



Force 30 Force 40S Electrosurgical Generator

Instruction Manual



Force

Instruction Manual Force 30 Force 40S

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Foreword

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed.

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

Valleylab Part No.: 945 110 137

Effective Date: June, 1993

Equipment covered in this manual:

Force 30 and Force 40S Electrosurgical Generators

110 - 120 V~ nominal

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Electrosurgical Generators

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Mounting Fixtures (all models)

One Year from date of shipment.

Footswitches (all models)

One Year from date of shipment.

Patient Return Electrodes

Shelf life only as stated on packaging.

Sterile Disposables

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Sterility only as stated on packaging.

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

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Attention: Refer to the accompanying documents.



Type CF equipment Low Leakage Suitable for cardiac use Defibrillator proof



Drip Proof



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



The generator is high frequency isolated per IEC 601-2-2



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

Electrosurgery has been employed safely in numerous procedures. Before starting any surgical procedure, the physician should be familiar with the medical literature, complications, and hazards of electrosurgery in that procedure.

General

Warning: Hazardous Electrical Output: This equipment is for use only by qualified personnel.

Caution: This equipment is capable of producing a physiological effect.

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

Fire/Explosion

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

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

- flammable substances (such as alcohol based skin prepping agents and tinctures)
- naturally occurring flammable gases which may accumulate in body cavities such as the bowel
- oxygen enriched atmospheres
- oxidizing agents (such as nitrous oxide [N₂O] atmospheres)

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

Fire Hazard with Oxygen Circuit Connections

Warning: Fire/Explosion Hazard: Verify that all oxygen circuit connections are leak free before and during the use of electrosurgery. Verify that endotracheal tubes are leak free, and that the cuff is properly sealed to prevent oxygen leaks.

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

Warning: 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 which 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 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 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.

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

Electrosurgical Smoke

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

Servicing

Caution: Electrical Shock Hazard: Do not remove cover. Refer to authorized personnel for service.

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

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 and sparks, accessory malfunction, or unintended surgical effects.

Active Accessories

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

Contraindications

Patients with Pacemakers

Use electrosurgical generators with caution in the presence of internal or external pacemakers. Interference from the electrosurgical current can cause a pacemaker to enter an asynchronous mode or can block the pacemaker effect entirely. For further information, consult the pacemaker manufacturer or hospital Cardiology Department.

Circumcisions

Valleylab recommends against the use of monopolar or bipolar electrosurgery for circumcisions.

Contact with grounded metal objects

While using electrosurgery during a surgical procedure, 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 to achieve the desired effect.
- Place the patient return electrode as close to the surgical site as possible.
- Place gauze between the patient and the grounded object if possible.
- Continually monitor the contact point(s.)

Before Surgery

Active Accessories

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

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

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

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

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

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

Patient Return Electrodes

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

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

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

Warning: Do not apply a patient return electrode for a bipolar only procedure. Unintended surgical effects may occur.

Warning: Using a conventional nonREM Patient Return Electrode will not activate the Valleylab REM Contact Quality Monitoring System.

Generator

Warning: Electric Shock Hazard: Connect the generator electrical cord to a properly grounded receptacle.

Warning: Electric Shock Hazard: Do not use extension cords and/or adapter plugs.

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

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

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

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

During Surgery

Use near metal objects

Warning: Use extreme caution when using electrosurgery in close proximity to or in direct contact with any metal objects. These metal objects include but are not limited to Gomco clamps, Kocher clamps, speculums, and hemostats. Using electrosurgery in these circumstances may result in unintentional and unwanted tissue destruction and burns.

Generator Power Settings

Warning: Confirm proper electrosurgical generator settings before proceeding with surgery. Use the lowest appropriate power setting to achieve the desired effect.

Warning: Never increase the power settings without first checking both the active electrode and patient return electrodes and their connections. Use the active electrode 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 and where small appendages are involved.

Caution: The Force 30/40S electrosurgical generators cut effectively at power settings lower than previous models offered by Valleylab. Use caution in selecting initial power settings.

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 prior to bending or reshaping the coagulator suction tube.

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

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

Active Accessories

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

Warning: Fire Hazard: Do not place active accessories near or in contact with flammable materials (such as gauze or surgical drapes). Electrosurgical accessories which are activated or hot from use can cause a fire. Use the Valleylab E2400 Holster to hold electrosurgical pencils and similar accessories safely away from patients, personnel, and surgical drapes.

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

- Do not lean on the patient, the table, or the retractors while buzzing the hemostat.
- Activate Cut rather than Coag. Cut has a lower voltage than Coag and helps reduce the amount of current.
- Use the lowest power setting possible.
- 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 helps disperse 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.

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 after the patient is repositioned and during procedures involving long periods of activation.

Laparoscopy, endoscopy and related procedures

Warning: For procedures where visualization may be impaired (e.g., laparoscopy, endoscopy) be alert to these potential hazards:

- 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 trocar 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 comprised 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. Hybrid systems can produce capacitive coupling of RF current which can lead to inadvertent patient injury.
- When using laparoscopic instrumentation with metal cannulas, the potential exists
 for abdominal wall burns to occur due to direct electrode contact with 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.
- 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. Activate the generator only when the active electrode is near or in direct contact with the target tissue, to lessen the possibility of creating inadvertent burns.
- During laparoscopic surgery, using the lowest power setting that achieves the desired surgical effect and using a low voltage waveform (Cut), lessens the potential for the creation of capacitive currents.
- Carefully insert and withdraw active electrodes from trocar cannulas to avoid possible damage to the devices and/or injury to the patient.

Section 2 Installation

Introduction

Congratulations on your purchase of a Valleylab Electrosurgical Generator! This instruction manual will familiarize you with the controls of your Valleylab generator and instruct you on the proper use of the equipment.

The electrosurgical generator described in this manual is designed to provide the three most significant electrosurgical effects: cutting, desiccation, and fulguration. Both monopolar and bipolar outputs are provided in the Force 30/40S generators.

The monopolar outputs are designed with the capability of delivering smooth cutting, cutting with increasing degrees of hemostasis, desiccation, and fulguration with a minimum of cutting. The bipolar output is intended for desiccation without fulguration.

This manual is intended as a user's guide only. Additional technical information and descriptions are available in the Force 30/40S Service Manual.

Responsibility of the Manufacturer

Valleylab Inc is responsible for safety, reliability, and performance of the equipment only if:

- installation procedures in this manual are followed.
- assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by Valleylab Inc.
- 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 Valleylab instructions for use.

Environmental Conditions

Transport and Storage

Ambient Temperature:

Between -40 and +70 degrees C.

Relative Humidity:

Between 10% and 100%, noncondensing.

Atmospheric Pressure:

Between 500 and 1060 millibar.

Operation

Ambient Temperature:

Between +10 and +40 degrees C.

Relative Humidity:

Between 30% and 75%, noncondensing.

Atmospheric Pressure:

Between 700 and 1060 millibar.

Preparing The Generator For Use

The electrosurgical generator may be placed on a mounting cart available from Valleylab or on any sturdy table or platform. It is recommended that carts have conductive wheels. Refer to hospital procedures or local codes for detailed information.

Provide at least four to six inches of space around the sides and top of the generator for convection cooling. Under continuous use for extended periods of time, it is normal for the top and rear panel to be warm.

DANGER

Explosion Hazard. Do not install the electrosurgical generator in areas using flammable anesthetics.

Power Requirements

The Force 30/40S Electrosurgical Generators are designed to operate with full regulation between 90-135 V~, 50-60 Hz. This allows the output to remain constant in case of brownouts or power surges.

Check the Power Connector

The Force generator is supplied with a hospital grade power plug.

The connector meets all requirements for safe grounding. Its purpose should not be defeated by using extension cords or three-prong to two-prong adapters. Cords should always be grasped by the plug. Do not pull on the cord itself.

