

Operator's Manual

Rezūm® Generator Model G2200

Matherenations and a site.

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



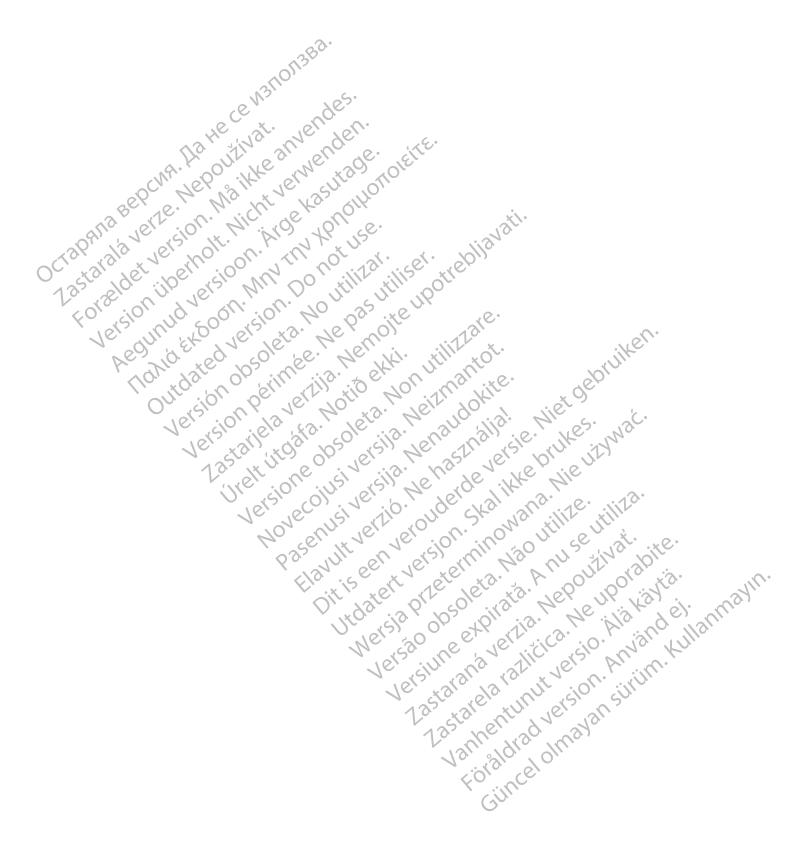


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About the Rezūm® Generator Chapter 1

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.

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1.1 Trademark and Copyright Information

Rezūm is a registered trademark of the NxThera Corporation.

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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.

Dangers, Warnings and Cautions 1.5.1

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



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



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. Novecollsiversila. Weizmani. Jama

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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

A protective ground connection by way of the grounding conductor in the power **WARNING:**

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.

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.

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

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.

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

the generator.

Do not use the generator if it is damaged, is not functioning properly, or fails to **WARNING:**

oraldrad version. And siring. Kulland meet an electrical safety check. Notify the appropriate personnel to ensure the

Versiune et verk repaired. Hid version Anviand. Versiune et verk version Anviand. Version Siriim. Van Anviand vers generator is removed from service and properly repaired.

WARNINGS CONTINUED

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 Rezum 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.

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

WARNING: Use of accessories other than those specified in this document may result in

increased emission or decreased immunity of the Rezūm Generator.

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

consumables, and components.

WARNING: Use only NxThera specified power cord.

WARNING: 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.

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

Before conducting maintenance work, turn the power OFF and unplug the power CAUTION:

cord from the outlet to prevent electric shock.

CAUTION:\ C 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: **CAUTION:**

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. **CAUTION:**

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

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.

Exposing the Rezum Generator to extreme environmental conditions outside of its **CAUTION:**

specified parameters may compromise the ability of the Rezūm Generator to

function properly and/or cause the plastic to warp and/or crack.

Follow your facility's procedures and applicable regulations when disposing of **CAUTION:**

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.

Input voltage range is 100 to 240V at 50 to 60 Hertz. Verify this voltage matches

that of the power outlet.

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.

The Rezum Generator USB port is only intended for use during maintenance by **CAUTION:**

authorized service personnel or to export therapy data.

The generator conforms to the requirements of the EMC standards (IEC 60601-1-**CAUTION:**

> 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.

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

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.

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

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

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. Elavult verzió. Ne Dit is een verouderde Versing expirate. And se Utiliza. Jidatert versjon. Skalil Wersja Przeterminowana. Versão obsoleta. Não utilize.

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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 Tohio ex 800h. My Inv Xonoll Delivery Device Kit Instructions for Use for the Rezūm Delivery Device Kit, 3032-0XX. Version ii berholt. Nich Lastarala verze. Aegunud versioon Argel Forældet version. Outdated Version Do Not 1126.

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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)
	ORDCHA.	Indicates on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals	IEC 60417	Alternating current (5032)
OCTAPATO	REF	Manufacturer's catalog number, so that the medical device can be identified	ISO 15223-1:2016	Catalog number (5.1.6)
135 2	Yedring to the Wedning	Contact with generator package should be avoided at low levels of relative	ISO 7010:2011	Electrostatic sensitive devices (5134)
	(3)	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)
	EC REP	Authorized Representative in the European Union	ISO 15223-1:2016	Indicates the Authorized representative in the European Community (5.1.2)

			Title of symbol and
Symbol	Description of the Symbol	Standard	(reference number)
Ī	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)
no yet e.s.	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)
8/24 10°	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.	Not Applicable IEC 60417	Non-Ionizing electromagnetic radiation (RF) (5140)
0	Indicates disconnection from the mains, at least for mains switches or their positions, and all those cases where safety is involved.	IEC 60417 ATA NEO	"OFF" (power) (5008)
ı	Indicates connection to the mains, at least for mains switches or their positions, and all those cases where safety is involved.	TEC 60417 UNITERS	"ON" (power) (5007)
$\mathbb{R}^{\scriptscriptstyleONLY}$	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
(1)	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)
SN	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1:2016	Serial number (5.1.7)
Jer Johns	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
<u> </u>	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)
C UL US	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	r Symbols Alongol	

1.5.4.2 User Interface Symbols

Symbol	Description
(3) Ba.	Priming the Delivery Device
13tho, choice	Perform a pre-treatment vapor cycle
CNA. TE LE SUNE CUTS	Back to previous screen Complete
agence in the property of	Complete
Elder liperhe Why to hos	Confirmation message
el only Ex. C Oleta. No	Continue Villi Ziot.
May Seine Seine	Critical error message
A KURE OUS	Critical error message Displayed for errors that are not of critical severity. Informational error messages
Pasenusi Pasenusi	Informational error messages
Pasavuli Elavuli	Export Verseletta. Na Problizhorabita.
?	Generator question that requires user response
	Home screen menure in the little in the litt
	Navigation buttons for back, forward, up and down

Symbol	Description
	Options Menu
4))	Volume Control

Table 2: User Interface Symbols

1.6 Operator Training

WARNING: The generator is not intended to be deployed in settings or situations that promote Persons authorized to operate the generator must have all the following minimum training.

