User's Guide

Valleylab Force FX[™] Instant Response[™] Electrosurgical Generator

Foreword

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 Force FX Electrosurgical Generator only. Additional technical information is available in the Force FX Electrosurgical Generator Service Manual.

Caution

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

Equipment covered in this manual:

Valleylab Force FX-8 Instant Response Electrosurgical Generator – 110-120 V ~ Nominal, 220-240 V ~ Nominal (auto selected)

Valleylab Part Number: 945 102 044 Effective Date: July 1997

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How the User's Guide is Organized

This User's Guide should contain the sections listed below. If any section is missing, please contact Valleylab.

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Conventions Used in this Guide

Important
Indicates an
operating tip or
maintenance
suggestion.

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 which may result in product damage.

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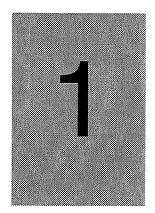
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Introducing the Force FX Electrosurgical Generator

This section includes information about:

- Instant Response Technology
- bipolar modes
- · monopolar cut and coag modes
- simultaneous coag
- REM Contact Quality Monitoring System
- ultrasonic electrosurgery

Cautions

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

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

The Force FX Instant Response Electrosurgical Generator is an isolated output electrosurgical generator that provides power for cutting, desiccating, and fulgurating tissue during bipolar and monopolar surgery.

Features include:

- Instant Response Technology
- three bipolar modes: precise (low), standard (medium), and macro (macrobipolar)
- three monopolar cut modes: low, pure, and blend
- three monopolar coag modes: desiccate (low), fulgurate (medium), and spray (high)
- support for simultaneous coagulation
- the Valleylab REM Contact Quality Monitoring System
- support for ultrasonic electrosurgery using the Valleylab CUSA System 200 and a CUSA handpiece with CEM nosecone
- handswitch or footswitch activation
- recall of most recently used mode and power settings
- adjustable activation tone volume
- an RF activation port, RS-232 serial port, and expansion port
- Force GSU system and Force Argon system compatibility

Instant Response Technology

The Force FX generator automatically senses resistance and adjusts the output voltage to maintain a consistent effect across different tissue density. This adjustment is based on the selected mode (bipolar or cut modes only), the power setting, and the level of tissue resistance. The maximum output voltage is controlled to reduce capacitive coupling and video interference and to minimize sparking.

Bipolar Modes

Delicate tissue requires less heat to desiccate quickly. The Force FX generator provides low voltage, continuous current for faster desiccation without sparking.

The possibility of sparking increases as desiccated tissue dries and becomes more resistant. The generator protects against sparking by limiting the bipolar voltage at relatively high levels of tissue resistance.

Three bipolar modes are available: precise, standard, and macrobipolar.

- Precise (low) may be used when a high degree of precision and fine
 control over the amount of desiccation are essential. Voltage is kept
 low to prevent sparking. The power remains constant over a specific
 range of tissue resistance, allowing a consistent tissue effect.
- Standard (medium) may be used for most bipolar 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.
- Macro (macrobipolar) may be used for bipolar cutting or rapid coagulation. Voltage is higher and there is more power than with the other two bipolar modes.

For details about the output characteristics, refer to Appendix A.

Monopolar Cut and Coag Modes

Three cut modes – low, pure, and blend – allow a wide range of power settings necessary to perform diverse surgical procedures.

- Low may be used for a cut with little or no sparking; useful for delicate tissue or laparoscopic surgery.
- *Pure* may be used when you desire a clean, precise cut in any tissue with little or no hemostasis.
- Blend may be used where slower cutting and additional hemostasis is desired.

The three coagulation modes – desiccate, fulgurate, and spray – help control the size of the area and the depth of penetration during tissue coagulation.

- Desiccate dehydrates and destroys tissue without sparking or cutting. Because the active electrode directly touches the tissue, more current reaches the patient. Desiccation places the greatest demand on the patient return electrode.
- Fulgurate coagulates tissue by sparking from the active electrode, through air, to the patient tissue. Since sparks may spray unpredictably from the electrode during fulguration, using fulguration for delicate tissue or in confined areas can complicate surgery. Accidental sparking to adjacent areas can occur as tissue at the surgical site dries and becomes more resistant to current flow.
- *Spray* affords optimum fulguration; penetration is less deep and the tissue area is larger than with the fulgurate mode.

For details about the output characteristics, refer to Appendix A.

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Simultaneous Coag

If you connect an instrument to each monopolar receptacle and activate them for coag simultaneously, each receives a percentage of the power set for the particular coag mode, dependent on the tissue resistance sensed by the generator at each surgical site. Generally, the site with lower resistance receives proportionately more power. The combined total output power does not exceed the coag power setting.

You can also use a CUSA handpiece with a CEM nosecone for simultaneous coag when you connect a monopolar instrument to the Monopolar 2 Instrument receptacle. Only Desiccate coag is available; the maximum power is 70 watts.

REM Contact Quality Monitoring System

During monopolar electrosurgery, a patient return electrode is always required to safely recover the current that flows through the patient's body and return it to the generator. A reduction in surface area contact or poor conductivity between the patient and the return electrode can cause the current to become concentrated, potentially resulting in burns at the return electrode site.

The Force FX generator uses the Valleylab REM Contact Quality Monitoring System to monitor the quality of electrical contact between the patient return electrode and the patient. The REM system eliminates the risk of burns at the return electrode site. Use of any return electrode other than a REM patient return electrode may compromise the REM safety feature. This could result in a patient burn.

How the REM System Works

The REM system continuously measures the resistance at the return electrode site and compares it to a standard range of safe resistance (between 5 and 135 ohms), thus eliminating intermittent false alarms that could result from small changes in resistance. The REM system also adapts to individual patients by measuring the initial contact resistance between the patient and the patient return electrode.

A REM alarm sounds and the generator stops producing output power when either of the following occurs:

- The measured resistance is below 5 ohms or above 135 ohms, the limits of the standard range of safe resistance.
- An increase in contact resistance is greater than 40% from the initial measurement.

Electrodes Without the REM Safety Feature

Warning

Using a conventional patient return electrode without the REM safety feature will not activate the Valleylab REM Contact Quality Monitoring System.

When you use a patient return electrode that does not have the REM safety feature, the REM system cannot monitor the patient contact area as previously described. The REM system can monitor only the pin-to-pin resistance at the connector and can detect broken wires or connectors in the return electrode cord.

Ultrasonic Electrosurgery

The Force FX generator works in conjunction with the Valleylab CUSA System 200 for procedures where combined ultrasonic dissection and electrosurgical cutting and coagulation is desired, either simultaneously or independently. In addition to convenience, the combination of ultrasonic vibration plus simultaneous electrosurgical current prevents charring of the tip and decreases sticking and disruption of coagulum, leading to more effective hemostasis.

When you connect a CUSA handpiece with a CEM nosecone to the generator for ultrasonic electrosurgery, it limits the monopolar output power automatically.

- The maximum power you can set for monopolar cut is 100 watts.
- The maximum power you can set for monopolar coag is 70 watts.

When you activate the handpiece for cut or coag output, the Low cut mode or the Desiccate coag mode is in effect automatically. The remaining cut modes and coag modes are not available.

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Notes

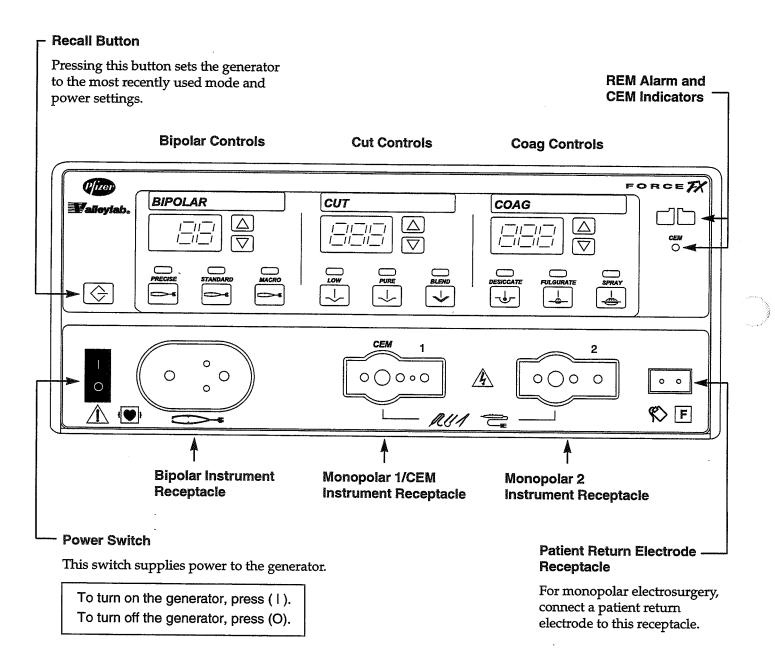




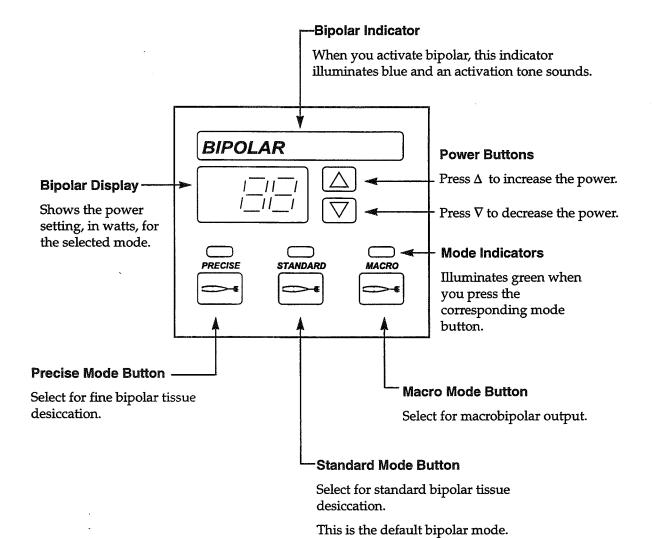
Controls, Indicators, and Receptacles

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

Front Panel



Bipolar Controls

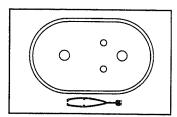


Bipolar Instrument Receptacle

Caution

Accessories must be connected to the proper receptacle type. In particular, bipolar accessories must be connected to the Bipolar receptacle only. Improper connection may result in inadvertent generator activation or a REM Contact Quality Monitor alarm.

You can connect either a footswitching or handswitching bipolar instrument to the Bipolar receptacle.

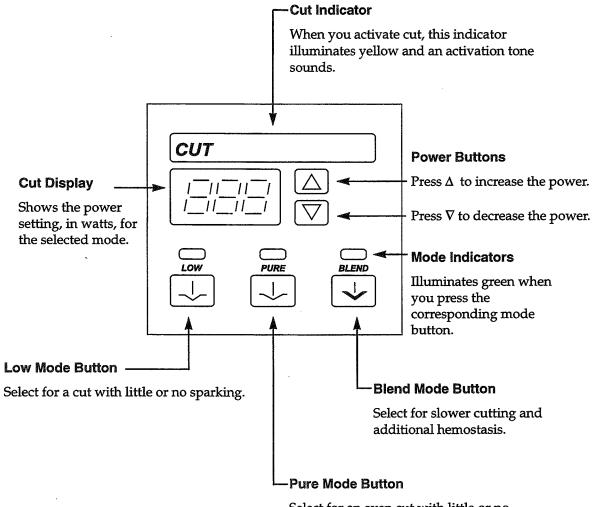


Connect a footswitching instrument with a two-pin connector.

or

Connect a handswitching instrument with a three-pin connector.

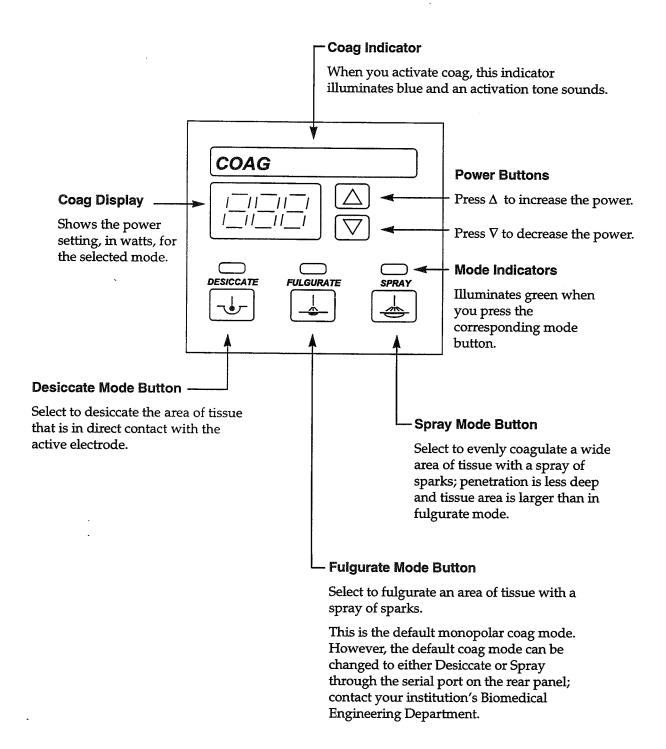
Monopolar Cut Controls



Select for an even cut with little or no hemostasis.

