Bovie®

DERM 941 • DERM 942

High-Frequency Desiccators

User's Guide

DERM 941/942

USER'S GUIDE

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INTRODUCTION

Thank you for purchasing the Bovie® DERM 941/942. Please visually check the unit to ensure that damage did not occur during shipment and that all standard items are included. If there are any discrepancies, please contact Bovie® at +1-727-384-2323. For the latest user information and technical bulletins, visit www.boviemed.com.

OPERATING PRINCIPLE

RF energy is generated and passed through an interconnecting cable to an accessory, where the energy is delivered to coagulate and desiccate tissue.

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 Bovie® DERM 941/942 High Frequency Desiccator, 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.

CE 0413

EC REP

Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

Bovie Part Number: MC-55-239-001 Rev. 0

WARNINGS AND CAUTIONS

In order to safely operate the Bovie® DERM 941/942, several precautions need to be followed.

WARNINGS:

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

Danger: Fire / Explosion Hazard - Do not use the Bovie® DERM 941/942 in the presence of flammable materials.

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

- Flammable substances (such as alcohol based skin prepping agents and tinctures)
- Naturally occurring flammable gases which may accumulate in body cavities such as the bowel
- Oxygen enriched atmospheres
- Oxidizing agents (such as nitrous oxide [N_20] 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.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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. Disconnect power cord from power source or unplug the power cord from the unit's power inlet to isolate the internal circuits from the supply mains.

WARNINGS:

Electric Shock Hazard - Connect the generator power cord to a properly grounded receptacle. 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.

No modification of this equipment is allowed.

This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the ME EQUIPMENT or ME SYSTEM or shielding the location.

Patient Safety - Use the generator following the directions described in the Setup Procedures. 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 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 devices such as pacemakers or pulse generators. Interference produced by the use of electrosurgical devices can cause devices such as pacemakers to enter an asynchronous mode or can block the pacemaker effect entirely. Consult the device manufacturer or hospital Cardiology Department for further information when use of electrosurgical appliances is planned for patients with cardiac pacemakers or other implantable devices.

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 unintended, 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.

For all Monopolar modes, any associated equipment and active electrodes must be rated to with stand the combination of output voltage, vp-p and crest factor as stated in this manual.

Associated equipment and active accessories should be selected that have a rated accessory voltage equal to or greater than the maximum output voltage.

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 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 return electrode to provide a direct current route between the surgical site and the return electrode which avoids skin-to-skin contact areas.
- In addition, place patient return electrodes according to the manufacturer's instructions.

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

Minor neuromuscular stimulation is possible when arcs between the ACTIVE ELECTRODE and tissue occur. The generator has been designed to minimize the possibility of neuromuscular stimulation.

The entire area of the neutral electrode (NE) should be reliably attached to the patient's body and as close to the operating field as possible. Refer to NE instructions for use.

The cables to surgical electrodes should be positioned in such a way that contact with the patient or other leads is avoided. Temporarily unused active electrodes should be stored so that they are isolated from the patient.

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

The use of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen should be avoided if a surgical procedure is carried out in the region of the thorax or the head, unless these agents are sucked away.

Non-flammable agents should be used for cleaning and disinfection wherever possible. Flammable agents used for cleaning or disinfecting, or as solvents of adhesives, should be allowed to evaporate before the application if HF surgery. There is a risk of pooling flammable solutions under the patient or in body depressions such as the umbilicus, and in body cavities such as the vagina. Any fluids pooled in these areas should be mopped up before HF surgical equipment is used. Attention should be called to the danger of ignition of endogenous gases. Some materials, for example cotton, wool and gauze, when saturated with oxygen may be ignited by sparks produced in Normal Use of the HF surgical equipment.

CAUTIONS:
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.

Non-function 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.

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. Monitoring systems incorporating high frequency current-limiting devices are recommended.

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 physicians, 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.

The patient should not come in contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc.). The use of antistatic sheeting is recommended for this purpose.

Remove any loose fitting jewelry from the patient before activation.

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. Refer to the accessories instructions for use for more detailed instructions.

Accessories must be connected to the proper receptacle type. In particular, bipolar accessories must be connected to the Bipolar Instrument output jack only. Improper connection may result in inadvertent generator activation.

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

Avoid HF output settings where maximum output voltage may exceed rated accessory voltage. Refer to the accessory's voltage rating.

To avoid incompatibility and unsafe operation, use suitable cables, accessories, active and neutral electrodes, including values for the highest allowed H.F. peak voltage.

Connected accessories need be rated for at least the maximum peak output voltage of the H.F. generator set at the intended output control setting in the intended operating mode.

The output power selected should be as low as possible for the intended purpose. Certain devices or accessories may present a safety hazard at low power settings.

Apparent low output or failure of the Bovie® DERM 941/942 to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections. In this case, the application of the neutral electrode and its connections should be checked before selecting a higher output power.

When using Monopolar mode, associated equipment and active accessories should be selected that have a voltage rating of 6.3 kVp or greater.

When using Bipolar mode, associated equipment and active accessories should be selected that have a voltage rating of 1 kVp or greater.