Ensure Proper Grounding

To ensure patient safety the electrosurgical generator must be properly grounded.

The ground wire in the power cord is connected to the generator chassis and ensures that no dangerous currents will flow from the cabinet of the generator in the event of internal electrical failure. Do not use extension cords or three-prong to two-prong electrical adapters.

Undesirable 50-60 Hz leakage currents are affected by the polarization of the 50-60 Hz input power. Ensure proper polarity and grounding of the power outlets supplying power to the electrosurgical generator.

IMPORTANT

Ensure that the electrical installation of the relevant room complies with local codes and regulatory requirements such as UL and CSA.

Routine Maintenance

Valleylab recommends that the Force 30/40S Electrosurgical Generators be inspected by qualified service personnel at least twice a year.

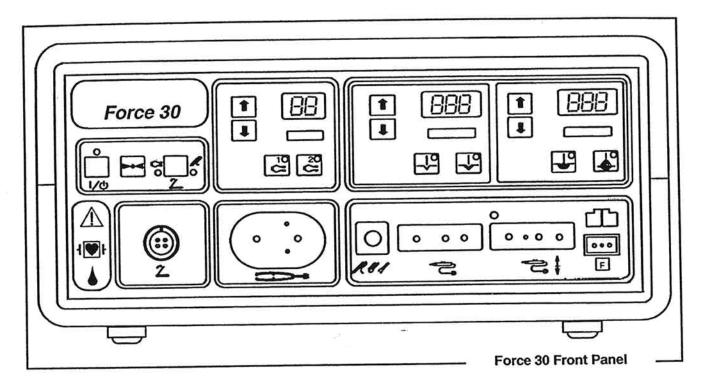
The power cord should be periodically checked for damaged insulation or connectors.

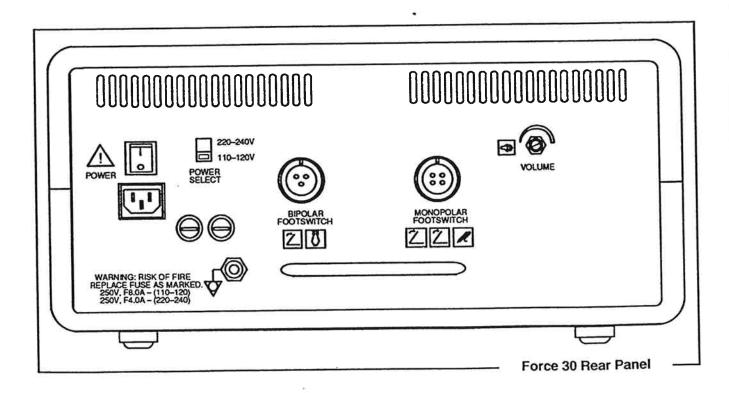
Cleaning Instructions

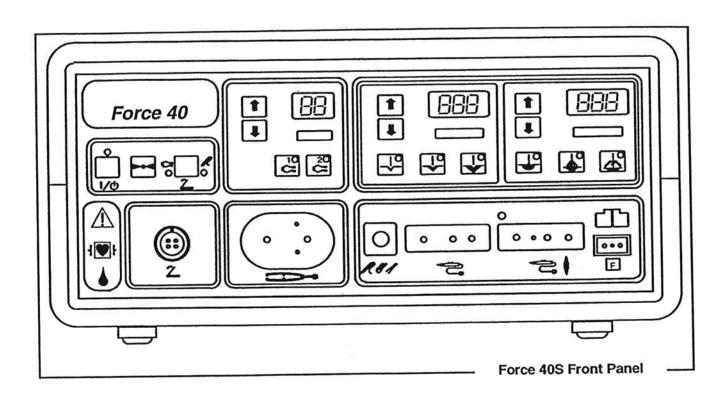
Use a mild detergent and damp cloth to clean the generator cover, keyboard, and cord. Do not allow fluids to enter the chassis. Do not use caustic, corrosive, or abrasive cleaning materials. The generator cannot be sterilized.

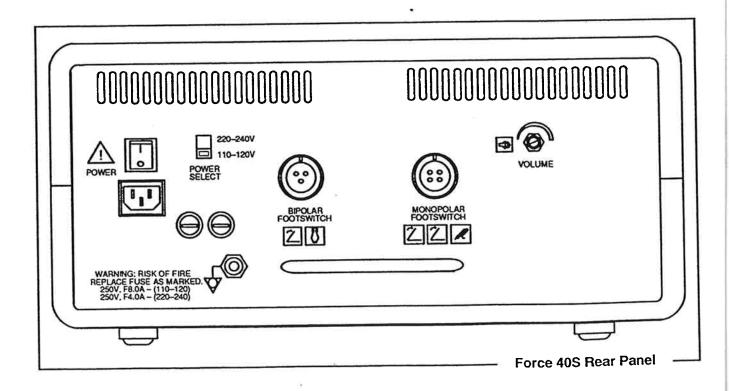
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Section 3 Descriptions Of Controls, Indicators, and Receptacles









Status

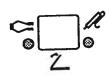


On/Off - Press this button to switch the generator on and off. When the generator is off, it is not available for use. When the generator is on, the indicator illuminates, modes and power levels can be set, and the generator can be activated.

When you turn off the generator, it saves the current mode and power level settings.



Reset - Press this button to display the mode and power settings last stored in memory before the generator was turned off.



Footswitch Selector - Press this button to switch between the monopolar and bipolar footswitch function. When the bipolar footswitching mode is selected the indicator on the left of the button illuminates. When the monopolar footswitching mode is selected the indicator to the right illuminates.

Power Controls



Power Up/Down - Increases or decreases power in the selected mode. Press this button to change the power by one increment. Continuously pressing the button gradually increases/decreases the power to maximum/minimum level.



Power Setting Display - The digital power setting display is visible when the generator is on. The number displayed indicates the nominal power in watts when the mode is activated. When the generator is off the displays are blank.

The color coded indicator located directly under each power setting display (Cut, Coag, Bipolar) illuminates when that output power is activated. One of the three distinct mode indicator tones sounds in conjunction with the visual output power indicator.



POWER CONTROL Power Control Feature - Insert a Valleylab Power Control Handswitching Pencil into the Power Control output receptacle to automatically activate this feature.

> When this feature is activated, the Power Control indicator illuminates and the alarm sounds once. When this indicator illuminates, the surgeon can make power changes using the power control pencil.

Bipolar



Standard - Press this button to select the Microbipolar mode for standard desiccation. When this mode is selected, the button indicator illuminates.



Precise - Press this button to select the Microbipolar mode for fine desiccation. When this mode is selected, the button indicator illuminates.

Monopolar Cut



Pure Cut - Press this button to select Cut with the lowest level of hemostasis. When this mode is selected, the button indicator illuminates.



Blend/Blend 1 - Press this button to select Cut with minimum hemostasis. When this mode is selected, the button indicator illuminates.



Blend 2 - (Force 40S only) Press this button to select Cut with maximum hemostasis. When this mode is selected, the button indicator illuminates.

Monopolar Coag



Desiccate - Press this button to select coagulation current waveform for low voltage desiccation. When this mode is selected, the button indicator illuminates.

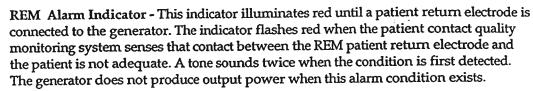


Fulgurate - Press this button to select coagulation current waveform for general fulguration applications. When this mode is selected, the button indicator illuminates.



Spray - (Force 40S only) Press this button to select coagulation current waveform for high performance fulguration. When this mode is selected, the button indicator illuminates.

Alarms



The alarm condition is cleared and the indicator changes to green when the REM Contact Quality Monitoring System senses that the patient/pad contact resistance is within the acceptance range.

