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Valleylab™

User's Guide

LigaSure™ Vessel Sealing Generator

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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 Valleylab LigaSure™ vessel sealing generator only. Additional technical information is available in the ***LigaSure™ Vessel Sealing Generator Service Manual***.

Caution

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

Equipment covered in this manual

Valleylab LigaSure™ vessel sealing generator – 120 V/240 V

Valleylab Part Number 1023797

Effective Date August 2009

Patents

One or more of the following U.S. patents and corresponding foreign patents cover the LigaSure vessel sealing generator and accessories:

5,776,130	6,068,627	6,464,704	6,743,229
5,599,344	6,179,834	6,458,130	D-424,694
5,720,744	6,228,083	6,511,480	D-425,201
5,827,271	6,277,117	6,585,735	D-449,886
6,033,399	6,398,779	6,682,528	D-457,958
6,039,733	6,402,743	6,685,701	D-457,959
6,050,996	6,451,018	6,726,686	

Additional patents pending.

Trademark acknowledgments

Valleylab™, ForceTriad™, Force FX™, Force EZ™, Force Argon™, LigaSure™, LigaSmart™, Smart™, Cool-Tip™, TissuFect™, REM™, RFG-3C™, OptiMumm™, SurgiStat™, EDGE™, AccuVac™, PolyHesive™, and Instant Response™ are trademarks of Valleylab. Klenzyme™ is a trademark of the STERIS Corporation. Enzol™ is a trademark of Johnson & Johnson Medical Inc.

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http://www.valleylab.com

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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 hazardous situation which, if not avoided, may result in minor or moderate injury.

Notice

Indicates a hazard that may result in product damage.

Important

Indicates an operating tip or maintenance suggestion.

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Warranty

Valleylab, a division of Tyco Healthcare Group LP, 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. Valleylab's obligation under this warranty is limited to the repair or replacement, at its 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 Valleylab's satisfaction, that the product is defective. This warranty does not apply to any product, or part thereof, which has been repaired or altered outside Valleylab's factory in a way so as, in Valleylab's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

The warranty periods for Valleylab products are as follows:

Footswitches (all models)	One year from date of shipment
Force Argon Units	One year from date of shipment
OptiMumm Smoke Evacuator	Two years from date of shipment
LigaSure Sterile Single Use Items	Sterility only as stated on packaging
Sterile Single Use Items	Sterility only as stated on packaging
Patient Return Electrodes	Shelf life only as stated on packaging

This warranty is in lieu of all other warranties, express or implied, including without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of Valleylab. Valleylab neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Valleylab's products.

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This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Colorado, USA. The sole forum for resolving disputes arising under or relating in any way to this warranty is the District Court of the County of Boulder, State of Colorado, USA.

Valleylab, its dealers, and representatives reserve the right to make changes in equipment built and/or sold by them at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.

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Table of Contents

Conventions Used in this Guide iv
Warranty v

Chapter 1. Introduction

Vessel Sealing 1-2
Bipolar Modes 1-2
Instant Response Technology 1-2
Accessories 1-3

Chapter 2. Controls and Receptacles

Front Panel 2-2
- Domestic 2-2
- Vessel Sealing Controls 2-4
- Vessel Sealing Instrument Receptacle (purple) 2-5
- Bipolar Controls 2-5
- Bipolar Instrument Receptacle (blue) 2-6

Rear Panel 2-7
- Vessel Sealing Footswitch Receptacle (purple) 2-8
- Bipolar Footswitch Receptacle (blue) 2-8
- Option Panel 2-9

Chapter 3. Patient and Operating Room Safety

General 3-2
- Fire/Explosion 3-3
- Fire Hazard with Oxygen Circuit Connections 3-3
- Electrosurgical Smoke 3-3
- Inadvertent Radiofrequency Burns 3-4
- Ensure Proper Connections 3-4
- Instrument Cords 3-4
- Servicing 3-4

Before Surgery 3-5
- Active Instruments 3-5
- Generator 3-5

During Surgery 3-6
- Generator Power Settings 3-6
- Contact with Metal Objects 3-6
- Active Accessories 3-6
- Laparoscopic LigaSure Instrument Procedures 3-7
- Open LigaSure Instrument Procedures 3-7

After Surgery 3-8

Chapter 4. Before Surgery

Quick Setup Instructions 4-2
Setting Up the Generator 4-3
Preparing for Surgery 4-4

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Footswitch Connections 4-5
Instrument Connections 4-5
Vessel Sealing Instrument Connection 4-5
Set the Output for the Vessel Sealing Mode 4-6
Bipolar Instrument Connection 4-7
Set the Output for the Bipolar Mode 4-7

Chapter 5. During Surgery

Checking Accessory Connections 5-2
Changing the Power or Intensity Setting 5-2
Vessel Sealing 5-2
Bipolar or Macrobipolar 5-3
Activating the Surgical Instrument 5-3
Vessel Sealing 5-3
Bipolar 5-3
Regrasp Indicator 5-4
Adjusting the Volume of Activation Tones 5-5
Responding to Alarms 5-5

Chapter 6. After Surgery

Preparing the Generator for Reuse 6-2
Disconnect the Accessories 6-2
Clean the Generator 6-2
Reprocessing Instruments 6-2
Clean the Reusable Instrument 6-2
Sterilization Parameters 6-3
Storing the Generator 6-3

Chapter 7. Troubleshooting

General Troubleshooting Guidelines 7-2
Correcting Malfunctions 7-3
Responding to System Malfunctions 7-7

Chapter 8. Maintenance and Repair

Responsibility of the Manufacturer 8-2
Routine Maintenance 8-2
Returning the Generator for Service 8-3
Obtain a Return Authorization Number 8-3
Clean the Generator 8-3
Ship the Generator 8-3
Service Centers 8-4

Chapter 9. Technical Specifications

Performance Characteristics 9-2
General 9-2
Dimensions and Weight 9-2
Operating Parameters 9-2

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Transport and Storage 9-3
Duty Cycle 9-3
Internal Memory 9-3
Audio Volume 9-3
Serial Port 9-4
RF Activation Port 9-4
Expansion Port 9-5
Low Frequency (50-60 Hz) Leakage Current (AAMI HF-18-1993) 9-5
High Frequency (RF) Leakage Current (IEC 601-2-2) 9-5
Input Power 9-6
Power Cord Specification 9-7
Standards and IEC Classifications 9-7
Class I Equipment (IEC 60601-1) 9-8
Type CF Equipment (IEC 60601-1)/Defibrillator Proof 9-8
Liquid Spillage (IEC 60601-2-2 Clause 44.3) 9-8
Static Electricity Discharge Interference (IEC 60601-1-2 and IEC 80801-2) 9-8
Electromagnetic Interference 9-8
Electromagnetic Compatibility (IEC 60601-1-2 and IEC 60601-2-2) 9-9
Voltage Transients (Emergency Generator Mains Transfer) 9-9
Output Characteristics 9-10
Maximum Generator Output 9-10
Output Waveform 9-10
Output Power vs. Resistance Graphs 9-13

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Chapter 1

Introduction

This chapter includes information about:

- LigaSure vessel sealing technology
- Bipolar modes
- Instant Response technology

Caution
Read all warnings, cautions, and instructions provided with this generator before using.
Read the instructions, warnings, and cautions provided with instruments and accessories before using. Specific instructions are not included in this manual.

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The LigaSure vessel sealing generator is an isolated output generator that provides power for vessel sealing and bipolar surgery.

It includes the following features:

- LigaSure vessel sealing technology
- Vessel sealing Regrasp indicator that alerts you to situations where a full seal cycle has not been achieved
- Bipolar and macrobipolar modes
- Instant Response technology
- Memory button to recall prior intensity and power settings used
- Smart interface for connecting a Valleylab LigaSure instrument or smart connector adapter
- Adjustable activation tone volume
- Handswitch or footswitch activation
- RF activation port, RS-232 serial port, and expansion port

Vessel Sealing

The LigaSure vessel sealing system can be used for vessels up to and including 7 mm in diameter, lympatics, and tissue bundles as large as will fit in the jaws of the instruments. This system provides precise energy delivery and electrode pressure to vessels for a controlled time period to achieve a complete and permanent tissue fusion. The system has been optimized to produce minimal sticking, charring, or thermal spread to adjacent tissue.

Bipolar Modes

Two modes are available: bipolar and macrobipolar.

- Bipolar may be used for most applications. The voltage is kept low to prevent sparking. The power remains constant over a specific range of tissue resistance, allowing a consistent tissue effect.
- Macrobipolar may be used for bipolar cutting or rapid coagulation. Voltage is higher and there is more power than with the bipolar mode.

Instant Response Technology

The LigaSure generator automatically senses tissue resistance and adjusts the output voltage to maintain a consistent effect across different tissue density. This adjustment is based on the power setting and the level of tissue resistance. The maximum output voltage is controlled to reduce tissue damage and to minimize sparking.

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Accessories

The accessories that complete the LigaSure vessel sealing system include multiple reusable and single use instruments for open and laparoscopic procedures. Each reusable instrument requires a corresponding single use electrode.

