# rezūm™ Generator

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## Important Information

**ONLY**

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

**WARNING**

Users of the Rezūm Delivery Device Kit and Generator should read this manual thoroughly before attempting surgical procedure. Pay attention to all warnings, contraindications, precautions, and adverse events in this manual and other related material. Failure to thoroughly understand and follow all instructions may result in harm to the patient or the user of the laser system.

**SAFETY**

This section contains information about the Rezūm Generator including safety. Please make sure you read this entire operator’s manual prior to using the Rezūm Generator.

**Note:** Field service is not available, all repairs are done at the original equipment manufacturer.

**NOTICE**

This section contains important safety information. Boston Scientific requires that you read and understand all warnings, cautions, and the operator’s manual prior to using 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

**DEVICE 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 triggering 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 vapor at slightly above 100°C. The generator delivers this thermal energy in the form of vapor through precision 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.

**INTENDED USE/INDICATIONS FOR USE**

The Rezūm Generator is intended to be used with the Rezūm Delivery Device Kit, Model D2001 only. Refer to the Directions for Use for the Rezūm Delivery Device Kit for the Indications for Use/Intended Use.

**CONTRAINDICATIONS**

Refer to the Directions for Use for the Rezūm Delivery Device Kit for the Contraindications.

**WARNINGS**

A protective ground connection by way of the grounding conductor in the power cord is essential for safe operation. To avoid a 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. After visual inspection, if the generator is damaged or a message is indicated to not use the generator, please contact Boston Scientific Technical Service and take the generator out of service.

Before conducting routine care, turn the power off and unplug the power cord from the outlet to prevent electric shock.

Do not modify this equipment.

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.

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

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

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

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

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.

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 detailed maintenance schedule. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the Rezūm Generator.

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

If the generator measurement readings or messages seem dubious or abnormal, check the condition of the patient first and stop using the 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 Rezūm Delivery Device DFU. Turn on again to restart the generator to begin a new therapy session.

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

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.

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.

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

The generator is not intended to be deployed in settings or situations that promote high noise levels.

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.

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

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

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

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

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

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

Use only specified power cord.

Use with the specified AC voltage and frequency.

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

**PRECAUTIONS**

None.

**CAUTIONS**

After cleaning, complete drying before plugging into an outlet.

Before conducting maintenance work, turn the power OFF and unplug the power cord from the outlet.

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

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.).

Do not place anything on this generator.

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

**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.

**REPORTED ADVERSE EVENTS**

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

A summary of the adverse events observed in clinical studies is presented in the Rezūm Delivery Device Kit DFU.
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.

OPERATIONAL INSTRUCTIONS

GETTING STARTED

Overview
This section contains information on how to get started with your Rezūm™ Generator.

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.

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 approved equipment and accessories shall be connected to the generator.

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

Table 1: Front and Top of Generator Description Table

<table>
<thead>
<tr>
<th>ID</th>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Display Screen</td>
<td>Touch screen display to provide system feedback to the user.</td>
</tr>
<tr>
<td>C</td>
<td>Delivery Device Port</td>
<td>The delivery device cable is the RF energy line and the connections for the switches and thermocouples.</td>
</tr>
<tr>
<td>D</td>
<td>Roller Pump</td>
<td>Delivers saline during procedure.</td>
</tr>
<tr>
<td>E</td>
<td>Power Indicator</td>
<td>Displays system status.</td>
</tr>
<tr>
<td>F</td>
<td>Power Switch</td>
<td>Turns system on/off.</td>
</tr>
<tr>
<td>G</td>
<td>USB Port</td>
<td>Allows data from system to be exported onto USB device.</td>
</tr>
</tbody>
</table>
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 4.

Table 4: Tone Description

<table>
<thead>
<tr>
<th>Tone Name</th>
<th>Tone Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Start-up</td>
<td>A single high-pitched tone is played when the generator power on sequence.</td>
</tr>
<tr>
<td>2. Treatment Warning</td>
<td>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.</td>
</tr>
<tr>
<td>3. Partial Treatment Tone</td>
<td>A high-pitched tone followed by a low-pitched tone is played whenever the delivery device vapor activation button has been deactivated prior to the completion of a treatment.</td>
</tr>
<tr>
<td>4. Treatment Ready</td>
<td>Beep tone is repeated once per second while performing Priming and Treatment operations.</td>
</tr>
<tr>
<td>5. Treatment Priming</td>
<td>A single high-pitched tone is played when there is a critical error. In addition, three quick tones in succession are played whenever the generator displays a critical error message on the generator screen.</td>
</tr>
<tr>
<td>6. Success</td>
<td>A high-pitched tone followed by a low-pitched tone is played when the delivery device is disabled.</td>
</tr>
</tbody>
</table>

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.

