Valleylab™

User's Guide

SurgiStat™ II-20 Electrosurgical Generator

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the Valleylab SurgiStat™ II-20 electrosurgical generator only. Additional technical information is available in the *SurgiStat™ II Electrosurgical Generator Service Manual*.

Equipment covered in this manual
Surg II-20 electrosurgical generator

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Conventions Used in this Guide

Warning

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

Caution

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

▶ ***Important***

Indicates an operating tip or maintenance suggestion.

Notice

Indicates a hazard which may result in product damage.

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Introducing the SurgiStat II Electrosurgical Generator

This section includes the following information:

- Key features
- Components and accessories
- Safety

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.

Key Features

The SurgiStat II electrosurgical generator includes the latest technology. This unit offers unsurpassed performance, flexibility, reliability, and convenience.

It includes the following features:

- **Two levels of coagulation: desiccation and fulguration**   Desiccation provides precise control of bleeding in localized areas. Fulguration provides greater control of bleeding in highly vascular tissue over broad surface areas.

▶ *Important*

The RECQMS system requires that you use a split-plate patient return electrode.

- **Return electrode sensing and contact quality monitoring**   The SurgiStat II incorporates a return electrode contact quality monitoring system (RECQMS). This system determines the type of patient return electrode: single or split-plate. The system also continually monitors the contact quality between the patient and the split-plate return electrode. This feature is designed to eliminate patient burns at the return electrode site.

- **Memory**   The unit automatically powers up to the most recently used modes and power settings.

- **Power adjustment during activation**   You can change the power setting while you activate the unit. If you change the power setting for the mode you are using, your change affects the power you are applying to the patient. You can increase or decrease power as much as three watts per second while activating the unit.

- **Isolated RF output**   This minimizes the potential of alternate site burns.

- **Standard connectors**   These connectors accept the latest monopolar and bipolar instruments.

- **Self diagnostics**   These diagnostics continually monitor the unit to ensure proper performance.

Valleylab electrosurgical generators, patient return electrodes, and active accessories are designed to work as a system. Valleylab 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.

Components and Accessories

You should receive the following components:

• SurgiStat II electrosurgical generator

• Hospital grade power cord

• User's guide

• Service manual

The following items are optional accessories that you can use with the SurgiStat II generator:

• E6008 – Monopolar footswitch 4.6 m (15 ft) cord

• E6008B – Monopolar footswitch 4.6 m (15 ft) cord

• E8007 – Compact mounting cart

• E8002 – Mounting stand

Safety

The safe and effective use of electrosurgery depends to a large degree on factors solely under the control of the operator. There is no substitute for a properly trained and vigilant medical staff. It is important that they read, understand, and follow the operating instructions supplied with this electrosurgical equipment.

Physicians have used electrosurgical equipment safely in numerous procedures. Before starting any surgical procedure, the surgeon should be familiar with the medical literature, complications, and hazards of using electrosurgery in that procedure.

To promote the safe use of the SurgiStat II electrosurgical generator, this section presents the warnings and cautions that appear throughout this user's guide. So that you can operate this equipment with maximum safety, it is important that you read, understand, and follow the instructions in these warnings and cautions. It is also important that you read, understand, and follow the instructions for use in this user's guide.

Warnings

<div style="background:black;color:white">**Warning**</div>

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

Danger: Fire/Explosion Hazard   Do not use the SurgiStat II electrosurgical generator in the presence of flammable anesthetics.

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

• Flammable substances (such as alcohol based skin prepping agents and tinctures)

• Naturally occurring flammable gases that may accumulate in body cavities such as the bowel

• Oxygen enriched atmospheres

• Oxidizing agents (such as nitrous oxide [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.

Electric Shock Hazard   Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit. Do not use power plug adapters.

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

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.

Failure of the high frequency electrosurgical equipment could result in an unintended increase of output power.

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.

Use the lowest output setting necessary to achieve the desired surgical effect. Use the active electrode only for the minimum time necessary in order to reduce 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.

Warning

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

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

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 irreversible tissue necrosis.

For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.

In some circumstances, the 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 5 to 8 cm (2 to 3 in.) 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 that avoids skin-to-skin contact areas.

- In addition, place patient return electrodes according to the manufacturer's instructions.

Potential for alternate site burns increases if the return electrode is compromised. Valleylab recommends the use of split-plate patient return electrodes and Valleylab generators with a contact quality monitoring system.

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.

Cautions

Caution

At no time should you touch the active electrode or bipolar forceps. A burn could result.

Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow 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 at a distance from the generator and set the generator volume control at a level that ensures that the activation tones can be heard.

The use of high frequency current can interfere with the function of other electromagnetic equipment.

When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes.

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

To avoid the possibility of an electrosurgical burn to either the patient or the physician, do not allow the patient to come in contact with a grounded metal object during activation. When activating the unit, do not allow direct skin contact between the patient and the physician.

Remove any loose fitting jewelry from the patient before activation.

Caution

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

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.

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.[1]

Notice

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

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

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

Controls, Indicators, and Receptacles

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

Front Panel

Figure 2-1.
Layout of controls, indicators,
and receptacles on the front
panel
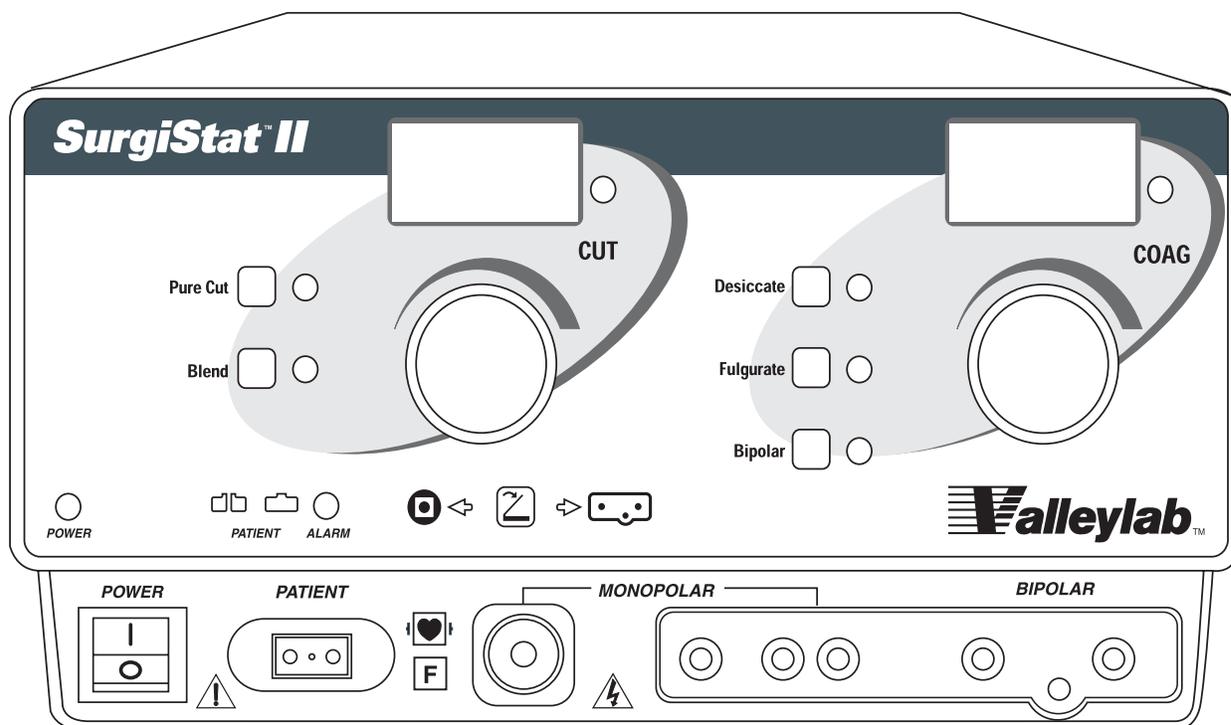
Cut and Blend Controls

Figure 2-2.
*Controls for the Cut and Blend
modes*

Cut Indicator
Illuminates when
Pure Cut mode is
selected.