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Chapter 2

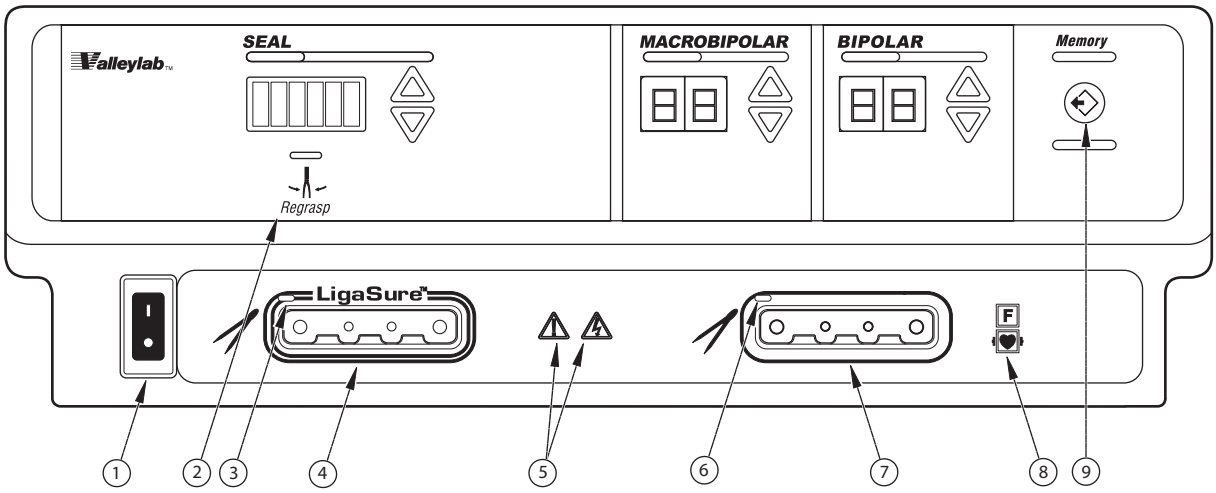
Controls and Receptacles

This chapter describes the front and rear panels, including all controls, receptacles, the fuse drawer, and ports.

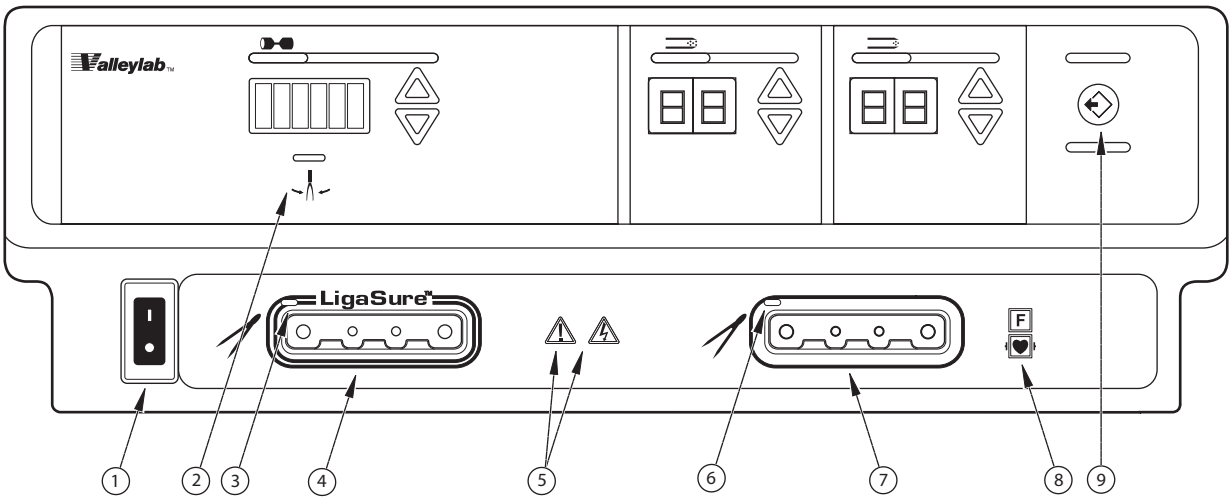
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Front Panel

Domestic



International



These callouts refer to both the domestic and international front panels:

① **Power Switch**

To turn on the generator, press (|).

To turn off the generator, press (O).

② **Regrasp Indicator**

③ **Vessel Sealing Receptacle Light**

④ **Vessel Sealing Instrument Receptacle**

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⑤ **Standard and IEC Classifications**

⑥ **Bipolar Receptacle Light**

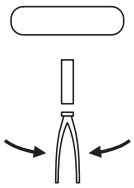
⑦ **Bipolar Instrument Receptacle**

⑧ **Standard and IEC Classifications**

⑨ **Memory Button**

Pressing this button resets the generator to recall prior intensity and power settings used.

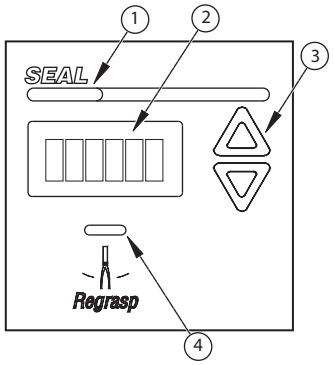
For details of the vessel sealing and bipolar controls, refer to the following pages in this chapter.

Symbol	Indicates
	Vessel Sealing
	Regrasp
	Macrobipolar
	Bipolar
	Memory

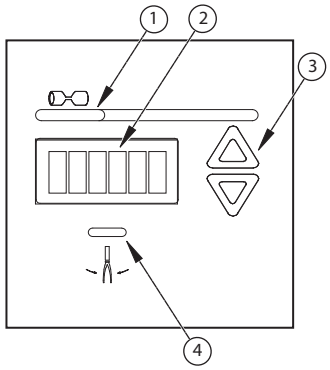
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Vessel Sealing Controls

Domestic



International



① **Seal RF Activation Light**

Illuminates with handswitch or footswitch activation

② **Vessel Sealing Intensity Display**

Bar graph indicates the relative seal intensity setting

③ **Vessel Sealing Intensity Buttons**

Press ∆ to increase the intensity. Press ∇ to decrease the intensity.

④ **Regrasp Indicator**

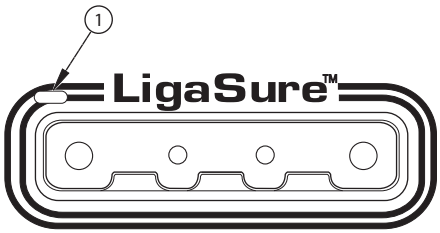
Illuminates if the tissue is not sealed. This may be due to:

- **Tissue not responding to RF energy**
- **Tissue impedance is out of range**
- **The seal cycle was interrupted before the cycle was complete.**
- **Maximum seal cycle time has been reached**

A pulsed tone sounds and vessel sealing output is disabled.

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Vessel Sealing Instrument Receptacle (purple)



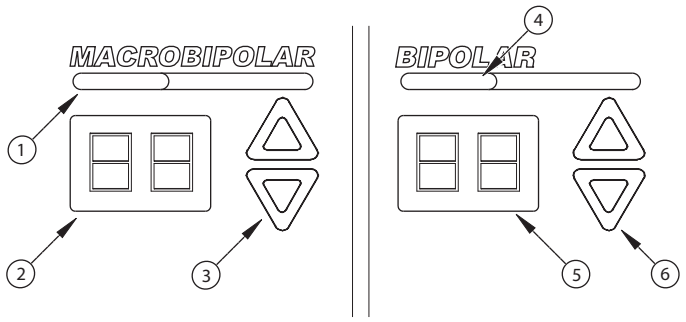
① Light

You can only connect a LigaSure vessel sealing instrument to this receptacle.

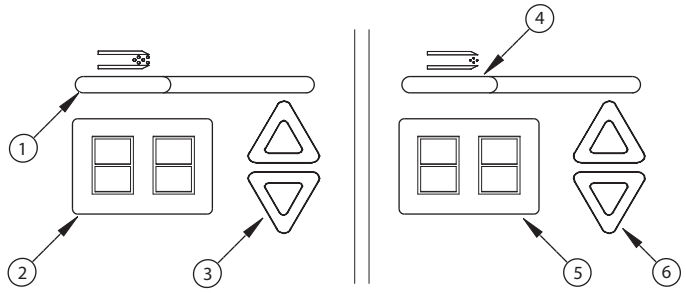
When the instrument is correctly connected, the vessel sealing receptacle light changes from red to green. The light must be green for the system to operate.

Bipolar Controls

Domestic



International



① Macrobipolar RF Activation Light

Illuminates gray with handswitch or footswitch activation

② Macrobipolar Power Display

Shows the power setting in watts for the macrobipolar mode

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③ **Macrobipolar Power Buttons**

Press ∆ to increase the power. Press ∇ to decrease the power.

④ **Bipolar RF Activation Light**

Illuminates blue with handswitch or footswitch activation

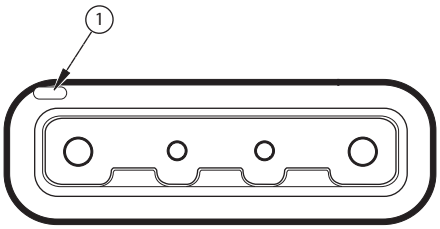
⑤ **Bipolar Power Display**

Shows the power setting in watts for the bipolar mode

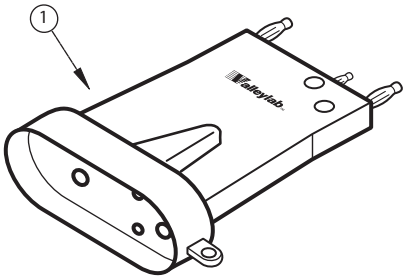
⑥ **Bipolar Power Buttons**

Press ∆ to increase the power. Press ∇ to decrease the power.