Volume Control

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

- 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 alert tones cannot be silenced by the volume control.
- The volume resets to default when the generator is turned off and on again.
- Set the volume loud enough to be heard adequately in the actual use environment.

Detachable Parts and Accessories

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

Caution: The Rezūm Generator power cord and delivery device cable may cause a trip hazard while attached to the generator.

The Rezūm Generator has the following detachable parts and accessories:

Detachable Parts - Supplied with the Rezūm Generator

Table 5: Detachable Parts

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Description, Function</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>1519-001</td>
<td>Power Cord</td>
<td>Reusable</td>
</tr>
<tr>
<td>1519-002</td>
<td>Power Cord</td>
<td>Reusable</td>
</tr>
<tr>
<td>1519-003</td>
<td>Power Cord</td>
<td>Reusable</td>
</tr>
<tr>
<td>1519-004</td>
<td>Power Cord</td>
<td>Reusable</td>
</tr>
<tr>
<td>1519-005</td>
<td>Power Cord</td>
<td>Reusable</td>
</tr>
<tr>
<td>1519-006</td>
<td>Power Cord</td>
<td>Reusable</td>
</tr>
</tbody>
</table>

Accessories - Supplied Separately

Table 6: Accessories

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Description, Function</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>02201</td>
<td>Delivery Device Kit</td>
<td>Disposable, single use</td>
</tr>
</tbody>
</table>

USING THE REZŪM GENERATOR

Overview

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

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 power cord and delivery device cable may cause a trip hazard while 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 cautery units, 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.

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

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 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 approved and specified parts, accessories, optional parts, consumables, and components.

Warning: Use with the specified AC voltage and frequency.
- Make sure that the AC outlet is properly grounded and supplies the specified voltage and frequency.
- Connect the female connector end of the power cord to the AC power connector on the back of the generator.
- Plug the male connector end of the power cord into a properly grounded AC power outlet.

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.

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 DFU. Turn on again to restart the generator to begin a new therapy session.

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 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 approved and specified parts, accessories, optional parts, consumables, and components.

Warning: Use with the specified AC voltage and frequency.
- Make sure that the AC outlet is properly grounded and supplies the specified voltage and frequency.
- Connect the female connector end of the power cord to the AC power connector on the back of the generator.
- Plug the male connector end of the power cord into a properly grounded AC power outlet.

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.

Figure 8: 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: Delivery 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

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.
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.

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 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, pretreatment, or treatment operation will not be initiated until the vapor trigger is released and reengaged.

### Figure 12: Priming Screen

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 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

### 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

### 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.

**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, double tap flush activation button and hold. Treatments will not be performed during this mode.

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

### 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

### Turning Off the Rezum™ 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 DFU. 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.

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.

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

- **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

- **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

- **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

- **Export Procedure Record**
  Caution: Only approved equipment and accessories shall be connected to the generator.

Caution: The Rezūm Generator USB port is only intended for use 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.
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.

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.

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.

Export Logs
Caution: Only approved equipment and accessories shall be connected to the generator.

Caution: The Rezum™ Generator USB port is only intended for use by authorized service personnel or to export treatment data.

Encrypted log files can be exported to a USB drive for use by service personal only. Select files to export from the list of options and Click OK.
**Proper Care and Cleaning**

**Overview**
Proper care of the Rezūm™ Generator is very simple, yet it is an important factor in its reliability. This section describes the proper care and cleaning 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.

**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.

**Recommended Care**

**Warning:** Failure on the part of all responsible individuals, hospitals, or institutions employing the use of Rezūm Generator, to implement the recommended cleaning 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 proper care and cleaning, 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 approved equipment and accessories shall be connected to the generator.

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

To ensure the Rezūm Generator is always functional when required, Boston Scientific recommends performing the following routine activities:

- Performing a Visual Inspection.
- Cleaning the Rezūm Generator.
- Routine Care 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.

**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 Customer service. The generator should be carefully inspected prior to installation and use.

- Carefully inspect the generator case for stress or physical damage.
- Inspect all external connections for loose connectors.
- Inspect the external power cord 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.