Cut Selector
When pressed,
selects the Pure Cut
mode.

Pure Cut

Blend

Blend Selector
When pressed,
selects the Blend
mode.

Blend Indicator
Illuminates when
Blend mode is
selected.

**Cut and Blend
Power Display
(watts)**
Indicates the
power set for the
Pure Cut or Blend
mode.

**Cut and Blend
Activation
Indicator**
Illuminates when
either Pure Cut or
Blend mode is
activated.

CUT

Cut and Blend Power Control Dial
Increases or decreases the Cut or
Blend power output in increments of
one watt.

Coag and Bipolar Controls

Figure 2-3.
Controls for the Desiccate,
Fulgurate, and Bipolar modes
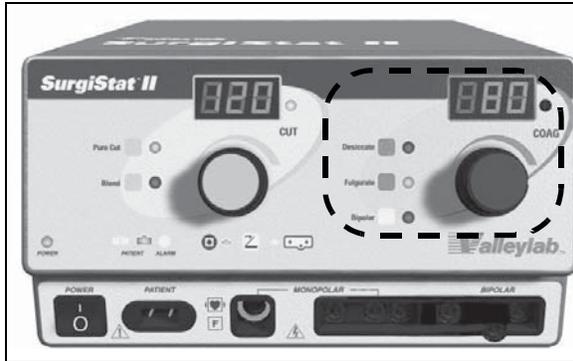
Desiccate Indicator
Illuminates when Desiccate mode is selected.

Desiccate Selector
When pressed, selects the Desiccate mode.

Fulgurate Indicator
Illuminates when Fulgurate mode is selected.

Fulgurate Selector
When pressed, selects the Fulgurate mode.

Bipolar Selector
When pressed, selects the Bipolar mode.

Bipolar Indicator
Illuminates when Bipolar mode is selected.

Coag and Bipolar Power Display (watts)
Indicates the power set for any Coag or Bipolar mode.

Coag and Bipolar Activation Indicator
Illuminates when Desiccate, Fulgurate, or Bipolar modes are activated.
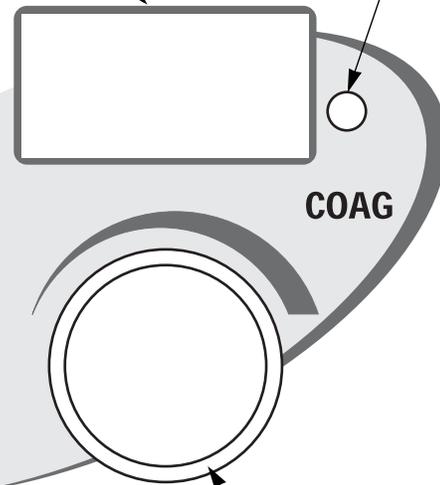
Coag and Bipolar Power Control Dial
Increases or decreases the Coag or Bipolar power output in increments of one watt.

Desiccate

Fulgurate

Bipolar

COAG

Indicators

Figure 2-4.
Indicators for power, return electrodes, and footswitch control

Bipolar Footswitch Control Indicator and Symbol
Illuminates when bipolar foot control is selected.

Patient Return Electrode Alarm Indicator
Illuminates when the system detects a patient return electrode alarm condition.

POWER   PATIENT   ALARM

Power Indicator
Illuminates when the unit is on.

Monopolar Footswitch Control Indicator and Symbol
Illuminates when monopolar foot control is selected.

Split-Plate Patient Return Electrode Indicator
Illuminates when the system detects a split-plate.

Single-Plate Patient Return Electrode Indicator
Illuminates when the system detects a single-plate.

Footswitch Control Selector
When pressed, switches between monopolar and bipolar foot control.

Power Switch and Receptacles

Figure 2-5.
Location of the unit power switch
and front panel receptacles

Bipolar Receptacle
Accepts standard
cables for Bipolar
handpieces.

Power On/Off Switch
Turns the unit on or off.

**Patient Return Electrode
Receptacle**
Accepts a standard patient return
electrode plug.

**Monopolar Footswitching
Receptacle**
Accepts cables or adapters equipped
with standard (Bovie #12) active plugs.
Connect footswitching accessories.

**Monopolar Handswitching
Receptacle**
Accepts standard three-pin
handpieces. Connect
handswitching accessories.

Rear Panel

Figure 2-6.
*Layout of connectors and controls
on the rear panel*

Equipotential Connector
Allows attaching a standard grounding
cable to chassis ground for additional
protection against leakage current.

Volume Control
Controls the volume of the audible tones
produced during normal unit activation. To
increase volume, rotate the knob clockwise.

MONOPOLAR
FOOTSWITCH

Valleylab™ *SurgiStat™ II*

REF
CAT.

SN

CE
0086

WARNING: RISK OF FIRE.
REPLACE FUSE
AS MARKED.
250V, T5.0A (110-120)

Controls, Indicators,
and Receptacles
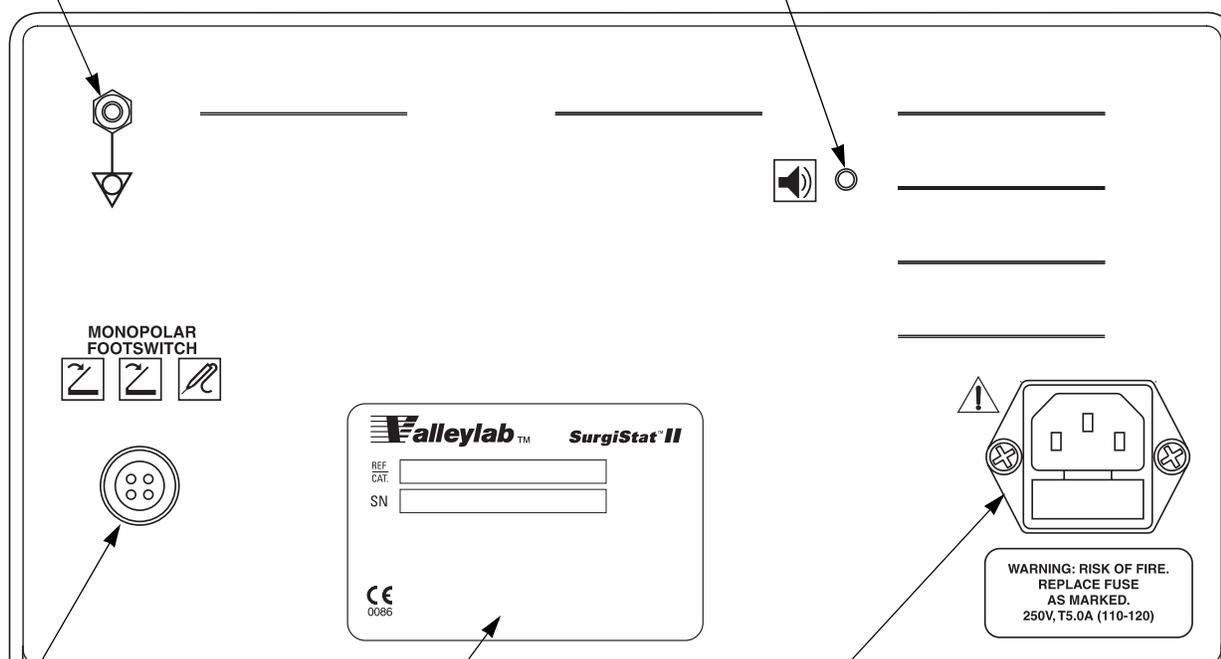
Footswitch Receptacle
Accepts the E6008 or E6008B
monopolar footswitch. Use the
monopolar footswitch for both
monopolar and bipolar
activation. Use only a Valleylab
monopolar footswitch with the
SurgiStat II-20 generator. Use
of an incompatible footswitch
may cause unexpected output.