If a nonREM patient return electrode is inserted into the Patient receptacle, this indicator does not illuminate unless the generator detects a break in continuity between the patient return electrode and the generator. In this case, the indicator illuminates red.

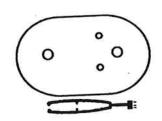
Do not apply a patient return electrode in a bipolar only procedure. When the bipolar forceps are connected to the Bipolar Active receptacle, the REM indicator illuminates, but the generator can be activated in the Bipolar mode.

Dosage Error Alarm - If the measured generator output exceeds the output power displayed on the front panel by 35 watts or 35%, whichever is greater, an alarm sounds, the error code "87" appears in the Power Setting Display, and the generator does not deliver output power. To reset the generator, press the On/Off button on the front panel to turn the generator off and on. There is not an indicator for this alarm.

Front Panel Receptacles



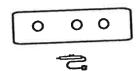
Monopolar Footswitch Receptacle - This four-pin receptacle accepts a two-treadle Monopolar footswitch connector. Connecting a monopolar footswitch to this receptacle allows the surgeon to use the footswitch in either the Monopolar or Bipolar mode, by using the Footswitch Select button on the front panel.



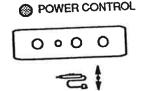
Bipolar Active Receptacle - This receptacle accepts three-pin handswitching bipolar accessories. These accessories can also be footswitch activated. This receptacle also accepts two-pin bipolar footswitching accessories.



Monopolar Active Footswitching Receptacle - This receptacle accepts standard one-pin footswitching accessories which can be activated by either the footswitch receptacle located on the front panel or the footswitch receptacle located on the rear panel. Some accessories may require an adapter. Do not connect bipolar active accessories to this receptacle.



Monopolar Active Handswitch Receptacle - This receptacle accepts standard three-pin handswitching active accessories. Cut and Coag modes may be activated at this receptacle. Power output from this receptacle is activated only by using the handswitch mechanism. Do not connect bipolar active accessories to this receptacle.



Power Control Monopolar Active Handswitch Receptacle - This receptacle accepts both standard three-pin handswitching active accessories and the Valleylab Power Control Pencil. The indicator illuminates when a Power Control Pencil is inserted in this receptacle. Power output from this receptacle is activated only by using the handswitch mechanism. Cut and Coag modes may be activated at this receptacle. Note: The Power Control feature is only functional through this receptacle. Do not connect bipolar active accessories to this receptacle.



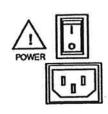
Patient Return Electrode Receptacle - This two-pin receptacle accepts the patient return electrode connector used in monopolar procedures. The receptacle accepts both REM (dual-section) and conventional patient return electrode connectors.

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Rear Panel Functions



Input Power Source Switch - The Force 30/40S generators are shipped with the input power source switch in the 110-120V position for operation at 110-120V~ (nominal). The generator will not function with the switch in the 220-240V position.



Power Switch - This switch assembly meets IEC power on/off requirements and includes a fuse and power cord receptacle. To reduce the risk of fire, replace the fuse with the type and rating as marked.



Equipotential Ground Lug - This lug may be connected to earth ground with the furnished equipotential grounding cable.



Bipolar Footswitch Receptacle - This three-pin receptacle accepts a single-treadle bipolar footswitch connector. Only bipolar output can be activated from this receptacle.



Monopolar Footswitch Receptacle - This four-pin receptacle accepts a two-treadle monopolar footswitch connector. Only monopolar output can be activated from this receptacle.



Audio Volume Control - The volume of the Cut, Coag, and Bipolar mode indicator tones produced when the generator is activated may be adjusted with this control. The volume of the tone for alarm conditions is not adjustable.

Section 4 Instructions for Use

Generator Setup Procedure

Plug the generator into a grounded receptacle (extension cords and/or adapter plugs should not be used). Turn the power on using the power switch located on the rear panel. This supplies power to the generator.

Generator Self Test

Press the On/Off button on the front panel to begin the generator's internal self test sequence.

All LED's and indicators on the generator front panel illuminate sequentially from left to right. (If any LED or indicator fails to illuminate, return the generator for service.)

The generator is then ready for use with all power setting displays reading 1 watt.

The generator defaults to the monopolar footswitch function, Standard Bipolar mode, Pure Cut mode, and Fulgurate mode.

A malfunctioning generator displays an error code in the Power Setting Display, sounds a tone and won't deliver output power. Note the error code number and contact your Valleylab representative or service center for assistance.

Selecting Modes and Power Levels

Press the Reset button to recall previously stored settings, if desired.

Press the Footswitch Select button to select Monopolar or Bipolar footswitch operation.

Set the desired power settings and modes for Bipolar, Cut, and Coag.

IMPORTANT

When used in conjunction with the Force GSU System, set the generator's coagulation mode to Fulgurate (Force 30 or Force 40S) or Spray (Force 40S.) Use of the low voltage desiccation mode will limit the hemostatic effect of the Force GSU System.

Patient Return Electrode Application

A patient return electrode is always required for monopolar electrosurgery. For correct application and removal of the patient return electrode, follow all instructions found on the product packaging.

Do not apply a patient return electrode for a bipolar only procedure. If bipolar forceps are connected to the Bipolar output receptacle, the REM alarm indicator illuminates, but a patient return electrode should not be connected to extinguish the alarm. The Bipolar mode can be activated with an active REM alarm condition.

Capacitive Pads

Valleylab does not recommend the use of capacitive patient return electrodes due to the potential of a high impedance condition at the patient/pad interface.

Shunt Cord (S-Cord)

Some surgical instruments, such as colonoscopes, have capacitances to ground which allow substantial leakage current. To shunt the current safely to the generator, use the S-Cord which requires a special Valleylab adapter. When the S-Cord is used, it is recommended that a REM (dual-section) patient return electrode be used.

Keying/Activation Systems

The Force generator can be activated with either a footswitch or handheld switching instruments such as forceps or handswitching pencils.

If the generator senses a defective keying device (handswitching accessory or footswitch) it will sound a tone and display an error code (111 - 122) in the Power Setting Display. Note the error code number and contact your Valleylab representative or service center for assistance.

Footswitches

The Force generator may be used with the Valleylab monopolar two-pedal footswitch and/or the bipolar single pedal footswitch.

The monopolar footswitch can be connected to the rear panel Monopolar Footswitch receptacle for monopolar activation only. The monopolar footswitch can also be connected to the Footswitch receptacle located on the front panel. This allows the surgeon to use the monopolar footswitch in either the Monopolar or Bipolar mode by using the Footswitch Select button on the front panel.

The bipolar footswitch connects to the Bipolar Footswitch receptacle on the rear panel.

Footswitching Accessories

Monopolar footswitching accessories, such as endoscopes, forceps or chuckhandles connect to the one-pin Monopolar Active Footswitch output receptacle on the front panel. These accessories can then be activated by pressing the appropriate pedal on the monopolar footswitch.

Bipolar footswitching forceps are connected to the Bipolar Active output receptacle and are activated by either the bipolar footswitch or by the monopolar footswitch connected to the front panel receptacle switched to the Bipolar mode.

Handswitching Pencils and Forceps

The two handswitching receptacles in the monopolar section of the front panel are designed to accept electrosurgical accessories such as handswitching pencils and monopolar switching forceps. The handswitching Power Control receptacle accepts either the Valleylab Power Control Pencil or conventional handswitching accessories.

Handswitching pencils employ a switching mechanism, such as buttons or a rocker switch, that allows the surgeon to activate the generator in either Cut or Coag by pressing the appropriate button.

Monopolar handswitching forceps produce a Coag output when the switch contacts on the forceps are closed.

Bipolar handswitching forceps connect to the Bipolar Active receptacle on the front panel. After grasping tissue between the tines of the forceps, closing the switch contacts on the forceps activates the generator.

