

# User's Guide

# CoolSeal™



## GENERATOR

### CoolSeal™ Generator

**REF** CSL-200-50

- en – User's Guide
- da – Brugsanvisning
- de – Gebrauchsanweisung
- el – Οδηγίες χρήσης
- es – Instrucciones de uso
- fi – Käyttöohjeet
- fr – Mode d'emploi
- is – Notkunarleiðbeiningar
- it – Istruzioni per l'uso
- nl – Gebruiksaanwijzing
- no – Bruksanvisning
- pt – Instruções de utilização
- ro – Ghidul utilizatorului
- sv – Bruksanvisning
- tr – Kullanıcı Kılavuzu

**BOLDER™**  
SURGICAL

---

# Table of Contents

<b>Preface</b> .....	<b>4</b>
Equipment covered in this manual .....	4
Patent Information: .....	4
Trademark acknowledgements .....	4
Manufactured by: .....	4
For information call.....	4
Conventions Used in this Guide.....	4
<b>Chapter 1. Overview and General Features</b> .....	<b>5</b>
Introduction .....	5
Indication for Use.....	5
Contraindications for Use .....	5
Front Panel .....	6
Rear Panel.....	6
Bottom View .....	7
List of Accessories.....	7
Compatible Vessel-Sealing Instruments.....	7
<b>Chapter 2. Patient and Operating Room Safety</b> .....	<b>8</b>
Warnings and Cautions .....	8
Overview.....	8
Generator Setup Safety.....	8
Electromagnetic Compatibility.....	9
Fire Hazard During Oropharyngeal Surgery.....	9
Pacemakers and ICDs .....	9
Connecting a CoolSeal™ Instrument.....	10
Cleaning the CoolSeal™ Generator .....	10
Servicing the CoolSeal™ Generator .....	10
<b>Chapter 3. Setup and Use of the CoolSeal™ Generator</b> .....	<b>11</b>
Unpacking the CoolSeal™ Generator .....	11
Inspecting the CoolSeal™ Generator.....	11
Setup Safety .....	11
Setting up the CoolSeal™ Generator .....	12
Adjusting the volume.....	13

Connecting a CoolSeal™ Instrument.....	13
Connecting a CoolSeal™ Instrument to the CoolSeal™ Generator .....	13
Activating a CoolSeal™ Instrument.....	13
Descriptions of Alert Conditions .....	14
<b>Chapter 4. After Surgery .....</b>	<b>17</b>
Turning Off the CoolSeal™ Generator .....	17
Preparing the CoolSeal™ Generator for Reuse.....	17
<b>Chapter 5. Troubleshooting.....</b>	<b>18</b>
General Troubleshooting Guidelines .....	18
Correcting Malfunctions.....	18
Abnormal Patient Response.....	18
CoolSeal™ Generator Malfunctions.....	18
Potential interactions with other device .....	20
<b>Chapter 6. Periodic Functional Testing, Maintenance and Service.....</b>	<b>21</b>
Responsibility of the Manufacturer .....	21
Periodic Functional Testing and Maintenance .....	21
When should Periodic Functional Testing be performed?.....	21
When must the power cord be replaced?.....	21
When should the fuses be replaced? .....	21
How can the fuses be replaced?.....	21
Product Service.....	22
Returning the CoolSeal™ Generator for Service.....	22
Software Upgrades .....	22
<b>Chapter 7. Technical Specifications.....</b>	<b>23</b>
Performance Characteristics.....	23
General.....	23
Dimensions and Weight.....	23
Operating Parameters .....	23
Transport and Storage.....	23
Internal Memory.....	23
Activation Tone .....	24
Alert Tones .....	24
Input Power.....	24
Power Cord Specification .....	24

---

<b>Technical Specifications .....</b>	<b>25</b>
Input Frequency.....	25
Input Current .....	25
Backup Power .....	25
Equipotential Connection .....	25
Duty Cycle .....	25
Low Frequency (50/60 Hz) Leakage Current.....	25
Standards and IEC Classifications.....	25
<b>Symbols.....</b>	<b>26</b>
<b>Classifications.....</b>	<b>27</b>
Class I Equipment (IEC 60601-1) .....	27
Electromagnetic Compatibility (IEC 60601-1-2).....	27
Type CF Equipment (IEC 60601-1).....	27
IP XX Liquid Ingress/Spillage (IEC 60601-1 and IEC 60601-2-2).....	27
Voltage Transients – Energy Platform Mains Transfer (IEC60601-1 and IEC 60601-2-2).....	27
Electromagnetic Compatibility (IEC 60601-1-2 and IEC60601-2-2) .....	27
<b>Output Characteristics.....</b>	<b>27</b>
Maximum Output for the CoolSeal™ Generator .....	27
Electromagnetic Immunity .....	28
<b>Appendix A – Periodic Functional Test .....</b>	<b>32</b>
Definitions .....	32
Equipment Required:.....	32
Pass/Fail Criteria:.....	32
Procedure: .....	33
Periodic Functional Test Summary Form.....	36
<b>Warranty.....</b>	<b>38</b>

---

# Preface

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the CoolSeal™ Generator only.

## Equipment covered in this manual

CoolSeal™ Generator – CSL-200-50

## Patent Information

<https://BolderSurgical.com/patents/>

## Trademark acknowledgements

CoolSeal™ Generator

## Manufactured by:



Bolder Surgical  
331 S. 104th Street, Suite 200  
Louisville, CO 80027  
Made in USA  
Tel: 866.683.1743  
[www.BolderSurgical.com](http://www.BolderSurgical.com)

## Authorized Representative:



Emergo Europe B.V.  
Prinsessegracht 20  
2514 AP The Hague  
The Netherlands

## For information call

866.683.1743

## Conventions Used in this Guide

### Warning

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury

### Caution

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury

### Notice

Indicates a hazard, which may result in product damage.

### Important

Indicates an operating tip or maintenance suggestion.

---

# Chapter 1. Overview and General Features

This section includes the following information:

- Introduction
- Indications for Use
- Contraindications for Use
- Front Panel
- Rear Panel
- Bottom View
- List of Accessories
- Compatible Vessel-Sealing Instruments

## Caution

Read all warnings, cautions, and instructions provided with this generator before use. Specific instructions for CoolSeal™ instruments are not included in this manual. Refer to the CoolSeal™ instrument's instructions for use for warnings, cautions, and instructions for its use.

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

## Introduction

The CoolSeal™ Generator provides Radio Frequency (RF) energy for vessel-sealing applications.

The CoolSeal™ Generator automatically detects coded instruments and configures the CoolSeal™ Generator accordingly. Safety and diagnostic functionality include automatic fail-safe functions.

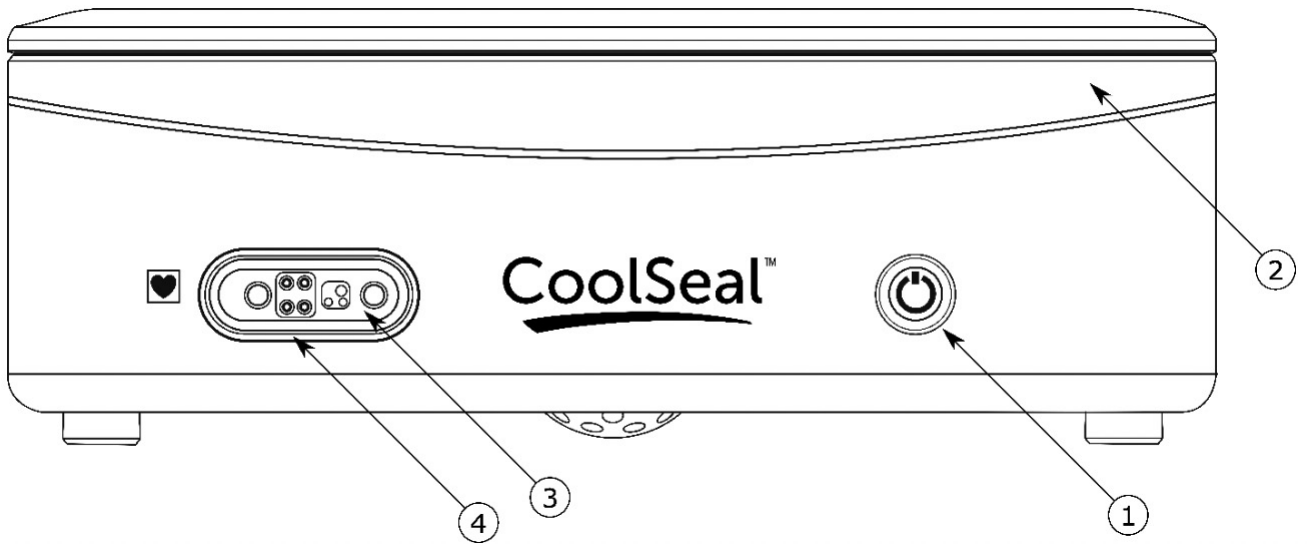
## Indication for Use

The CoolSeal™ Generator is intended to provide Radio Frequency (RF) energy to compatible CoolSeal™ instruments for vessel-sealing applications. The specific application will depend on the compatible surgical device that is connected to the generator. This generator is designed to be used only with surgical devices compatible with the CoolSeal™ technology.