Bipolar Instrument Receptacle (blue)



① **Light**



① **Smart Connector Adapter**

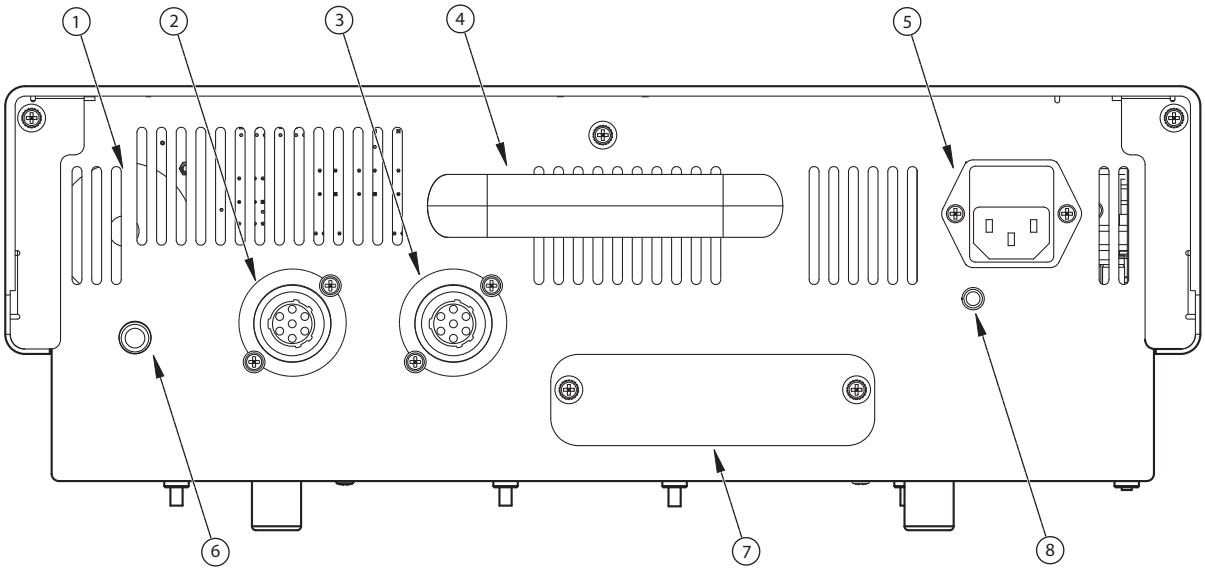
This receptacle is designed to accept a blue bipolar Valleylab smart connector adapter. You must use this smart connector adapter to connect any bipolar instrument.

You can connect either a footswitching (two-pin connector) or handswitching (three-pin connector) bipolar/macrobipolar instrument to the smart connector.

When the blue bipolar Valleylab smart connector adapter is correctly connected, the bipolar receptacle light changes from red to green. The light must be green for the system to operate.

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Rear Panel



① **Speaker**

② **Bipolar Footswitch Receptacle (blue)**

③ **Vessel Sealing Footswitch Receptacle (purple)**

④ **Handle**

⑤ **Power Entry Module**

Contains a fuse drawer, with two fuses, and a receptacle for connecting the generator power cord

⑥ **Volume Knob**

To increase the volume, turn the knob clockwise.

To decrease the volume, turn it counterclockwise.

You cannot deactivate the activation tone or adjust the regrasp indicator tone volume.

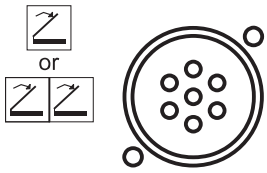
⑦ **Option Panel**

⑧ **Grounding Lug**

Use to connect the generator to earth ground.

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Vessel Sealing Footswitch Receptacle (purple)



Connect either the single pedal vessel sealing footswitch or the two pedal vessel sealing footswitch to the purple receptacle.

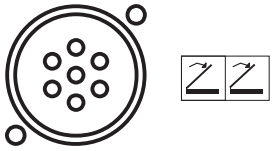
Two Pedal Footswitch

For the LigaSure instrument connected to the vessel sealing instrument receptacle on the front panel, the connected two pedal footswitch activates either the vessel sealing output function (round purple pedal) or the bipolar output function (blue square pedal).

Single Pedal Footswitch

For the LigaSure instrument connected to the vessel sealing instrument receptacle on the front panel, the connected single pedal footswitch activates only the vessel sealing output function.

Bipolar Footswitch Receptacle (blue)



Connect the bipolar/macrobipolar footswitch when you connect a bipolar footswitching instrument to the generator.

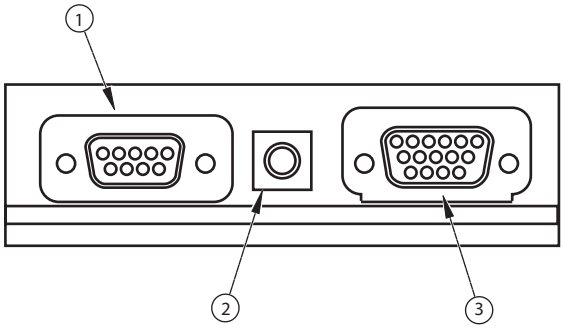
Connect the two pedal bipolar footswitch to this receptacle.

The connected footswitch activates bipolar (blue pedal) or macrobipolar (gray pedal) output for the bipolar instrument that is connected to the bipolar instrument receptacle on the front panel.

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Option Panel

A removable plate on the rear panel covers a serial port, an RF activation port, and an expansion port. To review the technical specifications for each port, refer to *Chapter 9, Technical Specifications*.



① **Serial Port**

Allows connection of a computer to the generator to obtain information using RS-232 communications protocol

② **RF Activation Port**

Allows a connected device to receive information during RF activation of the generator, which can then generate a response in the device

③ **Expansion Port**

Allows a connected device to receive information about RF output from the generator

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Chapter 3

Patient and Operating Room Safety

The safe and effective use of the LigaSure system 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 be read, understood, and followed.

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 the LigaSure system in the procedure.

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General

Warning

The LigaSure generator and LigaSure instruments are intended for use as a system. Using non-LigaSure instruments with the LigaSure generator can result in seal failures or other unintended surgical effects.

If the seal cycle complete tone has not sounded, an optimal seal may not have been achieved. Reactivate the RF energy until a seal complete tone is heard.

Accidental and unintended burn injury has occurred during procedures in small surgical fields and on small appendages. See *Contact with Metal Objects* in this chapter for further information on the dangers of contact with metal instruments.

Use the LigaSure system with caution in the presence of internal or external pacemakers. Interference produced by the LigaSure generator can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use is planned in patients with cardiac pacemakers.

If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer for instructions before using the LigaSure system. The LigaSure system may cause multiple activations of ICDs.

The LigaSure vessel sealing system has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this system for these procedures.

The LigaSure vessel sealing system is not recommended for sealing pulmonary vasculature. Use the LigaSure tissue fusion mode of the ForceTriad energy platform for sealing this type of vasculature.

Use caution during surgical cases in which patients exhibit certain types of vascular pathology (atherosclerosis, aneurysmal vessels, etc.). For best results, apply the seal to unaffected vasculature.

Do not use the LigaSure system unless properly trained to use it in the specific procedure being undertaken. Use of this equipment without such training may result in serious, unintended patient injury.

Always use the lowest output setting in the bipolar/macrobipolar mode to achieve the desired surgical effect. The higher the current flow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small structures.

Hazardous Electrical Output This equipment is for use only by trained, licensed physicians.

Caution

Read all warnings, cautions, and instructions provided with this generator before using.

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Fire/Explosion

Warning

Danger: Explosion Hazard Do not use the LigaSure system in the presence of flammable anesthetics.

Fire/Explosion Hazard The following substances will contribute to increased fire and explosion hazards in the operating room:

- Flammable substances (such as alcohol based skin prepping agents and tinctures)
- Naturally occurring flammable gases that may accumulate in body cavities such as the bowel
- Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [n2o] atmospheres)

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.

Fire Hazard with Oxygen Circuit Connections

Warning

Fire/Explosion Hazard Verify that all oxygen circuit connections are leak free before and during the use of electrosurgery. Verify that endotracheal tubes are leak free, and that the cuff is properly sealed to prevent oxygen leaks. Enriched oxygen atmospheres may result in fires and burns to patients or to the surgical team.

Electrosurgical Smoke

Caution

Studies have shown that smoke generated during surgical 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.[1]

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.

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Inadvertent Radiofrequency Burns

Warning

Electrodes and probes used with monitoring, stimulation, and imaging devices (or similar equipment) can provide a path for high frequency current even if the electrodes or probes are isolated at 50-60 Hz, insulated, and/or battery operated.

Ensure Proper Connections

Caution

Examine all instruments and accessories, and all connections to the LigaSure generator before using. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

Instrument Cords

Warning

Position instrument cords to avoid contact with the patient or other leads. Do not wrap the instrument cords around metal objects. This may induce currents that could lead to shocks, fires, or injury to the patient or surgical team.

Servicing

Warning

Electric Shock Hazard Do not remove the LigaSure generator cover. Contact authorized personnel for service.

Notice

Refer to the ***LigaSure Vessel Sealing Generator Service Manual*** for maintenance recommendations and function and output power verification procedures.

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Before Surgery

Active Instruments

Warning

Electric Shock Hazard Do not connect wet instruments or accessories to the LigaSure generator.

Connect instruments to the proper receptacle. Improper connection may result in inadvertent activation or other potentially hazardous conditions. Follow the instructions provided with LigaSure instruments for proper connection and use.

Electric Shock Hazard Ensure that all instruments and accessories are dry and correctly connected. Accessory devices connected to the LigaSure generator shall have an insulative rating capable of withstanding a maximum generator output of 380 volts peak.

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

Caution

Read the instructions, warnings, and cautions provided with LigaSure instruments before using. Specific instructions are not included in this manual.