CAUTION

Do not activate the generator until the forceps have made contact with the patient.

Accessory Connections to the Generator

Refer to the instructions for use provided with the accessory before using.

IMPORTANT

A patient return electrode is always required for monopolar electrosurgery.

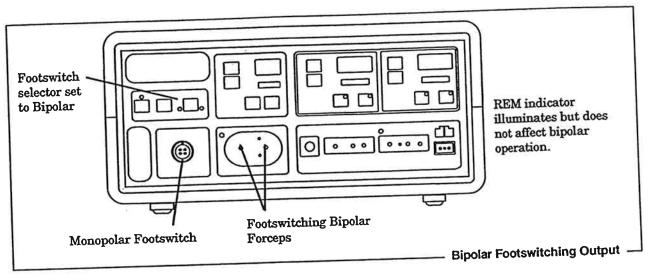
If bipolar forceps are connected to the Bipolar Active output receptacle, the REM Alarm indicator illuminates, but a patient return electrode should not be connected to extinguish the alarm. The Bipolar mode can be activated safely with an active REM alarm condition.

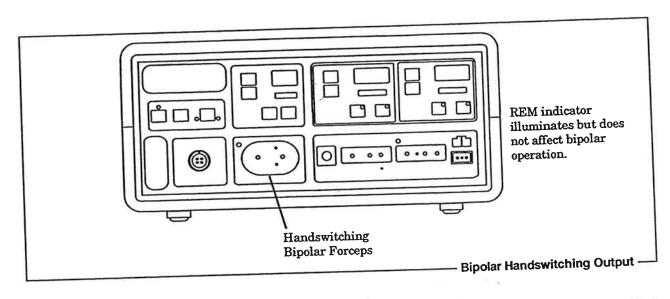
CAUTION

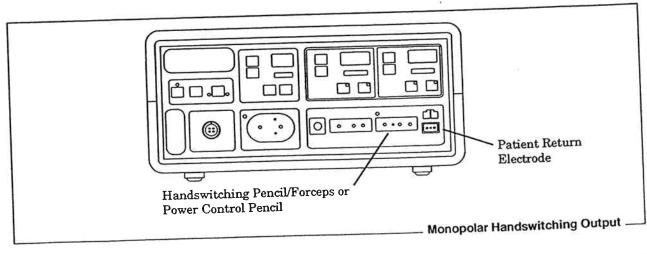
Accessories must be connected to the proper receptacle type. In particular, bipolar accessories must be connected to the Bipolar Active receptacle only. Improper connection of accessories may result in inadvertent generator activation or a REM Contact Quality Monitor alarm.

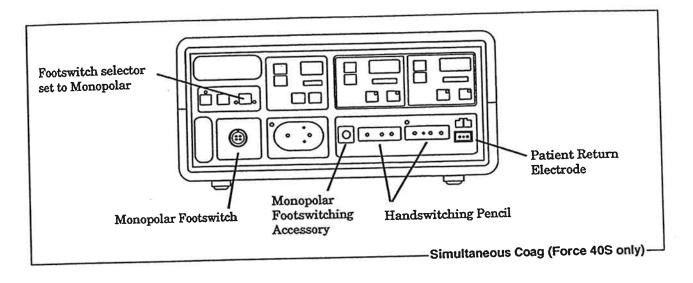
Do not apply a patient return electrode in a bipolar only procedure. Unintentional surgical effects may occur.

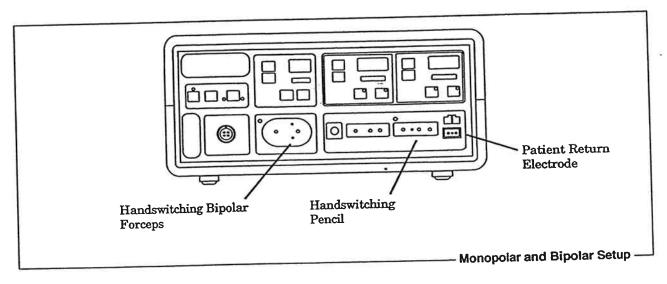
Common Generator/Accessory Setups

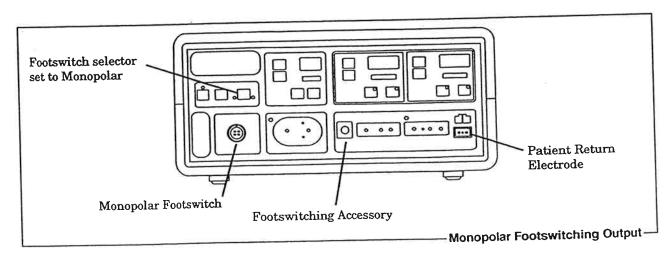












Power Changes

To change power settings in each mode, press the appropriate Up/Down power buttons (marked with arrows) until the desired power setting appears in the Output Power Display. Press the button once to increase/decrease the power by one power setting. Holding the button increases/decreases the power at a rate of eight power settings per second. If the two buttons are pressed simultaneously, the Down button has priority.

Changing Power Settings While the Generator is Activated

Power settings may be changed on the front panel while the generator is activated. Press and release the appropriate button to increase/decrease the power by one power setting. While the generator is activated, holding the Up button increases the power setting by not more than 50% of the current power setting displayed, or one setting (whichever is greater) to mode maximum. Holding the Down button decreases the power setting by not more than 50% of the current power setting displayed, or one watt (whichever is less).

Remote Power Changes Using the Valleylab Power Control Pencil

If a Valleylab Power Control Pencil is used, the surgeon can control the power settings by pressing the Up/Down buttons located on the pencil. When a Power Control Pencil is inserted into the Power Control receptacle, the Power Control mode is activated and the indicator illuminates.

Press the "+" or "-" buttons on the pencil to increase or decrease the power of the last used mode (Cut or Coag). Press and release the appropriate button to increase/decrease the power setting by one power setting unit. Each time the power setting is changed from the pencil, a tone sounds and the new power level displays on the generator. The power control pencil will not change power settings while the generator is activated in any mode.

Available Monopolar Power Settings (in watts)

1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 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, 250, 275, 300.

Available Bipolar Power Settings (in watts)

0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1.0, 1.2, 1.4, 1.6, 1.8, 2.0, 2.2, 2.4, 2.6, 2.8, 3.0, 3.2, 3.4, 3.6, 3.8, 4.0, 4.2, 4.4, 4.6, 4.8, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 45, 50.

Simultaneous Coag (Force 40S only)

The Force 40S generator permits simultaneous, independent use of two or three active electrodes in Coag from the monopolar output receptacles. If any combination of monopolar outputs are activated in the Coag mode at the same time, they all receive power.

All activated electrodes are driven in parallel with the indicated power output shared between them. The percentage of power delivered to each electrode depends on the impedance between the active electrode and the patient return electrode. The electrode with the lowest impedance receives the most power.

High voltage relays connect the outputs. These relays cannot be opened or closed while current is flowing through them. For this reason, there is a momentary cessation of generator output when the second or third output is activated or released.

Using Two Generators at the Same Time

Occasionally it may be desirable to use two generators simultaneously on the same patient. Since the two generators are not synchronized, there are frequent periods, moment to moment, when one patient return electrode has a high positive voltage while the other acquires an opposite negative voltage. Whenever this occurs, there is a large potential difference between the patient return electrodes and current flows from one patient return electrode to the other. This current causes no harm provided that it produces no sparks or high current densities on the patient's body. To avoid problems, place each patient return electrode as close as possible to the site of surgery, and make sure that there is no possibility of the two patient return electrodes touching.

When using two generators, do not stack the generators or place them close together. Avoid interference and allow for adequate cooling.

