COVIDIEN

User's Guide

Force FX™

Electrosurgical Generator C

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1012638

Preface

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for servicing the Force FX™ Electrosurgical Generator C only. Additional information is available in the *Force FX Electrosurgical Generator C Service Manual*.

Equipment covered in this manual:

Force FX Electrosurgical Generator C
110 V ~ Nominal/230 V ~ Nominal (auto select)

Conventions Used in this Guide

Warning

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

Caution

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

Notice

Indicates a hazard which may result in product damage.

Important

Indicates *an operating tip or maintenance suggestion.*

Limited Warranty

Covidien warrants each covered product listed below to be free from defects in material and workmanship for normal use and service for the period(s) set forth below. Covidien'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 authorized distributor) within the applicable time period shown below after delivery of the product to the original purchaser, and which examination discloses, to Covidien's satisfaction, that the product is defective. This limited warranty does not apply to any product, or part thereof, which has been repaired or altered in a way so as, in Covidien's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

The warranty periods for Covidien products are as follows:

ForceTriad™ Energy Platform	One year from date of shipment
Electrosurgical Generators	One year from date of shipment
Cool-tip™ RFA Generator	One year from date of shipment
RFG-3C™ Plus Lesion Generator	One year from date of shipment
LigaSure™ Vessel Sealing System	One year from date of shipment
LigaSure™ Reusable Instruments	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
Valleylab™ Argon Gas Delivery Unit II	One year from date of shipment
RapidVac™ Smoke Evacuator	One year from date of shipment
LigaSure™ Sterile Single Use Items	Sterility only as stated on packaging
Cool-tip™ Sterile Single Use Items	Sterility only as stated on packaging
Sterile Single Use Items	Sterility only as stated on packaging
Patient Return Electrodes	Shelf life only as stated on packaging

Notwithstanding any other provision herein or in any other document or communication, Covidien's liability with respect to this limited warranty and the products sold hereunder shall be limited to the aggregate purchase price for the products sold to the customer. This limited warranty is non-transferable and runs only to the original purchaser of the covered product(s). There are no warranties which extend beyond the terms hereof. Covidien disclaims any liability hereunder or elsewhere in connection with the sale of products and for any form of indirect, tort, or consequential damages.

This limited 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 limited warranty is the District Court of the County of Boulder, State of Colorado, USA.

Covidien reserves the right to make changes in covered products built or sold by it at any time without incurring any obligation to make the same or similar changes to equipment previously built or sold by it.

THE OBLIGATION TO REPAIR OR REPLACE A DEFECTIVE OR NONPERFORMING PRODUCT IS THE SOLE REMEDY OF THE CUSTOMER UNDER THIS LIMITED WARRANTY. **EXCEPT AS EXPRESSLY PROVIDED HEREIN, COVIDIEN DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, ORAL OR WRITTEN, WITH RESPECT TO PRODUCTS, INCLUDING WITHOUT LIMITATION ALL IMPLIED WARRANTIES, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

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Chapter 1

Introduction

This chapter includes information about:

- Instant Response™ technology
- Bipolar modes
- Monopolar cut and coag modes
- Simultaneous coag
- REM Contact Quality Monitoring System
- Ultrasonic electrosurgery.

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

Overview

The Covidien Force FX Electrosurgical Generator C (also called the Force FX-C generator in this manual) is an isolated output electrosurgical generator that provides power for cutting, desiccating, and fulgurating tissue during bipolar and monopolar surgery.

Features include:

- Instant Response technology
- Three bipolar modes: precise (low), standard (medium), and macro (macrobipolar)
- Three monopolar cut modes: low, pure, and blend
- Three monopolar coag modes: desiccate (low), fulgurate (medium), and spray (high)
- Support for simultaneous coagulation
- The Covidien REM Contact Quality Monitoring System
- Support for ultrasonic electrosurgery using the CUSA™ System 200 or CUSA EXcel™ and a CUSA handpiece with CUSA electrosurgical module (CEM™) nosecone
- Handswitch or footswitch activation
- Recall of most recently used mode and power settings
- Adjustable activation tone volume
- An RF activation port, RS-232 serial port, and expansion port
- Force GSU™ system and Force Argon system compatibility.

Covidien electrosurgical generators, patient return electrodes, and active accessories are designed to work as a system. Covidien offers a selection of patient return electrodes and electrosurgical instruments that are fully compatible with this generator. When considering other manufacturer's patient return electrodes and/or active accessories, customers should seek detailed user instructions and warning information from the manufacturer.

Instant Response Technology

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

Bipolar Modes

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

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

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

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

For details about the output characteristics, refer to *Output Characteristics* on page 9-11.

Monopolar Cut and Coag Modes

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

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

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

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

For details about the output characteristics, refer to *Output Characteristics* on page 9-11.

Simultaneous Coag

When you simultaneously activate two monopolar instruments for coag output, each receives a percentage of the power setting set for the selected mode. The amount of power each instrument receives 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.

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

REM Contact Quality Monitoring System

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

The Force FX-C generator uses the REM Contact Quality Monitoring System to monitor the quality of electrical contact between the patient return electrode and the patient. The REM™ system is designed to minimize the risk of burns at the return electrode site due to a reduction in patient contact area during monopolar electrosurgery. Use of any return electrode other than a REM Polyhesive™ patient return electrode may compromise the REM safety feature. This could result in a patient burn.

How the REM System Works

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

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

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

Electrodes Without the REM Safety Feature

Warning

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

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

Ultrasonic Electrosurgery

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

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

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

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

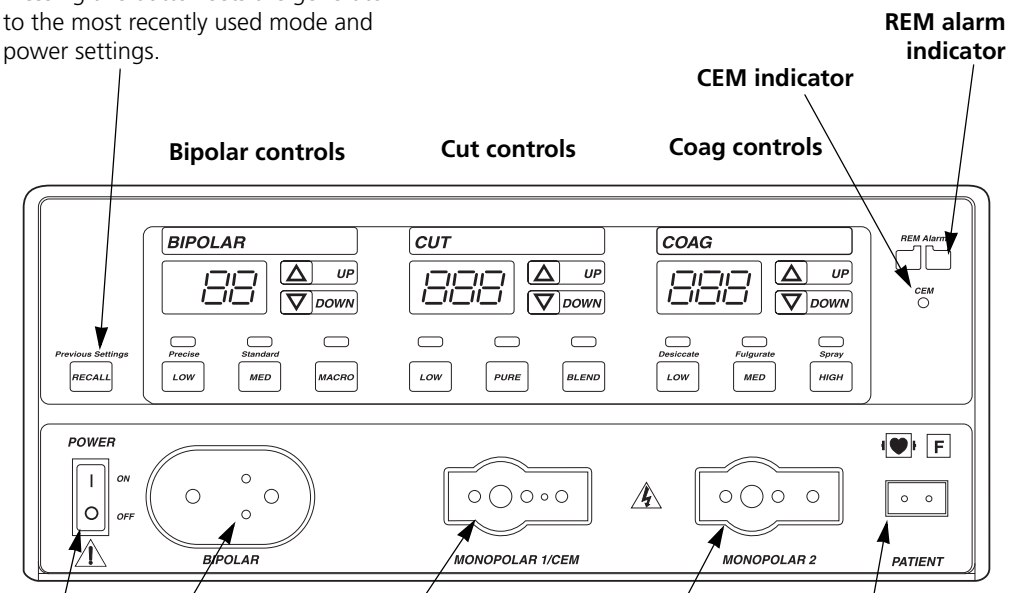
Chapter 2

Controls, Indicators and Receptacles

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

Front Panel

Recall button
Pressing this button sets the generator to the most recently used mode and power settings.



Bipolar Instrument receptacle

Monopolar 1/CEM Instrument receptacle

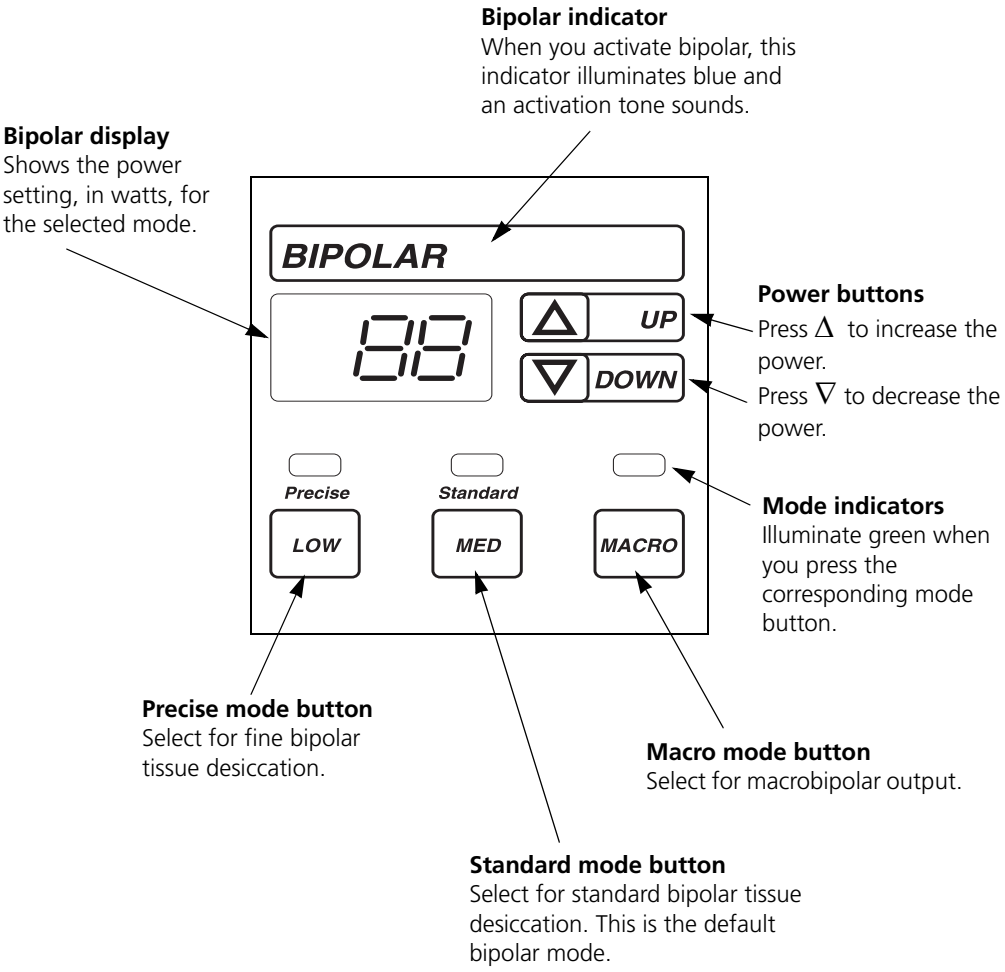
Monopolar 2 Instrument receptacle

Power Switch
This switch supplies power to the generator.

Press (|) to turn on the generator.
Press (O) to turn off the generator.

Patient return electrode receptacle
For monopolar electrosurgery, connect a patient return electrode to this receptacle.

Bipolar Controls



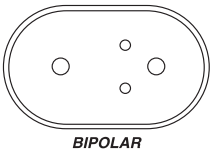
Bipolar Instrument Receptacle

Caution

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

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

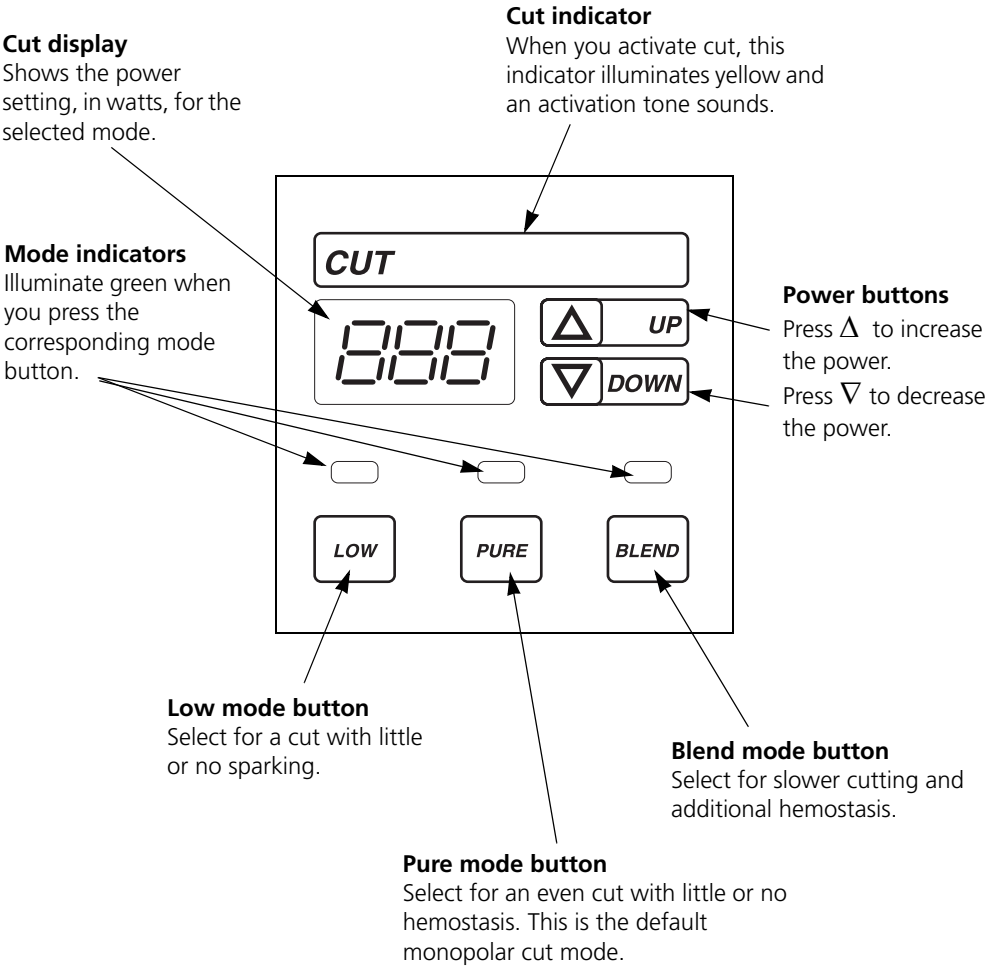
Connect a footswitching instrument with a two-pin connector.



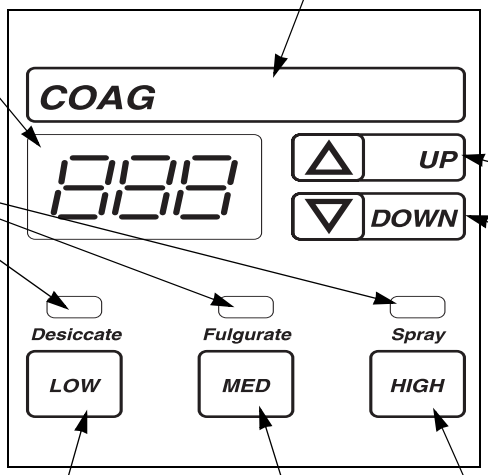
or

Connect a handswitching instrument with a three-pin connector.

Monopolar Cut Controls



Monopolar Coag Controls



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

Coag indicator
When you activate coag, this indicator illuminates blue and an activation tone sounds.

Mode indicators
Illuminates green when you press the corresponding mode button.

Power buttons
Press Δ to increase the power.
Press ∇ to decrease the power.

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

Spray mode button
Select to evenly coagulate a wide area of tissue with a spray of sparks; penetration is less deep and tissue area is larger than in fulgurate mode.

Fulgurate mode button
Select to fulgurate an area of tissue with a spray of sparks. This unit is equipped with an additional fulgurate mode which incorporates a lower crest factor (LCF) than the factory default fulgurate mode.

Details about this additional fulgurate mode, LCF fulgurate, are provided in Chapter 4, *Before Surgery*.

This is the default monopolar coag mode. However, the default coag mode can be changed to either Desiccate or Spray through the serial port on the rear panel; contact your institution's Biomedical Engineering Department.

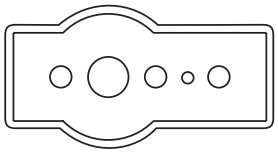
Monopolar Instrument Receptacles

Warning

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

You can connect a footswitching or handswitching monopolar instrument to the monopolar receptacles. Some footswitching instruments may require a single-pin adapter (E0502 Series or E0017), available from Covidien.

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



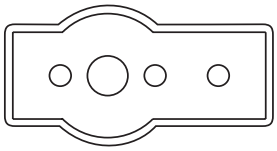
MONOPOLAR 1/CEM

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

  or

- A four-pin CUSA handpiece with CEM nosecone. (The CEM indicator in the upper right of the front panel illuminates green. Refer to *Connecting the CUSA Handpiece with CEM Nosecone* on page 4-13.)

Connect one monopolar instrument to the Monopolar 2 Instrument receptacle:



MONOPOLAR 2

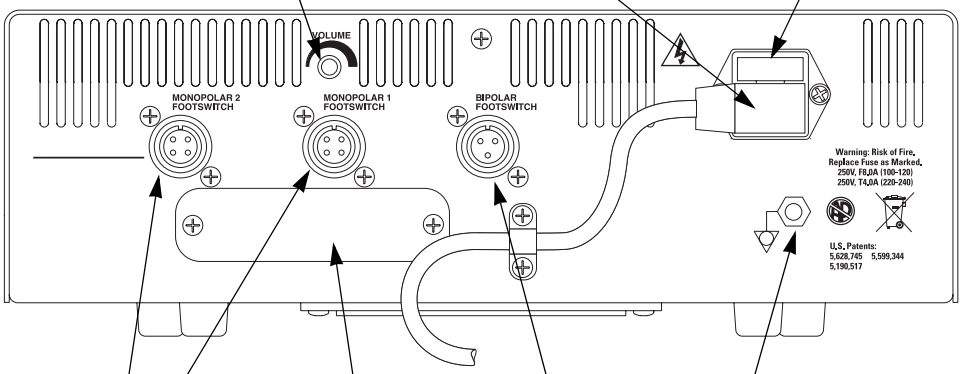
- A single-pin footswitching instrument or a three-pin handswitching instrument.

REM Alarm Indicator

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

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

Rear Panel



Volume control

Line fuse locator

Power entry module

Bipolar Footswitch receptacle

Option panel

Monopolar Footswitch receptacles

Equipotential grounding lug
Use to connect the generator to earth ground.

Footswitch Receptacles

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

Monopolar Footswitch Receptacles

You must connect a monopolar footswitch if you connect a monopolar footswitching instrument to the generator. Use only a Valleylab monopolar footswitch with the Force FX-C generator. Use of an incompatible footswitch may cause unexpected output.

