*User's Guide*

# Valleylab Force FX™ Electrosurgical Generator

225 110 171

# 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.

**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 Electrosurgical Generator

**Valleylab Part Number:** 945 102 020 **Effective Date:** March 1996

**Patents Pending**

**Manufactured by:**
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## How the User's Guide is Organized

The **Force FX 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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# Service Centers

Valleylab Inc
Boulder, Colorado, USA
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# 1 Introducing the Force FX

This user's guide will instruct you in the use of the Valleylab Force FX Electrosurgical Generator. This section introduces the Force FX, discusses its capabilities, and lists the precautions associated with using the generator safely.

This guide and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. Additional technical information is available in the **Force FX Service Manual**.

## Product Description

The Valleylab Force FX is an isolated output electrosurgical generator that provides the power for cutting, desiccating, and fulgurating tissue during surgery. The generator is used for bipolar and monopolar electrosurgical procedures. The main features of the Force FX are listed below:

- automatic control of output power in relation to tissue impedance
- three bipolar modes: precise, standard, and macrobipolar
- three monopolar cut modes: low voltage cut, pure cut, and blended cut
- three monopolar coag modes (desiccate, fulgurate, and spray) and support for simultaneous coagulation
- the Valleylab REM® Contact Quality Monitoring System, which protects patients against burns at the patient return electrode site
- support for ultrasonic electrosurgery using the Valleylab CUSA® System 200 and CEM™ handpiece

You can use handset or footswitch controls to activate the generator. Receptacles are marked to ensure the correct connection of accessories. Indicators alert you when the generator is activated.

The Force FX allows you to adjust the activation tone volume and reset the mode and power settings used previously. An RF activation port, RS-232 serial port, and expansion port are also included.

The Force FX can be used in conjunction with the Valleylab Force GSU® System and the Valleylab Electroshield Monitor. Refer to the manuals provided with these products for more information.

Specific details about all Force FX features and their functions are provided in Section 2, *Controls, Indicators, and Receptacles.*

## Surgical Applications

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 (desiccate and fulgurate) tissue.

*Electrosurgical cutting* severs tissue with short, intense electric sparks from the active electrode, across air, to the patient tissue.

*Electrosurgical desiccation* dehydrates and destroys tissue without sparking or cutting. More current reaches the patient because the active electrode directly touches the tissue. Desiccation places the greatest demand on the patient return electrode.

*Electrosurgical fulguration* 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.

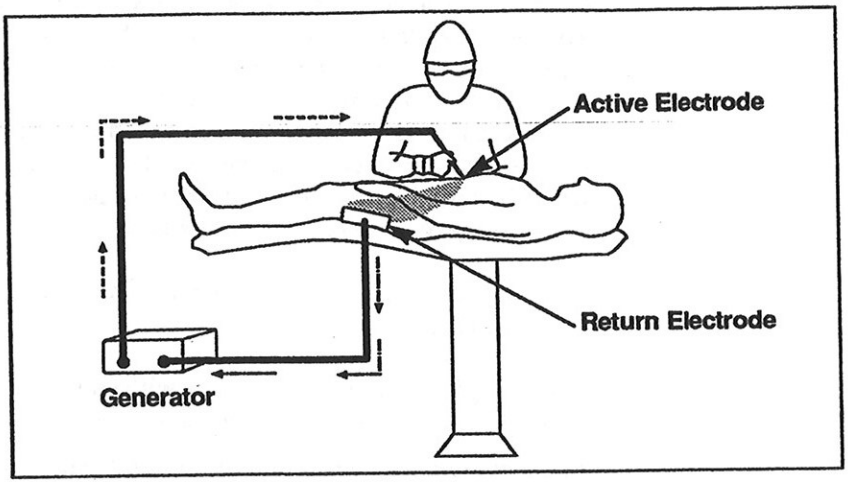
### Effect Mode

The Force FX senses resistance and automatically adjusts the output voltage to maintain a consistent tissue effect across different tissue types. The adjustment, or *effect mode*, is based on the selected mode, the power setting, and the level of tissue resistance. The generator maintains constant output power over a wide range of tissue resistance. The maximum output voltage is controlled to reduce capacitive coupling and video interference and to minimize sparking.

Effect mode is invoked automatically for all bipolar modes and all cut modes. It is not applied to the coag modes because of their fulguration capability.

# 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.

## Force FX Cut and Coag Modes

The Force FX offers three cut modes: ***Low***, ***Pure***, and ***Blend***. These modes provide the power curves surgeons require for diverse surgical applications.

The Force FX permits simultaneous coagulation. It offers three coagulation modes: ***Low (Desiccate)***, ***Med (Fulgurate)***, and ***High (Spray)***. Each mode helps the surgeon control the size of the area and the depth of penetration when coagulating tissue.

For details about the monopolar output characteristics, see Appendix A.

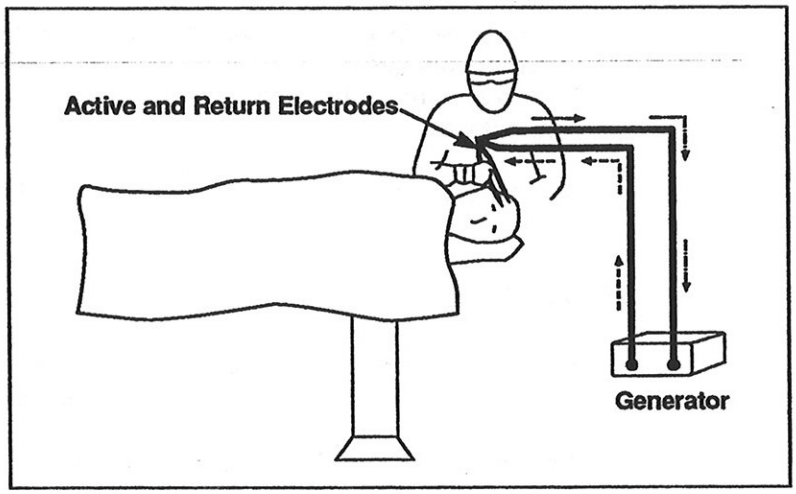
## REM Contact Quality Monitoring System

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 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 hazard of burns at the return electrode site.

## 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 be in laparoscopic surgical environments, or the procedures involve delicate and highly conductive tissue, such as brain, spinal, or eye tissue, in irrigated surgical environments.

- Delicate tissue requires less heat to desiccate quickly. The Force FX provides low voltage, continuous current for faster desiccation without sparking.
- The possibility of sparking increases as desiccated tissue dries and becomes more resistant. The Force FX protects against sparking by limiting the bipolar voltage at relatively high levels of tissue resistance.

### Force FX Bipolar Modes

The Force FX offers three bipolar modes: precise, standard, and macrobipolar.

- *Low (Precise)* may be used when a high degree of precision and fine control over the amount of desiccation are essential.
- *Med (Standard)* may be used for most bipolar applications.
- *Macro* may be used for macrobipolar electrosurgery, during which higher voltages and a higher power curve are necessary. This mode makes a monopolar type waveform available from the bipolar receptacle.

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

## Ultrasonic Electrosurgery

The Force FX works in conjunction with the Valleylab CUSA System 200 for procedures where ultrasonic electrosurgery is desirable.

When you connect a CEM handpiece to the Force FX for ultrasonic electrosurgery, the generator 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 CEM handpiece for cut or coag output, the *Low* cut mode or the *Low (Desiccate)* coag mode is in effect automatically. The remaining cut modes and coag modes are not available to the connected CEM handpiece for ultrasonic electrosurgery.

# 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 operating room staff. 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 Instruments" on page 1-9, *infra*, 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 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 with 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.

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

2. 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.

## General

**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.

**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.

**Caution:** Read the instructions, cautions, and warnings provided with electrosurgical accessories before using.

### 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 [$N_2O$] 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.

## General

### 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 surgical personnel.

### Electrosurgical Smoke

**Caution:** Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and surgical personnel. These studies recommend using surgical masks and adequately ventilating the smoke by using a surgical smoke evacuator or other means.

### 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.

## General

**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 skin-to-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 personnel.

### Servicing

**Warning:** Electric Shock Hazard. Do not remove the cover. Contact authorized personnel for service.

**Notice:** Refer to the **Force FX Service Manual** for maintenance recommendations and function and output power verification procedures.

## Before Surgery

### Active Accessories

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

**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:** 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 operating room personnel.

**Caution:** Accessories labeled "disposable" are single use only. Do not reuse or resterilize.

### 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.

## Before Surgery

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

### 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.

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

**Warning:** The accessory output receptacle is designed for connecting either a handswitching (three-pin) or footswitching (one-pin) accessory, but not both at the same time. Connecting more than one accessory to the accessory output receptacle will activate both accessories simultaneously.

**Caution:** Do not stack equipment on top of the Force FX or place the generator on top of electrical equipment (except the Valleylab Force GSU Unit and the Valleylab Electroshield Monitor). 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 personnel 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.

## During Surgery

### 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).

### 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.

### Forceps

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

## During Surgery

### 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.

### Active Accessories

**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.

**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, surgical personnel, and flammable materials.

**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.

## During Surgery

**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 surgical personnel.

### 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.

### 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.

## During Surgery

- 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 the target tissue.
- Use the lowest power setting that achieves the desired surgical effect and use a low voltage waveform (*Low* cut or *Pure* cut) 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 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.

# 2 Controls, Indicators, and Receptacles

The controls, indicators, and receptacles for accessories are located on the front and rear panels of the Force FX. This section describes each component of the generator and its function.

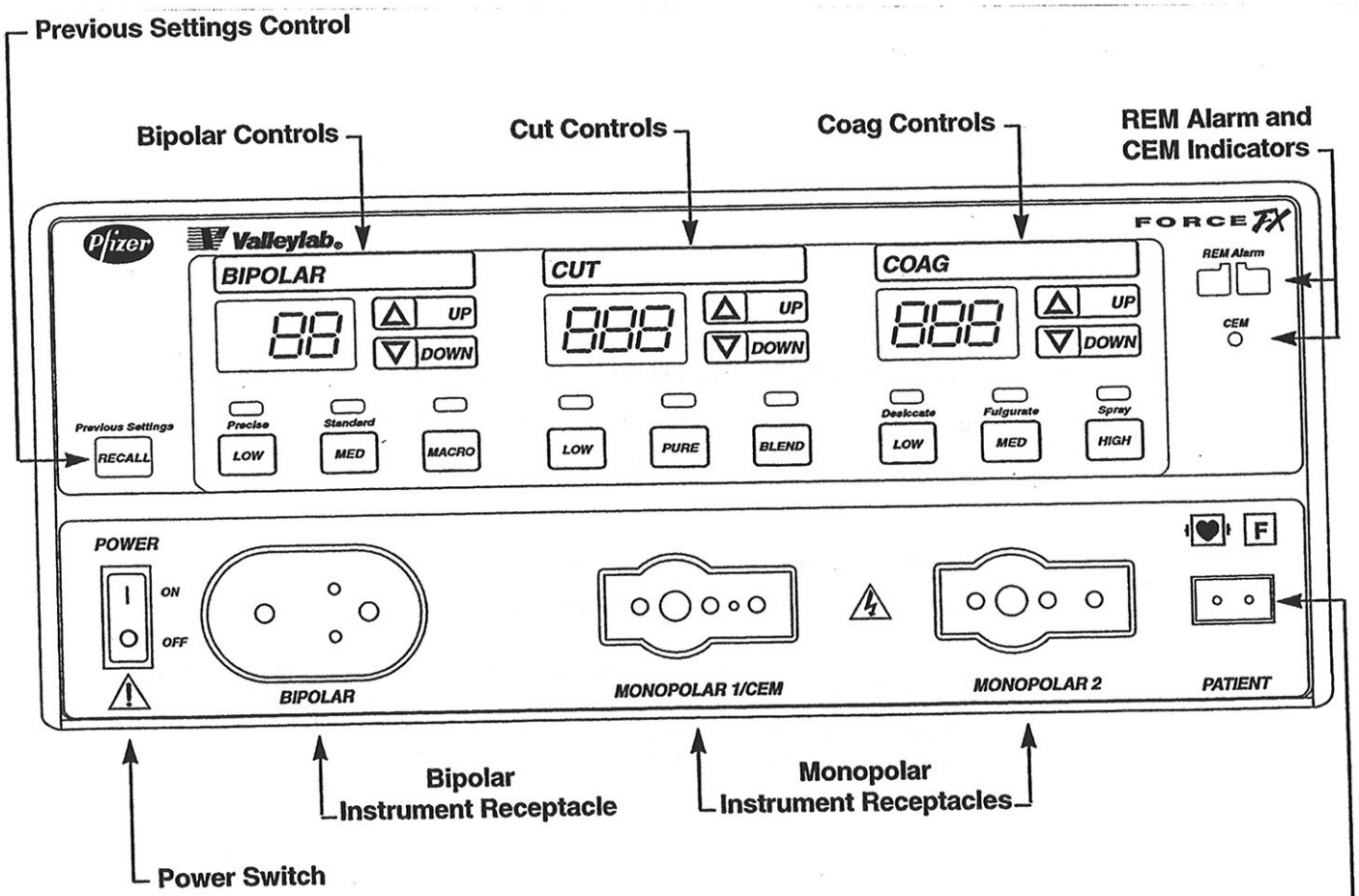
Detailed procedures for setting up the generator for bipolar and monopolar electrosurgery are in Section 3.

**Caution**

Read all warnings, cautions, and instructions provided with the Valleylab Force FX Electrosurgical Generator before using.

## Front Panel

The front panel features are illustrated below. The bipolar, cut, and coag controls are described in detail on the following pages. Information about the *Previous Settings* control, the instrument receptacles, and the REM patient return electrode monitoring feature is also provided.