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]

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.

CONTRAINDICATIONS

There are no known contraindications.

NOTICES:
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.

CATALOG NUMBERS

The Bovie® DERM 941/942 has 2 models – A941 and A942:

DERM 941™	Monopolar mode only unit, with 110 VAC Hospital-grade power cord
DERM 942™	Monopolar & Bipolar modes unit, with 110 VAC Hospital-grade power cord

APPLICATION SPECIFICATION

Description

- A 40 Watt RF desiccator used to coagulate tissue using RF waveform.
- Power setting is selectable by front panel manipulation of a rotary encoder knob.
- Power and activation are indicated on the unit display.

Medical Purpose / Indication

- Intended for the removal and destruction of skin lesions and coagulation of tissue,

Site Condition

- Clean and protect from infection from start through completion of procedure

Site of Use

- Soft tissue (skin, muscle)

Patient Population – * Patient should not be user.

- Age: Infant to geriatric
- Weight: > 2.5kg
- Patient State: Alert, relaxed, may be sedated, having had local anesthetic applied.

Intended User Profile

- Education – Trained physician, physician's assistant, nurse, nurse practitioner. No maximum
- Knowledge:
  - Minimum:
    - Understands electrosurgery and electrosurgical techniques;
    - Read and understands supplied User's Guide (Accompanying Document)
    - Understands hygiene
  - Maximum:
    - There is no maximum
- Language Understanding – Languages are as specified in the marketing distribution plan
- Experience:
  - Minimum:
    - Some training on techniques or training under surveillance/supervision
    - No special experience needed
  - Maximum:
    - There is no maximum
  - Permissible Impairments:
    - Mild reading / vision impairment or vision correction to 20/20
    - Partial hearing impairment, allowing for audible detection of tones at 0.5-2.0 kHz.

UNIT OPERATION

The Bovie® DERM 941/942 produces radio frequency current which is useful for the removal and destruction of superficial cutaneous and mucosal lesions. This is done by performing desiccation and fulguration procedures. Electrosurgical desiccation occurs when the electrode is placed directly onto the surface of the lesion. Fulguration occurs when the electrode is held slightly above the lesion and an arc is delivered to the lesion. The unit also provides fast and efficient bleeding control by coagulation of capillaries and small blood vessels.

For the majority of desiccation, fulguration, and coagulation procedures utilizing the standard handpiece in the monopolar output, the patient plate is optional. When used, the patient plate will intensify the coagulation properties of the unit and also lessen the opportunity for an electrosurgical burn. The optional footswitch adds versatility when using the standard handpiece in the monopolar output, as the footswitch allows you to activate the unit by either the handpiece or the footswitch. Bipolar outputs are available for those physicians who prefer to utilize bipolar forceps to perform coagulation procedures. A footswitch is required when using the bipolar output and the patient plate is not used. Procedures that are performed in sensitive areas may require an anesthetic. Flammable anesthetics should not be used.

If you are unfamiliar with the operation of a low powered electrosurgery unit, it is advisable to practice on chicken or lean flank steak to visualize the effects at various output and power levels.

INSPECTING THE DESICCATOR AND ACCESSORIES

Before each use of the Bovie® DERM 941/942, verify that the unit and all accessories are in good working order:

- Inspect for damage to the desiccator 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 (e.g. under magnification)
- Verify that no errors occur when you turn on the unit.

