Operator's Manual

Rezūm® Generator

Model G2200

WARNING: Carefully read and understand all instructions, indications, warnings, and cautions in this operator's manual prior to using the Rezūm Generator. Failure to do so could result in compromised patient safety, patient complications and/or insufficient treatment.

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Table of Contents

Chapter 1 About the Rezūm® Generator

Overview

This chapter contains information about the Rezūm Generator including safety. Please make sure you read this entire instruction manual prior to using the Rezūm Generator.

1.1 Trademark and Copyright Information

Rezūm is a registered trademark of the NxThera Corporation.

1.2 Contact Information

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EC REP

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1.3 Indications for Use/Intended Use and Contraindications

The Rezūm generator is intended to be used with the NxThera Rezūm Delivery Device Kit, Model D2201 only. Refer to the Instructions for Use for the Rezūm Delivery Device Kit for the Indications for Use/Intended Use and Contraindications.

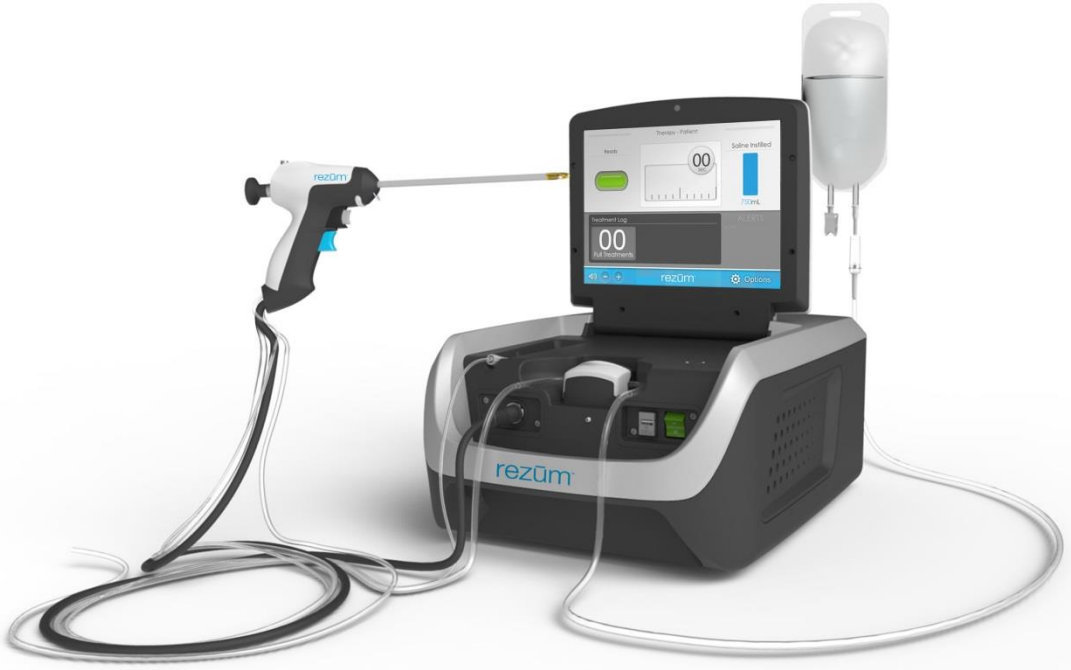
1.4 Product Description

The Rezūm generator is designed to heat the RF coil within the hand-held Delivery Device rapidly. The device uses radio frequency (RF) energy to heat water into vapor outside the body.

The vapor is injected into the tissue and rapidly disperses through the interstitial spaces between the tissue cells. The vapor begins to cool and condenses immediately on contact with tissue. The stored heat energy is released, gently denaturing the cell membranes and causing instantaneous cell death.

The denatured tissue is absorbed by the body over time. The vapor condensation process also causes a rapid collapse of blood vessels in the ablation treatment zone, resulting in a bloodless procedure.

The generator rapidly heats and converts sterile water into nearly pure or “dry vapor” at slightly above 100°C. The generator delivers this thermal energy in the form of dry vapor at temperatures through precise vapor emitter openings at the tip of the Vapor Emitter Needle. The rate and time over which the thermal energy in the form of vapor is delivered is monitored and regulated by the generator.



1.5 Safety

This section contains important safety information. NxThera requires that you read and understand all warnings, cautions, and the operator's manual prior to using the Rezūm Generator.

1.5.1 Dangers, Warnings and Cautions

The symbol and signal words shown below identify potential hazard categories. The definition of each category is as follows:

DANGER

This alert identifies hazards that will cause serious personal injury or death.

WARNING

This alert identifies hazards that may cause serious personal injury or death.

CAUTION

This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

1.5.1.1 DANGERS

DANGER: Do not take or use the device in locations where combustible anesthetics or flammable gases are used or in high-pressure oxygen rooms or inside oxygen tents.

1.5.1.2 WARNINGS

WARNING: A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. To avoid electrical shock, plug the power cord into a properly wired receptacle, use only the power cord supplied with the generator, and make sure the power cord is in good condition.

WARNING: After visual inspection, if the generator is damaged or a message is indicated to not use the generator, please contact Customer Service and take the generator out of service.

WARNING: Before conducting maintenance work, turn the power off and unplug the power cord from the outlet to prevent electric shock.

WARNING: Do not modify this equipment without authorization of NxThera.

WARNING: Carefully read and understand all instructions, indications, warnings, and cautions in this operator's manual prior to using the Rezūm Generator. Failure to do so could result in compromised patient safety, patient complications and/or insufficient treatment.

WARNING: Do not connect a grounding wire from a grounding stud to a gas pipe or water pipe.

WARNING: Do not connect to an electrical outlet controlled by a wall switch because the device may be accidentally turned off.

WARNING: Do not plug power cord into an outlet (or unplug it) with wet hands.

WARNING: Do not submerge the device in liquids or pour cleaning liquids over, into or onto the generator.

WARNING: Do not use the generator if it is damaged, is not functioning properly, or fails to meet an electrical safety check. Notify the appropriate personnel to ensure the generator is removed from service and properly repaired.

WARNING: Failure on the part of all responsible individuals, hospitals, or institutions, employing the use of Rezūm generator, to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. The manufacturer does not, in any manner, assume the responsibility for performing the recommended maintenance schedule. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the Rezūm Generator.

WARNING: If a critical error message is displayed, take the generator out of service and call BSC Tech Services. Do not attempt to service or maintain the generator while in use with a patient.

WARNING: If the generator measurement readings or messages seem dubious or abnormal, check the condition of the patient first and stop using the generator.

WARNING: In the event of power failure, the generator will automatically shut off. Turn the power button off. Please remove the Delivery Device from the patient **immediately** per instructions in the IFU, 3032-0XX Section 9. Turn on again to restart the generator to begin a new therapy session.

WARNING: No modification of this equipment is allowed. Do not attempt to service or maintain the generator while in use with a patient.

WARNING: RF Interference -Known RF sources, such as cell phones, radio or TV stations, and two-way radios, may cause unexpected or adverse operation of this generator. Consult qualified personnel regarding system configuration.

WARNING: Shock Hazard - Do not open, disassemble, or alter the Rezūm Generator! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

WARNING: The generator contains magnets in the LCD lid. Avoid close or prolonged contact with electrical devices or devices that have strong magnetic fields.

WARNING: The generator is not intended to be deployed in settings or situations that promote use by untrained personnel. Operation by untrained personnel can result in injury or death.

WARNING: The generator needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information in Chapter 5 provided in this operator's manual.

WARNING: The generator should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, test the generator to verify normal operation. Refer to the Electromagnetic Immunity information in Chapter 5.

WARNING: The Rezūm Generator is equipped with a USB port that is sensitive to ESD that may potentially result in injury or device failures.

WARNINGS CONTINUED

WARNING: The Rezūm Generator is reusable, but is restricted to a single patient at a time for a therapy session.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: Use a grounded AC outlet for the power supply and ground this generator.

WARNING: Use of accessories other than those specified in this document may result in increased emission or decreased immunity of the Rezūm Generator.

WARNING: Use only NxThera approved and specified parts, accessories, optional parts, consumables, and components.

WARNING: Use only NxThera specified power cord.

WARNING: Use with the specified AC voltage and frequency.

WARNING: When transporting the generator, it is important to position it with the display facing away from the body.

1.5.1.3 CAUTIONS

CAUTION: After cleaning, allow complete drying before plugging into an outlet.

CAUTION: Before conducting maintenance work, turn the power OFF and unplug the power cord from the outlet to prevent electric shock.

CAUTION: Before moving this generator, turn the power OFF, remove all accessories from the patient, and unplug the power cord from the outlet.

CAUTION: Do not install this generator in the following locations:

- Locations where gases and flames are used
- Locations where the air includes dust, salt, or sulfur
- Locations exposed to prolonged direct sunlight
- Locations that vibrate or are subject to sharp impacts
- Locations near heating equipment
- Locations where chemicals are stored
- This generator cannot be used in any room in which noise-generating apparatuses are used (such as an MRI room, CT room, X-ray room, etc.)

CAUTION: Do not place anything on this generator.

CAUTION: Do not soak the generator or accessories in any medical liquid. Also, keep liquids out of the generator and accessories.

CAUTIONS CONTINUED

CAUTION: Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI), which could affect the performance of this device. Avoid operating the Rezūm Generator near cauterizers, diathermy equipment, FM 2-way radios, or cellular phones. Turn power off to radio, cellular and other like equipment near the Rezūm Generator. Refer to the EMI tables in Chapter 5.

CAUTION: Exposing the Rezūm Generator to extreme environmental conditions outside of its specified parameters may compromise the ability of the Rezūm Generator to function properly and/or cause the plastic to warp and/or crack.

CAUTION: Follow your facility's procedures and applicable regulations when disposing of anything that has been used on patients.

CAUTION: The generator should be at room temperature prior to use.

CAUTION: If there is condensation on the generator, dry it thoroughly before turning the power on.

CAUTION: Input voltage range is 100 to 240V at 50 to 60 Hertz. Verify this voltage matches that of the power outlet.

CAUTION: Observe the following cautions when connecting this generator with other equipment:

- Ensure that the connected equipment is in accordance with the IEC60601-1 or IEC safety standards.
- Employ additional protective measures (e.g., additional protective earthing) as necessary.

CAUTION: Only NxThera approved equipment and accessories shall be connected to the generator.

CAUTION: The Rezūm Generator USB port is only intended for use during maintenance by authorized service personnel or to export therapy data.

CAUTION: The generator conforms to the requirements of the EMC standards (IEC 60601-1-2:2007 and IEC 60601-1-2:2014), so it can be used at the same time as other electrical simulators. However, it may be affected by electrical scalpels and microwave treatment devices and there may be an impact on measurement precision for patients using cardiac pacemakers and the like. Check the operation of this generator during and after use of such equipment and with such patients.

CAUTION: The Rezūm Generator is intended to be used indoors at a medical facility or physician office environment only.

CAUTIONS CONTINUED

CAUTION: The Rezūm Generator cables may cause a trip hazard while cables are attached to the generator.

CAUTION: The Rezūm Generator needs special precautions regarding Electromagnetic compatibility (EMC) and care should be taken in accordance to the EMC information provided in Chapter 5 of this document.

CAUTION To prevent damage to equipment, do not clean any part of the generator with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the generator.

CAUTION: Use of portable and mobile RF communications equipment near the Rezūm Generator may affect its operation.

CAUTION: Using this generator with the air vent blocked could cause a breakdown. Clean this generator with care.

CAUTION: When any of the following occur, turn the power off, remove all accessories from the patient, and unplug the power cord from the outlet.

- There is smoke or a strange odor leaking out of the generator.
- The generator has been dropped or impacted by an object.
- Liquid or foreign matter gets inside the generator.
- If you think the generator may have been damaged.

CAUTION: When using disinfectant solutions, follow the manufacturer's directions.

CAUTION: Input voltage is pre-selected as labeled on the generator

CAUTION: Please use caution in opening the shipping box and try not to use sharp utility knives and such, as you risk cutting into yourself and/or product.

1.5.2 Potential Adverse Events

The following adverse events have not been reported in the clinical trials: erectile dysfunction, pelvic abscess, rectal wall injury, and fistula. Delivering a form of thermal therapy or misuse of the device has potential for producing these adverse effects.

1.5.3 Reported Adverse Events

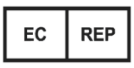
The types of device related, or procedure related adverse events reported are typical of thermal BPH ablation procedures. There were no clinically significant complications resulting from the treatment.

A summary of the adverse events observed in NxThera clinical studies is presented in the Rezūm Delivery Device Kit Instructions for Use for the Rezūm Delivery Device Kit, 3032-0XX.

1.5.4 Symbols

The following symbols may appear in this manual, on the generator labeling and/or packaging. Some of the symbols represent standards and compliances associated with the generator and its use.