This switch supplies power to the generator.

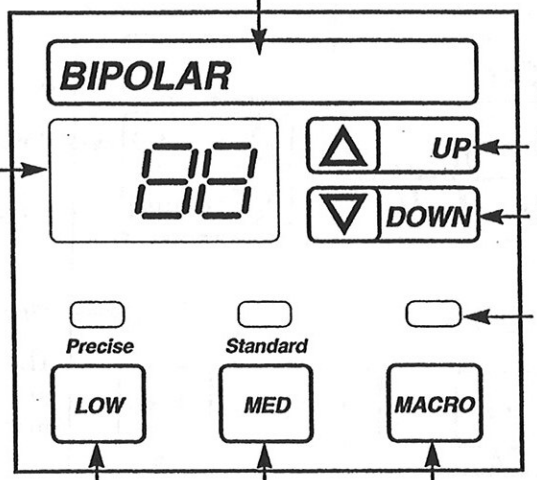
- To turn on the generator, press *On* (I).
- To turn off the generator, press *Off* (O).

## Bipolar Controls

The bipolar controls are described below. For information about changing modes and adjusting the power, see *Changing the Mode and Power Settings* later in this section.

**Bipolar Indicator Bar**

When you activate bipolar, this bar illuminates blue and the bipolar activation tone sounds.




**Power Buttons**

Press Δ to increase the power.

Press ∇ to decrease the power.

**Power Display**

Shows the power setting, in watts, for the selected mode.

**Mode Indicators**

The indicator illuminates green when you press the mode button below it.

**Low (Precise) Mode Button**

Select for fine bipolar tissue desiccation. 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 Mode Button**

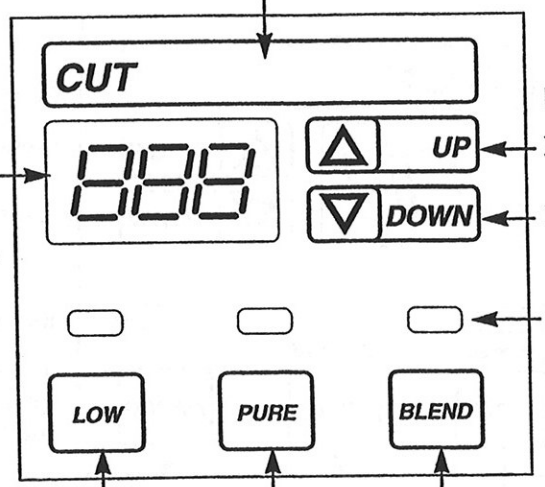
Select for macrobipolar output. This mode provides the higher voltages and power curve necessary for macrobipolar electrosurgery. It makes a higher voltage sinusoidal waveform available from the ***Bipolar*** receptacle.

**Med (Standard) Mode Button**

Select for standard bipolar tissue desiccation. The voltage is kept low to prevent sparking. The power remains constant over a specific range of tissue resistance, allowing a consistent tissue effect. When you turn on the Force FX, this mode is selected.

## Monopolar Cut Controls

The cut controls are described below. For information about changing modes and adjusting the power, see *Changing the Mode and Power Settings* later in this section.




**Cut Indicator Bar**

When you activate cut, this bar illuminates yellow and the cut activation tone sounds.

**Power Buttons**

Press Δ to increase the power.

Press ∇ to decrease the power.

**Power Display**

Shows the power setting, in watts, for the selected mode.

**Mode Indicators**

The indicator illuminates green when you press the mode button below it.

**Low Mode Button**

Select for a cut with little or no sparking. As tissue resistance increases, the power drops off quicker than the *Pure* mode. This mode provides a continuous sine waveform. It is useful for laparoscopic surgery.

**Blend Mode Button**

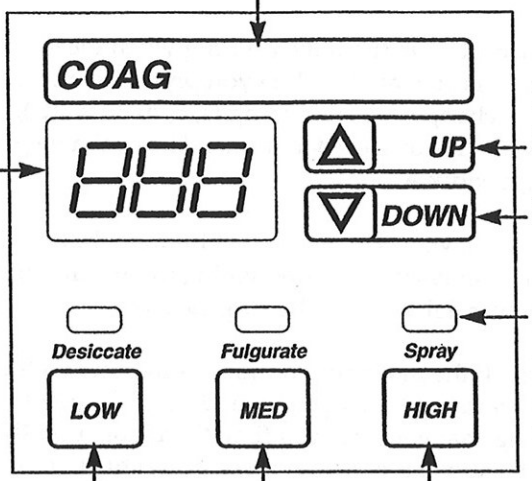
Select for slower cutting and additional hemostasis. This mode provides a blended waveform.

**Pure Mode Button**

Select for an even cut with little or no hemostasis. This mode offers good performance over a wide range of tissue resistance. It provides the maximum output power curve available from the Force FX. Like the *Low* mode, this mode's sine waveform is continuous. When you turn on the Force FX, this mode is selected.

## Monopolar Coag Controls

The coag controls are described below. For information about changing modes and adjusting the power, see *Changing the Mode and Power Settings* later in this section.




**Coag Indicator Bar**

When you activate coag, this bar illuminates blue and the coag activation tone sounds.

**Power Display**

Shows the power setting, in watts, for the selected mode.

**Power Buttons**

Press Δ to increase the power.

Press ∇ to decrease the power.

**Mode Indicators**

The indicator illuminates green when you press the mode button below it.

**Low (Desiccate) Mode Button**

Select to desiccate the area of tissue that is in direct contact with the active electrode.

**High (Spray) Mode Button**

Select to evenly coagulate a wide area of tissue with a spray of sparks. This mode offers optimum fulguration over a wider area and with less spot penetration than *Med (Fulgurate)*.

**Med (Fulgurate) Mode Button**

Select to fulgurate an area of tissue. This mode is useful for general fulguration applications. When you turn on the Force FX, this mode is selected.

## Changing the Mode and Power Settings

When you press a mode button to select a mode, the indicator above that button illuminates green. You can activate only one mode at a time. You cannot change the mode while the generator is activated.

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 for ***Low*** *(Desiccate)*, when you select ***Med*** *(Fulgurate)*, the power setting does not change.

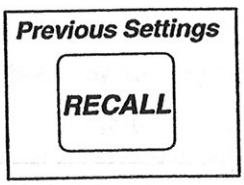
You can change the power setting when the generator is on, including when it is activated. When you press and release the power button, the power changes by one setting (1, 5, or 10 watts), based on the settings available for the selected mode. The available power settings are listed in Appendix A.

Each time you press the power button while the generator is activated, the power changes by one setting to prevent rapid increases or decreases in power delivered to the surgical site.

To reach the maximum or minimum power setting for the selected mode, press and hold the ***Up*** ( Δ ) or ***Down*** ( ∇ ) power button. The power setting changes slowly at first, then more rapidly. If you try to set the power above the maximum or below the minimum for the selected mode, a warning tone sounds.

## Recalling the Previous Settings

When you turn off the generator or disconnect the power cord, the Force FX saves the most recently used mode settings and power settings automatically.



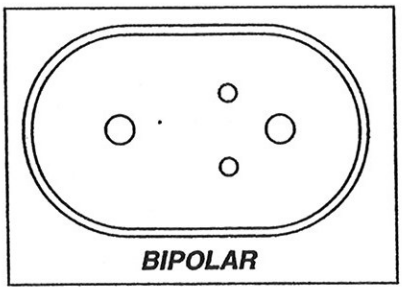

When the generator is on, press ***Recall*** to reset the previous settings. When you press ***Recall***, the previous power settings are displayed and the indicators for the selected modes illuminate.

## Bipolar Instrument Receptacle

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




Connect a footswitching instrument with a two-pin connector.

**or**

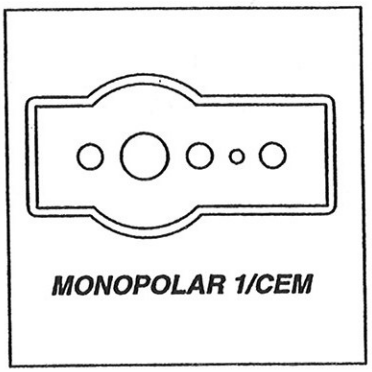
Connect a handswitching instrument with a three-pin connector.

## Monopolar Instrument Receptacles

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

**Warning**

**The accessory output receptacle is designed for connecting either a handswitching (three-pin) or footswitching (one-pin) accessory, but not both at the same time. Connecting more than one accessory to the accessory output receptacle will activate both accessories simultaneously.**




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

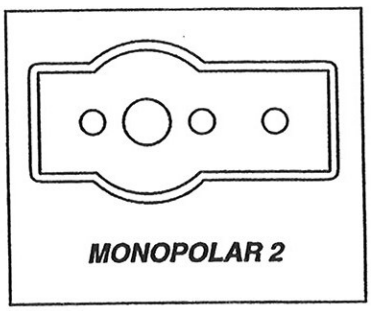
- a single-pin footswitching instrument

  **or**

- a three-pin handswitching instrument

  **or**

- a four-pin CEM handpiece (See *Connecting a CEM Handpiece* later in this section.)




Connect one monopolar instrument to the ***Monopolar 2*** receptacle:

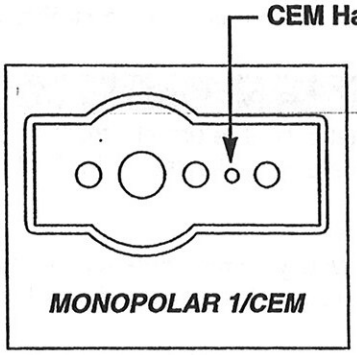
- a single-pin footswitching instrument

  **or**

- a three-pin handswitching instrument

### Connecting a CEM Handpiece

You can use the Force FX with the Valleylab CUSA System 200 for ultrasonic electrosurgery by connecting a CEM handpiece to the ***Monopolar 1/CEM*** receptacle.




The ***Monopolar 1/CEM*** receptacle contains a port for connecting a CEM handpiece.

When you connect a CEM handpiece, the ***CEM*** indicator on the upper right of the front panel illuminates green.

While a CEM handpiece is connected, the generator limits the monopolar output power automatically.

- The maximum power setting for monopolar cut is 100 watts.
- The maximum power setting for monopolar coag is 70 watts.

When you activate cut or coag output, ***Low*** cut or ***Low (Desiccate)*** coag is in effect automatically. The remaining cut and coag modes are not available to the connected CEM handpiece for ultrasonic electrosurgery.

### 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 coag mode: ***Low (Desiccate)***, ***Med (Fulgurate)***, or ***High (Spray)***. 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 coag power setting. Simultaneous cut is not available.

You can use a CEM handpiece for simultaneous coag when you connect a second instrument to the ***Monopolar 2*** receptacle. Only ***Low (Desiccate)*** coag is available to the second instrument and the maximum power is limited to 70 watts.

## Activating Connected Instruments

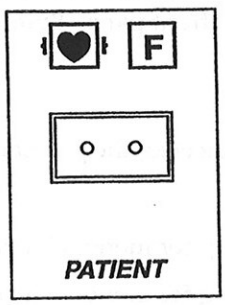
To activate a handswitching instrument or a CEM handpiece, use the controls on the instrument **or** on the appropriate footswitch (bipolar or monopolar). To activate a footswitching instrument, you must use a footswitch. See *Footswitch Receptacles* later in this section.

# Patient Return Electrode Monitoring

A patient return electrode is required for monopolar electrosurgery. When you activate monopolar output, the generator connects the patient return electrode path. If you activate bipolar output when a patient return electrode is applied to the patient, the generator disconnects the return electrode path to eliminate the possibility of current dispersal.

**Warning**

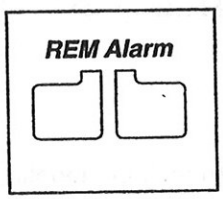
Using a conventional patient return electrode without the REM safety feature will not activate the Valleylab REM Contact Quality Monitoring System.




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

For monopolar electrosurgery, apply a Valleylab REM patient return electrode to the patient and connect it to the ***Patient*** receptacle on the front panel.

## REM Alarm Indicator




The ***REM Alarm*** indicator illuminates red until you connect a REM patient return electrode to the ***Patient*** receptacle. Then the indicator illuminates green. (When you connect an electrode that does not have the REM safety feature, the indicator light is extinguished. It does not illuminate green.)

If the REM system senses an alarm condition, the indicator flashes red, a tone sounds twice, and the generator disables RF output. The ***REM Alarm*** indicator illuminates red until you correct the alarm condition.

When you correct the REM alarm condition, RF output is enabled and the ***REM Alarm*** 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.

### REM Alarm Situations

The conditions listed below 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 is not in 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.

## How the REM System Works

The Valleylab REM Contact Quality Monitoring system is activated when you apply a REM patient return electrode to the patient and connect it to the ***Patient*** receptacle. The REM system measures resistance continuously.

The REM system compares the resistance at the return electrode site to a standard range of safe resistance (between 5 and 135 ohms). This built-in acceptance range eliminates 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.
- The resistance increases 40% above the initial patient and REM electrode contact resistance as measured by the REM system.

## 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 described above in *How the REM System Works*. 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.

When you connect a patient return electrode that does not have the REM safety feature to the generator, the ***REM Alarm*** indicator does not illuminate green. Instead, the indicator light is extinguished. If the generator detects a break in continuity between the electrode and the generator, the ***REM Alarm*** indicator illuminates red.