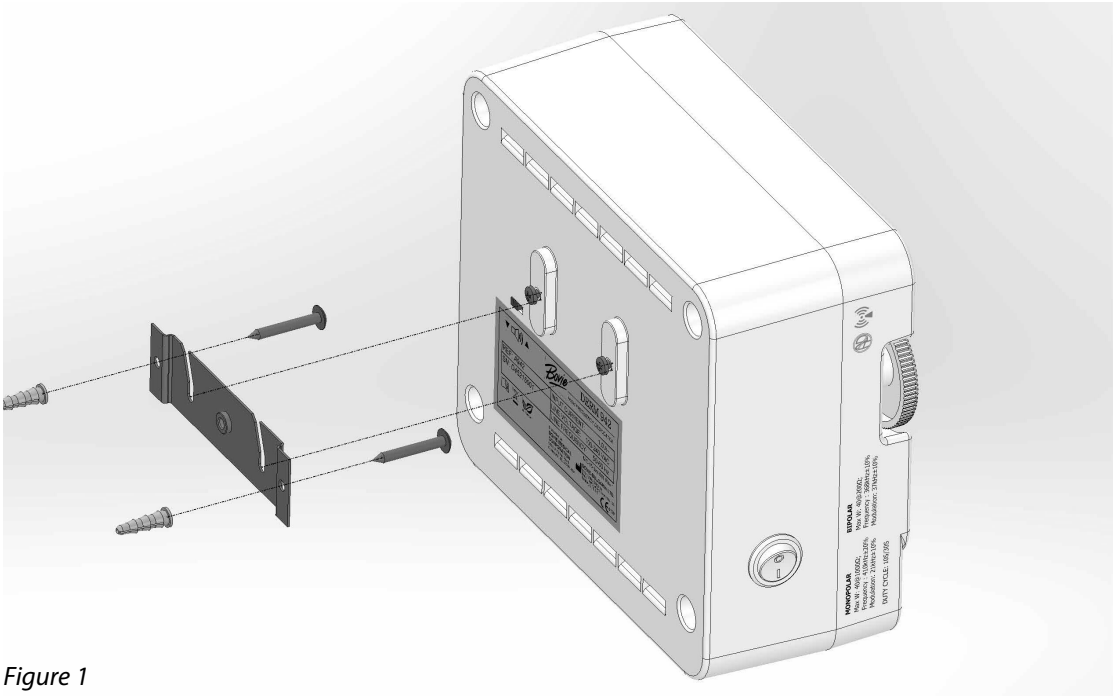


Figure 1

SETUP PROCEDURES

1. Mount the Bovie® DERM 941/942 on the wall or optional mobile stand using the standard mounting kit (see figure 1). Do not operate the unit in the horizontal position, as liquids may spill into unit.

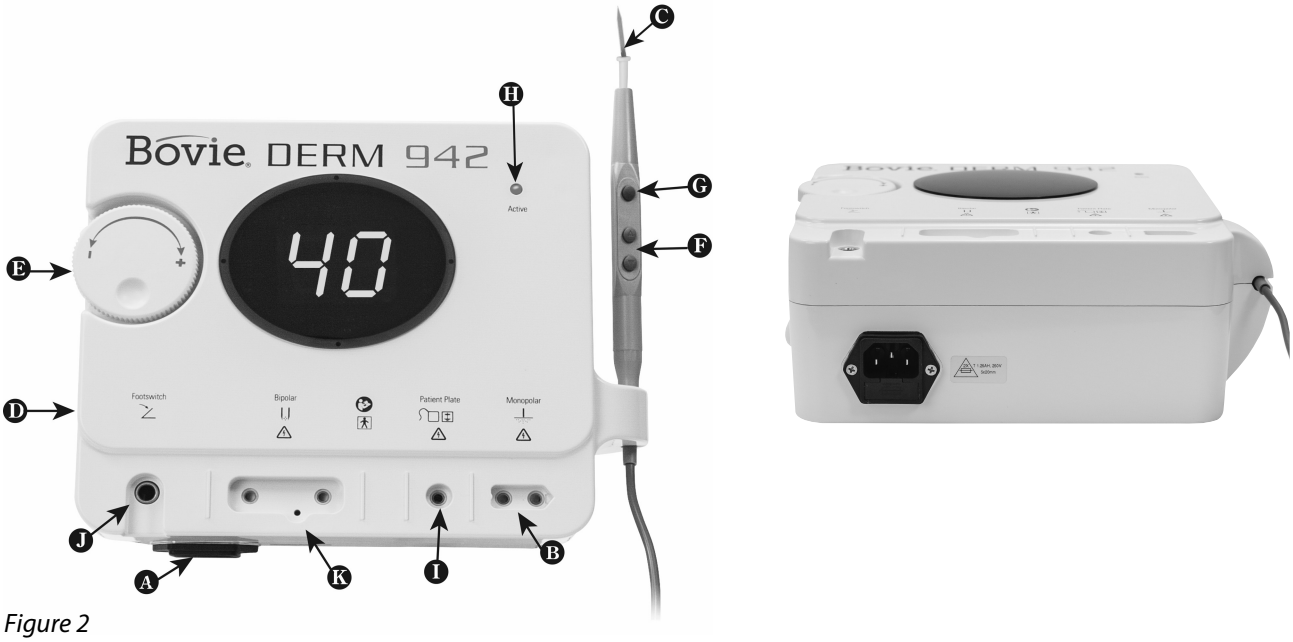


Figure 2

2. Plug the female end of the power cord into the base of the unit (see figures 2 and 3, letter A).

3. Plug the male end of the power cord into a grounded wall receptacle.

4. The monopolar output for the handpiece is on the lower right front of the unit (see figures 2 and 3, letter B). The handpiece plug is designed to fit in only one direction. Plug the connector from the handpiece into the receptacle on the bottom of the unit (see figures 2 and 3, letter B). The three button handpiece is designed to give the doctor complete fingertip control of the power output settings.