Serial Number Label
Specifies the unit model
number, serial number,
nominal line voltage,
frequency, current, and
power consumption.

**Power Cable Receptacle and Fuse
Holder**
Connects a hospital grade power
cord to supply AC mains power to
the unit.

Symbols on the Front Panel

Symbols	Description
Indicators	
	Single-plate patient return electrode
	Split-plate patient return electrode
	Monopolar footswitch control
	Footswitch (on the selector button)
	Bipolar footswitch control
Power Switch and Handpiece Connectors	
	Read instructions before use
	Type CF equipment
	RF isolated – patient connections are isolated from earth at high frequency
	Caution – high voltage

Symbols on the Rear Panel

Symbols	Description
	Equipotential ground stud
	Nonionizing radiation
	Volume control
	Danger Explosion risk if used with flammable anesthetics
	Monopolar footswitch
	Read instructions before use

Controls, Indicators,
and Receptacles

Getting Started

This section includes the following information:

• Initial inspection

• Installing the unit

• Checking unit functions

• Testing unit performance

Initial Inspection

When you first unpack your SurgiStat II generator, inspect it visually:

• Look for any signs of damage.

• Verify that the shipping package contains all items listed on the packing list.

If the unit or any accessories are damaged, notify Valleylab Customer Service immediately. Do not use any damaged equipment.

Installation

Place the SurgiStat II on any flat surface with a tilt angle not more than 10°. The unit relies on natural convection cooling. Do not block its bottom or rear vents. Ensure that air flows freely on all sides of the unit.

Warning

Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.

Function Checks

Upon initial installation of the unit, perform the following checks. Refer to the figures in the previous chapter for the location of connectors and controls.

Caution

At no time should you touch the active electrode or bipolar forceps. A burn could result.

Setting Up the Unit

1. Verify that the Power Switch is in the Off (O) position and that no accessories are connected to the unit.

2. Connect a hospital grade power cable to the AC power cable receptacle on the back of the unit, then to a properly grounded wall outlet.

3. Connect a two-pedal footswitch to the appropriate footswitch receptacle on the back of the unit. Use only a Valleylab footswitch with the SurgiStat II-20 generator. Although other types of footswitches may fit, they may not be compatible. Use of an incompatible footswitch may cause unexpected output.

4. Do not connect a patient return electrode at this time.

5. Turn the unit on by switching the power switch to the On (|) position.

Checking the Patient Return Electrode Alarm

1. Adjust the power settings for each mode (Cut, Blend, Desiccate, Fulgurate, and Bipolar) to one watt.

2. Press the Cut pedal of the footswitch.

3. Verify that an alarm sounds for three seconds and the Patient Return Electrode Sensing Alarm Indicator Light illuminates, indicating that you have not connected a patient return electrode to the unit.

4. Verify that adjusting the volume control on the back of the unit while the alarm is sounding cannot change the alarm sound level.

Confirming Modes

Confirm that you can select each mode and adjust power up and down.

Checking Bipolar Mode (with Footswitch)

1. Select Bipolar mode by pressing the Bipolar Mode Selector.

   Note: The unit automatically changes to bipolar footswitching when the bipolar mode is selected.

2. Verify that the Bipolar Mode Indicator illuminates and that the system generates the Coag tone when you press the Coag pedal (Blue) or the Cut pedal (Yellow) on the footswitch.

3. While activating the Bipolar mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

4. Confirm that releasing the Coag pedal or the Cut pedal returns the unit to an idle state.

Checking Monopolar Mode (with Footswitch)

1. Select monopolar foot control by pressing the Footswitch Control Selector until the Monopolar Footswitch Control Indicator illuminates.

2. Connect a single-plate patient return electrode to the Return Electrode receptacle of the unit. Verify that the green single-plate patient return electrode indicator illuminates.

3. Press the Cut pedal on the footswitch. Verify that the Cut and Blend Activation Indicator illuminates and that the system generates the Cut activation tone.

4. While activating the Cut mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

Getting Started

5. Press the Coag pedal on the footswitch. Verify that the Desiccate, Fulgurate, and Bipolar Activation Indicator illuminates and that the system generates the Coag activation tone.

6. While activating the Coag mode, rotate the volume control over the full range to verify that the sound is audible throughout the range.

Checking Monopolar Mode (with Handswitch)

1. Connect a handswitching handpiece to the Monopolar Handswitching receptacle.

2. Activate, one at a time, the Cut and Coag handswitching controls.

3. Verify that each control causes the correct indicator to illuminate and tone to sound.

Performance Checks

After the unit has passed the preliminary functional test, it is ready for performance testing. A qualified biomedical engineer who is thoroughly familiar with electrosurgical devices should conduct this testing. The testing should include checking all modes of operation for proper function and power output.

For a detailed description of performance testing procedures, refer to the *SurgiStat II Electrosurgical Generator Service Manual*.

Using the SurgiStat II

This section contains the following procedures:

- Inspecting the generator and accessories

- Setup safety

- Setting up

- Preparing for monopolar surgery

- Preparing for bipolar surgery

- Activation safety

- Activating the unit

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

Inspecting the Generator and Accessories

Before each use of the SurgiStat II, verify that the unit and all accessories are in good working order:

- Inspect for damage to the generator and all its connections.

- Verify that the appropriate accessories and adapters are present.

- Inspect all cords and connectors for signs of wear, damage, and abrasion.

- Verify that no errors occur when you turn on the unit.

Setup Safety

Warning
Hazardous Electrical Output   This equipment is for use only by trained, licensed physicians.
Electric Shock Hazard   Connect the generator power cord to a properly grounded receptacle. Do not use power plug adapters.
Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.
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.
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.
Failure of the high frequency electrosurgical equipment could result in an unintended increase of output power.
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 irreversible tissue necrosis.
For surgical procedures where the high frequency current could flow through parts of the body having a relatively small cross-sectional area, the use of bipolar techniques may be desirable to avoid unwanted coagulation.
If the patient has an implantable cardioverter defibrillator (ICD), contact the ICD manufacturer for instructions before performing an electrosurgical procedure. Electrosurgery may cause multiple activation of ICDs.

Warning

In some circumstances, the 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 5 to 8 cm (2 to 3 in.) 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 that avoids skin-to-skin contact areas.

• In addition, place patient return electrodes according to the manufacturer's instructions.

Potential for alternate site burns increases if the return electrode is compromised. Valleylab recommends the use of split-plate patient return electrodes and Valleylab generators with a contact quality monitoring system.

Caution

Do not stack equipment on top of the generator or place the generator on top of electrical equipment. These configurations are unstable and/or do not allow 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.

Using the SurgiStat II

Setting Up

1. Verify that 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 Valleylab cart. Carts with conductive wheels are recommended. For details, refer to the procedures for your institution or to local codes.

    Provide at least 10 to 15 cm (4 to 6 in.) of space from the sides and top of the generator for cooling. Normally, the top, sides, and rear panel are warm when you use the generator continuously for extended periods of time.

3. Plug the generator power cord into the AC Power Cable Receptacle on the rear panel.

4. Plug the generator power cord into a grounded receptacle.

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

    *   All visual indicators and displays on the front panel illuminate.

    *   Activation tones sound to verify that the speaker is working properly.

6. *If the self-test is successful,* a tone sounds. Verify the following:

    *   A Cut mode is selected, and a Coag or Bipolar mode is selected.