• Training as required by creating.

Training as required by state, province, or country regulations.
 Training on operation and use of the generator
 Additional training as required.

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- Additional training as required by a physician or Medical Director.

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Getting Started Chapter 2

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Overview

OCTAPANA BEPCINA, ITA HE CE NATION This chapter contains information on how to get started with your Rezūm Generator. Lasterala vertee wersion. Warke anvendes.

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 Rezum 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

- 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.
- Check for any damage or defects. Do not attempt to set up the Rezum Generator if anything is Novecollishersila. Neizhhanto Versione obsoleta. Non util Trelt Litolata. Notio ekki damaged or defective. Contact Customer Service immediately if anything is damaged or defective. Pasenusi Versija. Nenaudokite. Lastarjela verzija.

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

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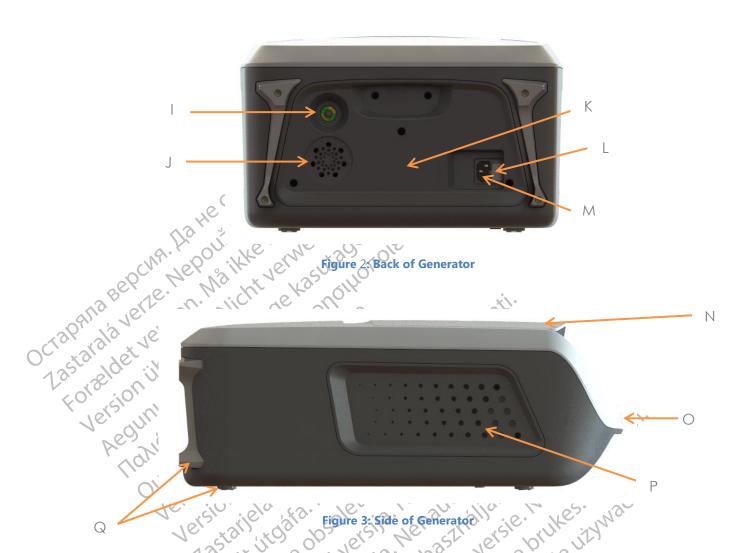
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ID	Item	Description Version Mill Mad 1711 Service.
Α	Display Screen	Touch screen display to provide system feedback to the user
В	Syringe / Syringe Cradle	Holds water for vapor treatment
С	Electrical cable port	The electrical cable is the RF energy 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



	1 2 20 30	611 18 18 118
ID	Item Olegisio Collina	Description
I	Grounding stud	Grounding stud used for grounding product
	Ho seliling	(Required in Europe)
J	Air vent	Outgoing air vent
K	Product Label	Provides information about the generator
L	Fuse box	Holds generator fuses
М	Power cord plug	Connection plug for electrical power cord
N	Lid	Cover to protect display screen, syringe and pressure
		sensor ports
0	Handle	Use to transport the device by hand
Р	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.

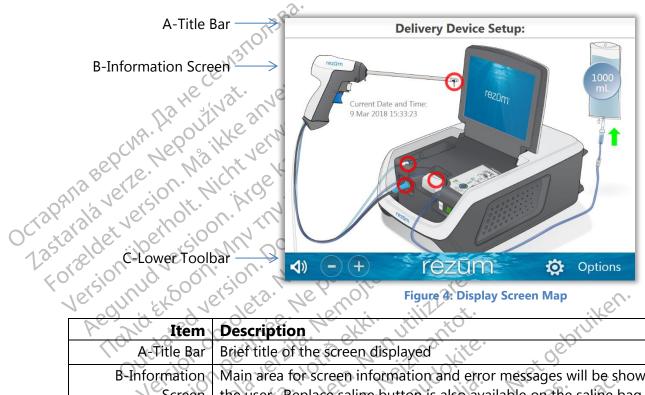


Figure 4: Display Screen Map

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

То	ne 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 Exponential Solety Property	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.
		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. A high-pitched tone followed by a low-pitched tone played when the delivery device is disabled. able 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 volume resets to the default when the generator is turned off and on again.
 Set the volume loud enough to be heard adaptive. The Critical Error and Delivery Device Disabled alarm tones cannot be silenced by the
 - Set the volume loud enough to be heard adequately in the actual use environment.

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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 Rezum Generator has the following detachable parts and accessories:

Detachable Parts - Supplied with the Rezum Generator

Model	Description, Function	Туре
Number	2 12t 125 110	
1519-001	Power cord	Reusable
1 16, 510, 1x	3.05 meter hospital grade power cord	
19 161, 01	North American, 15 amp	
1519-002	Power cord	Reusable
Jos in Gis	3.05 meter hospital grade power cord	
6. noi:	Continental Europe, 10 amp	
1519-003	Power cord	Reusable
695 484 9	2.50 meter hospital grade power cord	
RI THU TEN	Swiss, 10 amp	

Model Number	Description, Functi	on Neder Chaliff	A Type
D2201	Delivery Device,	SI, 1610:00: 100/0	Disposable, single use
	Delivers the vapor in	nto the tissue	
	7/1/0	phie 8: Accessories leta. Italia. Lersia objection de la lersia objection de la lersia della lersia della lersia de la lersia de la lersia della ler	Nepolity orabita. Nepolity orab
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Using the Rezūm Generator Chapter 3

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Overview

OCTAPANA BEPCHA, Halle Ce Walton This chapter provides step by step instructions and sequence of operation for the Rezūm Lastarara vertee wersion. Waikke anvendes.