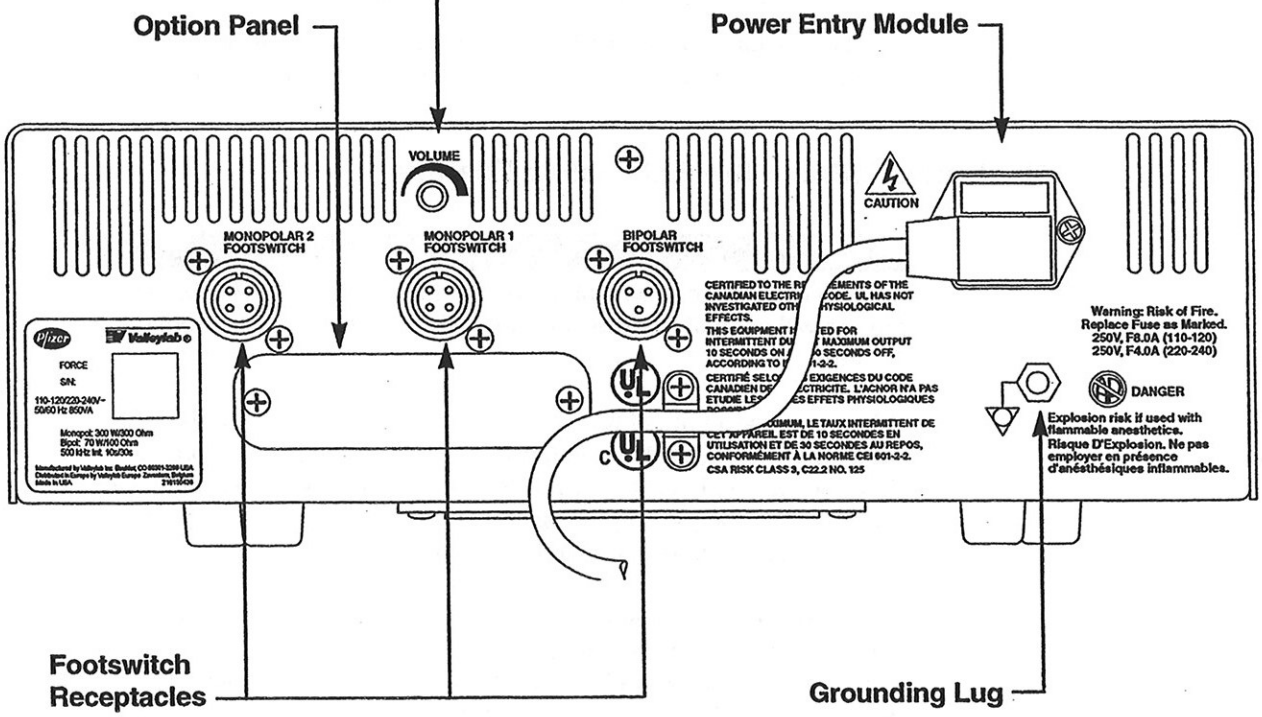
## Rear Panel

The rear panel features are illustrated below. The footswitch receptacles, power entry module, and option panel are described on the following pages.

### Volume Control

You can adjust the volume of the tones that sound when the generator is being activated. To ensure that the surgical team is alerted to inadvertent activation, the activation tones cannot be silenced. The alarm tone volume is not adjustable.

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




### Grounding Lug

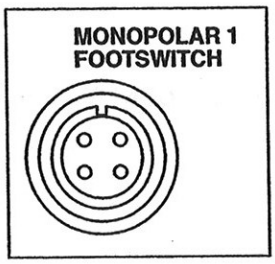
Some institutions require that electrosurgical generators be connected to protective earth ground, using an equipotential grounding cable. The Force FX is equipped with an equipotential grounding lug for that purpose.

# Footswitch Receptacles

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

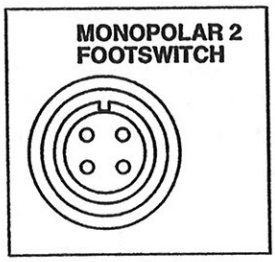
## Monopolar Footswitch Receptacles

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*** receptacle on the front panel.

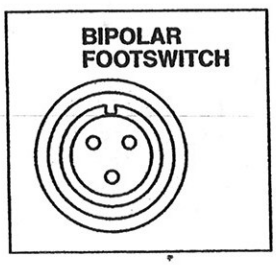



Connect a two-pedal monopolar footswitch to the ***Monopolar 2 Footswitch*** receptacle.

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

## Bipolar Footswitch Receptacle

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

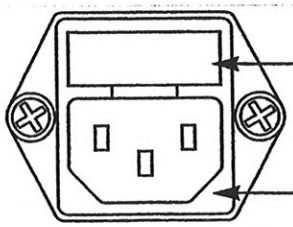



Connect a single-pedal bipolar footswitch to the ***Bipolar Footswitch*** receptacle.

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

## Power Entry Module

The power entry module consists of a power cord receptacle and a fuse drawer. A power cord with a three-prong hospital grade connector is provided with the generator.



**Fuse Drawer**

The fuse drawer contains two fuses. The **Force FX Service Manual** contains instructions for changing the fuses.

**Power Cord Receptacle**

## Option Panel

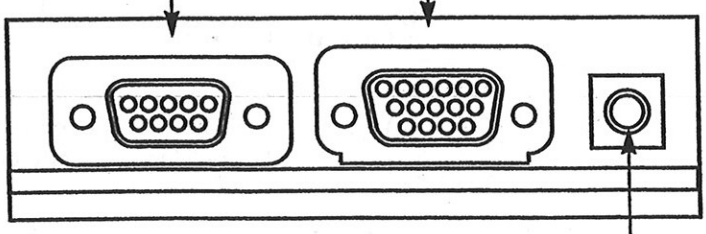
A removable plate on the rear panel covers a serial port, an expansion port, and an RF (radio frequency) activation port. To review the technical specifications for each port, refer to Appendix A.

**Serial Port**

This port accepts a 9-pin connector. Service personnel can connect a computer to the serial port and obtain information about the generator, using the RS-232 communications protocol.

**Expansion Port**

This 15-pin port allows a connected device to receive information about the RF voltage and current being generated. The connected device can signal the generator to halt RF output through this port.



**RF Activation Port**

This port allows a connected device to receive information about RF activation of the generator, which can generate a response in the device.

# 3 Before Surgery

This section contains procedures for setting up and verifying the operation of the Force FX. Specific instructions for preparing the generator for bipolar, monopolar (including simultaneous coag), and ultrasonic electrosurgery are provided.

**Caution**

Read all warnings, cautions, and instructions provided with the Valleylab Force FX Electrosurgical Generator before using.

**Caution**

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

## Setup Procedure Summary

The general procedure describing what you must do to prepare for electrosurgery is summarized below. If you are an experienced user who is familiar with the Force FX, you may prefer to follow this abbreviated procedure. If, however, you are not familiar with how the generator should be set up, refer to *Preparing the Force FX for Surgery* later in this section. Then, follow the appropriate steps to prepare for bipolar, monopolar, or ultrasonic electrosurgery.

1. Set up the generator in the operating room and connect the generator power cord to a wall receptacle.
2. Turn on the generator and verify that the self-test is successfully completed.

*Bipolar Surgery:*

a. If you plan to use a footswitch, connect a bipolar footswitch to the ***Bipolar Footswitch*** receptacle on the rear panel.

b. Connect the bipolar instrument (handswitching or footswitching) to the ***Bipolar*** receptacle on the front panel.

c. Verify or change the bipolar mode and power setting. If desired, press ***Recall*** to display the previous settings.

*Monopolar Surgery:*

a. If you plan to use a footswitch, connect a monopolar footswitch to the rear panel.

- For output to the instrument you plan to connect to the ***Monopolar 1/CEM*** receptacle, connect the footswitch to the ***Monopolar 1 Footswitch*** receptacle.
- For output to the instrument you plan to connect to the ***Monopolar 2*** receptacle, connect the footswitch to the ***Monopolar 2 Footswitch*** receptacle.

b. Apply the patient return electrode to the patient and connect it to the ***Patient*** receptacle on the front panel.

c. Connect the monopolar instrument (handswitching or footswitching) to either monopolar receptacle on the front panel. For simultaneous coag, connect two monopolar instruments.

d. Verify or change the cut and coag modes and power settings. If desired, press ***Recall*** to display the previous settings.

*Ultrasonic Surgery:*

a. Assemble the CEM handpiece and set up the CUSA System 200.

b. If you plan to use a footswitch, connect a monopolar footswitch to the ***Monopolar 1 Footswitch*** receptacle on the rear panel.

c. Apply the patient return electrode to the patient and connect it to the ***Patient*** receptacle on the front panel.

d. Connect the CEM handpiece to the ***Monopolar 1/CEM*** receptacle on the front panel. For simultaneous coag, connect a second monopolar instrument to the ***Monopolar 2*** receptacle.

e. Verify or change the cut and coag power settings.

# Preparing the Force FX for Surgery

## Step 1 – Set up the generator.

1. Turn off the generator by pressing the front panel *Off* (O) switch.

**Caution**

Do not stack equipment on top of the Force FX or place the generator on top of electrical equipment (except the Valleylab Force GSU Unit and the Valleylab Electroshield Monitor). These configurations are unstable and/or do not allow for adequate cooling.

**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.

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

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

   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.

**Notice**

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

3. Plug the generator power cord into the rear panel receptacle.

**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.

**Caution**

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

4. Plug the generator power cord into a grounded receptacle. Grasp the plug, not the power cord. Do not pull on the cord itself.

# Preparing the Force FX for Surgery

## Step 2 – Verify the operation of the generator.

Turning on the generator initiates an internal self-test to verify the calibration. The self-test also checks the operation of the speaker, all visual indicators, and the displays.

**Warning**

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

**Caution**

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

1. Turn on the generator by pressing the front panel *On* ( | ) switch. Verify the following:
   - All visual indicators and displays on the front panel illuminate.
   - Activation tones sound to verify that the speaker is working properly.

**Caution**

Do not turn the activation tone down to an inaudible level. The activation tone alerts personnel when an accessory is active.

**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.

2. If the test is successful, a tone sounds. Verify the following:
   - Indicators above the selected mode buttons (*Med* bipolar, *Pure* cut, and *Med* coag) illuminate green.
   - Each digital display shows a power setting of 1 watt.
3. If the test is not successful, an alarm tone sounds. A number may momentarily appear in the *Cut* display and, in most cases, RF output is disabled. Note the number and refer to *Responding to System Alarms* in Section 6.

Next, connect the accessories and set the generator controls for surgery. See *Preparing for Bipolar or Macrobipolar Surgery*, *Preparing for Monopolar Surgery*, or *Setting Up for Ultrasonic Electrosurgery* later in this section.

# Preparing for Bipolar or Macrobipolar Surgery

## Step 1 – Connect the bipolar footswitch.


Connect a bipolar footswitch if you plan to use a footswitching bipolar instrument. You may use the footswitch to activate a handswitching instrument, if desired.

On the rear panel, insert the three-pin connector for the single-pedal bipolar footswitch into the ***Bipolar Footswitch*** receptacle.

## Step 2 – Connect the bipolar instrument.

**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 operating room personnel.

1. Prepare the surgical instrument to be used for the procedure. Refer to the instructions provided with the instrument.

**Warning**

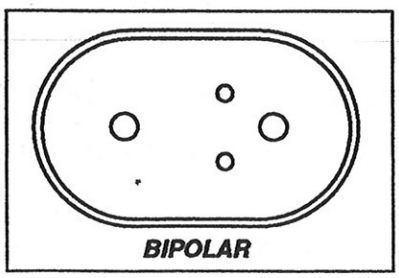
Electric Shock Hazard.

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

**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.

2. Connect the bipolar instrument to the receptacle on the front panel.




**Handswitching Instrument**

Insert the three-pin connector into the ***Bipolar*** receptacle.

**Footswitching Instrument**

Insert the two-pin connector into the ***Bipolar*** receptacle.

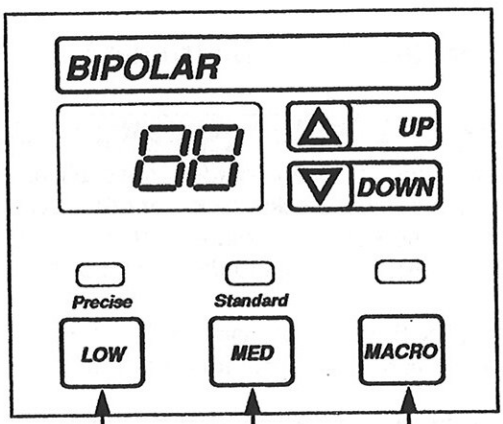
If you connect a footswitching instrument or wish to use a footswitch, see *Step 1 – Connect the bipolar footswitch.*

# Preparing for Bipolar or Macrobipolar Surgery

## Step 3 – Set the bipolar output.

After the internal self-test, preset power and mode settings are in effect. If desired, you can recall the settings that were in use the last time the generator was turned off.

1. (Optional) To display the previous settings, press *Recall*.
2. To set the bipolar mode, press the *Low*, *Med*, or *Macro* button. The indicator above the button you press illuminates green.




**Low (Precise)**

Use for fine bipolar tissue desiccation. 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**

Use to access the higher voltages and power curve for macrobipolar electrosurgery. A higher voltage cut waveform is made available from the bipolar receptacle for this mode.

**Med (Standard)**

Use for standard bipolar tissue desiccation. The voltage is kept low to prevent sparking. The power remains constant over a specific range of tissue resistance, allowing a consistent tissue effect.

**Caution**

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

3. To increase the power for the selected mode, press the white *Up* ( Δ ) button. To decrease the power, press the white *Down* ( ∇ ) button.

   The maximum bipolar (and macrobipolar) power setting is 70 watts.

The Force FX is now ready for bipolar or macrobipolar electrosurgery.