## Contraindications for Use

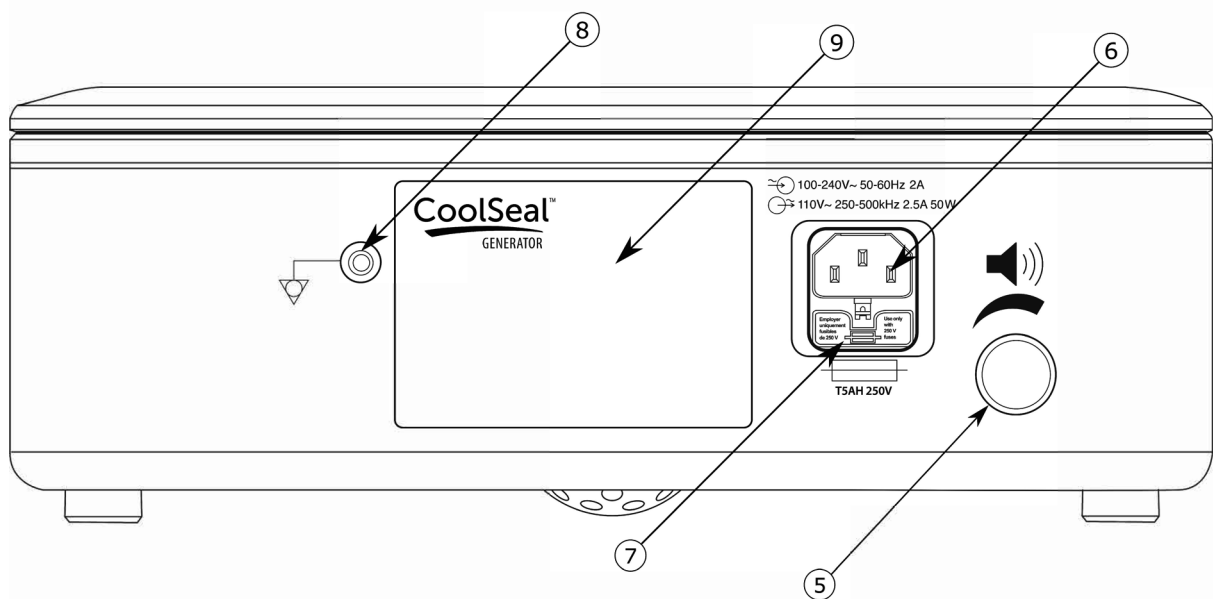
None known specifically for the CoolSeal™ Generator.

## Front Panel



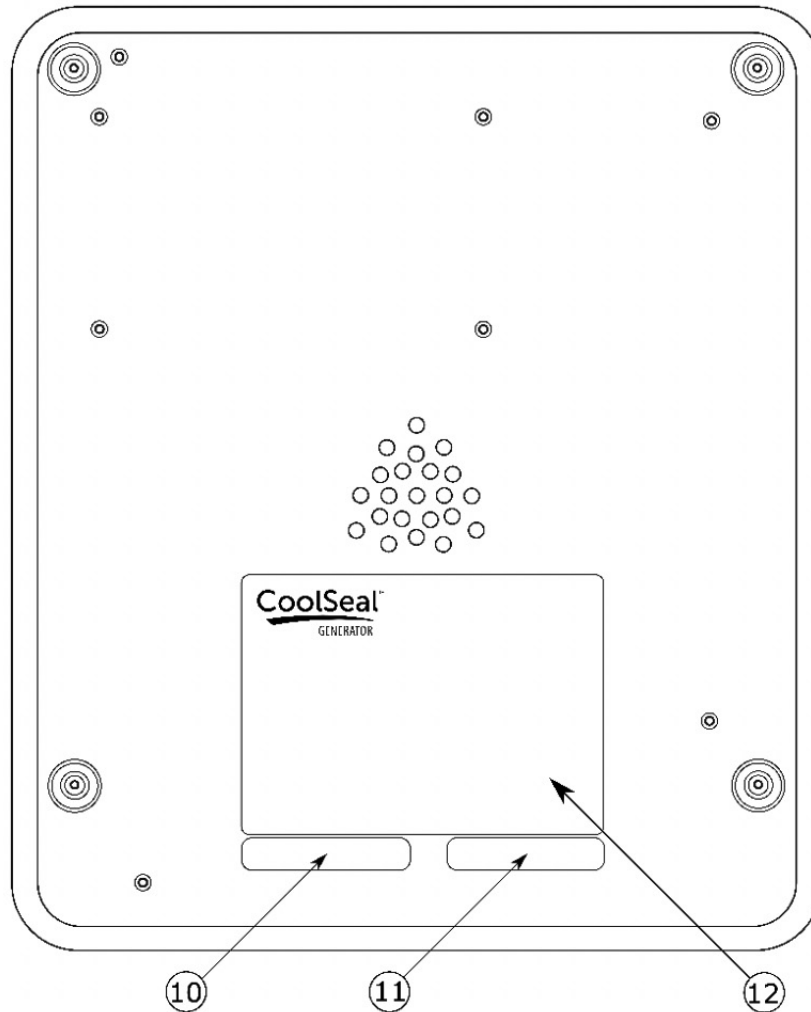
- (1) Illuminated Power Button
- (2) Activation Display
- (3) CoolSeal™ Instrument Receptacle
- (4) Instrument Receptacle Display

## Rear Panel



- (5) Volume Adjustment Control
- (6) Power Cord Inlet
- (7) Fuse Drawer
- (8) Equipotential Connector
- (9) Safety Warnings & Cautions Label

## Bottom View



- (10) Final Test Date Label
- (11) Software Version Label
- (12) Manufacturing Information Label

## List of Accessories

Power Cord - US Specific  
CSL-FTC Functional Test Cable (not included)

## Compatible Vessel-Sealing Instruments

Compatible CoolSeal™ instruments will have connectors that match the following illustration. Refer to the CoolSeal™ instrument's instructions for use for compatibility with the CoolSeal™ technology.





## Chapter 2. Patient and Operating Room Safety

The safe and effective use of electrosurgery depends to a large degree upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant surgical team. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood and followed. Electrosurgery has been used safely in numerous procedures. Before starting any surgical procedure, the surgeon should be trained in the particular technique and surgical procedure to be performed, should be familiar with the medical literature related to the procedure and potential complications, and should be familiar with the risks versus the benefits of utilizing electrosurgery in the procedure.

To promote the safe use of the CoolSeal™ Generator, this section presents the warnings and cautions that appear throughout this user's guide. It is also important that you read, understand, and follow the instructions for use in the CoolSeal™ instrument's instructions for use.

### Warnings and Cautions

#### Overview

Caution
Read all warnings, cautions, and instructions provided with this generator before use. Specific instructions for CoolSeal™ instruments are not included in this manual. Refer to the CoolSeal™ instrument's instructions for use for warnings, cautions, and instructions for its use.
Federal (USA) law restricts this device to sale by or on the order of a physician.

#### Generator Setup Safety

Warning
<b>Electric Shock Hazard:</b> Connect the system power cord to a properly grounded power receptacle. Do not use power plug adapters.
<b>Fire Hazard:</b> Do not use extension cords or multiple socket outlets.
<b>Patient Safety:</b> Use the CoolSeal™ Generator only if the power-up self-test has been completed as described in this manual, otherwise inaccurate power outputs may result.
This equipment is for use only by trained, licensed physicians. Use of this equipment without such training can result in serious patient injury.
The CoolSeal™ Generator is only compatible with CoolSeal™ Instruments. No other bipolar instruments can be used.
Do not wrap the instrument cords around metal objects. This may induce stray currents that could lead to shocks, fires, or injury to the patient or surgical team.
<b>Electric Shock Hazard:</b> Do not connect wet instrument connectors to the CoolSeal™ Generator. Ensure that all instruments and adapters are correctly connected.
Inspect equipment cable for breaks, cracks, nicks and other damage before every use. If damaged, do not use. Damaged equipment cables may result in injury or electrical shock to the patient or surgical team.

### Caution

Set the system volume control at a level that ensures the activation tones can be heard.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when the CoolSeal™ Generator is delivering RF energy.

Examine all instruments and connections to the system before using. Ensure that the instruments function as intended. Improper connection may result in arcs, sparks, instrument malfunction, or unintended surgical effects.

A non-functioning CoolSeal™ Generator may cause interruption of surgery. A backup system should be available for use.

The use of appliance couplers, i.e., power cords, other than those specified may result in increased emissions or decreased immunity of the equipment.

Provide as much distance as possible between the CoolSeal™ Generator and other electronic equipment such as monitors. Do not cross or bundle electronic devices cords. This generator may cause interference with other electronic equipment. If interference occurs, relocate the equipment.