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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 Rezum Generator is intended to be used indoors at a medical facility or Atendes. Walley anyendes. Alegaria version. Walke anyendes. OCTAPANA BEPCHA. HAHE CEY Jersion il Derholt. Micht Verwenden. Lastarala verze. Nepolizivat.

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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.

- Open the lid of the generator to show the display screen and make sure it is fully open.
- przeterminowana. Nie używa 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.



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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.





Octapana Bepcha. Ilah Lastarala verze. Nep 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. Zastajela verzija. Vernojte uli Version perimee. We pas Jesione obsoleta. Non litilizzar. nand Ex800'n Version obsoleta. No Vedilund A. Outdated version Version Elavult vertuo iveriore in astraliai in historia de de de versie in historia de de versie in historia de de versie in historia de de versie in historia de versie in historia de de versie in historia de versie de versie

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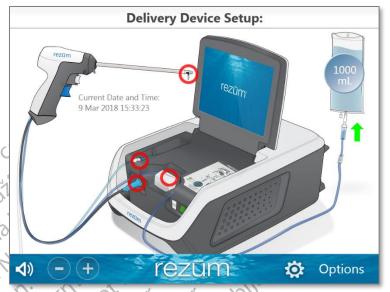
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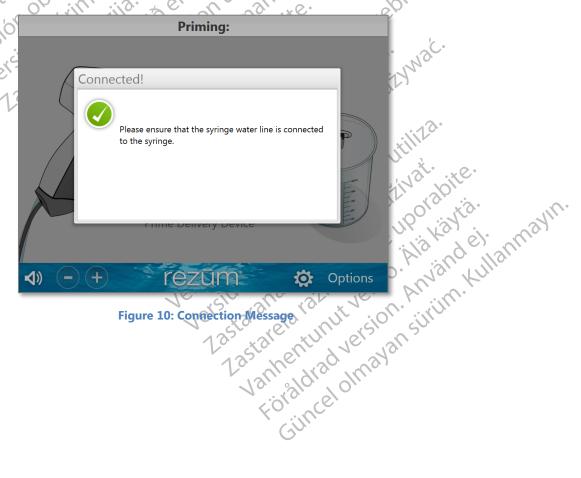
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5. After the Start-up Diagnostics are completed, the generator will display the *Delivery Device* Setup screen.



Octapana Bepcha, La Hepour Lastarala verze, Nepour Lastarala verze, ion, ma Lastarala verze, ion, ma 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 contact that the user know that items have been connected and then the Priming screen will be displayed.



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.

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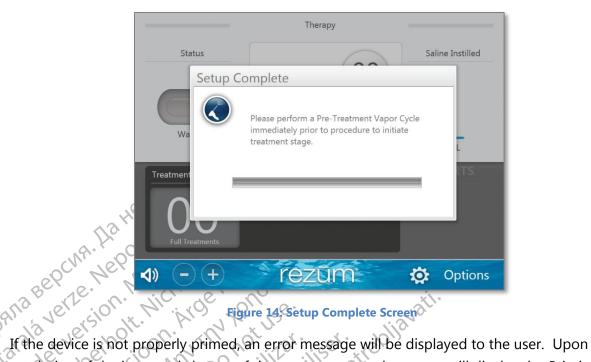


Figure 12: Priming Screen



The Setup Complete will be displayed when the Delivery Device has been successfully primed. 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.



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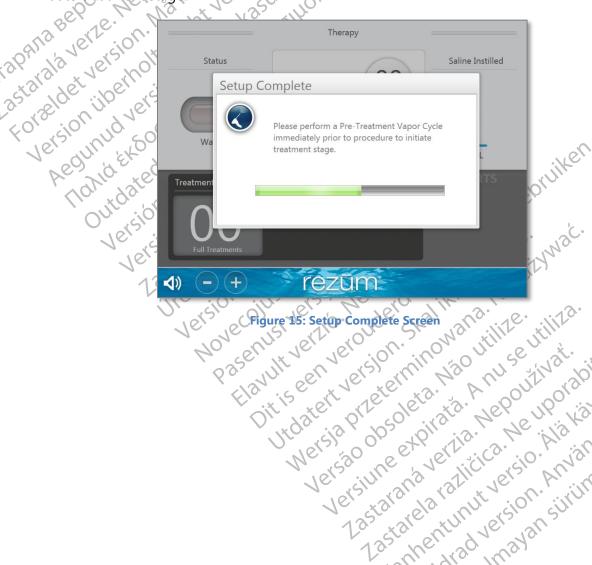
3.1.4 Performing the Therapy

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 octaphila Bep initiate treatment stage. Zastarala Verze.



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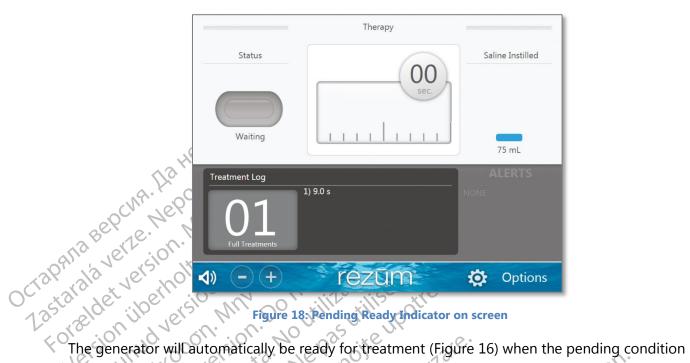
After performing a pre-treatment vapor cycle, a screen will be displayed indicating the generator is ready for treatment.



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.



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.