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

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

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

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

Bipolar Footswitch Receptacle

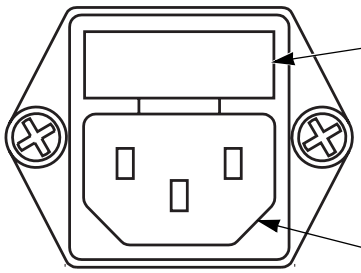
You must connect a bipolar footswitch if you connect a bipolar footswitching instrument to the generator.

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

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

Power Entry Module

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



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

Power cord receptacle

Activation Tone Volume Control

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

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

To *decrease* the volume, turn the knob counterclockwise.

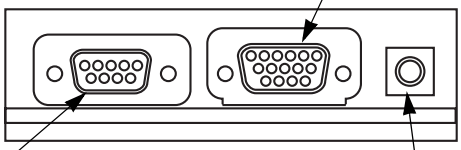
Option Panel

A removable plate on the rear panel covers a serial port, an expansion port, and an RF (radio frequency) activation port. Remove this plate to obtain information through the RS-232 port or to install a peripheral device such as a Bipolar Current Monitor, but retain the original cover plate. After obtaining information or removing a peripheral device, reinstall the original cover plate.

Notice
Do not operate the Force FX-C generator without an appropriate cover plate in place.

To review the technical specifications for each port, refer to *Output Characteristics* on page 9-11.

Expansion port
Allows a connected device to receive information about the RF voltage and current being generated as well as signal the generator to halt RF output.



Serial port
Allows connection of a computer to the generator.

You can obtain information about the generator using RS-232 communications protocol or change the default coag mode from Fulgurate to Desiccate or Spray.

Refer to the *Force FX Electrosurgical Generator C Service Manual*.

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

Chapter 3

Patient and Operating Room Safety

The safe and effective use of electrosurgery depends to a large degree upon factors solely under the control of the operator. There is no substitute for a properly trained and vigilant surgical team. It is important that the operating instructions supplied with this or any electrosurgical equipment be read, understood, and followed.

Electrosurgery has been used safely in numerous procedures. Before starting any surgical procedure, the surgeon should be trained in the particular technique and surgical procedure to be performed, should be familiar with the medical literature related to the procedure and potential complications, and should be familiar with the risks versus the benefits of utilizing electrosurgery in the procedure.

General

Warning

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 structures.

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

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

Covidien recommends against the use of laparoscopic surgery on pregnant patients.

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.

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

Caution

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

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.

Fire Hazard with Oxygen Circuit Connections

Warning

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

Electrosurgical Smoke

Caution

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

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

Inadvertent Radio Frequency Burns

Warning

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

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

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

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. Covidien recommends the use of REM Polyhesive patient return electrodes and Covidien generators with the REM system.

Ensure Proper Connections

Caution

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

Accessories

Warning

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

Servicing

Warning

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

Notice

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

Before Surgery

Active Accessories

Warning

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

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.

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

Caution

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

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.

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

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

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

Patient Return Electrodes

Covidien recommends the use of REM Polyhesive 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.

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

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.

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

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

Shunt Cords

Warning

Some surgical instruments (e.g., colonoscopes) may allow substantial leakage current which could burn the surgeon. If the instrument manufacturer recommends the use of a shunt cord (s-cord) to direct the current back to the generator, you must also use a Covidien E0507B adapter. To avoid a REM alarm, you must use a REM Polyhesive patient return electrode with the E0507B adapter.

Generator

Warning

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

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

Fire Hazard—Do not use extension cords.

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

Caution

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

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.

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.

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

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.

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

During Surgery

Generator Power Settings

Warning

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

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-C generator cuts effectively at power settings lower than previous models offered by Covidien. 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.

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.

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.

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

Contact with Metal Objects

Warning

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

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

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

Active Accessories

Warning

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

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

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.
- When using a stainless steel blade electrode, place the flat surface against the hemostat or other metal instrument.
- When using a coated or nonstick blade electrode, place the edge of the electrode against the hemostat or other metal instrument.

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

Patient Return Electrodes

Warning

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

Laparoscopic Procedures

Warning

For laparoscopic procedures, be alert to these potential hazards:

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

After Surgery

Warning

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

Caution

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

Notice

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

Chapter 4

Before Surgery

This chapter contains procedures for:

- Preparing the generator for surgery
- Preparing for bipolar or macrobipolar surgery
- Preparing for monopolar surgery
- Preparing for ultrasonic electrosurgery.

Caution

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

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

Quick Setup Instructions

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

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

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

To prepare for bipolar or monopolar surgery:

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

To prepare for ultrasonic surgery:

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

Setting Up the Generator

Warning

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

Fire Hazard—Do not use extension cords.

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

Caution

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

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

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

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

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

Notice

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

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

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

   Provide at least four to six inches of space from the sides and top of the generator for cooling. Normally, the top, sides, and rear panel are warm when the generator is used continuously for extended periods of time.

   You can also mount the generator on the CUSA EXcel system and CUSA System 200, using the optional CUSA mounting brackets.
3. Plug the generator power cord into the rear panel receptacle.

4. Plug the generator power cord into a grounded receptacle.
5. Turn on the generator by pressing the power switch on (|). Verify the following:
   - All visual indicators and displays on the front panel illuminate.
   - Activation tones sound to verify that the speaker is working properly.

Important

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

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

   If the self-test is not successful, an alarm tone sounds. A number may momentarily appear in the Cut display and, in most cases, the generator is disabled. Note the number and refer to *Responding to System Alarms* on page 7-10.

Once the self-test is successful, connect the accessories and set the generator controls. Refer to *Preparing for Bipolar or Macrobipolar Surgery* on page 4-5, *Preparing for Monopolar Surgery* on page 4-7, or *Preparing for Ultrasonic Electrosurgery* on page 4-13.

Preparing for Bipolar or Macrobipolar Surgery

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

Connections for Bipolar or Macrobipolar Surgery

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

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.

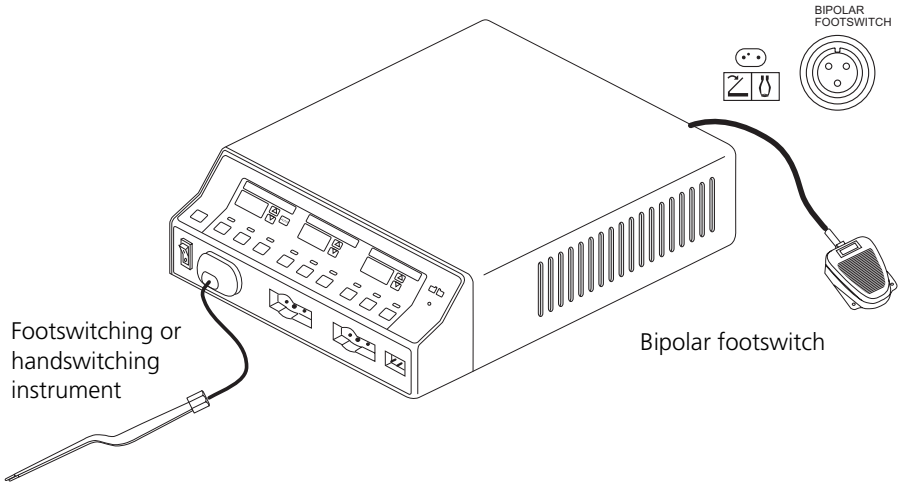
Caution

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

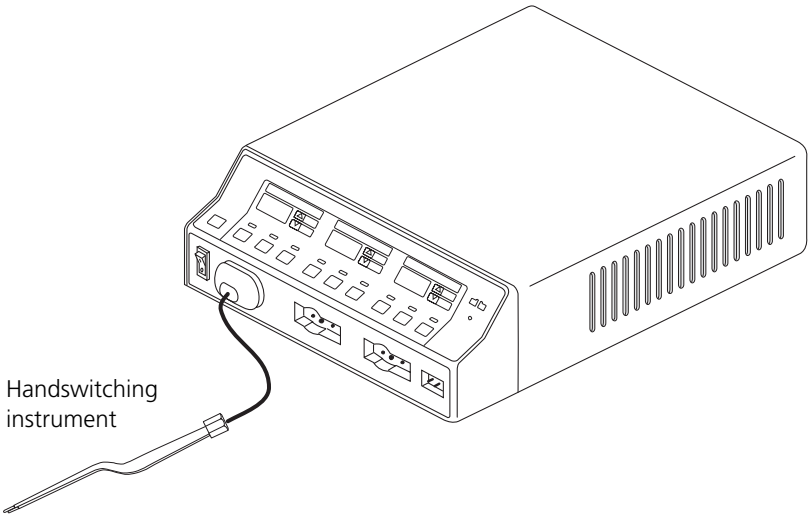
Inspect accessories and cords (especially reusable accessories and cords) for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or surgical team.

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

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



Connection for bipolar or macrobipolar surgery using a handswitching instrument



Setting the Bipolar Output

Caution

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

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

Preparing for Monopolar Surgery

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

Connections for Monopolar Surgery

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.

Use only a Valleylab monopolar footswitch with the Force FX-C generator. Use of an incompatible footswitch may cause unexpected output.

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

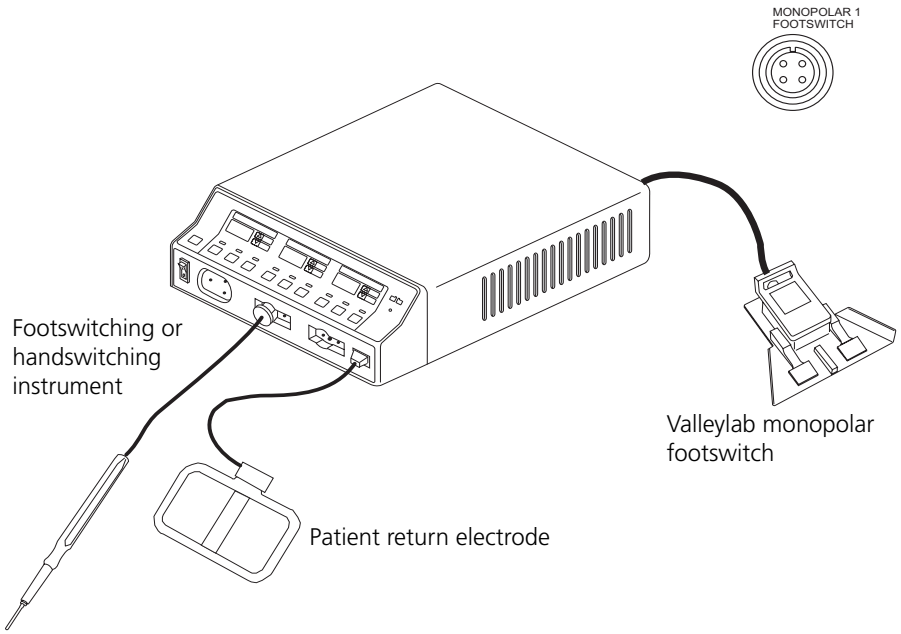
The instrument receptacles on this generator are designed to accept only one instrument at a time. Do not attempt to connect more than one instrument at a time into a given receptacle. Doing so will cause simultaneous activation of the instruments.

Caution

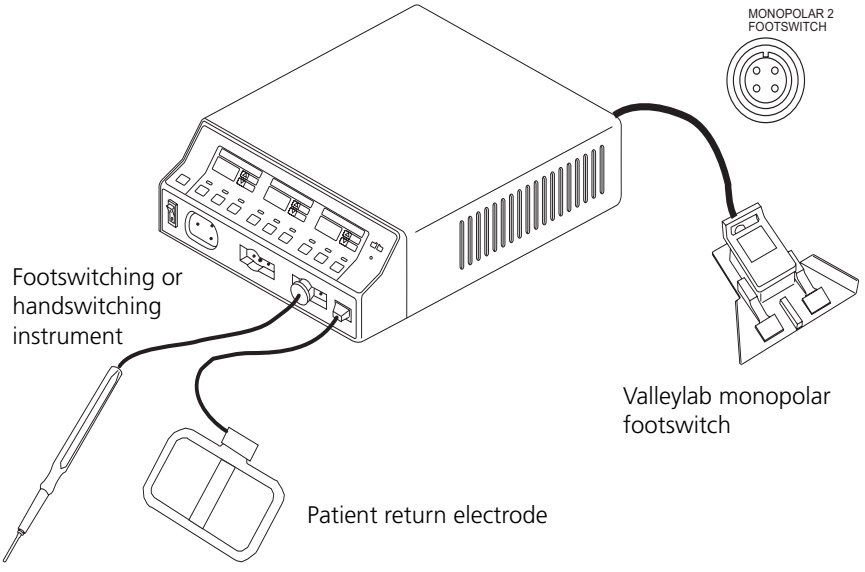
Read the instructions, warnings, and cautions provided with electrosurgical accessories before using. Specific instructions are not included in this manual.

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

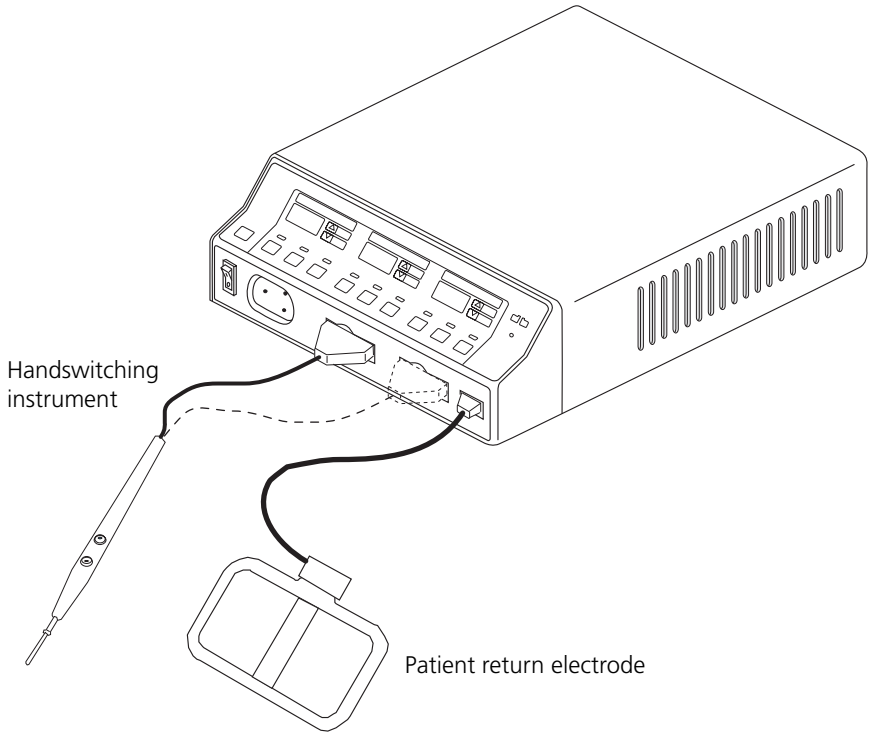
Connection for monopolar surgery using footswitch activation and a footswitching or handswitching instrument – using Monopolar 1 Footswitch receptacle and Monopolar 1/CEM Instrument receptacle



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



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



Applying a Patient Return Electrode to the Patient

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.

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

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

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

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

Using Two Generators Simultaneously

Caution

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

Two generators (and two patient return electrodes) may be used simultaneously on the same patient, provided the generators are the same type (both are isolated or both are ground referenced). However, the two generators are not synchronized.

One return electrode frequently acquires a high positive voltage while the other acquires an opposite negative voltage. When this occurs, the potential voltage difference between them may cause the current to flow from one patient return electrode to the other. The current causes no harm if it produces no sparks or high current densities on the patient.

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

Pacemakers

Warning

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

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

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

Selecting Cut and Coag Modes

Caution

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

1. (Optional) To display the previous settings, press the Recall button.
2. ***To select a cut mode****,* press the Low, Pure, or Blend button. The corresponding indicator illuminates green.
3. *To increase the power for the cut mode you selected,* press the yellow up arrow (Δ) button. To decrease the power, press the yellow down arrow (∇) button. The maximum power setting for Low and Pure is 300 watts. The maximum power setting for Blend is 200 watts.
4. ***To select a coag mode****,* press the Low (Desiccate), Med (Fulgurate), or High (Spray) button. The corresponding indicator illuminates green.

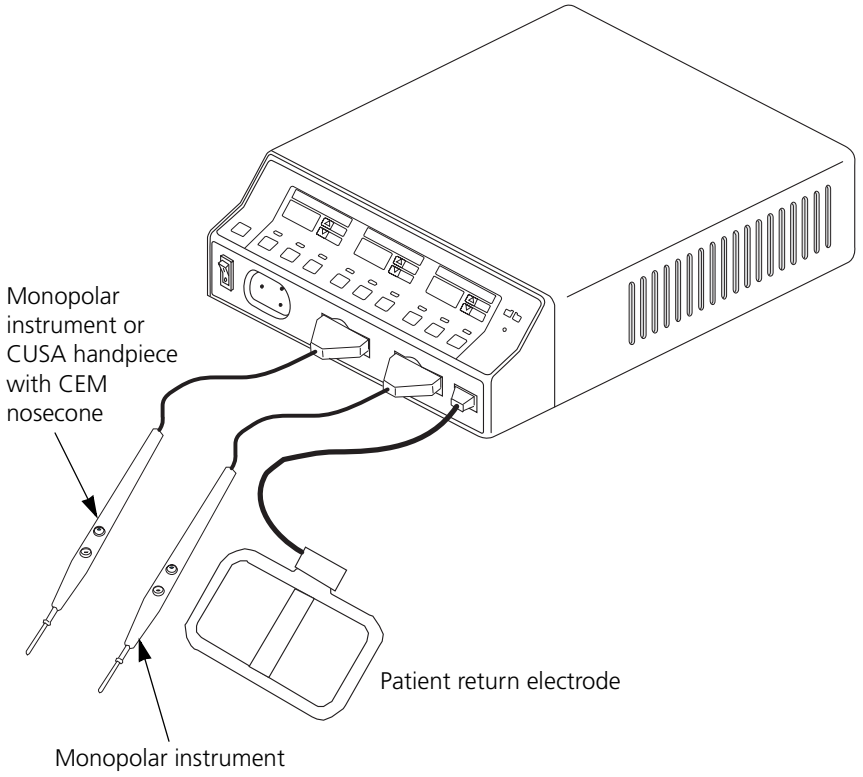
   To select the LCF fulgurate mode, press the Med button and hold for two seconds. A tone sounds and an "L" appears on the left side of the Coag display. To return to the standard fulgurate mode, press the Med button and hold for two seconds. A tone sounds and the "L" disappears from the left side of the Coag display.
5. *To increase the power for the selected coag mode,* press the blue up arrow (Δ) button. To decrease the power, press the blue down arrow (∇) button. The maximum power setting for each coag mode is 120 watts.

   In the LCF fulgurate mode, an "L" appears on the left side of the Coag display. When the LCF fulgurate power is set above 95 watts, the power setting display alternates between showing the power setting (for example, 110 watts) and "L--".