1.5.4.1 Generator Symbols

Symbol	Description of the Symbol	Standard	Title of symbol and (reference number)
	Indicates on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals	IEC 60417	Alternating current (5032)
	Manufacturer's catalog number, so that the medical device can be identified	ISO 15223-1:2016	Catalog number (5.1.6)
	Electrostatic sensitive device Caution: Contains parts and assemblies susceptible to damage by electrostatic discharge (ESD) Contact with generator package should be avoided at low levels of relative humidity, especially if insulating footwear is being worn or the ground/floor is nonconductive. Low levels of relative humidity must in particular be expected on hot, dry summer days and very cold winter days.	IEC 60417	Electrostatic sensitive devices (5134)
	Consult accompanying documents (Printed in blue on generator label)	ISO 7010:2011	Refer to instruction manual/booklet (M002)
	Indicates the date when the medical device was manufactured	ISO 15223-1:2016	Date of Manufacture (5.1.3)
	Authorized Representative in the European Union	ISO 15223-1:2016	Indicates the Authorized representative in the European Community (5.1.2)

Symbol	Description of the Symbol	Standard	Title of symbol and (reference number)
	Indicates a medical device that can be broken or damaged if not handled carefully. The generator package should be handled carefully and should never be tipped over or slung	ISO 15223-1:2016	Fragile, handle with care (5.3.1)
	Indicates a medical device that needs to be protected from moisture. The generator package must be protected from excessive humidity and must accordingly be stored under cover.	ISO 15223-1:2016	Keep dry (5.3.4)
	Indicates the medical device manufacturer	ISO 15223-1:2016	Manufacturer (5.1.1)
MFG PN	Manufacturing internal part number reference	Not Applicable	Not Applicable
MODEL	Model Number	Not Applicable	Not Applicable
	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	IEC 60417	Non-Ionizing electromagnetic radiation (RF) (5140)
	Indicates disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.	IEC 60417	"OFF" (power) (5008)
	Indicates connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.	IEC 60417	"ON" (power) (5007)
℞ ONLY	US Federal law restricts this device to sale by or on the order of a physician.	FDA Register Vol. 81, No. 115	Prescription device (IIG, page 38919)

Symbol	Description of the Symbol	Standard	Title of symbol and (reference number)
IPx0	Protection against Ingress of Solids and Liquids	IEC 60529	Non-protected
	Identifies any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode.	IEC 60417	Protective earth; protective ground (5019)
	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1:2016	Serial number (5.1.7)
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.	BS EN 50419:2006	WEEE wheeled bin
	Identifies a type BF applied part complying with IEC 60601-1.	IEC 60417:2002 ANSI/AAMI/IEC TIR60878:2003 IEC 60601-1	Type BF applied part (5333)
	Universal Serial Bus (USB) port connector	Not Applicable	Not Applicable
	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1:2016	Caution (5.4.4)
	Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with ANSI/AAMI ES 60601-1 AMD 1 (2012), CAN/CSA C22.2 No 60601-1 (2014)	ANSI/AAMI ES 60601-1 AMD 1 (2012), CAN/CSA C22.2 No 60601-1 (2014)	Medical Equipment recognized by Underwriters Laboratory Inc.

Table 1: Generator Symbols

1.5.4.2 User Interface Symbols

Symbol	Description
	Priming the Delivery Device
	Perform a pre-treatment vapor cycle
	Back to previous screen
	Complete
	Confirmation message
	Continue
	Critical error message
	Displayed for errors that are not of critical severity.
	Informational error messages
	Export
	Generator question that requires user response
	Home screen menu
	Navigation buttons for back, forward, up and down

Symbol	Description
	Options Menu
	Volume Control

Table 2: User Interface Symbols

1.6 Operator Training Requirements

WARNING: The generator is not intended to be deployed in settings or situations that promote use by untrained personnel. Operation by untrained personnel can result in injury or death.

Persons authorized to operate the generator must have all the following minimum training.

- Training as required by state, province, or country regulations.
- Training on operation and use of the generator.
- Additional training as required by a physician or Medical Director.
- A thorough understanding of the procedures in this manual.

Chapter 2 Getting Started

Overview

This chapter contains information on how to get started with your Rezūm Generator.

2.1 Unpacking and Inspecting

CAUTION: Please use caution in opening the shipping box and try not to use sharp utility knives and such, as you risk cutting into yourself and/or product.

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

The Rezūm Generator is designed for simplicity of operation and set-up and requires minimal assembly. The following items are included in the Rezūm Generator box:

One (1) Rezūm Generator

One (1) Power cord

1. Carefully inspect each item as it is unpacked for any signs of damage that may have occurred during shipment.
2. Check the components according to the packing list.
3. Check for any damage or defects. Do not attempt to set up the Rezūm Generator if anything is damaged or defective. Contact Customer Service immediately if anything is damaged or defective.

2.1.1 Generator Controls and Connections

WARNING: The generator contains magnets in the LCD lid. Avoid close or prolonged contact with electrical devices or devices that have strong magnetic fields.

WARNING: The Rezūm Generator is equipped with a USB port that is sensitive to ESD that may potentially result in injury or device failures.

WARNING: Do not connect a grounding wire from a grounding stud to a gas pipe or water pipe.

CAUTION: Using this generator with the air vent blocked could cause a breakdown. Clean this generator with care.

CAUTION: Only NxThera approved equipment and accessories shall be connected to the generator.

CAUTION: The Rezūm Generator USB port is only intended for use during maintenance by authorized service personnel or to download therapy data.

The following figures and table explain the controls, connections, and their function.

Figure 1: Front and Top of Generator

ID	Item	Description
A	Display Screen	Touch screen display to provide system feedback to the user
B	Syringe / Syringe Cradle	Holds water for vapor treatment
C	Electrical cable port	The electrical cable is the RF energy line and the connections for the switches and thermocouples
D	Roller pump	Delivers saline during procedure
E	Power Indicator	Displays system status
F	Power switch	Turns system on / off
G	USB port	Allows data from system to be exported onto USB device

Table 3: Front and Top of Generator Description Table

Figure 2: Back of Generator

Figure 3: Side of Generator

ID	Item	Description
I	Grounding stud	Grounding stud used for grounding product (Required in Europe)
J	Air vent	Outgoing air vent
K	Product Label	Provides information about the generator
L	Fuse box	Holds generator fuses
M	Power cord plug	Connection plug for electrical power cord
N	Lid	Cover to protect display screen, syringe and pressure sensor ports
O	Handle	Use to transport the device by hand
P	Air vent and speaker	Incoming air vent (both sides) and speaker (left side only)
Q	Rubber feet (on bottom and side)	Allows product to be stored on base or bottom end

Table 4: Back and Side of Generator Description Table

2.1.2 Display Screen Map

The Rezūm Generator is equipped with a color touchscreen that can be viewed up to 8 feet away from the generator. The display allows interaction with the generator using screen buttons icons and menus with the touch of a finger with or without latex gloves.

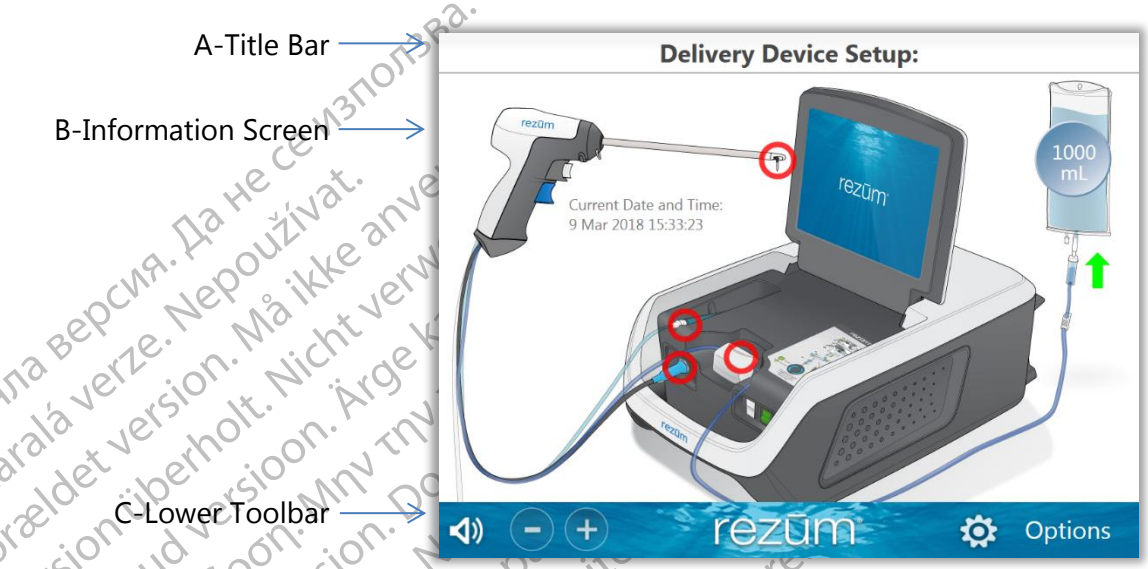


Figure 4: Display Screen Map

Item	Description
A-Title Bar	Brief title of the screen displayed
B-Information Screen	Main area for screen information and error messages will be shown to the user. Replace saline button is also available on the saline bag.
C-Lower Toolbar	The bottom of all screens, except the start-up screens, will include the same lower bar. This will have three features on it: volume adjustment, product logo, and the Options menu button (if applicable).

Table 5: Display Screen Map

2.1.3 Audible Tones

The generator emits different audible tones to indicate to the user different events. These tones vary with the type of message and its content. The description of each tone is explained in Table 6.

Tone Name	Tone Description
1. Start-up	A musical tone is played during generator power on sequence.
2. Treatment Warning	A single quick tone played when there is a warning after treating—running low on treatments, running low on treatment time, and other alerts that may require user intervention.
3. Partial Treatment Tone	Tone emitted when the delivery device vapor activation button has been deactivated prior to the completion of a treatment.
4. Treatment Ready	Played when the system is ready to perform a treatment
5. Treatment and Priming	Beep tone is repeated once per second while performing Priming and Treatment operations.
6. Success	Tone emitted when a full treatment has been administered, after successful priming, and as feedback while adjusting the volume.
7. Error Message	Two quick tones in succession are played whenever the generator displays an error message on the generator screen.
8. Critical Error Message	A single high-pitched tone is played when the generator encounters a critical error. In addition, three quick tones in succession are played whenever the generator displays a critical error message on the generator screen.
9. Delivery Device Disable Tone	A high-pitched tone followed by a low-pitched tone played when the delivery device is disabled.

Table 6: Tone Description

2.1.4 Volume Control

The generator has an on-screen volume control as depicted in Figure 5.

Figure 5: Volume Control

- Touch the minus symbol to decrease or silence the volume and touch the plus symbol to increase the volume. A tone will be emitted upon each button press.
- The *Critical Error and Delivery Device Disabled* alarm tones cannot be silenced by the volume control.
- The volume resets to the default when the generator is turned off and on again.
- Set the volume loud enough to be heard adequately in the actual use environment.

2.1.5 Detachable Parts and Accessories

WARNING: Use only NxThera approved and specified parts, accessories, optional parts, consumables, and components.

CAUTION: The Rezūm Generator cables may cause a trip hazard while cables are attached to the generator.

The Rezūm Generator has the following detachable parts and accessories:

Detachable Parts – Supplied with the Rezūm Generator

Model Number	Description, Function	Type
1519-001	**Power cord** 3.05 meter hospital grade power cord North American, 15 amp	Reusable
1519-002	**Power cord** 3.05 meter hospital grade power cord Continental Europe, 10 amp	Reusable
1519-003	**Power cord** 2.50 meter hospital grade power cord Swiss, 10 amp	Reusable

Table 7: Detachable Parts

Accessories – Supplied Separately

Model Number	Description, Function	Type
D2201	**Delivery Device,** Delivers the vapor into the tissue	Disposable, single use

Table 8: Accessories

Chapter 3 Using the Rezūm Generator

Overview

This chapter provides step by step instructions and sequence of operation for the Rezūm Generator.

3.1 Step by Step Instructions

This section contains step by step instruction on how to connect the power cord, turn on and off the generator, prime the delivery device, perform treatment, and use the option menu.

WARNING: When transporting the generator, it is important to position it with the display facing away from the body.

CAUTION: Follow your facility's procedures and applicable regulations when disposing of anything that has been used on patients.

CAUTION: Do not install this generator in the following locations:

- Locations where gases and flames are used
- Locations where the air includes dust, salt, or sulfur
- Locations exposed to prolonged direct sunlight
- Locations that vibrate or are subject to sharp impacts
- Locations near heating equipment
- Locations where chemicals are stored

This generator cannot be used in any room in which noise-generating apparatuses are used (such as an MRI room, CT room, X-ray room, etc.)

CAUTION: Do not place anything on this generator.

CAUTION: Observe the following cautions when connecting this generator with other equipment:

- Ensure that the connected equipment is in accordance with the IEC60601-1 or IEC safety standards.

Employ additional protective measures (e.g., additional protective earthing) as necessary.

CAUTION: Exposing the Rezūm Generator to extreme environmental conditions outside of its normal conditions may compromise the ability of the Rezūm Generator to function properly and/or cause the plastic to warp and/or crack.

CAUTION: The Rezūm Generator cables may cause a trip hazard while cables are attached to the generator.

CAUTION: If the Rezūm Generator is stored in an environment with a temperature below the operating temperature, the unit should be allowed to warm up to the needed operating temperature before using.