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3.1.4.1 Turbo Flush

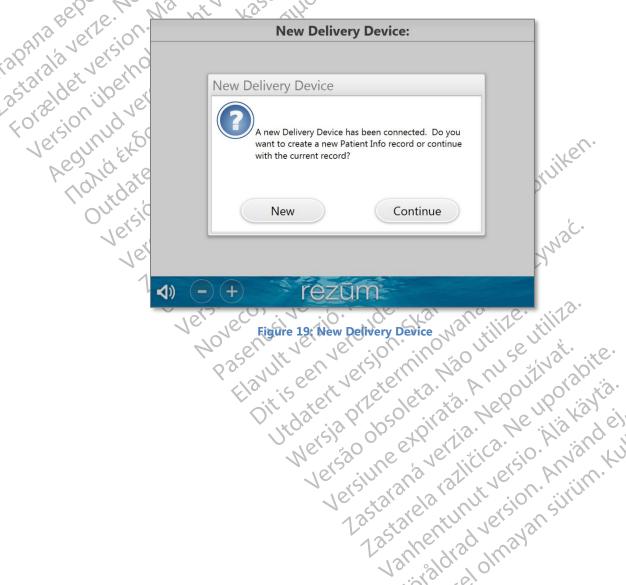
If visualization becomes cloudy during the procedure, Turbo Flush can be activated to improve the visualization by increasing the saline flow rate. To activate Turbo Flush, press twice and hold vapor release button. Treatments will not be performed during this mode.

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. Zastarala verze.



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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 Zastarala verze. Nepoliżnat.



Note: In the event of loss of power, a new procedure record is created. Previously completed Jitdatert versjon. Kalikke brukes Justy C. Justing Justing Justy C. Justy Dit is een verouderde versie. Elavult verzió. Ne használi treatments will be saved in the prior procedure record. Versioneop Paseniisi versija.

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Rezūm Generator Options Menu Items

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





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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

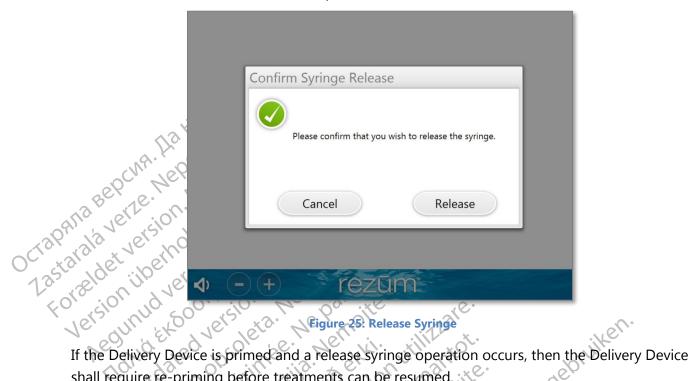
When saline is replaced, select the Replace Saline from the Options Menu and select the appropriate size saline from the available options. The saline source volume will be set to the previously selected value upon power up of the generator.



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.



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.

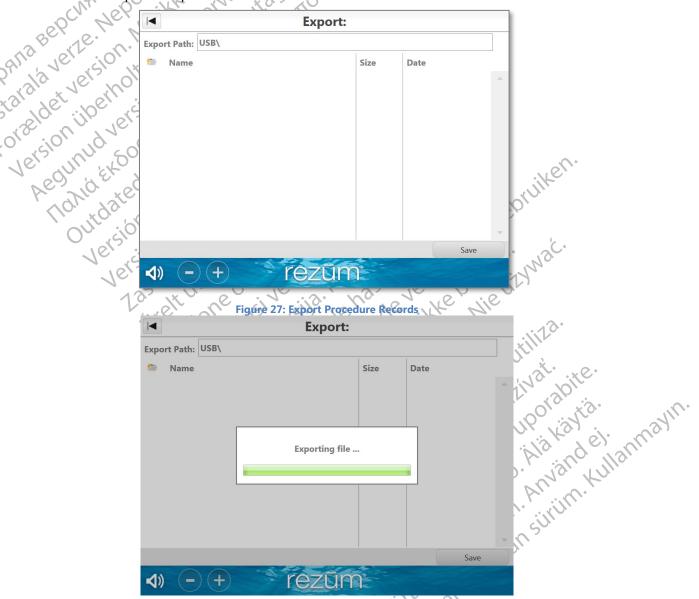


Figure 28: Export Procedure Records Progress

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



OCTAPANA BEPCHA. ILAH Lastarala verze. Nep9 Figure 29: Export Procedure Records Success

The device will store up to a maximum of 1000 procedure records. Once the generator reaches Version perimee. Ne P it maximum record capacity, the generator will automatically delete the oldest record to perform Jrd t

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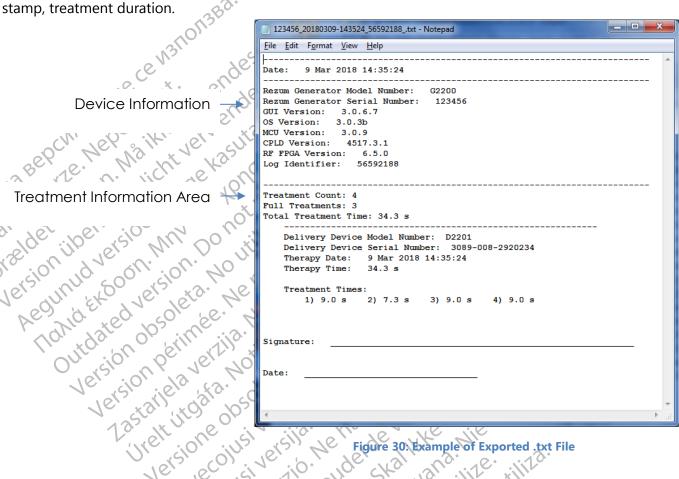
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The procedure records are saved in both a .csv and .txt format. The serial number plus date/time, and unique number are saved as the file name. The .txt file contains all the userviewable information stored in the procedure record (Figure 30). The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



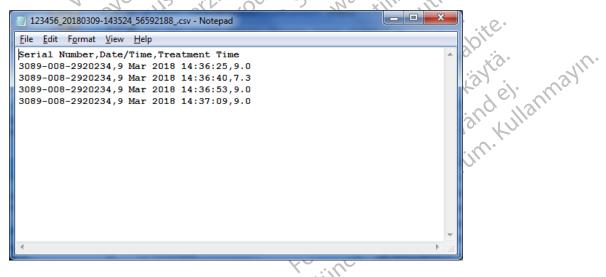


Figure 31: Example of Exported .csv File

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.



