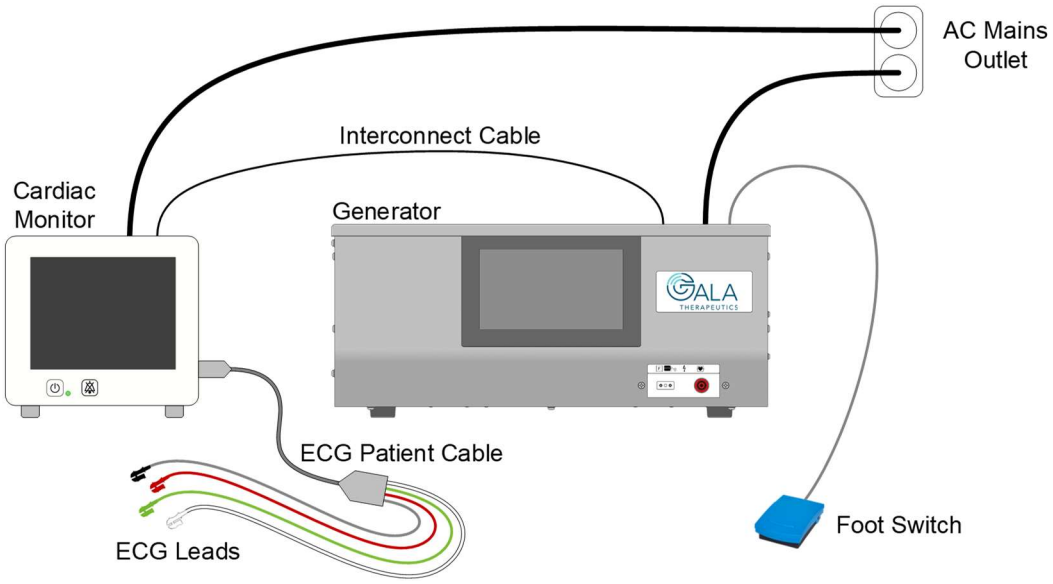
1. Unpack all components of the Cardiac Monitor.
2. Confirm the shipping package of the Cardiac Monitor contains each of the following components.
   - User manual
   - Power cord
   - ECG patient cable
   - Set of 4 ECG lead wires
   - Interconnect cable
   - Cardiac Monitor
3. Place the Cardiac Monitor on a flat surface near the Generator.

NOTE: The Cardiac Monitor is configured for immediate use with Generator without any additional configuration required during installation. Consult the Cardiac Monitor user manual for instructions if further cardiac monitor configuration is desired, such as setting the date and time and alarm volume.

System Connections

WARNING: Do not connect any cables or equipment to RheOx that are not specified by Gala. Doing so could potentially damage the system or cause injury.

Follow the steps below to complete all the connections of RheOx.



1. Plug the power cord supplied with the Generator into the receptacle on the rear panel of the Generator. Plug the other end of the power cord into a grounded wall outlet.

2. Lift the power cord retention cage on the back of the Cardiac Monitor and plug the power cord supplied with the Cardiac Monitor into the receptacle. Plug the other end of the power cord into a grounded wall outlet.

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

3. Connect one end of the interconnect cable supplied with the Cardiac Monitor to the SYNCHRONIZED OUTPUT on the rear panel of the Cardiac Monitor. Connect the other end of the interconnect cable to the SYNCHRONIZED INPUT on the rear panel of the Generator. Ensure each connection is securely fastened.

4. Plug the foot switch cable into the foot switch receptacle on the rear panel of the Generator. Push the connector into the receptacle with the red dot facing up to secure the connection.

5. Connect the set of 4 ECG leads to the ECG patient cable.

6. Plug the ECG patient cable supplied with the Cardiac Monitor to the ECG receptacle into the side panel of the Cardiac Monitor.

Generator Power-on Test

WARNING: If the Generator does not perform as expected during the power on sequence, do not use and contact a Gala representative.

1. Complete the **Pre-Procedure Power-On Sequence** as specified in the **System Operation** section to confirm the Generator has been installed 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 bronchoscopy and any time the Generator is turned off during a procedure.