CAUTION: Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI), which could affect the performance of this device. Avoid operating the Rezūm Generator near cauterizers, diathermy equipment, FM 2-way radios, or cellular phones. Turn power off to radio, cellular and other like equipment near the Rezūm Generator. Refer to the EMI tables in Chapter 5.

CAUTION: The Rezūm Generator is intended to be used indoors at a medical facility or physician office environment only.

3.1.1 Connecting the Power Cord

WARNING: Do not connect to an electrical outlet controlled by a wall switch because the generator may be accidentally turned off.

WARNING: Do not plug power cord into an outlet (or unplug it) with wet hands.

WARNING: Use only NxThera specified power cord.

WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

WARNING: A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. To avoid electrical shock, plug the power cord into a properly wired receptacle, use only the power cord supplied with the generator, and make sure the power cord is in good condition.

WARNING: Use a grounded AC outlet for the power supply and ground this generator.

WARNING: Use only NxThera approved and specified parts, accessories, optional parts, consumables, and components.

WARNING: Use with the specified AC voltage and frequency.

1. Make sure that the AC outlet is properly grounded and supplies the specified voltage and frequency.
2. Connect the female connector end of the power cord to the AC power connector on the back of the generator.
3. Plug the male connector end of the power cord into a properly grounded AC power outlet.

3.1.2 Turning on the Rezūm Generator

DANGER: Do not take or use the device in locations where combustible anesthetics or flammable gases are used or in high-pressure oxygen rooms or inside oxygen tents.

WARNING: The Rezūm Generator is reusable, but is restricted to a single patient at a time for a therapy session.

CAUTION: If there is condensation on the generator, dry it thoroughly before turning the power on.

CAUTION: When any of the following occur, turn the power off, remove all accessories from the patient, and unplug the power cord from the outlet.

- There is smoke or a strange odor leaking out of the generator.
- The generator has been dropped or impacted by an object.
- Liquid or foreign matter gets inside the generator.
- If you think the generator may have been damaged.

To turn ON:

1. Open the lid of the generator to show the display screen and make sure it is fully open.

2. Turn on the generator by pushing the top of the *Power button* located on the front of the generator as depicted in Figure 6.

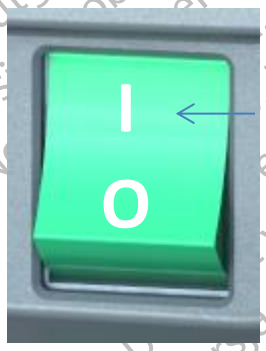


Figure 6: Power button

3. While the generator is powering up, it initially displays two start-up screens and a test screen.

WARNING: In the event of power failure, the generator will automatically shut off. Turn the power button off. Please remove the Delivery Device from the patient **immediately** per instructions in the IFU, 3032-0XX Section 9. Turn on again to restart the generator to begin a new therapy session.

Figure 7: NxThera Start-up Screens

Figure 8: NxThera Test Screen

4. It will automatically run the Start-up Diagnostics. During this time the test screen is displayed, and a bar and text will indicate status of the tests on the screen.

5. After the Start-up Diagnostics are completed, the generator will display the *Delivery Device Setup* screen.

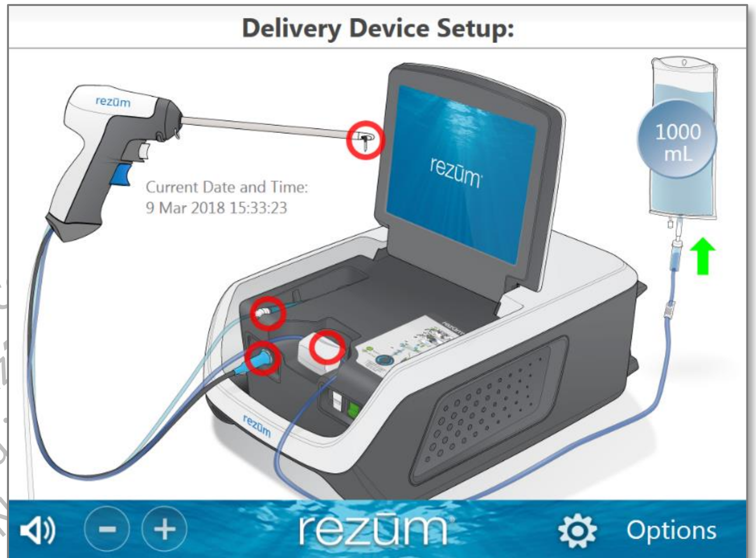


Figure 9: Deliver Device Setup

After all connections are properly made, a message will be displayed for 5 seconds letting the user know that items have been connected and then the *Priming* screen will be displayed.

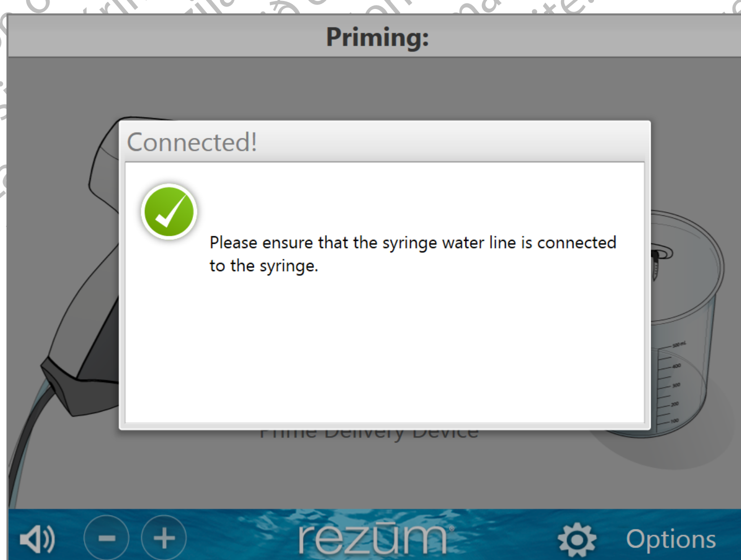


Figure 10: Connection Message

3.1.3 Priming the Delivery Device

CAUTION: When any of the following occur, turn the power off, remove all accessories from the patient, and unplug the power cord from the outlet.

- There is smoke or a strange odor leaking out of the generator.
- The generator has been dropped or impacted by an object.
- Liquid or foreign matter gets inside the generator.
- If you think the generator may have been damaged.

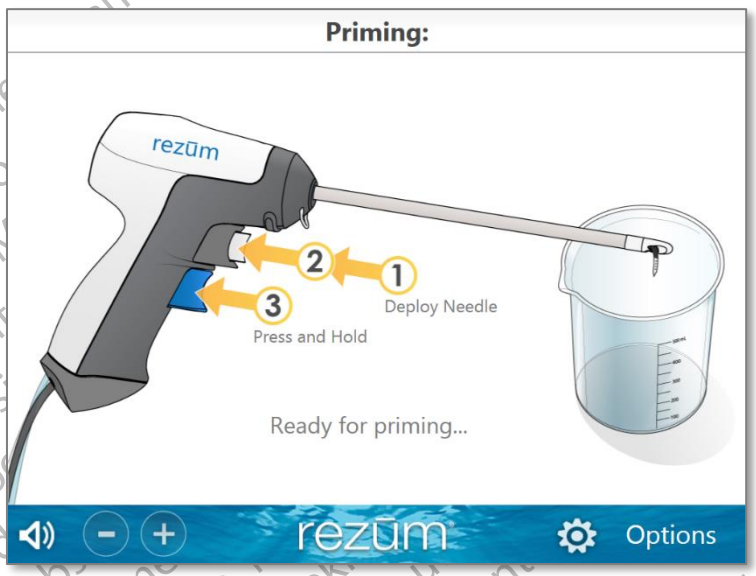


Figure 11: Ready for Priming

When the operator starts priming the Delivery Device, a progress bar will be initiated and displayed. The text will change, and a tone will be generated to indicate that the operation is in progress. Priming is initiated by deploying the needle and holding the Delivery Device vapor activation button for the priming duration, which lasts approximately 30 seconds. A message will be displayed indicating when Priming is complete.

If the vapor activation trigger is activated while the needle is being deployed, priming, pre-treatment, or treatment operation will not be initiated until the vapor trigger is released and reengaged.

Figure 12: Priming Screen

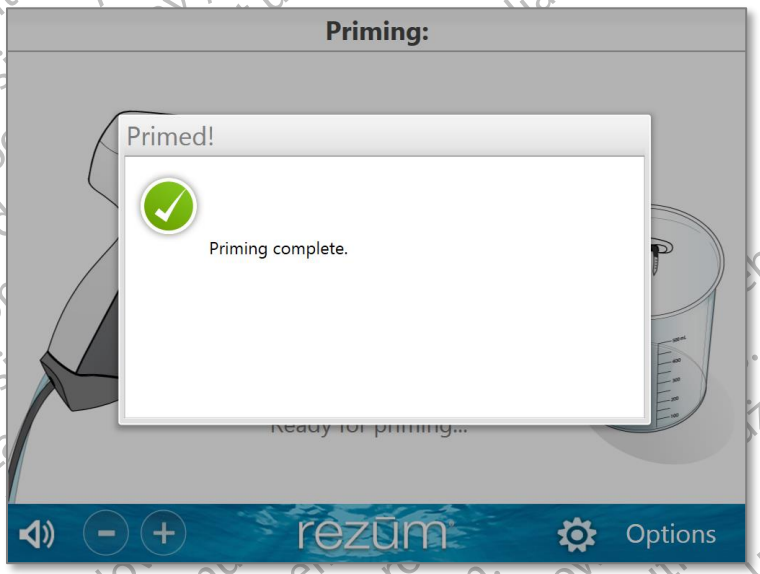


Figure 13: Priming Complete

The *Setup Complete* will be displayed when the Delivery Device has been successfully primed. There will also be an audible tone that indicates success. Pre-treatment vapor cycle shall be performed prior to treatment.

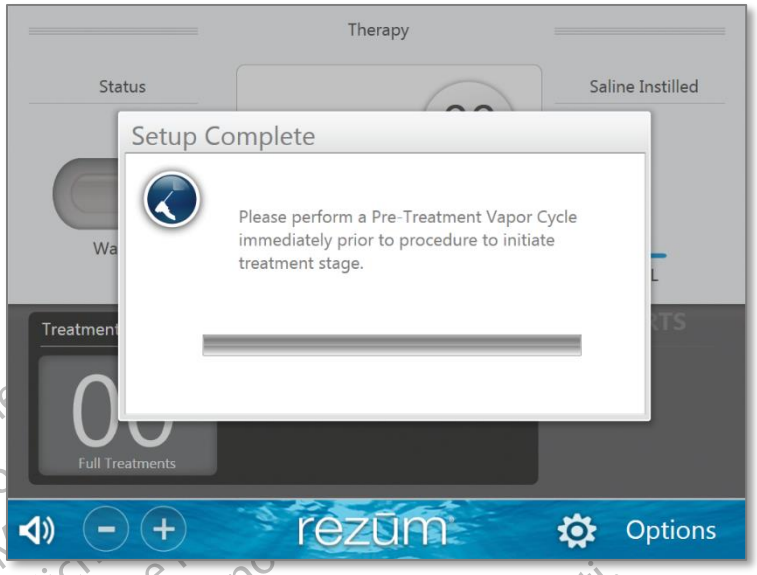


Figure 14: Setup Complete Screen

If the device is not properly primed, an error message will be displayed to the user. Upon resolution of the issue and closure of the error message, the screen will display the *Priming* Screen and the steps should be repeated.

3.1.4 Performing the Therapy

WARNING: If the generator measurement readings or messages seem dubious or abnormal, check the condition of the patient first and stop using the generator.

CAUTION: When any of the following occur, turn the power off, remove all accessories from the patient, and unplug the power cord from the outlet.

- There is smoke or a strange odor leaking out of the generator.
- The generator has been dropped or impacted by an object.
- Liquid or foreign matter gets inside the generator.
- If you think the generator may have been damaged.

After setup is complete, perform a Pre-Treatment Vapor Cycle immediately prior to procedure to initiate treatment stage.

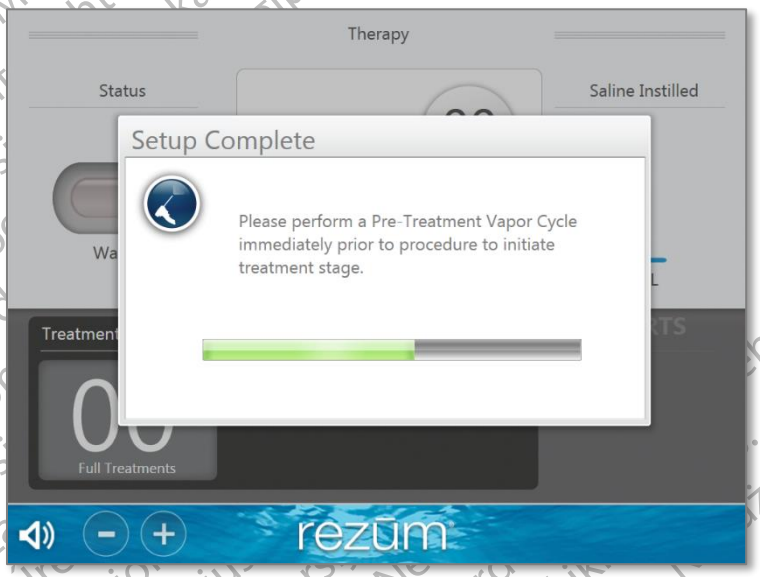


Figure 15: Setup Complete Screen

After performing a pre-treatment vapor cycle, a screen will be displayed indicating the generator is ready for treatment.