Generator

Warning

Patient Safety Use the generator only if the self-test has been completed as described, or inaccurate power outputs may result.

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

Fire Hazard Do not use extension cords.

Caution

Do not stack equipment on top of the generator or place the generator on top of electrical equipment. This is an unstable configuration and does not allow for adequate cooling.

When using a smoke evacuator in conjunction with the LigaSure generator, place the smoke evacuator at a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

Provide as much distance as possible between the LigaSure generator and other electronic equipment (such as monitors). Do not cross or bundle electronic device cords. The LigaSure generator may cause interference with other electronic equipment.

A nonfunctioning generator may cause interruption of surgery. A backup generator should be available for use.

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Notice

If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

Connect the power cord to a wall receptacle with the correct voltage, or product damage may result.

During Surgery

Generator Power Settings

Warning

Confirm proper power or intensity settings before proceeding with surgery. Use the lowest setting possible in the bipolar/macrobipolar mode that will achieve the desired effect.

Caution

LigaSure generators with Instant Response technology work effectively at power and intensity settings lower than other generators.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an instrument is active and energy is being delivered to the tissue.

Important

Generator output does not automatically stop in the bipolar mode.

Contact with Metal Objects

Warning

Contact between an active instrument electrode and any metal (hemostats, staples, clips, retractors, etc.) may increase current flow and may result in unintended surgical effects.

Active Accessories

Warning

Do not activate the generator in the vessel sealing mode until the vessel sealing instrument has been applied with the proper pressure. Activating the generator before this is done will result in an improper seal and may increase thermal spread to tissue outside the surgical site.

Fire Hazard Do not place LigaSure or bipolar instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire. When not in use, place instruments safely away from patients, the surgical team, and flammable materials.

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Caution

Do not press both the handswitch and footswitch during the same seal cycle. Generator output will stop and the seal WILL NOT be completed. The seal cycle complete tone will not sound.

Energy based devices, such as ESU pencils or ultrasonic scalpels, that are associated with thermal spread should not be used to transect seals.

Laparoscopic LigaSure Instrument Procedures

Warning

Tissue sealing requires the application of RF energy and pressure from the instrument. Tissue to be sealed must be firmly grasped between the instrument jaw electrodes. Tissue in the jaw hinge, or outside the instrument jaw will not be sealed even if thermal blanching occurs.

Do not use this instrument on vessels in excess of 7 mm in diameter.

For laparoscopic procedures, be alert to these potential hazards:

- The external surfaces of the LigaSure instrument jaws may remain hot enough to cause burns after the RF current is deactivated.
- Inadvertent activation or movement of the activated LigaSure instrument outside of the field of vision may result in injury to the patient.
- Do not activate the instrument while the instrument jaws are in contact with, or in close proximity to, other instruments including metal cannulas, as localized burns to the patient or physician may occur.
- Do not activate the LigaSure generator in an open circuit condition. Activate the generator only when the instrument is near or in direct contact with the target tissue to reduce the possibility of unintended burns.
- Carefully insert and withdraw LigaSure instruments from cannulas to avoid possible damage to the devices and/or injury to the patient.

Confirm proper LigaSure generator settings before proceeding with surgery.

Conductive fluids (e.g, blood or saline) in direct contact with LigaSure instruments or in close proximity may carry electrical current or heat, which may cause unintended surgical effects or burns.

- Clear fluid from the LigaSure instrument jaws prior to activating the instrument.

Open LigaSure Instrument Procedures

Warning

Tissue sealing requires the application of RF energy and pressure from the instrument. Tissue to be sealed must be firmly grasped between the instrument jaw electrodes. Tissue in the jaw hinge or outside the instrument jaw will not be sealed even if thermal blanching occurs.

Do not use this instrument on vessels in excess of 7 mm in diameter.

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Warning

The LigaSure instruments are intended for use ONLY with the Valleylab LigaSure vessel sealing system. Use of these instruments with other Valleylab generators or with generators produced by other manufacturers could result in injury to the patient or surgical team, or cause damage to the instrument.

LigaSure instruments that require single use electrodes must be used with the correct electrode type. Use of these instruments with any other electrodes could result in injury to the patient or surgical team, or cause damage to the instrument.

Before installing or removing electrodes, ensure that the instrument cord is not connected to the LigaSure generator and that the generator is OFF or in Standby mode (one orange bar).

Conductive fluids (e.g, blood or saline) in direct contact with LigaSure instruments or in close proximity may carry electrical current or heat, which may cause unintended surgical effects or burns.

Caution

Avoid placing fingers in the handle ratchet mechanism. Injury to the user may result.

After Surgery

Warning

Electric Shock Hazard Always turn off and unplug the generator before cleaning.

Caution

Do not reuse or resterilize accessories labeled “disposable” or “single use only.”

Notice

Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

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Chapter 4

Before Surgery

This chapter contains procedures for preparing the generator for surgery.

Caution
Read all warnings, cautions, and instructions provided with this generator before using.
Read the instructions, warnings, and cautions provided with LigaSure instruments and accessories before using.

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Quick Setup Instructions

If you are familiar with the LigaSure generator, you may prefer to follow this abbreviated procedure.

If, however, you are not familiar with the generator setup procedure, detailed instructions follow this chapter.

1. Plug the generator power cord into the rear panel receptacle.
2. Plug the generator power cord into a grounded wall receptacle.
3. Turn on the generator and verify that the self-test is successfully completed.
4. Prepare for vessel sealing or bipolar applications.

   Vessel sealing applications:

   - Connect the single pedal or two pedal footswitch to the vessel sealing footswitch receptacle (purple) on the rear panel.
   - Connect a LigaSure instrument to the vessel sealing instrument receptacle (purple) on the front panel.
   - When the instrument is correctly connected, the vessel sealing receptacle light changes from red to green. The light must be green for the system to operate.
   - Verify or change the intensity setting.

     (Optional – Press the **MEMORY** button on the front panel to recall prior intensity and power settings used.)

   Bipolar or macrobipolar applications:

   - If using a footswitch, connect it to the bipolar footswitch (blue) receptacle on the rear panel.
   - Connect a bipolar instrument to the blue smart connector adapter.
   - When the blue bipolar Valleylab smart connector adapter is correctly connected, the bipolar receptacle light changes from red to green. The light must be green for the system to operate.
   - Verify or change the power settings.

     (Optional – Press the **MEMORY** button on the front panel to recall prior intensity and power settings used.)

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Setting Up the Generator

Warning

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

Fire Hazard Do not use extension cords.

Patient Safety Use the generator only if the self-test has been completed as described, or inaccurate power outputs may result.

Caution

Do not stack equipment on top of the generator or place the generator on top of electrical equipment. This is an unstable configuration and does not allow for adequate cooling.

Provide as much distance as possible between the LigaSure generator and other electronic equipment (such as monitors). Do not cross or bundle electronic device cords. The LigaSure generator may cause interference with other electronic equipment.

A nonfunctioning generator may cause interruption of surgery. A backup generator should be available for use.

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an accessory is active and the seal cycle is complete.

When using a smoke evacuator in conjunction with the LigaSure generator, place the smoke evacuator at a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

Notice

If required by local codes, connect the generator to the hospital equalization connector with an equipotential cable.

Connect the power cord to a wall outlet having the correct voltage. Otherwise product damage may result.

1. Verify the generator is off.
2. Place the generator on a stable flat surface, such as a table, platform, or Valleylab cart. Carts with conductive wheels are recommended. For details, refer to the procedures for your institution or to local codes.

   Provide at least four to six inches of space around the sides and top of the generator for cooling. Normally, the top, sides, and rear panel are warm when the generator is used continuously for extended periods of time.
3. Plug the generator power cord into the rear panel receptacle.
4. Plug the generator power cord into a grounded receptacle.

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5. Turn on the generator by pressing the power switch on (|). Verify the following:

   - All visual indicators and displays on the front panel illuminate.
   - Activation tones sound to verify that the speaker is working properly.

   If the self-test is successful:

   - Two tones sound.
   - The bipolar and macrobipolar power displays show a setting of 1.
   - The vessel sealing intensity display shows a setting of one orange bar

   If the self-test is not successful:

   - An alarm tone sounds.
   - RF output is disabled.
   - "E" and a single number flash in the macrobipolar power display and two numbers flash in the bipolar power display. Note the number and refer to *Chapter 7, Responding to System Malfunctions*.

   Once the self-test is successful, connect the accessories and set the generator controls.

Preparing for Surgery

Warning

Electric Shock Hazard

- Do not connect wet instruments or accessories to the LigaSure generator.
- Ensure that all instruments and adapters are dry and correctly connected and that no metal is exposed at plug or connectors.
- Instruments and adapters connected to the LigaSure generator shall have an insulative rating capable of withstanding a maximum generator output of 380 volts peak.

Caution

Read the instructions, warnings, and cautions provided with LigaSure instruments before using. Specific instructions are not included in this manual.

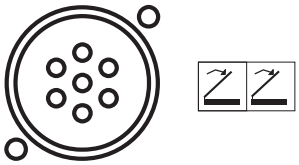
Inspect instruments and cords (especially reusable instruments and cords) for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Damage may result in injury or electrical shock to the patient or surgical team.

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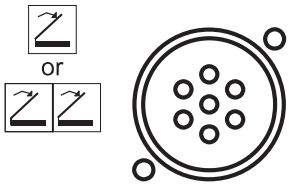
Footswitch Connections

Connect the appropriate footswitch to the corresponding receptacle on the rear panel.