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

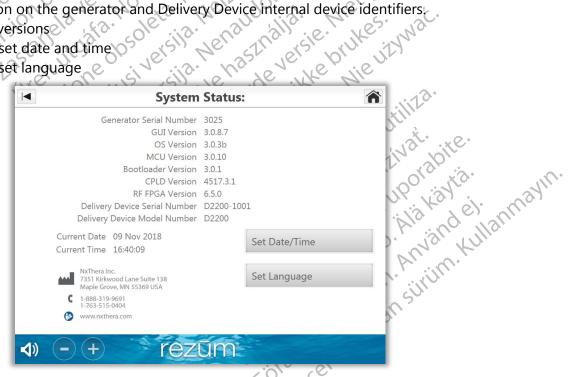
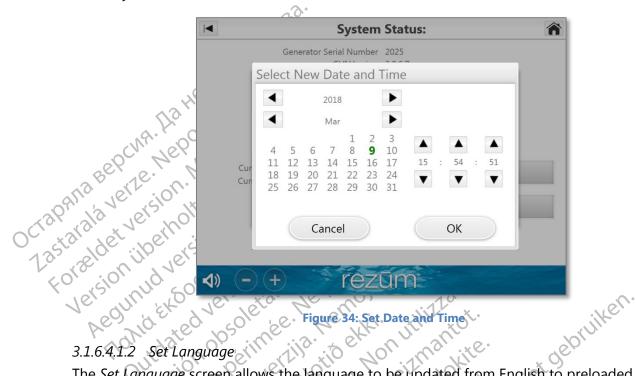


Figure 33 System Status

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.

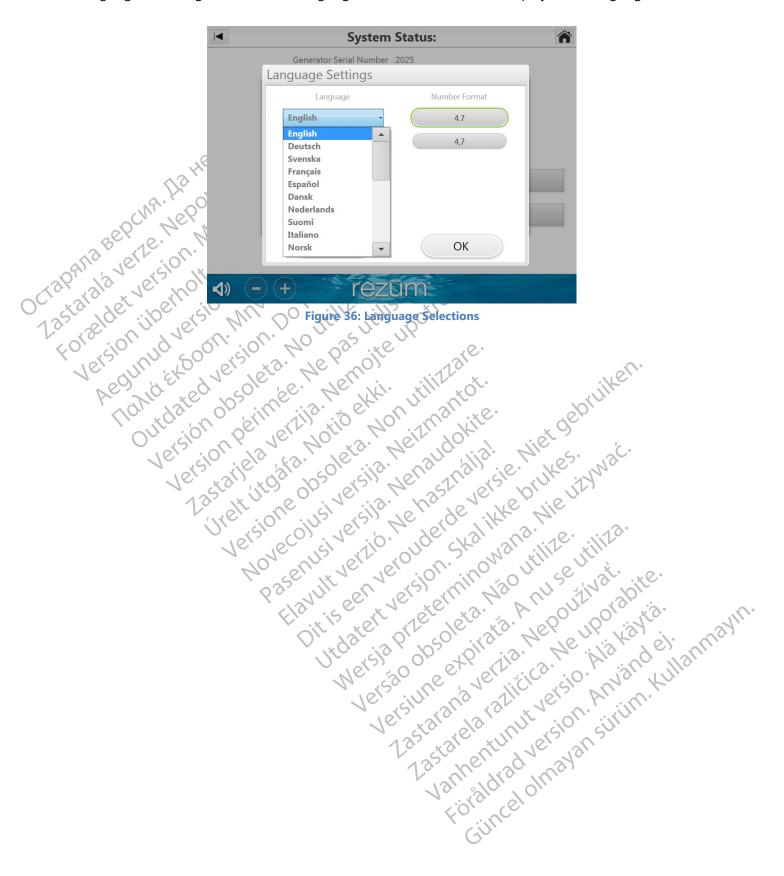


3.1.6.4.1.2 Set Language
The Set Language The Set Language screen allows the language to be updated from English to preloaded language options and desired number format. These settings do not change when powering on and off the generator.



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.



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.

.0

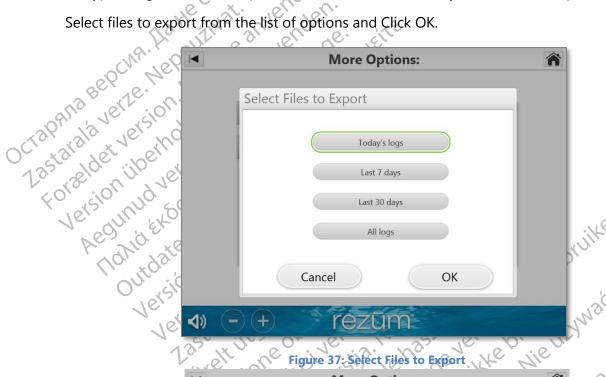
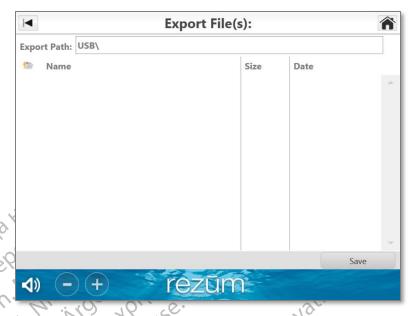




Figure 38: Reading Files

Select export path and select Save.