**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.

**Warning:** 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.

**Recommended Cleaning Products**
The following cleaning products may be used to clean the exterior surfaces of the generator:
- Water
- 70% Isopropanol Alcohol
- Super Sani-Cloth® Germicidal Disposable Wipes by PDI only

**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.

**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% isopropanol alcohol. Super Sani- Cloth wipes 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.
Routine Care Checklist
Routine Care 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:

Table 7: Routine Care Checklist

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protection Against Electric Shock</td>
<td>Class I Equipment (generator)</td>
</tr>
<tr>
<td>Model Number</td>
<td>02200</td>
</tr>
<tr>
<td>Power Input</td>
<td>10 Amps Maximum</td>
</tr>
<tr>
<td>External Fuses</td>
<td>Two, 10ah-250v, 5 x 20mm</td>
</tr>
<tr>
<td>Mode of Operation</td>
<td>Continuous Operation</td>
</tr>
<tr>
<td>System Control</td>
<td>Provides controlled flow of water vapor at ambient temperatures below 25°C</td>
</tr>
<tr>
<td>Case Dimensions</td>
<td>23L x 16W x 9H Inches</td>
</tr>
<tr>
<td>Weight</td>
<td>50 Pounds or less (generator only)</td>
</tr>
<tr>
<td>Power Cord Length</td>
<td>9 feet</td>
</tr>
<tr>
<td>Applied Parts Protection</td>
<td>Type BF</td>
</tr>
</tbody>
</table>

Warning: Set-up generator and turn on power to check the start-up diagnostics.

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 Technical Service.

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

TECHNICAL SPECIFICATIONS

Overview

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

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 use.

Table 8: Generator Specification

<table>
<thead>
<tr>
<th>Description</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protection Against Electric Shock</td>
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<tr>
<td>Power Cord Length</td>
<td>9 feet</td>
</tr>
<tr>
<td>Applied Parts Protection</td>
<td>Type BF</td>
</tr>
</tbody>
</table>

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 section.

Caution: The Rezūm Generator needs special precautions regarding Electromagnetic compatibility (EMC) and care should be taken in accordance to the EMC information provided in 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.

Table 9: 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.

<table>
<thead>
<tr>
<th>Emissions Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiated emissions GSIPR 11:2015</td>
<td>Group 2</td>
<td>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.</td>
</tr>
<tr>
<td>Conducted emissions GSIPR 11:2015</td>
<td>Class A</td>
<td>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.</td>
</tr>
<tr>
<td>Harmonic current emissions IEC 61000-3-2:2014</td>
<td>Class A</td>
<td></td>
</tr>
<tr>
<td>Voltage fluctuations and flicker IEC 61000-3-3:2013</td>
<td>Complies</td>
<td></td>
</tr>
</tbody>
</table>

Table 10: Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>Compliance Level</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrostatic discharge (ESD) IEC 61000-4-2:2008</td>
<td>±8 kV contact ±15 kV AIR</td>
<td>Floors should be wood, concrete or ceramic. If floors are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Electrical fast transient/burst immunity IEC 61000-4-2:2012</td>
<td>±1 kV common mode; ±1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Surge immunity IEC 61000-4-5:2014</td>
<td>±1 kV differential mode</td>
<td>Mains power quality should be that of a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Power frequency magnetic field IEC 61000-4-8:2009</td>
<td>30 A/m, 50/60 KHz</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
<tr>
<td>Voltage dips and interruptions immunity 61000-4-11:2004</td>
<td>Six dips each at 100%, 60%, 30%, voltage reduction; one interrupt</td>
<td>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.</td>
</tr>
</tbody>
</table>
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.

### 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.

#### Table 11: Electromagnetic Immunity

<table>
<thead>
<tr>
<th>Immunity Test</th>
<th>Compliance</th>
<th>Electromagnetic Environment - Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conducted RF</td>
<td>IEC 61000-4-6:2013</td>
<td>Portable and mobile RF communications equipment should be used no closer to any part of the Rezūm Generator, including power cord and delivery device cable, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</td>
</tr>
<tr>
<td>Radiated RF</td>
<td>IEC 61000-4-3:2010</td>
<td>Recommended separation distance:</td>
</tr>
</tbody>
</table>

\[
d = 1.2 \sqrt{P} \\
\text{for } 80 \text{ MHz to } 800 \text{ MHz} \\
\text{and } 2.3 \sqrt{P} \text{ for } 800 \text{ MHz to } 2.7 \text{ GHz}
\]

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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

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

#### Table 12: 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.

<table>
<thead>
<tr>
<th>Rated Maximum Output Power of Transmitter (W)</th>
<th>Separation Distance According to Frequency of Transmitter (m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>0.1</td>
<td>0.38</td>
</tr>
<tr>
<td>1</td>
<td>1.2</td>
</tr>
<tr>
<td>10</td>
<td>3.8</td>
</tr>
<tr>
<td>100</td>
<td>12</td>
</tr>
</tbody>
</table>

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 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 8.795 MHz, 13.563 MHz to 13.567 MHz, 26.953 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 2.7 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. |

### 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 provided in this operator’s manual.

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

#### Caution:
The generator conforms to the requirements of the EMC standard (IEC 60601-1-2:2007 and IEC 60601-1-2:2014). 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.
TROUBLESHOOTING

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

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 Boston Scientific Technical Service.