Surgical Applications

Monopolar Applications

Monopolar electrosurgery includes all three electrosurgical effects: cutting, fulguration, and desiccation. Since fulguration involves sparking, monopolar applications require high voltage waveforms. Desiccation puts the greatest demand on the patient return electrode during monopolar surgery, because the active electrode directly touches the tissue. More current reaches the patient since it does not have to overcome the high impedance of air.

Monopolar applications include most surgical procedures, especially those that require coagulation over wide areas or sparking to tissue such as during fulguration or cutting. However, the high voltages suited to these procedures can complicate surgery on delicate tissues or in confined areas. During coagulation a high voltage waveform can cause accidental sparking to adjacent areas as the tissue at the surgical site dries and becomes more resistant.

Microbipolar Applications

Procedures involving delicate, highly conductive tissue, such as brain, spinal, or eye tissue may require microbipolar electrosurgery. These procedures are frequently performed in confined areas where sparking could damage adjacent structures, under magnification and/or irrigation and require an additional degree of precision. Since these types of procedures are often performed in confined surgical sites where sparking could damage adjacent structures, it is desirable to limit sparking and produce a desiccation effect.

The three features of microbipolar which deal with these special demands are: instrumentation, cut waveforms, and a self-limiting power curve.

- Microbipolar instruments prevent damage to tissues adjacent to the surgical site by incorporating the active and return electrodes in a single forceps or other handpiece and by limiting the amount of tissue involved in the electrosurgical circuit.
- Microbipolar outputs use cut waveforms because they provide low voltage, continuous current for faster desiccation without sparking.
- The possibility of sparking always increases when desiccated tissue dries and becomes more resistant. Self-limiting power on the microbipolar output protects against sparking during microbipolar applications by peaking at relatively low levels of impedance. As necrosis occurs, tissue impedance increases and delivered power decreases.

Macrobipolar outputs are also available and are capable of providing the higher voltages and power curves necessary for use in more demanding applications.

Recommendations During Surgery

Refer to the cautions and warnings at the front of this manual.

Keep power settings as low as possible to enhance patient and user safety.

Remove eschar build up from electrodes to maximize surgical effect.

Avoid unnecessary and prolonged activation of the generator to reduce the possibility of alternate site burns which may be caused by RF leakage currents.

If a higher than normal power setting is required, check patient return electrode and generator connecting cables for proper application and/or continuity.

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

The Force 30/40S generators are equipped with a REM Contact Quality Monitoring Circuit that operates in conjunction with a REM PolyHesiveII Patient Return Electrode. Any substitutions of the REM Patient Return Electrode may compromise the REM safety feature and may result in an unintended burn.

Typical Power Settings

The power level used for various surgical procedures varies considerably with the surgeon's technique and the size of the active electrode. A needle electrode requires less power to sustain a spark than a large ball electrode. One surgeon may perform a procedure by electrosurgically severing tissue with a cutting or blended waveform while another surgeon might perform the same procedure by using a coag waveform using a lower power level.

CAUTION

The Force 30/40S electrosurgical generators cut effectively at power settings lower than previous models offered by Valleylab. Use caution in selecting initial power settings.

If the proper setting is not known from personal experience, one should set the generator at a very low setting and cautiously increase power until the desired effect is achieved.

Low Power - Under 30 watts

- a) Neurosurgery (both bipolar and monopolar)
- b) Laparoscopic sterilization (both monopolar and bipolar)
- c) Vasectomies
- d) Dermatology
- e) Oral surgery
- f) Plastic surgery

Medium Power - Coag 30 to 70 watts, Cut 30 to 150 watts

- a) General surgery
- b) Laparotomies
- c) Head and neck surgery (ENT)
- d) Major orthopedic surgery
- e) Major vascular surgery
- f) Routine thoracic surgery
- g) Polypectomy

High Power - Coag over 70 watts, Cut over 150 watts

- a) Transurethral resections (Cut 120-300 watts; Coag 50-120 watts, depending on the thickness of the resection loop and the technique of the surgeon)
- b) Thoracotomies (heavy fulguration, 70 to 120 watts)
- c) Ablative cancer surgery, mastectomies, etc. (Cut 180-300 watts; Coag 70-120 watts)

der .

Low Power Settings

The higher the power settings and the longer the operative time a surgical procedure requires, the greater the risk it poses for electrosurgical burns. Keeping power settings as low as possible during all electrosurgical procedures minimizes the hazards by reducing the amount of current delivered to the patient and the demand placed on the patient return electrode.

Techniques that keep power settings low during electrosurgery include:

- Concentrating the current with a small active electrode. A needle electrode can often cut as well as a blade, but at lower power settings.
- Using fulguration to coagulate tissue rather than desiccation. Since it sparks to tissue using a high voltage waveform, fulguration can coagulate tissue with less current.
- Cutting by sparking, not desiccating tissue. Sparking cuts cleanly and quickly and delivers less current to the patient than does desiccation.
- Using bipolar surgery. Bipolar surgery requires less power and limits the amount of tissue involved in the electrosurgical circuit.

Section 5 Operating Room Troubleshooting

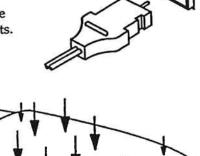
Problem - REM Alarm (2 tones)

Conventional (single-section) Patient Return Electrode

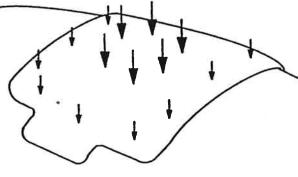
- a) Inspect the plug, cord and the pad of patient return electrode for excessive wear or visible damage. Replace if necessary.
- b) If a REM alarm persists, use a backup generator.

REM (dual-section) Patient Return Electrode

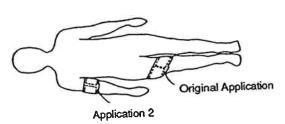
a) Leave the generator in the Ready mode (On.) Unplug the patient return electrode from the Patient receptacle of the generator. Inspect the plug pin to ensure it is not bent or missing. Carefully reinsert the plug into the Patient receptacle. Ensure that the pin goes into the hole and that the plug fully inserts. If the alarm condition is not corrected, proceed to step b.



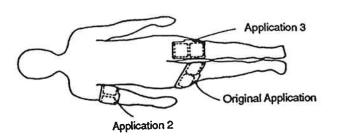
b) Apply firm pressure over the entire surface area of the patient return electrode, particularly the center. If the REM alarm persists, turn the generator Off, and unplug the patient return electrode from the generator. Do not remove the return electrode from the patient. Proceed to step c.



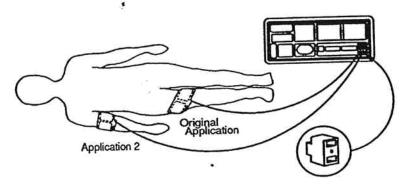
c) Apply a second REM electrode to the patient's thigh, upper biceps, calf or lower back. Turn the generator On. Connect the return electrode to the generator. If the alarm condition is not corrected, turn the generator Off, and unplug the patient return electrode from the patient. Proceed to step d or e.



d) Apply a third return electrode to the patient, selecting the next best, well vascularized, convex area close to the surgical site. Turn the generator On. Connect the plug of the return electrode to the generator. If the REM alarm has not been cleared, turn the generator Off, unplug the patient return electrode from the generator and proceed with step e.



e) Insert a Valleylab Multiple Return Adapter into the Patient receptacle. Turn the generator On. Insert the plugs of two patient return electrodes which have already been applied into the adapter. Choose the two return electrodes which are on the most vascularized, convex areas, in closest proximity to the surgical site.



If the REM alarm cannot be cleared by these procedures, use a backup generator and repeat steps a through e.

Once the REM alarm clears, leave the generator On during draping to ensure that the return electrode(s) is not disturbed. Remove any return electrodes which are not in use.