# Preparing for Monopolar Surgery

If you plan to use the Force FX for simultaneous coag, review the information in *Using the Force FX for Simultaneous Coag* below. Preparing for monopolar surgery, including simultaneous coag, includes the following tasks:

- Connect a monopolar footswitch, if desired.
- Select the patient return electrode.
- Choose an appropriate site for the patient return electrode.
- Apply the patient return electrode to the patient and connect it to the generator.
- Connect the surgical instrument(s) to be used for monopolar surgery.
- Select the cut mode and set the power.
- Select the coag mode and set the power.

## Using the Force FX for Simultaneous Coag

The Force FX permits simultaneous coagulation, using two active electrodes from the two monopolar output receptacles. Simultaneous cut is not available.

When you simultaneously activate two monopolar instruments for coag output, each receives a percentage of the coag power setting. The amount each receives depends on the tissue resistance 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.

### Simultaneous Coag with the CUSA CEM System

You can use a CEM handpiece and a second instrument for simultaneous coag. When you connect the CEM handpiece, the maximum power setting for coag output is 70 watts.

When you activate the CEM handpiece for simultaneous coag, ***Low (Desiccate)*** coag is in effect automatically. The remaining coag modes are not available to the CEM handpiece or the second instrument.

As long as the CEM handpiece remains connected to the generator, the maximum power available to the second instrument for each coag mode is limited to 70 watts.

# Preparing for Monopolar Surgery

## Step 1 – Connect the monopolar footswitch.

You must connect a monopolar footswitch if you plan to use a footswitching monopolar instrument. You may use a footswitch to activate a handswitching instrument or a CEM handpiece, if desired.

### Simultaneous Coag

Connect two monopolar footswitches if you want to use them to activate simultaneous coag output for instruments connected to both monopolar receptacles on the front panel.

1. If you plan to use a footswitch for monopolar activation, connect the two-pedal monopolar footswitch to the rear panel.


**Monopolar 1 Output**

Insert the four-pin connector for the monopolar footswitch into the ***Monopolar 1 Footswitch*** receptacle.

The footswitch activates the instrument you connect to the ***Monopolar 1/CEM*** receptacle on the front panel.


**Monopolar 2 Output**

Insert the four-pin connector for the monopolar footswitch into the ***Monopolar 2 Footswitch*** receptacle.

The footswitch activates the instrument you connect to the ***Monopolar 2*** receptacle on the front panel.

# Preparing for Monopolar Surgery

## Step 2 – Choose a patient return electrode.

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

**Warning**

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

### Electrodes Without the REM Safety Feature

The REM Contact Quality Monitoring System operates in conjunction with the REM patient return electrode. Using a patient return electrode without the REM safety feature may result in a patient burn.

### Capacitive Pads

Valleylab does not recommend the use of capacitive pads because of a potential for high resistance at the interface between the patient and the patient return electrode.

### Shunt Cord

Some surgical instruments (e.g., colonoscopes) allow substantial leakage current. To safely shunt the current to the generator, use a REM return electrode and a shunt cord (s-cord), which requires a special Valleylab adapter.

### Metal Plates

Use a conductive gel specifically designed for electrosurgery. Using a metal plate bypasses the REM safety feature.

# Preparing for Monopolar Surgery

## Step 3 – Choose a site for the patient return electrode.

Choose an appropriate site on the patient for the patient return electrode. Refer to the manufacturer's instructions. Follow these guidelines when choosing a site:

- as close to the surgical site as possible
- good muscle tone and blood supply—Give special consideration to patients with tourniquets or who have especially dry, oily, or frail skin.
- no hairy surfaces, bony prominences, scar tissue, fat, or surface area irregularities

### Pacemakers

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 will follow 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.

**Warning**

**Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced with 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.**

### Using Two Generators Simultaneously

When you use two generators (and two patient return electrodes) simultaneously on the same patient, 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.

To allow for adequate cooling, do not stack the generators or place them close together.

# Preparing for Monopolar Surgery

## Step 4 – Connect the patient return electrode.

**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.

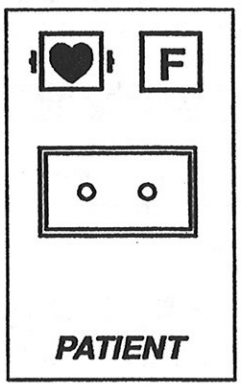
**Warning**

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.

1. Apply the patient return electrode to the patient. For correct application of the patient return electrode, follow all instructions found in the product packaging.
2. Connect the patient return electrode to the generator.




Insert the connector for the patient return electrode into the ***Patient*** receptacle on the front panel.

# Preparing for Monopolar Surgery

## Step 5 – Connect the monopolar instrument.

For most procedures, you will connect only one monopolar instrument (handswitching or footswitching). Cut or coag output is available from both monopolar receptacles.

### Simultaneous Coag

Connect two monopolar instruments for simultaneous coag.

If you plan to use the CUSA CEM System for simultaneous coag, first connect a monopolar instrument to the ***Monopolar*** 2 receptacle as described below in steps 1 and 2. Then, refer to *Setting Up for Ultrasonic Electrosurgery* later in this section for instructions on connecting the CEM handpiece and changing the monopolar settings.

**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 operating room personnel.

1. Prepare the surgical instrument to be used for the monopolar procedure. Refer to the instructions provided with the instrument.

**Warning**

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.

**Warning**

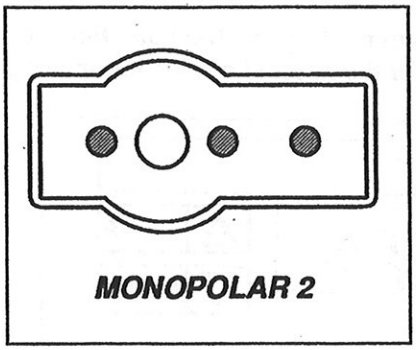
Connect accessories to the proper receptacle. Improper connection of accessories may result in inadvertent accessory activation or other potentially hazardous conditions. Follow the instructions provided with electrosurgical accessories for proper connection and use.

2. Connect the monopolar footswitching or handswitching instrument to the ***Monopolar*** 2 receptacle on the front panel as illustrated on the next page.

# Preparing for Monopolar Surgery

**Warning**

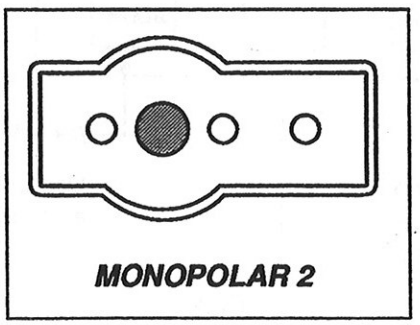
The accessory output receptacle is designed for connecting either a handswitching (three-pin) or footswitching (one-pin) accessory, but not both at the same time. Connecting more than one accessory to the accessory output receptacle will activate both accessories simultaneously.




**Handswitching Instrument**

Insert the three-pin connector into the ***Monopolar 2*** receptacle.

If you wish to use a footswitch to activate the handswitching instrument, connect a footswitch as described earlier in this section. See *Step 1 – Connect the monopolar footswitch.*




**Footswitching Instrument**

Insert the single-pin connector into the ***Monopolar 2*** receptacle.

Verify that a monopolar footswitch is connected to the ***Monopolar 2 Footswitch*** receptacle as described earlier in this section. See *Step 1 – Connect the monopolar footswitch.*

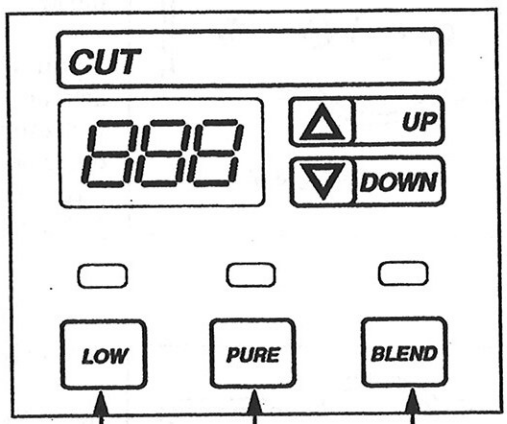
3. To connect an instrument to the ***Monopolar 1/CEM*** receptacle, complete steps 1 and 2, substituting ***Monopolar 1/CEM*** for ***Monopolar 2.***

# Preparing for Monopolar Surgery

## Step 6 – Set the cut output.

After the internal self-test, preset power and mode settings are in effect. If desired, you can recall the settings that were in use the last time the generator was turned off.

1. (Optional) To display the previous settings, press *Recall*.
2. To set the cut mode, press the *Low*, *Pure*, or *Blend* button. The indicator for the selected mode illuminates green.




**Low**

Use for a cut with little or no sparking. As tissue resistance increases, the power drops off quicker than the *Pure* mode. This mode is useful for laparoscopic surgery.

**Pure**

Use for an even cut with little or no hemostasis. This mode offers good performance over a wide range of tissue resistance. It provides the maximum output power curve available from the Force FX.

**Blend**

Use for slower cutting and additional hemostasis.

**Caution**

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

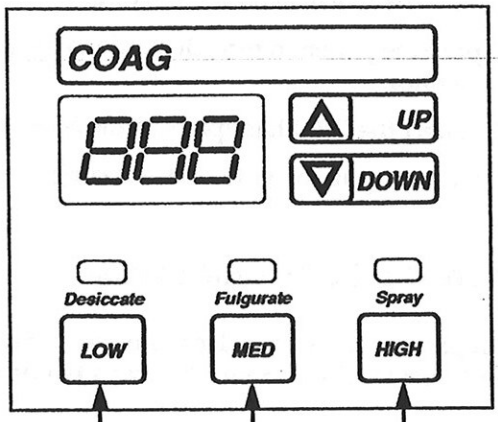
3. To increase the power for the cut mode you selected, press the yellow *Up* ( Δ ) button. To decrease the power, press the yellow *Down* ( ∇ ) button.

   The maximum power setting for *Low* and *Pure* is 300 watts. The maximum power setting for *Blend* is 200 watts.

# Preparing for Monopolar Surgery

## Step 7 – Set the coag output.

1. To set the coag mode, press the *Low, Med,* or *High* button. The indicator for the selected mode illuminates green.




**Low (Desiccate)**

Use to desiccate the area of tissue that is in direct contact with the active electrode.

**High (Spray)**

Use to evenly coagulate a wide area of tissue with a spray of sparks. This mode offers optimum fulguration over a wider area and with less spot penetration than *Med (Fulgurate).*

**Med (Fulgurate)**

Use to fulgurate an area of tissue. This mode is useful for general fulguration applications.

**Caution**

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

2. To increase the power for the selected coag mode, press the blue *Up* ( Δ ) button. To decrease the power, press the blue *Down* ( ∇ ) button.

   The maximum power setting for each coag mode is 120 watts.

The Force FX is now ready for monopolar electrosurgery.

# Setting Up for Ultrasonic Electrosurgery

You use the Valleylab CUSA System 200 and CEM handpiece with the Force FX for ultrasonic electrosurgery. Setting up for ultrasonic electrosurgery includes the following tasks:

- Assemble the CEM handpiece and set up the CUSA System 200.
- Connect a footswitch for CEM output, if desired.
- Apply the patient return electrode to the patient and connect it to the generator.
- Connect the CEM handpiece to the ***Monopolar 1/CEM*** receptacle.
- Set the output power for cut and coag.

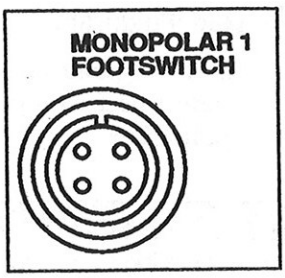
## Step 1 – Prepare the CUSA CEM system.

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

1. Assemble and sterilize the CUSA handpiece with the CEM nosecone prior to the time of use.
2. Set up the CUSA system.

## Step 2 – Connect the monopolar footswitch.

You may use a footswitch to activate a CEM handpiece, if desired.




On the rear panel, insert the four-pin connector for the monopolar footswitch into the ***Monopolar 1 Footswitch*** receptacle.

# Setting Up for Ultrasonic Electrosurgery

## Step 3 – Connect the patient return electrode.

Valleylab recommends the use of REM patient return electrodes to maximize patient safety. For further information, refer to *Preparing for Monopolar Surgery, Step 2 – Choose a patient return electrode.*

**Warning**

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

1. Choose an appropriate site for the patient return electrode as described earlier in *Preparing for Monopolar Surgery, Step 3 – Choose a site for the patient return electrode.*

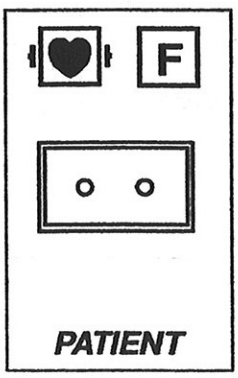
**Warning**

The safe use of monopolar electrosurgery requires proper placement of the patient return electrode. To avoid radio frequency 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.

2. Apply the patient return electrode to the patient. For correct application of the patient return electrode, follow all instructions found in the product packaging.
3. Connect the patient return electrode to the generator.




Insert the connector for the patient return electrode into the ***Patient*** receptacle on the front panel.

# Setting Up for Ultrasonic Electrosurgery

## Step 4 – Connect the CEM handpiece.

**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 operating room personnel.

1. Verify that the CUSA system is set up properly and the CEM handpiece has been assembled and sterilized.

**Warning**

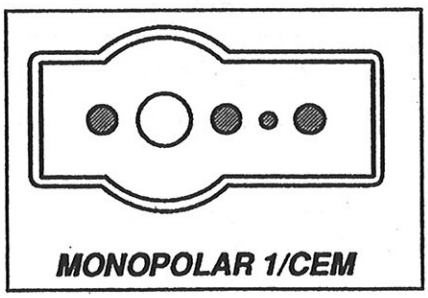
Electric Shock Hazard.