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical smoke evacuator or other means.<sup>1</sup>

1. U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). Control of Smoke from Laser/Electric Surgical Procedures. HAZARD CONTROLS, Publication No. 96-128, September 1996.

### Electromagnetic Compatibility

#### Warning

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communication equipment should be used no closer than 30 cm (12 inches) to any part of the CoolSeal™ Generator including cables specified by Bolder Surgical. Otherwise, degradation of the performance of this equipment could result.

### Fire Hazard During Oropharyngeal Surgery

#### Warning

Verify endotracheal tubes are free from leaks and that the cuff seals properly to prevent oxygen leaks.

### Pacemakers and ICDs

#### Warning

DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

## Connecting a CoolSeal™ Instrument

### Warning

#### Electric Shock Hazard

- Do not connect wet instruments to the CoolSeal™ Generator
- Ensure that all instruments are correctly connected and that no metal is exposed at any connection point

Properly seat the instrument in the receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with CoolSeal™ Vessel Sealing Instruments.

The instrument receptacle on this system is designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

### Caution

Inspect instruments and cords for breaks, cracks, nicks and other damage before every use. If damaged, do not use. Damaged instruments or cords may result in injury or electrical shock to the patient or surgical team.

## Cleaning the CoolSeal™ Generator

### Warning

#### Electric Shock Hazard

Always turn off and unplug the CoolSeal™ Generator before cleaning.

## Servicing the CoolSeal™ Generator

### Warning

#### Electric Shock Hazard

Do not remove the CoolSeal™ Generator cover.

Do not attempt to service the CoolSeal™ Generator. All service and repair must be conducted by a Bolder Surgical™ technician.

### Caution

The CoolSeal™ Generator must not be disposed of at the end of life with other waste. To recycle waste equipment, obtain instructions from Bolder Surgical (call 866.683.1743) or contact your local sales representative to discuss local waste disposal solutions and processes. The CoolSeal™ Generator poses disposal risks similar to consumer electronics such as computers. There are no radioactive substances, batteries, or hazardous liquids that may leak in the CoolSeal™ Generator.

# Chapter 3. Setup and Use of the CoolSeal™ Generator

This chapter covers the following topics:

- Unpacking the CoolSeal™ Generator
- Inspecting the CoolSeal™ Generator
- Setup Safety
- Setting up the CoolSeal™ Generator
- Adjusting the volume of activation tones
- Connecting a CoolSeal™ Instrument
- Activating the CoolSeal™ Instrument
- Descriptions of Alert Conditions

### Caution

Read all warnings, cautions, and instructions provided with this generator before use. Specific instructions for CoolSeal™ instruments are not included in this manual. Refer to the CoolSeal™ instrument's instructions for use for warnings, cautions, and instructions for its use.

## Unpacking the CoolSeal™ Generator

1. Remove the CoolSeal™ Generator from the shipping box and packaging material.
2. Inspect the device for visible damage.

## Inspecting the CoolSeal™ Generator

Before each use of the CoolSeal™ Generator, verify that the unit and all accessories are in good working order:

- Inspect for damage to the Generator and all its connections.
- Inspect all cords and connectors for signs of wear, damage, and abrasion.
- Verify that no errors occur when you turn on the unit.

## Setup Safety

### Warning

**Electric Shock Hazard:** Connect the system power cord to a properly grounded power receptacle. Do not use power plug adapters.

**Fire Hazard:** Do not use extension cords or multiple socket outlets.

**Patient Safety:** Use the CoolSeal™ Generator only if the power-up self-test has been completed as described in this manual, otherwise inaccurate power outputs may result.

This equipment is for use only by trained, licensed physicians. Use of this equipment without such training can result in serious patient injury.

The CoolSeal™ Generator is only compatible with CoolSeal™ Instruments. No other bipolar instruments can be used.

Do not wrap the instrument cords around metal objects. This may induce stray currents that could lead to shocks, fires, or injury to the patient or surgical team.

**Electric Shock Hazard:** Do not connect wet instrument connectors to the CoolSeal™ Generator. Ensure that all instruments and adapters are correctly connected.

Inspect equipment cable for breaks, cracks, nicks and other damage before every use. If damaged, do not use. Damaged equipment cables may result in injury or electrical shock to the patient or surgical team.

### Caution

Set the system volume control at a level that ensures the activation tones can be heard.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when the CoolSeal™ Generator is delivering RF energy.

Examine all instruments and connections to the system before using. Ensure that the instruments function as intended. Improper connection may result in arcs, sparks, instrument malfunction, or unintended surgical effects.

A non-functioning CoolSeal™ Generator may cause interruption of surgery. A backup system should be available for use.

The use of appliance couplers, i.e., power cords, other than those specified may result in increased emissions or decreased immunity of the equipment.

Provide as much distance as possible between the CoolSeal™ Generator and other electronic equipment such as monitors. Do not cross or bundle electronic devices cords. This generator may cause interference with other electronic equipment. If interference occurs, relocate the equipment.

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and the surgical team. These studies recommend adequately ventilating the smoke by using a surgical smoke evacuator or other means.<sup>1</sup>

1. U.S. Department of Health and Human Services. National Institute for Occupational Safety and Health (NIOSH). Control of Smoke from Laser/Electric Surgical Procedures. HAZARD CONTROLS, Publication No. 96-128, September 1996.

## Setting up the CoolSeal™ Generator

1. Place the CoolSeal™ Generator on a flat, stable surface such as a table, platform, boom system, or cart. Carts with non-conductive wheels are recommended. Refer to the procedures for your local institution or your local codes.
2. If required by institution or local codes, connect the equipotential connector to a ground source.
3. Connect the system power cord to the electrical inlet on the rear panel.
4. Connect the system power cord to a grounded AC wall receptacle.


### Notice

Do not connect the CoolSeal™ Generator to a power strip or extension cord.

Do not position the device so that it is difficult to disconnect the power cord.

### Important

If transported or stored at temperatures outside the operating temperature range, allow one hour for the CoolSeal™ Generator to reach operating temperature before use.

Turn on the system by pressing the power stand-by button () on the front of the unit. Observe the following during the power-up self-test:

- Unit performs start-up self-test.
- The power button illuminates green.
- Audible alert sounds three (3) ½ second tones after successful completion of self-check.

### Notice

Verify that the system has successfully completed the start-up self-test before connecting instruments.

If unit fails start-up self-test:

- Power button does not illuminate or illuminates red
- Audible alert tone sounds one (1) ½ second tone after unsuccessful self-check

Refer to the Alert Conditions or Troubleshooting sections for additional information

---

## Adjusting the volume

The volume of alert and activations tones may be adjusted by turning the volume knob on the back panel of the CoolSeal™ Generator.

### Notice

The minimum volume for alert tones will always be louder than the activation tone.

## Connecting a CoolSeal™ Instrument

### Warning

#### Electric Shock Hazard

- Do not connect wet instruments to the CoolSeal™ Generator.
- Ensure that all instruments are correctly connected and that no metal is exposed at any connection point.

Properly seat the instrument in the receptacle. Improper connection may result in inadvertent instrument activation or other potentially hazardous conditions. Follow the instructions provided with CoolSeal™ Instruments for proper connection and use.

The instrument receptacle on this system is designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

### Caution

Inspect instruments and cords for breaks, cracks, nicks and other damage before every use. If damaged, do not use. Damaged instruments or cords may result in injury or electrical shock to the patient or surgical team.

## Connecting a CoolSeal™ Instrument to the CoolSeal™ Generator

1. Connect a CoolSeal™ Instrument to the instrument receptacle on the front panel of the CoolSeal™ Generator.
2. Verify proper placement and connection by observing the green lit instrument receptacle display.

*If the CoolSeal™ Generator does not recognize the attached instrument, the instrument receptacle display will illuminate red or not illuminate and a single alert tone will sound. Refer to the Alert Conditions or Troubleshooting sections.*

## Activating a CoolSeal™ Instrument

1. Activate the CoolSeal™ Instrument per the Instrument's instructions for use.
2. Observe the following during instrument activation:
  - The activation display illuminates blue and varies in brightness for the duration of energy delivery.
  - An activation tone sounds continuously during energy delivery.
3. When the seal cycle is complete, observe the following:
  - A three-toned sequence will sound when the seal is completed. The activation button should then be released.
  - The activation display on the CoolSeal™ Generator front panel will momentarily brighten blue.
  - The activation display will then extinguish.