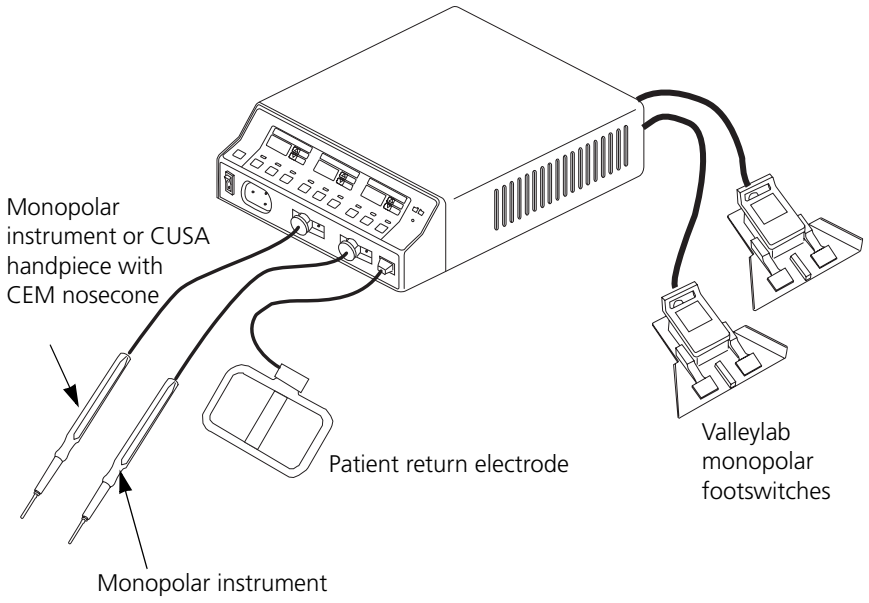
Simultaneous Coag

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

Connection for simultaneous coag using two handswitching instruments



Connection for simultaneous coag using two footswitching instruments



Preparing for Ultrasonic Electrosurgery

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

Assemble and sterilize the CUSA handpiece and the CEM nosecone.

Connecting the Patient Return Electrode

Covidien recommends using a REM Polyhesive patient return electrode to maximize patient safety. For further information, refer to *Applying a Patient Return Electrode to the Patient* on page 4-9.

Connecting the CUSA Handpiece with CEM Nosecone

Warning

Electric Shock Hazard—

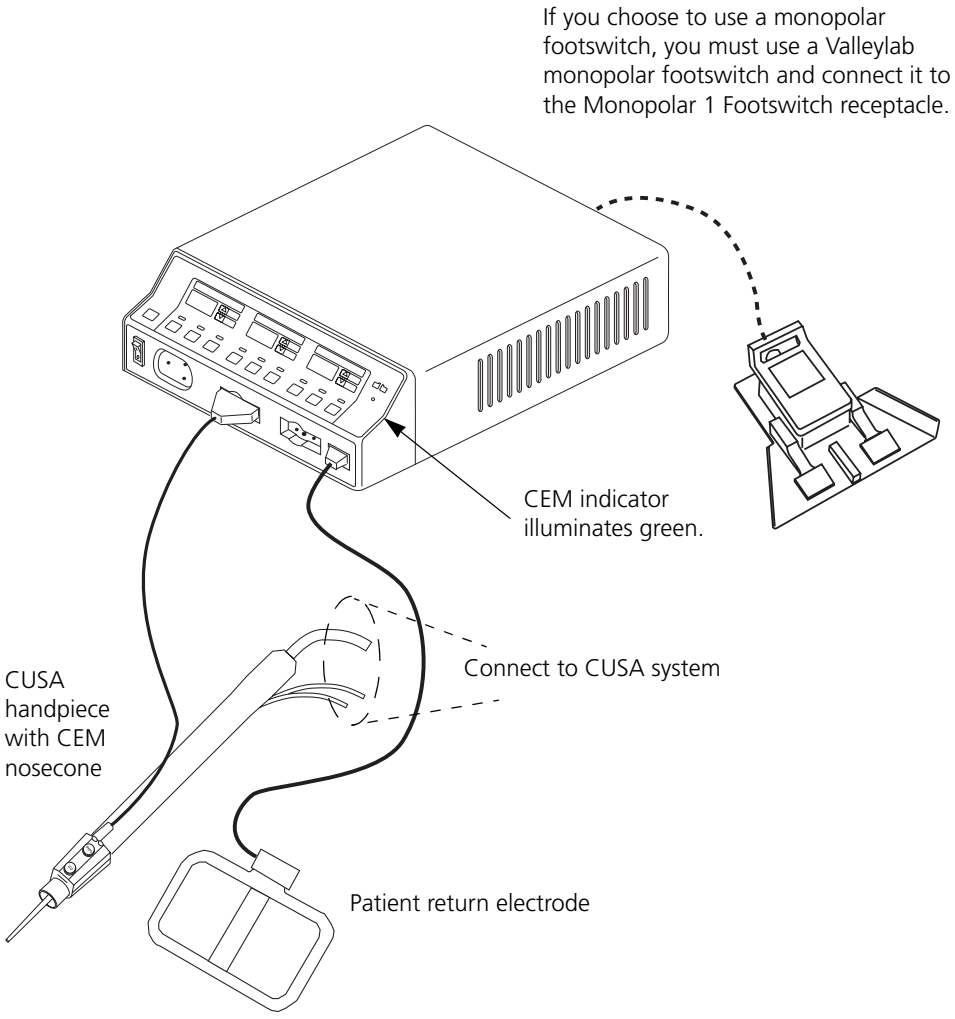
- Do not connect wet accessories to the generator.
- Ensure that all accessories and adapters are correctly connected and that no metal is exposed.

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

Caution

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

Connection for combined monopolar/ultrasonic surgery



Setting the Output Power

Caution

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

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

To verify or change the Low cut power setting:

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

To verify or change the Desiccate coag power setting:

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

Simultaneous Coag

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

Refer to *Preparing for Monopolar Surgery* on page 4-7 for more information.

Chapter 5

During Surgery

This chapter covers the following topics:

- Checking accessory connections
- Checking the patient return electrode
- Changing the mode
- Selecting the power setting
- Activating the surgical instrument
- Adjusting the volume of activation tones
- Responding to alarms

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

Checking Accessory Connections

Warning

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

Caution

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

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

Checking the Patient Return Electrode

Warning

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

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

Changing the Mode

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

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

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

Selecting 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.

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.

During a surgical procedure, the amount of current delivered during a given time period determines the amount of heating that occurs under the electrode. All Covidien patient return electrodes are designed for use during traditional surgical procedures and duty cycles (on time compared to off time). Users should consult Chapter 9, *Technical Specifications*, for the recommended maximum duty cycle specifications.

It is not possible to foresee what combination of current and duty cycle may be safely used in every situation, such as when higher currents and/or longer duty cycles are used on procedures such as tissue lesioning, tissue ablation, tissue vaporization, and procedures where conductive fluid is introduced into the surgical site. Under these conditions there can be greater risk that the heating under a fully applied return electrode may be high enough to injure the patient.

When using a Covidien generator or patient return electrode during these types of surgical procedures the user should seek written guidance from the manufacturer of the active accessory regarding the currents and duty cycles that can be expected as well as detailed user instructions. In some instances, the application of additional patient return electrodes may help mitigate the increased risk.

Changing the Power Setting

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

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

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

When you press and release the power button, the power changes by one setting (1, 5, or 10 watts), based on the settings available for the selected mode. The available power settings are listed in Chapter 9, *Technical Specifications*.

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

Techniques for Keeping Power Settings Low

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

The following are techniques for keeping power settings low.

Concentrating the current by using a small active electrode

The smaller the active electrode, the higher the current density it delivers to tissue, and the less power it requires to produce the same surgical effect. For example, a needle electrode cuts at a lower power setting than a blade electrode. A small ball electrode desiccates or fulgurates tissue at a lower power setting than a large ball electrode.

Coagulating tissue by using fulguration rather than desiccation

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

Cutting by sparking rather than by desiccating tissue

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

Using bipolar surgery

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

Typical Power Settings

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

Caution

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

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

Activating the Surgical Instrument

Notice

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

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

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

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

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

Adjusting the Volume of Activation Tones

Caution

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

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

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

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

Responding to Alarms

REM Alarm

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

Important

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

Alarm Situations

The following conditions can generate a REM alarm:

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

To correct an alarm condition, refer to *Correcting a REM Alarm Condition* on page 7-2.

Non-REM Patient Return Electrode Alarm

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

System Alarm

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

1. Turn off the generator.
2. Turn on the generator and verify that the self-test is completed successfully. If the alarm number reappears, note the number and refer to *Responding to System Alarms* on page 7-10.

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

Chapter 6

After Surgery

This chapter instructs you on:

- Preparing the generator for reuse
- Storing the generator

Preparing the Generator for Reuse

Caution

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

Step 1 – Disconnect the Accessories

A. Turn off the generator.

B. If applicable, remove the patient return electrode from the patient. Disconnect all accessories from the front panel.

   – If the accessory is disposable (single use only), dispose of it according to the procedures for your institution.

   – If the accessory is reusable, clean and sterilize it according to the manufacturer's instructions.

C. Disconnect and store any footswitch(es) used.

Step 2 – Clean the Generator

Warning

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

Notice

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

A. Turn off the generator, and unplug the power cord from the wall outlet.

B. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth.

   Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. The generator cannot be sterilized.

Storing the Generator

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

The generator can be stored indefinitely. However, if you store it longer than one year, you must perform specific checkout procedures before use (refer to the service manual).

Chapter 7

Troubleshooting

This chapter includes:

- Correcting a REM alarm condition
- Correcting malfunctions
- Responding to system alarms

General Troubleshooting Guidelines

If the Force FX-C generator malfunctions, check for obvious conditions that may have caused the problem:

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

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

Correcting a REM Alarm Condition

To correct a REM alarm condition, follow these steps:

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

   If you are using a REM Polyhesive patient return electrode, apply another REM electrode. Refer to *Applying Additional Patient Return Electrodes* on page 7-3.

   or

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

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

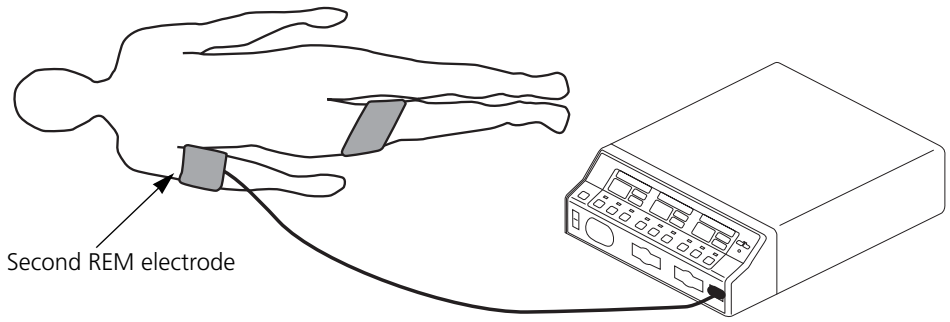
- If you are using a REM Polyhesive patient return electrode, the indicator illuminates green.
- If you are using a patient return electrode without the REM safety feature, the red indicator light is extinguished.

Applying Additional Patient Return Electrodes

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

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

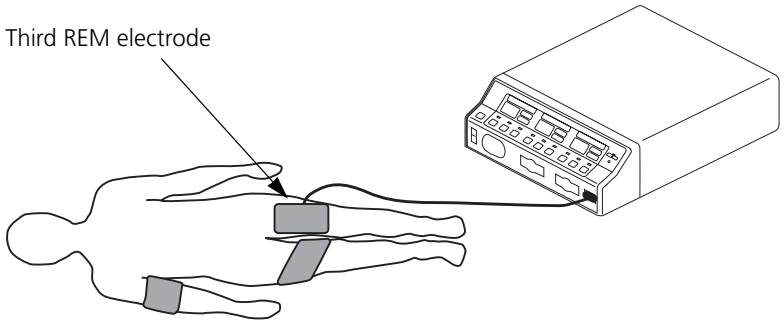
      If the alarm persists, go to the next step.
2. Apply firm pressure over the entire surface area of the patient return electrode, particularly the center. If the alarm persists, go to the next step.
3. Apply a *second* patient return electrode.
   a. Unplug the patient return electrode from the generator. *Do not* remove it from the patient.
   b. Apply a second REM electrode to an appropriate site and connect it to the Patient Return Electrode receptacle on the generator.



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

      If the alarm persists, go to the next step.
4. Apply a *third* patient return electrode.
   a. Unplug the second patient return electrode from the generator. Do not remove either return electrode from the patient.

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



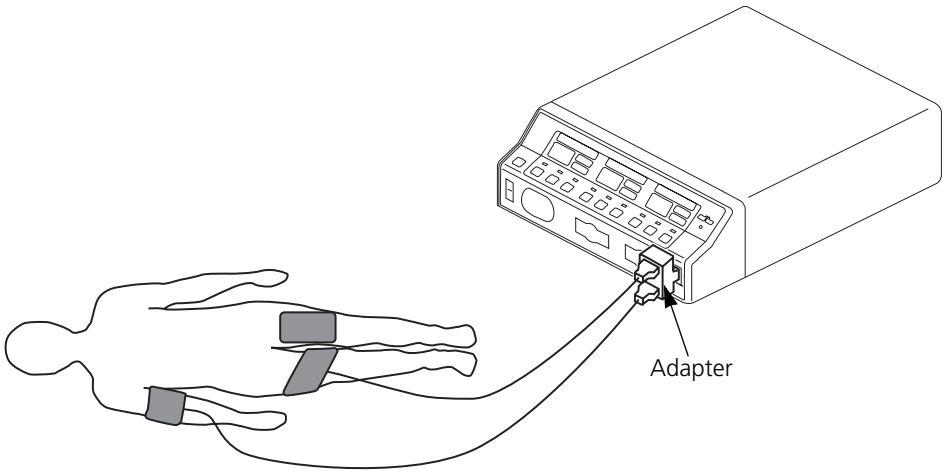
If the alarm clears, leave the generator on during draping to avoid disturbing the return electrode. Remove the return electrodes that is not in use.

If the alarm persists, go to the next step.

5. Unplug the patient return electrode from the generator.

Use a Covidien multiple return/S cord adapter (E0507B) to connect two patient return electrodes to the generator.

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



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

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

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

Correcting Malfunctions

If a solution is not readily apparent, use the table below to help identify and correct specific malfunctions. After you correct the malfunction, verify that the generator completes the self-test as described in *Setting Up the Generator* on page 4-3.

Situation	Possible Cause	Solution
Abnormal neuromuscular stimulation (stop surgery immediately).	Metal-to-metal sparking.	Check all connections to the generator, patient return electrode, and active electrodes.
	Can occur during coag.	Use a lower power setting for the Fulgurate and the Spray modes or select the Desiccate mode.
	Abnormal 50–60 Hz leakage currents.	Refer to your Biomedical Engineering Department or contact a Covidien Representative for assistance.
Generator does not respond when turned on.	Disconnected power cord or faulty wall outlet.	Check power cord connections (generator and wall outlet). Connect the power cord to a functional outlet.
	Faulty power cord.	Replace the power cord.
	Fuse drawer is open or fuses are blown.	Close the fuse drawer. Replace the blown fuse(s). Refer to the *Force FX Electrosurgical Generator C Service Manual*.
	Internal component malfunction.	Use a backup generator. Refer to your Biomedical Engineering Department or contact a Covidien Representative for assistance.

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

Situation	Possible Cause	Solution
Generator is on and accessory is activated, but generator does not deliver output.	Malfunctioning footswitch or handswitching instrument.	Turn off the generator. Check and correct all accessory connections. Turn on the generator. Replace the accessory if it continues to malfunction.
	Incompatible footswitch.	Use only a Covidien footswitch with the Force FX-C generator.
	Footswitch connected to Monopolar 1 Footswitch receptacle is being used for surgical instrument in Monopolar 2 receptacle.	Connect the footswitch to the Monopolar 2 Footswitch receptacle. **or** Connect the instrument to the Monopolar 1/CEM receptacle.
	Footswitch connected to Monopolar 2 Footswitch receptacle is being used for instrument connected to Monopolar 1/CEM receptacle.	Connect the footswitch to the Monopolar 1 Footswitch receptacle. **or** Connect the instrument to the Monopolar 2 receptacle.
	Power set too low.	Increase the power setting. Refer to *Changing the Power Setting* on page 5-3.
	An alarm condition exists.	Check the Cut display for an alarm number. Note the number and refer to *Responding to System Alarms* on page 7-10. In case of a REM alarm, refer to *Correcting a REM Alarm Condition* on page 7-2.
	Internal component malfunction.	Use a backup generator. Contact your Biomedical Engineering Department or a Covidien Representative for assistance.

Situation	Possible Cause	Solution
Continuous monitor interference.	Faulty chassis-to-ground connections.	Check and correct the chassis ground connections for the monitor and for the generator. Check other electrical equipment in the room for defective grounds.
	Electrical equipment is grounded to different objects rather than a common ground. The generator may respond to the resulting voltage differences between grounded objects.	Plug all electrical equipment into line power at the same location. Contact your Biomedical Engineering Department or a Covidien Representative for assistance.
	Malfunctioning monitor.	Replace the monitor.
Interference with other devices only when the generator is activated.	Metal-to-metal sparking.High settings used for fulguration.	Check all connections to the generator, patient return electrode, and accessories.
	High settings used for fulguration.	Use lower power settings for fulguration or select the Desiccate mode.
	Electrically inconsistent ground wires in the operating room	Verify that all ground wires are as short as possible and go to the same grounded metal.
	If interference continues when the generator is activated, the monitor is responding to radiated frequencies.	Ask your Biomedical Engineering Department to check with the manufacturer of the monitor. Some manufacturers offer RF choke filters for use in monitor leads. The filters reduce interference when the generator is activated and minimize the potential for an electrosurgical burn at the site of the monitor electrode.

Situation	Possible Cause	Solution
Pacemaker interference.	Intermittent connections or metal-to-metal sparking.	Check the active and patient return electrode cord connections. It may be necessary to reprogram the pacemaker.
	Current traveling from active to return electrode during monopolar electrosurgery is passing too close to pacemaker.	Use bipolar instruments, if possible. If you must use a monopolar instrument, place the patient return electrode as close as possible to the surgical site. Make sure the current path from the surgical site to the patient return electrode does not pass through the vicinity of the heart or the site where the pacemaker is implanted. Always monitor patients with pacemakers during surgery and keep a defibrillator available. Consult the pacemaker manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned in patients with cardiac pacemakers.
Internal Cardiac Defibrillator (ICD) activation.	ICD is activated by electrosurgical generator.	Stop the procedure and contact the ICD manufacturer for instructions.

Responding to System Alarms

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

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

After correcting the alarm condition, verify that the generator completes the self-test as described in *Setting Up the Generator* on page 4-3.