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

**Warning**

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.

2. Connect the CEM handpiece to the generator.




Insert the four-pin connector for the CEM handpiece into the *Monopolar 1/CEM* receptacle on the front panel.

The *CEM* indicator on the upper right of the front panel illuminates green when you connect the CEM handpiece.

# Setting Up for Ultrasonic Electrosurgery

## Step 5 – Set the output power.

When you use the CEM handpiece for ultrasonic electrosurgery you do not need to select a mode. ***Low*** cut or ***Low (Desiccate)*** coag is in effect automatically when you activate the handpiece for cut or coag output.

### Simultaneous Coag

When you activate the CEM handpiece for simultaneous coag, ***Low (Desiccate)*** coag is in effect automatically. The remaining coag modes are not available to the CEM handpiece or the second instrument.

The maximum power available to the second instrument for each coag mode is limited to 70 watts as long as the CEM handpiece remains connected to the generator.

**Caution**

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

1. Verify or change the ***Low*** cut power setting.

   To increase the cut power, press the yellow ***Up*** ( Δ ) button. To decrease the power, press the yellow ***Down*** ( ∇ ) button.

   The maximum cut power is 100 watts.

2. Verify or change the ***Low (Desiccate)*** coag power setting.

   To increase the coag power, press the blue ***Up*** ( Δ ) button. To decrease the power, press the blue ***Down*** ( ∇ ) button.

   The maximum coag power is 70 watts.

The Force FX is now ready to be used with the Valleylab CUSA System 200 for ultrasonic electrosurgery.

## *Notes*

# 4 During Surgery

Just prior to surgery, review the general precautions and check the connections of all accessories. For monopolar electrosurgery, check the patient return electrode. Verify the mode and power settings with the surgeon and review the information on using low power settings. Activate the surgical instrument, adjust the volume of activation tones, and respond to alarms, as needed.

## General Precautions

### Patients with Pacemakers

Monitor pacemakers and keep a defibrillator available during surgery.

**Warning**

Use electrosurgery with caution in the presence of internal or external pacemakers. Interference produced with 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.

## Electrosurgical Smoke

**Caution**

Studies have shown that smoke generated during electrosurgical procedures can be potentially harmful to patients and surgical personnel. These studies recommend using surgical masks and adequately ventilating the smoke by using a surgical smoke evacuator or other means.

## Active Accessories

**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.

**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, surgical personnel, and flammable materials.

## 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).

## Checking Accessory Connections

Verify that all accessories are properly connected to the generator.

**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 personnel.**

**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.**

When multiple accessories are used, keep lead wires separate. To reduce cross coupling, do not twist, bundle, or clamp them together.

## Checking the Patient Return Electrode

The Force FX is equipped with the Valleylab REM Contact Quality Monitoring System, which operates in conjunction with a REM patient return electrode. Any substitutions of the REM patient return electrode may compromise the REM safety feature and result in a patient burn.

**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 bipolar, cut, and coag modes with the surgeon. You can change modes when the generator is on, but not activated.

*To change the mode,* press the desired bipolar, cut, or coag mode button.

# Changing the Power Setting

**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.

Verify the power settings for the selected modes 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*** ( Δ ) button for the selected mode.

*To decrease the power*, press the ***Down*** ( ∇ ) 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.

Each time you press the power button while the generator is activated, the power changes by one setting to prevent rapid changes in power delivered to the surgical site.

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

## Using Low Power Settings

Keep the power settings as low as possible to produce the desired surgical effect. Low power settings enhance patient and user safety.

- High power settings and long operative times for a surgical procedure increase the risk of electrosurgical burns.
- Low power settings reduce the amount of current delivered to the patient, minimize the demand on the patient return electrode, and protect the patient and operating room personnel from accidental burns and shocks.

## Typical Power Settings

The power required for a surgical procedure varies considerably with the surgeon's technique, the waveform being used, and the size of the active electrode. For guidance in selecting an appropriate waveform and active electrode, refer to *Techniques for Keeping Power Settings Low* in this section.

**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.

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

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

## Techniques for Keeping Power Settings Low

One surgeon may use a cut waveform to electrosurgically sever tissue while another surgeon might use a coag waveform for the same procedure. The power setting required to produce the desired surgical effect will vary depending on the waveform the surgeon uses and also on the size of the active electrode. Thus, the power used by different surgeons for the same procedure varies considerably with each surgeon's technique.

Always use the lowest power setting necessary to achieve the desired surgical effect. Several techniques for keeping power settings low are listed below:

### Concentrate 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 will cut at a lower power setting than a blade electrode. A small ball electrode will desiccate or fulgurate tissue at a lower power setting than a large ball electrode.

### Coagulate tissue by using fulguration rather than desiccation.

Because the fulguration waveform sparks to a wider area of tissue, surface coagulation can be achieved with a lower power setting using *Med (Fulgurate)* rather than *Low (Desiccate)*.

### Cut by sparking rather than by desiccating tissue.

The cut waveform 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.

### Use 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.

# Activating the Surgical Instrument

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

**Notice**

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

Use a footswitch or controls on the instrument handset to activate the surgical instrument.

### Handswitching Instruments

Pencils: Press the cut or coag button on the handset.

Forceps: Close the forceps tines.

CEM handpiece: Press the cut or coag button on the CEM handswitching nosecone.

### Footswitching Instruments

Bipolar: Press the pedal on the bipolar footswitch.

Monopolar cut: Press the cut pedal on the monopolar footswitch.

Monopolar coag: Press the coag pedal on the monopolar footswitch.

## Activation Indicators

Bipolar: The bipolar activation tone sounds and the ***Bipolar*** indicator bar illuminates blue.

Monopolar cut: The cut activation tone sounds and the ***Cut*** indicator bar illuminates yellow.

Monopolar coag: The coag activation tone sounds and the ***Coag*** indicator bar illuminates blue.

## Adjusting the Volume of Activation Tones

**Caution**

Do not turn the activation tone down to an inaudible level. The activation tone alerts personnel when an accessory is active.

Turn the *Volume* knob, located on the rear panel, to change the volume of activation tones.


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

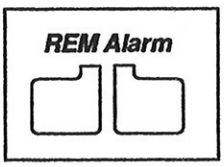
To decrease the volume, turn the knob counterclockwise.

You cannot silence the activation tones or adjust the alarm tone volume.

## Responding to Alarms

When the generator senses an alarm condition, an alarm tone sounds. Two types of alarms are possible: REM alarms and system alarms.

### REM Alarm




A tone sounds twice and the *REM Alarm* indicator flashes red when the REM system senses an alarm condition. The *REM Alarm* indicator remains red and RF output is disabled until the alarm condition is corrected.

To correct the alarm condition, refer to *Correcting a REM Alarm Condition* in Section 6.

### 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 6.

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

# 5 After Surgery

After surgery, prepare the generator for reuse. To do so, disconnect all accessories and clean the generator. If you plan to store the generator, refer to the information in this section regarding storage considerations.

## Preparing the Generator for Reuse

### Step 1 – Disconnect the accessories.

1. Turn off the generator.
2. Disconnect the surgical instrument from the front panel.

**Caution**

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

- If the instrument is disposable (single use only), dispose of the instrument according to the procedures for your institution.
- If the instrument is reusable, clean and sterilize the instrument according to the manufacturer's instructions for the instrument.

3. Disconnect the patient return electrode from the ***Patient*** receptacle. Remove it from the patient.

   For correct removal of the patient return electrode, follow all instructions found in the product packaging.

4. Disconnect and store the footswitch(es), if applicable.

# Preparing the Generator for Reuse

## Step 2 – Clean the generator.

Use a mild cleaning solution or disinfectant and a damp cloth to clean the generator surfaces and power cord. Do not allow fluids to enter the chassis. The generator cannot be sterilized.

**Warning**

Electric Shock Hazard. Always unplug the generator before cleaning.

1. Unplug the generator power cord from the wall outlet.

**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.

2. Thoroughly wipe all surfaces with a cleaning solution or disinfectant.

   Follow the procedures approved by your institution or use a validated infection control procedure.

# Storing the Generator

The Force FX can be stored indefinitely. However, if you store the generator longer than one year, you must perform specific checkout procedures before use. The procedures you follow are provided in the **Force FX Service Manual.**

If you store the generator at a temperature that is outside its normal operating range of 50° to 104° F (10° to 40° C), allow one hour for the generator to reach room temperature before use.

# 6 Troubleshooting

Troubleshooting gives instructions for identifying and correcting malfunctions and responding to alarms. Specific instructions for correcting a REM alarm condition are included.

## General Troubleshooting Guidelines

If the Force FX 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 cables are connected and attached properly.

If the malfunction persists, the generator may require service.

## Correcting a REM Alarm Condition

When you correct the 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.

To correct the REM alarm condition, follow these steps:

1. Verify that the 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.

   If the REM alarm persists, go to step 4.
4. 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.

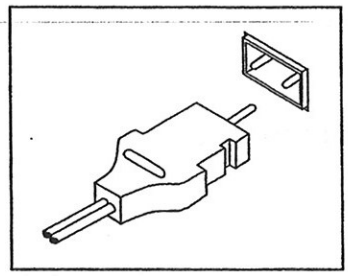
   **or**

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

## Applying Additional Patient Return Electrodes

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

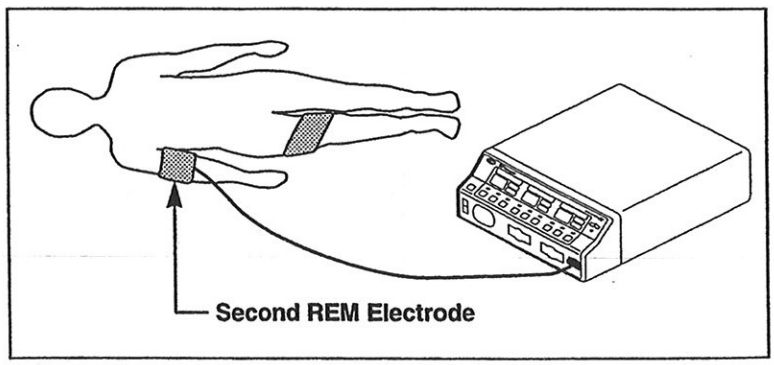
1. Inspect the return electrode connector.
   a. Turn off the generator by pressing *Off* (O). Then, unplug the patient return electrode from the generator.



   b. Verify that the pin on the plug is present and not bent. Carefully reinsert the plug into the ***Patient*** receptacle. Ensure that the pin enters the hole and that the plug inserts fully.
   c. Turn on the generator by pressing *On* ( | ). If the alarm persists, go to the next step.

2. 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. Turn off the generator. 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*** receptacle on the generator.




   c. Turn on the generator. If the alarm persists, go to the next step.

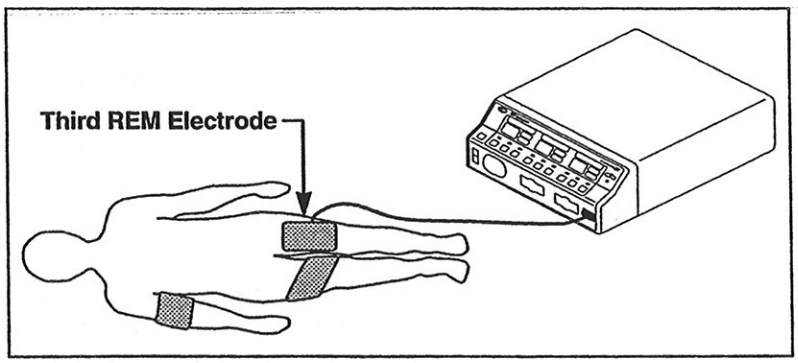
      If the alarm clears, leave the generator on during draping to avoid disturbing the return electrode. Remove the return electrode that is not in use.

## Applying Additional Patient Return Electrodes

4. Apply a *third* patient return electrode.

   a. Turn off the generator. Unplug the second patient return electrode. Do not remove either return electrode from the patient.

   b. Apply a third REM electrode to the patient and connect it to the ***Patient*** receptacle. Select the next best well vascularized, convex area close to the surgical site.

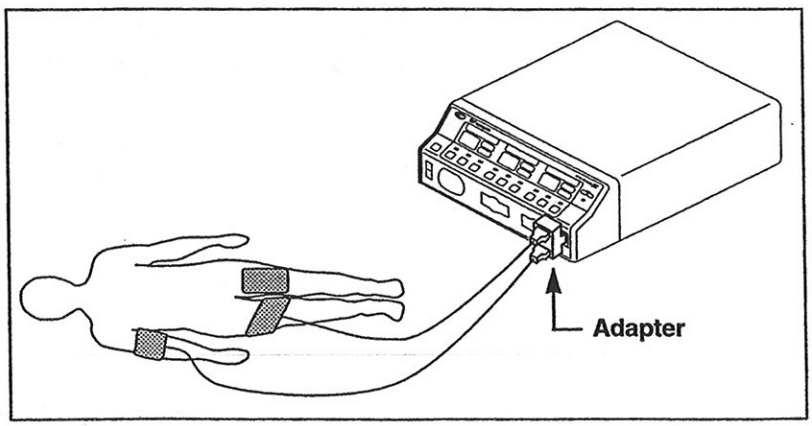



   c. Turn on the generator. If the alarm persists, go to the next step.

      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.