*In the case of an alert condition, refer to the Alert Conditions or Troubleshooting sections.*

## Descriptions of Alert Conditions

When an alert condition occurs:

- An alert tone will sound
- One of the displays on the CoolSeal™ Generator will display blue, amber or red
- Energy delivery will be interrupted

Energy will be available after the alert condition has been corrected. Refer to the following table to resolve alert conditions:

Alert condition:	Indicated by:	Causes:	To Resolve:
Seal Complete	<ul style="list-style-type: none"> <li>• A <b>three</b> sequential tone alert</li> <li>• RF energy delivery stops</li> <li>• Activation display brightens <b>blue</b> for a half (0.5) second</li> </ul>	Successful vessel seal.	None. Normal operation.
Reactivate / Incomplete Seal	<ul style="list-style-type: none"> <li>• A <b>three-pulsed</b> alert tone</li> <li>• RF energy delivery stops</li> <li>• Activation display brightens <b>amber</b> for one (1) second</li> </ul>	Seal time exceeds five (5) seconds OR User either opened the instrument jaws or released the activation button, which causes the seal cycle to be interrupted before seal was completed OR Current stays at the maximum current limit for longer than four (4) seconds, which indicates an electrical short between the jaws has occurred OR The instrument has been activated in open air.	<ol style="list-style-type: none"> <li>1. Release the activation button</li> <li>2. Press the activation button to reactivate the seal cycle without repositioning the instrument</li> <li>3. Open the instrument jaws and inspect for a successful seal</li> <li>4. If possible, reposition the instrument and regrasp tissue in another location, then reactivate the seal cycle</li> <li>5. Visually inspect seal before cutting</li> </ol>
		<b>Possible use conditions include:</b>	
		Grasping thin tissue or activating in open air.	Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure
		Grasping too much tissue between the jaws.	Open the jaws and reduce the amount of tissue which is grasped, and reactivate the seal cycle
		Grasping a metal object.	Avoid grasping objects, such as staples, clips or encapsulated sutures in the jaws of the instrument
		Activating in excess pooled fluids around the instrument tip.	<ol style="list-style-type: none"> <li>1. Minimize or remove excess fluids</li> <li>2. Reactivate the seal cycle without repositioning the instrument</li> </ol>
Excessive tissue eschar on electrode tips.	Use a wet gauze pad to clean surfaces and edges of instrument jaws.		

System Error	<ul style="list-style-type: none"> <li>• A <b>single-pulsed</b> alert tone</li> <li>• RF energy delivery stops</li> <li>Power button illuminates and remains <b>red</b></li> </ul>	Generator not functioning properly, failed an internal self-check.	<ol style="list-style-type: none"> <li>1. Press the power button to turn off the generator</li> <li>2. Wait at least 30 seconds</li> <li>3. Press the power button to turn on the generator</li> <li>4. Confirm the power button illuminated green before use.</li> </ol> <p>If the system error reoccurs:</p> <ul style="list-style-type: none"> <li>• Do not use the generator.</li> <li>• Use a different CoolSeal™ Generator or alternate means to complete the procedure.</li> </ul> <p>Return the malfunctioning generator as instructed in the Product Service section of this guide.</p>
Instrument Error	<ul style="list-style-type: none"> <li>• A <b>single-pulsed</b> alert tone</li> <li>• Instrument receptacle display illuminates <b>amber</b> and flashes continuously</li> <li>• Generator will not allow RF energy delivery</li> </ul>	Generator not functioning properly, failed an internal self-check.	<ol style="list-style-type: none"> <li>1. Disconnect instrument from the generator.</li> <li>2. Ensure instrument activation button is not being pressed.</li> <li>3. Reconnect instrument to the generator.</li> <li>4. Confirm the instrument receptacle display illuminates green</li> </ol> <p>If the Instrument Error reoccurs:</p> <ul style="list-style-type: none"> <li>• Do not use the instrument</li> <li>• Use a different CoolSeal™ Instrument.</li> </ul>
		<b>Possible use conditions include:</b>	
		Inadvertent depression of the instrument activation button during instrument connection.	Remove anything depressing the instrument activation button and reconnect instrument.
The instrument switch is malfunctioning.	Replace the instrument.		



Invalid Instrument	<ul style="list-style-type: none"> <li>• A <b>single-pulsed</b> alert tone</li> <li>• Instrument receptacle display illuminates and remains <b>red</b></li> <li>• Generator will not allow RF energy delivery</li> </ul>	An unusable instrument has been connected.	<ol style="list-style-type: none"> <li>1. Disconnect instrument from the generator.</li> <li>2. Ensure instrument is CoolSeal™ compatible</li> <li>3. Reconnect instrument to the generator.</li> <li>4. Confirm the instrument receptacle display illuminates green</li> </ol> <p>If the Instrument Error reoccurs:</p> <ul style="list-style-type: none"> <li>• Do not use the instrument</li> <li>• Use a different CoolSeal™ Instrument.</li> </ul>
		<b>Possible use conditions include:</b>	
		Instrument connected is not CoolSeal™ technology compatible.	Confirm CoolSeal™ technology compatibility of the instrument from the instrument instructions for use.
		Instrument connected has been used previously.	Discard instrument.
Instrument is not usable with software version.	<p>Confirm the software version required by the instrument is not greater than the software version labelled on the bottom of the CoolSeal™ Generator.</p> <p>For a software upgrade refer to the Software Upgrade section.</p>		

---

## Chapter 4. After Surgery

This chapter covers the following topics:

- Turning Off the CoolSeal™ Generator
- Preparing the CoolSeal™ Generator for Reuse

### Caution

Read all warnings, cautions, and instructions provided with this generator before use. Specific instructions for CoolSeal™ instruments are not included in this manual. Refer to the CoolSeal™ instrument's instructions for use for warnings, cautions, and instructions for its use.

### Turning Off the CoolSeal™ Generator

1. Turn off the system by pressing the power stand-by button (⏻) on the front of the unit. Observe the following:
  - The power stand-by button light turns off.

If necessary, the generator can be powered off by removing the power cord connection from either the power inlet or wall.

### Preparing the CoolSeal™ Generator for Reuse

#### Step 1 – Disconnecting the CoolSeal™ Instruments

1. Disconnect instrument from the front panel.
2. Dispose of the single-use instrument according to the procedures for your institution.

#### Step 2 – Clean the CoolSeal™ Generator

### Warning

#### Electric Shock Hazard

Always turn off and unplug the CoolSeal™ Generator before cleaning.

### Notice

Clean the CoolSeal™ Generator with non-flammable agents and disinfectants whenever possible. Do not use abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator, such as, chlorinated hydrocarbons or other plastic solvents.

- Turn off the generator and disconnect the power cord from the wall outlet.
- Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and damp cloth. If using chlorine-based bleaches dilute before cleaning.
- Follow procedures approved by your institution or use validated infection control procedures.
- Do not submerge, aggressively rinse or otherwise allow fluids to enter the chassis.

# Chapter 5. Troubleshooting

This chapter covers the following topics:

- General Troubleshooting Guidelines
- Correcting Malfunctions

### Caution

Read all warnings, cautions, and instructions provided with this generator before use. Specific instructions for CoolSeal™ instruments are not included in this manual. Refer to the CoolSeal™ instrument's instructions for use for warnings, cautions, and instructions for its use.

## General Troubleshooting Guidelines

If the CoolSeal™ Generator malfunctions, check for obvious conditions that may have caused the problem:

- Verify that all cords are connected and attached properly.
- Check the system for visible signs of physical damage.
- Turn the system off and turn it back on.

If the malfunction persists, the system may require service. Contact your institution's biomedical engineering department, Bolder Surgical or the authorized distributor.

If any incidents occur while using the CoolSeal™ system users should report these issues directly to Bolder Surgical by phone (866.683.1743) or by email (complaints@boldsurg.com) and to your local competent authority.

## Correcting Malfunctions

If a solution is not readily apparent, use the table below to help identify and correct specific malfunctions. After you correct the malfunction, verify that the system completes the self-test as described in the System Setup chapter.

### Abnormal Patient Response:

Condition:	Causes:	To Resolve:
Abnormal neuromuscular stimulation <b>(stop surgery immediately)</b>	Metal-to-metal sparking	Check all connections to the CoolSeal™ Generator.
	Abnormal 50 Hz-60 Hz leakage currents	Use a backup CoolSeal™ Generator. Contact your biomedical engineering department or a Bolder Surgical™ technical service representative for assistance.

### CoolSeal™ Generator Malfunctions:

Condition:	Causes:	To Resolve:
CoolSeal™ Generator does not respond when turned on	Disconnected power cord or faulty wall outlet	Check power cord connections (CoolSeal™ Generator and wall outlet). Connect the power cord to a functional outlet.
	Faulty power cord	Replace the power cord.
	Fuses are blown	Contact your biomedical engineering department or a Bolder Surgical™ technical service representative for assistance.
	Internal component malfunction	Use a backup CoolSeal™ Generator. Contact your biomedical engineering department or a Bolder Surgical™ technical service representative for assistance.