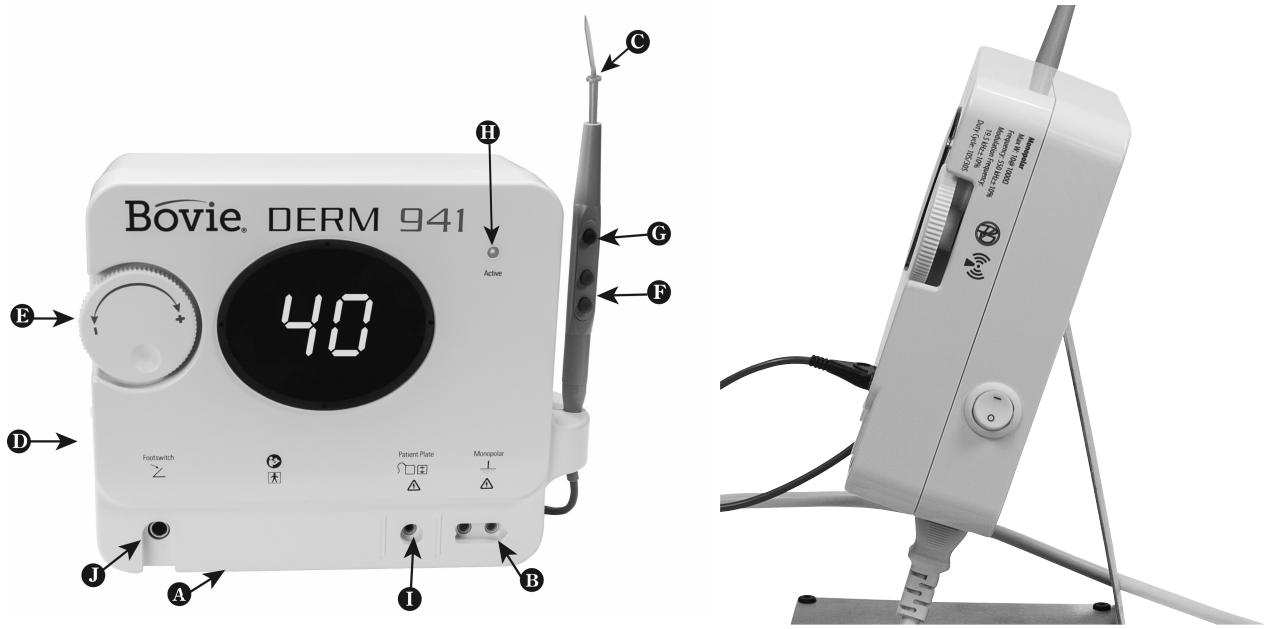


Figure 3

5. Slide the standard electrode into the handpiece until it is firmly seated (see figures 2 and 3, letter C). The handpiece will accept most standard 3/32" electrodes.

6. Slide the handpiece into the holder on the right side of the unit before powering on the unit.

7. Turn the unit power on utilizing the switch on the left side panel of the unit (see figures 2 and 3, letter D).

Figure 4

8. Set the power output either by using the dial on the front of the unit (see figures 2 and 3, letter E) or the up and down buttons on the handpiece (see figures 2 and 3, letter F). When power level adjustment is being made by the handpiece an audible tone will sound to indicate that the power level has been changed. Depressing and holding the up or down buttons will cause the power settings to change more rapidly for quick adjustment of the output settings. Power output is displayed in ".1" watt increments from 0.1 to 10 watts.

NOTICE:
The output settings can not be adjusted when the unit is being activated.

9. To activate the unit, remove the handpiece from the holder. Place the handpiece in the desired position and depress the activation button (see figures 2 and 3, letter G). When the unit is activated, an audible tone is sounded and the blue active light will illuminate (see figures 2 and 3, letter H).

10. To use the optional grounding plate with cord (A802EU), insert the plug of the cord into the grounding plate output (see figures 2 and 3, letter I) and connect the other end into the grounding plate. The plate should be placed underneath the patient at a point where the entire plate is covered by bare skin. The use of conductive gel is recommended.

11. To use the optional bipolar cord (A827V), insert the plugs into the bipolar outputs (see figure 2, letter K). The cord is then plugged into the forceps. A sliding gate behind the monopolar and bipolar outputs prevents the user from using both simultaneously.

12. The optional footswitch (A803) is plugged into the footswitch output and placed on the floor (see figures 2 and 3, letter J). The footswitch can be used with monopolar procedures and must be used with bipolar procedures.

13. When the procedure is completed, turn the unit off utilizing the switch on the left side panel of the unit.

14. Return the handpiece to the holder on the right side of the unit and remove the electrode. The electrode should be disposed of after each procedure. If contamination has occurred to the handpiece, the handpiece should also be sterilized.

15. Adjustment of the audible tone is achieved by a switch located on the rear of the unit (see figure 4). Two tone choices are available, high and low. A small screwdriver will be necessary to make the adjustment.

PERFORMANCE CHECKS

Bovie Medical Corporation 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. 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.

MAINTENANCE

The Bovie® DERM 941/942 requires periodic cleaning. When the unit case requires cleaning, simply utilize a soap and water solution and wipe clean. Be careful to not have any water enter into the unit through the various openings. Dry the unit with a clean, lint-free cloth.

STERILIZATION AND CLEANING OF THE ACCESSORIES

The Bovie® DERM 941/942 standard accessories are supplied sterile and non-sterile. The handpiece may be cleaned and sterilized. Refer to the instruction sheet that accompanies the electrode, NE and handpiece for specific instructions on cleaning and/or sterilization. We recommend that all contaminated electrodes and handpieces be sterilized prior to disposal. Read the accessories' Instructions for Use for additional cleaning, disinfection and sterilization details.