Bipolar Footswitch Receptacle (blue)



Vessel Sealing Footswitch Receptacle (purple)



Instrument Connections

The LigaSure system can be used in several different configurations:

- With only a vessel sealing instrument attached to the LigaSure receptacle (purple)
- With only a bipolar instrument attached to the bipolar instrument receptacle (blue)
- With both a vessel sealing instrument and a bipolar instrument attached to their respective receptacles (simultaneous activation is not available)

The instrument connected to the LigaSure instrument receptacle can be activated in either the vessel sealing mode (using the single-pedal or two-pedal footswitch) or standard bipolar mode (using the two-pedal blue and grey footswitch). However, the instrument connected to the bipolar instrument receptacle can only be activated in the bipolar and macrobipolar modes using the two-pedal footswitch.

Vessel Sealing Instrument Connection

1. Prepare the reusable LigaSure instruments to be used for the procedure.
   a. Slip the base of the white shaft of the electrode onto the instrument ring handle with the retaining post.
   b. Snap the body of the electrode shaft onto the instrument handle. The white shaft of the electrode must be completely flush on the reusable instrument shaft.
   c. Snap each electrode into the appropriate instrument jaw, matching electrode curvature to jaw curvature. Insert the proximal pin first. Verify that there is no gap between the electrode and the instrument jaw.

      Note: Note: Bent or broken electrode pins will not function properly and must be discarded.

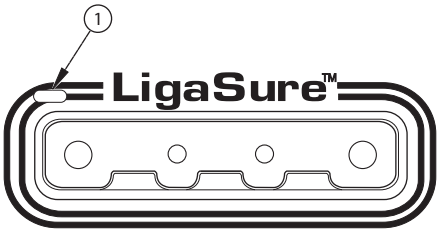
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d. Gently ratchet the instrument closed on a folded 4x4 to ensure the electrodes are properly seated in the instrument jaws.

2. Connect all LigaSure instruments (reusable and single use).

   a. Connect the instrument to the vessel sealing receptacle on the front panel.

   b. Verify that the receptacle indicator illuminates from red to green to confirm a proper connection to the generator.



① **Light**

Set the Output for the Vessel Sealing Mode

1. (Optional) Press the **Memory** button to recall prior intensity settings used.
2. Set the vessel sealing intensity.

   In the vessel sealing mode, the sealing intensity level changes in 1 light bar increments, with a range of 1 to 5 bars. Increasing the intensity increases the total energy delivered to the tissue for the duration of the seal cycle.

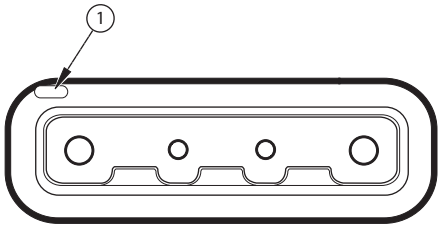
   To increase the intensity , press the **Up** (Δ) button.

   To decrease the intensity, press the **Down** (∇) button.
3. The instrument connected to the LigaSure instrument receptacle is activated utilizing the LigaSure footswitch.

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Bipolar Instrument Connection

1. Connect the bipolar instrument to the bipolar instrument receptacle on the front panel using the blue bipolar smart connector adapter.
2. Verify that the receptacle indicator illuminates green to confirm a proper connection.



① **Light**

Set the Output for the Bipolar Mode

1. (Optional) Press the **Memory** button to recall prior power settings used.
2. Set the bipolar or macrobipolar output power.

   In the bipolar or macrobipolar modes, the power level changes numerically, in 1 watt increments from 1 to 40, and in 5 watt increments from 40 to 95.

   To increase the power, press the **Up** (Δ) button.

   To decrease the power, press the **Down** (∇) button.
3. The instrument connected to the Bipolar instrument receptacle can only be activated in the bipolar and macrobipolar modes using the bipolar footpedal.

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Chapter 5

During Surgery

This chapter covers the following topics:

- Checking accessory connections
- Changing the power or intensity setting
- Activating the surgical instrument
- Adjusting the volume of activation tones
- Responding to alarms

Caution
Read all warnings, cautions, and instructions provided with this generator before using.
Read the instructions, warnings, and cautions provided with LigaSure instruments before using. Specific instructions are not included in this manual.

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Checking Accessory Connections

Warning

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

Caution

Examine all instruments and accessories and all connections to the LigaSure generator before using. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

Verify that all accessories are properly connected to the generator. When multiple accessories are used, keep cords separate. To reduce cross coupling, do not twist, bundle, or clamp cords together.

Changing the Power or Intensity Setting

Warning

Confirm proper power or intensity settings before proceeding with surgery. In the bipolar/macrobipolar mode use the lowest setting that will achieve the desired surgical effect.

Caution

LigaSure generators with Instant Response technology work effectively at power and intensity settings lower than other generators.

Vessel Sealing

Increase the intensity: Press the **Up** (Δ) button for the selected mode.

Decrease the intensity: Press the **Down** (∇) button for the selected mode.

When you press and release the intensity button, the sealing intensity changes by one green light bar. The optimal setting for the LigaSure system instruments is two to three green bars. Increasing the intensity increases the total energy delivered to the tissue for the duration of the seal cycle. You cannot change the setting during activation.

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Bipolar or Macrobipolar

When you press and release the power button, the power changes in 1 watt increments between 1 and 40, and in 5 watt increments between 40 and 95. Each time you press the power button while the generator is activated, the power changes by one setting only to prevent rapid changes in power delivered to the surgical site.

To reach the maximum or minimum power setting for the selected mode, *press and hold* the **Up** (Δ) or **Down** (∇) button. The setting changes slowly at first, then more rapidly. Release the button when the desired setting is displayed.

Activating the Surgical Instrument

Warning

Do not activate the generator in the vessel sealing mode until the vessel sealing instrument has been applied with the proper pressure. Activating the generator before this is done may result in an improper seal and may increase thermal spread to tissue outside the surgical site.

If the seal cycle complete tone has not sounded, an optimal seal may not have been achieved. Reactivate the RF energy until a seal complete tone is heard.

Use the bipolar/macrobipolar mode only until you achieve the desired surgical effect in order to minimize the possibility of burns. This is especially true in pediatric and neonatal patients or in any patient where small appendages are involved. The LigaSure generator does not automatically shut off in bipolar/ macrobipolar mode.

Caution

Do not press both the handswitch and footswitch during the same seal cycle. Generator output will stop and the seal WILL NOT be completed. The seal cycle complete tone will not sound.

To activate the generator:

- Press the pedal on the footswitch, or
- Activate the handswitch if the instrument has one

Vessel Sealing

When you activate the generator for vessel sealing, the corresponding indicator illuminates blue and a continuous tone sounds to indicate the presence of RF output. Keep your foot on the pedal or your finger on the handswitch until you hear a short tone. The tone indicates that RF output is disabled and the seal cycle is complete.

Bipolar

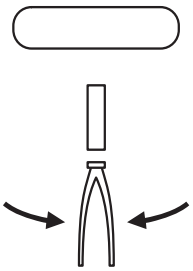
The generator does not automatically shut off when using the bipolar mode.

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Regrasp Indicator

When using the vessel sealing mode, the Regrasp indicator illuminates if the tissue is not sealed. This may be due to:

- Tissue not responding to RF energy
- Tissue impedance is out of range
- The seal cycle was interrupted before the cycle was complete.
- Maximum seal cycle time has been reached



A pulsed tone sounds and RF output is disabled.

If the Regrasp indicator illuminates and four pulsed tones sound while sealing, RF current is automatically discontinued. You should:

1. Release the footswitch pedal.
2. Open the jaws and inspect the tissue for a successful seal. Repeat the procedure if necessary.

Possible Regrasp indicator conditions

Instant Regrasp Indicator

Open circuit/High impedance detection – Regrasp tissue and repeat procedure. If an instantaneous Regrasp condition continues, replace the instrument.

Delayed Regrasp Indicator

Pooled fluids around the instrument tip – Minimize fluids. Inspect the tissue for a successful seal and repeat the procedure if necessary.

Thin tissue – 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 metal object – Avoid grasping metal objects, such as staples or clips, in the jaws of the instrument.

Interrupted Seal Cycle Regrasp

No end tone sounded –

- The footswitch or handswitch was released before the seal cycle was complete.
- The generator has detected removal of the instrument plug from the front panel connector.
- The generator has detected a problem with the plug/generator interface. Verify that the instrument connector is fully inserted into the front panel receptacle and the indicator is illuminated green.

The generator needs more time and energy to complete the seal. Reactivate the seal cycle without removing or repositioning the clamp.

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Time Out Reseal Indicator

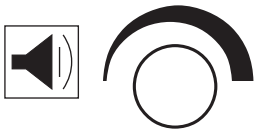
Maximum seal cycle time has been reached – The generator needs more time and energy to complete the seal. Reactivate the seal cycle without removing or repositioning the clamp.

You may also choose to continue the procedure using traditional hemostatic techniques or bipolar current. Set the Bipolar power level on the front panel of the generator as described in Changing the Power or Intensity Settingsin this chapter. Grasp the tissue in the jaws but do not latch the handle in the locked position. Step on the square (blue) bipolar pedal of the vessel sealing footswitch. Release the pedal when done.

Adjusting the Volume of Activation Tones

Caution

Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an instrument is active and energy is being delivered to the tissue.



To change the volume of activation tones, turn the Volume knob on the rear panel:

- Clockwise, to increase the volume
- Counterclockwise, to decrease the volume

You cannot silence the activation tones.

Responding to Alarms

When the generator senses a system malfunction condition, an alarm tone sounds and the generator is deactivated. “E” and a single number flash in the macrobipolar power display and two numbers flash in the bipolar power display.