System is on, but did not successfully complete the self-test or stopped functioning during use – A <b>single-pulsed</b> tone and power button illuminates <b>red</b>	Unit stored in a cold location	Allow unit to warm to ambient temperature.
	Recoverable Software Malfunction	Use a backup CoolSeal™ Generator. Contact your biomedical engineering department or a Bolder Surgical™ technical service representative for assistance.
	Internal component malfunction or Non-recoverable Software Malfunction	Internal component malfunction.
System is on, with a <b>single tone</b> , and a <b>flashing amber</b> instrument receptacle display.	System initiated with faulty instrument plugged into Instrument Receptacle	Disconnect Instrument. Turn off the CoolSeal™ Generator.
	Incorrect or expired instrument	Turn on the CoolSeal™ Generator. Plug in the instrument.
	Instrument Failure	Replace the instrument if it continues to Malfunction.
	CoolSeal™ Instrument is not usable with software version	Ask your biomedical engineering department to check with the manufacturer of the device. For a software upgrade refer to the Software Upgrade section.
System is on, power button illuminated <b>green</b> when plugging in the instrument a <b>single tone</b> is heard and a <b>red</b> instrument receptacle display is seen.	Instrument recognition failed due to intermittent connection	Remove instrument plug Firmly re-insert the instrument.
	Recoverable Software Malfunction	Turn off the system, then turn the system back on.
	Internal component malfunction or Non-recoverable Software Malfunction	Use a backup CoolSeal™ Generator. Contact your biomedical engineering department or a Bolder Surgical™ technical service representative for assistance.
CoolSeal™ Generator is on and instrument is activated, but system does not deliver output – no tones or activation display	An alert condition exists	Refer to the Alert Conditions section.
	System does not detect vessel sealing instrument	Firmly insert the connector into the receptacle on the CoolSeal™ Generator front panel. Ensure the receptacle display is illuminated green to indicate a CoolSeal™ instrument has been properly seated and recognized.
	Internal component malfunction or Non-recoverable Software Malfunction	Contact your biomedical engineering department or a Bolder Surgical™ technical service representative for assistance.
Incomplete Seal / Reactivate – <b>Three-pulsed</b> tone sounds, <b>amber</b> activation display on generator front panel and RF output is disabled	Seal cycle was in excess of 5 seconds OR Handswitch was released before the end tone sounded	Additional time and energy are needed to complete the sealing cycle. Reactivate the seal cycle without removing or repositioning the instrument.  Visually inspect seal before cutting.
	Metal or other foreign object is grasped within jaws	Avoid grasping objects, such as staples, clips, or encapsulated sutures in the jaws of the instrument.
	Tissue grasped within jaws is too thin	Open the jaws and confirm that a sufficient amount of tissue is inside the jaws. If necessary, increase the amount of tissue and repeat the procedure.
	Pooled fluids around instrument tip	Minimize or remove excess fluids. Clean electrode tips and jaws with a wet gauze pad.
	Instrument has been activated in open air	Release activation button. Grasp tissue and activate the seal cycle.
Instrument is connected but vessel sealing will not activate	Instrument is not fully seated in instrument receptacle	Disconnect instrument, reconnect and wait a moment.

**Potential interactions with other devices:**

<b>Condition:</b>	<b>Causes:</b>	<b>To Resolve:</b>
Continuous monitor interference	Malfunctioning monitor	Refer to Monitor's Instructions for Use to Troubleshoot.
	Faulty chassis-to-ground connections	Check and correct the chassis ground connections for the monitor and for the CoolSeal™ Generator. Check other electrical equipment in the room for defective grounds.
	Electrical equipment is grounded to different objects rather than a common ground. CoolSeal™ Generator may respond to the resulting voltage differences between grounded objects.	Connect all electrical equipment into line power at the same location. Contact your biomedical engineering department or a Bolder Surgical™ technical service representative for assistance.
	If interference continues when the CoolSeal™ Generator is activated, the monitor is responding to radiated frequencies.	Ask your biomedical engineering department to check with the manufacturer of the monitor. Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference when the CoolSeal™ Generator is activated and minimize the potential for an electrosurgical burn at the site of the monitor electrode.
Pacemaker interference	Intermittent connections or metal- to-metal sparking	Always monitor patients with pacemakers during surgery and keep a defibrillator available.
Internal Cardiac Defibrillator (ICD) activation	ICD is activated by CoolSeal™ Generator	Stop the procedure and contact the ICD manufacturer for instructions.
Interference with other devices only when the CoolSeal™ Generator is activated	Electrically inconsistent ground wires in the operating room	Verify that all ground wires are as short as possible and go to the same grounded metal.
	If interference continues when the CoolSeal™ Generator is activated, the device is responding to radiated frequencies.	Ask your biomedical engineering department to check with the manufacturer of the device.

---

## Chapter 6. Periodic Functional Testing, Maintenance and Service

This chapter presents the following information:

- The manufacturer's responsibility
- Periodic Functional Testing and Maintenance
- Returning the generator for service
- Software Upgrades

### Caution

Read all warnings, cautions, and instructions provided with this generator before use. Specific instructions for CoolSeal™ instruments are not included in this manual. Refer to the CoolSeal™ instrument's instructions for use for warnings, cautions, and instructions for its use.

### Responsibility of the Manufacturer

Bolder Surgical is responsible for the safety, reliability, and performance of the CoolSeal™ Generator only if all the following conditions have been met:

- Installation and setup procedures in this manual are followed.
- Persons authorized by Bolder Surgical carry out assembly, operation, re-adjustments, modifications, or repairs.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as IEC and BSI.
- The equipment is used in accordance with the Bolder Surgical instructions for use. For warranty information, refer to the Warranty section in this manual.

### Periodic Functional Testing and Maintenance

#### When should Periodic Functional Testing be performed?

Bolder Surgical recommends that a Periodic Functional Test of the CoolSeal™ Generator be performed at least once every two years. The Periodic Functional Test should only be performed by a qualified biomedical technician or the CoolSeal™ Generator may be returned to Bolder Surgical or its distributor for Periodic Functional Testing. See Appendix A for detailed instructions on the Periodic Functional Test.

#### When must the power cord be replaced?

Replace the power cord if you find exposed wires, cracks, frayed edges, or a damaged connector.

#### When should the fuses be replaced?

The hospital biomedical engineering department may occasionally need to replace fuses. Fuses should be replaced either when a fuse has sacrificially protected the CoolSeal™ Generator or as specified by hospital biomedical engineering for preventative maintenance. If repeated fuse failures occur in a short period do not continue replacing fuses and return the CoolSeal™ Generator for service.

#### How can the fuses be replaced?

1. Turn off the generator and disconnect the power cord from the wall outlet.
2. Disconnect the system power cord from the electrical inlet on the rear panel.
3. Unlatch the fuse tray from below the electrical inlet.
4. Remove both fuses.
5. Obtain fuses rated as labelled below the electrical inlet on the rear panel.
6. Insert both fuses.
7. Insert and latch fuse tray.

---

## Product Service

### Warning

**Electric Shock Hazard:** Do not remove the CoolSeal™ Generator cover.

Do not attempt to service the CoolSeal™ Generator. All service and repair must be conducted by authorized Bolder Surgical™ personnel.

### Returning the CoolSeal™ Generator for Service

Before you return the CoolSeal™ Generator, call your Bolder Surgical™ sales representative for assistance. If you are instructed to send the generator to Bolder Surgical, do the following:

1. Call the Bolder Surgical™ Customer Service Center for your area to obtain a Return Authorization Number. Have the following information ready when you call:
  - Hospital/clinic name/customer number
  - Your telephone number
  - Department/address, city, state, and zip code
  - Model number
  - Serial number
  - Description of the problem
  - Type of service, upgrade or repair to be done
2. Clean the CoolSeal™ Generator.
  - See the Cleaning section above.
3. Ship the CoolSeal™ Generator.
  - Attach a tag to the generator that includes the return authorization number and the information (hospital, phone number, etc.) listed in step 1.
  - Be sure the generator is completely dry before you pack it for shipment. Package it in its original shipping container, if available.
  - Ship the generator, prepaid, to the Bolder Surgical™ Service Center.

## Software Upgrades

Bolder Surgical™ personnel must perform software upgrades. See *Returning the CoolSeal™ Generator for Service* (above) for instructions.

## Chapter 7. Technical Specifications

All specifications are nominal and subject to change without notice.

A specification referred to as "Typical" is within  $\pm 20\%$  of a stated value at room temperature (25°C / 77°F) and a nominal line input voltage.

### Caution

Read all warnings, cautions, and instructions provided with this generator before use. Specific instructions for CoolSeal™ instruments are not included in this manual. Refer to the CoolSeal™ instrument's instructions for use for warnings, cautions, and instructions for its use.

## Performance Characteristics

### General

Output configuration:	Isolated output
Cooling:	Ambient natural convection
Display:	Indicator lamps and power stand-by switch
Connector ports:	LED illuminated connector detection
Mounting:	Operating room boom systems Any stable, flat surface such as a table or cart top

### Dimensions and Weight

Width:	30.5 cm (12 in.)
Depth:	38.1 cm (15 in.)
Height:	10.9 cm (4.3 in.)
Weight:	5.4 kg (12 lbs.)

### Operating Parameters

Ambient temperature range:	+10°C to +35°C
Relative humidity:	30% to 75% (non-condensing)
Atmospheric pressure:	67 kilopascals to 111 kilopascals
Warm-up time:	If transported or stored at temperatures outside the operating temperature range, allow one hour for the CoolSeal™ Generator to reach operating temperature before use.