ACCESSORIES

The accessories listed below are original Bovie® accessories to be used with the Bovie® DERM 941/942. Accessories, replacement parts, and disposable items that are not listed should only be used when their safety and technical suitability have been checked. Additional accessories are available from your local Bovie® dealer.

Reusable items must be checked for damage before each re-sterilization (e.g. electrode cables should be inspected under magnification). Accidental burns can be caused by damaged accessories. See the accessories' Instructions for Use for additional details.

Supplied or Recommended, Standard Accessories (Applied Parts - (AP))

Catalog #	Description	Quantity	Models
A902*	3-button handpiece (AP) (9.8ft (3m))	1 pcs	All models
A804	Sharp Dermal tip Non- Sterile (AP)	5 pcs	All models
A805	Sharp dermal tip – sterile (AP)	2 pcs	All models
A806	Blunt dermal tip – non-sterile (AP)	5 pcs	All models
A806DE	DERM-Elite™ Blunt dermal tip – non-sterile (AP)	2 pcs	All models
A807	Blunt dermal tip – sterile (AP)	2 pcs	All models
A807DE	DERM-Elite™ Blunt dermal tip – sterile (AP)	2 pcs	All models
See Catalog	Bipolar Forceps – non-strl. (AP)	Recommended	DERM 942 only
A827V	Bipolar Forceps Cord (AP) (8ft (2.4m))	Recommended	DERM 942 only
A802EU	Reusable Grounding Pad (AP) (9.8ft (3m))	Recommended	All Models
A803	Footswitch (9.8ft (3m))	Recommended	All Models
A837	Wall Mount Kit	1 pcs	All models
A910	Disposable handpiece sheath, non-sterile	2 pcs	All models
A910ST	Disposable handpiece sheath, sterile	2 pcs	All models
09-064-001	110 VAC Hospital-grade power cord (10ft (3.048m))	1 pcs	For 110VAC models only (220VAC cord to be shipped only with special order units)
IP-55-239	User's/Service Manual CD	1 pcs	All models

NOTICES:
**A902 Handpiece shall be used with the DERM 941/942 Only.*
Bipolar accessories are for use with the DERM 942™ Only.

TECHNICAL DESCRIPTION

Mains Connection

Main Voltage:	100 – 240 VAC ± 10%
Main Frequency:	50 – 60 Hertz
Main Current:	1.1A Max.
Power Consumption:	110 VA
Duty Cycle:	10sec on / 30sec off
Main Fuses:	T 1.25AH, 250V

Safety

Basic Construction:	In accordance with EN 60601-1
Mode of Operation:	Intermittent operation
Protection Class:	CLASS I EQUIPMENT
Output Type:	TYPE BF

Dimensions and Weight

Length x Width x Height = 8.98" (228mm) x 7.40" (188mm) x 4.13" (105mm)
Weight: <5 lbs.

IEC CLASSIFICATIONS

EN 60529

This equipment is rated IPX0. It is protected against spillage (EN 60601-2-2), i.e the generator enclosure is constructed so that liquid spillage in normal use does not wet electrical insulation or other components which, when wet, are likely to affect adversely the safety of the generator.

IEC 60601-1

Equipment not suitable for use in the presence of flammable mixtures.

EMC COMPLIANCE

Special precautions should be taken regarding the Bovie® DERM 941/942. Medical electrical equipment needs special precautions regarding emc and needs to be installed and put into service according to the emc information provided in the manual.

Understand that only the Accessories supplied with or ordered from Bovie Medical should be used with your device. The use of Accessories, transducers, and cables other than those specified, may result in increased Emissions or decreased Immunity of the Bovie® DERM 941/942. The Bovie® DERM 941/942 and its accessories are not suitable for interconnection with other equipment.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment. The Bovie® DERM 941/942 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the Bovie® DERM 941/942 should be observed to verify normal operation in the configuration in which it will be used.

Recommended separation distances between portable and mobile RF communications equipment and the Bovie® DERM 941/942.

The Bovie® DERM 941/942 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Bovie® DERM 941/942 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Bovie® DERM 941/942 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter in metres (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – electromagnetic emissions

The Bovie® DERM 941/942 is intended for use in the electromagnetic environment listed below. The customer or the user of the Bovie® DERM 941/942 should assure that is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The Bovie® DERM 941/942 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The Bovie® DERM 941/942 is a HF surgical generator which according to EN 60601-2-2 shall be tested as group 1 equipment (with the HF output not energised).
RF Emissions CISPR 11	Class B	The Bovie® DERM 941/942 is suitable for use in domestic establishments and in establishments directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes. (see following Notice and Warning, pages 12 and 13.)
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

NOTICE:

The Bovie® DERM 941/942 may be used for procedures that can be performed in small clinics and in small dermatologist's offices. Such offices are usually located in domestic establishments, where the patients can receive treatment for minor dermatological problems witout the need to go to a hospital.