    *   Each display shows a power setting. The unit automatically powers up to the most recently used power settings.

    *   The Patient Return Electrode 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 *Troubleshooting,* Section 6.

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

Preparing for Monopolar Surgery

Applying the Patient Return Electrode

Monopolar surgery requires a patient return electrode.

Valleylab recommends using return electrode contact quality monitoring system (RECQMS) patient return electrodes to maximize patient safety. 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. Using a patient return electrode without the RECQMS safety feature may result in a patient burn.

1. Apply the patient return electrode to the patient. 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. Select a patient return electrode site with good blood flow. While a properly applied electrode results in minimal tissue heating beneath the electrode, a good blood flow helps carry heat away from the site.

▶ **Important**

The RECQMS system requires that you use a split-plate patient return electrode.

2. Connect the cable to the Patient Return Electrode Receptacle on the front of the unit.

3. After a delay of approximately three seconds, the unit will sense the presence of a single or split-plate patient return electrode. The unit will then constantly monitor the resistance of the single-plate electrode or the resistance at the contact between the split-plate electrode and the patient.

Connecting Accessories

1. Connect a monopolar active electrode to the unit:

If you are using ...	Connect it to ...
Standard 3-pin handswitching pencil	Monopolar Handswitching Receptacle
Footswitching pencil	Monopolar Footswitching Receptacle

2. If using a footswitch activated device, connect an appropriate Valleylab footswitch to the Footswitch Connecting Socket on the rear of the unit. Use only a Valleylab footswitch with the SurgiStat II-20 generator. Use of an incompatible footswitch may cause unexpected output.

Preparing for Bipolar Surgery

1. Select the Bipolar Mode by pressing the Bipolar Mode Selector. The Bipolar Mode Indicator will illuminate.

    Note: The unit automatically changes to Bipolar Footswitching mode when you select Bipolar mode.

2. Connect a Bipolar cable to the Bipolar Receptacle.

3. Connect the appropriate Valleylab Footswitch to the Footswitch Receptacle on the rear of the unit.

4. Connect a forceps instrument to the Bipolar cable.

Using the SurgiStat II

Activation Safety

> **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.

> **Danger: Fire/Explosion Hazard**   Do not use the SurgiStat II electrosurgical generator in the presence of flammable anesthetics.

> **Fire/Explosion Hazard**   The following substances will contribute to increased fire and explosion hazards in the operating room:
>
> • Flammable substances (such as alcohol based skin prepping agents and tinctures)
>
> • Naturally occurring flammable gases that may accumulate in body cavities such as the bowel
>
> • Oxygen enriched atmospheres
>
> • Oxidizing agents (such as nitrous oxide [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.

> Use the lowest output setting necessary to achieve the desired surgical effect. Use the active electrode 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 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 for patients with cardiac pacemakers.

Caution

The use of high frequency current can interfere with the function of other electromagnetic equipment.

When high frequency surgical equipment and physiological monitoring equipment are used simultaneously on the same patient, place any monitoring electrodes as far as possible from the surgical electrodes.

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

To avoid the possibility of an electrosurgical burn to either the patient or the physician, do not allow the patient to come in contact with a grounded metal object during activation. When activating the unit, do not allow direct skin contact between the patient and the physician.

Remove any loose fitting jewelry from the patient before activation.

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.[1]

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

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.

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

Using the SurgiStat II

Activating the Unit

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 Valleylab patient return electrodes are designed for use during traditional surgical procedures and duty cycles (on time compared to off time). Users should consult the Technical Specifications section of the generator user manual 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 Valleylab 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.

When you turn on your unit, remember these features:

• SurgiStat II will power up to the most recently used modes and most recently used settings. For example, if you set Pure Cut mode at 50 watts when you turned the unit off, it will automatically return to Pure Cut mode at 50 watts when you turn it on again. Similarly, if you set Desiccate mode at 40 watts before you turned the unit off, it will return to Desiccate mode at 40 watts when you turn it on again.

• When you switch from Pure Cut mode to Blend (or the reverse), the unit maintains its power setting. Also, when you switch among Desiccate, Fulgurate, and Bipolar, the unit maintains its power setting.

For example, if you are working in Pure Cut at 75 watts and you switch to Blend, the unit maintains a power setting of 75 watts.

EXCEPTION: If you are working in Pure Cut mode at 110 watts and switch to Blend mode, the unit automatically reduces its power setting to the maximum setting for Blend mode, 90 watts.

Similarly, if you are working in Desiccate mode at 25 watts and switch to Fulgurate or Bipolar, the unit maintains 25 watts.

EXCEPTION: If you are working in Desiccate mode at a power setting of 80 watts and switch to Fulgurate mode, the unit automatically reduces its power setting to the maximum for Fulgurate, 40 watts. If you switch to Bipolar, the unit automatically reduces its power setting to the maximum for Bipolar, 30 watts.

• You can change the power setting while you activate the unit. If you change the power setting for the mode you are using, your change affects the power you are applying to the patient. You can increase or decrease power as much as three watts per second while activating the unit.

For example, if you have activated Pure Cut at 50 watts, you can increase the Pure Cut power to 60 watts while continuing to activate the unit. The power output increases from 50 to 60 watts.

At the same time, you can increase the power setting of the mode that is not currently active. For example, if you have activated Blend mode at 50 watts, you can increase the power setting in the Desiccate mode from 30 to 40 watts. The setting for Desiccate increases to 40 watts, but the Blend power output remains at 50 watts.

1. Monopolar Cut: Select the desired Cut power settings by rotating the Cut and Blend Power Control Dial.

2. Monopolar Coag: Select the mode of operation for coagulation: Desiccate or Fulgurate, then select the coagulation power settings by rotating the Desiccate, Fulgurate, and Bipolar Power Control Dial.

3. Bipolar: Select the mode of operation for Bipolar, then select the Bipolar power settings by rotating the Desiccation, Fulguration, and Bipolar Power Control Dial.

4. Activate the generator by pressing the appropriate button:

▶ **Important**

One footswitch activates either monopolar or bipolar footswitching accessories.

To activate...	press this...	on this device...
Monopolar		
Cut or Blend modes	yellow button yellow pedal	handswitching pencil footswitch
Desiccate or Fulgurate modes	blue button blue pedal	handswitching pencil footswitch
Bipolar		
Any Bipolar	yellow (Cut) or blue (Coag) pedal	footswitch

Using the SurgiStat II

Maintaining the SurgiStat II

This section covers the following topics:

• Cleaning

• Periodic inspection

• Fuse replacement

Valleylab recommends that you complete periodic inspection and performance testing. Perform inspections and performance testing every six months. A qualified biomedical technician should conduct this testing to ensure that the unit is operating effectively and safely.

Cleaning

After each use, clean the unit.

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

Caution
Do not allow fluids to enter the generator chassis.
Do not sterilize the generator.

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

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

2. Thoroughly wipe all surfaces of the generator and power cord with a mild cleaning solution or disinfectant and a damp cloth. Follow the procedures approved by your institution or use a validated infection control procedure.

Periodic Inspection

Every six months, visually inspect the SurgiStat II for signs of wear or damage. In particular, look for any of the following problems:

- Damage to the power cord

- Damage to the power cable receptacle

- Obvious damage to the unit

- Damage to any receptacle

- Accumulation of lint or debris in or around the unit

Fuse Replacement

Fuses for the unit reside directly below the Power Cable Receptacle on the rear of the unit.

To replace the fuses, follow this procedure:

1. Unplug the power cord from the wall outlet.

2. Remove the power cord from the Power Cable Receptacle on the rear panel.

3. To release the fuse drawer, insert a small flathead screwdriver into the slot on the drawer below the power cord receptacle and slide the drawer out.