### Transport and Storage

Ambient temperature range:	-20°C to +60°C
Relative humidity:	0% to 90% (non-condensing)
Atmospheric pressure:	46 kilopascals to 111 kilopascals

### Internal Memory

Nonvolatile:	RAM
Storage capacity:	Memory can store information for the last 2000 seal cycles. Data is not patient specific and not user accessible.



## Activation Tone

The audio levels stated below are for activation tones of sealing at a distance of one meter.

Volume (adjustable):	40 dBA to 80 dBA
Frequency	
CoolSeal™ sealing:	349.2 Hz
Duration:	Continuous while the system is actively delivering RF energy

## Alert Tones

Volume (adjustable):	65 dBA to 80 dBA
Frequency	
System Error & Instrument Error:	One 550 msec tone pulse High = 2637 Hz, Low = 440 Hz 550 msec
Seal Complete:	Three sequential tones 349.2 Hz, 392 Hz & 440 Hz 75 msec, 150 msec & 300 mSec duration
Reactivate / Incomplete Seal:	Three tone pulses High = 2489 Hz, Low = 349.2 Hz 80 msec pulses, 100 msec pauses between

## Input Power

Maximum power at nominal line voltage: 110W
Mains current (maximum) Idle: 250 mA Sealing: 1 A
Mains line frequency range (nominal): 50 Hz to 60 Hz
Mains line voltage range (nominal): 100-240 V
Fuses (2): Type T5AH 250V or equivalent, 5 mm x 20 mm 5A, 250V, slow acting, high breaking capacity
Power inlet: IEC 60320 C14

## Power Cord Specification

This unit was equipped from the factory with a 110 VAC hospital grade power cord with a NEMA5-15 mains connector. When replacing the AC power cord to match another mains connector configuration, the replacement connector/cable/receptacle configuration must meet or exceed the following specifications:

### 100-120 VAC

Cable:	SJT 18/3, IEC color code, maximum length 10ft. (3 m)
Mains connector:	Hospital grade, meets requirements of local country
Minimum:	10 A - 125 VAC
Unit receptacle:	IEC 60320 C13, minimum 10 A - 125 VAC

### 220-240 VAC

Cable:	H05VVF3G1.0, maximum length 10 ft. (3 m)
Mains connector:	Hospital grade, meets requirements of local country
Minimum:	6 A - 250 VAC
Unit receptacle:	IEC 60320 C13, minimum 6 A - 250 VAC

---

## Technical Specifications

### Input Frequency

The CoolSeal™ Generator operates within specification at all line input frequencies between 47 Hz and 63 Hz. The User does not need to reconfigure the CoolSeal™ Generator for different line frequencies.

### Input Current

The CoolSeal™ Generator draws no more than 5A at any line input voltage.

### Backup Power

The CoolSeal™ Generator retains calibration and statistical data when switched off and unplugged. The CoolSeal™ Generator operates within specification when switched over to a supplied line power by hospital backup systems.

### Equipotential Connection

An equipotential connector is provided on the rear of the CoolSeal™ Generator to allow connection of a potential equalization conductor if required.

### Duty Cycle

Under maximum power settings and rated load conditions, the CoolSeal™ Generator is capable of operating a duty cycle of 25%, defined as 5 seconds active RF delivery and 15 seconds inactive.

### Low Frequency (50/60 Hz) Leakage Current

Complies with IEC 60601-1, Ed. 3.1

Low frequency limits:

Earth Leakage:	5 mA Normal Conditions	10 mA Single Fault Condition
Touch Current:	100 µA Normal Conditions	500 µA Single Fault Condition
Patient Leakage: <i>(based on Type CF applied part)</i>	10 µA Normal Conditions	50 µA Single Fault Condition (DC or AC current)
Patient Leakage with mains on the F-type applied part: <i>(based on Type CF applied part)</i>		50 uA

### Standards and IEC Classifications

The CoolSeal™ Generator meets all pertinent clauses of the IEC 60601-1 Ed. 3.1, IEC 60601-1-2 Ed. 4.0 and IEC 60601-2-2 Ed. 6.0 .

## Symbols

	Consult instructions for use		AC Power Input (Mains)
	Warning, Electricity To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified service personnel.		AC Power Output (RF)
	Serial Number		Stand-by, Power
	Authorized Representative in the European Community		Temperature limit
	Catalog, reorder or reference number		Humidity limit
	Medical Device		Atmospheric pressure limitation
	Manufacturer of record		Keep dry
	Date of Manufacture		Classified with respect to electrical shock, fire, and mechanical hazards only in accordance with IEC 60601-1 and CAN/CSA C22.2 No. 601.1.
	The generator is designated for a type CF applied part		Complies with requirements of FCC, part 15.
	Equipotentiality		Volume adjustment for activation tones, clockwise increases volume
	Fuse		Equipment must not be disposed in trash

---

## Classifications

### Class I Equipment (IEC 60601-1)

Accessible conductive parts cannot become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor.

### Electromagnetic Compatibility (IEC 60601-1-2)

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) This device must accept any interference received, including interference that may cause undesired operation.

### Type CF Equipment (IEC 60601-1)

This generator provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type CF isolated (floating) output and may be used for procedures involving the heart.

### IP XX Liquid Ingress/Spillage (IEC 60601-1 and IEC 60601-2-2)

The CoolSeal™ Generator is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which when wetted are likely to adversely affect the safety of the equipment.

### Voltage Transients – Energy Platform Mains Transfer (IEC60601-1 and IEC 60601-2-2)

The CoolSeal™ Generator continues to operate normally with no errors or system failures when transfer is made between line AC and an emergency energy platform voltage source. (IEC 60601-1- 2)

### Electromagnetic Compatibility (IEC 60601-1-2 and IEC60601-2-2)

The CoolSeal™ Generator complies with the appropriate IEC 60601-1-2 and 60601-2-2 specifications regarding electromagnetic compatibility.

#### Warning

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the CoolSeal™ Generator including cables specified by Bolder Surgical. Otherwise, degradation of the performance of this equipment could result.

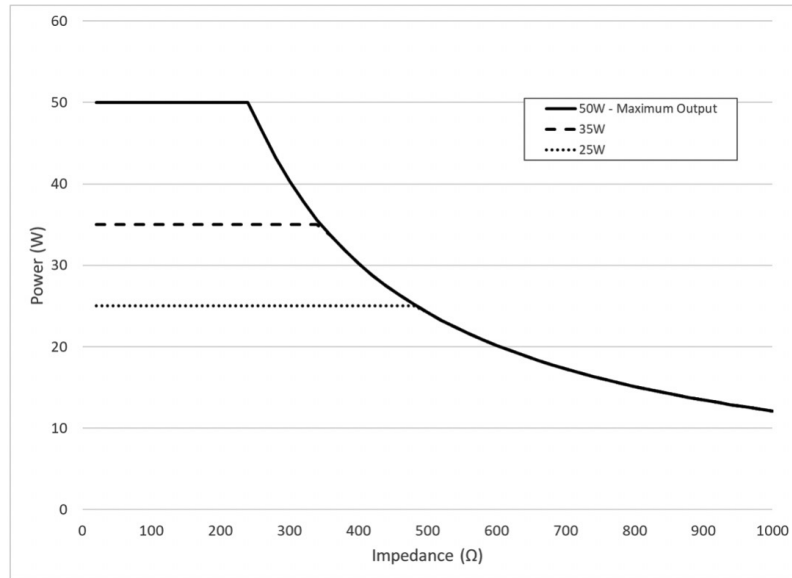
## Output Characteristics

### Maximum Output for the CoolSeal™ Generator

Power readouts agree with actual power into rated load to within 20% or 5 watts, whichever is greater.

Open Circuit Peak Voltage (max)	Rated Load	Rated Output Power (max)	Crest Factor	Waveform Duty Cycle
190 V	20 Ω	50 W	1.9	100%

## Output Power vs. Impedance Graph



## Electromagnetic Immunity

### Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The CoolSeal™ Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the CoolSeal™ Generator should ensure that it is used in such an environment.

RF emissions CISPR 11	Group 2	The CoolSeal™ Generator must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
Conducted Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class A	
Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class A	The CoolSeal™ 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 purposes.
Harmonic Emissions IEC/EN 61000-3-2:2014	Class A Device	
Voltage Fluctuations/Flicker Emissions IEC/EN 61000-3-3:2013	Per Clause 5 of the Standard	

Basic safety per IEC 60601-1 is the performance requirement used during immunity testing. Essential performance does not apply.