Figure 16: Ready for Treatment Screen

A treatment is initiated by activating flush, deploying the needle, and pulling in and holding the vapor activation button. When a treatment is in progress, the time clock will count in whole seconds to the maximum preset treatment time. After treatment time has elapsed, the generator will automatically end the treatment and will once again be ready for treatment. Releasing and reactivating the vapor activation button will initiate another treatment after the required rest period has elapsed.

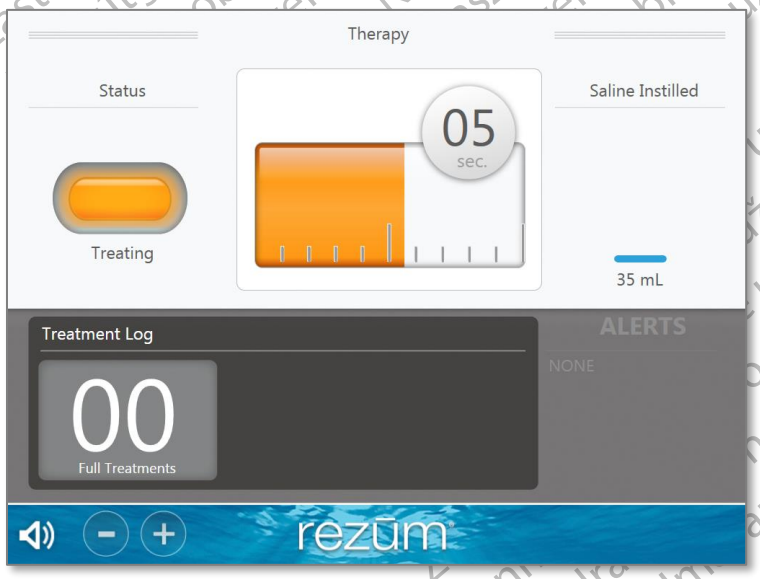


Figure 17: Treatment in Progress Screen

If at any time the generator is not ready to perform a treatment (e.g. rest period between treatments is in effect, etc.) the screen specified Waiting as depicted below and is grayed out.

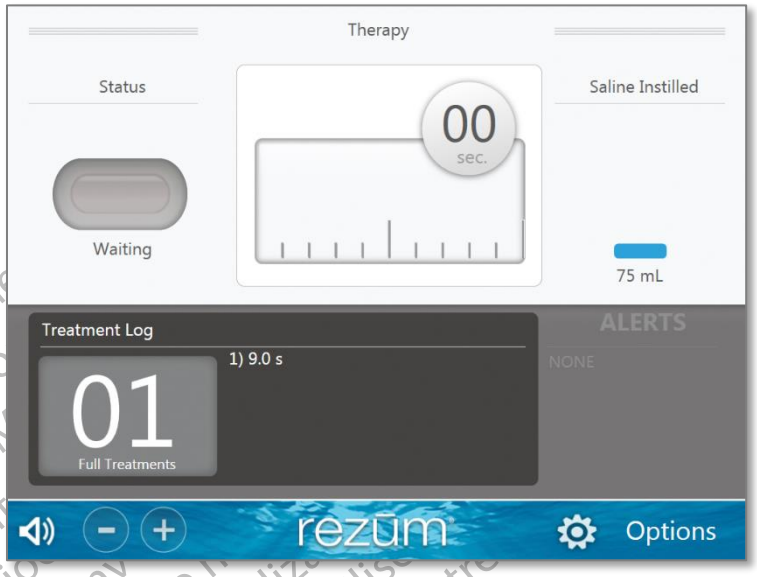


Figure 18: Pending Ready Indicator on screen

The generator will automatically be ready for treatment (Figure 16) when the pending condition is resolved. Monitor the ALERTS message area during treatment and take action when specified to do so.

3.1.4.1 Turbo Flush

If visualization becomes cloudy during the procedure, Turbo Flush can be activated to improve the visualization by increasing the saline flow rate. To activate Turbo Flush, press twice and hold vapor release button. Treatments will not be performed during this mode.

When visualization has been cleared, turn off Turbo Flush by releasing the button.

3.1.4.2 Connecting New Delivery Device during treatment session

The generator can detect if a new delivery device has been connected to the generator during a therapy session.

If a new Delivery Device is connected during the therapy session, select *New* to create a new procedure record or *Continue* to continue with current procedure record.

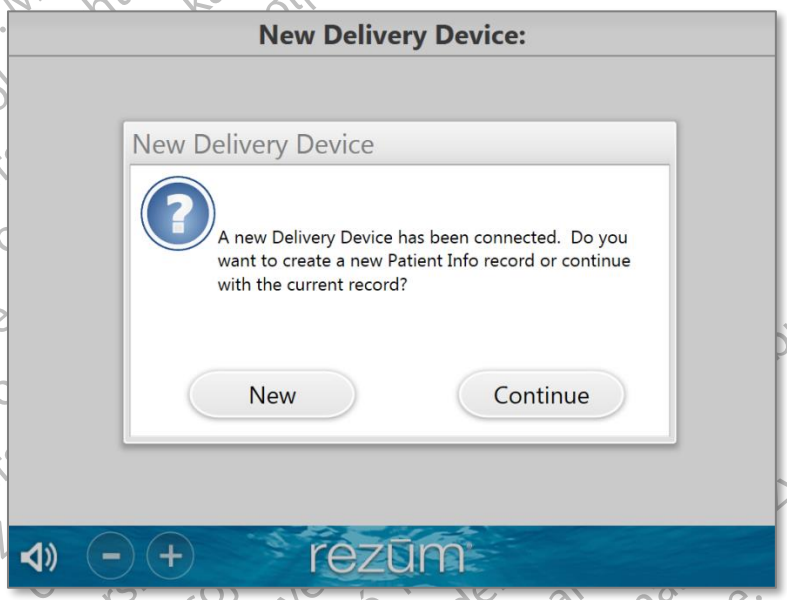


Figure 19: New Delivery Device

3.1.5 Turning off the Rezūm Generator

In the event of power failure, the generator will automatically shut off. Turn the power button off. Please remove the Delivery Device from the patient **immediately** per instructions in the IFU, 3032-0XX Section 9. Turn on again to restart the generator to begin a new therapy session.

CAUTION: Before moving this generator, turn the power OFF, remove all accessories from the patient, and unplug the power cord from the outlet.

1. Turn off the generator by pushing the bottom *Power button* located on the front of the generator.

Power button

Figure 20: Power button

Note: In the event of loss of power, a new procedure record is created. Previously completed treatments will be saved in the prior procedure record.

3.1.6 Rezūm Generator Options Menu Items

To configure the generator and setup before the therapy session begins, select the Options button on the lower toolbar.

Figure 21: Options Menu button

The following options (if applicable) are available and described in further detail in the sections below:

Figure 22: Options Menu choices

3.1.6.1 Drain Bladder

When 750ml of saline has been used, a message will be displayed to the physician to drain the bladder. When this has occurred, select from the Options Menu, Drain Bladder. A "Confirm Bladder Drain" dialog box shall appear when Drain Bladder is selected. Select Confirm to confirm the physician has done so.

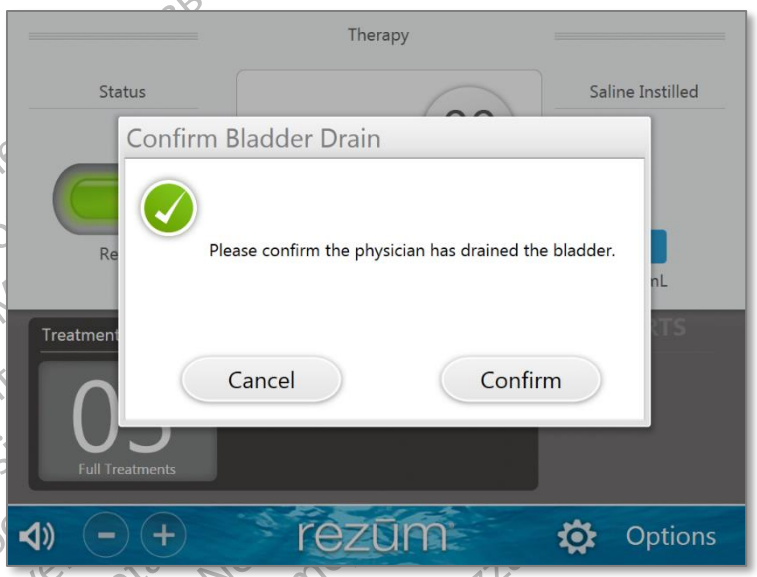


Figure 23: Drain Bladder Confirmation

3.1.6.2 Replace Saline

When saline is replaced, select the Replace Saline from the Options Menu and select the appropriate size saline from the available options. The saline source volume will be set to the previously selected value upon power up of the generator.

Figure 24: Replace Saline

3.1.6.3 Remove Device

From the Options Menu, select Remove Device. A "Confirm Syringe Release" dialog box shall appear when Remove Device item is selected. If the user selects "Release", then the syringe shall be released. If the user selects "Cancel", no action shall be taken.

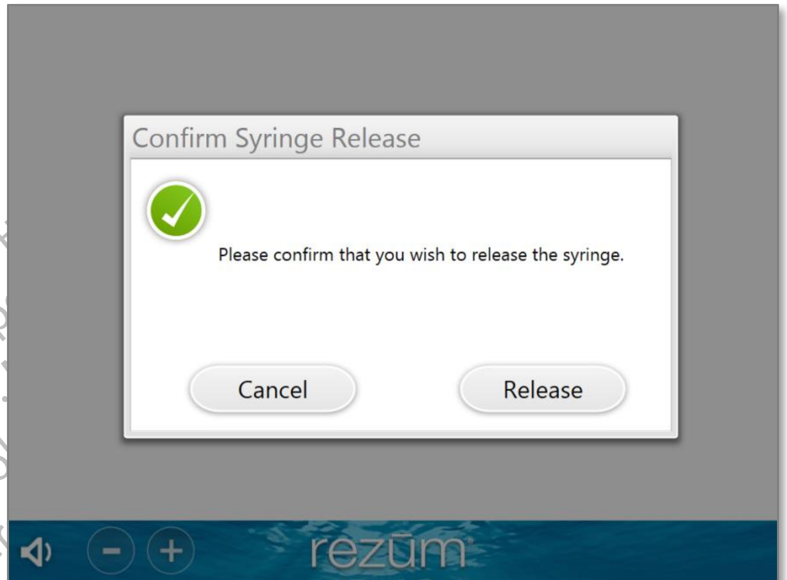


Figure 25: Release Syringe

If the Delivery Device is primed and a release syringe operation occurs, then the Delivery Device shall require re-priming before treatments can be resumed.

After the device is removed, procedure summary will be displayed. From this screen, procedure summary and options to continue, complete or export are available.

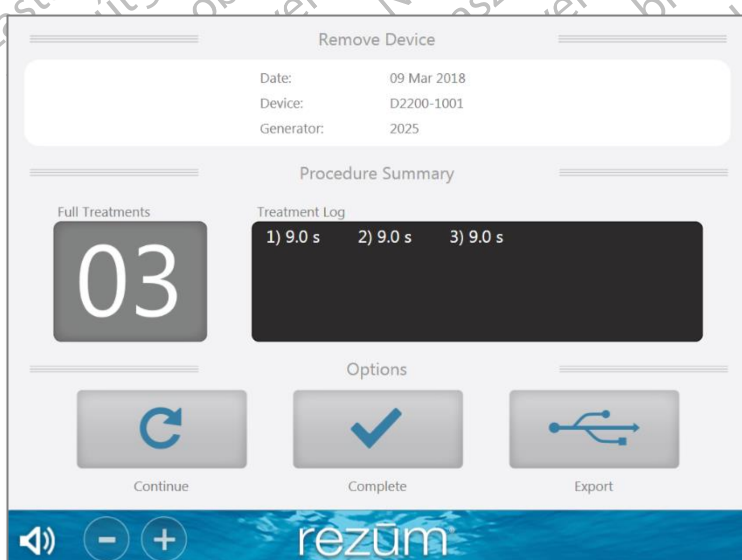


Figure 26: Procedure Summary

3.1.6.3.1 Export Procedure Record

CAUTION: Only NxThera approved equipment and accessories shall be connected to the generator.

CAUTION: The Rezūm Generator USB port is only intended for use during maintenance by authorized service personnel or to export treatment data.

This option is used to export selected procedure records. Therapy information can be exported to a USB memory stick.

Touch the desired folder to select the location on the USB drive to export the procedure records. Touch Save to export the procedure records.