Fuse Drawer

4. Remove the two fuses and replace them with new fuses with the same values.

5. Insert the fuse drawer into the Power Cable Receptacle.
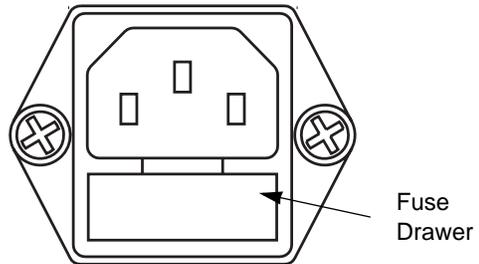
Use the following fuses:

	Surg II-20 110–120 V
VAC	250
Amps	5.0 A
Type	Slow Blow
Size	5 x 20 mm

Maintaining the SurgiStat II

Troubleshooting

This section includes error code descriptions and actions to take to resolve them.

General Troubleshooting Guidelines

The SurgiStat II includes automatic self-diagnostics. If the diagnostics detect an error, the system displays an error code, sounds an audible tone, and deactivates the unit output power.

Correcting Malfunctions

Most error codes result from faults in accessories attached to the unit. The following table lists the error codes, describes the error, and recommends actions to take to resolve the error.

Error Code	Description	Recommended Action
F1 (on the Cut/Blend Display) F1 (on the Desiccate/ Fulgurate/ Bipolar display)	Handswitch or monopolar footswitch cut pedal may be stuck Handswitch or monopolar footswitch coag pedal 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. Turn off, then turn on the generator again. 3. If the problem persists, replace the handpiece or footswitch and repeat Step 1. 4. If the alarm number reappears, record the number and call the Valleylab Service Center.
F2	Cut and Coag buttons activated simultaneously (pencil or footswitch)	The unit does not allow simultaneous activation of the cut and coagulation modes. Release either the cut or coag button on the handpiece, or the cut or coag pedal on the footswitch.
F3	Monopolar handpiece activated while in Bipolar mode	Release pressure on the handpiece buttons. Use the footswitch to activate Bipolar, or switch to Monopolar mode.
E4	Line voltage error (Line voltage too high)	1. Turn the unit off. 2. Verify that the unit is connected to the correct line voltage.

Error Code	Description	Recommended Action
E5	Internal pulse width measurement exceeds setting requirements	**1.** Turn unit off. **2.** If using a metal patient return electrode plate, verify that the cable connections are secure and replace cables with loose connections. Turn unit on. **3.** If error code occurred directly after changing mode of operation, turn on the unit and delay activation of the accessories after changing mode of operation. **4.** If alarm number reappears upon restarting the unit, record the number and call the Valleylab Service Center.
E6	Internal pulse width measurement conflicts with calibrated value	**1.** Turn unit off. **2.** If error code occurred directly after changing mode of operation, turn on the unit and delay activation of the accessories after changing mode of operation. **3.** If error code occurred directly after changing the power setting during activation, turn on the unit and limit the change of power to approximately three watts per second. **4.** If alarm number reappears upon restarting the unit, record the number and call the Valleylab Service Center.
E7	Internal temperature of the unit exceeded limit	**1.** Turn the unit off. **2.** Allow the unit to cool for 20 minutes.

Troubleshooting

If the unit displays any other error code, it requires service.

Repair Policy and Procedures

Refer to this section for information on

• The manufacturer's responsibility

• Returning the generator for service

• Returning circuit boards

• Finding service centers

Responsibility of the Manufacturer

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

- The user has followed the installation and setup procedures in this manual.

- Persons authorized by Valleylab performed assembly operation, readjustments, modifications, or repairs.

- The electrical installation of the relevant room complies with local codes and regulatory requirements, such as IEC and BSI.

- Equipment use is in accordance with the Valleylab instructions for use.

For warranty information, refer to Chapter 9, *Warranty.*

Returning the Generator for Service

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

Step 1 – Obtain a Return Authorization Number

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

- Hospital/clinic name/customer number

- Telephone number

- Department/address, city, state, and zip code

- Model number

- Serial number

- Description of the problem

- Type of repair to be done

Step 2 – Clean the Generator

Warning

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

Caution

Do not allow fluids to enter the generator chassis.

Do not sterilize the generator.

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.

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 the original shipping container is not available, request one when obtaining your Return Authorization Number.

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

Service Center

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

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

Repair Policy and Procedures

Technical Specifications

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

Performance Characteristics

Input Power

110–120 Volt
Nominal input power voltage for calibration: 120 V
Mains line frequency range (nominal): 50–60 Hz
Power consumption: 360 VA
Fuses (2): 5A (Slow Blow)

Duty Cycle

Under maximum power settings and rated load conditions (Pure Cut, 120 watt @ 500 Ω load), the generator is suitable for activation times of 10 seconds on, 30 seconds off for one hour.

Dimensions and Weight

Width	26 cm (10.25 in.)
Depth	30.5 cm (12 in.)
Height	15.2 cm (6 in.)
Weight	< 6.5 kg (< 14 lbs)

Operating Parameters

Ambient temperature range	10° to 40° C (50° to 104° F)
Relative humidity	15% 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	-34° to 65° C (-29° to 149° F)
Relative humidity	0% to 75%, noncondensing
Atmospheric pressure	500 to 1060 millibars

Audio Volume

The audio levels stated below are for activation tones (Bipolar, Cut, and Coag) and alarm tones (return electrode and system alarms) at a distance of one meter. Alarm tones meet the requirements for IEC 60601-2-2.

Activation Tone

Volume (adjustable)	45 to 65 dBA
Frequency	Cut: 1 kHz
	Blend: 1 kHz
	Desiccation: 2 kHz
	Fulguration: 2 kHz
	Bipolar: 2 kHz
Duration	Continuous while the generator is activated

Technical Specifications

Alarm Tone

Volume (not adjustable)	70 dBA ± 5 dBA
Frequency	2 kHz for 1 second, then 1 kHz for 1 second
Duration	4 seconds

Patient Return Electrode Sensing

Single-Plate	Measurement current: <100 µA
	Measurement frequency: 62.5 kHz ± 2.5 kHz
	Set resistance: $0\ \Omega$ to $5\ \Omega \pm 3\ \Omega$
	Continuous measurement: Once the system establishes the single-plate electrode resistance, an increase of $20\ \Omega \pm 5\ \Omega$ in resistance will cause an alarm. When the alarm condition exists, the system deactivates output power.
Split-Plate	Measurement current: <100 µA
	Measurement frequency: 62.5 kHz ± 2.5 kHz
	Set resistance: $10\ \Omega \pm 5\ \Omega$ to $135\ \Omega \pm 10\ \Omega$
	Continuous measurement: Once the system establishes the split-plate electrode resistance, an increase of 40% in resistance or up to $150\ \Omega$ (whichever is less) will cause an alarm. A decrease of resistance below $4\ \Omega \pm 2\ \Omega$ will cause an alarm. When the alarm condition exists, the system deactivates output power.

The system presents audible and visible alarms when it does not sense a patient return electrode.

- When a fault condition occurs, the alarm indicator flashes red, an alarm tone sounds, and the system disables output power.

- The red LED alarm indicator remains illuminated until the condition that caused the alarm is corrected.

- Activation attempts during an alarm condition result in an audio alarm and the alarm indicator flashes.

- When the alarm condition is resolved, the green single or split-plate indicator will illuminate.

- The system measures the return electrode sensing current according to IEC 60601-1.

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	< 39 mA $_{rms}$
Monopolar RF leakage current (additional tolerance)	< 150 mA $_{rms}$

Standards and IEC Classifications

The SurgiStat II-20 generator meets all pertinent clauses of the IEC 60601-1 second edition and IEC 60601-2-2 third edition.

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.

Technical Specifications

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

The SurgiStat II 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.