This is the default monopolar cut mode.

Monopolar Coag Controls

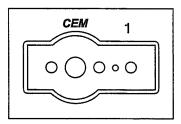


Monopolar Instrument Receptacles

Warning

The instrument receptacles on this generator are 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.

You can connect a footswitching or handswitching monopolar instrument to the monopolar receptacles. Some footswitching instruments may require a single-pin adapter (E0502 Series), available from Valleylab.

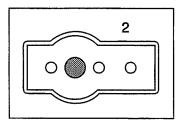


Connect one monopolar instrument to the Monopolar 1/CEM Instrument receptacle:

 a single-pin footswitching instrument or a three-pin handswitching instrument

or

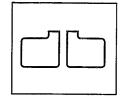
 a four-pin CUSA handpiece with CEM nosecone. (The CEM indicator in the upper right of the front panel illuminates green. Refer to Section 4, Connecting the CUSA Handpiece with CEM Nosecone)



Connect one monopolar instrument to the Monopolar 2 Instrument receptacle:

 a single-pin footswitching instrument or a three-pin handswitching instrument

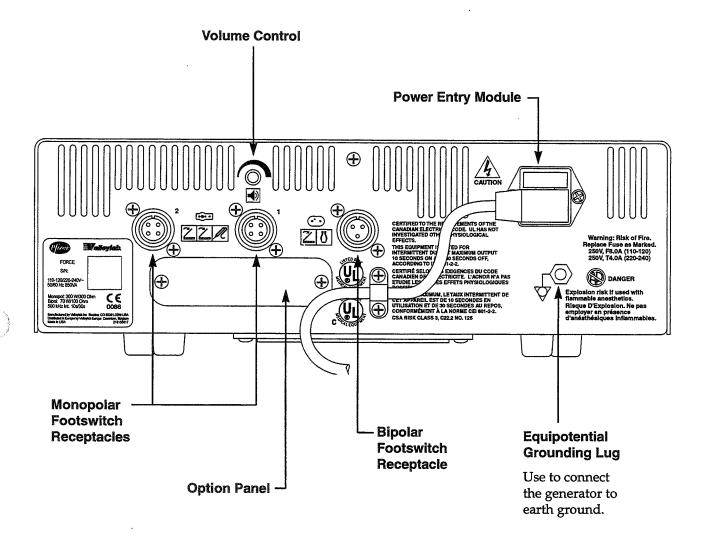
REM Alarm Indicator



This indicator illuminates red until you properly apply a REM patient return electrode to the patient and connect it to the generator. Then the indicator illuminates green. (When you connect an electrode without the REM safety feature, the indicator does not illuminate.)

If the REM system senses an alarm condition, the indicator flashes red until you correct the alarm condition – then the indicator illuminates green. (If you are using a return electrode without the REM safety feature, the red indicator light is extinguished when you correct the alarm condition.)

Rear Panel



Footswitch Receptacles

The rear panel contains three footswitch receptacles: two for monopolar and one for bipolar.

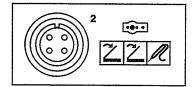
Monopolar Footswitch Receptacles

You must connect a monopolar footswitch if you connect a monopolar footswitching instrument to the generator.



Connect a two-pedal monopolar footswitch to the Monopolar 1 Footswitch receptacle.

The connected footswitch activates monopolar output for the instrument that is connected to the Monopolar 1/CEM Instrument receptacle on the front panel.

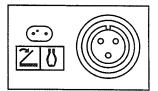


Connect a two-pedal monopolar footswitch to the Monopolar 2 Footswitch receptacle.

The connected footswitch activates monopolar output for the instrument that is connected to the Monopolar 2 Instrument receptacle on the front panel.

Bipolar Footswitch Receptacle

You must connect a bipolar footswitch if you connect a bipolar footswitching instrument to the generator.

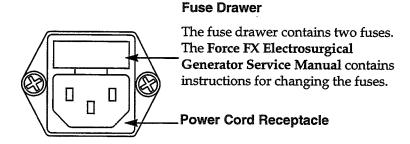


Connect a single-pedal bipolar footswitch to the Bipolar Footswitch receptacle.

The connected footswitch activates bipolar output for the instrument that is connected to the Bipolar Instrument receptacle on the front panel.

Power Entry Module

The power entry module consists of a power cord receptacle and a fuse drawer.



Activation Tone Volume Control



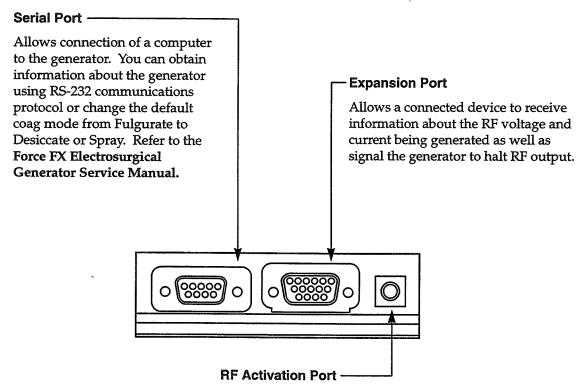
Turn to adjust the volume of the tones that sound when the generator is activated (activation tone). To ensure that the surgical team is alerted to inadvertent activation, these tones cannot be silenced.

To increase the volume of activation tones, turn the knob clockwise.

To decrease the volume, turn the knob counterclockwise.

Option Panel

A removable plate on the rear panel covers a serial port, an expansion port, and an RF (radio frequency) activation port. To review the technical specifications for each port, refer to Appendix A.



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



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.

General

Warning: Accidental and unintended burn injury has occurred during procedures in small surgical fields and on small appendages. Catastrophic results have been reported in the context of neonatal and pediatric circumcisions.¹ In those cases of confirmed thermal injury during neonatal and pediatric circumcisions, the mechanism of injury appears to have been associated with contact between a metal clamp (such as a Gomco clamp or a Kocher clamp) in the surgical field and the active electrode, which greatly increased current flow.² (See Contact with Metal Objects later in this section for further information on the dangers of contact with metal instruments.)

It has also been reported that properly trained physicians use electrosurgery safely in the performance of circumcisions, and that pediatric urologists use electrosurgery with surgical procedures performed on the genitals of male neonates. In performing such procedures, it is reported that many physicians use the electrosurgical generator in a coagulation mode to achieve hemostasis of bleeders, however "buzzing" hemostats clamped to bleeders may increase the risk of thermal injury.

Warning: Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause devices such as 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 of electrosurgical appliances is planned in patients with cardiac pacemakers.

Warning: If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activations of ICDs.

Warning: Valleylab recommends against the use of laparoscopic surgery on pregnant patients.

Warning: Do not use electrosurgical equipment unless properly trained to use it in the specific procedure being undertaken. Use by physicians without such training has resulted in serious, unintended patient injury, including bowel perforation and unintended, irreversible tissue necrosis.

Warning: *Hazardous Electrical Output* — This equipment is for use only by trained, licensed physicians.

¹ The American National Standard for Electrosurgical Devices (ANSI/AAMI HF 18-1993) provides: "Electrosurgery should not be used to perform circumcisions."

Information on the safe use and thermal hazards associated with the use of high frequency electricity (electrosurgical machines) in health care facilities appears in NFPA 99, Annex 2, reference in the JCAHO Accreditation Manual for Hospitals.

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

Caution: Always use the lowest output setting necessary that achieves the desired surgical effect. The active electrode should be utilized only for the minimum time necessary in order to lessen the possibility of unintended burn injury. Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. 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 appendages.

Fire/Explosion

Danger: Explosion Hazard — Do not use electrosurgery in the presence of flammable anesthetics.

Warning: *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 which 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 the surgical team.

Electrosurgical Smoke

Caution: 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.³

³ 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.

Inadvertent Radio Frequency 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.

To reduce the risk of an inadvertent electrosurgical burn at the electrode or probe site, place the electrode and/or probe as far away as possible from the electrosurgical site and/or patient return electrode. Protective impedances (resistors or RF inductors) installed in the monitoring leads may reduce the risk of such burns. Consult the hospital biomedical engineer for further information.

Warning: Do not use needles as monitoring electrodes during electrosurgical procedures. Inadvertent electrosurgical burns may result.

Warning: In some circumstances, potential exists for alternate site burns at points of skin contact (e.g., between the arm and the side of the body). This occurs when electrosurgical current seeks a path to the patient return electrode that includes the skin to skin contact point. Current passing through small skin to skin contact points is concentrated and may cause a burn. This is true for grounded, ground referenced, and isolated output generators.

To reduce the potential for alternate site burns, do one or more of the following:

- Avoid skin-to-skin contact points, such as fingers touching leg, when positioning the patient.
- Place two to three inches of dry gauze between contact points to ensure that contact does not occur.
- Position the patient return electrode to provide a direct current route between the surgical site and the return electrode which avoids skinto-skin contact areas.
- In addition, place patient return electrodes according to the manufacturer's instructions.

Potential for alternate site burns increases if the return electrode is compromised. Valleylab recommends the use of REM patient return electrodes and Valleylab generators with the REM system.

Ensure Proper Connections

Caution: Examine all accessories and connections to the electrosurgical generator before using. Ensure that the accessories function as intended. Improper connection may result in arcs, sparks, accessory malfunction, or unintended surgical effects.

Accessories

Warning: Do not wrap the accessory cords or patient return electrode 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 cover. Contact authorized personnel for service.

Notice: Refer to this generator's service manual for maintenance recommendations and function and output power verification procedures.

Before Surgery

Active Accessories

Warning: *Electric Shock Hazard* — Do not connect wet accessories to the generator.

Warning: Connect accessories to the proper receptacle. Improper connection may result in inadvertent accessory activation or other potentially hazardous conditions. Follow the instructions provided with electrosurgical accessories for proper connection and use.

Warning: *Electric Shock Hazard* — Ensure that all accessories and adapters are correctly connected and that no metal is exposed.

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

Caution: Accessories must be connected to the proper receptacle type. In particular, bipolar accessories must be connected to the bipolar receptacle only. Improper connection of accessories may result in inadvertent generator activation or a REM Contact Quality Monitor alarm.

Caution: Set power levels to the lowest setting before testing an accessory.

Caution: Inspect accessories and cords (especially reusable accessories and cords) for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

Caution: Do not reuse or resterilize accessories labeled "disposable" or "single use only."

Patient Return Electrodes

Valleylab recommends the use of REM patient return electrodes to maximize patient safety.

Warning: The safe use of monopolar electrosurgery requires proper placement of the patient return electrode. To avoid electrosurgical burns beneath the patient return electrode, follow all directions on the product package for proper return electrode placement and use.

Warning: Do not cut a patient return electrode to reduce its size. Patient burns due to high current density may result.

Warning: Do not apply a patient return electrode if only bipolar accessories are being used. Otherwise, the electrosurgical effect may not be limited to the tissue between the bipolar electrodes.

Warning: Using a patient return electrode without the REM safety feature will not activate the Valleylab REM Contact Quality Monitoring System.

Warning: Valleylab recommends against the use of capacitive pads. These pads do not activate the REM Contact Quality Monitoring System and require the use of higher power settings to achieve the desired surgical effect. This increases the possibility of alternate site burns.

Shunt Cords

Warning: Some surgical instruments (e.g., colonoscopes) may allow substantial leakage current which could burn the surgeon. If the instrument manufacturer recommends the use of a shunt cord (s-cord) to direct the current back to the generator, you must also use a Valleylab E0507-B adapter. To avoid a REM alarm, you must use a REM patient return electrode with the E0507-B adapter.

Generator

Warning: *Patient Safety* — Use the generator only if the self-test has been completed as described. Otherwise, inaccurate power outputs may result.

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

Warning: *Fire Hazard* — Do not use extension cords.

Warning: The instrument receptacles on this generator are 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.