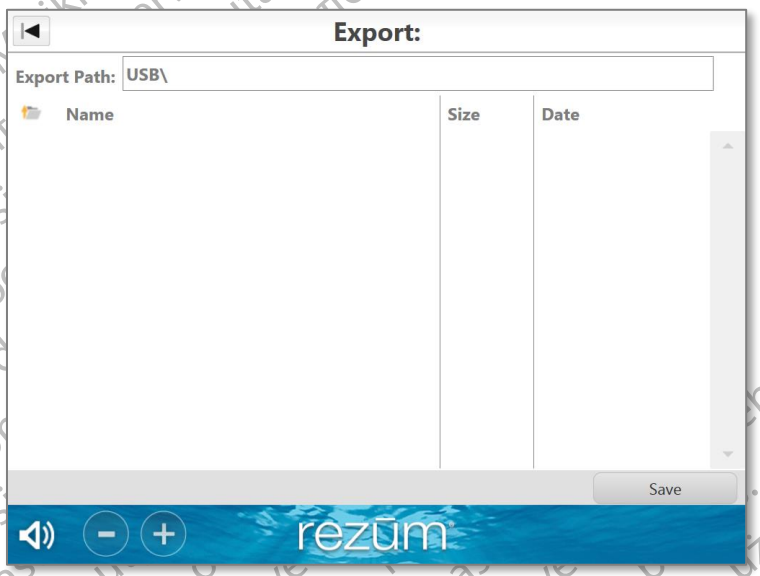


Figure 27: Export Procedure Records

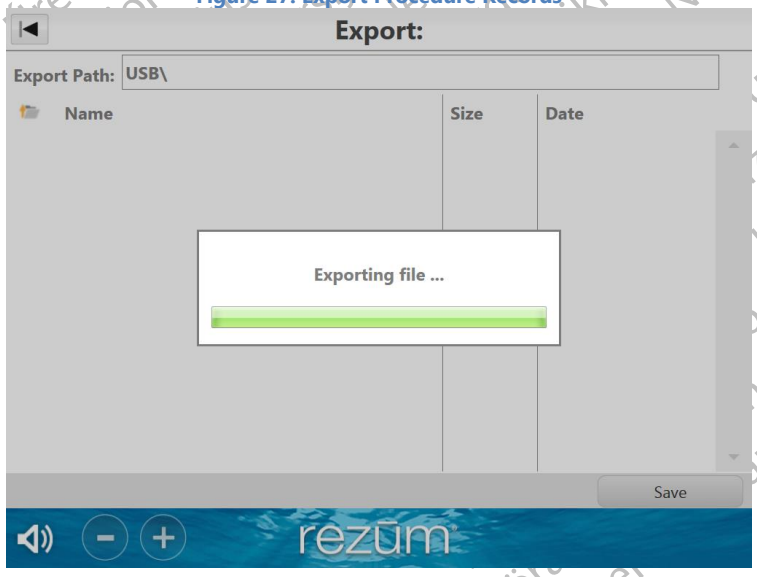


Figure 28: Export Procedure Records Progress

When the records are properly transferred to the USB memory stick, a confirmation message will be displayed on the screen.

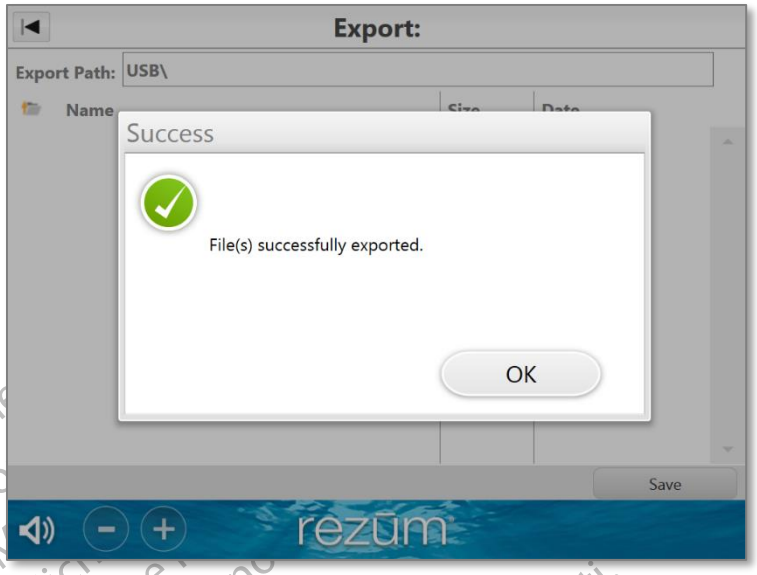


Figure 29: Export Procedure Records Success

The device will store up to a maximum of 1000 procedure records. Once the generator reaches it maximum record capacity, the generator will automatically delete the oldest record to perform another therapy session.

The procedure records are saved in both a .csv and .txt format. The serial number plus date/time, and unique number are saved as the file name. The .txt file contains all the user-viewable information stored in the procedure record (Figure 30). The .csv file contains details of individual treatments stored in that procedure record (Figure 31). Specifically, each comma-separated line of data contains: serial number of the Delivery Device, treatment start date/time stamp, treatment duration.

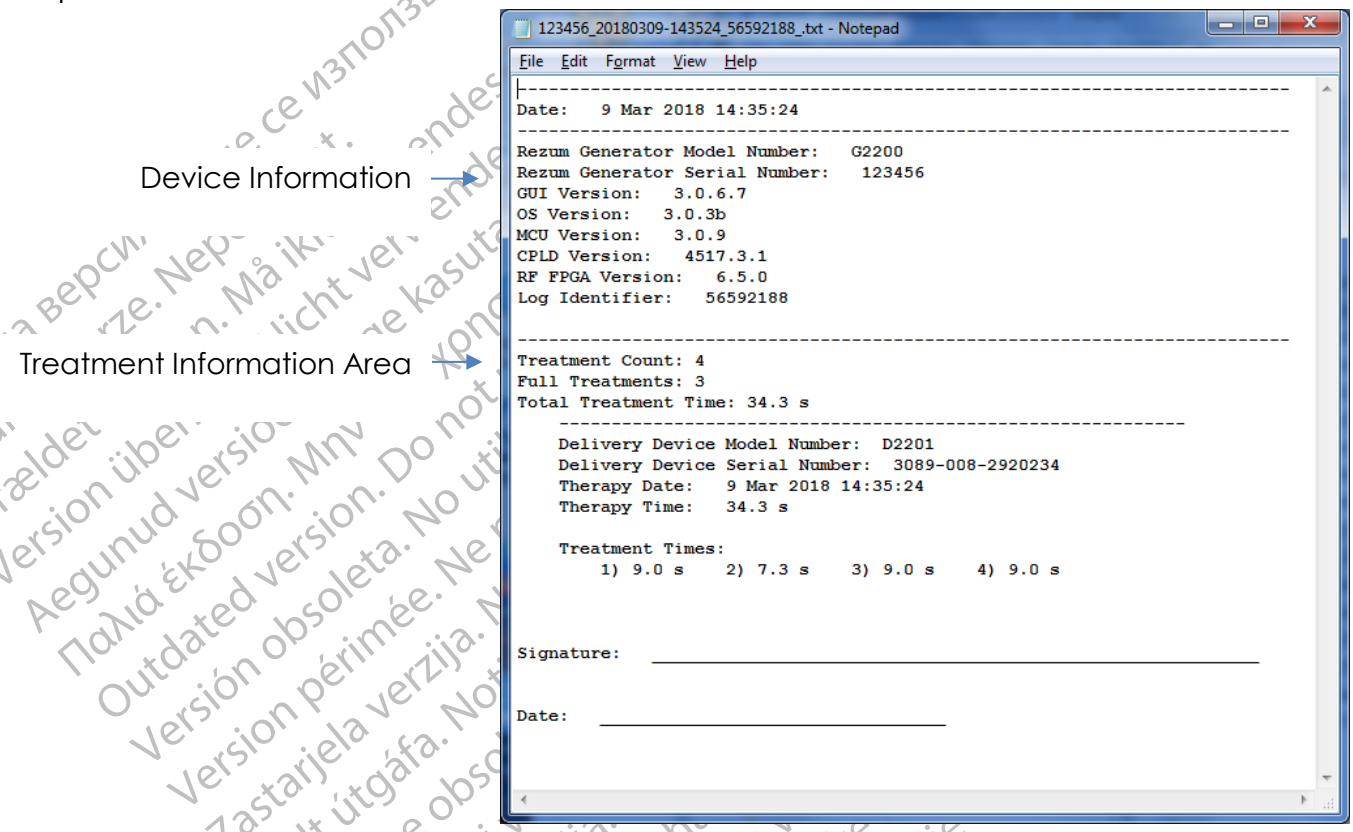


Figure 30: Example of Exported .txt File

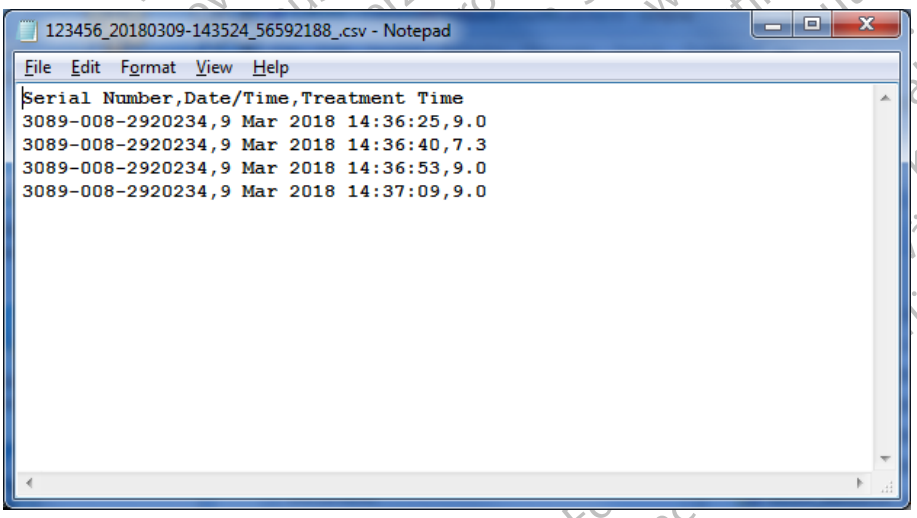


Figure 31: Example of Exported .csv File

3.1.6.4 More Options

From the Options menu, select More Options. The More Options screen allows the 6 options that can be selected.

Figure 32: More Options Screen

3.1.6.4.1 System Status

The *System Status* screen contains information.

- Information on the generator and Delivery Device internal device identifiers.
- Software versions
- Ability to set date and time
- Ability to set language

Figure 33 System Status

3.1.6.4.1.1 Set Date and Time

The *Select New Date and Time* screen allows the date and time of generator to be updated from factory defaults for time zone or daylight-saving time changes. The generator does not automatically adjust for daylight savings time changes. Valid dates are between 1900 and the current year.

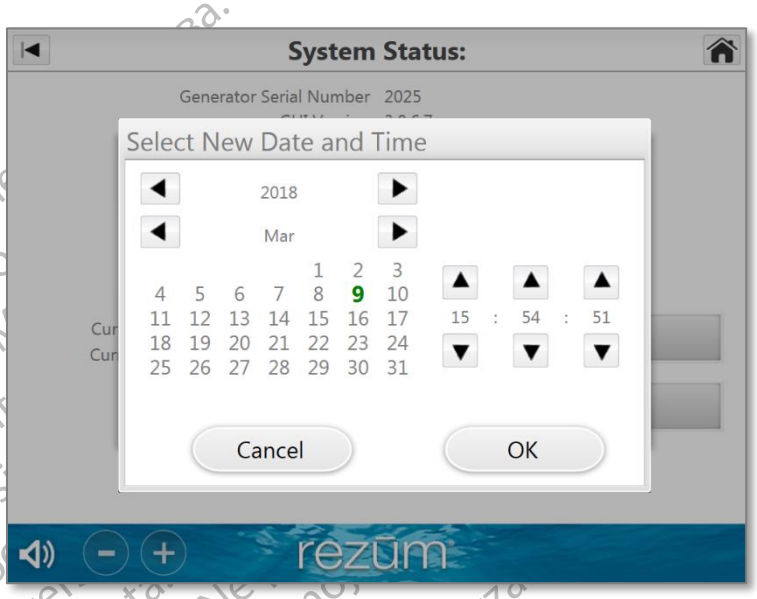


Figure 34: Set Date and Time

3.1.6.4.1.2 Set Language

The *Set Language* screen allows the language to be updated from English to preloaded language options and desired number format. These settings do not change when powering on and off the generator.

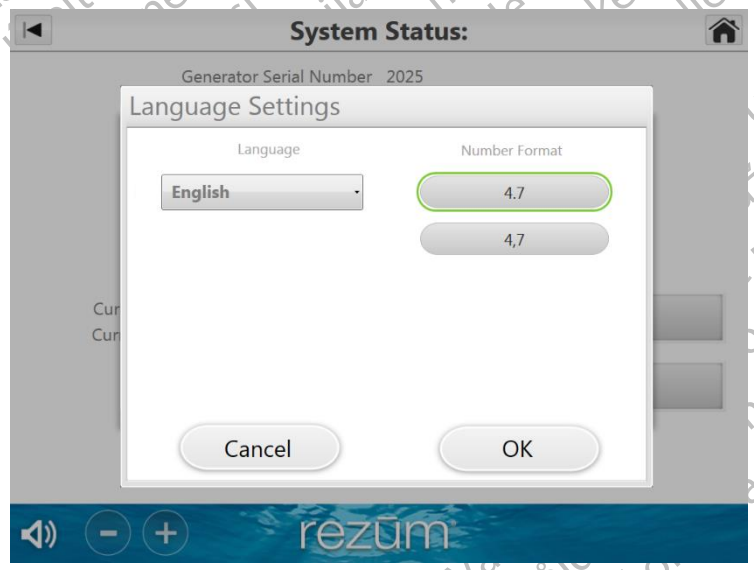


Figure 35: Language Settings

Select the desired language from the dropdown language list and click OK to change the language from English to desired language. Use the scroll bar to display more languages.