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

The SurgiStat II-20 generator enclosure is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which, when wetted, are likely to adversely affect the safety of the equipment.

Electromagnetic Interference

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

Voltage Transients (Emergency Generator Mains Transfer)

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

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

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

Notice
The SurgiStat II requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the SurgiStat II Service Manual.
Portable and mobile RF communications equipment can affect the SurgiStat II. Refer to the EMC information provided in the SurgiStat II Service Manual.

Output Characteristics

Maximum Output for Bipolar and Monopolar Modes

Power readouts agree with actual power into rated load to within 20% or 5 watts, whichever is greater. All measurements were taken at the nominal input power voltage used for calibration.

Mode	Output Power	Output Frequency	Repetition Rate	Vp-p max	Crest Factor* (Rated Load)
Cut	120 W @ 500 Ω	357 kHz ± 50 kHz	N/A	2.5 kV	2.9 ± 20%
Blend	90 W @ 800 Ω	357 kHz ± 50 kHz	30 kHz ± 5 kHz	3.5 kV	3.3 ± 20%
Desiccate	80 W @ 1000 Ω	475 kHz ± 50 kHz	57 kHz ± 5 kHz	4.5 kV	5.5 ± 20%
Fulgurate	40 W @ 1000 Ω	410 kHz ± 50 kHz	25 kHz ± 5 kHz	6.5 kV	7.7 ± 20%
Bipolar	30 W @ 200 Ω	520 kHz ± 50 kHz	32 kHz ± 5 kHz	2.0 kV	6.9 ± 20%

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

Technical Specifications

Output Power Curves

The curves that follow depict the changes for each mode at specific power settings. All measurements were taken at the nominal input power voltage used for calibration.

Monopolar Cut Curves

These measurements were taken using short (< 0.5 meter) leads. For each output power vs. impedance curve, the upper curve represents readings taken at full power; the lower curve, readings taken at half power.

Figure 8-1 .
Output power vs. impedance for Pure Cut mode

Figure 8-2.
Peak voltage vs. power setting for Pure Cut mode
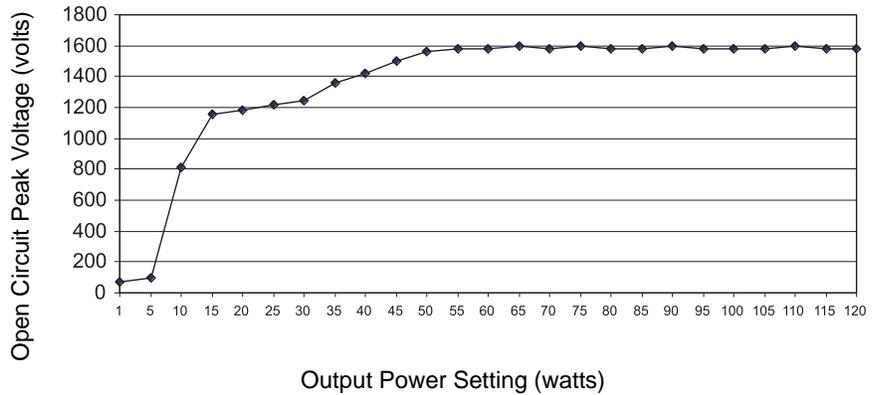
Figure 8-3.
Output power vs. generator settings for Pure Cut mode
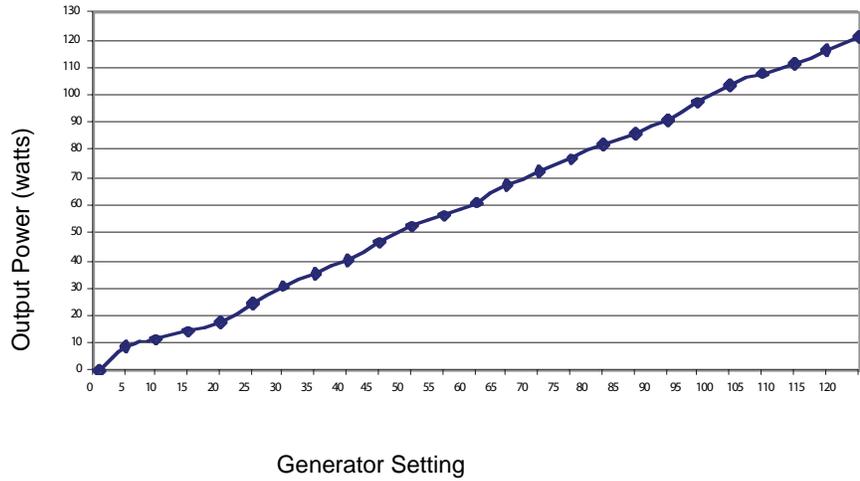
Generator Setting

Figure 8-4.
Output power vs. impedance for Blend mode

Load Resistance (ohms)

Technical Specifications
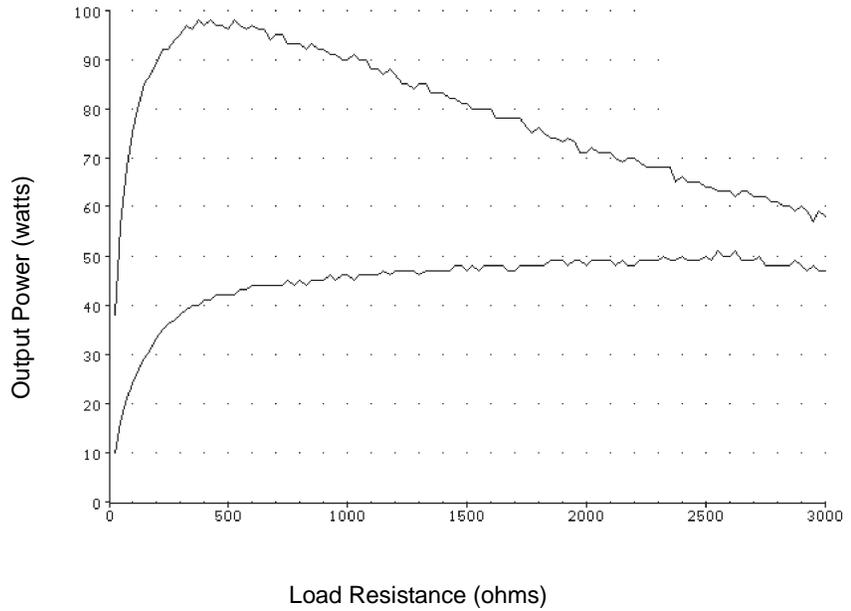
Figure 8-5.
Peak voltage vs. power setting for Blend mode
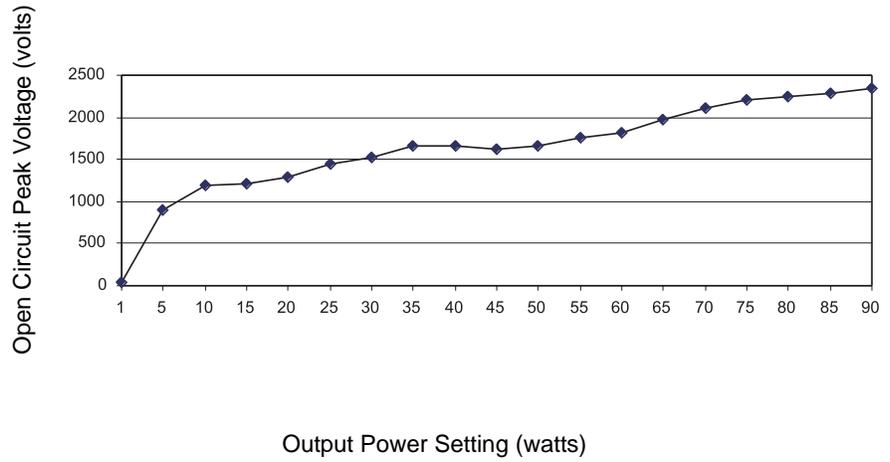
Figure 8-6.
Output power vs. generator settings for Blend mode
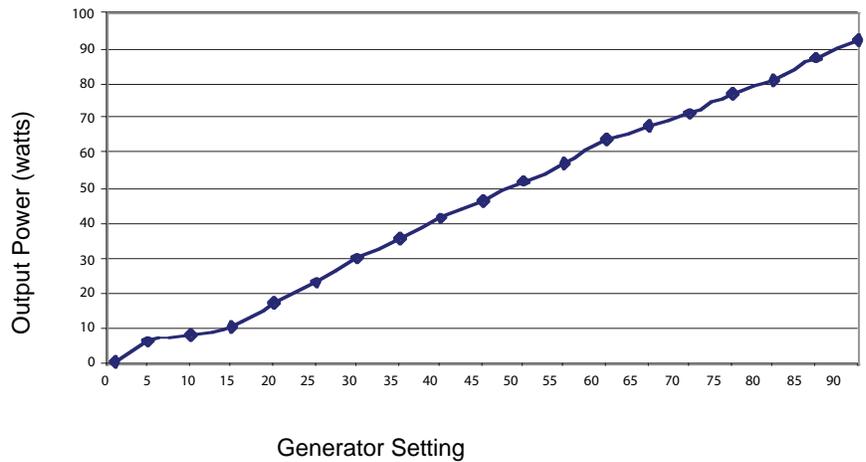
Monopolar Coag Curves