Generator - continued

Caution: Do not stack equipment on top of the generator or place the generator on top of electrical equipment (except a Force GSU unit or a Force Argon unit). These configurations are unstable and/or do not allow for adequate cooling.

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

Caution: Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.

Caution: Do not turn the activation tone down to an inaudible level. The activation tone alerts the surgical team when an accessory is active.

Caution: Nonfunction of the generator may cause interruption of surgery. A backup generator should be available for use.

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

Notice: Connect the power cord to a wall receptacle having the correct voltage. Otherwise, product damage may result.

During Surgery

Generator Power Settings

Warning: Confirm proper power settings before proceeding with surgery. Use the lowest power setting possible for the minimum time necessary to achieve the desired effect.

Warning: Never increase the power settings without first checking both the active electrode and the patient return electrode and their connections. Use the active electrode or forceps only for the minimum time necessary to 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.

Caution: The Force FX Electrosurgical Generator cuts effectively at power settings lower than previous models offered by Valleylab. If the proper setting is not known, set the generator at a very low setting and cautiously increase the power until the desired effect is achieved.

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Forceps

Notice: Do not activate the generator until the forceps have made contact with the patient. Product damage may occur.

Suction Coagulators

Warning: To avoid the possibility of a burn to the surgeon, always turn the generator off before bending or reshaping the coagulator suction tube.

Warning: Ensure that the outside of the coagulator suction tube remains free of blood and mucus. Failure to clean the coagulator suction tube can allow electrical conductance by means of the contaminants that may result in patient burns.

Warning: Do not immerse the suction coagulator handswitch mechanism in saline solution or other conductive fluids. Unintended activation may result.

Contact with Metal Objects

Warning: Contact of the active electrode with any metal (such as hemostats, Gomco clamps, Kocher clamps, etc.) will greatly increase current flow and can result in unintended, catastrophic burn injury.

Warning: While using electrosurgery, the patient should not be allowed to come into direct contact with grounded metal objects (e.g., surgical table frame, instrument table, etc.). If this is not possible during certain procedures (e.g., those in which noninsulated head frames are used), use extreme caution to maximize patient safety:

- Use the lowest power setting that achieves the desired effect.
- Place the patient return electrode as close to the surgical site as possible.
- Place dry gauze between the patient and the grounded object if possible.
- Continually monitor the contact point(s).

Active Accessories

Warning: Fire Hazard — Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories that are activated or hot from use can cause a fire. Use a holster to hold electrosurgical accessories safely away from patients, the surgical team, and flammable materials.

Warning: Simultaneously activating suction/irrigation and electrosurgical current may result in increased arcing at the electrode tip, burns to unintended tissues, or shocks and burns to the surgical team.

Warning: Some surgeons may elect to "buzz the hemostat" during surgical procedures. It is not recommended, and the hazards of such a practice probably cannot be eliminated. Burns to the surgeon's hands are possible. To minimize the risk:

- Do not lean on the patient, the table, or the retractors while buzzing the hemostat.
- Activate cut rather than coag. Cut has a lower voltage than coag.
- Use the lowest power setting possible for the minimum time necessary to achieve hemostasis.
- Activate the generator after the accessory makes contact with the hemostat. Do not arc to the hemostat.
- Firmly grasp as much of the hemostat as possible before activating the generator. This disperses the current over a larger area and minimizes the current concentration at the finger tips.
- "Buzz the hemostat" below hand level (as close as possible to the patient) to reduce the opportunity for current to follow alternate paths through the surgeon's hands.

Warning: When not using active accessories, place them in a holster or in a clean, dry, nonconductive, and highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.

Patient Return Electrodes

Warning: To avoid patient burns, ensure that the patient return electrode firmly contacts the skin. Always check the patient return electrode periodically and after the patient is repositioned and during procedures involving long periods of activation.

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Laparoscopic Procedures

Warning: For laparoscopic procedures, be alert to these potential hazards:

- Laparoscopic surgery may result in gas embolism due to insufflation of gas in the abdomen.
- The electrode tip may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of the activated electrode outside of the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrical currents carried through conductive objects (such as cannulas or scopes). Electrical current may be generated in conductive objects by direct contact with the active electrode, or by the active accessory (electrode or cable) being in close proximity to the conductive object.
- Do not use hybrid trocars that are composed of both metal and plastic components. For the operative channel, use all metal or all plastic systems. At no time should electrical energy pass through hybrid systems. Capacitive coupling of RF current may cause unintended burns.
- When using laparoscopic instrumentation with metal cannulas, the
 potential exists for abdominal wall burns to occur due to direct
 electrode contact or capacitive coupling of RF current. This is most
 likely to occur in instances where the electrosurgical generator is
 activated for extended periods at high power levels inducing high
 current levels in the cannula.
- Ensure that the insulation of disposable and reusable laparoscopic instrumentation is intact and uncompromised. Compromised insulation may lead to inadvertent metal-to-metal sparking and neuromuscular stimulation and/or inadvertent sparking to adjacent tissue.
- Do not activate electrodes while in contact with other instruments as unintended tissue injury may occur.
- Do not activate the generator in an open circuit condition. To reduce the chances of unintended burns, activate the generator only when the active electrode is near or touching the target tissue.
- Use the lowest power setting that achieves the desired surgical effect and use a low voltage waveform (pure cut or desiccate) to lessen the potential for the creation of capacitive currents.
- Carefully insert and withdraw active electrodes from cannulas to avoid possible injury to the patient or damage to the devices.

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.

Notes

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Before Surgery

This section contains procedures for:

- preparing the generator for surgery
- preparing for bipolar or macrobipolar surgery
- preparing for monopolar surgery
- preparing for ultrasonic electrosurgery

Cautions

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

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

Quick Setup Instructions

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

If, however, you are not familiar with how the generator should be set up, detailed instructions follow this section.

- 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 bipolar, monopolar, or ultrasonic electrosurgery:

To prepare for bipolar or monopolar surgery -

- If using a footswitch, connect it to the appropriate footswitch receptacle on the rear panel.
- Connect the instrument to the appropriate instrument receptacle on the front panel.
 - For simultaneous coag monopolar surgery, connect a monopolar accessory or a CUSA handpiece with CEM nosecone to the Monopolar 1/CEM Instrument receptacle. Connect a second monopolar accessory to the Monopolar 2 Instrument receptacle.
- For monopolar surgery only, apply the patient return electrode to the patient and connect it to the Patient Return Electrode receptacle on the front panel.
- Verify or change the mode and power settings.
 (Optional Press the Recall button on the front panel to display the previously used settings.)

To prepare for ultrasonic surgery –

- Assemble and sterilize the CUSA handpiece and CEM nosecone.
 Set up the CUSA System.
- If using a footswitch, connect it to the Monopolar 1 Footswitch receptacle on the rear panel.
- Apply the patient return electrode to the patient and connect it to the Patient Return Electrode receptacle on the front panel.
- Connect the handpiece to the Monopolar 1/CEM Instrument receptacle on the front panel. For simultaneous coag, connect a monopolar accessory to the Monopolar 2 Instrument receptacle.
- Verify or change the Low cut or Desiccate coag power settings.

Setting Up the Generator

Warnings

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. Otherwise, inaccurate power outputs may result.

Cautions

Do not stack equipment on top of the generator or place the generator on top of electrical equipment (except a Force GSU unit or a Force Argon unit). These configurations are unstable and/or do not allow for adequate cooling.

Provide as much distance as possible between the electrosurgical generator and other electronic equipment (such as monitors). An activated electrosurgical generator may cause interference with them.

Nonfunction of the 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.

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

Notices

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 by pressing the power switch off (O).
- 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 from 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.

You can also mount the generator on the Valleylab CUSA System 200, using the optional CUSA mounting brackets.

- 3. Plug the generator power cord into the rear panel receptacle.
- 4. Plug the generator power cord into a grounded receptacle.
- 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.
- 6. If the self-test is successful, a tone sounds. Verify the following:
 - Indicators above the default mode buttons (Standard bipolar, Pure cut, and Fulgurate coag) illuminate green.
 - Each display shows a power setting of 1 watt.
 - The REM Alarm indicator illuminates red.

If the self-test is not successful, an alarm tone sounds. A number may momentarily appear in the Cut display and, in most cases, the generator is disabled. Note the number and refer to Responding to System Alarms in Section 7.

Once the self-test is successful, connect the accessories and set the generator controls. Refer to *Preparing for Bipolar or Macrobipolar Surgery*, *Preparing for Monopolar Surgery*, or *Preparing for Ultrasonic Electrosurgery* later in this section.

Important
If the coag mode has been optionally changed to default to Desiccate or Spray, that corresponding indicator illuminates after the self-test is performed successfully.

Preparing for Bipolar or Macrobipolar Surgery

If you plan to use a footswitching bipolar instrument, you must connect a bipolar footswitch. You may also use a footswitch to activate a handswitching instrument.

Connections for Bipolar or Macrobipolar Surgery

Warnings

Electric Shock Hazard —

- Do not connect wet accessories to the generator.
- Ensure that all accessories and adapters are correctly connected and that no metal is exposed.

Do not apply a patient return electrode if only bipolar accessories are being used. Otherwise, the electrosurgical effect may not be limited to the tissue between the bipolar electrodes.

Cautions

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

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

Accessories must be connected to the proper receptacle type. In particular, bipolar accessories must be connected to the Bipolar receptacle only. Improper connection may result in inadvertent generator activation or a REM Contact Quality Monitor alarm.

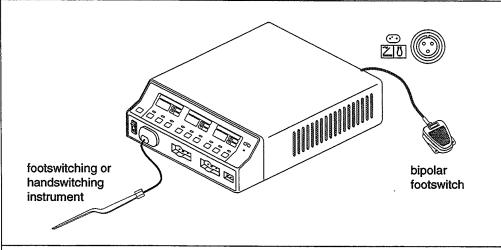


Figure 4.1 Connection for bipolar or macrobipolar surgery using footswitch activation and a handswitching or footswitching instrument.

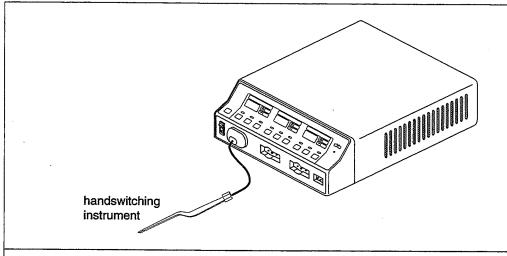


Figure 4.2 Connection for bipolar or macrobipolar surgery using a handswitching instrument.

Setting the Bipolar Output

Caution

Set power levels to the lowest setting before testing an accessory.

- 1. (Optional) To display the previous settings, press the Recall button.
- 2. To set the bipolar mode, press the Precise, Standard, or Macro button. The corresponding indicator illuminates green.
- 3. To increase the power for the selected mode, press the white up arrow (Δ) button. To decrease the power, press the white down arrow (∇) button. The maximum power setting is 70 watts.

Preparing for Monopolar Surgery

If you plan to use a footswitching monopolar instrument, you must connect a monopolar footswitch. You may also use a footswitch to activate a handswitching instrument or a CUSA handpiece with CEM nosecone.

Connections for Monopolar Surgery

Warnings

Electric Shock Hazard ---

- Do not connect wet accessories to the generator.
- Ensure that all accessories and adapters are correctly connected and that no metal is exposed.

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

The instrument receptacles on this generator are 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.

Cautions

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

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

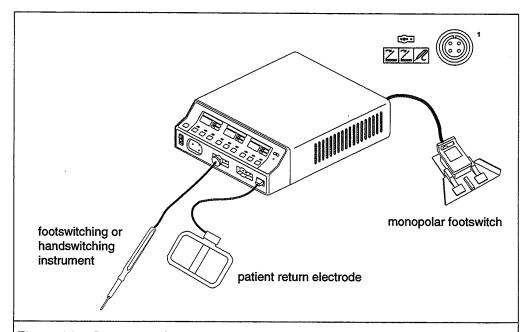


Figure 4.3 Connection for monopolar surgery using footswitch activation and a footswitching or handswitching instrument – using Monopolar 1 Footswitch receptacle and Monopolar 1/CEM Instrument receptacle.

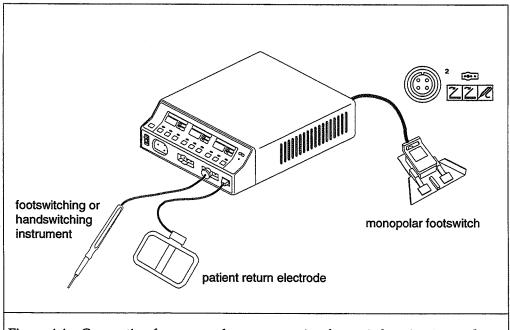


Figure 4.4 Connection for monopolar surgery using footswitch activation and a footswitching or handswitching instrument – using Monopolar 2 Footswitch receptacle and Monopolar 2 Instrument receptacle.