Figure 36: Language Selections

3.1.6.4.2 Export Logs

CAUTION: Only NxThera approved equipment and accessories shall be connected to the generator.

CAUTION: The Rezūm Generator USB port is only intended for use during maintenance by authorized service personnel or to export treatment data.

Encrypted log files can be exported to a USB drive for use by NxThera service personal only.

Select files to export from the list of options and Click OK.

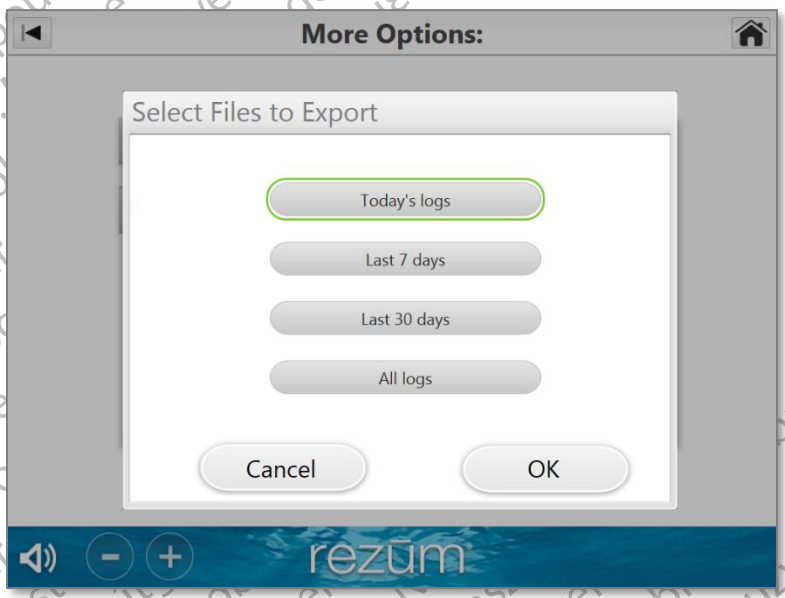


Figure 37: Select Files to Export

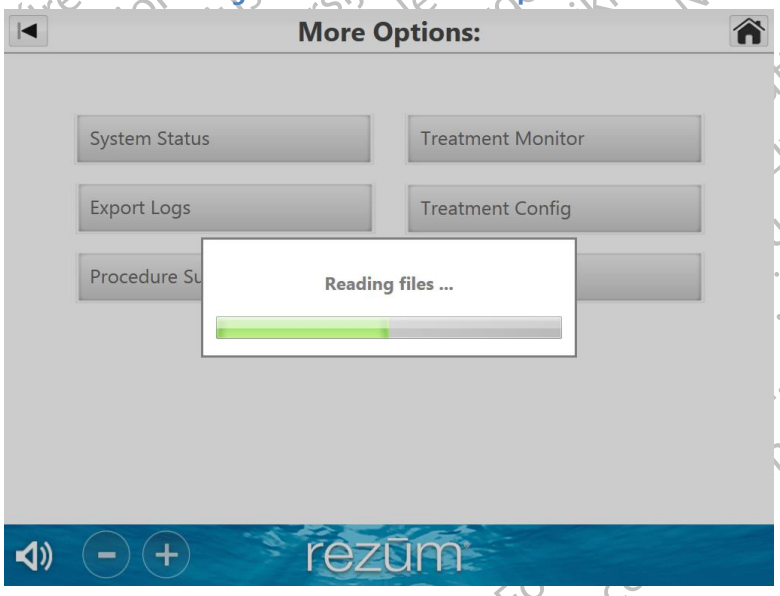


Figure 38: Reading Files

Select export path and select Save.

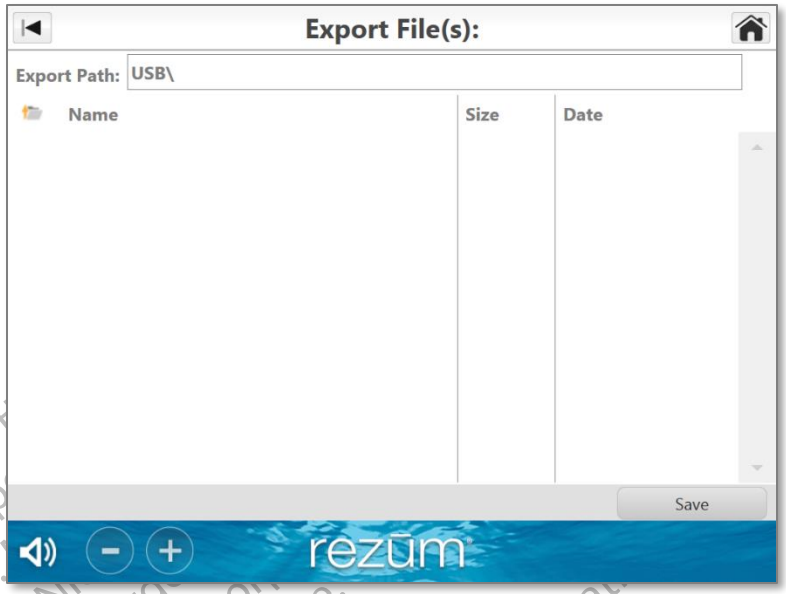


Figure 39: Export Files

After saving the files, the generator will build the archive, export the files, and prompt when it is successful.

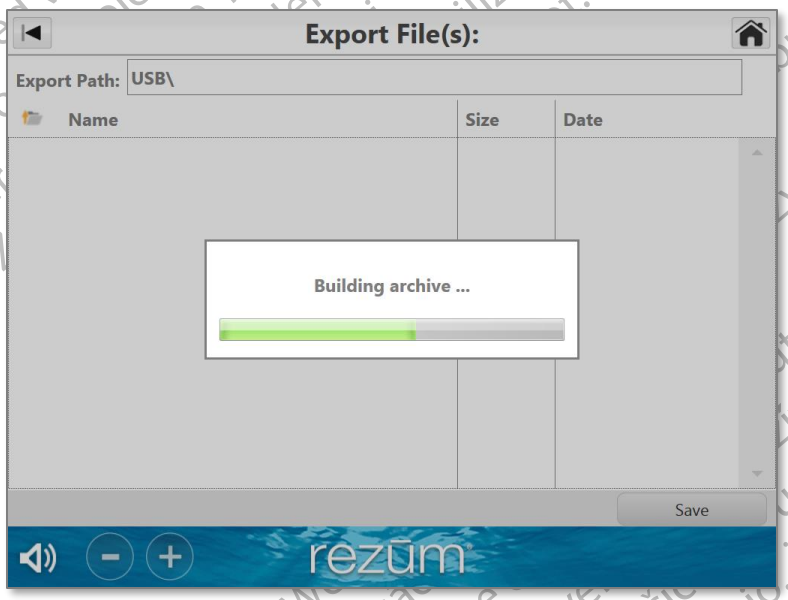


Figure 40: Building archive

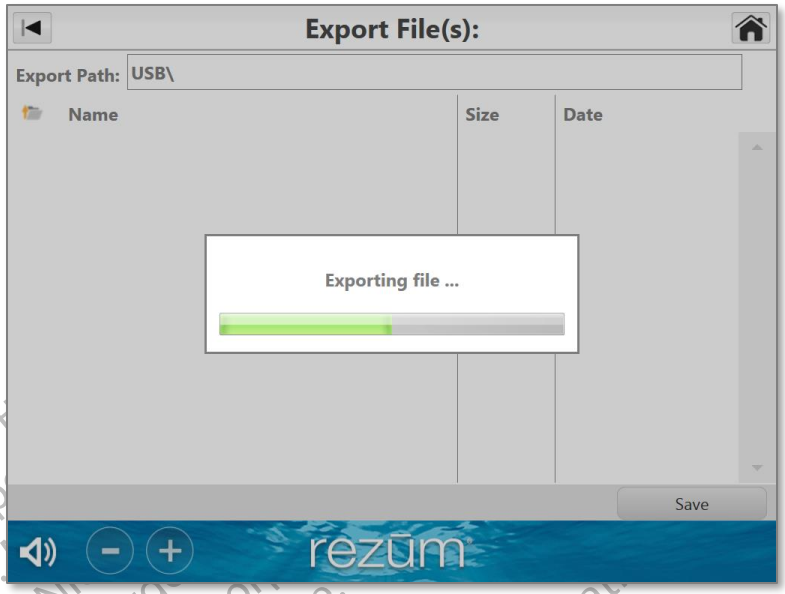


Figure 41: Exporting file

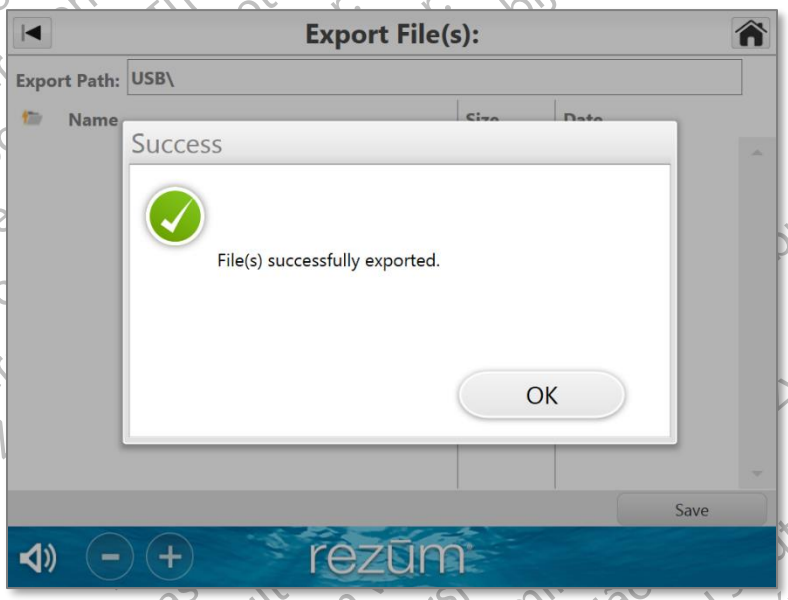


Figure 42: Export Successful

3.1.6.4.3 Procedure Summary

The *Procedure Summary* screen displays a sortable list of recently used devices.

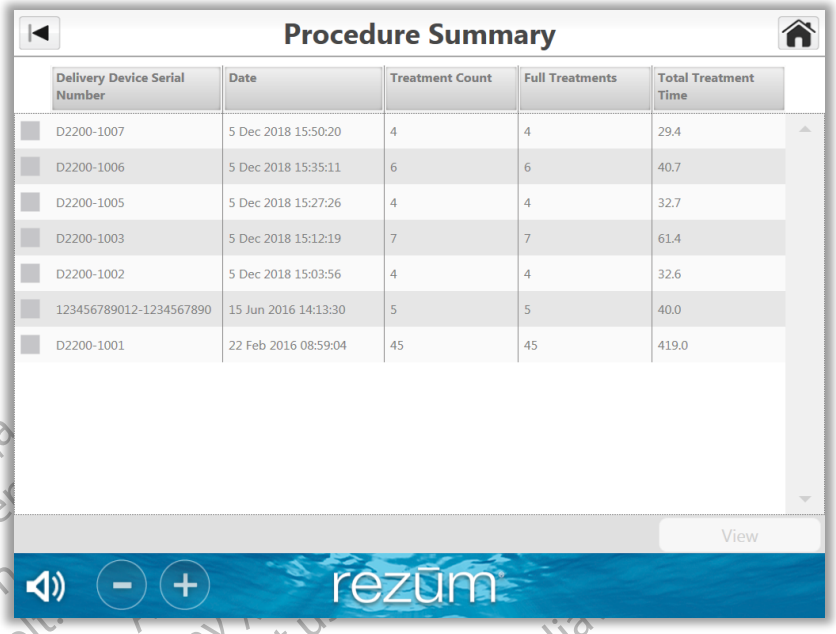


Figure 43: Procedure Summary

Select devices from the list using the check boxes on the left of the screen, and then select View. The generator will populate the summary report with the list of selected devices.