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

Figure 8-7.
Output power vs. impedance for Desiccate mode
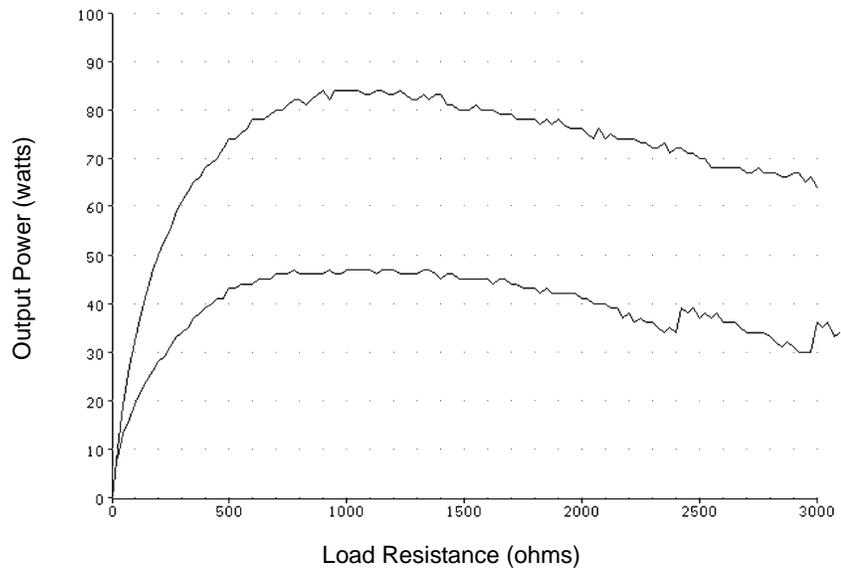
Figure 8-8.
Peak voltage vs. power setting for Desiccate mode

Technical Specifications
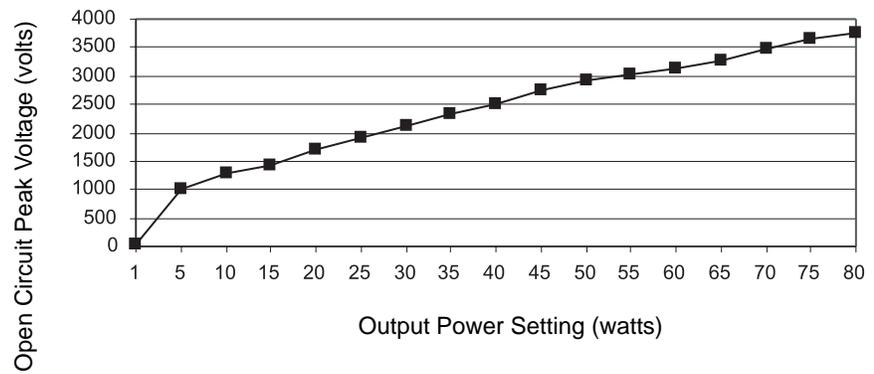
Figure 8-9.
Output power vs. generator settings for Desiccate mode
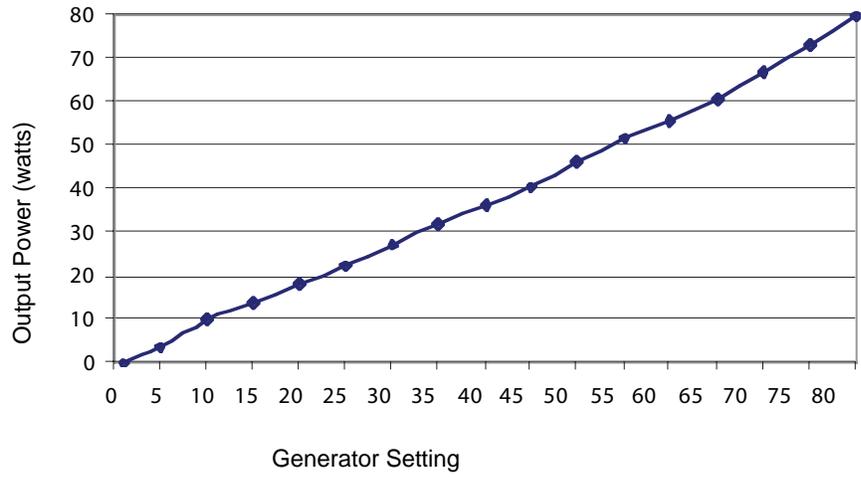
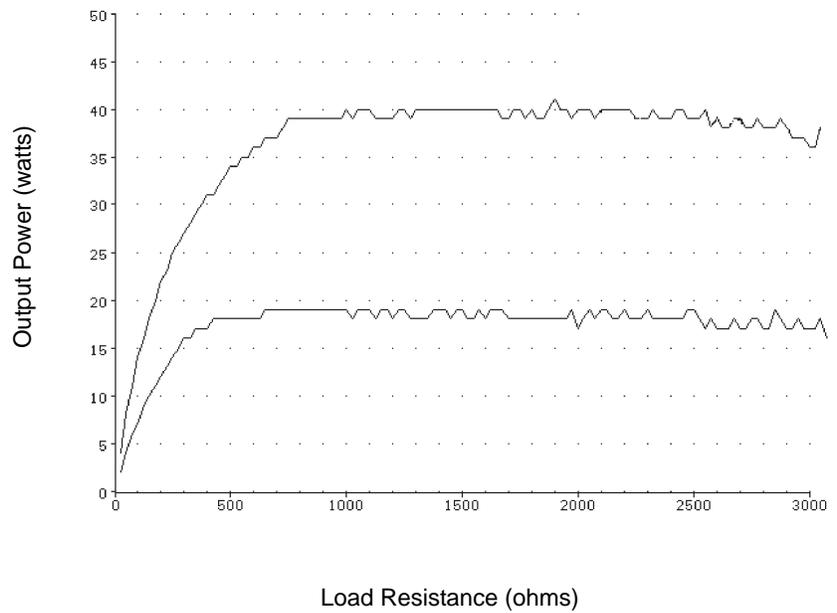**Figure 8-10.**
Output power vs. impedance for Fulgurate mode
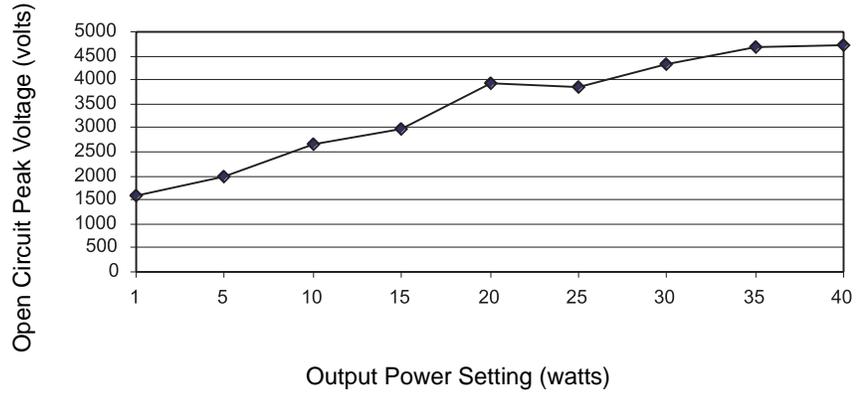
Figure 8-11.
Peak voltage vs. power setting for
Fulgurate mode