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

Critical Error Message

![Example Critical Error Message](image)

Table 13: Critical Error Message Table

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

Non-Critical Error message

![Example Error Message](image)

Informational Error message

![Example Informational Error Message](image)

Error Message Table
The following tables list all error messages that are displayed by the generator. Follow error message instructions to resolve the error.
### Non-Critical Error Messages

#### Table 14: Non-Critical Error Message Table

<table>
<thead>
<tr>
<th>Code</th>
<th>Error Title</th>
<th>Error Cause Text</th>
<th>Error Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>200</td>
<td>Faulty Delivery Device</td>
<td>Unable to Read from Delivery Device Memory</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>205</td>
<td>Faulty Delivery Device</td>
<td>Unable to Write to Delivery Device Memory</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>210</td>
<td>Faulty Delivery Device</td>
<td>Faulty Delivery Device Thermocouple</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>211</td>
<td>Faulty Delivery Device</td>
<td>Faulty Delivery Device Trigger Signals</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>215</td>
<td>Faulty Delivery Device</td>
<td>Invalid Therapy Code</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>218</td>
<td>Faulty Delivery Device</td>
<td>Delivery Device Impedance Error</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>219</td>
<td>Faulty Delivery Device</td>
<td>Delivery Device Frequency Error</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>220</td>
<td>Expired Delivery Device</td>
<td>Maximum Full Treatments Exceeded</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>225</td>
<td>Faulty Delivery Device</td>
<td>Delivery Device is Permanently Disabled</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>230</td>
<td>Expired Delivery Device</td>
<td>Maximum Vapor Time Exceeded</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>235</td>
<td>Prime Failed</td>
<td>Low Temperature (Prime)</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>236</td>
<td>Pre-Treatment Failed Failed</td>
<td>Low Temperature (Pre-Treatment)</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>240</td>
<td>Prime Failed</td>
<td>Low Water Pressure (Prime)</td>
<td>Check water line for leaks. Resume pre-treatment vapor cycle. If problem persists, replace Delivery Device.</td>
</tr>
<tr>
<td>241</td>
<td>Pre-Treatment Failed Failed</td>
<td>High Water Pressure (Prime)</td>
<td>Check water line for leaks. Resume pre-treatment vapor cycle. If problem persists, replace Delivery Device.</td>
</tr>
<tr>
<td>242</td>
<td>Pre-Treatment Failed</td>
<td>Low Water Pressure (Pre-Treatment)</td>
<td>Check water line for leaks. If bubbles are found, replace syringe and reprime Delivery Device.</td>
</tr>
<tr>
<td>243</td>
<td>Pre-Treatment Failed Failed</td>
<td>High Water Pressure (Pre-Treatment)</td>
<td>Check water line for leaks. If bubbles are found, replace syringe and reprime Delivery Device.</td>
</tr>
<tr>
<td>246</td>
<td>Pre-Treatment Failed Failed</td>
<td>High Temperature (Pre-Treatment)</td>
<td>Check water line for leaks. Resume pre-treatment vapor cycle. If problem persists, replace Delivery Device.</td>
</tr>
<tr>
<td>255</td>
<td>Treatment Halted</td>
<td>Low Temperature (Treatment)</td>
<td>Retract the needle and remove the Delivery Device from patient. Replace Delivery Device.</td>
</tr>
<tr>
<td>260</td>
<td>Treatment Halted</td>
<td>High Water Pressure (Treatment)</td>
<td>Check water line for leaks. Resume treatment. If problem persists, replace Delivery Device.</td>
</tr>
<tr>
<td>265</td>
<td>Treatment Halted</td>
<td>Low Water Pressure (Treatment)</td>
<td>Check water line for leaks. If bubbles are found, replace syringe and reprime Delivery Device.</td>
</tr>
<tr>
<td>270</td>
<td>Syringe is Empty</td>
<td>Syringe Empty</td>
<td>Retract the needle and remove the Delivery Device from patient. Replace syringe and reprime Delivery Device.</td>
</tr>
<tr>
<td>275</td>
<td>Prime Failed</td>
<td>Syringe Water Fill Error</td>
<td>Refill syringe and reprime Delivery Device.</td>
</tr>
<tr>
<td>280</td>
<td>Treatment Halted</td>
<td>Elevated Coil Temperature</td>
<td>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.</td>
</tr>
<tr>
<td>290</td>
<td>Faulty Delivery Device</td>
<td>High Temperature (Idling)</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>291</td>
<td>Faulty Delivery Device</td>
<td>High Water Pressure (Idling)</td>
<td>Replace Delivery Device.</td>
</tr>
<tr>
<td>295</td>
<td>Faulty Delivery Device</td>
<td>Needle Deployment Error</td>
<td>Ensure needle is retracted. Replace Delivery Device.</td>
</tr>
<tr>
<td>296</td>
<td>Faulty Delivery Device</td>
<td>Needle Retraction Error</td>
<td>Restart needle retraction. If problem persists, retract needle manually and replace Delivery Device.</td>
</tr>
<tr>
<td>300</td>
<td>Saline Pump Error</td>
<td>Saline Pump Encoder Error</td>
<td>Ensure Delivery Device saline flush line is correctly inserted into saline pump and pump door is closed. If problem persists, contact Technical Support.</td>
</tr>
<tr>
<td>325</td>
<td>Confirm Bladder Drain</td>
<td>Saline Instilled Limit Exceeded</td>
<td>Saline instilled limit exceeded. Please confirm the physician has drained the bladder.</td>
</tr>
</tbody>
</table>