Problem - No Output

- a) Generator not plugged in.
- b) Generator not turned on.
- c) Malfunction in accessory or footswitch.
- Patient return electrode not in contact with patient.
- e) Patient return electrode not connected to generator.
- f) Broken patient return electrode cord.
- g) An alarm condition exists.
- h) Power set too low.
- i) An internal generator failure; use backup generator.

Problem - Monitor Interference

Continuous Interference

- a) Check the chassis ground connections for both monitor and generator.
- b) Check all other electrical equipment in the operating room for defective grounds.
- c) If the electrical equipment is grounded to different objects, rather than a common ground, voltage differences can appear between the two grounded objects. The monitor may respond to these voltages. Some types of input amplifiers can be balanced to achieve optimum common mode rejection and may possibly correct the problem. Refer to your Biomed Department or call Valleylab Service for further information.

Interference Only When Generator Is Activated

- a) Check all connections to the generator, patient return electrode, and active accessory to look for possible metal-to-metal sparking.
- b) Interference is usually greatest during fulguration. The amount of interference can be reduced by using lower power settings or using the Desiccate mode.
- c) If interference continues when the generator is activated and while the active electrode is not in contact with the patient, the monitor is responding to radio frequencies. Some manufacturers offer RF choke filters for use in the monitor leads. These filters reduce interference while the generator is activated. RF filters minimize the potential for an electrosurgical burn at the site of the monitor electrode.
- d) Check that the ground wires in the operating room are electrically consistent. All ground wires should go to the same grounded metal with wires that are as short as possible.
- e) If the above steps do not remedy the situation, the generator should be checked by qualified service personnel.

Problem - Neuromuscular Stimulation

- a) Stop the surgery.
- b) Check all connections to the generator, patient return electrode, and active electrodes to look for a possible metal-to-metal spark.
- c) Neuromuscular stimulation is more likely to occur in the Coag mode when fulgurating than when cutting, and is unlikely when desiccating. Lowering the power setting or using the Desiccate mode may alleviate the problem.
- d) If no problems are found, the generator should be checked by qualified service personnel for abnormal 50-60 Hz AC leakage currents.

Problem - Pacemaker Interference

- a) Check all connections of both active and patient return electrode cords to ensure that there is no intermittent or metal-to-metal sparking.
- b) Use bipolar instruments if possible.
- c) If monopolar instruments must be used, place the patient return electrode as close as possible to the site of surgery and make sure that the current path from the site of surgery to the patient return electrode does not pass through the vicinity of the heart.
- d) Always monitor pacemaker patients during surgery.
- e) Always keep a defibrillator available during electrosurgery on patients with pacemakers.
- f) Consult the pacemaker manufacturer for specific recommendations.

Section 6 The REM Contact Quality Monitoring System

The REM Contact Quality Monitoring System assures adequate patient contact area by measuring the resistance between the two sections of the REM Patient Return Electrode through the patient. Both sections of the pad and both connector pins carry the RF currents back to the generator. The pin-to-pin resistance measurement is performed continuously, even when the generator is activated. The measurement uses small currents at 80 kHz and will not produce nerve stimulation or interfere with ECG monitors. The alarm levels have acceptance ranges so that small changes in resistance will not cause intermittent alarms.

The REM Contact Quality Monitor is activated when a REM Patient Return Electrode connector is inserted in the Patient receptacle.

The REM Contact Quality Monitor alarms and disables the monopolar output under the following conditions:

- 1. The patient return electrode is not plugged into the generator.
- 2. A patient return electrode cord is broken.
- 3. The patient return electrode is not in contact with patient.
- There is a reduction of patient return electrode contact area due to movement, loss of adhesion, or drying of contact gel.
- There is excessive impedance in the patient return electrode cord.

If a conventional, single-section patient return electrode is used, the REM System monitors the pin-to-pin resistance at the connector and is capable of detecting broken wires or connectors in the patient return electrode cord.

The REM Contact Quality Monitor is not able to monitor the patient contact area if conventional, single-section patient return electrodes are used.

Adaptive REM Monitoring

After the patient return electrode is applied, and the initial impedance is between 5 and 135 ohms, the "adaptive" REM system measures the contact impedance and uses it as a reference value. If the patient-to-pad impedance increases 40% above this reference value or above 135 ohms, the REM alarm sounds and the monopolar output is disabled. The adaptive REM system is designed to calibrate itself with respect to each patient.

Section 7 Performance Specifications

Specifications are subject to change without notice.

In this section, "typical" refers to a specification that is within ± 20% of a stated value at room temperature (25°C/77°F) and a nominal input power voltage.

Output Configuration

Isolated output.

Input Power Source

Nominal Voltage:

110-120 Volts RMS

Regulation Voltage:

90-135 Volts RMS

Operating Range:

85-140 Volts RMS

Current:

Idle

0.4 A, max

Cut

7.0 A, max

Coag

4.0 A, max

Bipolar 2.0 A, max

Low Frequency Leakage, 50-60 Hz

Source Current Polarity

Ground

Leakage (110-120V~)

Normal

intact

 $< 10 \mu A$

Normal

open

 $< 100 \,\mu A$

Reverse

open

 $< 100 \mu A$

High Frequency Risk Parameters

Monopolar RF leakage current

< 150 mA RMS

Bipolar RF leakage current

< 50 mA RMS

REM Contact Quality Monitor

Frequency

Measurement Measurement

Current Single area pad

Acceptable Resistance Range Dual area pad

 $80 \pm 10 \text{ kHz}$

 $< 10 \mu A$

< 20 ohms

5 - 135 ohms

If the impedance measured is outside the acceptance range, a REM fault condition occurs. In the REM mode, if resistance increases by more than 40% above the nominal value or 135 ohms resistance, and alarm occurs. REM current limit is measured using an IEC 601-1 measuring device.

Audio Volume

The activation tones are adjustable. The alarm tones are not adjustable

Audio level @ 1 meter

Activation tone

45 to > 65 dBA

Alarm tone (fixed)

> 65 dBA

Weight

20 lb (9.1 kg)

Overall Dimensions

7.8 in H \times 16.1 in W \times 11.9 in D (199 mm \times 409 mm \times 303 mm)

Classification

Class I Equipment per IEC 601-1

Protection against electric shock is provided by connection of accessible conductive parts to the protective earth conductor in such a way that they cannot become live in the event of a failure of basic insulation.

Type CF Equipment per IEC 601-1

The Force 30/40S generators provide a high degree of protection against electric shock, particularly regarding allowable leakage currents and has a CF type isolated (floating) applied part. The applied part may be used on the heart.

Defibrillator-Proof

The neutral electrode terminals of the Force 30/40S generators can withstand the effects of defibrillator discharge.

Drip Proof per IEC 601-1

The enclosure of the Force 30/40S generators prevents reasonable amounts of falling liquid from interfering with the generator's safe and satisfactory operation.

Intermittent Operation

The generator is cooled by natural convection. Under maximum power setting and rated load conditions (Pure Cut, 300 watt setting, 300 ohmn load) the Force 30/40S are suitable for 10 seconds on, 30 seconds off operation for one hour. With lesser settings and other load impedances, the Force 30/40S generators can be used for greater activation durations without generating excessive internal temperatures.

Note: Power readouts agree with actual power into rated load to within 15% or 5 watts, whichever is greater. Dosage error occurs when the measured output power exceeds the displayed units by 35 watts or 35%, whichever is greater.

Force 30 Output Waveform

Cut

500 kHz sinusoid.

Blend

500 kHz bursts of sinusoid @ 50% duty cycle, recurring @ 31.25 kHz.

Desiccate

 $500\ \mathrm{kHz}$ damped sinusoidal bursts with a repetion frequency of $250\ \mathrm{kHz}$.

Fulgurate

500 kHz damped sinusoidal bursts with a repetion frequency of 62.5 kHz.

Standard Bipolar

500 kHz sinusoid.