WARNING: Power on Generator and allow completion of self-test prior to patient prep / accessing the patient's airway. If the Generator does not perform as expected during the power on sequence, do not use RheOx and contact a Gala representative.

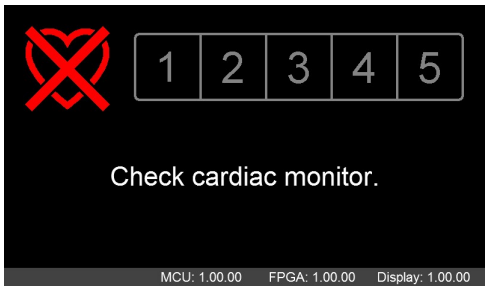
WARNING: When powering on Generator and preparing it for use, do NOT connect ccatheter cable to front panel of Generator. If the catheter cable is connected to the Generator while preparing the device for use, injury to the operator or the patient could happen.

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 speaker plays audio tones for approximately 3 seconds.

2. When instructed by the Generator display, ensure the catheter cable is not connected before pressing the CONTINUE button on Generator touchscreen. Confirm no faults occur and generator displays 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 as yet).



Pre-Bronchoscopy 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.

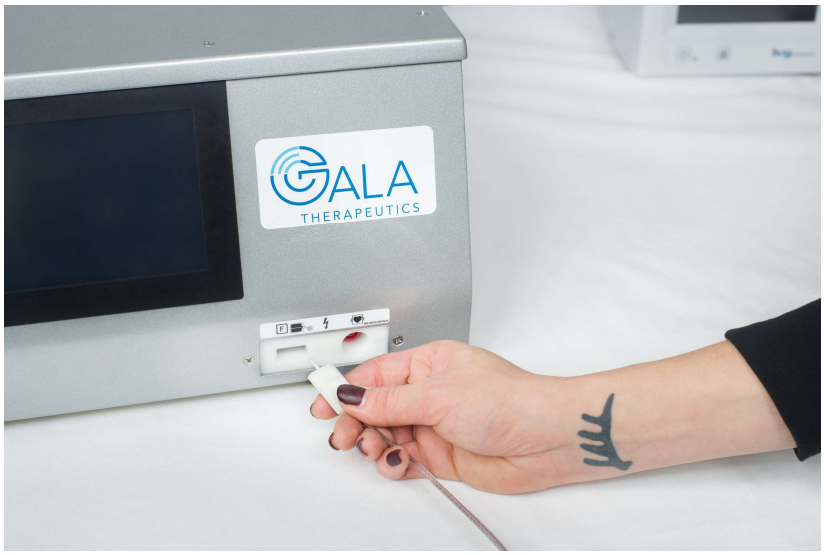
1. Place the foot switch in an area on the floor such that the operator can press the foot switch when ready to activate energy output.

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 thigh (shave if necessary for good contact).

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.

3. Plug the dispersive electrode into the appropriate receptacle on the front panel of the Generator.



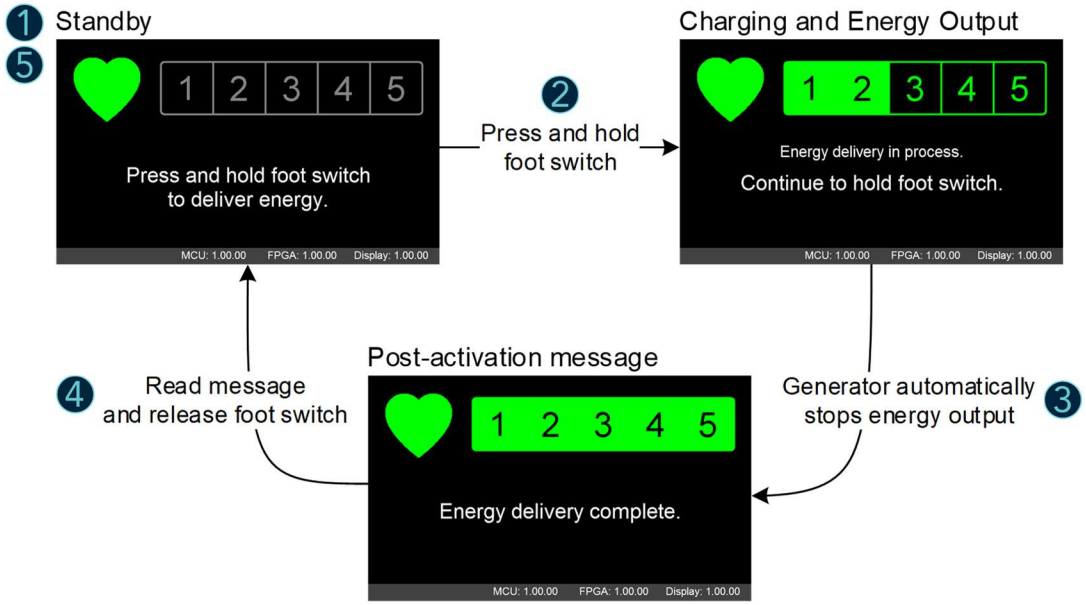
4. Prepare each ECG electrode site and apply the ECG electrodes to the patient using standard technique.
5. Attach each ECG lead to the appropriate ECG electrode.
6. Prepare the RheOx Catheter per the Catheter IFU.