1. Turn off the generator.
2. Turn on the generator and verify that the self-test is completed successfully. If the error code number reappears, note the number and refer to *Chapter 7, Responding to System Malfunctions*.

If you are unable to correct the system malfunction condition, use a backup generator or traditional hemostatic techniques to complete the surgical procedure.

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Chapter 6

After Surgery

This chapter instructs you on:

- Preparing the generator for reuse
- Reprocessing instruments
- Storing the generator

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Preparing the Generator for Reuse

Caution

Do not reuse or resterilize instruments or accessories labeled “disposable” or “single use only.”

Disconnect the Accessories

1. Turn off the generator.
2. Disconnect all accessories from the front panel.
   - If the accessory is single use only (disposable), dispose of it according to the procedures for your institution.
   - If the accessory is reusable, clean and sterilize it according to the manufacturer’s instructions.
   - Do not dispose of the blue bipolar smart connector adapter.
3. Disconnect and store any footswitch(es) used.

Clean the Generator

Warning

Electric Shock Hazard Always turn off and unplug the generator before cleaning.

Notice

Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

1. Turn off the generator, and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth. Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis.

Reprocessing Instruments

Clean the Reusable Instrument

1. Remove and dispose of single use electrodes.
2. Wipe all surfaces with a cleaning agent and a damp cloth.
3. Follow the procedures approved by your healthcare facility.
4. Soak in an enzymatic cleaning agent, such as Klenzyme or Enzol, according to the manufacturer’s instructions.

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5. Scrub all surfaces with a soft brush. It is important that the jaw surfaces and instrument electrode holes are cleaned of blood and tissue to ensure proper electrode assembly.
6. Rinse with water and dry with a soft cloth

Sterilization Parameters

The reusable instrument hinges are extremely tight and require additional flash sterilization times to ensure steam penetration into the hinge.

Unwrapped (Flash) for a pre-vac autoclave system:
132° C (270° F) for 10 minutes

Unwrapped (Flash) for a gravity autoclave system:
132° C (270° F) for 15 minutes

Wrapped pre-vac autoclave system:
132° C (270° F) for 10 minutes
Use the standard hospital dry cycle

Wrapped for a gravity autoclave system:
132° C (270° F) for 15 minutes
Use the standard hospital dry cycle

Wrapped for a gravity autoclave system:
121° C (250° F) for 30 minutes
Use the standard hospital dry cycle

Storing the Generator

If the generator is stored at a temperature outside its normal operating range of 10° to 40° C (50° to 104° F), allow it to sit at room temperature for one hour prior to use.

The generator can be stored indefinitely. However, if you store it longer than one year, you must perform specific checkout procedures before use (refer to the ***LigaSure Vessel Sealing Generator Service Manual***).

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Chapter 7

Troubleshooting

This chapter includes the following information:

- Correcting malfunctions
- Responding to system malfunctions

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General Troubleshooting Guidelines

If the generator malfunctions, check for obvious conditions that may have caused the problem:

- Check the generator for visible signs of physical damage.
- Make sure the fuse drawer is tightly closed.
- Verify that all cords are connected and attached properly.
- If an error code is displayed, turn the generator off, then on again.

If the malfunction persists, the generator may require service. Contact your institution's Biomedical Engineering Department.

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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 generator completes the self-test as described in *Chapter 4, Setting Up the Generator*.

Situation	Possible Cause	Solution
Abnormal neuromuscular stimulation (stop surgery immediately)	Metal-to-metal sparking	Check all connections to the generator and active electrodes.
	Abnormal 50-60 Hz leakage currents	Refer to your Biomedical Engineering Department or contact a Valleylab representative for assistance.
Generator does not respond when turned on	Disconnected power cord or faulty wall outlet	Check power cord connections (generator and wall outlet). Connect the power cord to a functional outlet.
	Faulty power cord	Replace the power cord.
	Fuse drawer is open or fuses are blown	Close the fuse drawer. Replace the blown fuse(s). Refer to the ***LigaSure Vessel Sealing Generator Service Manual***.
	Internal component malfunction	Use a backup generator. Refer to your Biomedical Engineering Department or contact a Valleylab representative for assistance.
Generator is on, but did not complete the self-test	Software or internal component malfunction	Turn off, then turn on the generator. If the error code number reappears: • Use a backup generator. • Record the number and refer to *Responding to System Malfunctions* in this chapter.

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Situation	Possible Cause	Solution
Generator is on and accessory is activated, but generator does not deliver output	Malfunctioning footswitch or handswitching instrument	Turn off the generator. Check and correct all accessory connections. Turn on the generator. Replace the accessory if it continues to malfunction.
	Power or intensity set too low	Increase the power or intensity setting. Refer to *Chapter 5, Changing the Power or Intensity Setting*.
	A malfunction condition exists	Check the bipolar display for an error code number. Note the number and refer to *Responding to System Malfunctions* in this chapter.
	Internal component malfunction	Use a backup generator. Contact your Biomedical Engineering Department or a Valleylab representative for assistance.
	Generator does not detect vessel sealing instrument, bipolar instrument, or blue bipolar smart connector adapter.	Firmly insert the LigaSure instrument or blue bipolar smart connector adapter into the appropriate receptacle on the generator front panel. Ensure the vessel sealing and/or bipolar receptacle indicator light changes from red to green.
Vessel sealing intensity display and intensity buttons do not function. Only the first orange light bar is illuminated. Red light on instrument receptacle remains illuminated.	The vessel sealing instrument is not completely inserted into the receptacle.	Firmly insert the LigaSure instrument or blue bipolar smart connector adapter into the appropriate receptacle on the generator front panel. Ensure the vessel sealing and/or bipolar receptacle indicator light changes from red to green.

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Situation	Possible Cause	Solution
The **Regrasp** indicator illuminates, four pulsed tone sounds, and RF output is disabled	Open circuit/High impedance detection	Regrasp tissue and repeat procedure. If an instantaneous Regrasp condition continues, replace the instrument.
	Pooled fluids around the instrument tip	Minimize fluids. Inspect the tissue for a successful seal and repeat the procedure if necessary.
	Thin tissue	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 metal object	Avoid grasping metal objects, such as staples or clips, in the jaws of the instrument.
	Maximum seal cycle time has been reached	The generator needs more time and energy to complete the seal. Reactivate the seal cycle without removing or repositioning the clamp.
	Interrupted seal cycle, no end tone heard	Verify that the instrument connector is fully inserted into the front panel receptacle and that the indicator is illuminated green. Reactivate the seal cycle without removing the clamp. Verify that the handswitch/foot pedal was not released during the seal cycle.
Continuous monitor interference	Faulty chassis-to-ground connections	Check and correct the chassis ground connections for the monitor and for the generator. Check other electrical equipment in the room for defective grounds.
	Electrical equipment is grounded to different objects rather than a common ground. The generator may respond to the resulting voltage differences between grounded objects.	Plug all electrical equipment into line power at the same location. Contact your Biomedical Engineering Department or a Valleylab representative for assistance.
	Malfunctioning monitor	Replace the monitor.

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Situation	Possible Cause	Solution
Interference with other devices only when the generator is activated	Metal-to-metal sparking	Check all connections to the generator and accessories.
	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 generator is activated, the monitor is responding to radiated frequencies.	Ask your Biomedical Engineering Department to check with the monitor manufacturer. Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference when the 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	Check the active electrode cord connections. It may be necessary to reprogram the pacemaker. Always monitor patients with pacemakers during surgery and keep a defibrillator available. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of the LigaSure system is planned in patients with cardiac pacemakers.
Internal Cardiac Defibrillator (ICD) activation	ICD is activated by the LigaSure generator	Stop the procedure and contact the ICD manufacturer for instructions.

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Responding to System Malfunctions

When a system malfunction condition exists, an alarm tone sounds and an error code number flashes in the macrobipolar and bipolar power displays. “E” and a single number flash in the macrobipolar power display and two numbers flash in the bipolar power display. The generator is disabled until the condition is cleared.

Turn off, then turn on the generator. If the generator completes the self-test successfully, proceed with surgery. If the error code reappears, proceed according to the following table:

Error Code Number	Recommended Action
001 003-025 100-104 109 115-119 134 140-146 162-170 172 174-199 214-227 229-234	Turn the power switch off, then on again. If the error code reappears, record the error code number and contact your Biomedical Engineering department or Valleylab service center.
120-125	Turn the power switch off, then on again. Do not activate accessories during the self-test. If the generator completes the self-test successfully, proceed with surgery. If the error code reappears, disconnect all accessories. Turn the power switch off, then on again. If the generator completes the self-test successfully, proceed with surgery. If the error code reappears, record the number and contact your Biomedical Engineering Department or Valleylab Service Center.
126-132	Turn the power switch off, then on again. Do not activate accessories during the self-test. If the generator completes the self-test successfully, proceed with surgery. If the error code reappears, record the number and contact your Biomedical Engineering Department or Valleylab Service Center.
451	Verify that the location of the generator allows for adequate cooling. If possible, discontinue using the generator until it has cooled. Use the lowest power setting that achieves the desired effect. Limit activation times, if possible. Turn the power switch off, then on again. If the generator completes the self-test successfully, proceed with surgery. If the error code reappears, record the number and contact your Biomedical Engineering Department or Valleylab Service Center.