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

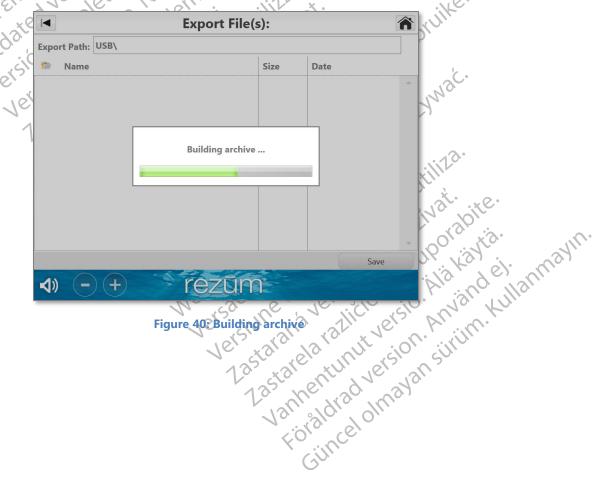


Figure 402 Building archive

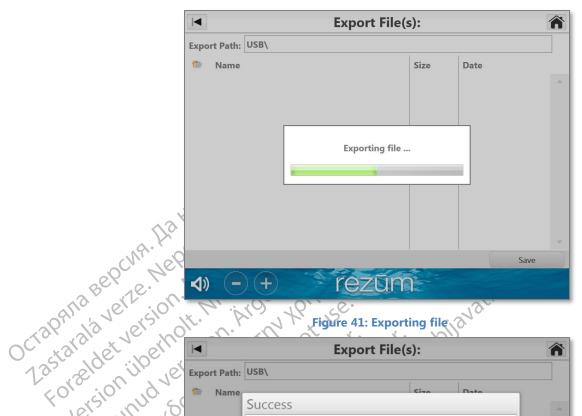
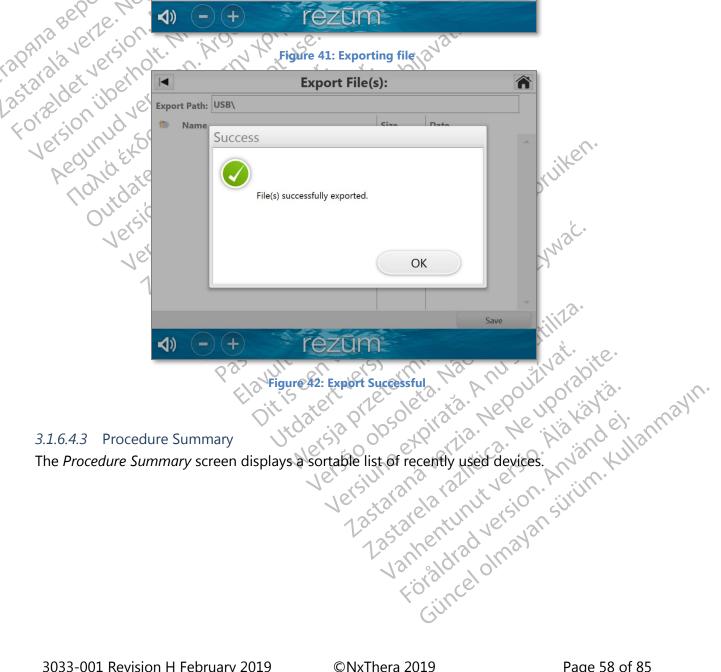
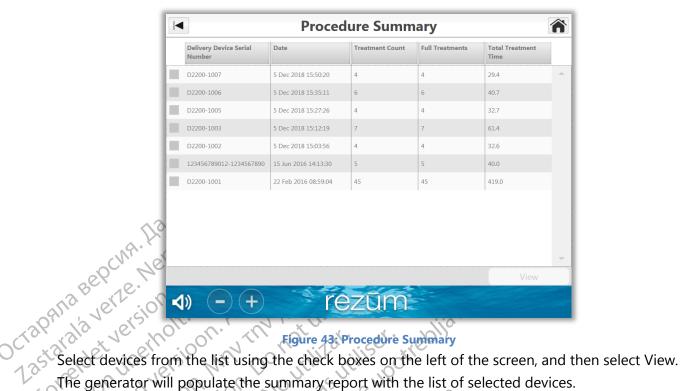
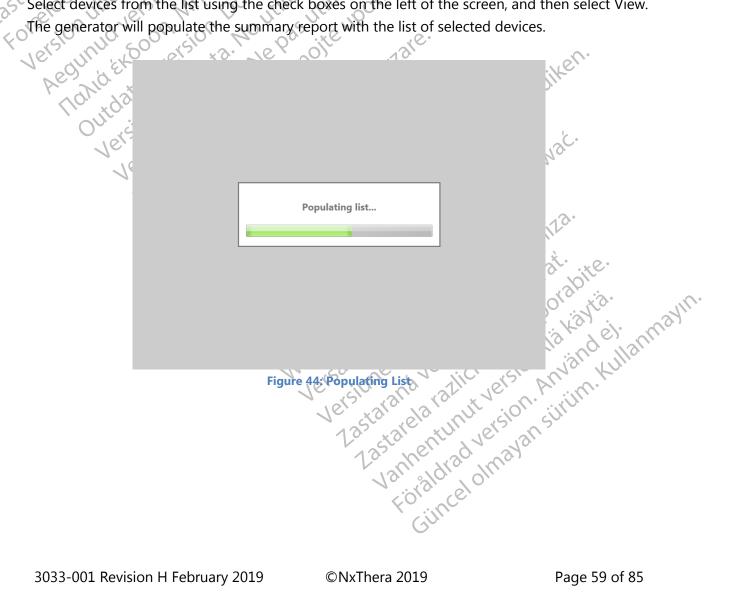


Figure 41: Exporting file







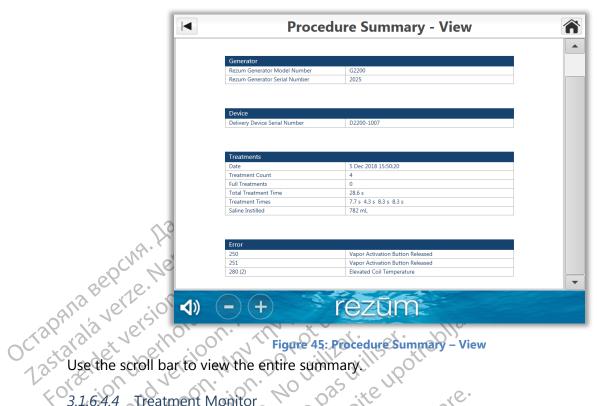


Figure 45: Procedure Summary – View

Treatment Monitor 3.1.6.4.4

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

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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.

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- There is smoke or a strange odor leaking out of the generator.
- The generator has been dropped or impacted by an object. Havilly er verouder de versie. Wiet gebruiken.

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- Liquid or foreign matter gets inside the generator.
- If you think the generator may have been damaged. Move Collisiversila. Weizinantot. Tastariela verzija. Ner The Hilling at 3. Notito exxi. Jersione obsoleta. Non utili Jersion Périmée. Version obsoli Outdated Lloyigi Pasenusi Versija. Nenaudokite.

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

The Rezūm Generator requires no calibration. performing the following maintenance activities:

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.