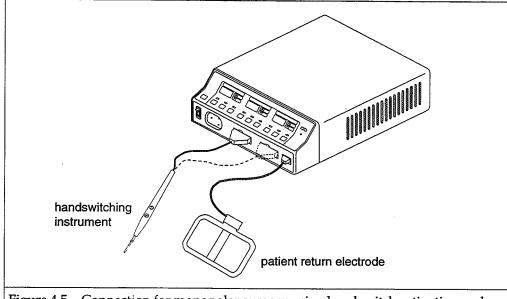


Figure 4.5 Connection for monopolar surgery using handswitch activation and a monopolar handswitching instrument – using either Monopolar Instrument receptacle.

Applying a Patient Return Electrode to the Patient

Warnings

The safe use of monopolar electrosurgery requires proper placement of the patient return electrode. To avoid electrosurgical burns beneath the patient return electrode, follow all directions on the product package for proper return electrode placement and use.

Do not cut a patient return electrode to reduce its size. Patient burns due to high current density may result.

Using a patient return electrode without the REM safety feature will not activate the Valleylab REM Contact Quality Monitoring System.

Valleylab recommends using REM patient return electrodes to maximize patient safety. Using a patient return electrode without the REM safety feature may result in a patient burn.

Refer to the manufacturer's instructions for application site and placement procedures. When using metal plate patient return electrodes, use a conductive gel specifically designed for electrosurgery.

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Using Two Generators Simultaneously

Caution

Do not stack equipment on top of the generator or place the generator on top of electrical equipment (except a Force GSU unit or a Force Argon unit). These configurations are unstable and/or do not allow for adequate cooling.

Two generators (and two patient return electrodes) may be used simultaneously on the same patient, provided the generators are the same type (both are isolated or both are ground referenced). However, the two generators are not synchronized. One return electrode frequently acquires a high positive voltage while the other acquires an opposite negative voltage. When this occurs, the potential voltage difference between them may cause the current to flow from one patient return electrode to the other. The current causes no harm if it produces no sparks or high current densities on the patient.

Place each patient return electrode as close as possible to the site of the surgery to be performed by the generator to which it is connected. Ensure that the two patient return electrodes do not touch.

Pacemakers

Warnings

Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced by the use of electrosurgical devices can cause devices such as 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 of electrosurgical appliances is planned in patients with cardiac pacemakers.

If the patient has an internal cardiac defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activations of ICDs.

To avoid interference with pacemakers, place the patient return electrode as close as possible to the site of surgery. Make sure the path the current follows from the site of surgery to the return electrode does not pass through the vicinity of the heart or the site where the pacemaker is implanted.



Selecting Cut and Coag Modes

Caution

Set power levels to the lowest setting before testing an accessory.

- 1. (Optional) To display the previous settings, press the Recall button.
- 2. *To select a cut mode*, press the Low, Pure, or Blend button. The corresponding indicator illuminates green.

To increase the power for the cut mode you selected, press the yellow up arrow (Δ) button. To decrease the power, press the yellow down arrow (∇) button. The maximum power setting for Low and Pure is 300 watts. The maximum power setting for Blend is 200 watts.

To select a coag mode, press the Desiccate, Fulgurate, or Spray button. The corresponding indicator illuminates green.

To increase the power for the selected coag mode, press the blue up arrow (Δ) button. To decrease the power, press the blue down arrow (∇) button. The maximum power setting for each coag mode is 120 watts.

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Simultaneous Coag

Connect two monopolar instruments for simultaneous coag. Each receives a percentage of the overall power setting. The amount of power provided to each instrument depends on the tissue resistance sensed by the generator at each surgical site. Generally, the site with lower resistance receives proportionately more power. The combined total output power does not exceed the overall power setting for the coag mode selected.

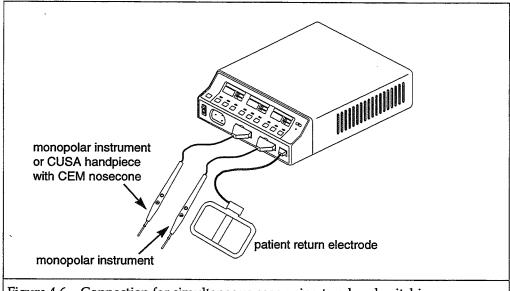
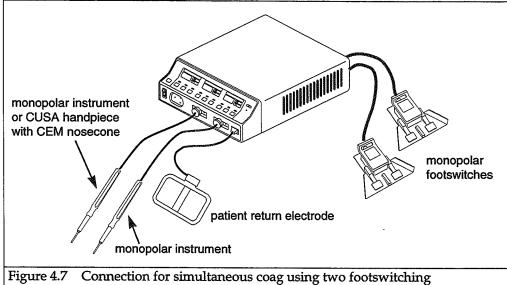


Figure 4.6 Connection for simultaneous coag using two handswitching instruments.



instruments.

Preparing for Ultrasonic Electrosurgery

To prepare for ultrasonic electrosurgery, first prepare the CUSA System. Refer to the CUSA System 200 User's Guide for assembly and setup instructions.

Assemble and sterilize the CUSA handpiece and the CEM nosecone.

Connecting the Patient Return Electrode

Valleylab recommends using a REM patient return electrode to maximize patient safety. For further information, refer to *Preparing for Monopolar Surgery – Applying a Patient Return Electrode to the Patient*, earlier in this section.

Connecting the CUSA Handpiece with CEM Nosecone

Warnings

Electric Shock Hazard ---

- · Do not connect wet accessories to the generator.
- Ensure that all accessories and adapters are correctly connected and that no metal is exposed.

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

Caution

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

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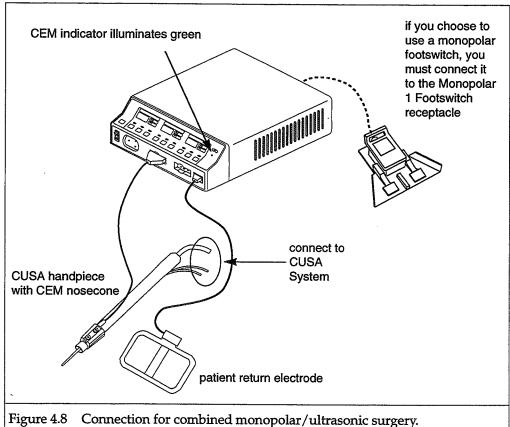


Figure 4.8 Connection for combined monopolar/ultrasonic surgery.

Setting the Output Power

Caution

Set power levels to the lowest setting before testing an accessory.

When you use the CUSA handpiece with CEM nosecone for ultrasonic electrosurgery, only Low cut or Desiccate coag are available when you activate the handpiece.

To verify or change the Low cut power setting:

To increase the power, press the yellow up arrow (Δ) button. To decrease the power, press the yellow down arrow (∇) button. The maximum cut power is 100 watts.

To verify or change the Desiccate coag power setting:

To increase the power, press the blue up arrow (Δ) button. To decrease the power, press the blue down arrow (∇) button. The maximum coag power is 70 watts.

Simultaneous Coag

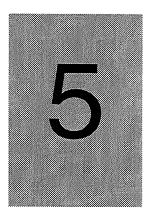
To use a CUSA handpiece with CEM nosecone for simultaneous coag, connect the handpiece to the Monopolar 1/CEM Instrument receptacle. Then connect a monopolar instrument to the Monopolar 2 Instrument receptacle. During simultaneous coag, only Desiccate coag is available; the maximum power is limited to 70 watts.

Refer to *Preparing for Monopolar Surgery – Simultaneous Coag*, earlier in this section for more information.

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Notes





During Surgery

This section covers the following topics:

- checking accessory connections
- · checking the patient return electrode
- changing the mode
- selecting the power setting
- activating the surgical instrument
- adjusting the volume of activation tones
- responding to alarms

Cautions

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

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

Checking Accessory Connections

Warning

Do not wrap the accessory cords or patient return electrode 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 accessories and connections to the electrosurgical generator before using. Ensure that the accessories function as intended. 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.

Checking the Patient Return Electrode

Warning

To avoid patient burns, ensure that the patient return electrode firmly contacts the skin. Always check the patient return electrode periodically and after the patient is repositioned and during procedures involving long periods of activation.

If a higher than expected power setting seems required or if the patient is repositioned, check the patient return electrode for secure placement and check all connecting cables for continuity.

Changing the Mode

Verify the selected mode with the surgeon. You cannot change the mode while the generator is activated.

To change the mode, press the desired bipolar, cut, or coag mode button. The indicator above that button illuminates green. You can activate only one mode at a time.

When you change modes within a function (bipolar, cut, coag), the power setting remains the same unless it exceeds the maximum for the new mode. In that case, it reverts to the maximum for the new mode. For example, if you set the power to 250 for Pure cut, when you select Blend, the power setting changes to 200, the maximum for Blend. If, however, you set the power to 65 in Desiccate, when you select Fulgurate, the power setting does not change because it falls within that mode's range.

Selecting the Power Setting

Warnings

Confirm proper power settings before proceeding with surgery. Use the lowest power setting possible for the minimum time necessary to achieve the desired effect.

Never increase the power settings without first checking both the active electrode and the patient return electrode and their connections. Use the active electrode or forceps only for the minimum time necessary to 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.

Changing the Power Setting

Verify the power settings for the selected mode with the surgeon. You can change the power setting when the generator is on, including when it is activated.

To increase the power, press the up arrow (Δ) button for the selected mode.

To decrease the power, press the down arrow (∇) button for the selected mode.

When you press and release the power button, the power changes by one setting (1, 5, or 10 watts), based on the settings available for the selected mode. The available power settings are listed in Appendix A.

To reach the maximum or minimum power setting for the selected mode, press and hold the up arrow (Δ) or down arrow (∇) button. The setting changes slowly at first, then more rapidly. Release the button when the desired setting is displayed. If you try to set the power above the maximum setting or below the minimum setting for the selected mode, a tone sounds.

Techniques for Keeping Power Settings Low

The power setting required to produce the desired surgical effect varies depending on the surgeon's technique, the selected mode, and the size of the active electrode. Low power settings reduce the amount of current delivered to the patient, minimize the demand on the patient return electrode, and help protect the patient and surgical team from accidental burns and shocks.

The following are techniques for keeping power settings low.

Concentrating the current by using a small active electrode.

The smaller the active electrode, the higher the current density it delivers to tissue, and the less power it requires to produce the same surgical

effect. For example, a needle electrode cuts at a lower power setting than a blade electrode. A small ball electrode desiccates or fulgurates tissue at a lower power setting than a large ball electrode.

Coagulating tissue by using fulguration rather than desiccation.

Because fulguration sparks to a wider area of tissue, surface coagulation can be achieved with a lower power setting using Fulgurate rather than Desiccate.

Cutting by sparking rather than by desiccating tissue.

Cut produces continuous sparks that cut cleanly and quickly when the active electrode is held just above the tissue and kept in motion. Placing the active electrode in contact with the tissue produces desiccation that increases tissue resistance. A higher power setting may be required to overcome the increased resistance.

Using bipolar surgery.

Bipolar surgery requires lower power because the amount of tissue included in the electrosurgical circuit is limited to the tissue that is grasped by the bipolar instrument.

Typical Power Settings

Use the following list of typical power settings for various surgical procedures as a general guideline.

Caution

The Force FX Electrosurgical Generator cuts effectively at power settings lower than previous models offered by Valleylab. If the proper setting is not known, set the generator at a very low setting and cautiously increase the power until the desired effect is achieved.

Power	Surgical Procedure	
Low Power < 30 watts	Dermatology	
voo wates	Laparoscopic sterilization (both bipolar and monopolar)	
	Neurosurgery (both bipolar and monopolar)	
	Oral surgery	
	Plastic surgery	
	Vasectomies	
Medium Power Cut: 30 – 100watts	General surgery	
Coag: 30 – 70 watts	Head and neck surgery (ENT)	
	Laparotomy	
	Orthopedic surgery (major)	
	Polypectomy	
	Thoracic surgery (routine)	
	Vascular surgery (major)	
High Power Cut: > 100 watts Coag: > 70 watts	Ablative cancer surgery, mastectomies, etc. (cut 180 – 300 watts; coag 70 – 120 watts)	
Coag. > 70 watts	Thoracotomy (heavy fulguration, 70 – 120 watts)	
	Transurethral resections (cut 100 – 170 watts; coag 70 – 120 watts, depending on the thickness of the resection loop and the technique)	

Activating the Surgical Instrument

Notice

Do not activate the generator until the forceps have made contact with the patient. Product damage may occur.