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Chapter 8

Maintenance and Repair

Refer to this chapter for the following information:

- The manufacturer’s responsibility
- Routine maintenance
- Returning the generator for service
- Service centers

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Responsibility of the Manufacturer

Valleylab is responsible for the safety, reliability, and performance of the generator only under the following circumstances:

- Installation and setup procedures in this manual are followed.
- Assembly operation, readjustments, modifications, or repairs are carried out by persons authorized by Valleylab.
- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as the IEC and BSI.
- The equipment is used in accordance with the Valleylab instructions for use.

For warranty information, refer to Preface, *Warranty* in this guide.

Routine Maintenance

Notice

Refer to the **LigaSure Vessel Sealing Generator Service Manual** for maintenance recommendations and function and output power verification procedures.

When should the generator be checked or serviced?

Valleylab recommends that the generator be inspected by qualified service personnel at least once a year. This inspection should include checking the calibration of the generator.

When should the power cord be checked or replaced?

Check the power cord each time you use the generator or at the intervals recommended by your institution. Replace the power cord if you find exposed wires, cracks, frayed edges, or a damaged connector.

When should the fuses be replaced?

An internal component malfunction can damage the fuses. You may need to replace the fuses if the generator fails the self-test or if the generator stops functioning, even though it is receiving power from a wall outlet. Refer to the ***LigaSure Vessel Sealing Generator Service Manual*** for instructions.

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Returning the Generator for Service

Before you return the generator, call your Valleylab Representative for assistance. If you are instructed to send the generator to Valleylab, first obtain a Return Authorization Number. Then, clean the generator and ship it to Valleylab for service.

Obtain a Return Authorization Number

Call the Valleylab Service Center for your area to obtain a Return Authorization Number. Have the following information ready when you call:

- Hospital/clinic name/customer number
- Telephone number
- Department/address, city, state, and zip code
- Model number
- Serial number
- Description of the problem
- Type of repair to be done

Clean the Generator

Warning

Electric Shock Hazard Always turn off and unplug the generator before cleaning.

Notice

Do not clean the generator with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the generator.

1. Turn off the generator, and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth. Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. The generator cannot be sterilized.

Ship the Generator

1. Attach a tag to the generator that includes the Return Authorization Number and the information (hospital, phone number, etc.) listed in *Obtain a Return Authorization Number*.
2. Be sure the generator is completely dry before you pack it for shipment. Package it in its original shipping container, if available.
3. Ship the generator, prepaid, to the Valleylab Service Center.

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Service Centers

For a complete list of service centers worldwide, please refer to the Valleylab website:

http://www.valleylab.com/valleylab/international/service-world.html

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Chapter 9

Technical Specifications

All specifications are nominal and subject to change without notice. A specification referred to as “typical” is within ± 20% of a stated value at room temperature (25° C / 77° F) and a nominal input power voltage.

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Performance Characteristics

General

Output configuration	isolated output
Cooling	natural convection
Display	two (2) digital seven-segment displays: 1.9 cm (0.75 in.) each six (6) bar graph displays: 1.0 cm (0.4 in.) each
Mounting	a Valleylab cart (UC8009) or a stable flat surface

Dimensions and Weight

Width	38.6 cm (15.2 in.)
Depth	40.6 cm (16.0 in.)
Height	12.7 cm (5.0 in.) not including feet
Weight	5.9 kg (13 lbs) typical

Operating Parameters

Ambient temperature range	10° to 40° C (50° to 104° F)
Relative humidity	15% to 90%, noncondensing
Atmospheric pressure	700 to 1060 millibars
Warm-up time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the generator to reach room temperature before using.

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Transport and Storage

Ambient temperature range	– 34° to 70° C (– 29° to 158° F)
Relative humidity	0% to 95%, noncondensing
Atmospheric pressure	500 to 1060 millibars
Duration of storage	If stored over one year, check the battery to measure the Vdc minimum and complete a full checkout (including calibration) before use. Contact Valleylab Service for information.

Duty Cycle

Under maximum output settings and rated load conditions (100 ohm load) the generator is suitable for activation times of 10 seconds on, 30 seconds off, for 1 hour. With lesser settings and loads, you can activate the generator for greater durations without generating excessive internal temperatures.

Internal Memory

Nonvolatile, battery-backed RAM	Battery type: 3 V lithium button cell Battery life: 5 years

Audio Volume

The stated audio levels are at a distance of one meter. Alarm tones meet the requirements of IEC 601-2-2.

Activation Tone

Volume (adjustable)	45 dB minimum
Frequency (nominal)	Seal Mode – 440 Hz Macrobipolar Mode – 520 Hz Bipolar Mode – 660 Hz
Duration	continuous while the generator is activated in all modes

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Seal Complete Tone

Volume (not adjustable)	65 dB minimum
Frequency (nominal)	440 Hz
Duration	two short beeps when vessel sealing cycle is complete

Regrasp Tone

Volume (not adjustable)	65 dB minimum
Frequency (nominal)	780 Hz
Duration	four pulsed tones

Alarm Tone

Volume (not adjustable)	65 dB minimum
Frequency	985 Hz - 780 Hz; 985 Hz nominal

Serial Port

RS-232 compatible; 9600 baud, 8 data bits, 1 stop bit, no parity

9-pin connector supporting the following signals:

- pin 2 – isolated transmit (serial data output transmit line)
- pin 3 – isolated receive (serial data input receive line)
- pin 5 – isolated ground (reference for transmit and receive.)

RF Activation Port

The RF activation port is a subminiature phone jack attached to the contacts of a small relay. The contacts are closed when the output is energized and open at all other times. This port provides a means to tell other equipment that RF current is being generated. This may be useful when making EEG or ECG measurements.

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Expansion Port

15-pin connector; supports the following signals:	• pin 2 – isolated transmit (serial data output transmit line) • pin 3 – isolated receive (serial data input receive line) • pin 5 – isolated ground (reference for transmit and receive) • pin 9 – RF disable: input signal which, when activated by an external device, disables active RF output • pin 10 – RF current: output signal proportional to active RF current • pin 11 – RF voltage: output signal proportional to active RF voltage
Expansion power (from the low voltage power supply)	+ 5 V (pin 6), – 12 V (pin 14), + 12 V (pin 15), and ground (pins 12 & 13)

Low Frequency (50-60 Hz) Leakage Current (AAMI HF-18-1993)

Enclosure source current, ground open	< 300 µA
Source current, patient leads, all outputs	Normal polarity, intact ground: < 10 µA Normal polarity, ground open: < 50 µA Reverse polarity, ground open: < 50 µA
Sink current at high line, all inputs	< 50 µA

High Frequency (RF) Leakage Current (IEC 601-2-2)

Bipolar RF leakage current	≤ 69 mA_{rms}

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Input Power

120 Volt	240 Volt
Maximum power at nominal line voltage: Idle: 35 VA Bipolar: 360 VA Seal: 480 VA	Maximum power at nominal line voltage: Idle: 35 VA Bipolar: 360 VA Seal: 480 VA
Full regulation range: 90 to 135 Vac	Full regulation range: 186 to 264 Vac
Operating range: 85 to 140 Vac	Operating range: 170 to 264 Vac
Mains current maximum: Idle: 300 mA_{rms} Bipolar: 3.0 A_{rms} Seal: 4.0 A_{rms}	Mains current maximum: Idle: 300 mA_{rms} Bipolar: 1.5 A_{rms} Seal: 2.0 A_{rms}
Mains line frequency range (nominal): 50 to 60 Hz	Mains line frequency range (nominal): 50 to 60 Hz
Fuses (2): 4 A, 250 V, 3 AG, SLO-BLO	Fuses (2): 4 A, 250 V, 3 AG, SLO-BLO[1]
Power plug: 3-prong hospital grade connector	Power plug: 3-prong locally approved connector

1. The nominal operating power of the LigaSure generator is 480 VA for a maximum operating current of 2.0 A. However, because the unit is fused for 4.0 A, the worst-case power would be 960 VA (due to input voltages of 220–240 Volts), as indicated by the labeling on the rear panel of the generator.

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Power Cord Specification

This unit was equipped from the factory with either a 110VAC hospital grade NEMA 5-15 power cord or a 220VAC CEE7/7 power cord. Should the AC power cord need to be replaced to match another plug configuration, the replacement plug/cable/receptacle configuration must meet or exceed the following specifications:

100-120 VAC

Cable - SJT16/3, IEC color code, maximum length 15 ft (5 m)
Plug - minimum 10 A - 125 VAC
Unit receptacle - IEC female, minimum 10 A - 125 VAC

220-240 VAC

Cable - H05VVF3G1.0 VDE, maximum length 15 ft (5 m)
Plug - minimum 6 A - 250 VAC
Unit receptacle - IEC female, minimum 6 A - 250 VAC

Standards and IEC Classifications



ATTENTION

Consult accompanying documents.



The generator output is floating (isolated) with respect to ground.



Danger

Explosion risk if used with flammable anesthetics.



To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified service personnel.

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Non-Ionizing Radiation



Classified with respect to electrical shock, fire, and mechanical hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1.

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.

Type CF Equipment (IEC 60601-1)/Defibrillator Proof



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.

This generator complies with the ANSI/AAMI HF18 specifications for “defibrillator proof” designation and IEC 60601-2-2.

Liquid Spillage (IEC 60601-2-2 Clause 44.3)

The LigaSure vessel sealing 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.

Static Electricity Discharge Interference (IEC 60601-1-2 and IEC 80801-2)

This generator enclosure can withstand an 8 kV electrostatic air discharge.

Electromagnetic Interference

When placed on or beneath an activated Valleylab electrosurgical generator, this generator operates without interference. The generator minimizes electromagnetic interference to video equipment used in the operating room.

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

This generator complies with the appropriate IEC 60601-1-2 and 60601-2-2 specifications regarding electromagnetic compatibility.