7. Wipe the catheter cable with a disinfecting wipe or alcohol pad. Plug one end of the catheter cable into the appropriate receptacle on the front panel of the generator. Plug the other end of the catheter cable into the receptacle on the RheOx Catheter.

Delivering Energy Output

Refer to the RheOx Catheter IFU for clinical procedure steps necessary to place the Catheter and prepare for energy delivery.

This section describes the sequence of operations for delivering energy to the airway. The image below depicts only the typical messages displayed on the Generator screen during energy delivery. Refer to the **Audio and Display Information** section of this user manual for a description of other informational messages that may be displayed during energy delivery.



1. Prior to delivering energy, the Generator is in Standby state. The cardiac synchronization icon should be flashing green.
2. Press the foot and hold the foot switch to activate energy output. The Generator will automatically charge the internal circuitry, followed by the delivery of packets.
3. Wait for the device to automatically discontinue the activation following the delivery of the 5 packets, then release the foot switch. The user can also release the foot switch at any time during the activation to discontinue delivery of the packets.
4. 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.
5. Following the message acknowledgement, the Generator is in Standby state and the steps listed above can be repeated as necessary to delivery energy to additional treatment sites.

Post Procedure

Perform the following steps after the procedure is complete.

WARNING: Once used, the RheOx Catheter, patient dispersive electrode, and ECG electrodes are considered biohazardous material; dispose in accordance with hospital policies, local governing ordinances and recycling plans.

1. Disconnect the catheter cable from the catheter and front panel receptacle of Generator.
2. Disconnect the ECG leads from the ECG electrodes.
3. Remove the ECG electrodes from the patient.
4. Disconnect the dispersive electrode from the front panel receptacle of Generator.
5. Remove the dispersive electrode from the patient.
6. Dispose of the RheOx Catheter, ECG electrodes and dispersive electrode.
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 ◯ position.
9. Refer to the **Cleaning and Maintenance** section for cleaning of RheOx components.
10. If transporting the Generator, refer to **Transporting RheOx** section.

8. Transporting RheOx

WARNING: Use caution when transporting the Generator, which may be heavy for some users. Dropping the Generator may result in harm to the user or the Generator.

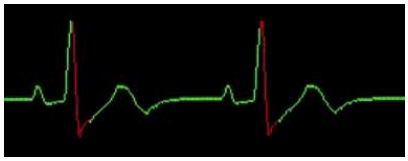
Perform the following steps prior to transporting RheOx.

1. Disconnect the Generator power cord from both the back panel of the Generator and the wall outlet.
2. Disconnect the interconnect cable from both the back panel of the Generator and the Cardiac Monitor.
3. Disconnect the foot switch from the back panel of the Generator.
4. Disconnect the Cardiac Monitor power cord from both the back panel of the Generator and the wall outlet.
5. Disconnect the ECG lead cable from the side panel of the Cardiac Monitor.

9. 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 Gala 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 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 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 interconnect cable is connected between the Cardiac Monitor and the Generator.

Problem	Troubleshooting Steps
A yellow flashing heart is displayed.	• Ensure the cardiac signal displayed on Cardiac Monitor is regular and 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 Catheter and all connections" message.	• Ensure the catheter cable is connected to the front panel of the Generator. • Ensure the catheter cable is connected to the handle of the Catheter. • 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.