WARNING:

HF SURGICAL EQUIPMENT performs its CUTTING and COAGULATION functions through the use of radio frequency energy; and HF EMISSION present during this function will frequently exceed the CISPR 11 limits, preventing compliance. The power levels and harmonic content of the output of the HF SURGICAL EQUIPMENT are necessary to enable the HF SURGICAL EQUIPMENT to carry out its clinical function effectively. HF surgery is a very long established modality with known interference inherent during activation. Since the clinical benefits of HF SURGICAL EQUIPMENT outweigh the risks of interference and since HF SURGICAL EQUIPMENT is normally operated for short periods only, this type of equipment is exempt from complying with the CISPR 11 limits when it is activated.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Bovie® DERM 941/942 is intended for use in the electromagnetic environment listed below. The customer or the user of the Bovie® DERM 941/942 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_t (>95 % dip in U_t) *for 0.5 cycle* 40 % U_t (60 % dip in U_t) *for 5 cycles* 70 % U_t (30 % dip in U_t) *for 25 cycles* <5 % U_t (>95 % dip in U_t) *for 5 sec*	<5 % U_t (>95 % dip in U_t) *for 0.5 cycle* 40 % U_t (60 % dip in U_t) *for 5 cycles* 70 % U_t (30 % dip in U_t) *for 25 cycles* <5 % U_t (>95 % dip in U_t) *for 5 sec*	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Bovie® DERM 941/942 requires continued operation during power mains interruptions, it is recommended that the Bovie® DERM 941/942 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_t is the a.c. mains voltage prior to application of the test level.			

NOTICE*:*

For the purposes of EN60601-1-2 the Bovie DERM has an essential performance which is that there shall be no component failure, change in operating mode or false alarm, the delivered power shall remain within +/-20% of the set power and there shall be no reset or interruption of the HF power unless this is clearly indicated on the product.

Guidance and manufacturer's declaration – electromagnetic immunity continued...			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms (V_1)	Portable and mobile RF communications equipment should be used no closer to any part of the Bovie® DERM 941/942, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{3}] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m (E_1)	$d = [\frac{3.5}{3}] \sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{3}] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicated theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location which the Bovie® DERM 941/942 is used exceeds the applicable RF compliance level above, the Bovie® DERM 941/942 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Bovie® DERM 941/942. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [3] V/m.			

WARRANTY

The Bovie® DERM 941/942 is covered under warranty for a period of four years. The handpiece is covered under warranty for a period of one year or 25 steam autoclave cycles, whichever comes first. The warranty becomes null and void if damage occurs from incorrect handling or misuse of the product.

SERVICING AND REPAIR

It is recommended that all Bovie® parts be returned to an authorized Bovie® service center. On request, Bovie® will provide circuits diagrams, component part lists, descriptions and instructions to assist service personnel in parts repair. Refer to DERM 941/942 Service Guide.

NOTICE*:*
The Bovie® ESU is a programmable electrical medical system (PEMS). The firmware revision level of the ESU can be located on a label inside the unit by the responsible Service personnel.

For warranty and repair work, please contact Bovie® and obtain a Return Materials Authorization number (RMA). Place the number so that it can be seen on the exterior of the package and ship directly to Bovie®. A return without an RMA may not be accepted.

TROUBLESHOOTING

The Bovie® DERM 941/942 has been designed and manufactured with the utmost safety in mind. The unit is equipped to automatically detect a malfunction. The following table list error codes, their meaning and recommended actions to be taken to resolve the error.

Error Code	Description of Error	Recommended Action
E1	Activation Calibration Error	• Switch unit off and on again.
E2	DC Supply Over Voltage Detection +70V	• Switch unit off and on again. • Make sure unit is connected to correct power source for the unit.
E3	Pulse Width	• Switch unit off and on again.
E4	DC Supply Over Voltage Detection +9VDC	• Switch unit off and on again. • Make sure unit is connected to correct power source for the unit.
E5	Temperature Sense Error	• Switch unit off. Allow unit to cool. Switch unit on.
E6	DC Supply Over Voltage Detection +12VDC	• Switch unit off and on again. • Make sure unit is connected to correct power source for the unit.
E7	DC Supply Over Voltage Detection +6VDC (RESERVED)	• Switch unit off and on again. • Make sure unit is connected to correct power source for the unit.
E8	NEM Calibration Error (RESERVED)	• Switch unit off and on again.
E9	Multiple Errors	• Switch unit off and on again.

The following table lists Bovie® DERM 941/942 fault codes, their meaning and recommended actions to be taken to resolve the faults. The faults are resettable, i.e it is not necessary to switch unit off and on again to reset the fault condition.

Fault Code	Description of Fault	Recommended Action
F1	Activation upon power up	• Check handpiece for activation. • Check footswitch for activation; once the activation is halted the unit will resolve the error. If the error persists the handpiece could be malfunctioning and may need to be replaced.
F2	Handpiece "Power-UP" upon power up	• Check handpiece for "Power-Up" command. Once the command is halted the unit will resolve the error. If the error persists the handpiece could be malfunctioning and may need to be replaced.
F3	Handpiece "Power-Down" upon power up	• Check handpiece for "Power-Down" command. Once the command is halted the unit will resolve the error. If the error persists the handpiece could be malfunctioning and may need to be replaced.
F4	Power UP and Power Down are simultaneously depressed	• Check handpiece for "Power-UP-Down" command. Once the command is halted the unit will resolve the error. If the error persists the handpiece could be malfunctioning and may need to be replaced.
F5	Duty Cycle Fault- unit is activated more than 30sec	• Do not exceed 30 sec activation time for one activation request.
F6	Footswitch activation fault Monopolar accessory	• Check that monopolar handpiece is plugged in to monopolar output..
F7	Footswitch activation fault Bipolar accessory	• Check that bipolar cable is plugged in to bipolar output..(DERM 942 ONLY)
F8	Simultaneous sense monopolar and bipolar accessory	• Unplug either the monopolar or bipolar accessory.