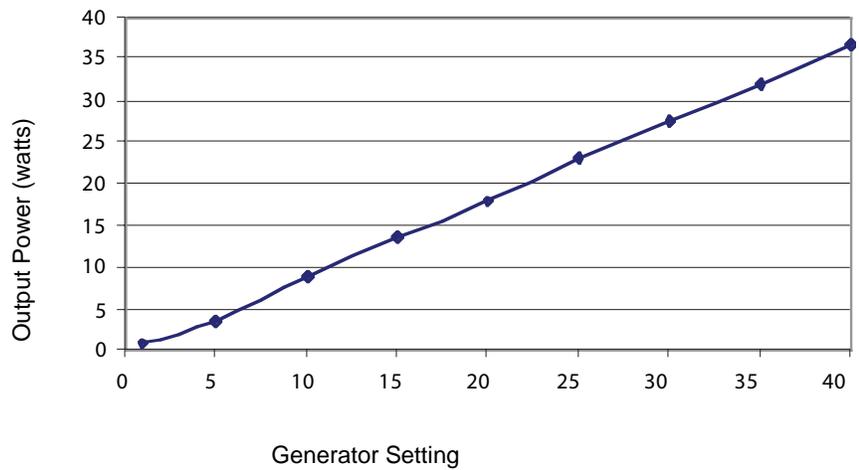**Figure 8-12.**
Output power vs. generator
settings for Fulgurate mode

Technical Specifications

Bipolar Curves

Figure 8-13.
Output power vs. impedance for Bipolar mode

Output Power (watts)

Load Resistance (ohms)
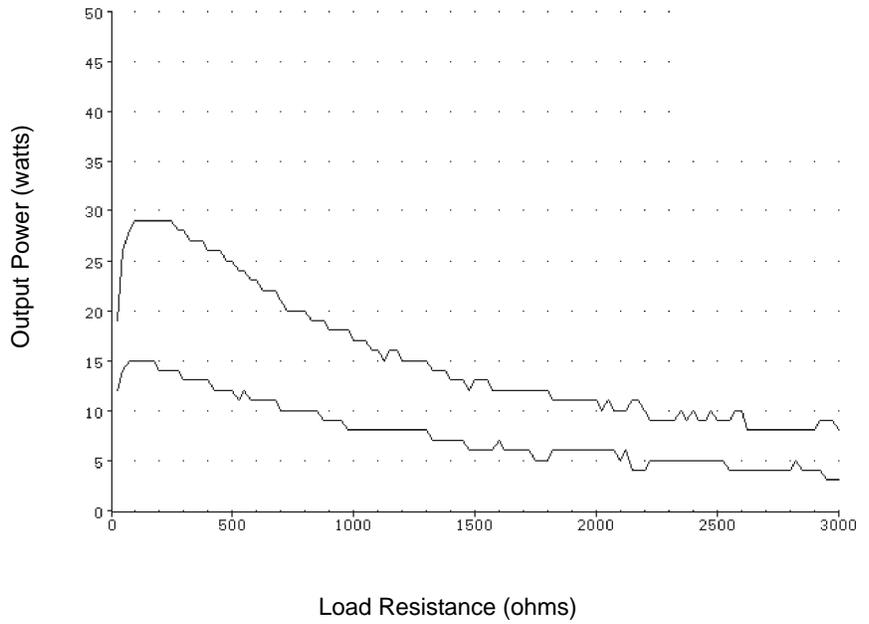
Figure 8-14.
Peak voltage vs. power setting for Bipolar mode

Open Circuit Peak Voltage (volts)

Output Power Setting (watts)
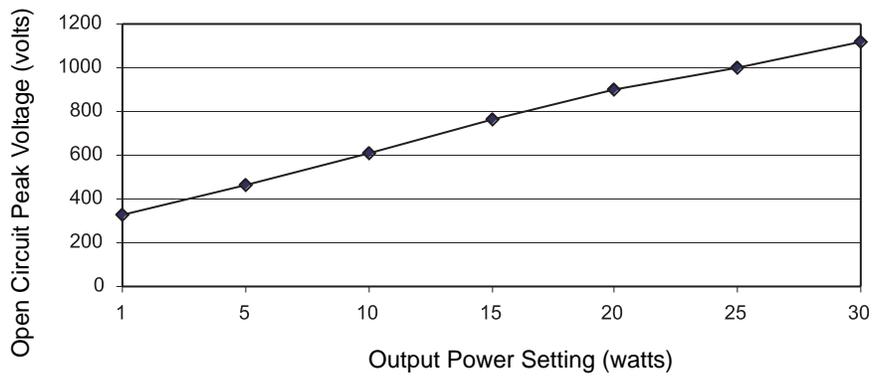
Figure 8-15.
*Output power vs. generator
settings for Bipolar mode*

Generator Setting

Technical Specifications
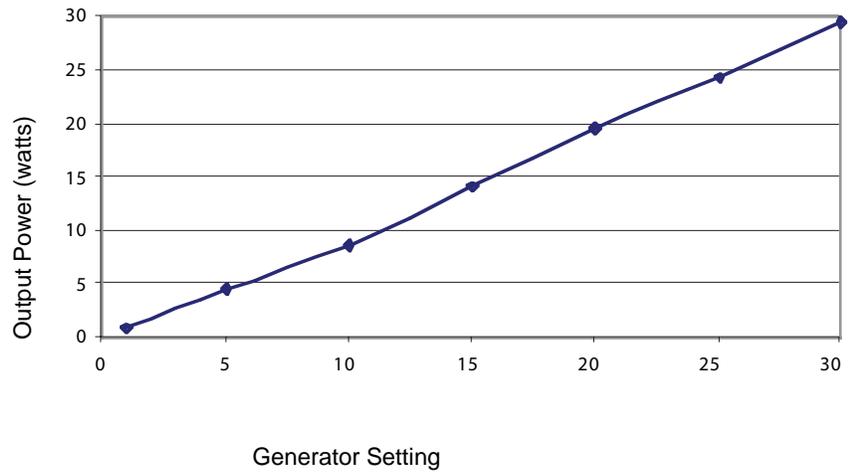
Warranty

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

The warranty periods for Valleylab products are as follows:

ForceTriad Energy Platform	One year from date of shipment
Electrosurgical Generators	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
Force Argon Units	One year from date of shipment
OptiMumm Smoke Evacuator	Two years from date of shipment
LigaSure Sterile Single Use Items	Sterility only as stated on packaging
Sterile Single Use Items	Sterility only as stated on packaging
Patient Return Electrodes	Shelf life only as stated on packaging

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

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

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

Valleylab, 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.