### Informational Error Messages

#### Table 15: Informational Error Message Table

<table>
<thead>
<tr>
<th>Code</th>
<th>Error Title</th>
<th>Error Cause Text</th>
<th>Error Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>250</td>
<td>Prime Paused</td>
<td>Vapor Activation Button Released</td>
<td>Delivery Device button was released before priming completed. Press and hold Vapor Activation Button (blue) to continue priming.</td>
</tr>
<tr>
<td>251</td>
<td>Pre-Treatment Paused</td>
<td>Vapor Activation Button Released</td>
<td>Delivery Device button was released before pre-treatment vapor cycle completed. Press and hold Vapor Activation Button (blue) to restart pretreatment vapor cycle.</td>
</tr>
<tr>
<td>341</td>
<td>Prime Paused</td>
<td>RF Power Tolerance Limit Exceeded</td>
<td>Wait for RF Power Supply reset to complete.</td>
</tr>
<tr>
<td>342</td>
<td>Pre-Treatment Paused</td>
<td>RF Power Tolerance Limit Exceeded</td>
<td>Wait for RF Power Supply reset to complete.</td>
</tr>
<tr>
<td>41000</td>
<td>Export Error</td>
<td>USB Drive Not Present or Invalid</td>
<td>Re-insert USB flash drive and try again. If problem persists, replace USB flash drive.</td>
</tr>
<tr>
<td>41002</td>
<td>Export Error</td>
<td>USB Drive Export Error</td>
<td>Insert a valid USB flash drive with sufficient available memory.</td>
</tr>
</tbody>
</table>

**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 41000 close automatically when the RF Power Supply reset is complete.
WARRANTY
These warranties cover the following Boston Scientific products (Warranted Product):

- Rezūm Generator
- Disposable Devices
- Rezūm Delivery Device

Equipment Warranty. Except as indicated otherwise below, Boston Scientific warrants for one year from the Warranty Commencement Date (as defined below) that the Equipment will be free from defects in title, material and workmanship under normal use and service. This warranty covers parts and is available only to end-users that purchase the Equipment from Boston Scientific or its authorized distributors. Any sale, rental or other transfer or use of Equipment Warranted Product to or by a user other than the original purchaser shall cause this warranty to terminate immediately. Customers purchasing through an authorized distributor must contact Boston Scientific promptly following such purchase to enable this warranty.

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Alternating Current

Electrostatic Sensitive Device

Date of Manufacture

Non-Ionizing Electromagnetic Radiation

Power Off

Power On

Protective earth (ground)

Separate Collection

Type BF Applied Part

USB Connection

CAUTION. Attention: Consult ACCOMPANYING DOCUMENTS.

Medical Equipment ANSI/AAMI ES 60601-1 CAN/CSA C22.2 No. B0801-1

Serial Number

Catalog Number

[blue safety sign] Follow Instructions For Use

Contents

EU Authorized/Representative

Legal Manufacturer

Serial/Number

Recyclable Package

Australian Sponsor Address

Argentina Local Contact

Brazil Local Contact

Do not use if package is damaged.

Alternating Current

Electrostatic Sensitive Device

Date of Manufacture

Non-Ionizing Electromagnetic Radiation

Power Off

Power On

Protective earth (ground)

Separate Collection

Type BF Applied Part

USB Connection

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