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 Covidien 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 Covidien Service Center.
13–14 16	Diagnostic/microcontroller malfunction.	Contact your Biomedical Engineering Department.
17–18	Internal component malfunction.	Do not attempt to use the generator. Record the number and call the Covidien Service Center.
19	Internal component malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien Service Center.
30–32 40 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 Covidien Service Center.
68	Microcontroller malfunction.	Contact your Biomedical Engineering Department.

Number	Description	Recommended Action
69–71 80	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien Service Center.
81	Internal component malfunction.	Do not attempt to use the generator. Record the number and call the Covidien Service Center.
90 95	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
100–105 110–119	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien 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 Covidien Service Center.
122 123–126	Calibration malfunction. Microcontroller malfunction.	Contact your Biomedical Engineering Department.
130–134 136–138 150	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien 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 Covidien 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 Covidien Service Center.

Number	Description	Recommended Action
161, 163–166 170–173	Dosage error. Microcontroller malfunction.	Contact your Biomedical Engineering Department.
174	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien Service Center.
180–185	Internal diagnostics.	Contact your Biomedical Engineering Department.
189	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien Service Center.

Number	Description	Recommended Action
190	Bipolar up arrow, bipolar down arrow, and/or a bipolar mode button (Precise, Standard, Macro) may be stuck.	1. Turn off, then turn on the generator. Do not press buttons or accessory activation devices during the self-test. 2. If the alarm number reappears, disconnect all accessories. Then, turn off and turn on the generator again. If the alarm number reappears, record the number and call the Covidien Service Center.
191	Cut up arrow, cut down arrow, and/or a cut mode button (Low, Pure, Blend) may be stuck.	
192	Coag up arrow, coag down arrow, and/or a coag mode button (Desiccate, Fulgurate, Spray) may be stuck.	
193	Recall button may be stuck.	
194	Handswitch or Monopolar 1 Footswitch cut pedal may be stuck.	
195	Handswitch or Monopolar 1 Footswitch coag pedal may be stuck.	
196	Handswitch or Monopolar 2 Footswitch cut pedal may be stuck.	
197	Handswitch or Monopolar 2 Footswitch coag pedal may be stuck.	
198	Handswitch or Bipolar Footswitch pedal may be stuck.	
199–203	Internal diagnostics or microcontroller malfunction.	Contact your Biomedical Engineering Department.
206–207	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien Service Center.
208–209	Microcontroller malfunction.	Contact your Biomedical Engineering Department.

Number	Description	Recommended Action
210–211	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien Service Center.
212–213 215	Internal diagnostics.	Contact your Biomedical Engineering Department.
220–226	Internal diagnostics or microcontroller malfunction.	
230–231	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien Service Center.
232	Microcontroller malfunction.	Contact your Biomedical Engineering Department.
240–242 244–245	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien Service Center.
246–247 260	Microcontroller malfunction. Internal diagnostics.	Contact your Biomedical Engineering Department.
261–262 270–271	Software malfunction.	Turn off, then turn on the generator. If the alarm number reappears, record the number and call the Covidien 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. Use the lowest power setting that achieves the desired effect. Limit activation times, if possible.

Chapter 8

Maintenance and Repair

Refer to this chapter for information on:

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

Responsibility of the Manufacturer

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

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

For warranty information, refer to the *Limited Warranty* in the front matter of this guide.

Routine Maintenance

Notice
Refer to the generator service manual for maintenance recommendations and function and output power verification procedures.

When should the generator be checked or serviced?

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

When should the power cord be checked or replaced?

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

When should the fuses be replaced?

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

Returning the Generator for Service

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

Step 1 – Obtain a Return Authorization Number

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

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

Step 2 – Clean the Generator

Warning

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

Notice

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

A. Turn off the generator, and unplug the power cord from the wall outlet.

B. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth.

   Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the chassis. The generator cannot be sterilized.

Step 3 – Ship the Generator

A. Attach a tag to the generator that includes the Return Authorization Number and the information (hospital, phone number, etc.) listed in *Step 1 – Obtain a Return Authorization Number*.

B. Be sure the generator is completely dry before you pack it for shipment. Package it in its original shipping container, if available.

C. Ship the generator, prepaid, to the Covidien Service Center.

Covidien Service Centers

For a complete list of service centers world-wide, please refer to the Covidien web site:

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

Chapter 9

Technical Specifications

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

Performance Characteristics

General

Output configuration	Isolated output
Cooling	Natural convection; side and rear panel vents; fan
Display	Eight digital seven-segment displays: 0.75" (1.9 cm) each
Mounting	Covidien carts, CUSA EXcel System, CUSA System 200 (using CUSA System 200 optional mounting brackets), a Force GSU unit, an Argon Gas Delivery Unit II, or any stable flat surface

Dimensions and Weight

Width:	14" (35.6 cm)
Depth	18" (45.7 cm)
Height	43/8" (11.1 cm)
Weight	<18 lb (<8.2 kg)

Operating Parameters

Ambient temperature range	50° to 104° F (10° to 40° C)
Relative humidity	30% to 75%, noncondensing
Atmospheric pressure	700 to 1060 millibars
Warm-up time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the generator to reach room temperature before use.

Transport and Storage

Ambient temperature range	-40° to 158° F (-40° to 70° C)
Relative humidity	25% to 85%, noncondensing
Atmospheric pressure	500 to 1060 millibars
Duration of storage	If stored longer than one year, the battery must be replaced and a full checkout, including calibration, must be completed before use. For instructions, refer to the *Force FX Electrosurgical Generator C Service Manual*.

Duty Cycle

Under maximum power settings and rated load conditions (Pure cut, 300 watt setting, 300 ohm load) the generator is suitable for activation times of 10 seconds on, 30 seconds off for 1 hour.

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

Internal Memory

Nonvolatile, battery-backed RAM	Battery type: 3 V lithium button cell Battery life: 5 years
Storage capacity	• One configuration, including three power settings and three mode settings • The last twenty error codes detected by the generator • The number of times and length of activation for each mode • The average power setting used for each mode • The total time the generator is on • Other service-related information

Audio Volume

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

Activation Tone

Volume (adjustable)	45 to ≥ 65 dB
Frequency	Bipolar: 940 Hz Cut: 660 Hz Coag: 940 Hz
Duration	Continuous while the generator is activated

Alarm Tone

Volume (not adjustable)	≥ 65 dB
Frequency	660 Hz
Duration	250 to 500 ms

REM Contact Quality Monitor

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

Measurement frequency	80 kHz ± 10 kHz
Measurement current	< 10 µA

Acceptable Resistance Range

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

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

Patient return electrode without the REM safety feature: When the measured resistance between the patient return electrode pins exceeds 20 ohms, the REM Alarm indicator flashes red, a tone sounds twice, and RF output is disabled. The indicator remains illuminated red until you correct the condition causing the alarm. Then, the red indicator is extinguished and RF output is enabled.

Serial Port

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

The 9-pin connector supports the following signals:

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

RF Activation Port

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

Expansion Port

The 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 rms at ð 50 W

Input Power

100–120 Volt	220–240 Volt
Maximum VA at nominal line voltage: Idle: 52 VA Bipolar: 450 VA Cut: 924 VA Coag: 530 VA	Maximum VA at nominal line voltage: Idle: 52 VA Bipolar: 450 VA Cut: 924 VA Coag: 530 VA
Input mains voltage, full regulation range: 100–132 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): Idle: 0.4 A Bipolar: 2.0 A Cut: 7.0 A Coag: 4.0 A	Mains current (maximum): Idle: 0.2 A Bipolar: 1.0 A Cut: 3.5 A Coag: 2.0 A
Mains line frequency range (nominal): 50 to 60 Hz	Mains line frequency range (nominal): 50 to 60 Hz
Fuses (2): F8 A	Fuses (2): T4 A
Power cord: 3-prong hospital grade connector	Power cord: 3-prong locally approved connector

Power Cord Specification

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

100-120 VAC

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

220-240 VAC

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

Standards and IEC Classifications

The Force FX-C generator meets all pertinent clauses of the IEC 60601-1 second edition and IEC 60601-2-2 third edition.

ATTENTION
Consult accompanying documents.

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

Danger
Explosion risk if used with flammable anesthetics.

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

Non-Ionizing Radiation

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

Class I Equipment (IEC 60601-1)

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

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

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

The Force FX-C generator patient return electrode terminal is protected from defibrillator discharge according to ANSI/AAMI HF18 and IEC 60601-2-2.

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

The Force FX-C generator enclosure is constructed so that liquid spillage in normal use des not wet electrical insulation or other components which when wetted are likely to adversely affect the safety of the equipment.

Electromagnetic Interference

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

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

The Force FX-C generator complies with the appropriate IEC 60601-1-2 and 60601-2-2 specifications regarding electromagnetic compatibility.

Applied Parts E2515, E2516, E2003, E4053-CT, E7507, E7506, E6008B, and E6009 were tested with the unit and the combination was found to be in compliance with IEC 60601-2-2 (Third Edition). Safety of use of other accessories, not identified in these instructions, has not been determined by Underwriters Laboratories, Inc.

Notice

The Force FX-C generator requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Force *FX Electrosurgical Generator C Service Manual*.

Portable and mobile RF communications equipment can affect the Force FX-C generator. Refer to the EMC information provided in the Force *FX Electrosurgical Generator C Service Manual*.

Voltage Transients (Emergency Generator Mains Transfer)

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

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				
Precise	450 V	100 Ω	70 W	1.5
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				
Desiccate	3500 V	500 Ω	120 W	5
Fulgurate	8500 V	500 Ω	120 W	7.0
LCF Fulgurate	6900 V	500 Ω	120 W	5.5
Spray	9000 V	500 Ω	120 W	8

* An indication of a waveform's ability to coagulate bleeders without a cutting effect

Maximum Output for Ultrasonic Electrosurgery

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				
Desiccate	3500 V	500 Ω	70 W	5

* An indication of a waveform's ability to coagulate bleeders without a cutting effect

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								

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

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

Bipolar

Precise	470 kHz sinusoid
Standard	470 kHz sinusoid
Macro	470 kHz sinusoid

Monopolar Cut

Low	390 kHz sinusoid. Similar to the Pure cut mode except the maximum voltage is limited to a lower value.
Pure	390 kHz sinusoid
Blend	390 kHz bursts of sinusoid, recurring at 27 kHz intervals; 50% duty cycle

Monopolar Coag

Desiccate	240 kHz sinusoid repeated at 39 kHz; 8% duty cycle
Fulgurate	470 kHz damped sinusoidal bursts with a repetition frequency of 30 kHz into 500 ohms
LCF Fulgurate	470 kHz damped sinusoidal bursts with a repetition frequency of 57 kHz into 500 ohms
Spray	470 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.

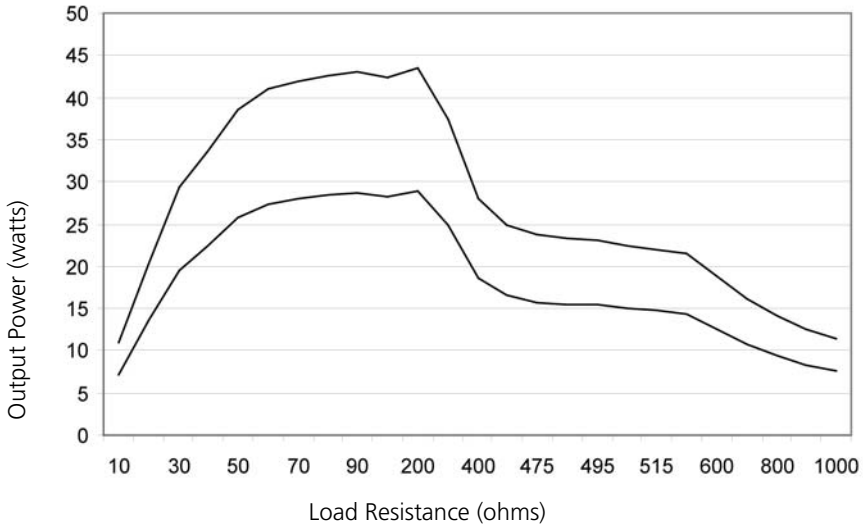
Note: These curves represent the lower and upper limits of output power with tolerance included. The normal output power will be halfway between these two curves.

Bipolar Graphs

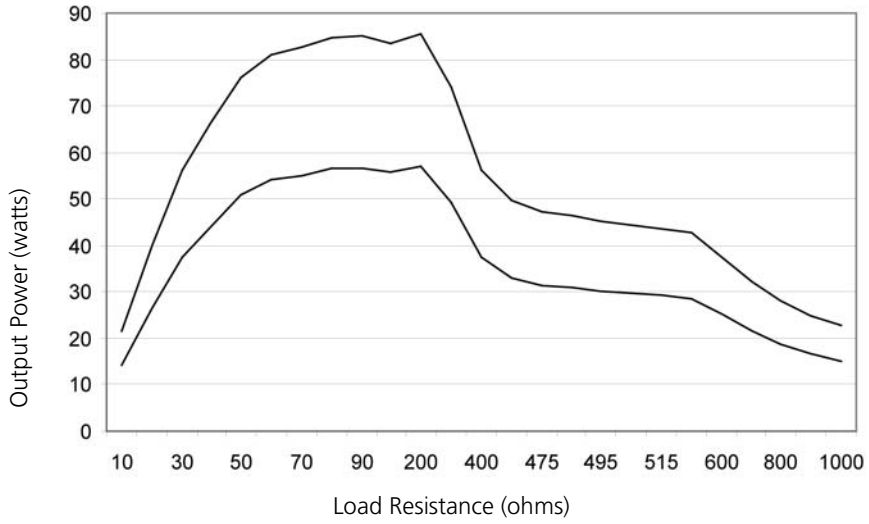
The insulating surface described in IEC 60601-2-2 was used to obtain the bipolar output measurements.

Precise Bipolar Mode

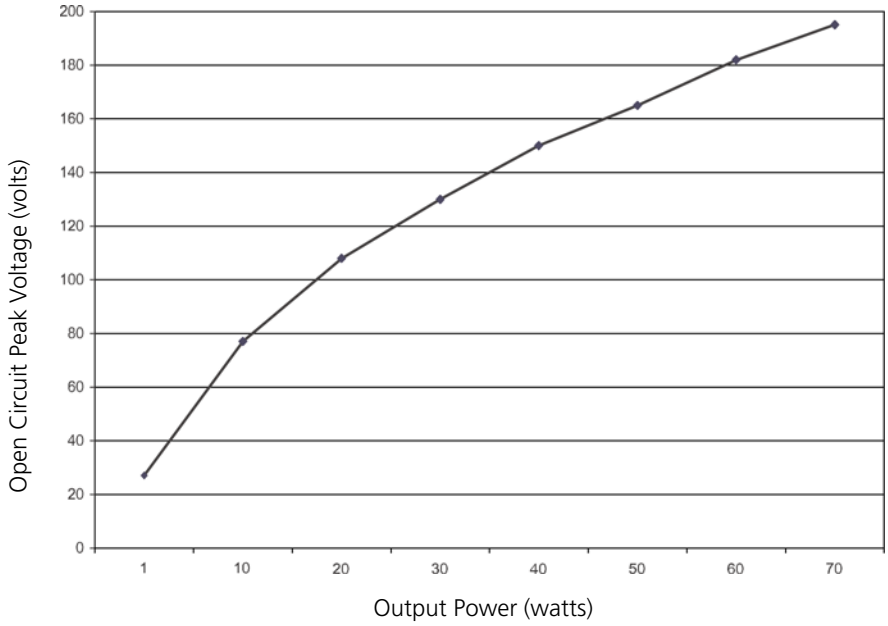
Output power vs. impedance for Precise bipolar 35W mode



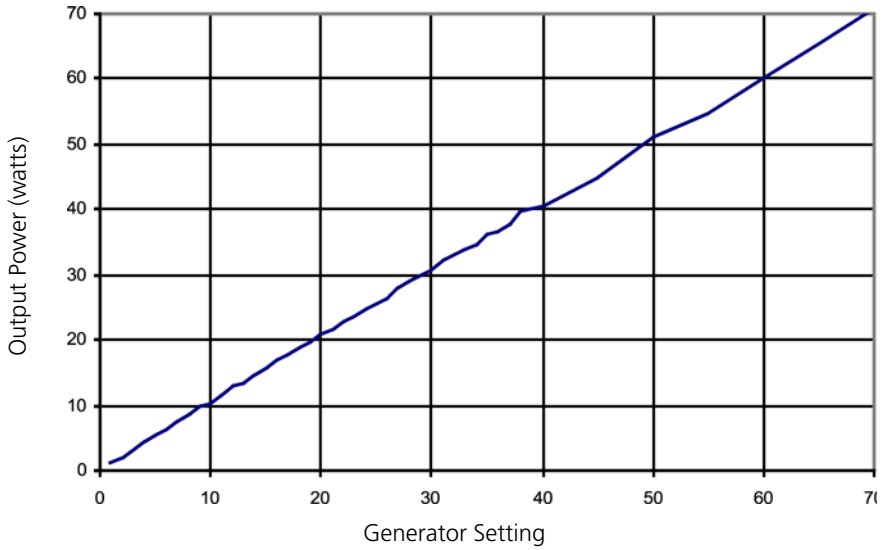
Output power vs. impedance for Precise bipolar 70W mode