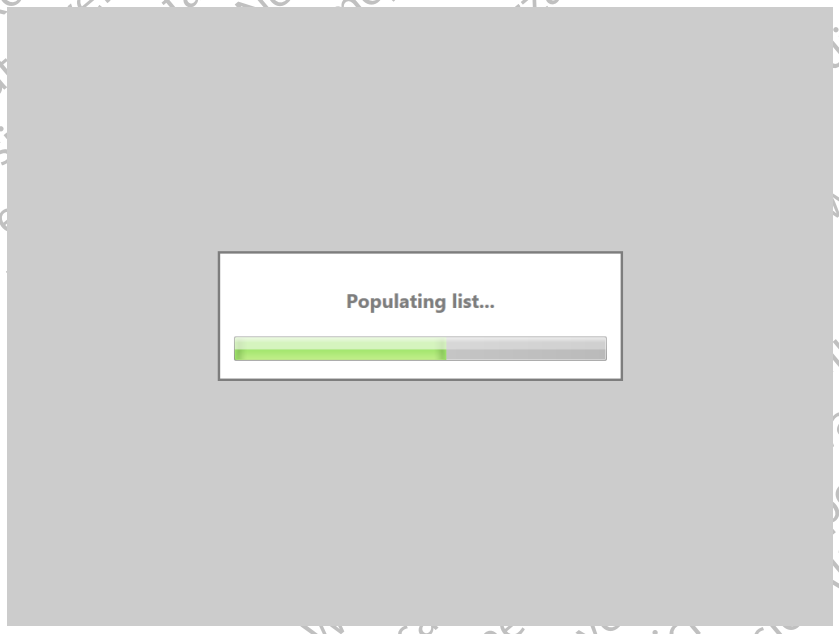


Figure 44: Populating List

Figure 45: Procedure Summary – View

Use the scroll bar to view the entire summary.

3.1.6.4.4 Treatment Monitor

This screen is password protected and accessed by NxThera service personal only.

3.1.6.4.5 Treatment Config

This screen is password protected and accessed by NxThera service personal only.

3.1.6.4.6 Servicing

This screen is password protected and accessed by NxThera service personal only.

Chapter 4 Maintenance and Service

Overview

Proper maintenance of the Rezūm Generator is very simple, yet it is an important factor in its reliability. This section describes the maintenance and service required for the generator.

WARNING: No modification of this equipment is allowed. Do not attempt to service or maintain the generator while in use with a patient.

WARNING: Do not modify this equipment without authorization of NxThera.

WARNING: If this equipment is modified with authorization from NxThera, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

CAUTION: When any of the following occur, turn the power off, remove all accessories from the patient, and unplug the power cord from the outlet.

- There is smoke or a strange odor leaking out of the generator.
- The generator has been dropped or impacted by an object.
- Liquid or foreign matter gets inside the generator.
- If you think the generator may have been damaged.

4.1 Recommended Maintenance and Care

WARNING: Failure on the part of all responsible individuals, hospitals, or institutions, employing the use of Rezūm Generator, to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. The manufacturer does not, in any manner, assume the responsibility for performing the recommended maintenance schedule. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the Rezūm Generator.

WARNING: Do not submerge the device in liquids or pour cleaning liquids over, into or onto the generator.

WARNING: Before conducting maintenance work, turn the power OFF and unplug the power cord from the outlet to prevent electric shock.

CAUTION: To prevent damage to generator, do not clean any part of the device with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the generator.

CAUTION: Using this generator with the ventilation ports blocked could cause a breakdown. Clean this generator with care.

CAUTION: Only NxThera approved equipment and accessories shall be connected to the generator.

CAUTION: The Rezūm Generator USB port is only intended for use during maintenance by authorized service personnel or to export treatment data.

To ensure the Rezūm Generator is always functional when required, NxThera recommends performing the following maintenance activities:

- Performing a Visual Inspection
- Cleaning the Rezūm Generator
- Maintenance per checklist in this section

It is important that the generator is stored at room temperature if it is expected to be used.

The Rezūm Generator requires no calibration.

4.1.1 Visual Inspection

WARNING: After the visual inspection, if the device is damaged or a message indicating the generator is not to be used, take the generator out of service and call NxThera Customer service.

The generator should be carefully inspected prior to installation, use, and each time the equipment is serviced.

- Carefully inspect the generator case for stress or physical damage.
- Inspect all external connections for loose connectors.
- Inspect all external cables for damage or cracking.
- Inspect the display for marks, scratches, or other damage.
- Verify that the Product label on the device is clearly legible and present.

4.1.2 Cleaning the Rezūm Generator

It is recommended that the generator be inspected after each use according to the Checklist in this manual and cleaned when appropriate. Listed below are recommendations for cleaning the generator. The generator does not need to be sterilized before or after use.

WARNING: Do not submerge the device in liquids or pour cleaning liquids over, into or onto the generator.

CAUTION: After cleaning, allow complete drying before plugging into an outlet by wiping with a dry, soft cloth.

CAUTION: Do not soak the generator or accessories in any medical liquid. Also, keep liquids out of the generator and accessories.

CAUTION: When using disinfectant solutions, follow the manufacturer's directions.

CAUTION: Using this generator with the air vent blocked could cause a breakdown. Clean this generator with care.

CAUTION: To prevent damage to equipment, do not clean any part of the generator with phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas-sterilize the generator.

4.1.2.1 Recommended Cleaning Products

The following cleaning products may be used to clean the exterior surfaces of the generator:

- Water
- 70% Isopropyl Alcohol
- Super Sani-Cloth® Germicidal Disposable Wipes by PDI only
- Cidex®

4.1.2.2 Not Recommended Cleaning Products

- Do not use abrasive cleaners or strong solvents such as acetone or acetone-based cleaners.
- Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may occur
- Do not clean electrical contacts or connectors with bleach.

4.1.2.3 Cleaning Instructions

1. Before cleaning the generator, turn the generator off and disconnect the power cord.
2. To remove any foreign material and fluid (e.g. dust, paper, etc.), wipe thoroughly with a soft cloth lightly dampened with water or 70% isopropyl alcohol. Super Sani-Cloth® wipes and Cidex® may be used per manufacturer instructions.

   To prevent scratching the display, the use of a soft cloth is recommended.
3. When cleaning, do not immerse.
4. Wring any excess moisture from the cloth before and during cleaning.
5. Avoid pouring fluids on the generator, and do not allow fluids to penetrate the exterior surfaces of the generator.
6. To dry the generator after cleaning, wipe with a dry, soft cloth.

4.1.3 Maintenance Checklist

Maintenance activities involve verifying operation and safety.

Maintenance should always be performed by the Customer at least once every 12 months. The following checklist is recommended to be utilized when checking the generator:

Visual Inspection ***WARNING:*** After the visual inspection, if the generator is damaged or a message indicates to not use, take the generator out of service and call NxThera Customer Service.
• Carefully inspect the generator case for stress or physical damage.
• Inspect all external connections for loose connectors.
• Inspect all external cables for damage or cracking.
• Inspect the display for marks, scratches, or other damage.
• Verify that the Safety label on the device is clearly legible and present.
Operating Test ***WARNING:*** If a Critical Error message is displayed, take the generator out of service and call NxThera Customer Service.
• Set-up generator and turn on power to check the start-up diagnostics.

Table 9: Maintenance Checklist

4.2 Authorized Repair or Service

WARNING: Shock Hazard - Do not open, disassemble, or alter the Rezūm Generator! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

WARNING: Do not use the generator if it is damaged, is not functioning properly, or fails to meet an electrical safety check. Notify the appropriate personnel to ensure the generator is removed from service and properly repaired.

The generator has no user-serviceable internal components. Try to resolve any maintenance issues with the generator by using the Troubleshooting Table presented in Section 6, Troubleshooting. If you are unable to resolve the problem, contact Customer Service.

The warranty will be void upon unauthorized disassembly or service of the Rezūm Generator.

Chapter 5 Technical Specifications

Overview

This chapter contains specifications for the Rezūm Generator and EMC information.

5.1 Generator Specifications

CAUTION: Exposing the Rezūm Generator to extreme environmental conditions outside of normal parameters may compromise the ability of the Rezūm Generator to function properly and/or cause the plastic to warp and/or crack.

CAUTION: If the Rezūm Generator is stored in an environment with a temperature below the room temperature, the unit should be allowed to warm up to the needed operating temperature before using.

Description	**Specification**
Protection against Electric Shock	Class I Equipment (generator)
Model Number	G2200
	100-240 VAC, 50-60Hz
Power Input	10 Amps maximum
External Fuses	Two, 10AH-250V, 5x20mm
Mode of Operation	Continuous Operation
System Control	Provides controlled flow of water vapor at ambient temperatures below 25˚C
Case dimensions	23L x16W x9H inches
Weight	50 pounds or less (generator only)
Power cable length	9 feet
Applied Parts protection	 Type BF
Protection against ingress of fluids and particulate matter	IPx0

Table 10: Generator Specification

5.2 Electromagnetic Compatibility Requirements

WARNING: Use of accessories other than those specified in this document may result in increased emission or decreased immunity of the Rezūm Generator.

WARNING: The Rezūm Generator should not be used adjacent or stacked with other equipment and, if necessary, observe its operation to verify its normal operation during use. Refer to the Electromagnetic Immunity information in this chapter.

CAUTION: The Rezūm Generator needs special precautions regarding Electromagnetic compatibility (EMC) and care should be taken in accordance to the EMC information provided in Chapter 5 of this document.

CAUTION: Use of portable and mobile RF communications equipment near the Rezūm Generator may affect its operation.

CAUTION: Observe the following cautions when connecting this generator with other equipment:

- Ensure that the connected equipment is in accordance with the IEC60601-1 or IEC safety standards.

Employ additional protective measures (e.g., additional protective earthing) as necessary.

CAUTION: Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI), which could affect the performance of this device. Avoid operating the Rezūm Generator near cauterizers, diathermy equipment, FM 2-way radios, or cellular phones. Turn power off to radio, cellular and other like equipment near the Rezūm Generator. Refer to the EMI tables in Chapter 5.

Table 11: Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Rezūm Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the Rezūm Generator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
Radiated emissions CISPR 11:2015	Group 2	The Rezūm Generator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Conducted emissions CISPR 11:2015	Class A	The Rezūm Generator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purpose.
Harmonic current emissions IEC 61000-3-2:2014	Class A	
Voltage fluctuations and flicker IEC 61000-3-3:2013	Complies	

Table 12: Electromagnetic Immunity

Immunity test	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2:2008	±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%
Electrical fast transient/burst immunity IEC 61000-4-4:2012	±1 kV common mode; 5kHz and 100kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge immunity IEC 61000-4-5:2014	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency magnetic field IEC 61000-4-8:2009	30 A/m, 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity test	Compliance level	Electromagnetic environment - guidance
Voltage dips and interruptions immunity 61000-4-11:2004	Six dips each at 100%, 60%, 30% voltage reduction; one interrupt Three 100% dips each at phase angles of 0, 45, 90, 135, 180, 225, 270, and 315; one interrupt	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Rezūm Generator requires continued operation during power mains interruptions, it is recommended that the Rezūm Generator be powered from an uninterruptible power supply.

Table 13: Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity		
The Rezūm Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the Rezūm Generator should assure that it is used in such an environment.		
Immunity test	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6:2013	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the Rezūm Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.57GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d]
Radiated RF IEC 61000-4-3:2010	3 V/m 80 MHz to 2.7 GHz	Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Rezūm Generator is used exceeds the applicable RF compliance level above, the Rezūm Generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Rezūm Generator.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Table 14: Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Rezūm Generator	
The Rezūm Generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Rezūm Generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Rezūm Generator as recommended below, according to the maximum output power of the communications equipment.	
	Separation distance according to frequency of transmitter (m)

Rated maximum output power of transmitter (W)	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.7 GHz d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

5.3 EN 60601-1-2 Compliance

WARNING: RF Interference - Known RF sources, such as cell phones, radio or TV stations, and two-way radios, may cause unexpected or adverse operation of this generator. Consult qualified personnel regarding system configuration.

WARNING: The generator should not be used adjacent to, or stacked with other equipment. If adjacent or stacked use is necessary, test the generator to verify normal operation. Refer to the Electromagnetic Immunity information in Chapter 5.

WARNING: The generator needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be put into service according to the EMC information in Chapter 5 provided in this operator's manual.

CAUTION: The generator conforms to the requirements of the EMC standard (IEC 60601-1-2:2009). However, it may be affected by electrical scalpels and microwave treatment devices and there may be an impact on measurement precision for patients using cardiac pacemakers and other similar devices. Check the operation of this generator during and after use of the above mentioned equipment and with patients potentially affected.

Chapter 6 Troubleshooting

Overview

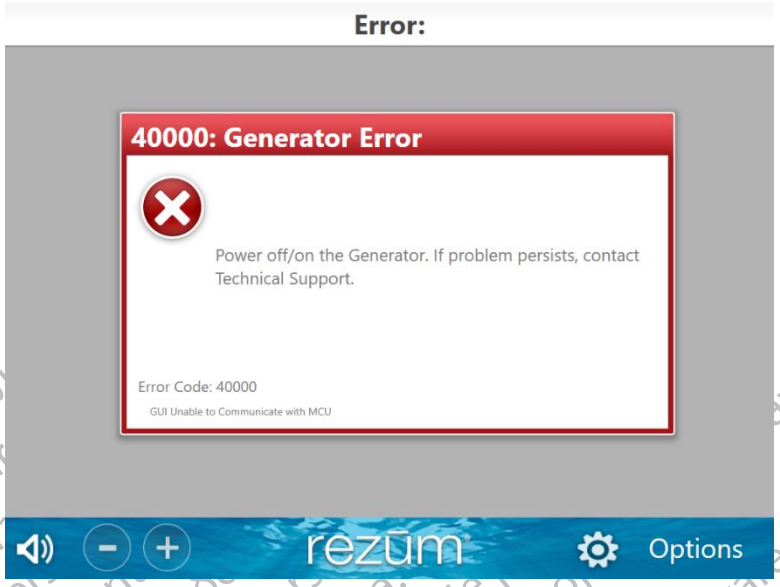
This chapter contains troubleshooting steps, error message description, error message table, and how to obtain technical assistance.