Notice

The LigaSure requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ***LigaSure Vessel Sealing Generator Service Manual.***

Portable and mobile RF communications equipment can affect the LigaSure. Refer to the EMC information provided in the ***LigaSure Vessel Sealing Generator Service Manual***.

Voltage Transients (Emergency Generator Mains Transfer)

This generator operates in a safe manner when the transfer is made between line AC and an emergency generator voltage source.

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Output Characteristics

Maximum Generator Output

Open circuit values were obtained using a Pearson 411 current measurement with a 1K ohm load attached to the instrument.

Mode	Maximum Open Circuit Voltage V_{pp} (V_p)	Maximum Short Circuit Current A_{rms}	Maximum Power Setting Watts	Crest Factor*
Macrobipolar	760 (380)	2.2	95	1.5
Bipolar	335 (168)	2.2	95	1.5
Seal	575 (288)	4.4	150	1.5

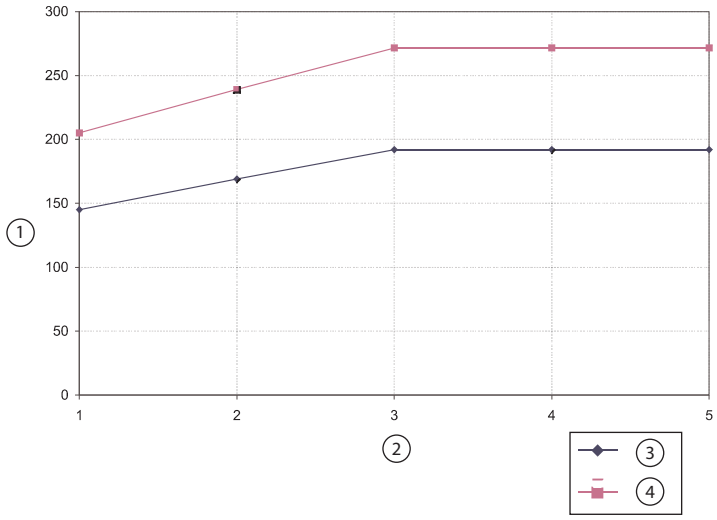
**Crest factor is an indication of a waveform's ability to coagulate bleeders without a cutting effect.*

Output Waveform

Macrobipolar/Bipolar	472 ± 5 kHz sinusoid, 100% duty cycle
Seal	472 ± 5 kHz sinusoid, pulsed

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Output Voltage vs. Intensity Setting Vessel Seal



① **Output Voltage (Volts)**

② **Intensity Setting (Bars)**

③ **Vrms**

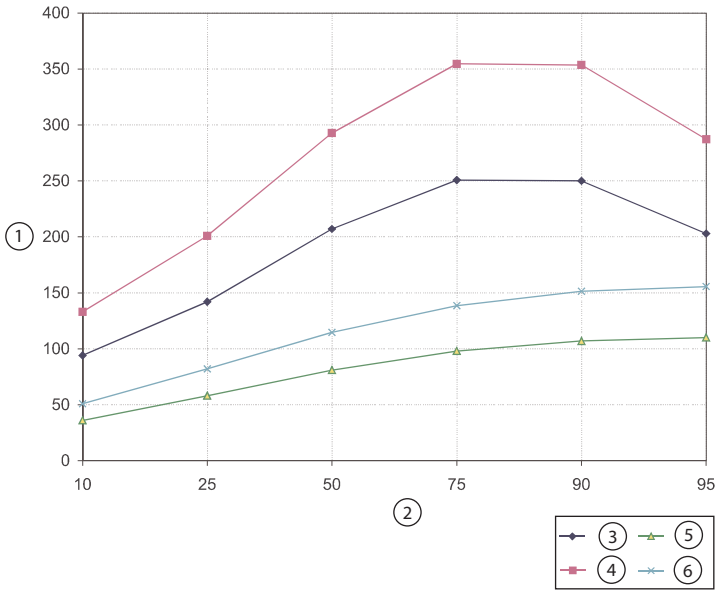
④ **Vp**

Open Circuit Output Volts Peak (rms)

	Generator Intensity Setting — Bars				
Mode	**1**	**2**	**3**	**4**	**5**
Seal	51 (36)	82 (58)	115 (81)	139 (98)	151 (107)

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Output Voltage vs. Power Setting Macrobipolar and Bipolar Modes



① **Output Voltage (Volts)**

② **Power Setting (Watts)**

③ **Macro Bipolar Vrms**

④ **Macro Bipolar Vp**

⑤ **Bipolar Vrms**

⑥ **Bipolar Vp**

Open Circuit Output Volts Peak (rms)

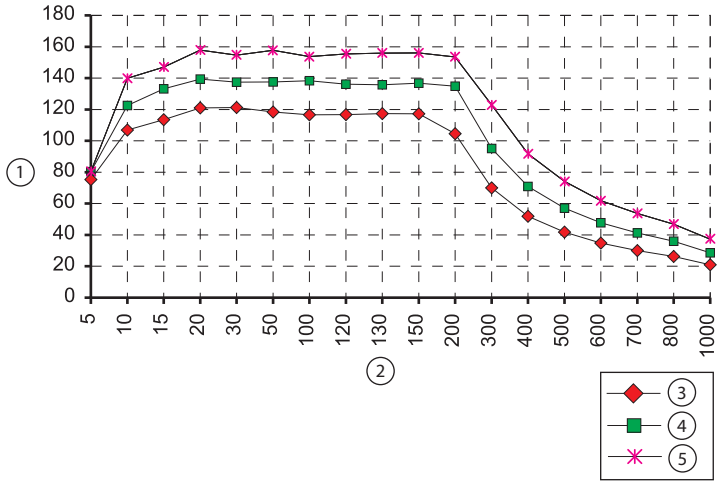
	Generator Power Setting — Watts					
Mode	**10**	**25**	**50**	**75**	**90**	**95**
Macrobipolar	133 (94)	201 (142)	293 (207)	355 (251)	354 (250)	287 (203)
Bipolar	51 (36)	82 (58)	115 (81)	139 (98)	151 (107)	266 (110)

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Output Power vs. Resistance Graphs

The following graphs depict the RF output as applied to tissue resistance for generator operative modes of vessel sealing, macrobipolar, and bipolar outputs.

Vessel Seal Power vs. Impedance



① Power (Watts)

② Load (Ohms)

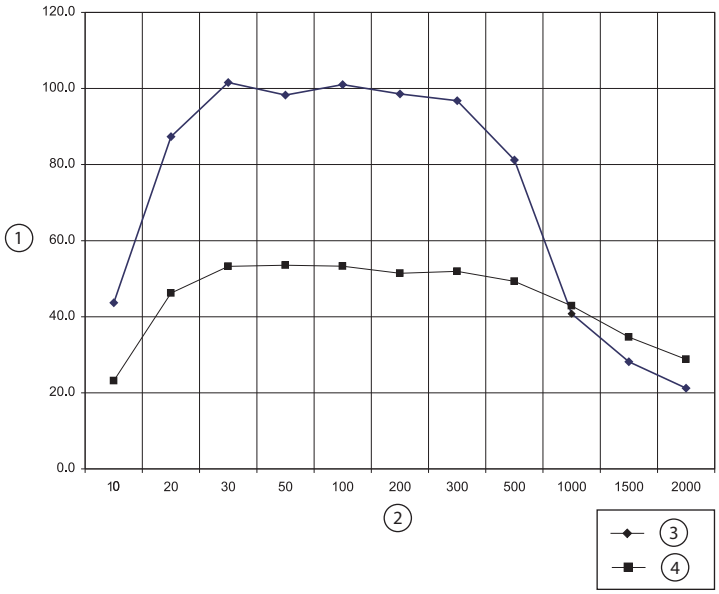
③ Intensity Bar 1

④ Intensity Bar 2

⑤ Intensity Bars 3, 4, 5

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Power vs. Impedance Macrobipolar



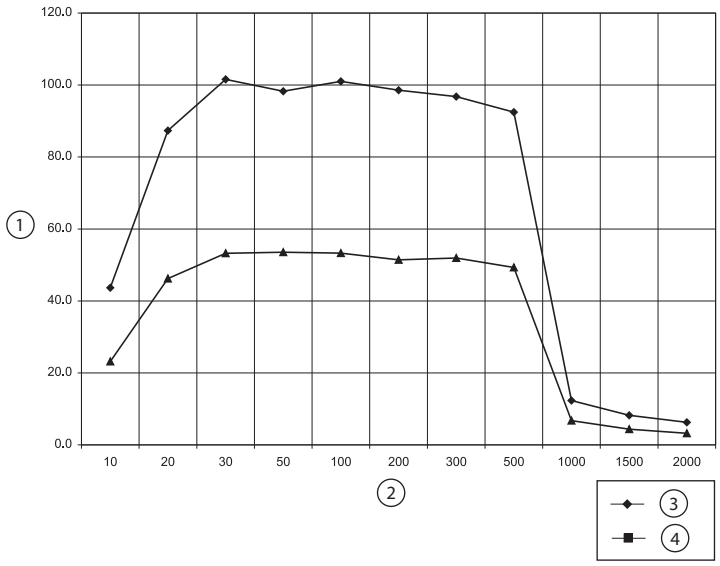
① Power (Watts)

② Load (Ohms)

③ Macro Bipolar 95 Watts

④ Macro Bipolar 50 Watts

Power vs. Impedance Bipolar



① Power (Watts)

② Load (Ohms)

③ Bipolar 95 Watts

④ Bipolar 50 Watts

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