If problems persist, the unit should be taken out of service and the manufacturer should be notified. For technical support or return authorization phone +1-800-537-2790.

Operating Parameters

Ambient temperature range	10° to 40° C
Relative humidity	30% to 75%, non-condensing
Atmospheric pressure	70kPa to 106kPa
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

Ambient temperature range	-40° to +70° C
Relative humidity	10% to 100%, including condensation
Atmospheric pressure	50kPa to 106kPa

Storage

Ambient temperature range	10° to 30° C
Relative humidity	10% to 75%, non-condensing
Atmospheric pressure	70kPa to 106kPa

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.

OUTPUT POWER CHARACTERISTICS

Power readouts agree with actual power into rated load:
- for Coagulation Mode - to within 20% or 0.1 watts, whichever is greater;
- for Bipolar Mode - to within 20% for power settings > = 1W;
- to within 0.3 watts for power settings < 1W.

Mode	Output Power	Fundemental Frequency	Repetition Rate	Crest Factor @ Rated Load	Vpeak max
Coagulation	40 W @ 1000 Ω	410 kHz ± 20%	21 kHz ± 10%	9.5 ± 20% @ 800Ω	6300 V
Bipolar	40 W @ 200 Ω	368 kHz ± 10%	37 kHz ± 10%	5.5 ± 20% @ 800Ω	950 V

GRAPHS

Figures 5 and 6 illustrates power settings versus Vpeak voltage for monopolar and bipolar modes. Figures 7 and 9 illustrate output power load curves. Figures 8 and 10 are the output waveforms as viewed on an oscilloscope. Figure 11 illustrates output power delivered to rated load for all available modes at selected power settings.