Open circuit peak voltage vs. output power for Precise bipolar mode

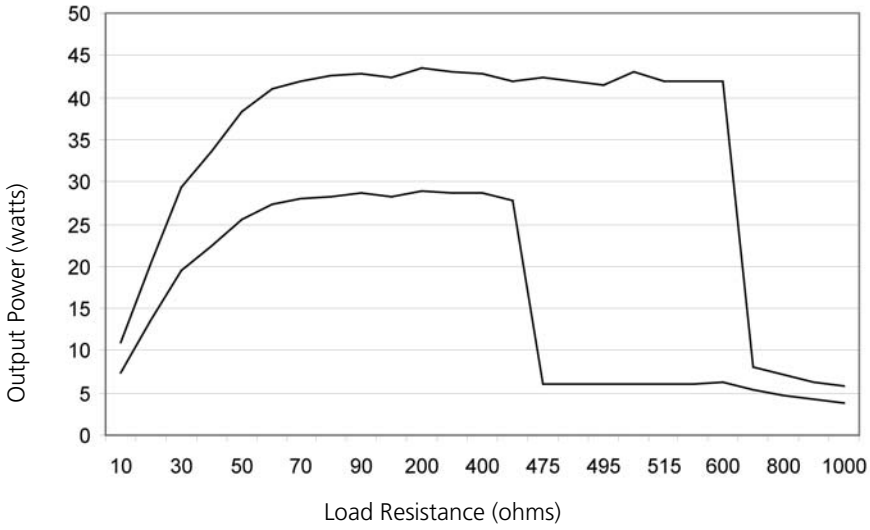


Output power vs. generator settings Precise bipolar mode

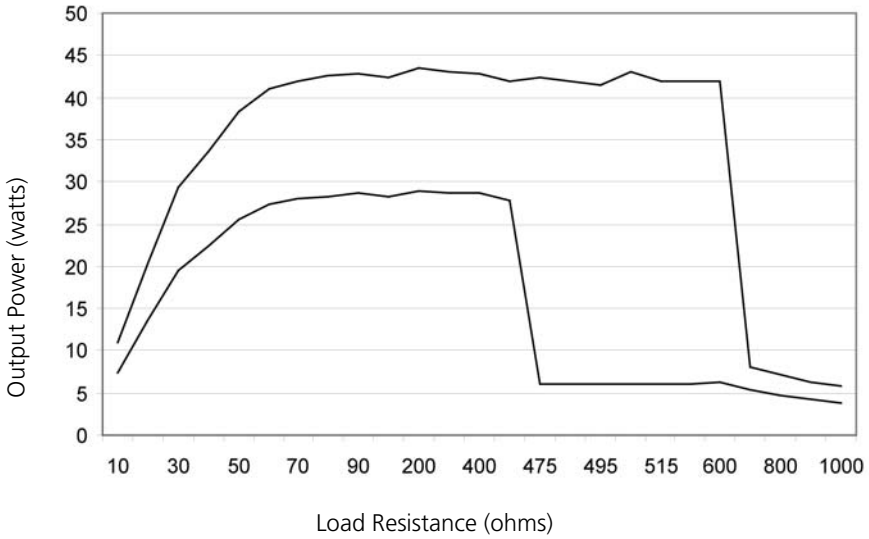


Standard Bipolar Mode

Output power vs. impedance for Standard bipolar 35W mode

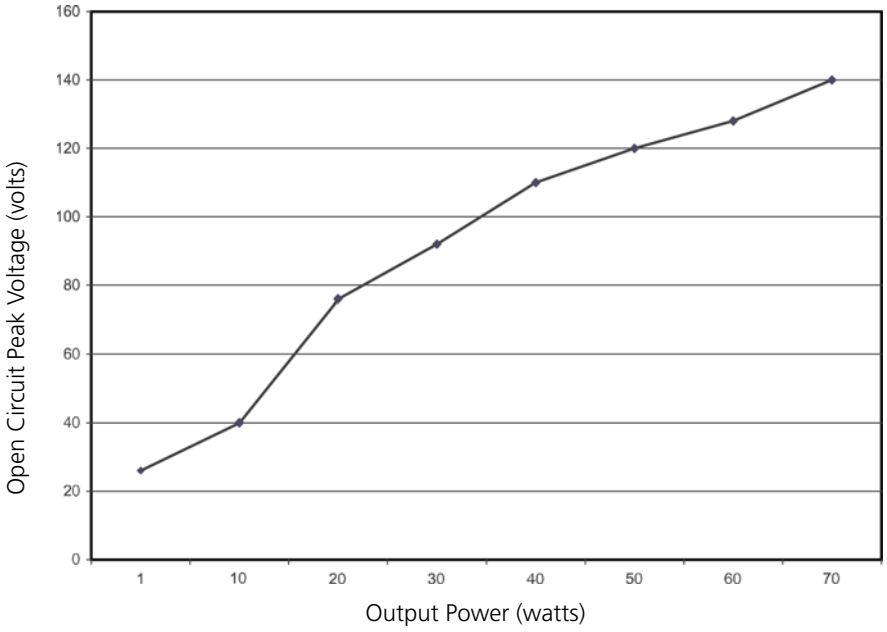


Output power vs. impedance for Standard bipolar 70W mode

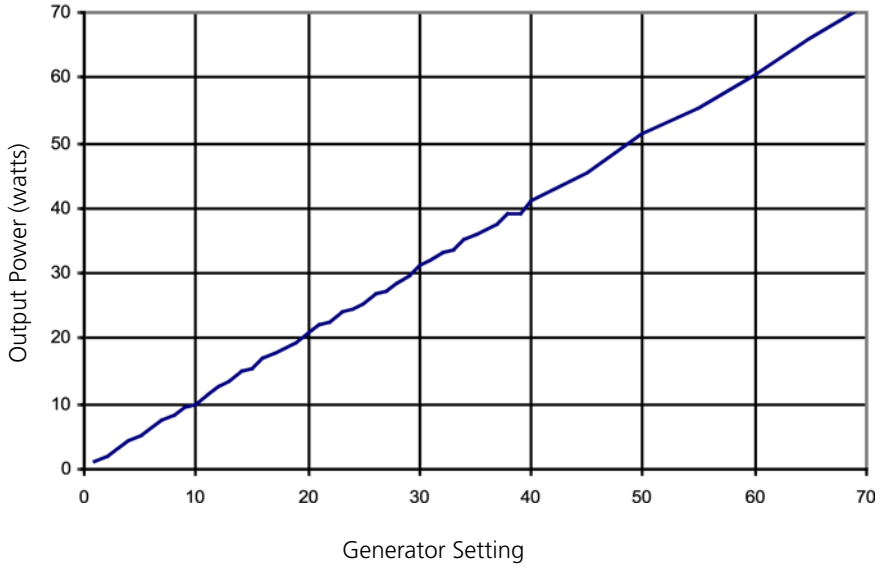


Note: In the Bipolar Standard mode only, the power curve will reflect both High and Low output values between the impedance range of 475-600 ohms. This is based on the sensed impedance value the generator calculates, and the tolerances of the sensing circuits. This is a function of the generator, as the software is designed to reduce (switch to Low output) the output power when the impedance exceeds a reference (475-600 ohms impedance) level. Clinically, above 475 ohms the tissue is almost completely desiccated. By dropping to lower output power levels, we allow the surgeon sufficient time to deactivate the output before tissue sticking occurs.

Open circuit peak voltage vs. output power for Standard bipolar mode

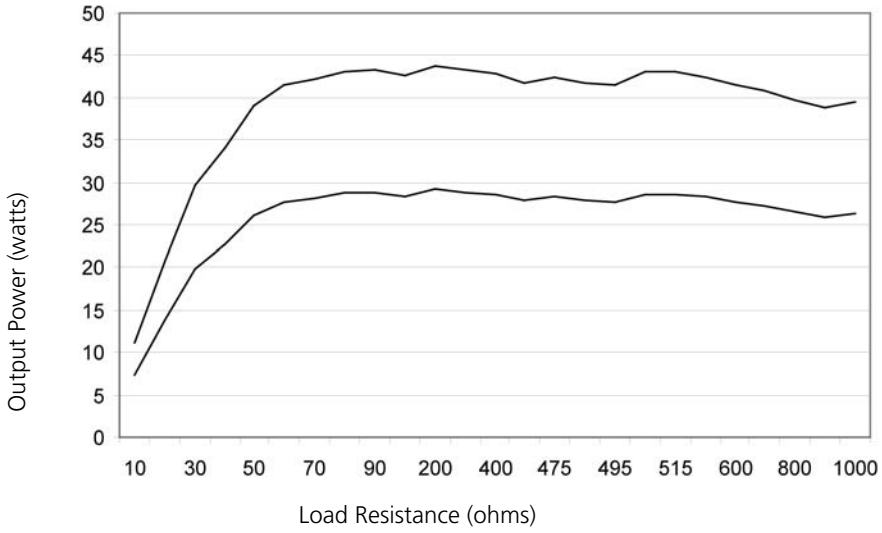


Open circuit peak voltage vs. output power for Standard bipolar mode

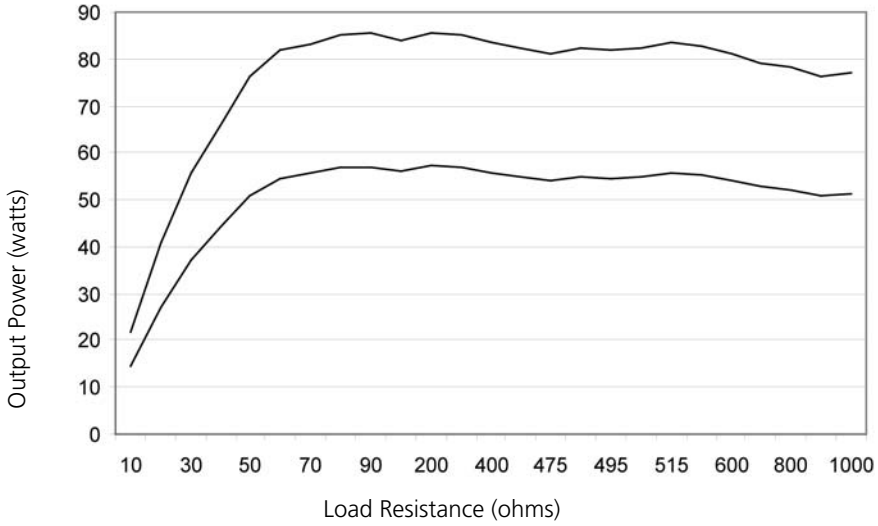


Macrobipolar Mode

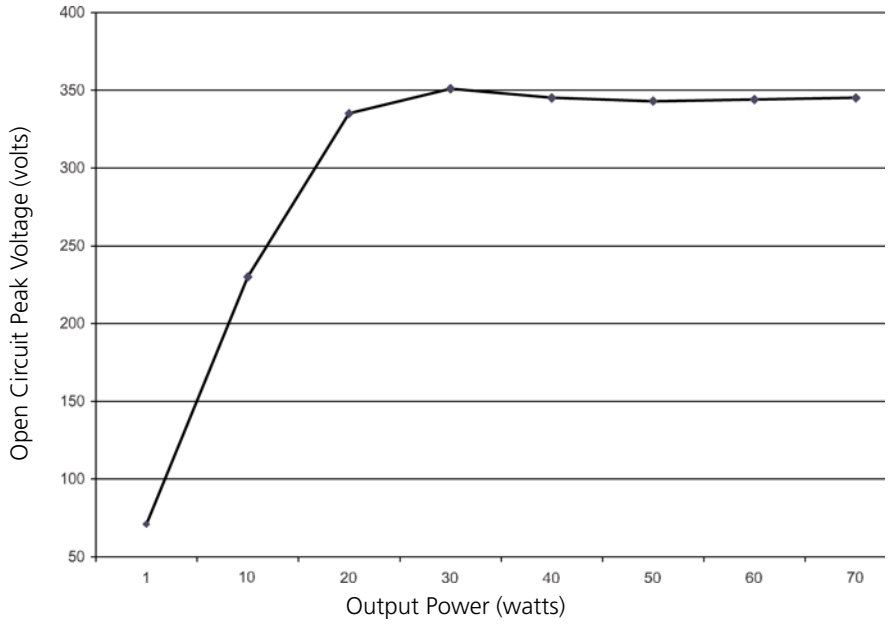
Output power vs. impedance for Macrobipolar 35W mode



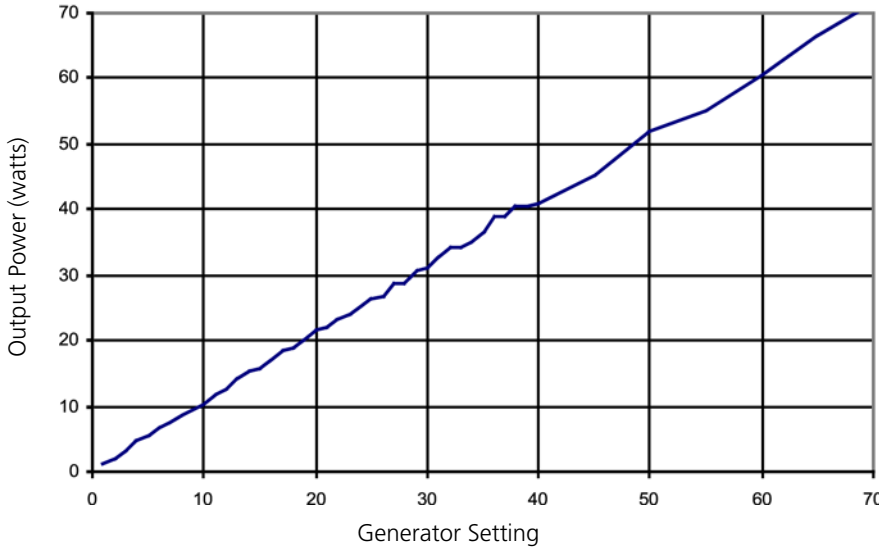
Output power vs. impedance for Macrobipolar 70W mode



Open circuit peak voltage vs. output power for Macrobipolar mode



Output power vs. generator settings Macrobipolar mode

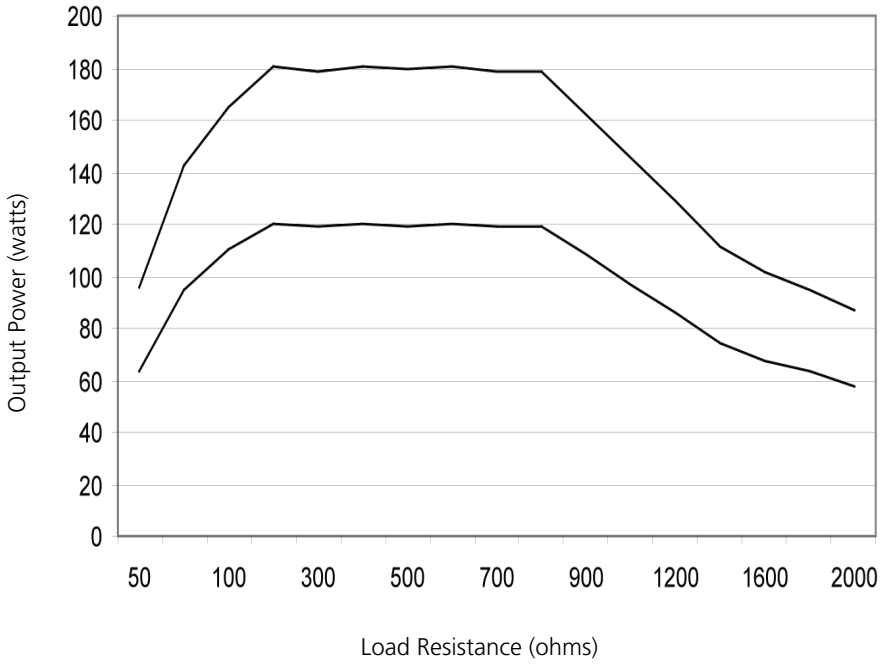


Monopolar Cut Graphs

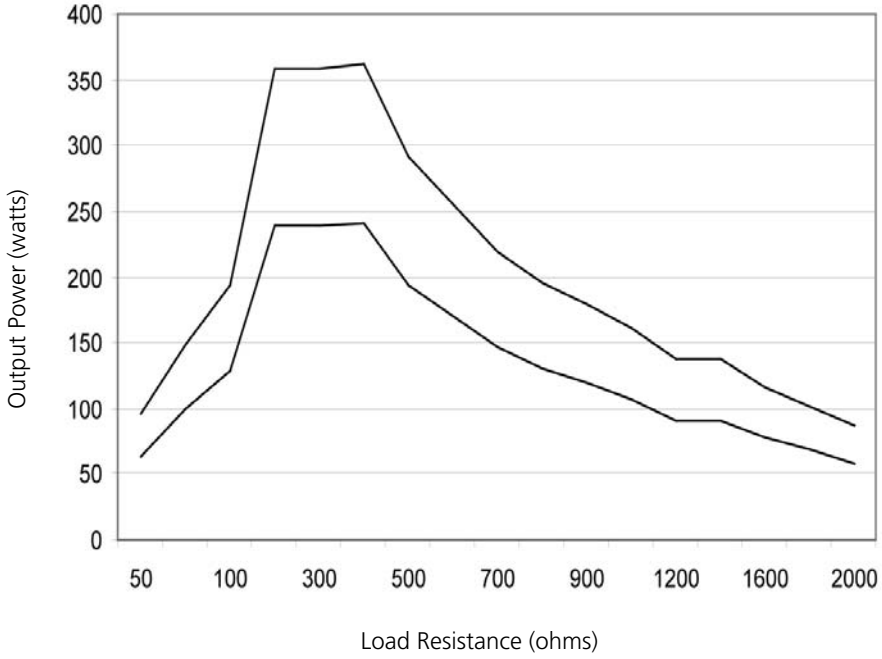
These measurements were taken using short (< 0.5 meter) leads.