To activate a handswitching instrument, use the controls on the instrument or on the appropriate footswitch. To activate a footswitching instrument, you must use a footswitch.

To reduce the possibility of alternate site burns that may be caused by RF leakage currents, avoid unnecessary and prolonged activation of the generator.

If you use bipolar output when a return electrode is applied to the patient, the return electrode circuit is deactivated automatically to eliminate the possibility of current dispersal.

	Handswitching	Footswitching	Activation Indicator
Bipolar	Close forceps tines firmly	Press pedal	Activation tone sounds – Bipolar indicator illuminates blue
Monopolar	Press Cut or Coag button or	Press Cut or Coag pedal	Activation tone sounds – Cut indicator illuminates yellow or Coag indicator illuminates blue
	Close forceps tines firmly	n/a	
CUSA Handpiece with CEM Nosecone	Press Cut or Coag button on CEM Nosecone	Press Cut or Coag pedal	Activation tone sounds – Cut indicator illuminates yellow or Coag indicator illuminates blue – CEM indicator on front panel illuminates green when handpiece is properly connected to the patient and to the generator

5-6

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 accessory is active.

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 or adjust the alarm tone volume.

Responding to Alarms

REM Alarm

A tone sounds twice, and the REM Alarm indicator flashes red. The indicator remains red and RF output is disabled until the alarm condition is corrected. When you correct a REM alarm condition, output is enabled and the REM Alarm indicator illuminates green..

Alarm Situations

Important
After successful
completion of the
self-test, the REM
Alarm indicator
flashes red and a
tone sounds twice.
No corrective action
is required.

The following conditions can generate a REM alarm:

- The patient return electrode is not connected to the generator when the generator is activated for monopolar surgery.
- The return electrode does not have adequate contact with the patient.
- The contact area is reduced due to movement, loss of adhesion, fluid pooling, or dry contact gel.
- The return electrode cord is damaged, causing excessive resistance.

To correct an alarm condition, refer to *Correcting a REM Alarm Condition* in Section 7.

Non-REM Patient Return Electrode Alarm

When a non-REM patient return electrode is connected and the generator detects a cord fault condition, the REM Alarm indicator illuminates red. When you correct the alarm condition, the indicator is extinguished.

System Alarm

When the generator senses a system alarm condition, an alarm tone sounds and the generator is deactivated. An alarm number flashes in the Cut display on the front panel.

- 1. Turn off the generator.
- 2. Turn on the generator and verify that the self-test is completed successfully. If the alarm number reappears, note the number and refer to *Responding to System Alarms* in Section 7.

If you are unable to correct the system alarm condition, use a backup generator to complete the surgical procedure.





After Surgery

This section instructs you on:

- preparing the generator for reuse
- storing the generator

Preparing the Generator for Reuse

Caution

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

Step 1 – Disconnect the accessories.

- 1. Turn off the generator.
- 2. If applicable, remove the patient return electrode from the patient. Disconnect all accessories from the front panel.
 - If the accessory is disposable (single use only), 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.
- 3. Disconnect and store any footswitch(es) used.

Step 2 - 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.
- 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.

Storing the Generator

If the generator is stored at a temperature outside its normal operating range of 50° to 104° F (10° to 40° C), 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 service manual).



Troubleshooting

This section includes:

- correcting a REM alarm condition
- · correcting malfunctions
- · responding to system alarms

General Troubleshooting Guidelines

If the Force FX 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.

Correcting a REM Alarm Condition

To correct a REM alarm condition, follow these steps:

- 1. Verify that the patient return electrode cord is correctly connected to the generator.
- 2. Inspect the plug, cord, and the connection of the cord to the return electrode. If you find evidence of excessive wear, cracks, breaks, or other visible damage, replace the return electrode.
- 3. Verify that the return electrode is in contact with the patient, per the package instructions for applying the return electrode.
- 4. If the REM alarm persists:

If you are using a REM patient return electrode, apply another REM electrode. Refer to *Applying Additional Patient Return Electrodes* below.

or

If you are using a patient return electrode without the REM safety feature, apply a new patient return electrode and/or use a backup generator to complete the surgical procedure.

When you correct a REM alarm condition, the generator is enabled and the REM Alarm indicator changes as described below:

- If you are using a REM patient return electrode, the indicator illuminates green.
- If you are using a patient return electrode without the REM safety feature, the red indicator light is extinguished.

Applying Additional Patient Return Electrodes

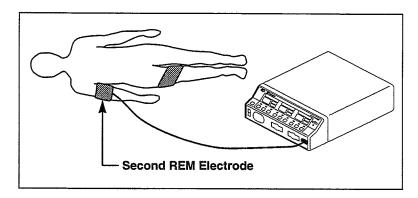
If you are using a Valleylab REM patient return electrode, follow this procedure to correct a REM alarm condition:

- 1. Inspect the return electrode connector.
 - a. Unplug the patient return electrode from the generator.
 - Verify that the pin on the plug is present and not bent. Carefully reinsert the plug into the Patient Return Electrode receptacle.
 Ensure that the pin enters the hole and that the plug inserts fully.

If the alarm persists, go to the next step.

Apply firm pressure over the entire surface area of the patient return electrode, particularly the center. If the alarm persists, go to the next step.

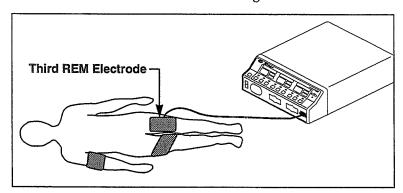
- 3. Apply a second patient return electrode.
 - a. Unplug the patient return electrode from the generator. *Do not* remove it from the patient.
 - b. Apply a second REM electrode to an appropriate site and connect it to the Patient Return Electrode receptacle on the generator.



If the alarm clears, leave the generator on during draping to avoid disturbing the return electrode. Remove the return electrode that is not in use.

If the alarm persists, go to the next step.

- 4. Apply a *third* patient return electrode.
 - a. Unplug the second patient return electrode from the generator. Do not remove either return electrode from the patient.
 - b. Apply a third REM electrode to the patient and connect it to the Patient Return Electrode receptacle. Select the next best, well vascularized, convex area close to the surgical site.



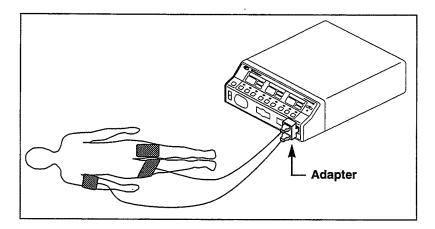
If the alarm clears, leave the generator on during draping to avoid disturbing the return electrode. Remove the return electrodes that are not in use.

If the alarm persists, go to the next step.

Unplug the patient return electrode from the generator.
 Use a Valleylab multiple return/s-cord adapter (E0507-B) to connect

two patient return electrodes to the generator.

a. Insert the adapter into the Patient Return Electrode receptacle.



b. Insert the plugs of two of the patient return electrodes into the adapter. Choose the two return electrodes that are on the most vascularized, convex areas in closest proximity to the surgical site.

If the alarm clears, leave the generator on during draping to avoid disturbing the return electrodes. Remove the return electrode that is not in use.

If the REM alarm persists, use a backup generator and repeat these steps.

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 Section 4.

Situation	Possible Cause	Solution
Abnormal neuromuscular stimulation (stop surgery immediately).	1. Metal-to-metal sparking.	Check all connections to the generator, patient return electrode, and active electrodes.
	2. Can occur during coag.	2. Use a lower power setting for the Fulgurate and the Spray modes or select the Desiccate mode.
	3. Abnormal 50-60 Hz leakage currents.	3. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance.

Situation	Possible Cause	Solution
	Disconnected power cord or faulty wall outlet.	 Check power cord connections (generator and wall outlet). Connect the power cord to a functional outlet.
	2. Faulty power cord.	2. Replace the power cord.
	3. Fuse drawer is open or fuses are blown.	3. Close the fuse drawer. Replace the blown fuse(s). Refer to the Force FX Electrosurgical Generator Service Manual.
	4. Internal component malfunction.	4. Use a backup generator. Refer to your Biomedical Engineering Department or contact a Valleyla Representative for assistance.

Situation Possible Cause Solution Generator is on, but did not complete the self-test. 2. Internal component malfunction. 2. Internal component malfunction. Solution 1. Turn off, then turn on the generator. 2. Use a backup generator. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance.

Situation

Generator is on and accessory is activated, but generator does not deliver output.

Possible Cause

- Malfunctioning footswitch or handswitching instrument.
- Footswitch connected to Monopolar 1 Footswitch receptacle is being used for surgical instrument in Monopolar 2 receptacle.
- Footswitch connected to Monopolar 2 Footswitch receptacle is being used for instrument connected to Monopolar 1/CEM receptacle.
- 4. Power set too low.
- 5. An alarm condition exists.

6. Internal component malfunction.

Solution

- 1. Turn off the generator. Check and correct all accessory connections.
 - Turn on the generator. Replace the accessory if it continues to malfunction.
- Connect the footswitch to the Monopolar 2 Footswitch receptacle. or Connect the instrument to the Monopolar 1/CEM receptacle.
- Connect the footswitch to the Monopolar 1 Footswitch receptacle. or Connect the instrument to the Monopolar 2 receptacle.
- 4. Increase the power setting. Refer to Section 5, Changing the Power Setting.
- 5. Check the Cut display for an alarm number. Note the number and refer to *Responding to System Alarms* later in this section.
 - In case of a REM alarm, refer to *Correcting a REM Alarm Condition* earlier in this section.
- Use a backup generator. Contact your Biomedical Engineering Department or a Valleylab Representative for assistance.

Situation

Continuous monitor interference.

Possible Cause

- 1. Faulty chassis-to-ground connections.
- 2. Electrical equipment is grounded to different objects rather than a common ground. The generator may respond to the resulting voltage differences between grounded objects.
- 3. Malfunctioning monitor.

Solution

- Check and correct the chassis ground connections for the monitor and for the generator.
 - Check other electrical equipment in the room for defective grounds.
- Plug all electrical equipment into line power at the same location. Contact your Biomedical Engineering Department or a Valleylab Representative for assistance.
- 3. Replace the monitor.

Situation

Interference with other devices only when the generator is activated.

Possible Cause

- Metal-to-metal sparking.
- High settings used for fulguration.
- Electrically inconsistent ground wires in the operating room.
- If interference continues when the generator is activated, the monitor is responding to radiated frequencies.

Solution

- Check all connections to the generator, patient return electrode, and accessories.
- Use lower power settings for fulguration or select the Desiccate mode.
- Verify that all ground wires are as short as possible and go to the same grounded metal.
- 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 generator is activated and minimize the potential for an electrosurgical burn at the site of the monitor electrode.

Situation	Possible Cause	Solution	
Pacemaker interference.	Intermittent connections of metal-to-metal sparking.	or 1. Check the active and patient return electrode cord connections	
		It may be necessary to reprogram the pacemaker.	
	Current traveling from active to return electrode during monopolar	Use bipolar instruments, if possible.	
	electrosurgery is passing too close to pacemaker.	If you must use a monopolar instrument, place the patient return electrode as close as possible to the surgical site. Make sure the current path from the surgical site to the patient return electrode does not pass through the vicinity of the heart or the site where the pacemaker is implanted.	
`		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 electrosurgical appliances is planned in patients with cardiac pacemakers.	
Situation	Possible Cause	Solution	

ICD is activated by

electrosurgical generator.

Internal Cardiac

activation.

Defibrillator (ICD)

Stop the procedure and contact the ICD manufacturer for instructions.

Responding to System Alarms

When a system alarm condition exists, an alarm tone sounds and a number flashes in the Cut display. The generator is disabled until the condition is cleared.

Most system alarms require some action on your part to correct the condition; however, some are corrected automatically. Use the following table to determine how to correct an alarm condition.

After correcting the alarm condition, verify that the generator completes the self-test as described in Section 4.

Number	Description	Recommended Action
0–7	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
10	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
11	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
12	Software malfunction. Turn off, then turn on the generator. If t number reappears, record the number a Valleylab Service Center.	
13-14 16	Diagnostic/microcontroller malfunction.	Contact your Biomedical Engineering Department.
17-18	Internal component malfunction.	Do not attempt to use the generator. Record the number and call the Valleylab Service Center.
19	Internal component malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
30-32 40 60-66	Software malfunction.	valleylab Service Center.
. 67	Internal diagnostics.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
68	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
69-71 80	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.