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Verify that the Product label on the device is clearly legible and present. Lastariela Verzina. Nemoite Inpotre Version Périmée. Ne pas utilisé Version obsoleta. No utiliza Regunud version Outdated version. Do Version liber Tand Ex 800n. Min

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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.
- Orangad version, kninging Killanmayin.
 Gincel olmayan siiriim. Kullanmayin. Vallienthin version. Anvandel Vanhentunut versio. Ala Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may Lastarelarazlicica. 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 5. To dry the generator after cleaning, wipe with a dry, soft cloth. surfaces of the generator.

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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.

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JCS. Set-up generator and turn on power to check the start-up diagnostics Pasenusi versija. Nenaudokite. Novecojusiversija. Neikmar Version périmé

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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, The warranty
Generator. Troubleshooting. If you are unable to resolve the problem, contact Customer Service.

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Technical Specifications Chapter 5

Overview

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

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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 A Thing and endere	Specification
Protection against Electric Shock	Class I Equipment (generator)
Model Number	G2200
Jersolion, Thy notices	100-240 VAC, 50-60Hz
Power Input	10 Amps maximum
Power Input External Fuses Mode of Operation	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 Weight Power cable length	23L x16W x9H inches
Weight Very Very Very Very Very Very Very Very	50 pounds or less (generator only)
Power cable length	9 feet mill Ma nu seithat abite
Applied Parts protection	Type BF 18 12 11 12 12 12 12 12 12 12 12 12 12 12
Protection against ingress of fluids and particulate matter	IPXOSTANIENITA OHNAYAN

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 Wersja Przeternino Versiume expiration Anuse phones. Turn power off to radio, cellular and other like equipment near the Rezum Generator. Zastaraná verzia. Nepolizivat 1. Zastaraná verzia. Versão obsoleta. Não Refer to the EMI tables in Chapter 5. Vanhentunut versio, iki aki kayta.

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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 environn guidance	nent –
adiated emissions	Ac and Group 2306 Active Rose Rose Rose Rose Rose Rose Rose Ros	The Rezūm Generator uses RF e for its internal function. Therefore emissions are very low and are of to cause any interference in near electronic equipment.	ore, its RF not likely
Conducted emissions	My Class Allizar	The Rezūm Generator is suitable all establishments other than do and those directly connected to low-voltage power supply netwo supplies buildings used for dom	mestic the public
CISPR 11:2015 Harmonic current emissions EC 61000-3-2:2014 /oltage fluctuations	Class A To ex	Meizmantor. Meizmantor. Meizmantor.	ruiker.
Voltage fluctuations and flicker IEC 61000-3-3:2013	Complies exp	A Neraldokite. Niet geb 3. Neraldokite. Niet geb 4. Neraldokite. Nie	iliza.
	Pase ultivery	low-voltage power supply network supplies buildings used for dom purpose. The purpose of the pur	Anvande Sirim.ki
3033-001 Revision H I	ebruary 2019	©NxThera 2019	Page 71 o

Table 12: Electromagnetic Immunity

	Immunity test	Compliance level	Electromagnetic environment - guidance
	Electrostatic	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors
	discharge	0131	are covered with synthetic material, the relative humidity
	(ESD)	±15 kV air	should be at least 30%
	IEC 61000-4- 2:2008	He CE WALL	den.
	Electrical fast	±1kV common	Mains power quality should be that of a typical commercial
	transient/burst	mode; 5kHz and	or hospital environment.
209	immunity	100kHz	1136
OC1.01	Halo the Hu	:00K. 77K	o, 131, 156, 160,,
1255	IEC 61000-4-	RICHARITY DO	Jtill Jtill DOI
60	4:2012	100kHzhion	or hospital environment.
		+1/01/	Mains power quality should be that of a typical commercial
	immunity	differential	
	Cuitos	mode	stio Horizme Kite of get
	IEC 61000-4-	100 000	leta. Heraldolia. Hiers. ac.
	5:2014	±2 kV common	sol sila levo trail sie. The My
		mode, J	ch silo die sile
	Power	30 A/m,	rower frequency magnetic fields should be affected
	frequency	30 A/m, 50/60 Hz	characteristic of a typical location in a typical commercial
	magnetic field	Paseni Paseni	or hospital environment.
		Elan	is sent leis, eight leis sig. Mebon housing spira.
	IEC 61000-4-	Ö	it is ater or color of the colo
	8:2009		Jit la teit vers etermin Mão nu su thười là bite tis een vers la prize termin Mão nu su thười là bite tis là
			characteristic of a typical location in a typical commercial or hospital environment.
			Jersie arania racut Jeon inin
			characteristic of a typical location in a typical commercial or hospital environment.
			Tay We Hiso May
			weigia proposition of the policy of the poli
	3033-001 Revisi	on H February 2019	

Immunity test	Compliance level	Electromagnetic environment - guidance
Voltage dips and interruptions immunity	Six dips each at 100%, 60%, 30% voltage reduction; 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.
11:2004	Three 100% dips each at phase angles of 0, 45, 90, 135, 180,	den.
61000-4- 11:2004 11:2004 12:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004 13:2004	angles of 0, 45, 90, 135, 180, 225, 270, and 315; one	ot sizar. is er. treplik
arala versing a self in the control of the control	oothisioti 20 2d versioti 20	otilizar. Itilizare. Otilizar. Itilizare. Otilizar. Itilizare. Otilizar. Itilizzare. Ot

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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
Octabal Lastar For	6:2013	6 Vrms in ISM bands	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
	Radiated RF IEC 61000-4- 3:2010	16,160	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:

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.

- 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.
- 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.
- 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)

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Rated maximum output power of transmitter (W)	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	d = 1.2√P	d = 1.2√P	d = 2.3√P
0.01	0.12	0.12	0.23
0,10	0.380	0.38	0.73
CNA 1 PO HA	er vil.2 or	1.2	2.3
Ber 10 No hi	3.81	3.8	7.3
100 181 100 M	9 1250	12,00	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 Javull Verlie Verouderde Versie Niet gebruiken.

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Chapter 6 Troubleshooting

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Overview

This chapter contains troubleshooting steps, error message description, error message table, Agalaid veile, version, Maikke anvendes Octabalia Bebona. Ila He Cel Jersion in Jerholt. Micht Verwenden. Zastarala verze. Nepoliziwat.