Precise Bipolar

500 kHz sinusoid.

Force 30 Output Characteristics

| Mode Cut Blend Desiccate Fulgurate Standard Bipolar | Max P-P voltage | Rated Load | Max Power | Crest Factor |
|---|-----------------|------------|-----------|--------------|
| | (open circuit) | (ohms) | (watts) | (typical) |
| | 3300 | 300 | 300 | 2.1 @ 100 W |
| | 3800 | 300 | 250 | 3.5 @ 100 W |
| | 3500 | 300 | 200 | 3.5 @ 100 W |
| | 6500 | 300 | 150 | 6.0 @ 100 W |
| | 550 | 300 | 50 | 1.9 @ 20 W |
| Standard Bipolar | 550 | 100 | 50 | 1.9@ 20 W |
| Precise Bipolar | 550 | 100 | 50 | 1.9@ 20 W |

Force 40S Output Waveform

Cut

500 kHz sinusoid.

Blend 1

 $500~\mathrm{kHz}$ bursts of sinusoid @ 50% duty cycle, recurring @ 31.25 kHz.

Blend 2

500 kHz bursts of sinusoid @ 37.5% duty cycle, recurring @ 31.25 kHz.

Desiccate

500 kHz damped sinusoidal bursts with a repetion frequency of 250 kHz.

Fulgurate

500 kHz damped sinusoidal bursts with a repetion frequency of 62.5 kHz.

Spray

500 kHz damped sinusoidal bursts with a repetion frequency of 31.25 kHz.

Standard Bipolar

500 kHz sinusoid.

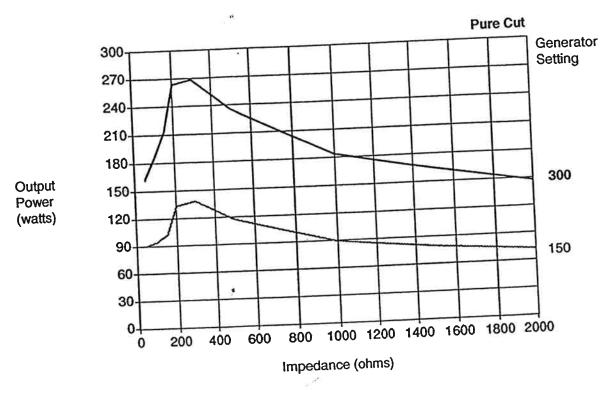
Precise Bipolar

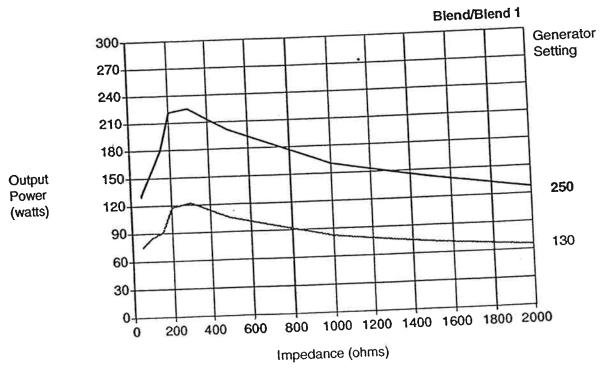
500 kHz sinusoid.

Force 40S Output Characteristics

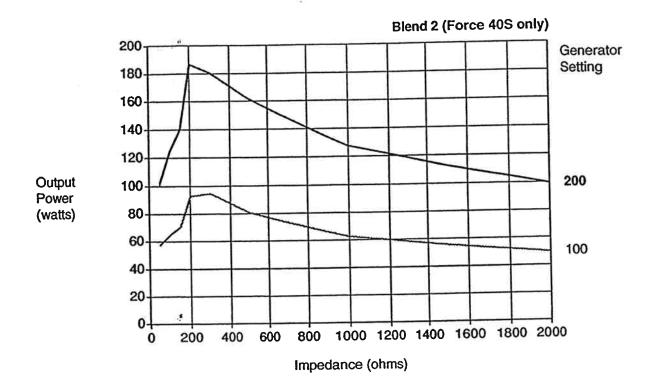
| Mode | Max P-P voltage (open circuit) | Rated Load (ohms) | Max Power (watts) | Crest Factor (typical) |
|------------------|--------------------------------|----------------------|-------------------|------------------------|
| Cut | 3300 | 300 | 300 | 2.1 @ 100 W |
| Blend 1 | 3800 | 300 | 250 | 3.5 @ 100 W |
| Blend 2 | 4000 | 300 | 200 | 4.0 @ 100 W |
| Desiccate | 3500 | 300 | 200 | 3.5 @ 100 W |
| Fulgurate | 6500 | 300 | 150 | 6.0 @ 100 W |
| · · | 9000 | 300 | 150 | 8.5 @ 100 W |
| Spray | 550 | 100 | 50 | 1.9 @ 20 W |
| Standard Bipolar | 550 | 100 | 50 | 1.9 @ 20 W |
| Precise Bipolar | 550 | 100 | 00 | |

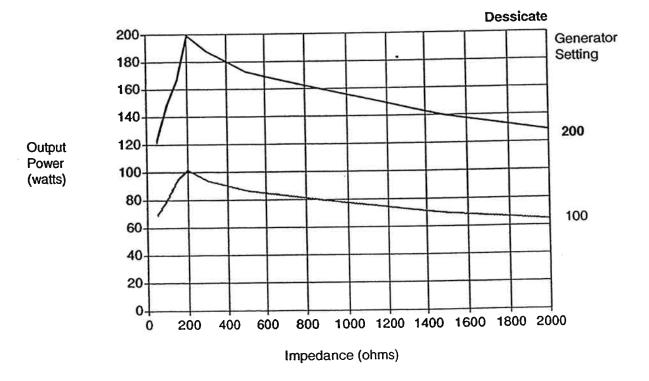
All monopolar output measurements are made using the procedures described in IEC 601-2-2.



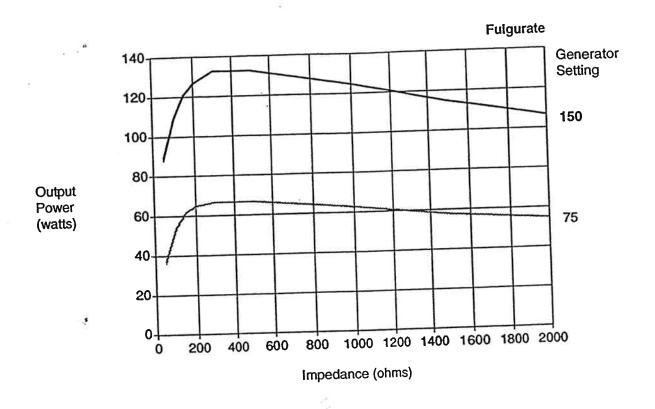


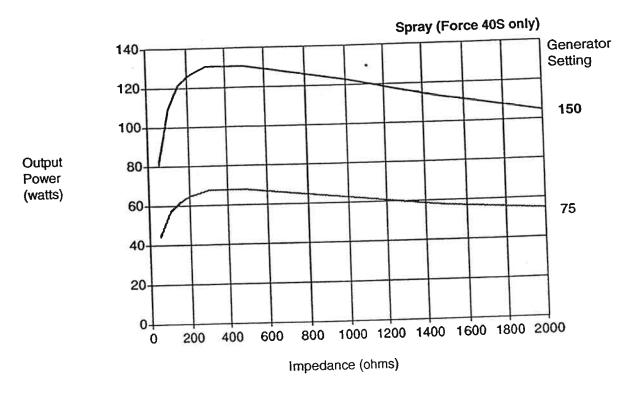
Force 30/40S Output Power vs Load





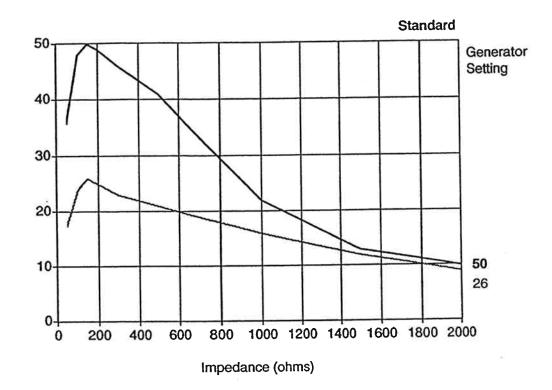
Force 30/40S Output Power vs Load (cont'd)