Low Cut Mode

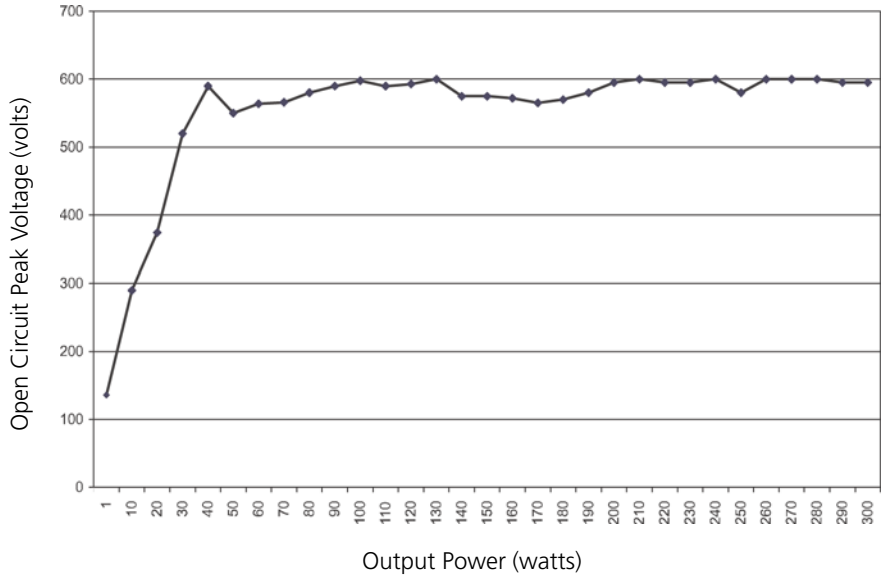
Output power vs. impedance for Low cut 150W mode



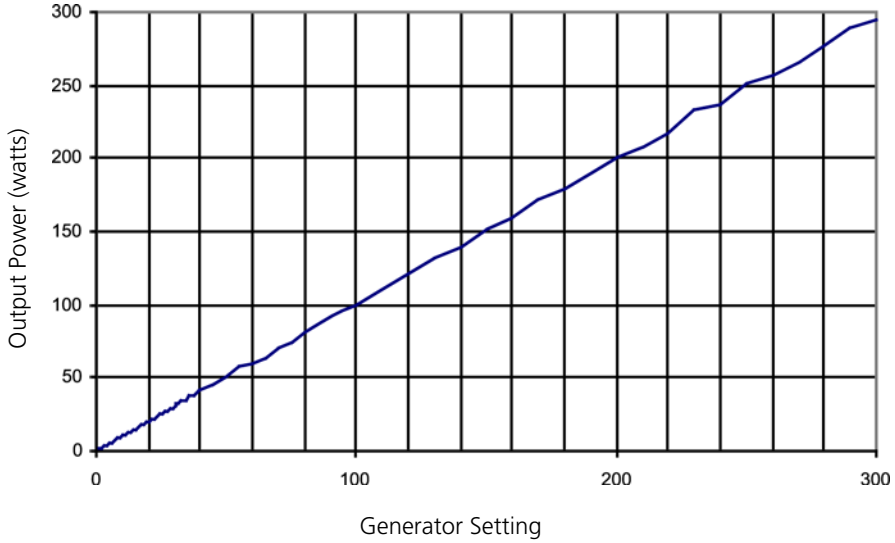
Output power vs. impedance for Low cut 300W mode



Open circuit peak voltage vs. output power for Low cut mode

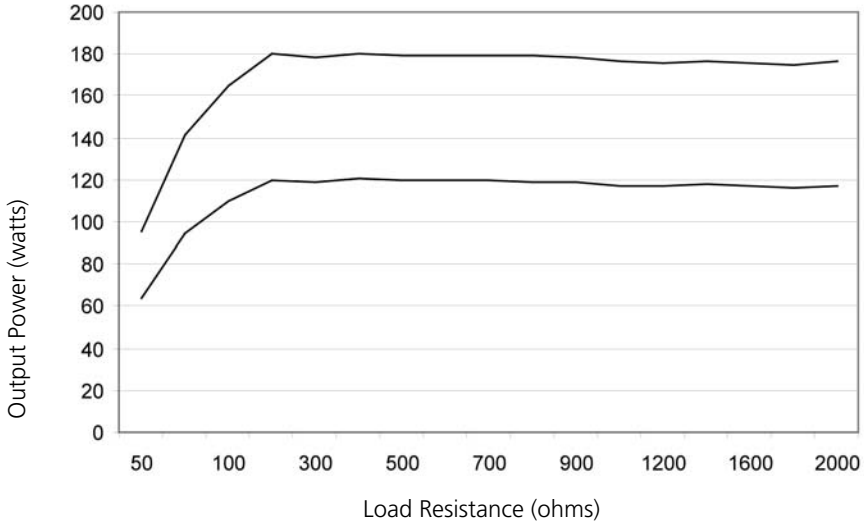


Output power vs. generator settings Low cut mode

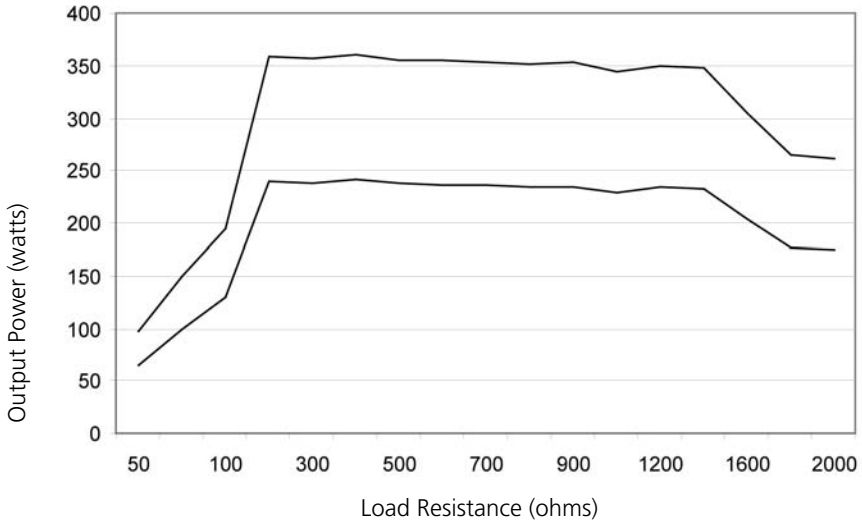


Pure Cut Mode

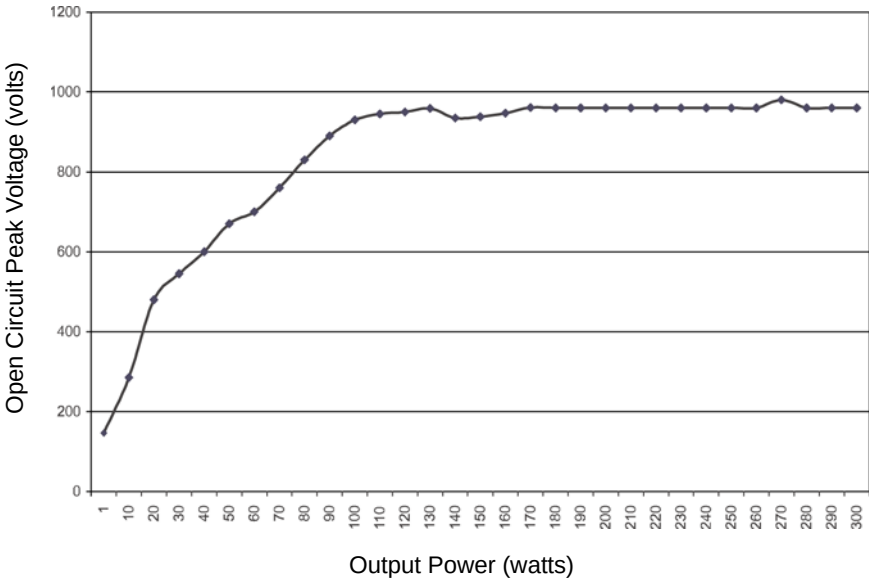
Output power vs. impedance for Pure cut 150W mode



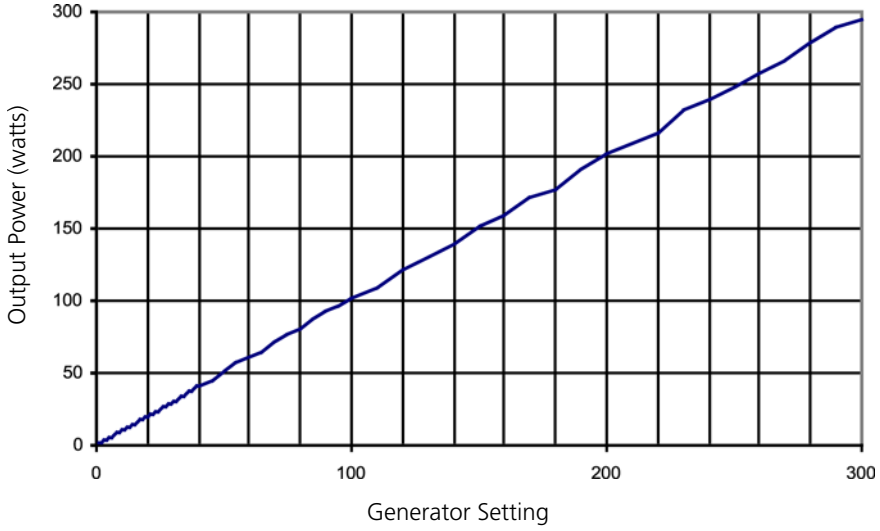
Output power vs. impedance for Pure cut 300W mode



Open circuit peak voltage vs. output power for Pure cut mode

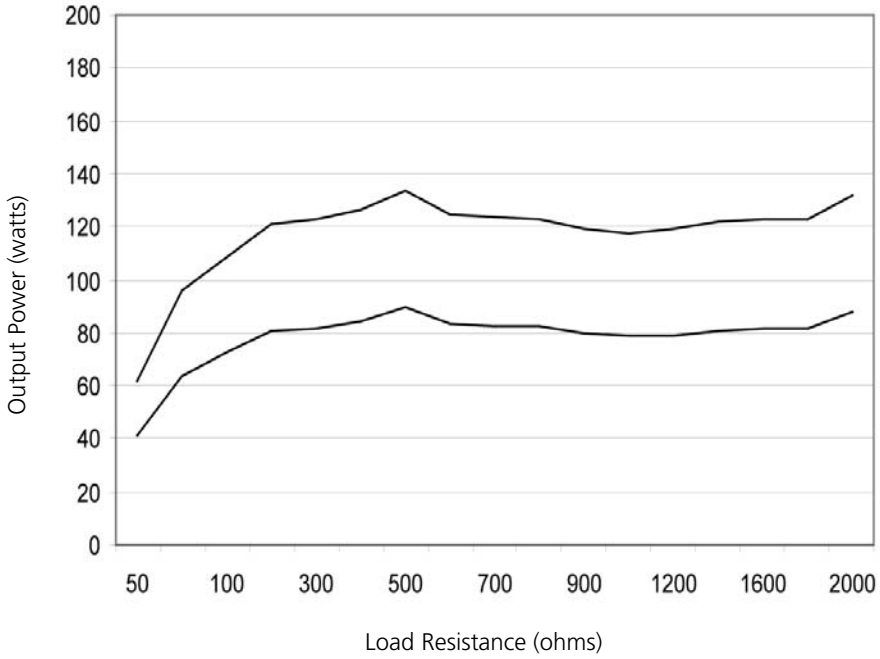


Output power vs. generator settings Pure cut mode

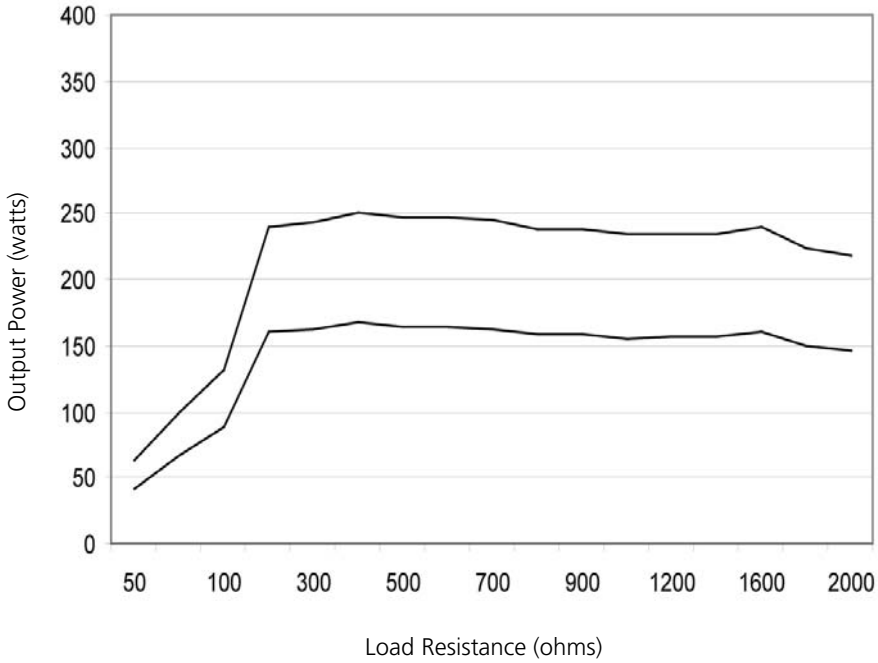


Blend Cut Mode

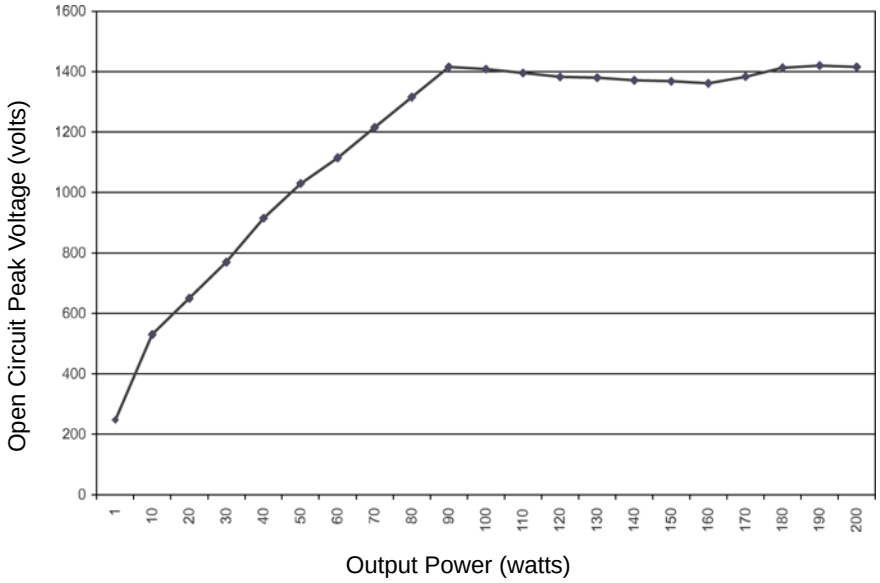
Output power vs. impedance for Blend cut 100W mode



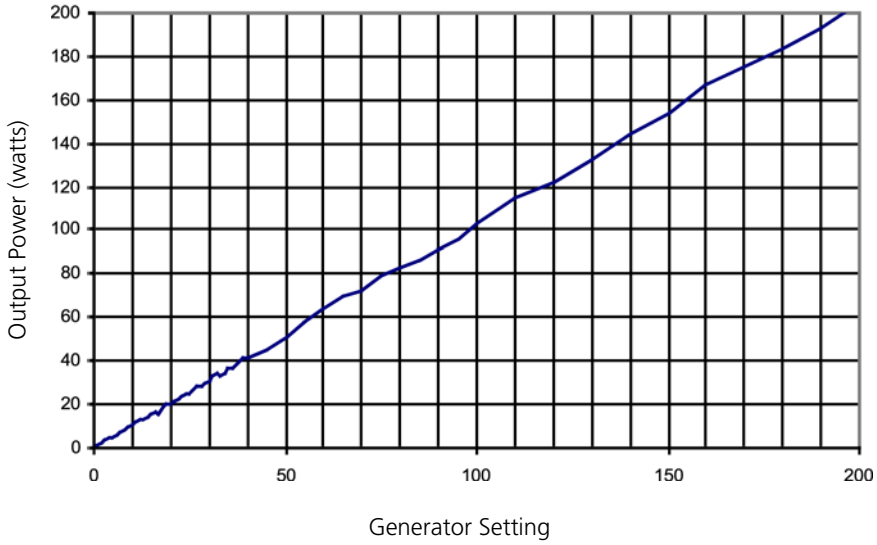
Output power vs. impedance for Blend cut 200W mode



Open circuit peak voltage vs. output power for Blend cut mode



Output power vs. generator settings Blend cut mode

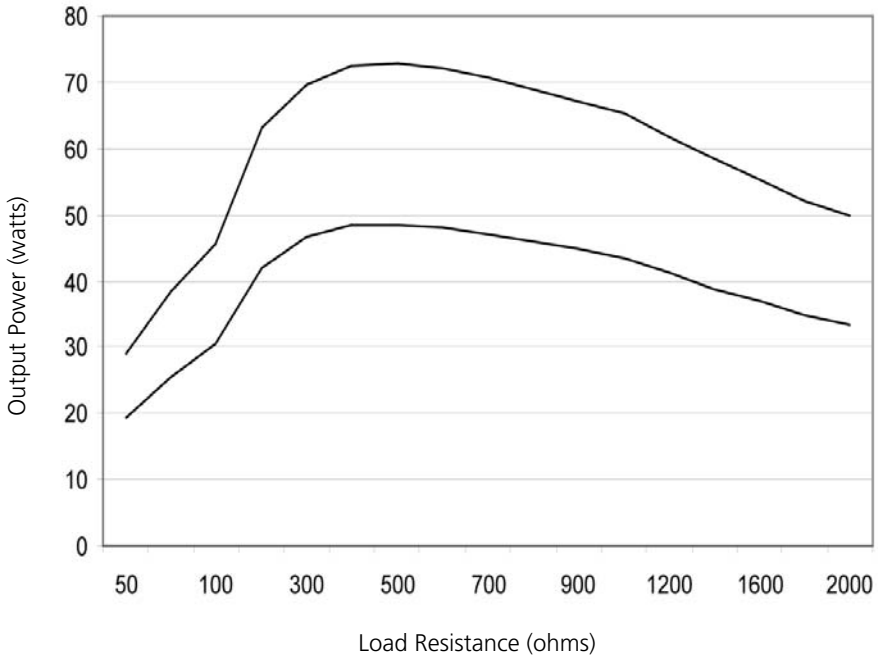


Monopolar Coag Graphs

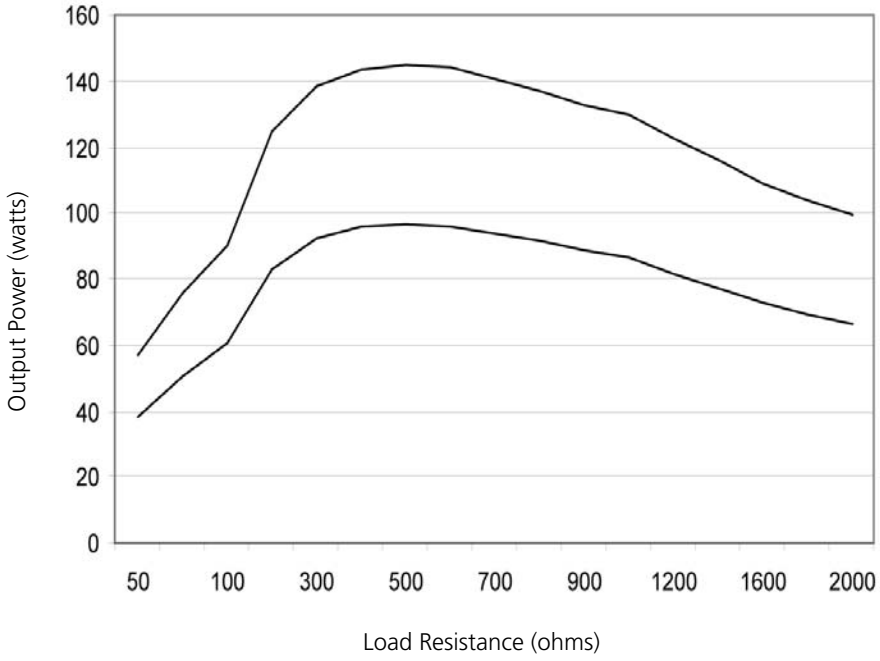
These measurements were taken using short (< 0.5 meter) leads.