5. Turn off the generator and unplug the patient return electrode. Use a Valleylab multiple return/s-cord adapter (E0507-B) to connect two patient return electrodes to the generator.

   a. Insert the Valleylab adapter into the ***Patient*** 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.

   c. Turn on the generator. 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 the solution is not readily apparent, use the table below to help you identify and correct specific malfunctions. After you correct the malfunction, verify that the generator completes the self-test as described in Section 3.

| Situation | Possible Cause | Solution |
|---|---|---|
| Abnormal neuromuscular stimulation (*stop surgery immediately*). | 1. Metal-to-metal sparking. | 1. 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 ***Med** (Fulgurate)* and the ***High** (Spray)* modes or select the ***Low** (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 |
|---|---|---|
| Generator does not respond when turned on. | 1. Disconnected power cord or faulty wall outlet. | 1. 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 Service Manual.** |
| | 4. Internal component malfunction. | 4. Use a backup generator. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance. |

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

## Correcting Malfunctions

| Situation | Possible Cause | Solution |
|---|---|---|
| Generator is on and accessory is activated, but generator does not deliver output. | 1. Malfunctioning footswitch or handswitching instrument. | 1. Turn off the generator. Check and correct all accessory connections.<br><br>Turn on the generator. Replace the accessory if it continues to malfunction. |
| | 2. Footswitch connected to ***Monopolar 1 Footswitch*** receptacle is being used for surgical instrument in ***Monopolar 2*** receptacle. | 2. Connect the footswitch to the ***Monopolar 2 Footswitch*** receptacle.<br><br>**or**<br><br>Connect the instrument to the ***Monopolar 1/CEM*** receptacle. |
| | 3. Footswitch connected to ***Monopolar 2 Footswitch*** receptacle is being used for instrument connected to ***Monopolar 1/CEM*** receptacle. | 3. Connect the footswitch to the ***Monopolar 1 Footswitch*** receptacle.<br><br>**or**<br><br>Connect the instrument to the ***Monopolar 2*** receptacle. |
| | 4. Power set too low. | 4. Increase the power setting. Follow the procedures in Section 4 under *Changing the Power Setting*. |
| | 5. An alarm condition exists. | 5. Check the display for an alarm number. Note the number and see *Responding to System Alarms* later in this section.<br><br>In case of a REM alarm, see *Correcting a REM Alarm Condition* earlier in this section. |
| | 6. Internal component malfunction. | 6. Use a backup generator. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance. |

## Correcting Malfunctions

| Situation | Possible Cause | Solution |
|---|---|---|
| Continuous monitor interference. | 1. Faulty chassis-to-ground connections. | 1. Check and correct the chassis ground connections for the monitor and for the generator.<br><br>Check other electrical equipment in the room for defective grounds. |
| | 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. | 2. Plug all electrical equipment into line power at the same location. Refer to your Biomedical Engineering Department or contact a Valleylab Representative for assistance. |
| | 3. Malfunctioning monitor. | 3. Replace the monitor. |

| Situation | Possible Cause | Solution |
|---|---|---|
| Interference with other devices only when generator is activated. | 1. Metal-to-metal sparking. | 1. Check all connections to the generator, patient return electrode, and accessories. |
| | 2. High settings used for fulguration. | 2. Use lower power settings for fulguration or select the ***Low*** *(Desiccate)* mode. |
| | 3. Electrically inconsistent ground wires in the operating room. | 3. Verify that all ground wires are as short as possible and go to the same grounded metal. |
| | 4. If interference continues when the generator is activated, the monitor is responding to radiated frequencies. | 4. Ask your Biomedical Engineering Department to check with the manufacturer of the monitor.<br><br>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. |

## Correcting Malfunctions

| Situation | Possible Cause | Solution |
|---|---|---|
| Pacemaker interference. | 1. Intermittent connections or metal-to-metal sparking. | 1. Check the active and patient return electrode cord connections.<br><br>It may be necessary to reprogram the pacemaker prior to surgery. |
| | 2. Current traveling from active to return electrode during monopolar electrosurgery is passing too close to pacemaker. | 2. Use bipolar instruments, if possible.<br><br>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.<br><br>Always monitor patients with pacemakers during surgery and keep a defibrillator available.<br><br>Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers. |

## Responding to System Alarms

An alarm tone sounds and a number flashes in the *Cut* display when a system alarm condition exists. The generator is disabled until the condition is cleared. Most system alarms require some action on your part to correct the condition. Some are corrected automatically.

Use the table below to determine how to correct the alarm condition. After correcting the alarm condition, verify that the generator completes the self-test as described in Section 3.

| 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 the alarm number reappears, record the number and call the Valleylab Service Center. |
| 13-14 | Diagnostics/microcontroller malfunction. | Contact your Biomedical Engineering Department. |
| 16 | Diagnostics/microcontroller malfunction. | Contact your Biomedical Engineering Department. |
| 17–18 | Internal component malfunction. | Do not attempt the 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<br>40<br>60–66 | Software malfunction. | |
| 67 | Internal diagnostics | Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center. |

| Number | Description | Recommended Action |
|---|---|---|
| 68 | Microcontroller malfunction. | Contact your Biomedical Engineering Department. |
| 69–71<br>80 | Software malfunction. | Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center. |
| 81 | Internal component malfunction. | Do not attempt to use the generator. Record the number and call the Valleylab Service Center. |
| 90<br>95 | Microcontroller malfunction. | Contact your Biomedical Engineering Department. |
| 100–105<br>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<br>136–138<br>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. |

## Responding to System Alarms

| Number | Description | Recommended Action |
|---|---|---|
| 180–185 | Internal diagnostics. | Contact your Biomedical Engineering Department. |
| 186–187 | Software malfunction. | Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Valleylab Service Center. |
| 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***, bipolar ***Down***, and/or a bipolar mode button (***Low, Med, Macro***) may be stuck. | 1. Turn off, then turn on the generator. Do not press buttons or accessory activation devices during the self-test.<br>2. If the alarm number reappears, disconnect all accessories. Then, turn off and turn on the generator again.<br>If the alarm number reappears, record the number and call the Valleylab Service Center. |
| 191 | Cut ***Up***, cut ***Down***, and/or a cut mode button (***Low, Pure, Blend***) may be stuck. | |
| 192 | Coag ***Up***, coag ***Down***, and/or a coag mode button (***Low, Med, High***) 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. | |

## Responding to System Alarms

| Number | Description | Recommended Action |
|---|---|---|
| 199–205 | 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. |
| 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<br>215<br><br>220–226 | Internal diagnostics.<br><br>Internal diagnostics or microcontroller malfunction. | Contact your Biomedical Engineering Department. |
| 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<br><br>260 | Microcontroller malfunction.<br><br>Internal diagnostics. | Contact your Biomedical Engineering Department. |
| 261-262<br>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.<br><br>Use the lowest power setting that achieves the desired effect. Limit activation times, if possible. |

# 7 Maintenance and Repair

This section lists the responsibilities assumed by Valleylab for the correct performance of the Force FX. It also describes when and how to perform routine maintenance. Instructions for returning the generator to Valleylab are provided.

## Responsibility of the Manufacturer

Valleylab is responsible for safety, reliability, and performance of the Force FX 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 details regarding the warranty, refer to the Warranty at the end of this guide.

## Routine Maintenance

**Notice**

Refer to the **Force FX Service Manual** for maintenance recommendations and function and output power verification procedures.

### When should the Force FX 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 **Force FX Service Manual** for instructions.

## Returning the Force FX 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 (1-800-255-8522) 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

# Returning the Force FX for Service

## Step 2 – Clean the generator.

Use a mild cleaning solution or disinfectant and a damp cloth to clean the generator surfaces and power cord. Do not allow fluids to enter the chassis. The generator cannot be sterilized.

**Warning**

Electric Shock Hazard. Always unplug the generator before cleaning.

1. Turn off the generator by pressing *Off* (O).
2. Unplug the generator power cord from the wall outlet.

**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.

3. Thoroughly wipe all surfaces with a cleaning solution or disinfectant.

   Follow the procedures approved by your institution or use a validated infection control procedure.

## 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 earlier 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.

## *Notes*

# A Technical Specifications

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

## 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), Force GSU Unit, or any stable flat surface

### Dimensions and Weight

Width: 14 in. (35.6 cm)

Depth: 18 in. (45.7 cm)

Height: $4\frac{3}{8}$ in. (11.1 cm)

Weight: < 18 lbs. (< 8.1 kg)

# Performance Characteristics

## Operating Parameters

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

Relative humidity: 30% to 75%, noncondensing

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 Service Manual**.

## Duty Cycle

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

If the internal temperature of the Force FX 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.

# Performance Characteristics

## 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.

### Activation Tone

Volume (adjustable): 45 to ≥ 65 dB

Frequency:

Bipolar: 940 Hz

Cut: 660 Hz

Coag: 940 Hz

### Alarm Tone

Volume (not adjustable): ≥ 65 dB

Frequency: 660 Hz

# Performance Characteristics

## 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 µA

### Acceptable Resistance Range

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 light 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)

# Performance Characteristics

## 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 mA at ≤ 50 W

# Performance Characteristics

## Input Power

| 120 Volt | 240 Volt |
|---|---|
| Maximum VA at nominal line voltage:<br>Idle: 52 VA<br>Bipolar: 450 VA<br>Cut: 924 VA<br>Coag: 530 VA | Maximum VA at nominal line voltage:<br>Idle: 52 VA<br>Bipolar: 450 VA<br>Cut: 924 VA<br>Coag: 530 VA |
| Input mains voltage, full regulation range: 104-132 Vac | Input mains voltage, full regulation range: 208-264 Vac |
| Input mains voltage, operating range: 85-132 Vac | Input mains voltage, operating range: 170-264 Vac |
| Mains current (maximum):<br>Idle: 0.4 A<br>Bipolar: 2.0 A<br>Cut: 7.0 A<br>Coag: 4.0 A | Mains current (maximum):<br>Idle: 0.2 A<br>Bipolar: 1.0 A<br>Cut: 3.5 A<br>Coag: 2.0 A |
| Mains line frequency range (nominal): 50 to 60 Hz | Mains line frequency range (nominal): 50 to 60 Hz |
| Fuses (2): 8 A | Fusing: 4 A |
| Power cord: 3-prong hospital grade connector | Power cord: 3-prong hospital grade 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)

The Force FX 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.

### Drip Proof (IEC 601-2-2)

The Force FX 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.

# Standards and IEC Classifications

## Electromagnetic Interference

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

**Caution**

Do not stack equipment on top of the Force FX or place the generator on top of electrical equipment (except the Valleylab Force GSU Unit and the Valleylab Electroshield Monitor). These configurations are unstable and/or do not allow for adequate cooling.

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

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

## Voltage Transients (Emergency Generator Mains Transfer)

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

## Defibrillator Proof

The Force FX complies with the ANSI/AAMI HF18 specifications for "defibrillator proof" designation.

# 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 Load (max) | Power (max) | Crest Factor * |
|---|---|---|---|---|
| **Bipolar** | | | | |
| *Low (Precise)* | 450 V | 100 Ω | 70 W | 1.5 |
| *Med (Standard)* | 320 V | 100 Ω | 70 W | 1.5 |
| *Macro* | 750 V | 100 Ω | 70 W | 1.5 |
| **Monopolar Cut** | | | | |
| *Low* | 1350 V | 300 Ω | 300 W | 1.5 |
| *Pure* | 2300 V | 300 Ω | 300 W | 1.5 |
| *Blend* | 3300 V | 300 Ω | 200 W | 2.5 |
| **Monopolar Coag** | | | | |
| *Low (Desiccate)* | 3500 V | 500 Ω | 120 W | 5 |
| *Med (Fulgurate)* | 6900 V | 500 Ω | 120 W | 5.5 |
| *High (Spray)* | 9000 V | 500 Ω | 120 W | 8 |

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

## Maximum Output for Ultrasonic Electrosurgery (CEM)

*Low* cut and *Low (Desiccate)* coag are the only monopolar modes available to a connected CEM handpiece.