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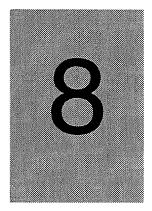
Number	Description	Recommended Action
81	Internal component malfunction.	Do not attempt to use the generator. Record the number and call the Valleylab Service Center.
90 95	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
100-105 110-119	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
120	Calibration malfunction.	Contact your Biomedical Engineering Department.
121	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
122	Calibration malfunction.	Contact your Biomedical Engineering Department.
123-126	Microcontroller malfunction.	
130-134 136-138 150	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
151	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
152	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
154	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
160	Internal component malfunction.	Do not attempt to use the generator. Record the number and call the Valleylab Service Center.
161-166	Dosage error.	Contact your Biomedical Engineering Department.
170-173	Microcontroller malfunction.	
174	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
180-185	Internal diagnostics.	Contact your Biomedical Engineering Department.

Number	Description	Recommended Action
189	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
190	Bipolar up arrow, bipolar down arrow, and/or a bipolar mode button (Precise, Standard, Macro) may be stuck.	1. Turn off, then turn on the generator. Do not press buttons or accessory activation devices during the self-test. If the alarm number reappears, record the number and call the Valleylab Service Center.
191	Cut up arrow, cut down arrow, and/or a cut mode button (Low, Pure, Blend) may be stuck.	2. If the alarm number reappears, disconnect all accessories. Then, turn off and turn on the generator again. If the alarm number reappears, record the number and call the Valleylab Service Center.
192	Coag up arrow, coag down arrow, and/or a coag mode button (Desiccate, Fulgurate, Spray) may be stuck.	
193	Recall button may be stuck.	
194	Handswitch or Monopolar 1 Footswitch cut pedal may be stuck.	
195	Handswitch or Monopolar 1 Footswitch coag pedal may be stuck.	
196	Handswitch or Monopolar 2 Footswitch cut pedal may be stuck.	
197	Handswitch or Monopolar 2 Footswitch coag pedal may be stuck.	
198	Handswitch or Bipolar Footswitch pedal may be stuck.	
199-203	Internal diagnostics or microcontroller malfunction.	Contact your Biomedical Engineering Department.
206-207	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.

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Number	Description	Recommended Action
208-209	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
210-211	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
212-213 215	Internal diagnostics.	Contact your Biomedical Engineering Department.
220-226	Internal diagnostics or microcontroller malfunction.	
230-231	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
232	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
240-245	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
246-247	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
260	Internal diagnostics.	
261-262 270-271	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center.
451	The internal temperature limit was exceeded due to length of activation time.	Verify that the location of the generator allows for adequate cooling.
	gat of activation time.	Use the lowest power setting that achieves the desired effect. Limit activation times, if possible.





Maintenance and Repair

Refer to this section for information on:

- the manufacturer's responsibility
- routine maintenance
- · returning the generator for service
- service centers

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 the Warranty at the end of this guide.

Routine Maintenance

Notice

Refer to the 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 twice 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 service manual for instructions.

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.

Step 1 - Obtain a Return Authorization Number.

Call the Valleylab 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
- telephone number
- department/address, city, state, and zip code
- model number
- serial number
- description of the problem
- type of repair to be done

Step 2 - 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.
- 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.

Step 3 - 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 Step 1 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

Valleylab Inc Boulder, Colorado, USA 800–255–8522

Valleylab Australia Sydney, AUSTRALIA 61-2-688-4888

Valleylab Benelux Huis Ter Heideweg, HOLLAND 31-3069-32800

Valleylab Canada Ontario, CANADA 800-668-1832

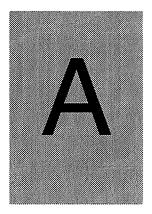
Valleylab Europe, Middle East and Africa London, UNITED KINGDOM 44-181-896-7600 0181-896-7600 (within the U.K.)

Valleylab France c/o Howmedica 39, Boulevard Ambroise Paré 69008 Lyon, FRANCE 33 (0)4 78 78 60 60

Valleylab Germany Wichmannstrasse 4 D-22607 Hamburg Postfach 520452 D-22594 Hamburg, GERMANY 49-(0)40-89 68 84

Valleylab Spain Príncipe de Vergara, 109 28002 Madrid, SPAIN TEL. 34-1-566-98-71 FAX. 34-1-561-79-89

Valleylab Italy (Valleylab Division of Pfizer Italiana S.p.A.) Via Valbondione, 113 00188 Rome, ITALY TEL. 39-06-33182 FAX. 39-06-33613207



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 (77° F/25° C) and a nominal input power voltage.

Performance Characteristics

General

Output configuration: isolated output

Cooling: natural convection; side and rear panel vents; fan

Display: eight digital seven-segment displays: 0.75 in. (1.9 cm) each

Mounting: Valleylab cart (E8006 or E8008), CUSA System 200 (using

CUSA System 200 optional mounting brackets), a Force GSU

unit, a Force Argon unit, or any stable flat surface

Dimensions and Weight

Width: 14 in. (35.6 cm) Depth: 18 in. (45.7 cm) Height: 4 3/8 in. (11.1 cm) Weight: < 18 lbs. (< 8.2 kg)

Operating Parameters

Ambient temperature range: 50° to 104° F (10° to 40° C)

Relative humidity: 30% to 75%, 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 use.

Transport and Storage

Ambient temperature range: -40° to 158° F (-40° to 70° C)

Relative humidity: 10% to 100%, condensing Atmospheric pressure: 500 to 1060 millibars

Duration of storage: If stored longer than one year, the battery must be

replaced and a full checkout, including calibration, must be completed before use. For instructions, refer to the Force FX Electrosurgical Generator

Service Manual.

Duty Cycle

Under maximum power settings and rated load conditions (Pure cut, 300 watt setting, 300 ohm load) the generator is suitable for activation times of 10 seconds on, 30 seconds off for one hour.

If the internal temperature of the generator is too high, an alarm tone sounds and a number (451) flashes in the Cut display alternately with the power settings. You can activate the generator and change the power settings while this condition exists.

Internal Memory

Nonvolatile, battery-backed RAM

Battery type: 3 V lithium button cell

Battery life: 5 years

Storage capacity:

- one configuration, including three power settings and three mode settings
- the last twenty error codes detected by the generator
- the number of times and length of activation for each mode
- the average power setting used for each mode
- the total time the generator is on
- other service-related information

Audio Volume

The audio levels stated below are for activation tones (bipolar, cut, and coag) and alarm tones (REM and system alarms) at a distance of one meter. Alarm tones meet the requirements for IEC 601-2-2.

Activation Tone

Volume (adjustable): $45 \text{ to } \ge 65 \text{ dB}$

Frequency: Bipolar: 940 Hz

Cut: 660 Hz Coag: 940 Hz

Duration: continuous while the generator is activated

Alarm Tone

Volume (not adjustable): \geq 65 dB

Frequency: 660 Hz Duration: 250 to 500 ms.

REM Contact Quality Monitor

REM current is measured according to IEC 601-1, Ed. 1988, Figure 15.

Measurement frequency: 80 kHz ± 10 kHz

Measurement current: $< 10 \mu A$

Acceptable Resistance Range

REM resistance measurements are \pm 10% during RF activation and \pm 5% when RF output is not activated.

REM patient return electrode: 5 to 135 ohms or up to a 40% increase in the initial measured contact resistance (whichever is less)

Patient return electrode without the REM safety feature (single section electrode): 0 to 20 ohms

If the measured resistance is outside the acceptable range(s) noted above, a REM fault condition occurs.

REM Alarm Activation

REM patient return electrode: When the measured resistance exceeds the standard range of safe resistance (below 5 ohms or above 135 ohms) or when the initial measured contact resistance increases by 40% (whichever is less), the REM Alarm indicator flashes red, a tone sounds twice, and RF output is disabled. The indicator remains illuminated red until you correct the condition causing the alarm. Then, the indicator illuminates green and RF output is enabled.

Patient return electrode without the REM safety feature: When the measured resistance between the patient return electrode pins exceeds 20 ohms, the REM Alarm indicator flashes red, a tone sounds twice, and RF output is

disabled. The indicator remains illuminated red until you correct the condition causing the alarm. Then, the red indicator is extinguished and RF output is enabled.

Serial Port

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

9-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)

RF Activation Port

The RF activation port is a subminiature telephone 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.

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

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

Bipolar RF leakage current: < 59.2 mA rms

Monopolar RF leakage current (additional tolerance): < 150 mA rms

CEM output modes: $< 150 \text{ mA at} \le 50 \text{ W}$

Input Power

110-120 Volt

220-240 Volt

Maximum VA at nominal line voltage:

Idle: 52 VA

Bipolar: 450 VA

Cut: 924 VA

Coag: 530 VA

Input mains voltage, full regulation range: 104-132 Vac

Input mains voltage, operating

range: 85-132 Vac

Mains current (maximum):

Idle: 0.4 A

Bipolar: 2.0 A

Cut: 7.0 A

Coag: 4.0 A

Mains line frequency range

(nominal): 50 to 60 Hz

Fuses (2): F8 A

Power cord: 3-prong hospital

grade connector

Maximum VA at nominal

line voltage:

Idle: 52 VA

Bipolar: 450 VA

Cut: 924 VA

Coag: 530 VA

Input mains voltage, full regulation range: 208-264 Vac

Input mains voltage, operating

range: 170-264 Vac

Mains current (maximum):

Idle: 0.2 A

Bipolar: 1.0 A

Cut: 3.5 A

Coag: 2.0 A

Mains line frequency range

(nominal): 50 to 60 Hz

Fuses (2): T4 A

Power cord: 3-prong locally

approved connector

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.



Caution

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

Class I Equipment (IEC 601-1)

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 601-1)/Defibrillator Proof



The Force FX 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.

The Force FX generator patient return electrode terminal is protected from defibrillator discharge according to ANSI/AAMI HF18 and IEC 601-2-2.

Drip Proof (IEC 601-2-2)

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

Electromagnetic Interference

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

Electromagnetic Compatibility (IEC 601-1-2 and IEC 601-2-2)

The Force FX generator complies with the appropriate IEC 601-1-2 specifications regarding electromagnetic compatibility.

Voltage Transients (Emergency Generator Mains Transfer)

The Force FX 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 Output for Bipolar and Monopolar Modes

Power readouts agree with actual power into rated load to within 15% or 5 watts, whichever is greater.

Mode	Open Circuit P-P Voltage (max)	Rated	Power	Crest Factor*	
Bipolar	Voltage (Illax)	Load (max)	(max)		
Precise	450 V	100 Ω	70 W	1.5	
Standard	320 V	100Ω	70 W	1.5	
Macro	750 V	100Ω	70 W	1.5	
Monopolar Cu	t				
Low	1350 V	300Ω	300 W	1.5	
Pure	2300 V	300 Ω	300 W	1.5	
Blend	3300 V	300Ω	200 W	2.5	
Monopolar Co	ag				
Desiccate	3500 V	500Ω	120 W	5	
Fulgurate	6900 V	500Ω	120 W	5.5	
Spray	9000 V	500Ω	120 W	8	

Maximum Output for Ultrasonic Electrosurgery

Open Circuit P-P	Rated	Power	Crest Factor*	
Voltage (max)	Load (max)	(max)		
Cut				
1000 V	300Ω	100 W	1.5	
Coag				
3500 V	500Ω	70 W	5	
	Voltage (max) Cut 1000 V Coag	Voltage (max) Load (max) Cut 1000 V 300 Ω Coag 300 Ω 300 Ω	Voltage (max) Load (max) (max) Cut 1000 V 300 Ω 100 W Coag 300 Ω 100 W	

^{*} an indication of a waveform's ability to coagulate bleeders without a cutting effect

Available Power Settings in Watts

Bipola	and M	acrobi	polar						
1	2	3	4	5	6	7	8	9	
11	12	13	14	15	16	17	18	19	
21	22	23	24	25	26	27	28	29	
31	32	33	34	35	36	37	38	39	
45	50	55	60	65	70				
Monop	olar Cu	ıt: <i>Lov</i>	vand F	Pure					
1	2	3	4	5	6	7	8	9	
11	12	13	14	15	16	17	18	19	
21	22	23	24	25	26	27	28	29	
31	32	33	34	35	36	37	38	39	
45	50	55	60	65	70	7 5	80	85	
95	100	110	120	130	140	150	160	1 7 0	1
190	200	210	220	230	240	250	260	27 0	2
290	300								
Monop	olar Cu	it: <i>Blei</i>	nd						
1	2	3	4	5	6	7	8	. 9	
11	12	13	14	15	16	17	18	19	
21	22	23	24	25	26	27	28	29	
31	32	33	34	35	36	37	38	39	
45	50	55	60	65	7 0	<i>7</i> 5	80	85	
95	100	110	120	130	140	150	160	1 7 0	1
190	200								
Monop	olar Co	ag							
1	2	3	4	5	6	7	8	9	
11	12	13	14	15	16	17	18	19	
21	22	23	24	25	26	27	28	29	
31	32	33	34	35	36	37	38	39	
45	50	55	60	65	<i>7</i> 0	<i>7</i> 5	80	85	
95	100	110	120						
CEM C	ut								
1	2	3	4	5	6	7	8	9	
11	12	13	14	15	16	17	18	19	
21	22	23	24	25	26	27	28	29	
31	32	33	34	35	36	37	38	39	
45	50	55	60	65	70	75	80 .	85	
95									

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CEM Coag

1	2	3	4	5	6	7	8	9	10
11	12	13	14	15	16	1 <i>7</i>	18	19	20
21	22	23	24	25	26	27	28	29	30
31	32	33	34	35	36	37	38	39	40
45	50	55	60	65	70				

Output Waveforms

Instant Response Technology, an automatic adjustment, controls all bipolar modes and all cut modes. It does not control the coag modes because of their fulguration capabilities. As tissue resistance increases from zero, the generator outputs constant current followed by constant power followed by constant voltage. The maximum output voltage is controlled to reduce capacitive coupling and video interference and to minimize sparking.