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.

Code	Fault Description	Recommended Action
F1	Watchdog timer fault	Turn off unit and turn back on. Contact Gala 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 Gala Therapeutics if message reappears.
F11	Calibration data corrupt	Turn off unit and turn back on. Contact Gala Therapeutics if message reappears.
F12	Self-test fault	
F13	Flash driver fault	
F14	Measurement packet fault	
F15	Therapy packet fault	

10. Cleaning and Maintenance

Cleaning

Clean RheOx components per the instructions below.

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

Generator

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.

Cardiac Monitor

1. Disconnect the unit from the wall plug 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 Cardiac Monitor.

Cables

1. Disconnect all cables from the Generator and Cardiac Monitor
2. Clean catheter cable per cable manufacturer's instructions for use.
3. Wipe down all other cables with 70 % to 90% isopropyl alcohol or an equivalent alcohol-based wipe.
4. Allow cables to dry before reconnecting.

Maintenance

Do not perform maintenance or service when RheOx is in use with a patient.

Routine Maintenance

RheOx does not require routine or preventative maintenance.

Electrical Safety Inspection: EN 62353

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

Fuse Replacement

The Generator has two fuses (6.3AH, 250V) that can be replaced in the field by qualified personnel. Replace with the same value fuses. 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. Refer to Cardiac Monitor user manual for fuse replacement on the Cardiac Monitor.

Service and Returns

Should service or repair be necessary, contact a Gala representative.

Use original packaging when shipping any component of RheOx. If the original packaging is not available, contact a Gala representative. A serial number identifying each individual Generator is printed on the back of the Generator. This serial number should be referenced in any correspondence regarding this Generator. Contact a Gala representative for replacement parts, such as cables and foot switches.

Intended Service Life

The intended service life of the Generator is 5 years.

End of Life Disposition

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

11. Product Specifications

Energy Output	2500 V peak output, ± 5 % 5 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) Accuracy of the timing characteristics is ± 5 %
Impedance Range	45 ohms – 500 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	49.5 cm x 45.7 cm x 21.6 cm (height x width x depth)
Weight	13.7 kg
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, synchronized input, catheter connector and dispersive electrode connections
Protection	Class 1, Defibrillator Proof - Type CF, IPX0. The Gala 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.
Intermittent Use	5 second treatment activation ON periodwith individual activations not to exceed once every 15 seconds, 150 activations maximum.

Environmental Conditions

	Transport or Storage	**Operating**
Temperature	-40 °C to +70 °C	15 °C to 40 °C
Humidity (non-condensing)	30 % to 90 %	30 % to 70 %
Atm. Pressure	500 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 Gala. Doing so could potentially damage the system or cause injury.

Component	Part Number
RheOx Generator	GTI-00006
Cardiac Monitor	GTI-00009

12. Technical Specifications

Essential Performance Characteristics

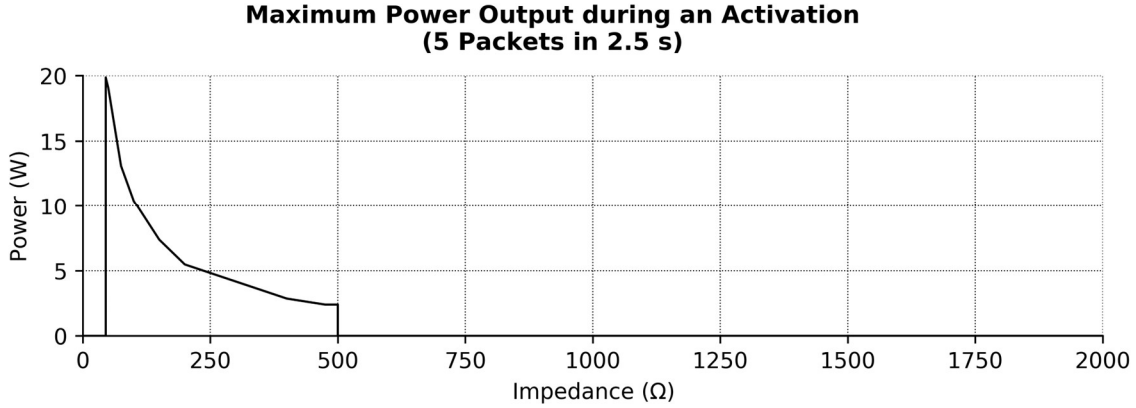
The characteristics related to safety (i.e., Essential Performance) of the RheOx Generator system include the following:

- The software must correctly deliver energy per the defined dosing scheme.*
- 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;
    - 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 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.