### Notice

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CoolSeal™ Generator is intended for use in the electromagnetic environment specified below. The customer or the user of the CoolSeal™ Generator should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	± Compliance level	Electromagnetic Environment – Guidance
Electrostatic Discharge IEC/EN 61000-4-2	± 8 kV contact discharge ± 2, 4, 8 & 15 kV air discharge	± 8 kV contact discharge ± 2, 4, 8 & 15 kV air discharge	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated Immunity IEC 61000-4-3:2006 + A1:2008 +A2:2010	80 MHz - 6 GHz 3 V/m  80% @ 1 kHz  28 V/m Spot frequencies 385 MHz – 2.7 GHz Pulse Modulation	80 MHz - 6 GHz 3 V/m  80% @ 1 kHz  28 V/m Spot frequencies 385 MHz – 2.7 GHz Pulse Modulation	Portable and mobile RF communications equipment should be used no closer to any part of the CoolSeal™ Generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Proximity field from RF wireless communications equipment IEC 61000-4-3	Per Table 9 of the IEC 60601-1-2 standard	See table on next page of frequency ranges and test conditions for RF wireless communications equipment	<b>Recommended separation distance</b> $d = [2] \sqrt{P}$ where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> , must be less than the compliance level in each frequency range <sup>b</sup> .
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	The ISM (industrial, scientific and medical) bands between 0,15 MHz 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 MHz to 40,70 MHz.
Electrical Fast Transients (AC Power) IEC/EN 61000-4-4	± 2 kV AC mains ± 1 kV - I/O lines 5/50 5 kHz & 100kHz	± 2 kV AC mains ± 1 kV - I/O lines 5/50 5 kHz & 100kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC/EN 61000-4-5	± 1 kV Line to Line Line to Ground	± 1 kV Line to Line Line to Ground	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic Immunity IEC/EN-61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips & Interruptions IEC/EN 61000-4-11	0% UT 0.5 cycle 0% UT 1 cycle 70% UT 25 cycles 0% UT 5 Sec	0% UT 0.5 cycle 0% UT 1 cycle 70% UT 25 cycles 0% UT 5 Sec	If the user of CoolSeal™ Generator requires continued operation during power mains interruptions, it is recommended that the CoolSeal Generator be powered from an uninterruptible power supply or a battery.

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

<sup>a</sup>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 CoolSeal™ Generator is used exceeds the applicable RF compliance level above, the CoolSeal™ 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 CoolSeal™ Generator.

<sup>b</sup>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

<b>Guidance and Manufacturer's Declaration – Electromagnetic Immunity</b>			
Frequency ranges and test conditions for RF wireless communications equipment			
<b>Frequency band (MHz)</b>	<b>Test frequency (MHz)</b>	<b>Modulation<sup>a</sup></b>	<b>Compliance level (V/m)</b>
380 - 390	380 - 390	Pulse – 18 Hz	27
430 - 470	450	FM ±5 kHz deviation 1 kHz sine	28
704 - 787	710	Pulse – 217 Hz	9
	745		
	780		
800 - 960	810	Pulse – 18 Hz	28
	870		
	930		
1700 - 1990	1720	Pulse – 217 Hz	28
	1845		
	1970		
2400 - 2570	2450	Pulse – 217 Hz	28
5100 - 5800	5240	Pulse – 217 Hz	9
	5500		
	5785		

<sup>a</sup>Pulse Modulation is defined as a square wave input with a 50% duty cycle at the listed frequency.

NOTE Portable RF communication equipment should be used no closer than 30 cm (12 inches) to any part of the CoolSeal™ Generator including cables specified by Bolder Surgical. Otherwise, degradation of the performance of this equipment could result.

### Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the CoolSeal™ Generator

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

Rated maximum output power of transmitter	Separation distance from transmitter $d = [2]\sqrt{P}$
0.01	0.20
0.1	0.63
1	2.00
10	6.32
100	20.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated 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 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



---

## Appendix A – Periodic Functional Test

The purpose of the test is to confirm proper function of the CoolSeal™ Generator. It is recommended that this test be performed at least every two years to ensure proper function is maintained over time. Refer to the final test date label for the last Bolder Surgical™ functional test date. This test may be used more frequently as required by hospital policies.

### Warning

Do not open the case of the CoolSeal™ Generator. There are no serviceable items within the case. Additional testing is required to confirm safe operation is maintained once the case has been opened. This testing is only available at the Bolder Surgical™ Service Center. Failure to comply may result in an increased risk of electrical shock.

### Notice

Only qualified individuals should conduct the CoolSeal™ Functional Test.

### Important

An optional form is supplied below to record the results of the Periodic Functional Test.

### Warning

Do not attempt to use the Functional Test Cable for any purpose other than the steps outlined herein.  
Do not use clinically.

### Definitions:

**UUT – Unit Under Test**

**ESA – Electrical Safety Analyzer**

**ESuA – Electro-Surgical Analyzer**

### Equipment Required:

UUT - CoolSeal™ Generator – CSL-200-50

ESA - Fluke Electrical Safety Analyzer Model ESA612 (or equivalent)

ESuA - Fluke Electro-Surgical Analyzer Model QA-E SII, QA-ES III (or equivalent)

Functional Test Cable – CSL-FTC

Stopwatch

### Pass/Fail Criteria:

- Follow the steps outlined below to obtain the indicated result, repeat if this result is not obtained.
- Contact Bolder Surgical to arrange for service in order to resolve failures or anomalies.
- Do not attempt to repair the CoolSeal™ Generator.
- Attempting to repair the CoolSeal™ Generator will violate the product warranty.

---

**Procedure:****RECORDING RESULTS:**

1. You can record the results of the following tests on a copy of the attached log. After each step below, record the result in the corresponding section as indicated by **<RECORD RESULTS>**. Capture numeric values where indicated and circle **P** for Pass or **F** for Fail.

**INSPECTION:**

1. Inspect the unit for external damage or missing components, no damage or missing components should be found. **<RECORD RESULTS>**
2. Inspect the power cord for damage, no damage should be found. **<RECORD RESULTS>**

**INDICATOR LIGHTS AND AUDIO INDICATORS:**

1. Apply power to the UUT and depress the power button, the power button should illuminate GREEN and a three (3) tone sequence should be heard. A RED power button illumination indicates a failure of the power on self-test. **<RECORD RESULTS>**
2. Insert the Functional Test Cable into the instrument receptacle, the instrument receptacle display should illuminate white. **<RECORD RESULTS>**
3. Turn off the power of the UUT. Depress and hold the activate button. Turn on power while holding the activate button down. The power button will illuminate GREEN and a three (3) tone sequence should be heard, followed by a second tone, then the instrument receptacle display will flash AMBER. **<RECORD RESULTS>**
4. Remove the Functional Test Cable and power the UUT off then on again. The power button should be GREEN. While depressing and holding the activate button on the Functional Test Cable, insert the Functional Test cable into the instrument receptacle. A single tone will sound followed by the instrument receptacle display flashing AMBER. **<RECORD RESULTS>**
5. Power the UUT off then on again to reset from the previous step. Set the switch on the Functional Test Cable to the 'Open' position and depress and hold the activate button. The activation display will momentarily display FUCHSIA and begin the sealing tone, followed by an AMBER display of approximately 1 second and the 3-tone regrasp alert. This may sound like 4-tones. **<RECORD RESULTS>**
6. Set the switch on the Functional Test Cable to the "Short" position. Depress and hold the activation button and confirm that the activation display is illuminated FUCHSIA and varying in intensity from off to full intensity with the sealing tone. This will be followed by an AMBER activation display and a 3-tone alert. **<RECORD RESULTS>**
7. With the switch of the Functional Test Cable still in the "Short" position, prepare to time with the stopwatch from pressing the activation button until the AMBER display. Depress the activate button, timing the FUCHSIA (sealing) phase. **<RECORD RESULTS>**
8. With the switch of the Functional Test Cable still in the "Short" position, prepare to twist the volume knob during the FUCHSIA (sealing phase). Depress the activate button, turn the volume knob to each extreme, confirming a volume change between Minimum and Maximum levels. **<RECORD RESULTS>**
9. Remove the test cable, power off and unplug the UUT.

**GROUND CONTINUITY TESTING:**

1. Turn on the ESA
2. Plug the power cable from the UUT into the ESA
3. Connect the test lead to the V/ $\Omega$ /A jack of the ESA to measure Ohms ( $\Omega$ ).
4. Connect the test lead to the ESA ground/null post.
5. Be sure the ESA is measuring resistance ( $\Omega$ )
6. Zero the ESA.
7. Attach the test lead to the UUT equipotential connector.
8. Record the resistance value seen through the power cable and UUT. **<RECORD RESULTS>**
9. Disconnect the UUT from the ESA, power off the ESA.

---

## EARTH LEAKAGE TESTING

1. Turn on the ESA.
2. Plug the power cable from the UUT into the ESA.
3. Insert the Functional Test Cable into the instrument receptacle.
4. Set the Functional Test Cable to Normal, stack the RED and BLACK banana connectors
5. Insert the stacked connectors into the RA/R (resistance) port of the ESA
6. Using the Micro Amp setting ( $\mu\text{A}$ ) and EARTH, perform the following series of tests.
7. Normal/Closed <RECORD RESULTS>
8. Normal/Open <RECORD RESULTS>
9. Reverse/Open <RECORD RESULTS>
10. Reverse/Closed <RECORD RESULTS>
11. Remove the Functional Test Cable and repeat the above series of tests.
12. Normal/Closed <RECORD RESULTS>
13. Normal/Open <RECORD RESULTS>
14. Reverse/Open <RECORD RESULTS>
15. Reverse/Closed <RECORD RESULTS>
16. Disconnect the UUT from the ESA, power off the ESA.