Bipolar

Precise

470 kHz sinusoid

Standard

470 kHz sinusoid

Macro

470 kHz sinusoid

Monopolar Cut

Low

 $390\ kHz$ sinusoid. Similar to the Pure cut mode except

the maximum voltage is limited to a lower value.

Pure

390 kHz sinusoid

Blend

390 kHz bursts of sinusoid, recurring at 27 kHz

intervals. 50% duty cycle.

Monopolar Coag

Desiccate

240 kHz sinusoid repeated at 39 kHz. 8% duty cycle.

Fulgurate

390 kHz damped sinusoidal bursts with a repetition

frequency of 57 kHz into 300 ohms.

Spray

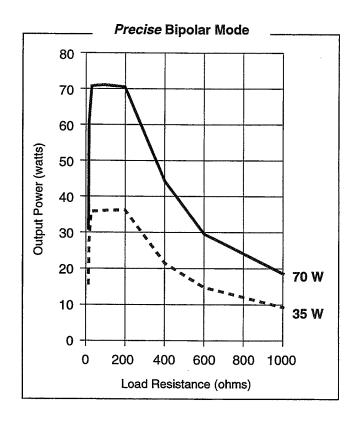
390 kHz damped sinusoidal bursts with a randomized repetition centered at 28 kHz. Frequencies include 21 kHz < f < 35 kHz. Output is further modulated by a random 250 Hz envelope with a variable duty cycle.

Output Power vs. Resistance Graphs

The graphs that follow depict the changes for each mode at specific power settings.

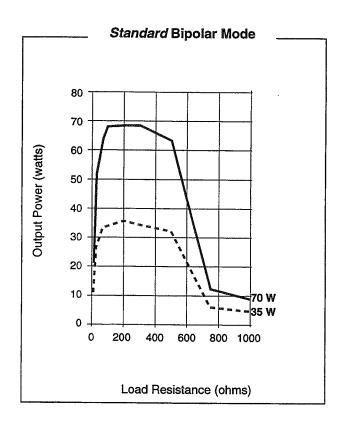
Bipolar Graphs

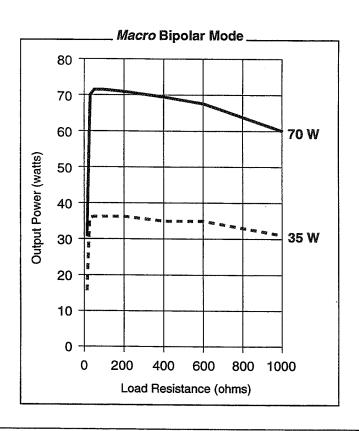
The insulating surface described in IEC 601-2-2 was used to obtain the bipolar output measurements.



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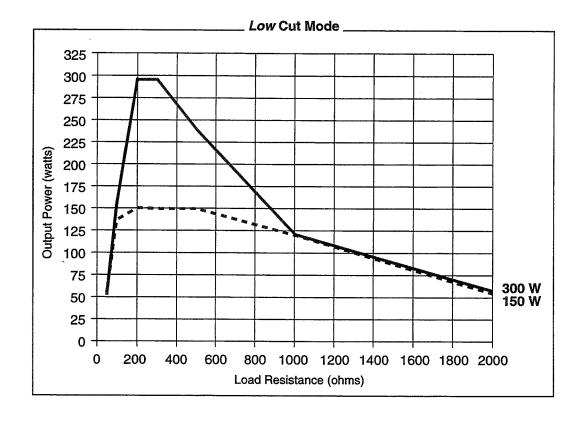
Bipolar Graphs - continued





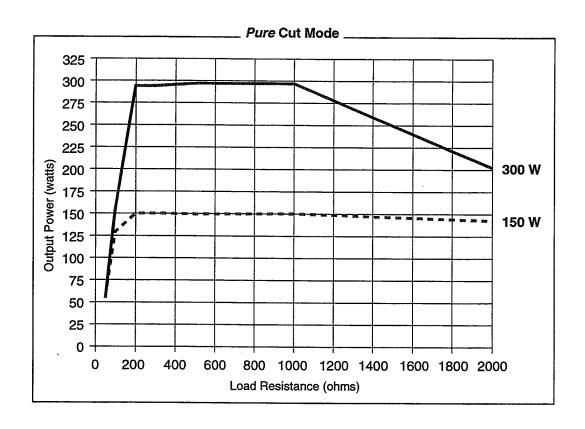
Monopolar Cut Graphs

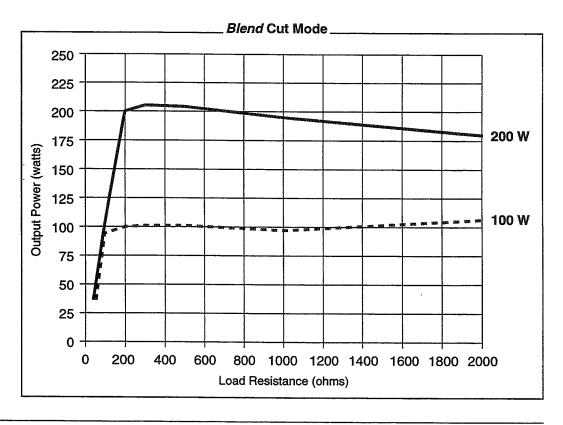
These measurements were taken using short (< 0.5 meter) leads.



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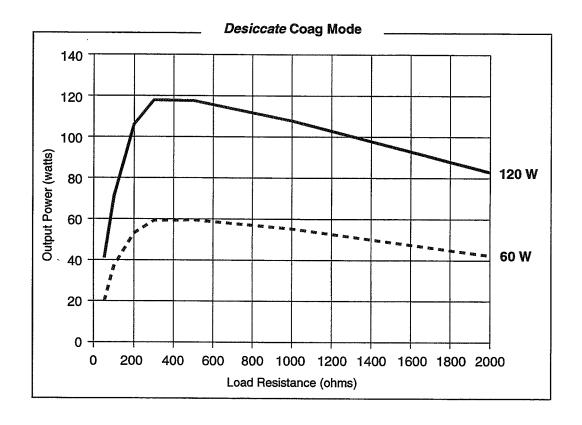
Monopolar Cut Graphs - continued





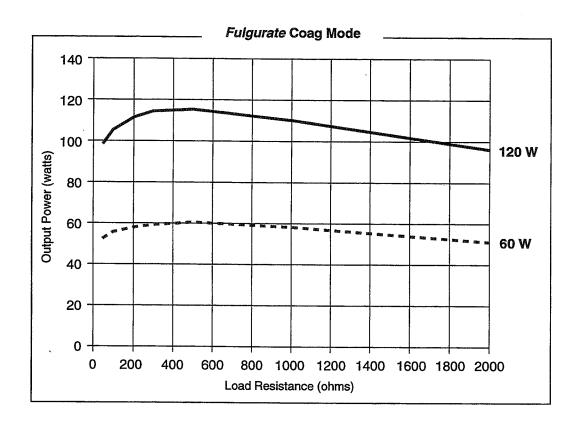
Monopolar Coag Graphs

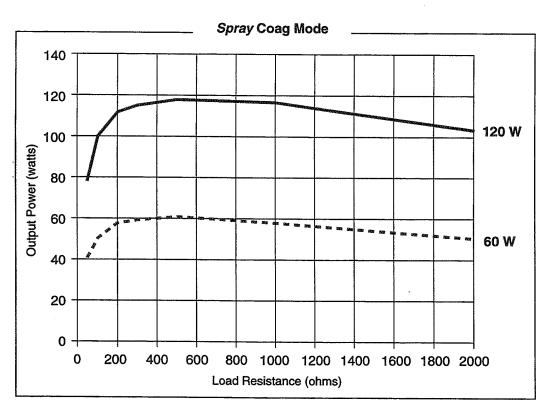
These measurements were taken using short (< 0.5 meter) leads.

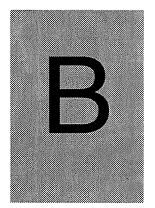


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Monopolar Coag Graphs - continued







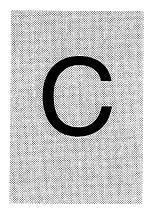
Accessories

The accessories listed in this section are recommended for use with the Force FX Electrosurgical Generator.

Catalog No.	Valleylab Accessory
E0502–1 or E0502–12	Adapter, Footswitching Instrument (single-pin) (for connecting some monopolar footswitching instruments to the Force FX generator)
E0507B	Adapter, Multiple Return/S-Cord (for connecting two patient return electrodes to the Patient Return Electrode receptacle)
E6009	Footswitch, Bipolar (three-pin connector)
E6008	Footswitch, Monopolar (four-pin connector)
E2515 or E2516	Handswitching Pencil (disposable)
E2500 or E2525	Handswitching Pencil (reusable)
E2400	Holster, Insulating (disposable)
E006 or E008	Mounting Cart
E7507 or E7509	REM PolyHesive Patient Return Electrode
E7510	Infant REM PolyHesive Patient Return Electrode

Notes





Basics of Electrosurgery

This section explains the basic principles of monopolar, bipolar, and ultrasonic electrosurgery.

Introduction

Electrosurgery is the passage of high frequency (radio frequency), electrical current through tissue for cutting or coagulating tissue.

During electrosurgery, radio frequency (RF) current flows from the generator to an active electrode, which delivers the current to the patient. The resistance to the current, provided by the patient's tissue and/or the air between the active electrode and the tissue, produces the heat that is necessary for the surgical effect. The RF current flows from the active electrode, through the patient's body tissue to the return electrode, which recovers the current and returns it to the generator. The amount of body tissue included in the electrical circuit depends on the type of electrosurgery—monopolar or bipolar.

Surgeons use electrosurgery to cut and coagulate tissue.

- Electrosurgical cutting severs tissue with short, intense electric sparks from the active electrode, across air, to the patient tissue.
- Electrosurgical coagulation clots blood or destroys tissue with no cutting effect.

Monopolar Electrosurgery

In monopolar electrosurgery, the surgical instrument contains only the active electrode. A separate return electrode—the patient return electrode—must be applied to the patient to recover the current that passes through the patient and return it safely to the generator.

Monopolar electrosurgery is used for most surgical procedures. It is especially useful for procedures that require sparking to tissue, such as those in which tissue must be cut or coagulated over wide areas.

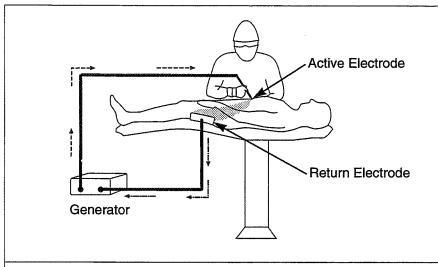


Figure C.1 Monopolar electrosurgical system.