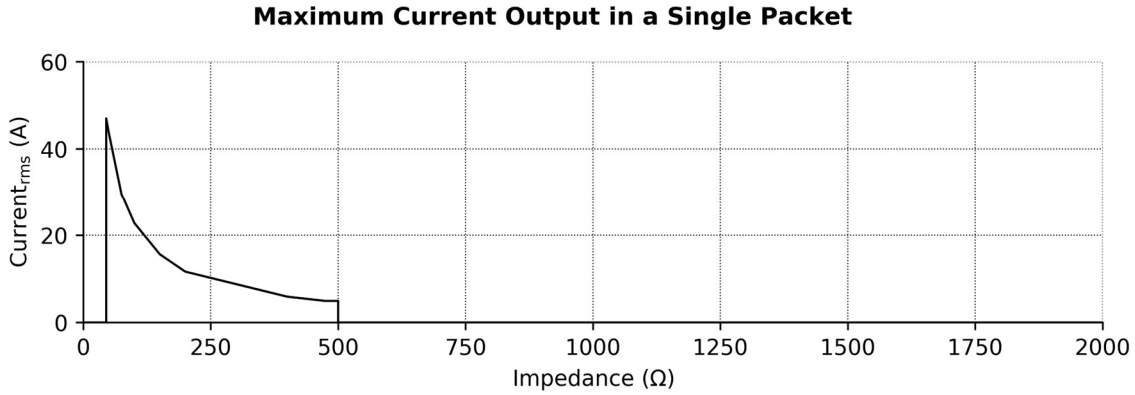
Power Output Diagram

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 5 packets synchronized to a 2.0 Hz trigger signal, which equates to 5 packets output in 2.5 seconds.



Current Output Diagram

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



Electromagnetic Compatibility (EMC)

RheOx 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. RheOx should be installed and put into service according to the EMC information provided in this section.

RheOx 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

- RheOx 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 RheOx 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 accessories and cables other than those specified and provided by Gala 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.

RheOx Cables

Cable	Maximum Length	Manufacturer / Reference
AC Power Cable (NEMA 5-15 Plug)	3.0 m	Gala Therapeutics / PRT020-01
Alternate AC Power Cable (AS/NZS 3112 Plug)	2.5 m	Gala Therapeutics / PRT020-02
Alternate AC Power Cable (CEE 7/7 Plug)	2.5 m	Gala Therapeutics / PRT020-03
Alternate AC Power Cable (CEI 23-50 S11 Plug)	2.5 m	Gala Therapeutics / PRT020-04
Interconnect Cable (BNC to BNC)	2.4 m	Ivy Biomedical / 1564-01-01
ECG Patient Cable (Cardiac Monitor to ECG Leads)	3.0 m	Ivy Biomedical / 590432
Set of 4 ECG Cable Leads	61 cm	Ivy Biomedical / 590433

Guidance and Manufacturer's declaration – Electromagnetic Emissions

RheOx has been verified and found to be in compliance with the emissions standards specified below as a Group 1, Class A device and 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)	RheOx meets the acceptance criteria of the referenced emissions test.	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 RheOx 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)	RheOx meets the acceptance criteria of the referenced emissions test.	
Harmonic emissions EN 61000-3-2	RheOx meets the acceptance criteria of the referenced emissions test.	RheOx 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.
Voltage fluctuations / flicker emissions EN 61000-3-3	RheOx meets the acceptance criteria of the referenced emissions test.	

Guidance and Manufacturer's declaration – Electromagnetic Immunity

The information provided within this section is applicable to RheOx.

RheOx 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.
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, 6 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 RheOx requires continued operation during mains power interruptions, it is recommended that RheOx 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.

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