6.1 Troubleshooting Steps

If you experience a problem while using the generator, please use the Error Message table to troubleshoot the issues. If you are unable to correct it, write down the error message and error code, if applicable, and contact qualified service personnel in your institution or contact Customer Service.

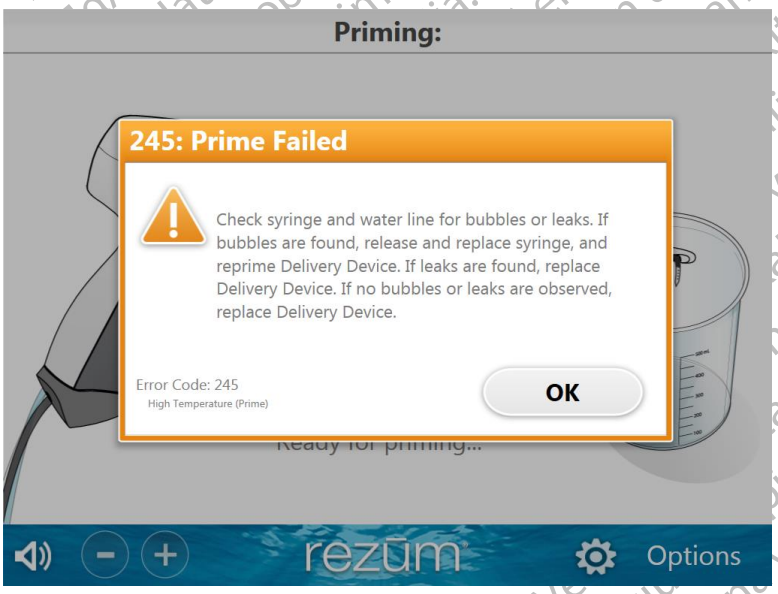
6.2 Error Messages

Error messages will be displayed on the screen. There are 3 types of error messages –Critical, Non-Critical Error, and Informational Error.



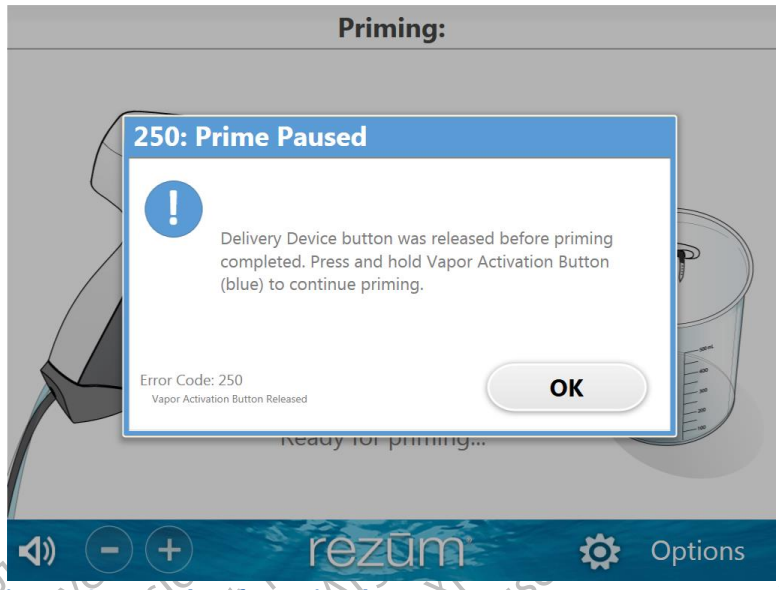
Critical Error message

Figure 46: Example Critical Error Message



Non-Critical Error message

Figure 47: Example Error Message



Informational Error message

Figure 48: Example Informational Error Message

6.3 Error Message Table

The following tables list all error messages that are displayed by the generator. Follow error message instructions to resolve the error.

6.3.1 Critical Error Messages

Code	Error Title	Error Cause Text	Error Message
400	Generator Error	RF Power Supply Error	Retract the needle and remove the Delivery Device from patient. Remove the Generator from service and contact Technical Support.
405	Generator Error	Power Supply Initialization Error	Retract the needle and remove the Delivery Device from patient. Remove the Generator from service and contact Technical Support.
425	Generator Error	SBC Communications Critical Timeout	Retract the needle and remove the Delivery Device from patient. Remove the Generator from service and contact Technical Support.
430	Generator Error	RF Power Supply Communication Error	Retract the needle and remove the Delivery Device from patient. Remove the Generator from service and contact Technical Support.
435	Generator Error	MCU Processing Error	Retract the needle and remove the Delivery Device from patient. Remove the Generator from service and contact Technical Support.
440	Generator Error	CPLD Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
450	Generator Error	Delivery Device Interface Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
455	Generator Error	Saline Pump Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
460	Generator Error	Syringe Pump Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
465	Generator Error	Water Pressure Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
470	Generator Error	Delivery Device Temperature Excessive	Retract the needle and remove the Delivery Device from patient. Power off/on the Generator. Replace Delivery Device.
475	Generator Error	Software Compatibility Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
480	Generator Error	Sensor Interface Error	Retract the needle and remove the Delivery Device from patient. If problem persists, contact Technical Support.
485	Generator Error	Internal Generator Temperature Error	Retract the needle and remove the Delivery Device from patient. Power off the Generator and allow it to cool down before using again.
490	Generator Error	RF Power Supply Operational Error	Retract the needle and remove the Delivery Device from patient. If problem persists, contact Technical Support.
495	Generator Error	RF Power Supply Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
35000	Generator Error	GUI Program Files Corrupted	Power off/on the Generator. If problem persists, contact Technical Support.
35001	Generator Error	Unexpected GUI Program Exit	Power off/on the Generator. If problem persists, contact Technical Support.
35002	Generator Error	Unable to Start GUI Program	Power off/on the Generator. If problem persists, contact Technical Support.
40000	Generator Error	GUI Unable to Communicate with MCU	Power off/on the Generator. If problem persists, contact Technical Support.
41020	Generator Error	MCU Reboot Detected	Retract the needle and remove the Delivery Device from patient. Remove the Generator from service and contact Technical Support.

Table 15: Critical Error Message Table

6.3.2 Non-Critical Error Messages

Code	Error Title	Error Cause Text	Error Message
200	Faulty Delivery Device	Unable to Read from Delivery Device Memory	Remove and reconnect Delivery Device electrical cable. If problem persists, replace Delivery Device.
205	Faulty Delivery Device	Unable to Write to Delivery Device Memory	Remove and reconnect Delivery Device electrical cable. If problem persists, replace Delivery Device.
210	Faulty Delivery Device	Faulty Delivery Device Thermocouple	Replace Delivery Device.
211	Faulty Delivery Device	Faulty Delivery Device Trigger Signals	Replace Delivery Device.
215	Faulty Delivery Device	Invalid Therapy Code	Remove and reconnect Delivery Device electrical cable. If problem persists, replace Delivery Device.
218	Faulty Delivery Device	Delivery Device Impedance Error	Replace Delivery Device.
219	Faulty Delivery Device	Delivery Device Frequency Error	Replace Delivery Device.
220	Expired Delivery Device	Maximum Full Treatments Exceeded	Replace Delivery Device.
225	Faulty Delivery Device	Delivery Device is Permanently Disabled	Replace Delivery Device.
230	Expired Delivery Device	Maximum Vapor Time Exceeded	Replace Delivery Device.
235	Prime Failed	Low Temperature (Prime)	Replace Delivery Device.
236	Pre-Treatment Failed	Low Temperature (Pre-Treatment)	Replace Delivery Device.
240	Prime Failed	Low Water Pressure (Prime)	Check syringe and water line for bubbles or leaks. If bubbles are found, replace syringe and reprime Delivery Device. If leaks are found, replace Delivery Device. If no bubbles or leaks are observed, replace Delivery Device.
241	Prime Failed	High Water Pressure (Prime)	Check water line for kinks. Resume priming. If problem persists, replace Delivery Device.
242	Pre-Treatment Failed	Low Water Pressure (Pre-Treatment)	Check syringe and water line for bubbles or leaks. If bubbles are found, replace syringe and reprime Delivery Device. If leaks are found, replace Delivery Device. If no bubbles or leaks are observed, replace Delivery Device.
243	Pre-Treatment Failed	High Water Pressure (Pre-Treatment)	Check water line for kinks. Resume pre-treatment vapor cycle. If problem persists, replace Delivery Device.
245	Prime Failed	High Temperature (Prime)	Check syringe and water line for bubbles or leaks. If bubbles are found, replace syringe and reprime Delivery Device. If leaks are found, replace Delivery Device. If no bubbles or leaks are observed, replace Delivery Device.
246	Pre-Treatment Failed	High Temperature (Pre-Treatment)	Check syringe and water line for bubbles or leaks. If bubbles are found, replace syringe and reprime Delivery Device. If leaks are found, replace Delivery Device. If no bubbles or leaks are observed, replace Delivery Device.
255	Treatment Halted	Low Temperature (Treatment)	Retract the needle and remove the Delivery Device from patient. Replace Delivery Device.
260	Treatment Halted	High Water Pressure (Treatment)	Check water line for kinks. Resume treatment. If problem persists, replace Delivery Device.
265	Treatment Halted	Low Water Pressure (Treatment)	Check syringe and water line for bubbles or leaks. If bubbles are found, replace syringe and reprime Delivery Device. If leaks are found, replace Delivery Device. If no bubbles or leaks are observed, replace Delivery Device.
270	Syringe is Empty	Syringe Empty	Retract the needle and remove the Delivery Device from patient. Replace syringe and reprime Delivery Device.
275	Prime Failed	Syringe Water Fill Error	Refill syringe and reprime Delivery Device.

Code	Error Title	Error Cause Text	Error Message
280	Treatment Halted	Elevated Coil Temperature	Partial treatment delivered. Check syringe and water line for bubbles or leaks. If no bubbles or leaks are found, resume treatment. If problem persists, replace Delivery Device. If bubbles are found, replace syringe and reprime Delivery Device. If leaks are found, replace Delivery Device.
290	Faulty Delivery Device	High Temperature (Idling)	Replace Delivery Device.
291	Faulty Delivery Device	High Water Pressure (Idling)	Replace Delivery Device.
295	Faulty Delivery Device	Needle Deployment Error	Ensure needle is retracted. Replace Delivery Device.
296	Faulty Delivery Device	Needle Retraction Error	Reattempt needle retraction. If problem persists, retract needle manually and replace Delivery Device.
300	Saline Pump Error	Saline Pump Encoder Error	Ensure Delivery Device saline flush line is correctly inserted into saline pump and pump door is closed. If problem persists, contact Technical Support.
325	Confirm Bladder Drain	Saline Instilled Limit Exceeded	Saline instilled limit exceeded. Please confirm the physician has drained the bladder.

Table 16: Non-Critical Error Message Table

6.3.3 Informational Error Messages

Code	Error Title	Error Cause Text	Error Message
250	Prime Paused	Vapor Activation Button Released	Delivery Device button was released before priming completed. Press and hold Vapor Activation Button (blue) to continue priming.
251	Pre-Treatment Paused	Vapor Activation Button Released	Delivery Device button was released before pre-treatment vapor cycle completed. Press and hold Vapor Activation Button (blue) to restart pre-treatment vapor cycle.
341	Prime Paused	RF Power Tolerance Limit Exceeded	Wait for RF Power Supply reset to complete.
342	Pre-Treatment Paused	RF Power Tolerance Limit Exceeded	Wait for RF Power Supply reset to complete.
343	Treatment Halted	RF Power Tolerance Limit Exceeded	Wait for RF Power Supply reset to complete.
41000	Export Error	USB Drive Not Present or Invalid	Re-insert USB flash drive and try again. If problem persists, replace USB flash drive.
41002	Export Error	USB Drive Export Error	Insert a valid USB flash drive with sufficient available memory.
Note: The error message dialog boxes associated with errors 250 and 251 close when the user engages the delivery device vapor button. The error message dialog boxes associated with errors 341, 342, and 343 close automatically when the RF Power Supply reset is complete.			

Table 17: Informational Error Message Table

6.4 Obtaining technical assistance

For technical information and assistance, contact:

NxThera, Inc.
7351 Kirkwood Lane North
Suite 138
Maple Grove, MN 55369
USA
www.nxthera.com

US Technical Assistance Center (TAC)
(+) 1-800-949-6708
Monday – Friday: 4:30 a.m. to 5:00 p.m. PT
CETechSupportUSA@bsci.com

European Technical Assistance Center (TAC)
(+) 31 45.546.7707
Monday –Friday: 8:30 a.m. to 5:00 p.m. CET
CEtechsupportEMEA@bsci.com