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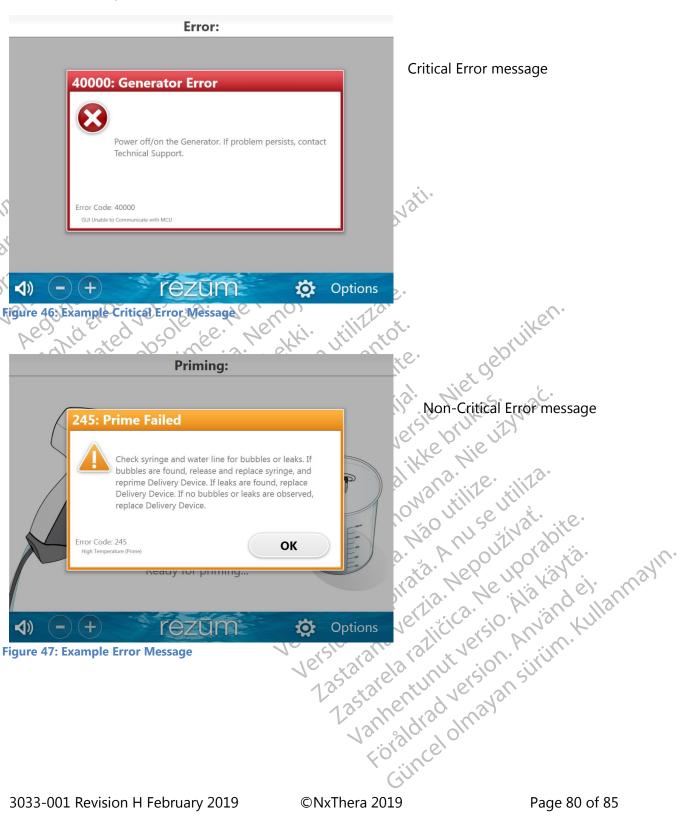
6.1 Troubleshooting Steps

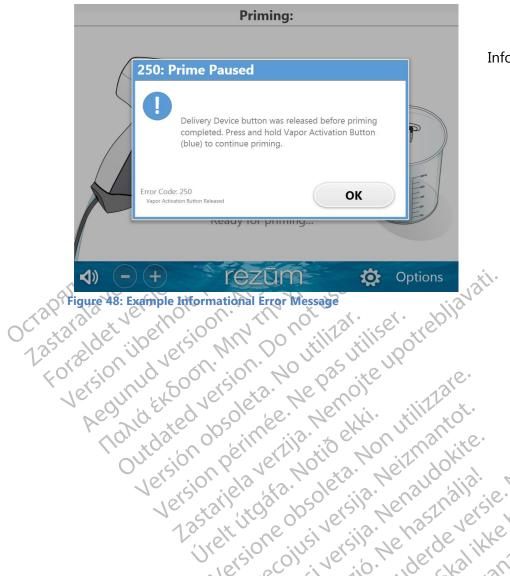
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If you experience a problem while using the generator, please use the Error Message table to troubleshoot the issues. If you are unable to correct it, write down the error message and error octapana Bepcha, Ila He ce wanona Be code, if applicable, and contact qualified service personnel in your institution or contact LOS Laidia Veile, inchinitivation, Maikke anvendes.

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.





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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

Cod	de l	Error Title	Error Cause Text	Error Message
400	0	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	5 (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	5 (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	990	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	5e/	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	0 8	Generator Error	CPLD Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
450	W 788	Generator Error	Delivery Device Interface Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
455	5 (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	0/0/0	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	5	Generator Error	Software Compatibility Self- Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
480	0	Generator Error	Sensor Interface Error	Retract the needle and remove the Delivery Device from patient. If problem persists, contact Technical Support.
485	5 (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	0	Generator Error	RF Power Supply Operational Error	Retract the needle and remove the Delivery Device from patient. If problem persists, contact Technical Support.
495	5 (Generator Error	RF Power Supply Self-Test Error	Power off/on the Generator. If problem persists, contact Technical Support.
3500	00 (Generator Error	GUI Program Files Corrupted	Power off/on the Generator. If problem persists, contact Technical Support.
3500	01	Generator Error	Unexpected GUI Program Exit	Power off/on the Generator. If problem persists, contact Technical Support.
3500	02 (Generator Error	Unable to Start GUI Program	Power off/on the Generator. If problem persists, contact Technical Support.
4000	00	Generator Error	GUI Unable to Communicate with MCU	Power off/on the Generator. If problem persists, contact Technical Support.
4102	20	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\E	the Generator from service and contact Technical Support.
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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.

Code	Error Title	Error Cause Text	Error Message
250	Prime Paused	Vapor Activation Button	Delivery Device button was released before priming completed. Press and hold
16/3	100	Released	Vapor Activation Button (blue) to continue priming.
251	Pre-Treatment	Vapor Activation Button	Delivery Device button was released before pre-treatment vapor cycle
De	Paused	Released	completed. Press and hold Vapor Activation Button (blue) to restart pre-
	191, 480 C	h :: (1): 7	treatment vapor cycle.
341	Prime Paused	RF Power Tolerance Limit	Wait for RF Power Supply reset to complete.
	0,50	Exceeded	y. 161, 90, 1 166,
342	Pre-Treatment	RF Power Tolerance Limit Wait for RF Power Supply reset to complete.	
	Paused	Exceeded	ile love to lie the the
343	Treatment Halted	RF Power Tolerance Limit	Wait for RF Power Supply reset to complete.
	1.0	Exceeded	113. No 16, 116, 116
41000	Export Error	USB Drive Not Present or	Re-insert USB flash drive and try again. If problem persists, replace USB flash
		Invalid	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. 7: Informational Error (Nessage Table)

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Table 17: Informational Error Wessage Table

6.4 Obtaining technical assistance

For technical information and assistance, contact:

NxThera, Inc. Maple Grove, MN 55369 USA

US Technical Assistance Center (TAC)
(+) 1-800-949-6708
Monday – Friday ادد، المادة الم پسی – Friday: 4:30 a.m. to 5:0(CETechSupportUSA@bsci.com

(+) 31.45.546.7707

Monday – Friday: 8:30 a.m. to 5:00 p.m. CET

CEtechsupportEMEA@bsci.com Versione obsoleta. Non vitilizzare. European Technical Assistance Center (TAC)

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