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

# Output Characteristics

## Available Power Settings in Watts

### Bipolar and Macrobipolar

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 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 | | | | |

### Monopolar Cut: *Low* and *Pure*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 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 | 75 | 80 | 85 | 90 |
| 95 | 100 | 110 | 120 | 130 | 140 | 150 | 160 | 170 | 180 |
| 190 | 200 | 210 | 220 | 230 | 240 | 250 | 260 | 270 | 280 |
| 290 | 300 | | | | | | | | |

### Monopolar Cut: *Blend*

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 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 | 75 | 80 | 85 | 90 |
| 95 | 100 | 110 | 120 | 130 | 140 | 150 | 160 | 170 | 180 |
| 190 | 200 | | | | | | | | |

### Monopolar Coag

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 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 | 75 | 80 | 85 | 90 |
| 95 | 100 | 110 | 120 | | | | | | |

### CEM Cut

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 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 | 75 | 80 | 85 | 90 |
| 95 | 100 | | | | | | | | |

# Output Characteristics

### CEM Coag

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 | 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`

Effect mode, an automatic adjustment, is applied to all bipolar modes and all cut modes. It is not applied to 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

| | |
|---|---|
| *Low (Precise)* | 470 kHz sinusoid |
| *Med (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 envelope. |

### Monopolar Coag

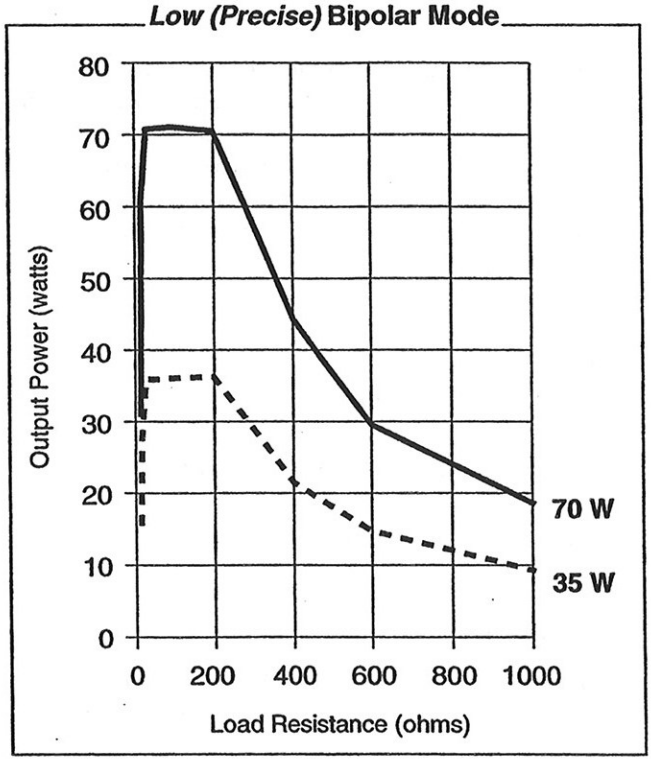
| | |
|---|---|
| *Low (Desiccate)* | 240 kHz sinusoid repeated at 39 kHz. 8% duty cycle. |
| *Med (Fulgurate)* | 390 kHz damped sinusoidal bursts with a repetition frequency of 57 kHz into 300 ohms. |
| *High (Spray)* | 390 kHz damped sinusoidal bursts with a randomized repetition centered at 28 kHz. 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

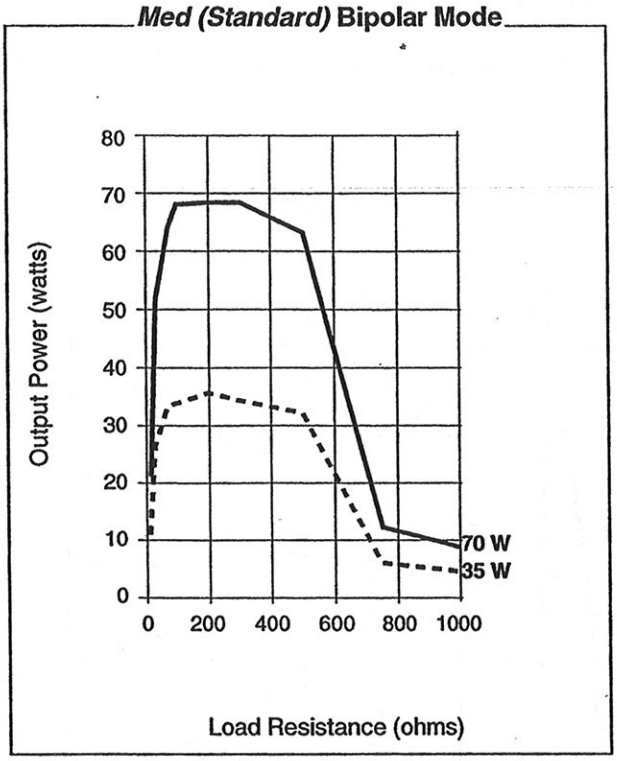
The graphs that follow depict the changes for each mode at specific power settings.