Desiccate 1 Coag Mode

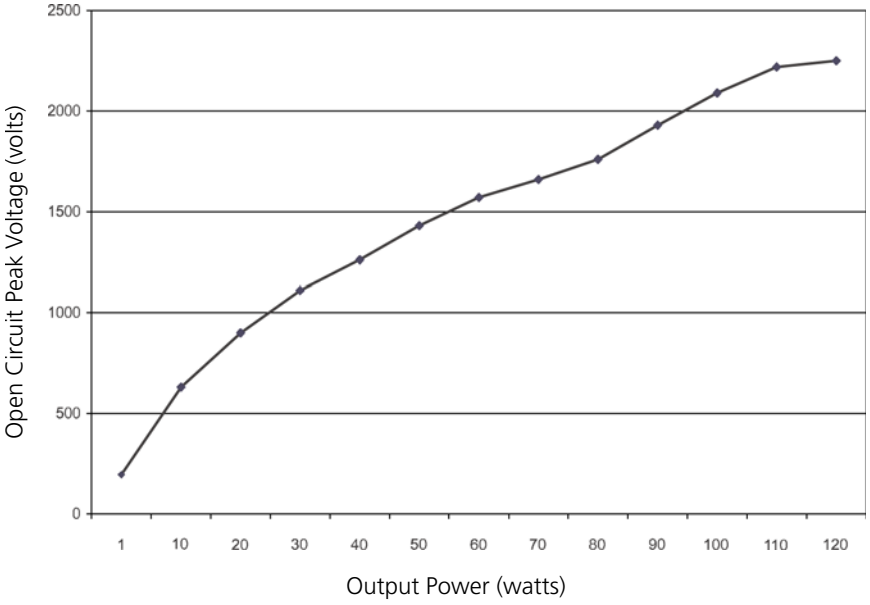
Output power vs. impedance for Desiccate 1 coag 60W mode



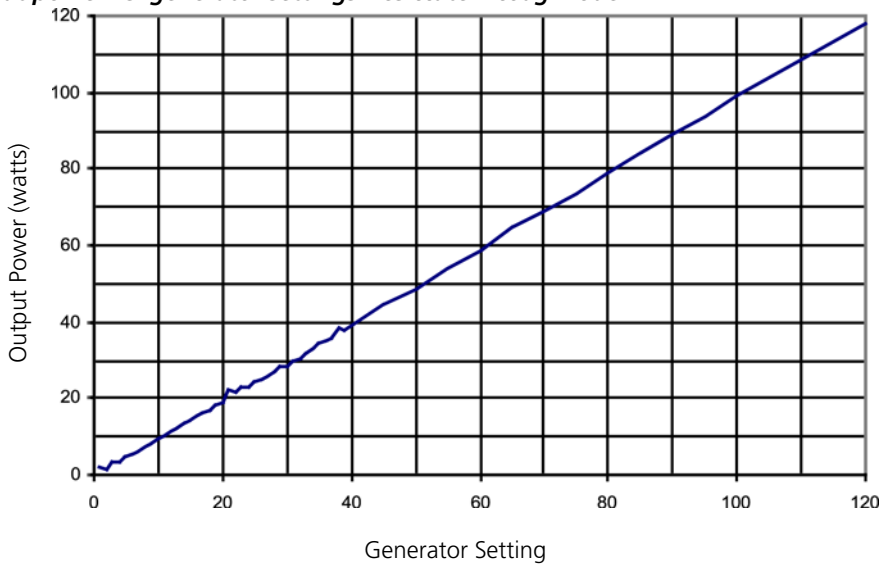
Output power vs. impedance for Desiccate 1 coag 120W mode



Open circuit peak voltage vs. output power for Desiccate 1 coag mode

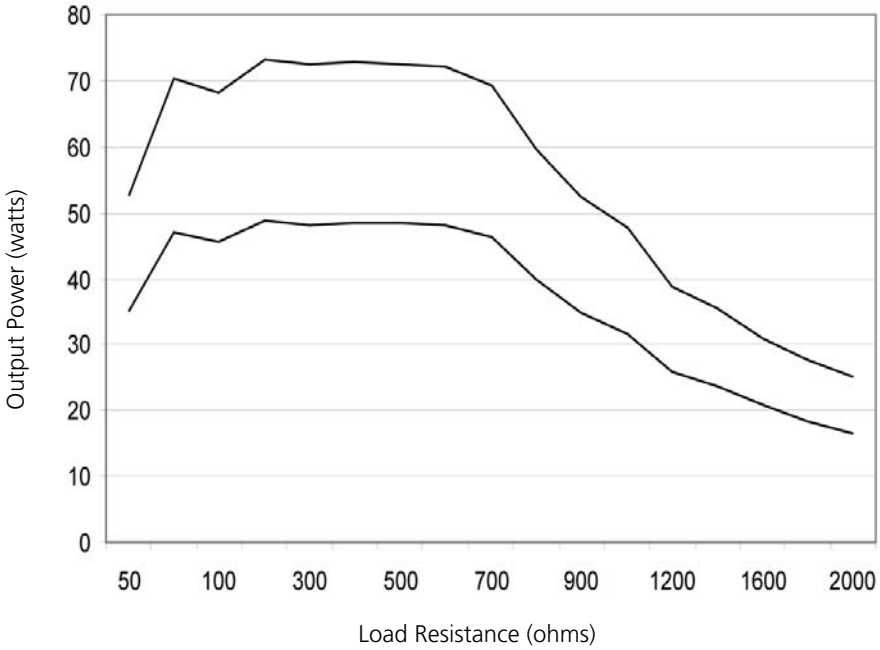


Output power vs. generator settings Desiccate 1 coag mode

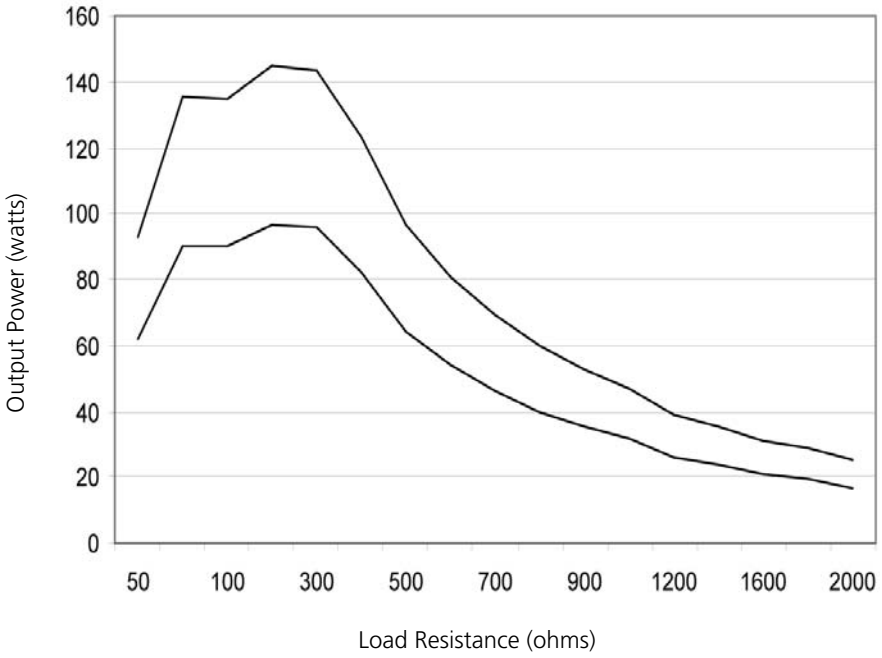


Desiccate 2 Coag Mode

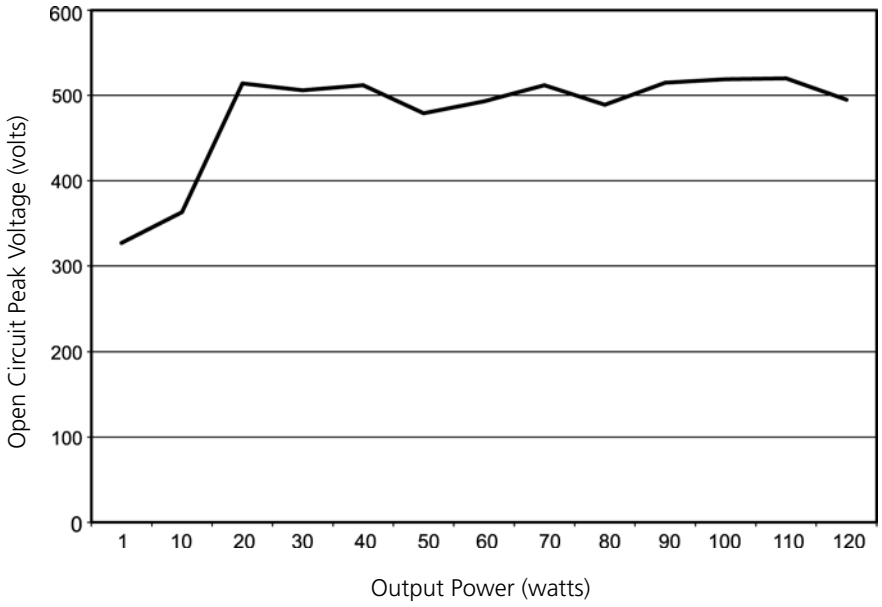
Output power vs. impedance for Desiccate 2 coag 60W mode



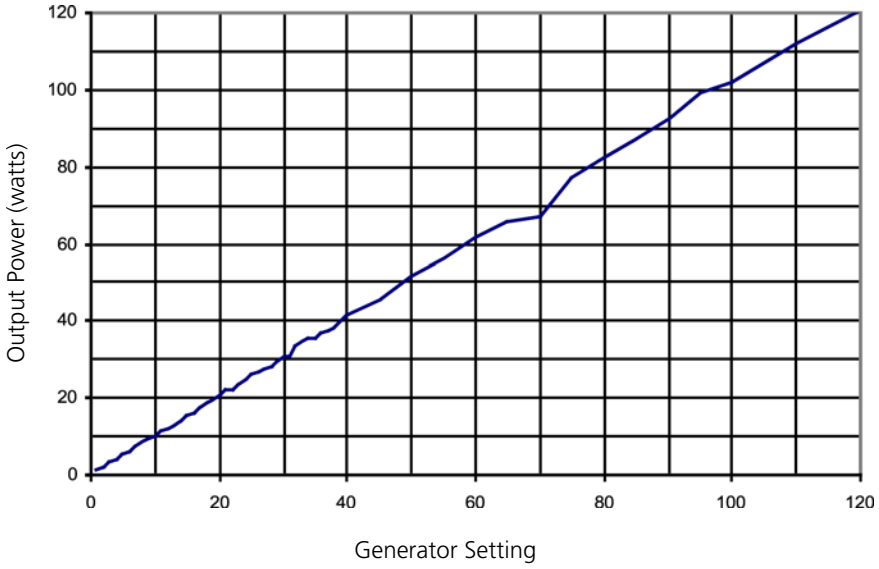
Output power vs. impedance for Desiccate 2 coag 120W mode



Open circuit peak voltage vs. output power for Desiccate 2 coag mode

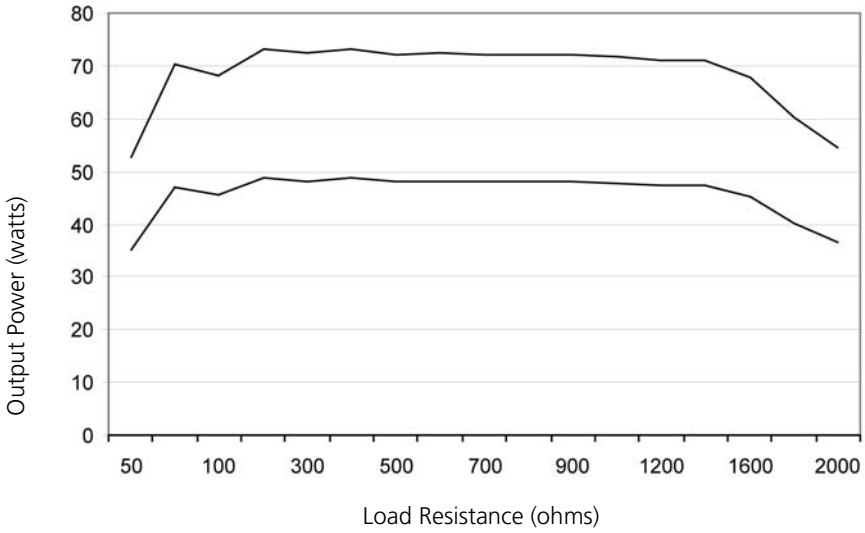


Output power vs. generator settings Desiccate 2 coag mode

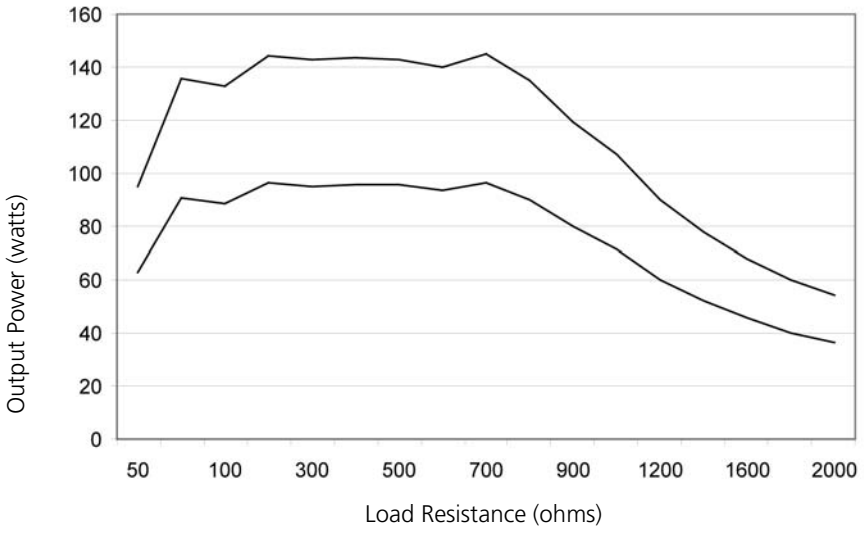


Desiccate 3 Coag Mode

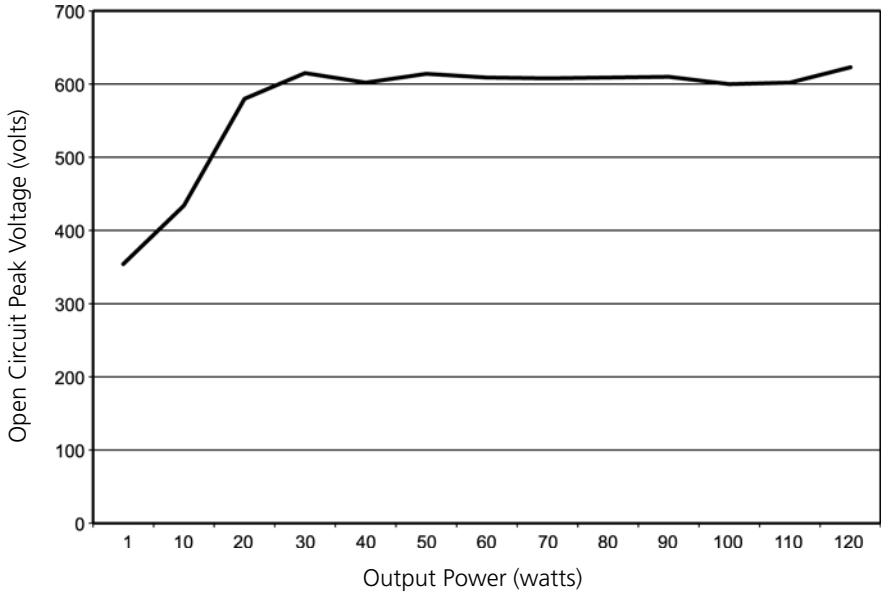
Output power vs. impedance for Desiccate 3 coag 60W mode



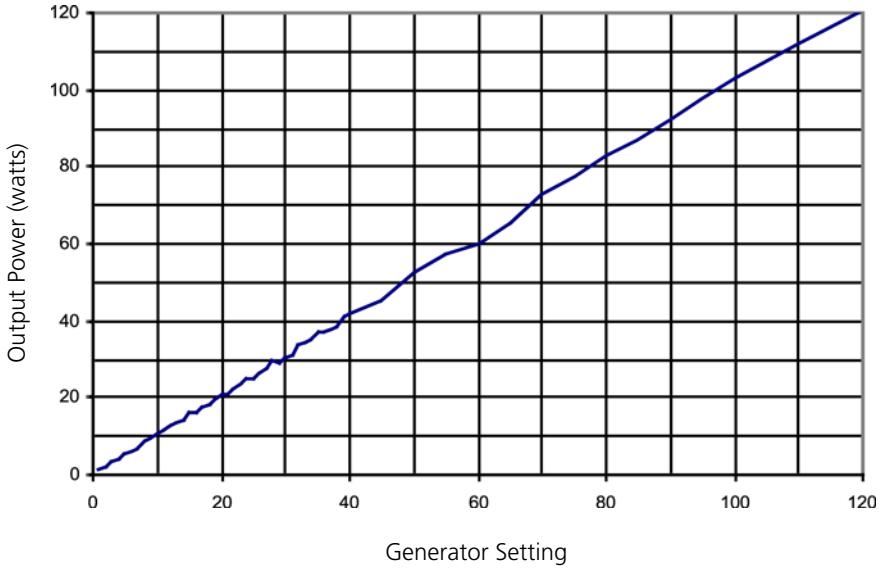
Output power vs. impedance for Desiccate 3 coag 120W mode