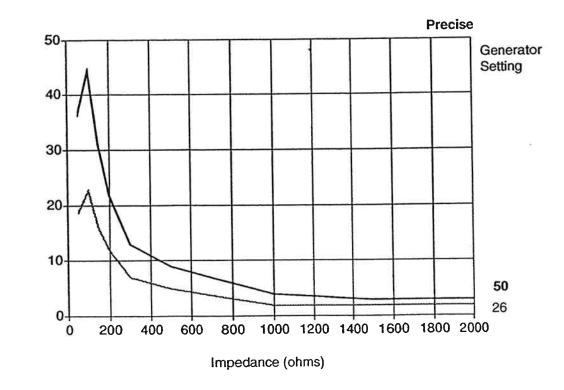




Force 30/40S Output Power vs Load (cont'd)

Bipolar measurements are made using bipolar forceps on the insulating surface described in IEC 601-2-2.



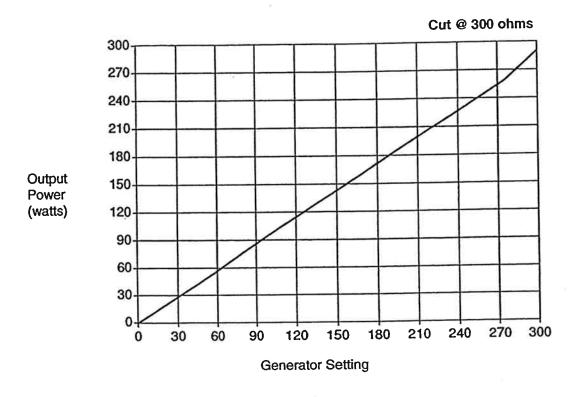


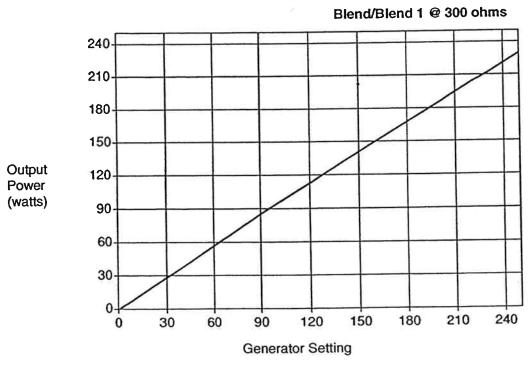
Force 30/40S Output Power vs Load (cont'd)

Output Power

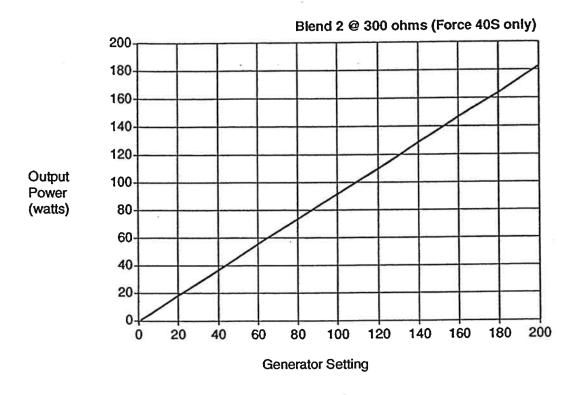
(watts)

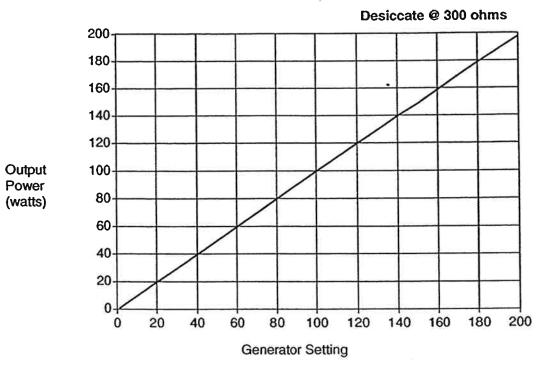
Output Power (watts)



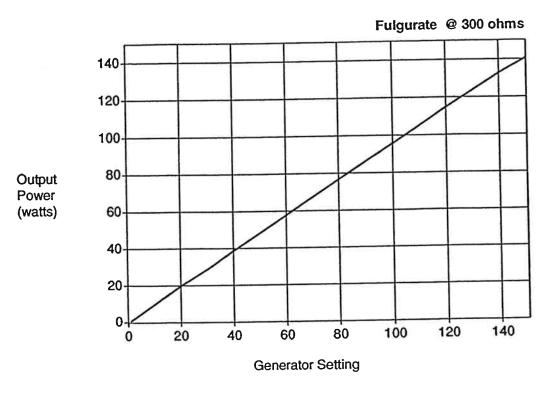


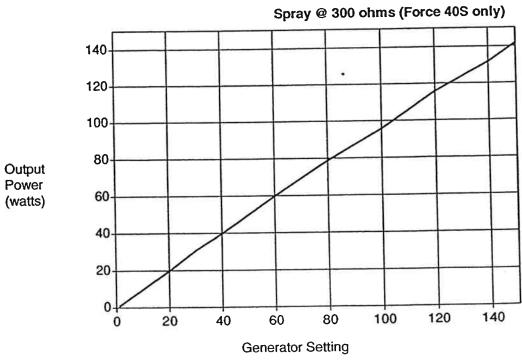
Force 30/40S Output Power vs Generator Setting



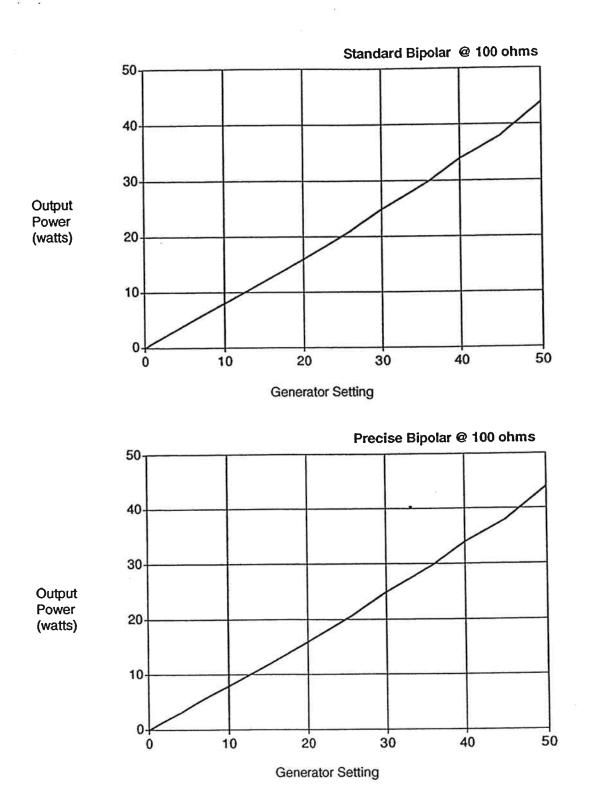


Force 30/40S Output Power vs Generator Setting (cont'd)





Force 30/40S Output Power vs Generator Setting (cont'd)



Force 30/40S Output Power vs Generator Setting (cont'd)