Figure 5 Power setting versus voltage (Vpeak) Monopolar

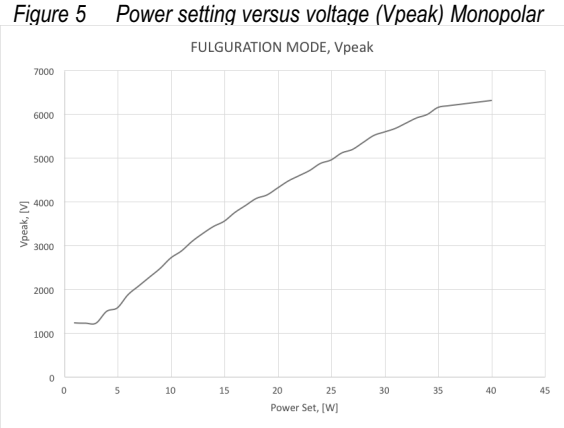


Figure 6 Power setting versus voltage (Vpeak) Bipolar

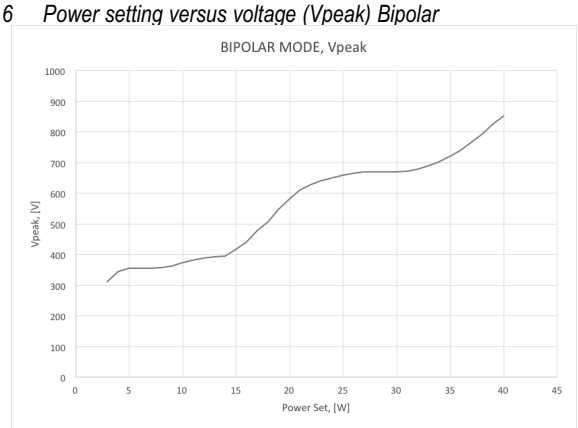


Figure 7 Output Power versus Load • Bipolar 100% / 50%

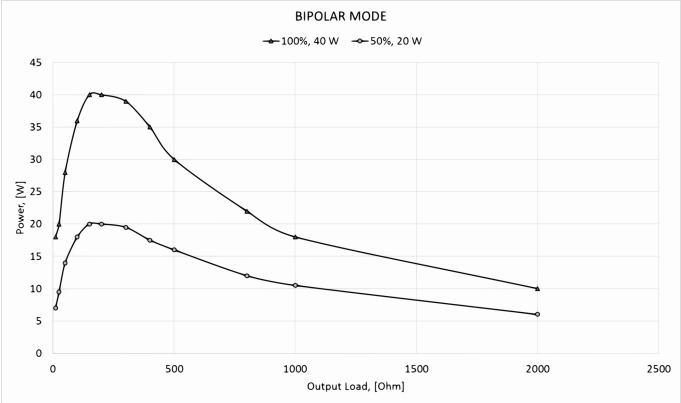


Figure 8 Bipolar Mode Waveform

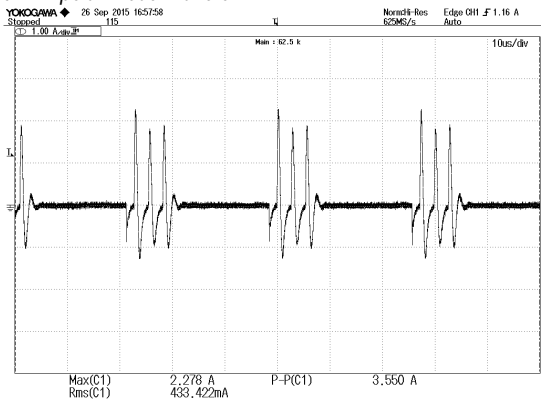


Figure 9 Output Power versus Load • Monopolar 100% / 50%

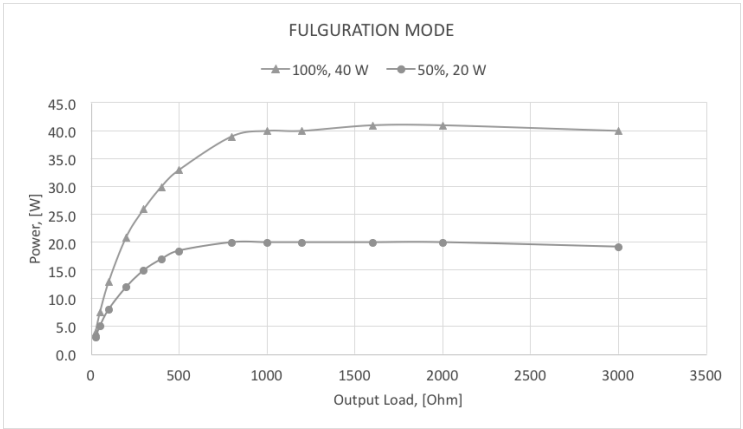


Figure 10 Monopolar Mode Waveform

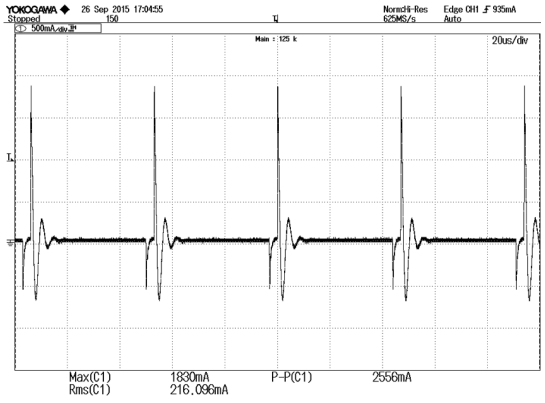
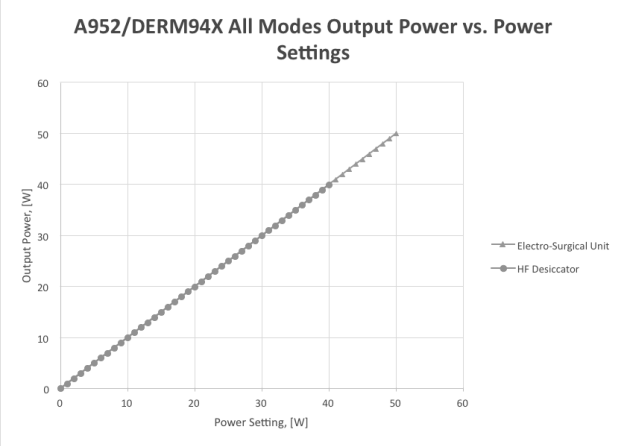


Figure 11 Output Power VS. Power Settings at Rated Load



DESCRIPTION OF SYMBOLS


Warning: Dangerous voltage.


Caution: Read directions for use prior to using equipment.

On (power: connection to the mains).


Off (power: disconnection from the mains).


* Do not dispose of this device in the unsorted municipal waste stream.


Monopolar output jack (hand control pencil jack).


Bipolar output jack.


Patient Plate, for use with Monopolar modes.


Footswitch jack, for foot controlled activation of monopolar (optional) and bipolar devices.


Type BF Applied Part.


Non-ionizing radiation.


Neutral Electrode referenced to earth.


Volume control.


Explosion Risk if used with flammable anesthetics.


Manufacturer


Mandatory: Refer to instruction manual / guide


Fuse type and rating. Slow blow (T), high capacity (H)


Conforms to European Union medical Directives 93/42/ECC and its revision 2007/47/EC. Compliant RoHS Directive (2011/65/EU).

NOTICES:

**Please note that infected medical devices must be disposed of as medical/biohazard waste and cannot be included in used electronic equipment disposal/recycling programs.*

In addition, certain electronic products must be returned directly to Bovie Medical Corporation. Contact your Bovie® sales representative for return instructions.

Bovie®

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