Open circuit peak voltage vs. output power for Desiccate 3 coag mode

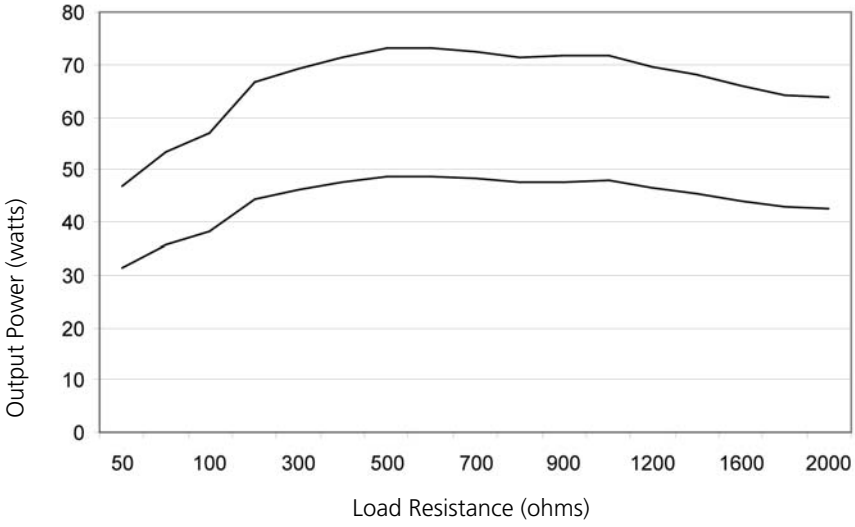


Output power vs. generator settings Desiccate 3 coag mode

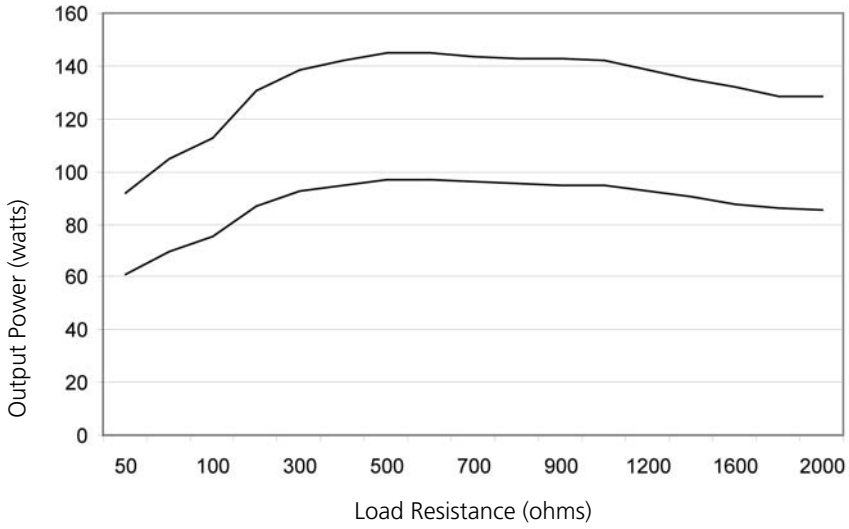


Fulgurate Coag Mode

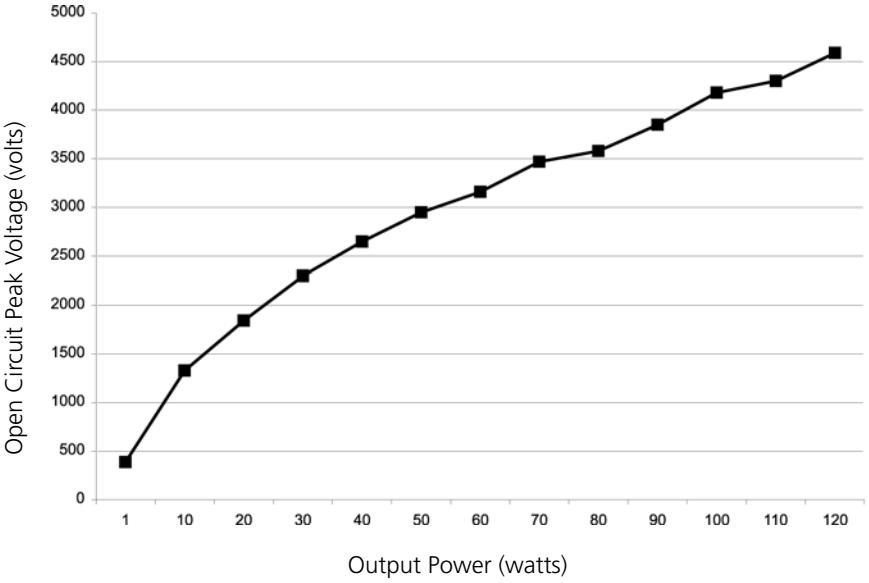
Output power vs. impedance Fulgurate coag 60W mode



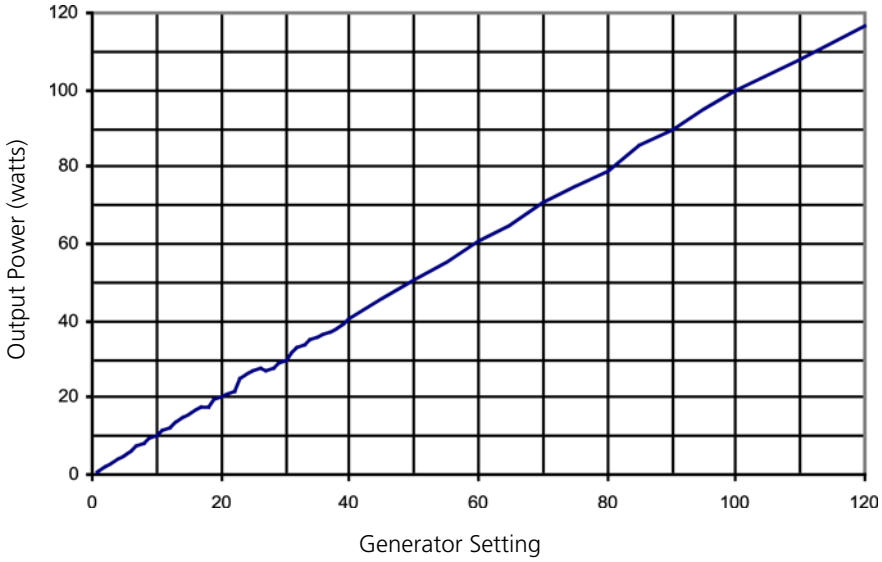
Output power vs. impedance Fulgurate coag 120W mode



Output power vs. peak voltage Fulgurate coag mode

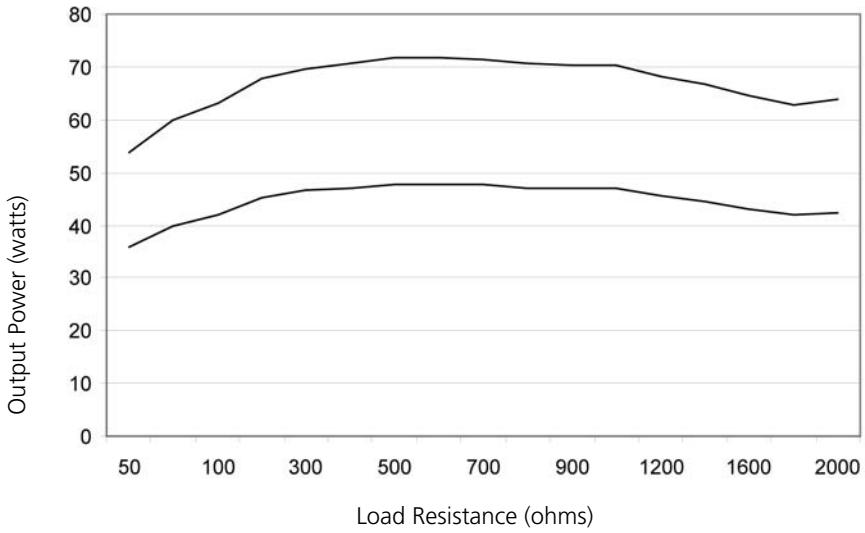


Output power vs. generator settings Fulgurate coag mode

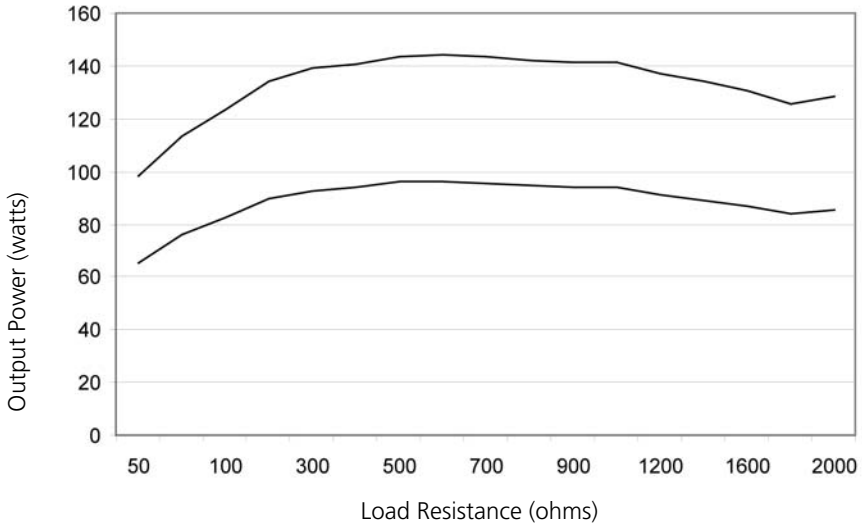


LCF Fulgurate Coag Mode

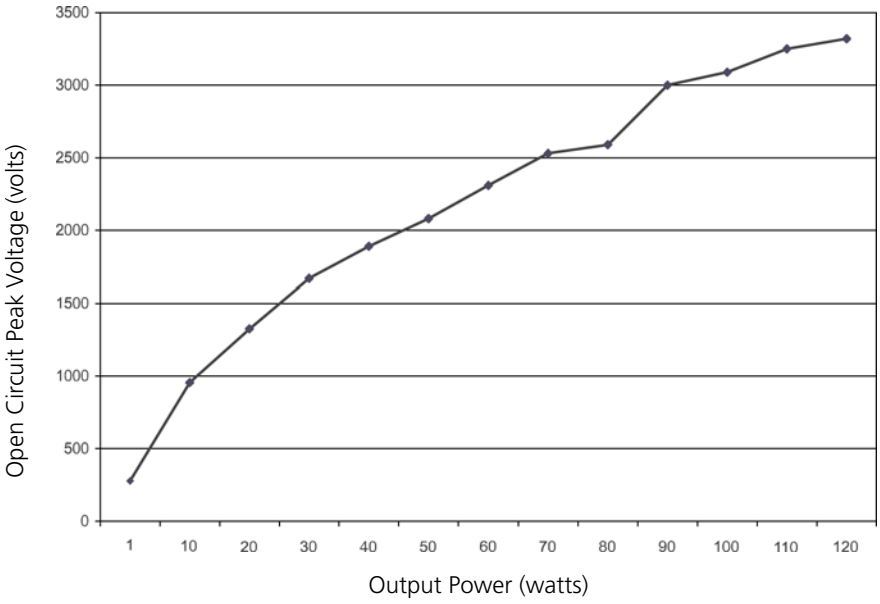
Output power vs. impedance LCF Fulgurate coag 60W mode



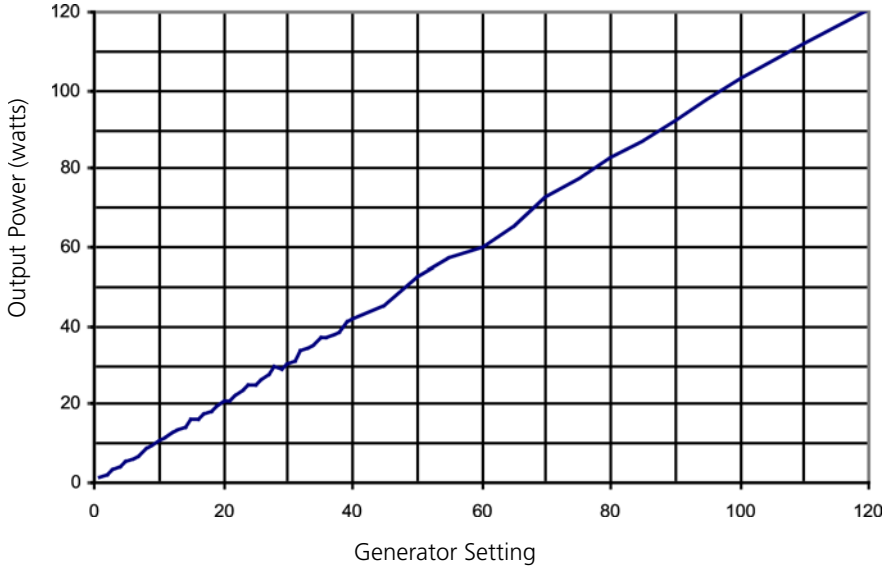
Output power vs. impedance LCF Fulgurate coag 120W mode



Output power vs. peak voltage LCF Fulgurate mode

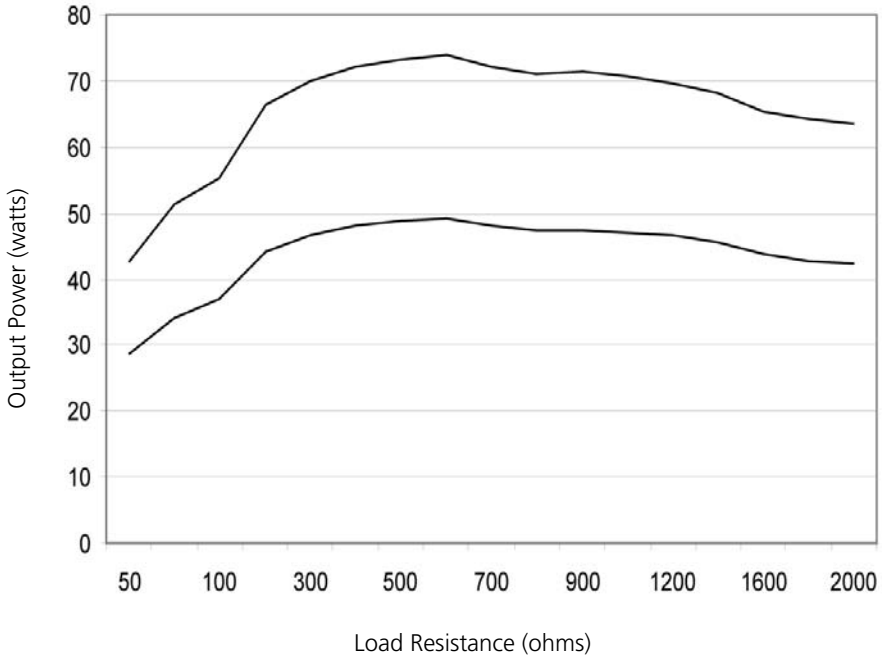


Output power vs. generator settings LCF Fulgurate mode

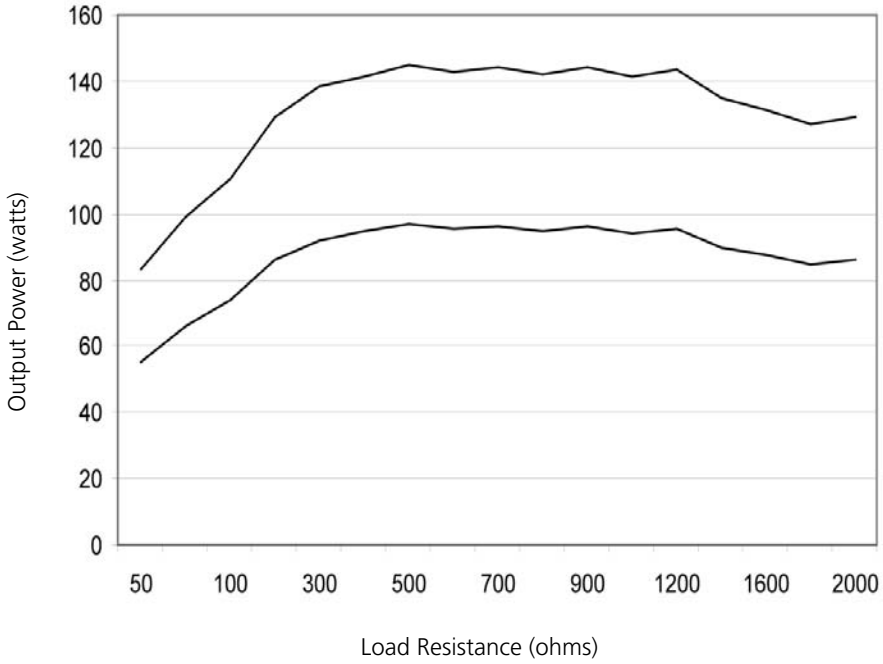


Spray Coag Mode

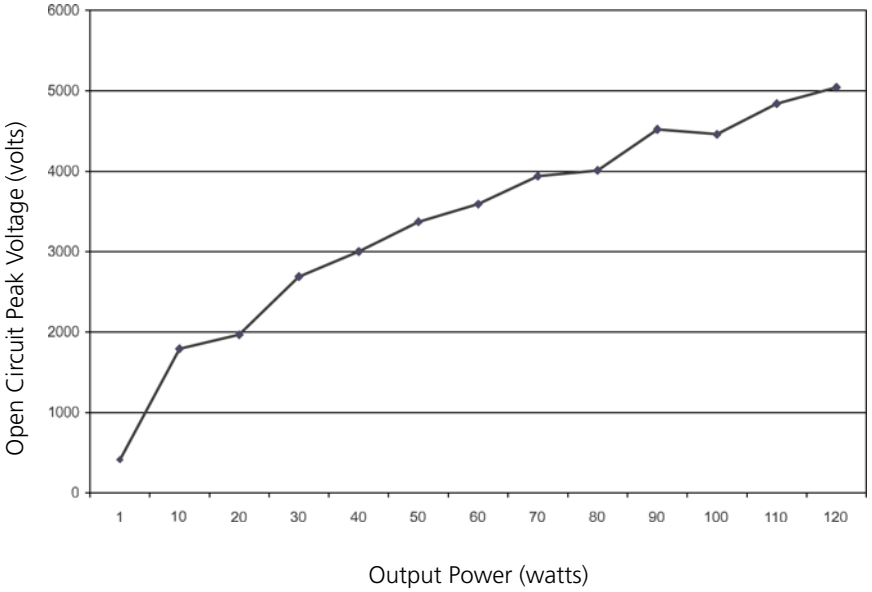
Output power vs. impedance Spray coag 60W mode



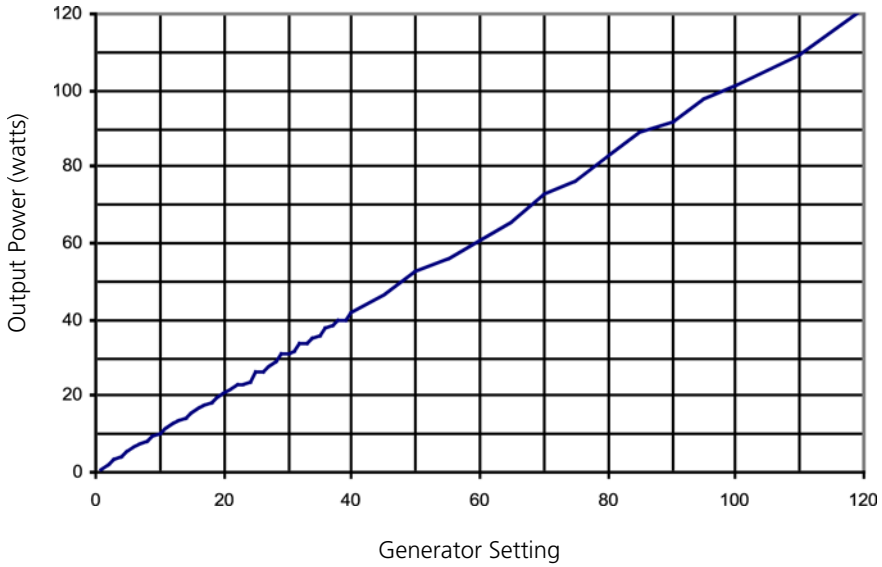
Output power vs. impedance Spray coag 120W mode



Output power vs. peak voltage Spray coag mode



Output power vs. generator settings Spray coag mode



Part No. 1012638

Made in USA. Printed in USA.

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