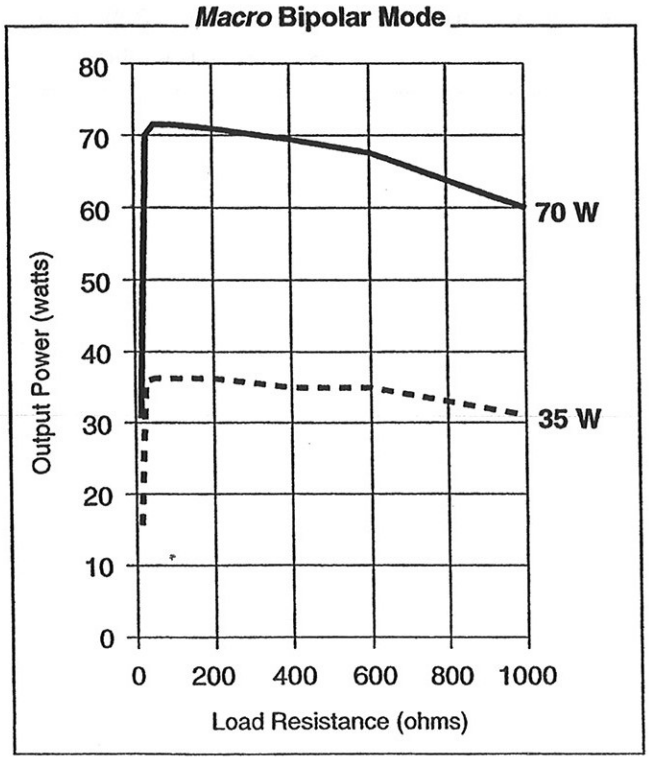
## Bipolar Graphs

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



## Output Power vs. Resistance Graphs

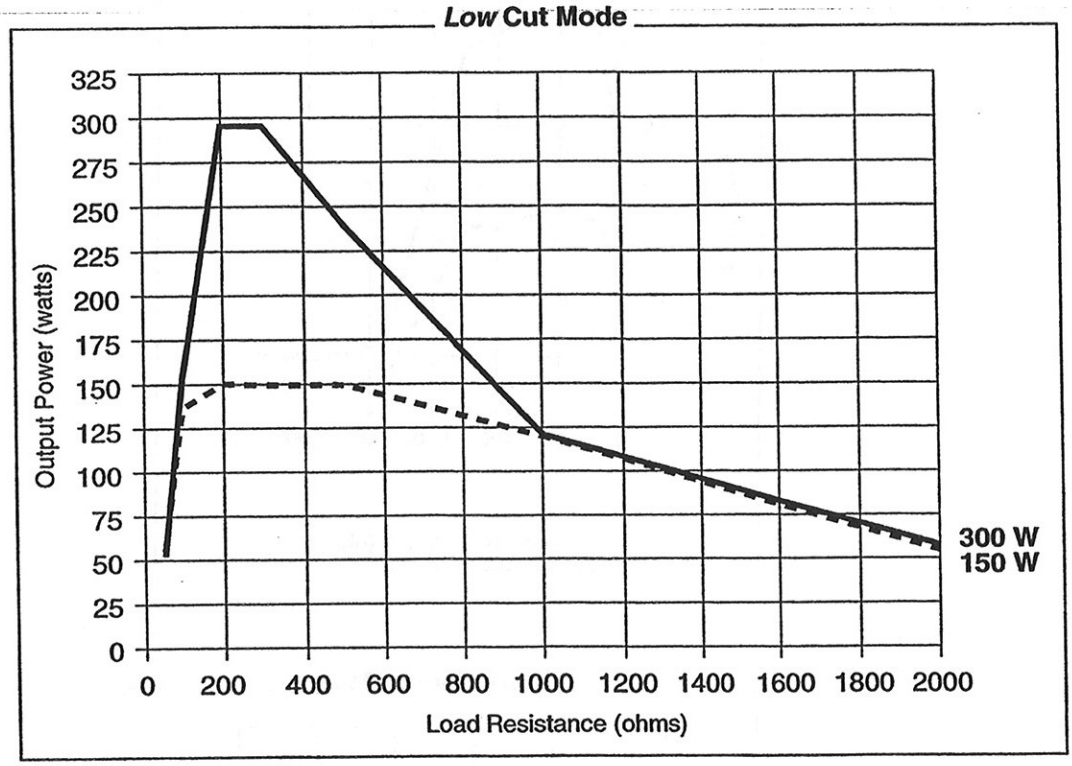


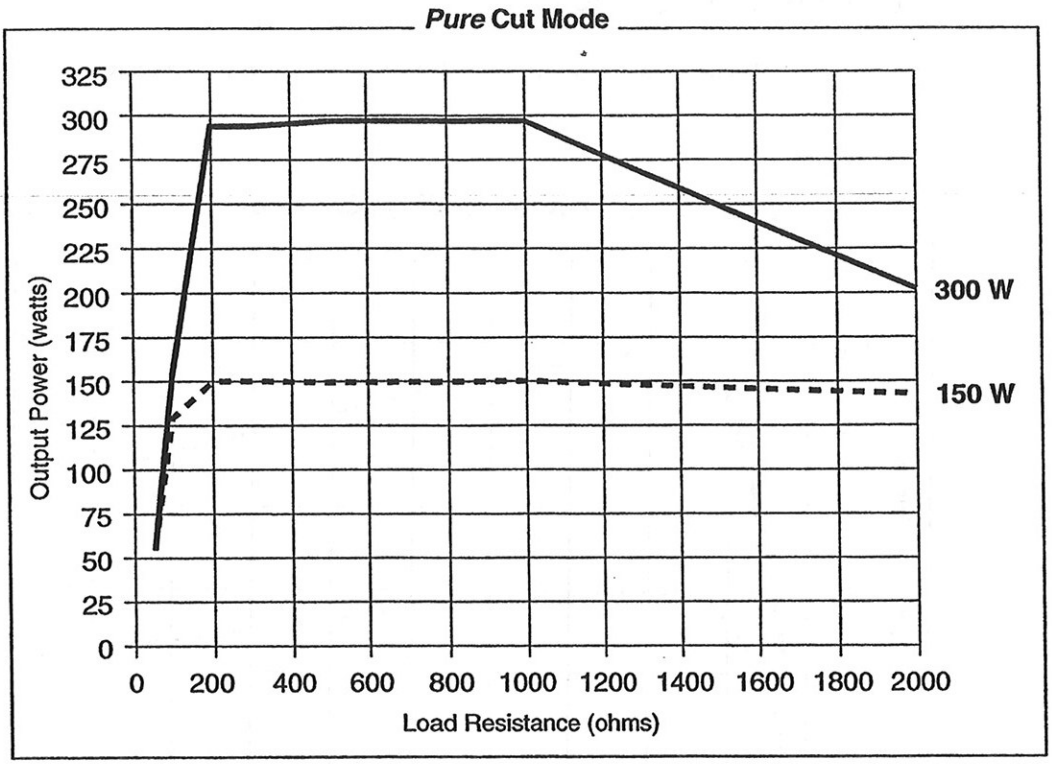
# Output Power vs. Resistance Graphs

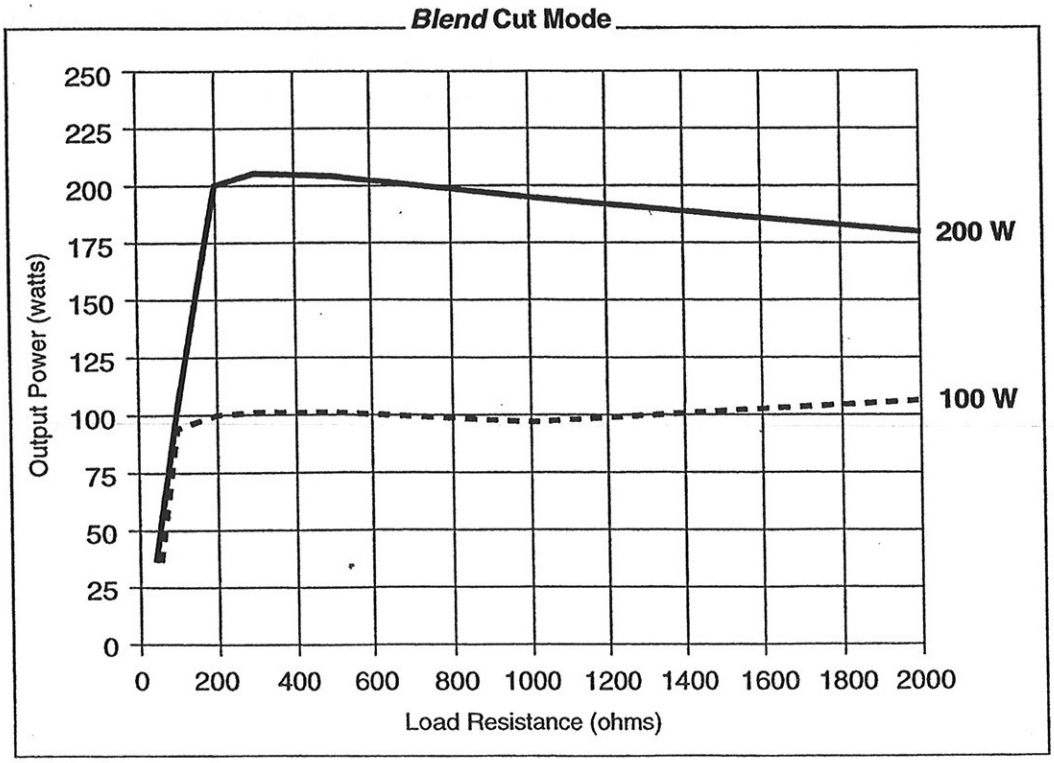
## Monopolar Cut Graphs

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



## Output Power vs. Resistance Graphs

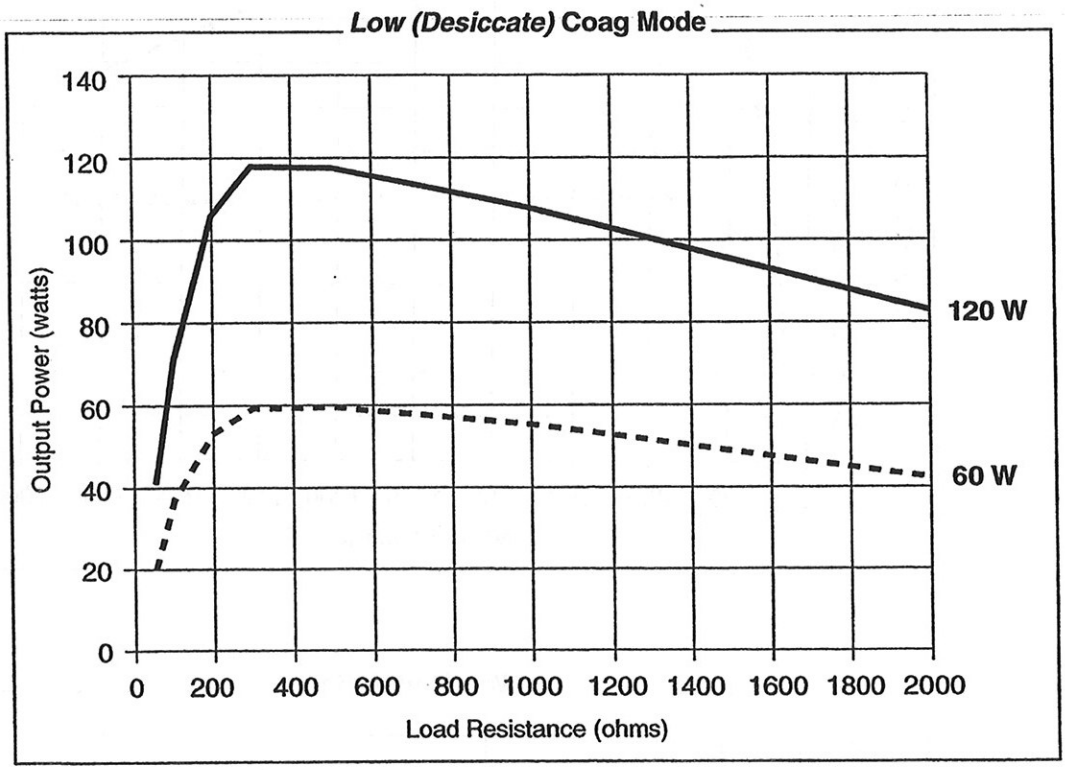


# Output Power vs. Resistance Graphs

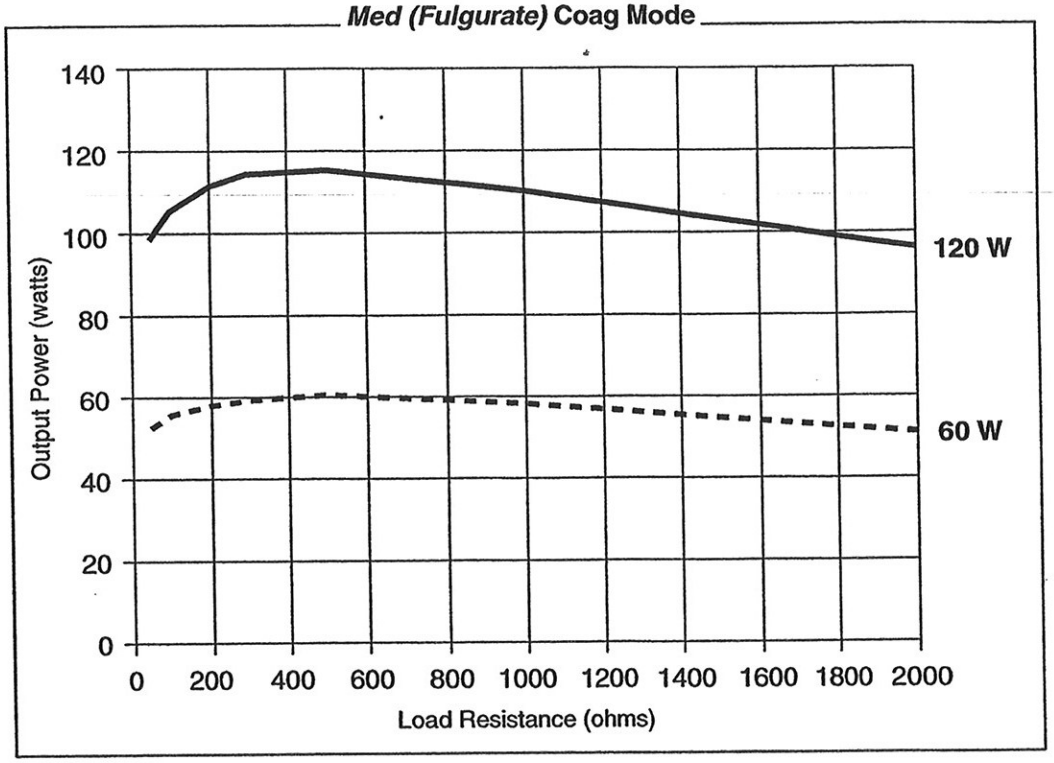
## Monopolar Coag Graphs

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

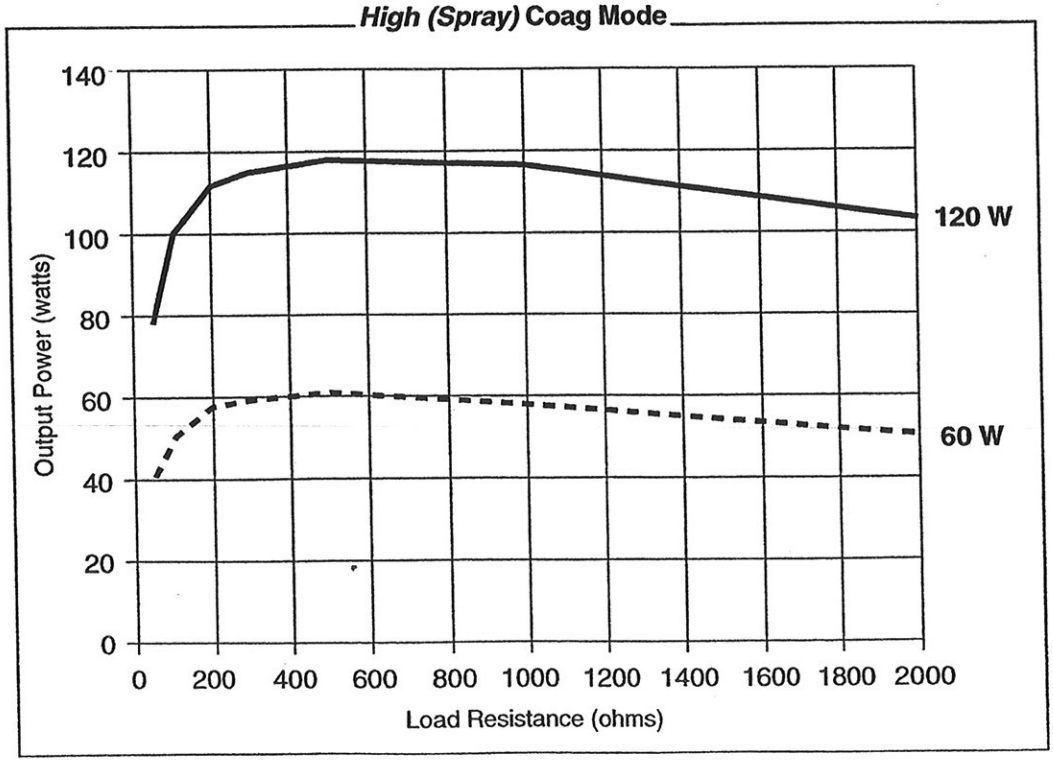


# Output Power vs. Resistance Graphs

***Med (Fulgurate)* Coag Mode**




***High (Spray)* Coag Mode**



## *Notes*

# B Accessories

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

## Miscellaneous Accessories

| Catalog No. | Valleylab Accessory |
|---|---|
| E0502–1 or E0502–2 | Adapter, Footswitching Instrument (single-pin) (for connecting some monopolar footswitching instruments to the Force FX) |
| E0507–B | Adapter, Multiple Return/S-Cord (for connecting two patient return electrodes to the ***Patient*** 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*

# Glossary

**A**

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

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

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

**B**

**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 another 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 output that removes the ground reference from the electrosurgical circuit and restricts current flow to the surgical instrument.

**blend** A waveform that combines features of cut and coag waveforms for cutting with varying degrees of hemostasis.

**buzzing the hemostat** A surgical technique for coagulating bleeding vessels with current delivered through the hemostat from the active electrode.

## 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** Occurs when electrical current is transferred from one conductor (the active electrode), through intact insulation, into adjacent conductive materials (tissue, trocars, 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, pulsed 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** The ratio of the peak voltage of a waveform to the root mean square (rms) voltage; an indication of the degree of fulguration provided by the waveform. Generally, waveforms with high crest factors provide a high degree of fulguration.

**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; current concentration is directly proportional to the amount of heat generated.

**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 with the Force FX in conjunction with a CEM™ handpiece for ultrasonic electrosurgery.

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

**cutting** The electrosurgical effect that severs tissue with electric sparks, focusing intense heat at the surgical site and exploding cell walls.

## D

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

**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

**effect mode** A feature of the Force FX in which the output voltage of the generator is constantly changed as a function of tissue resistance to maintain a consistent tissue effect across different tissue types.

**electrode** A conductor through which electrosurgical current is transmitted or received. *See also* active electrode; patient return electrode.

**electrosurgery** The passage of high frequency (RF) electric current through tissue from an electrode that concentrates the current to produce a surgical effect (cutting or coagulating) to a larger electrode that disperses the current and returns it to the generator; surgical diathermy.

**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.

**electrosurgical current** See radio frequency (RF).

**electrosurgical unit (ESU)** The electrosurgical generator and its connecting cables.

**endoscope** A fiberoptic tube used to examine body cavities or organs.

## F

**frequency** In electrosurgery, the number of cycles per second (hertz) that current alternates; the rate at which a cycle repeats itself.

**fulguration** The electrosurgical effect of tissue coagulation using electrical arcs (sparks) that jump from the electrode through the air to the tissue.

## G

**generator** The machine that converts low frequency alternating current to high frequency current used for electrosurgery; electrosurgical unit (ESU).

**ground** The universal conductor and common return point for electric circuits; earth ground.

## H

**hemostasis** In electrosurgery, the stopping of bleeding with heat produced by the electrosurgical circuit; coagulation.

**hemostat** A forceps used to clamp a bleeding vessel and stop blood flow.

**hertz (Hz)** The unit of measurement for frequency; cycles per second.

**holster** An insulated receptacle designed to hold active electrodes safely, when not in use during electrosurgery.

## I

**impedance** Resistance to the flow of alternating current, including simple direct current resistance and the resistance produced by capacitance or inductance.

**insufflation** The pumping of gas into a body cavity or organ.

**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** The examination of the abdominal cavity with an endoscopic instrument.

**leakage current** Current that flows along an undesirable path, usually to ground; in isolated electrosurgery, radio frequency (RF) current that regains its ground reference.

**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** A bipolar surgical procedure in which higher voltages and power curve are required to desiccate tissue as tissue resistance increases.

**monopolar electrosurgery** A surgical procedure in which only the active electrode is in the surgical wound; electrosurgery that directs current through the patient's body and requires the use of a 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 from an active electrode, through the patient, to a patient return electrode.

## N

**necrosis** The destruction of tissue.

## O

**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

**patient return electrode** A conductive plate or pad (dispersive electrode) that recovers the therapeutic current from the patient during electrosurgery, dispersing it over a wide surface area, and returns it to the electrosurgical generator. Plates are usually rigid and made of metal or foil-covered cardboard; 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®** Valleylab's unique conductive adhesive 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 above 550 kHz that transmit radio signals; the high frequency current used in electrosurgery.

**REM® system** Valleylab's exclusive Contact Quality Monitoring System that continuously monitors resistance levels at the patient return electrode. If dangerous levels of resistance caused by current concentration or lack of conductivity are detected, the REM system sounds an alarm and disables the generator. Adaptive REM adjusts the resistance level tolerances for individual patients; nonadaptive REM compares the resistance levels to a range of safe levels as determined by clinical studies.

**resistance** The lack of conductivity or the opposition to the flow of electric current, measured in ohms.

**return electrode** The conductive element that receives electrosurgical current and returns it to the generator. In monopolar electrosurgery, the patient return electrode; in bipolar electrosurgery, one pole of the bipolar instrument, usually one tine of a forceps.

**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 on the Force FX 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.

**spark** A discharge of electric current across an air gap; essential to electrosurgical cutting and fulguration.

**spray** A Valleylab coag mode that affords optimum fulguration; penetration is less deep and the tissue area is larger than fulguration; spray coag.

## 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.

## V

**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.

## W

**watt (W)** The unit of measurement for power in a circuit in which a current of one ampere flows across a potential difference of one volt; heat energy per second.

**waveform** A graphic depiction of electrical activity that can show how voltage varies over time as current alternates.

# Warranty

Valleylab Inc warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for the period(s) set forth below. Valleylab's obligation under this warranty is limited to the repair or replacement, at its sole option, of any product, or part thereof, which has been returned to it or its Distributor within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses, to Valleylab's satisfaction, that the product is defective. This warranty does not apply to any product, or part thereof, which has been repaired or altered outside Valleylab's factory in a way so as, in Valleylab's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

The warranty periods for Valleylab products are as follows:

| | |
|---|---|
| Electrosurgical generators: | One year from date of shipment |
| Mounting fixtures (all models): | One year from date of shipment |
| Footswitches (all models): | One year from date of shipment |
| Patient return electrodes: | Shelf life only as stated on packaging |
| Sterile disposables: | Sterility only as stated on packaging |

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

Notwithstanding any other provision herein or in any other document or communication, Valleylab's liability with respect to this agreement and products sold hereunder shall be limited to the aggregate purchase price for the goods sold by Valleylab to the customer. There are no warranties which extend beyond the terms hereof. Valleylab disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

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

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