Bipolar Electrosurgery

Bipolar electrosurgery combines the functions of the active and return electrodes in a single surgical instrument. A patient return electrode is not used. The bipolar instrument (forceps) contains an active electrode and a return electrode. Current flows from the active side, through the tissue grasped by the tines, to the return side of the instrument.

Bipolar systems provide desiccation and minimize damage to tissue adjacent to the active forceps by incorporating the active and return electrodes in the same device and by limiting the amount of tissue involved in the electrosurgical circuit. Bipolar procedures are often performed in confined surgical sites and under magnification. This requires a degree of precision because these procedures may involve delicate and highly conductive tissue, such as brain, spinal, or eye tissue, in irrigated surgical environments.

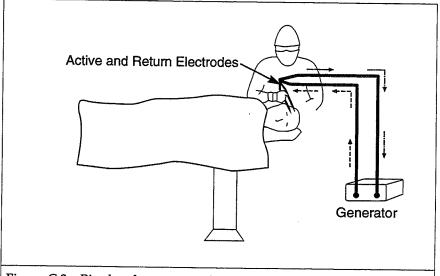


Figure C.2 Bipolar electrosurgical system.

Ultrasonic Electrosurgery

Ultrasonic surgery involves the use of a hollow tip, mechanically vibrating at ultrasonic frequencies, to selectively fragment and remove unwanted tissue. Because human tissue varies in consistency both in the degree of water content and the presence or absence of collagen (elastic content), the cavitational effect created by the vibrating tip will fragment certain tissue structures while having little, if any, effect on other structures. This selectivity allows the surgeon to remove high and low water content tissue while identifying and sparing critical structures such as vessels and ducts.

Sterile irrigation solution is delivered to the surgical field to suspend the fragmented tissue particles and keep the vibrating tip cool. A vacuum is created through the center of the tip to aspirate the fluid and particulate matter.

Ultrasonic electrosurgery is available only with selected Valleylab generators. For specific information about this generator, refer to Section 1.

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Notes



Glossary

Α

active electrode

An electrosurgical instrument or accessory that concentrates the electric (therapeutic) current at the surgical site.

active electrode monitoring

A system that continuously conducts stray current from the laparoscopic electrode shaft back to the generator and away from the patient tissue. It also monitors the level of stray current and interrupts the power should a dangerous level of leakage occur. Improved technique alone cannot completely eliminate the risks posed by insulation failure and capacitive coupling. In response to these risks, active electrode monitoring was developed. Active electrode monitoring surrounds the active electrode with a protective shield. This shield collects any stray current produced by insulation failure or capacitive coupling and safely returns it to the generator. Active electrode monitoring continuously shields and actively monitors any stray current. If the stray current produced becomes excessive, the active electrode monitoring system is designed to deactivate the generator before an injury can occur.

adapter

A connector between incompatible plugs (connectors) and jacks (receptacles) that allows correct connection and completion of the electric circuit.

alternate site burn

An electrosurgical burn at a grounded site on the patient, other than the surgical site or the patient return electrode, caused by a current division.

ampere (A)

The unit of measurement for electric current. One ampere (A) equals 6.242×10^{18} electrons per second.

В

bipolar electrosurgery

Electrosurgery where current flows between two bipolar electrodes that are positioned around tissue to create a surgical effect (usually desiccation). Current passes from one electrode, through the desired tissue, to the other electrode, thus completing the circuit without entering any other part of the patient's body.

bipolar instrument

An electrosurgical instrument or accessory that incorporates both an active and return electrode.

bipolar output

An isolated electrosurgical output where current flows between two bipolar electrodes that are positioned around tissue to create a surgical effect in that tissue (usually desiccation).

blend

A waveform that combines features of cut and coag waveforms; current that cuts with varying degrees of hemostasis.

buzzing the hemostat

A surgical technique for coagulating bleeding vessels in which the active electrode is touched to the hemostat, thereby delivering current through the hemostat to the target issue. Valleylab does not recommend this technique.

C

capacitance

The property of an electrical circuit that enables it to transfer an electrical charge from one conductor to another even when separated by an insulator.

capacitive coupling

The condition that occurs when electrical current is transferred from one conductor (the active electrode), through intact insulation, into adjacent conductive materials (tissue, trocars, wires, etc.).

capacitive pad

A patient return electrode that contains a nonconductor that allows the displacement of electric charges but not the flow of electric current.

circuit The path along which electricity flows.

coag A high voltage, intermittent waveform optimized for electrosurgical coagulation.

coagulation

The clotting of blood or destruction of tissue with no cutting effect; electrosurgical desiccation and fulguration.

conductor A substance that conducts electricity.

crest factor A

An indication of a coag waveform's ability to achieve hemostasis without "divoting" or cutting tissue. A higher crest factor would indicate better coagulation with less tissue damage.

cross coupling

The transfer of power between two adjacent circuits.

current The number of electrons moving past a given point per second, measured in amperes (A).

current density The amount of current flow per unit of surface area. The heat generated in the material is directly proportional to the current density.

current division Electrical current leaving the intended electrosurgical circuit and following an alternate path of least resistance to ground; typically the cause of alternate site burns on grounded generators.

CUSA system A cavitational ultrasonic surgical aspirator produced by Valleylab used for ultrasonic electrosurgery.

cut A low voltage, continuous waveform optimized for electrosurgical cutting.

The electrosurgical effect that results from high current density in the tissue causing cellular fluid to turn to steam, which in turn bursts the cell walls and disrupts the structure. Voltage is low and current flow is high.

D ----

default (default setting) The mode or power setting that is automatically selected when the generator is turned on.

cutting

electrode

desiccation The electrosurgical effect of tissue dehydration and protein denaturation caused by direct contact between the electrosurgical electrode and tissue.

direct coupling

The condition that occurs when one electrical conductor (the active electrode) comes into direct contact with another secondary conductor (scopes, graspers). Electrical current will flow from the first conductor into the secondary one and energize it.

duty cycle The ratio of the amount of time a given waveform is on to the total period of time; typically expressed as a percentage.

E

A conductor that transmits or receives electrosurgical current; see also active electrode, patient return electrode.

electrosurgery The passage of high frequency electrical current through tissue to create a desired surgical effect.

electrosurgical burn Tissue destruction caused by the concentration of high frequency electric current, including the surgical effect but usually referring to accidental injury. See also alternate site burn.

electrosurgical circuit The path traveled by the therapeutic current from the generator to the active electrode and through body tissue to the return electrode and back to the generator.

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Glossary-3

electrosurgical current See radio frequency (RF). The electrosurgical generator and its connecting cables, abbreviated as electrosurgical unit endoscope A fiberoptic tube used to examine body cavities or organs. frequency The rate at which a cycle repeats itself; in electrosurgery, the number of cycles per second that current alternates. fulguration Using electrical arcs (sparks) to coagulate tissue. The sparks jump from the electrode across an air gap to the tissue. G The machine that converts low frequency alternating current to high generator frequency electrosurgical current (electrosurgical generator, ESU). ground The universal conductor and common return point for electric circuits; earth ground. H hemostasis Coagulation; in electrosurgery, heat produced by the electrosurgical current applied to a transected blood vessel which stops bleeding. hemostat A forceps used to clamp a bleeding vessel and stop blood flow. hertz (Hz) The unit of measurement for frequency, equal to one cycle per second. holster An insulated receptacle in which to store electrosurgical active electrodes when not in use during surgery. Valleylab recommends the use of holsters. Resistance to the flow of alternating current, including simple direct impedance current resistance and the resistance produced by capacitance or inductance. The resistance of a material is its tendency, measured in ohms, to oppose the flow of electric current or, viewed another way, the material's tendency not to conduct the current. **Instant Response Technology** A generator technology that uses a feedback circuit to sense tissue density. As the density of the target tissue varies, the generator's computer-controlled output voltage in certain modes is automatically adjusted. The result is a constant output power to produce a consistent surgical effect in all tissue types.

The introduction or blowing of a gas, vapor or powder into a body cavity or organ (e.g., carbon dioxide into the abdominal cavity during

laparoscopic procedures).

insufflation

insulation failure	The condition that occurs when the insulation barrier around an electrical conductor is breached. As a result, current will travel outside the intended circuit.
insulator	A substance that does not conduct electrical current.
isolated output	The output of an electrosurgical generator that is not referenced to earth ground.
L	
laparoscopy	Examination of abdominal organs by visualization of the inside of the abdominal cavity through an optical instrument/endoscope introduced through a small port made in the cavity wall.
leakage current	Current that flows along an undesirable path, usually to ground; in isolated electrosurgery, radio frequency (RF) current that regains its ground reference.
LLETZ/LEEP	Loop electrosurgical excision procedure for the removal of the transformation zone of the cervix.
load	In electrosurgery, the body tissue involved in the electrosurgical circuit; the source of electrical impedance in a circuit that uses electrical energy for some purpose.
M	
macrobipolar	An electrosurgical waveform used in bipolar surgery, with higher voltage and power than usual bipolar electrosurgical waveforms. It is intended for bipolar cutting or rapid coagulation.
microbipolar	A low voltage bipolar waveform intended for precise desiccation.
monopolar electrosurgery	7
	A type of electrosurgery in which the active electrode is in the surgical wound and the current is directed through the patient's body to the site of the patient return electrode.
monopolar instrument	An electrosurgical instrument or accessory that represents only one electrode; an active electrode.
monopolar output	Grounded or isolated output on an electrosurgical generator that directs current through the patient to a patient return electrode.
N	
necrosis	The destruction of tissue.
0	
ohm (Ω)	The unit of measurement for electrical resistance; volts per ampere

output

The current, voltage, or power produced by an electrical device, such as an electrosurgical generator (ESU).

P

pad site burn

An electrosurgical burn caused by excessive current concentration or density at the patient return electrode.

patient return electrode (return electrode)

A conductive plate or pad (dispersive electrode) placed in direct contact with the patient's skin during electrosurgery. It recovers the radio frequency current from the patient during electrosurgery, disperses, and returns it to the electrosurgical generator completing the circuit. Plates are usually rigid and made of metal or foil-covered cardboard requiring use of a conductive gel; pads are usually flexible.

peak voltage

The maximum voltage of a waveform from zero (0) in either the positive or negative direction.

peak-to-peak voltage

The voltage of a waveform measured from its maximum negative value to its maximum positive value.

PolyHesive Conductive Adhesive

Valleylab's patented, conductive adhesive hydrogel designed to maximize safety at the patient return electrode.

power

The amount of heat energy produced per second, expressed in watts.

R

radio frequency (RF)

Frequencies at which radio signals can be transmitted; the high frequency current used in electrosurgery.

REM contact quality monitoring system

A safety system exclusive to Valleylab that continuously monitors impedance levels between the patient and the patient return electrode. If the REM System detects dangerous impedance levels due to poor pad to patient contact, an alarm will sound and the electrosurgical generator will be disabled.

Valleylab developed the REM contact quality monitoring system to protect patients from burns due to inadequate contact between the patient and the return electrode. Pad site burns are a result of increased impedance at the return electrode site. REM-equipped generators actively monitor the impedance levels at the patient/pad interface. The system is designed to deactivate the generator before an injury can occur, if it detects a dangerously high impedance level at the patient/pad interface.

In order to work properly, REM-equipped generators must use a patient return electrode that is compatible. You can identify this electrode because it has two separate areas and a special plug with a center pin. REM technology has been proven safe in over 85,000,000 procedures.

resistance The lack of conductivity or the opposition to the flow of electric current, measured in ohms. rms voltage Root mean square voltage; the effective average voltage (the average amount of voltage present at any instant) of a waveform. S self-limiting power A performance feature of the generator that limits power output to certain tissue resistance levels. short circuit The status of an electrosurgical circuit when the generator is activated and the active electrode directly touches the return electrode. An electric circuit with no load and, therefore, essentially no resistance. soft coag A coag mode that delivers a high voltage, gentle spark to tissue, with no cutting effect, and provides less depth of tissue necrosis than other coag modes. spark A discharge of electric current across an air gap; essential to electrosurgical cutting and fulguration. A coag mode that affords optimum fulguration. spray suction coagulator An active electrode that evacuates blood from the surgical site and coagulates bleeding vessels almost simultaneously. T transformer In electrosurgical generators, electrical circuitry that changes the ratios of current to voltage, converting low voltage, high current waveforms to high voltage, low current waveforms. volt (V) The unit of measurement for electric potential (voltage); watts (power) per ampere. voltage The force that pushes electric current through resistance; electromotive force or potential difference expressed in volts. The unit of measure of power. waveform A graphic depiction of electrical activity that can show how voltage varies over time as current alternates.

Notes