## IMPEDANCE TESTER

1. Turn on the ESuA
2. Power on the UUT
3. Set the Functional Test Cable switch to Normal
4. Plug the RED and BLACK Functional Test Cable plugs into the corresponding ESuA VAR LOAD sockets.
5. Insert the Functional Test Cable into the UUT
6. Confirm that the Power Button is GREEN, and the instrument receptacle display is WHITE before continuing.

### Important

The CoolSeal™ Generator tests a range of power outputs. The first activation is at a power output of 25 Watts, the second activation is at a power output of 35 Watts and the third activation is at a power output of 50 Watts. The fourth activation begins this sequence again. To restart the sequence from a known starting point, simply unplug the Functional Test Cable and reinsert it.

### Important

When using the Functional Test Cable the CoolSeal™ Generator will put the unit into a failure state if the resistive load changes significantly. This is unlikely to occur during the Functional Test, but if it were to happen, simply power the unit off and on again to reset the unit.

7. Set the load of the ESuA to 25 Ohms.
8. Start the test on the ESuA.
9. Press and hold the activation button.
10. At 25 Ohms, observe the maximum power reading at 25 Watts. <RECORD RESULTS>
11. Press and hold the activation button.
12. At 25 Ohms, observe the maximum power reading at 35 Watts. <RECORD RESULTS>

- 
13. Press and hold the activation button.
  14. At 25 Ohms, observe the maximum power reading at 50 Watts. <RECORD RESULTS>
  15. Stop the test on the ESuA.
  16. Set the load of the ESuA to 50 Ohms
  17. Start the test on the ESuA.
  18. Press and hold the activation button.
  19. At 50 Ohms, observe the maximum power reading at 25 Watts.<RECORD RESULTS>
  20. Press and hold the activation button.
  21. At 50 Ohms, observe the maximum power reading at 35 Watts. <RECORD RESULTS>
  22. Press and hold the activation button.
  23. At 50 Ohms, observe the maximum power reading at 50 Watts. <RECORD RESULTS>
  24. Stop the test on the ESuA.
  25. Set the load of the ESuA to 225 Ohms
  26. Start the test on the ESuA.
  27. Press and hold the activation button.
  28. At 225 Ohms, observe the maximum power reading at 25 Watts. <RECORD RESULTS>
  29. Press and hold the activation button.
  30. At 225 Ohms, observe the maximum power reading at 35 Watts.<RECORD RESULTS>
  31. Stop the test on the ESuA.
  32. Set the load of the ESuA to 200 Ohms
  33. Start the test on the ESuA.
  34. Press and hold the activation button.
  35. At 200 Ohms, observe the maximum power reading at 50 Watts. <RECORD RESULTS>
  36. Stop the test on the ESuA.
  37. Power everything down and disconnect the UUT from the test equipment.

## Periodic Functional Test Summary Form

Periodic Functional Test Summary Form Page 1/2

Generator SN: \_\_\_\_\_

Step	TEST	REQUIREMENT	Record Values	Circle Pass/ Fail
Inspection				
1	Unit Exterior Inspection	No Damage		P / F
2	Power Cord	No Damage		P / F
Indicator Lights and Audio Indicators				
1	Normal Power-up	GREEN Power Button and 3-Tones		P / F
2	Normal Instrument Insertion	White Receptacle Display		P / F
3	Stuck Button During Power On	1) GREEN Power Button and 3-Tones 2) 1-Tone then flashing AMBER Receptacle		P / F
4	Stuck Button After Power On	1-Tone then flashing AMBER Receptacle		P / F
5	Open Circuit Test	1) Short FUCHSIA Display w/Tone 2) AMBER Display w/ 3-Tone Alert		P / F
6	Short Circuit Test	1) 4 second FUCHSIA Display w/Tone 2) AMBER Display w/3-Tone Alert		P / F
7	Seal Timing	Approx. 4 seconds of varying FUCHSIA Display	_____ sec	P / F
8	Volume Test	Volume changes between Min. and Max. Levels		P / F

\_\_\_\_\_  
Tester Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Periodic Functional Test Summary Form Page 2/2**

**Generator SN:** \_\_\_\_\_

Step	TEST	REQUIREMENT	Record Values	Circle Pass/Fail
Ground Continuity Testing				
8	Ground Continuity Value	< .200 ohms	_____ ohms	P / F
Earth Leakage Testing				
7	Normal/Closed with Cable	< 500 μA	_____ μA	P / F
8	Normal/Open with Cable		_____ μA	P / F
9	Reverse/Open with Cable		_____ μA	P / F
10	Reverse/Closed with Cable		_____ μA	P / F
12	Normal/Closed no Cable		_____ μA	P / F
13	Normal/Open no Cable		_____ μA	P / F
14	Reverse/Open no Cable		_____ μA	P / F
15	Reverse/Closed no Cable		_____ μA	P / F
Impedance				
10	Impedance 25 Ω/Power 25 W	20 W – 30 W	_____ W	P / F
12	Impedance 25 Ω/Power 35 W	28 W – 42 W	_____ W	P / F
14	Impedance 25 Ω/Power 50 W	40 W – 60 W	_____ W	P / F
19	Impedance 50 Ω/Power 25 W	20 W – 30 W	_____ W	P / F
21	Impedance 50 Ω/Power 35 W	28 W – 42 W	_____ W	P / F
23	Impedance 50 Ω/Power 50 W	40 W – 60 W	_____ W	P / F
28	Impedance 225 Ω/Power 25 W	20 W – 30 W	_____ W	P / F
30	Impedance 225 Ω/Power 35 W	28 W – 42 W	_____ W	P / F
32	Impedance 200 Ω/Power 50 W	40 W – 60 W	_____ W	P / F

\_\_\_\_\_  
Tester Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

---

## Warranty

Bolder Surgical warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for the period(s) set forth below. Bolder Surgical's sole obligation and the customer's exclusive remedy for any breach of this warranty is limited to the repair or replacement, at Bolder Surgical's sole option, of any product, or part thereof, which has been returned to it or its Distributor within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses, to Bolder Surgical's satisfaction, that the product is defective. This warranty does not apply to any product, or part thereof, which has been repaired or altered by anyone other than Bolder Surgical or its authorized representatives, or which has been subjected to misuse, neglect, or accident. The warranty periods for Bolder Surgical products are as follows:

<b>Product Type</b>	<b>Warranty Period (time following shipment by Bolder Surgical)</b>
<b>CoolSeal™ Generator</b>	<b>1 year from date of shipment</b>

EXCEPT FOR THE LIMITED WARRANTIES ABOVE, BOLDER SURGICAL, TO THE EXTENT PERMITTED BY APPLICABLE LAW, EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS, IMPLIED OR STATUTORY, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND NONINFRINGEMENT.

NOTWITHSTANDING ANY OTHER PROVISION HEREIN OR IN ANY OTHER DOCUMENT OR COMMUNICATION TO THE CONTRARY, IN NO EVENT WILL BOLDER SURGICAL BE LIABLE FOR LOSS OF PROFIT OR REVENUES, LOSS OF PRODUCT, LOSS OF USE OF PRODUCTS, INTERRUPTION OF BUSINESS, OR FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, INDIRECT, PUNITIVE OR EXEMPLARY DAMAGES. BOLDER SURGICAL'S TOTAL LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATING TO THIS AGREEMENT AND ANY PRODUCT SHALL BE LIMITED TO GENERAL MONEY DAMAGES IN AN AMOUNT NOT TO EXCEED THE TOTAL PURCHASE PRICE FOR THE PRODUCT GIVING RISE TO THE CLAIM. These limitations and exclusions shall apply regardless of whether a claim is based in contract, warranty, indemnity, tort extracontractual liability (including negligence), strict liability or otherwise. Bolder Surgical neither assumes nor authorizes any other party to assume for it any other liability in connection with the sale or use of any of Bolder Surgical's products.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Colorado, USA. Any suit or action from or related to this warranty shall be brought exclusively in the state or federal courts located in Boulder or Denver, Colorado, USA, and any right to object to the venue of such courts is hereby waived by the customer. Bolder Surgical, its dealers, and representatives reserve the right to alter, modify, or redesign their products without any obligation to modify or replace any products previously built and/or sold by them.

---

# CoolSeal™

GENERATOR

**BOLDER**<sup>™</sup>  
SURGICAL

**Bolder Surgical**

Made in USA. Printed in USA.  
© 2021 Bolder Surgical  
All rights reserved.

[www.BolderSurgical.com](http://www.BolderSurgical.com)  
Tel: 866.683.1743

**Patent Information**

[www.BolderSurgical.com/patents](http://www.BolderSurgical.com/patents)

ICE-DO-18103 Rev. F  
Issue Date: 2021-09-30  
[www.BolderSurgical.com/IFUs](http://www.BolderSurgical.com/IFUs)

CE  
2797



**Bolder Surgical**

331 S. 104th Street, Suite 200  
Louisville, CO 80027  
USA