# System 5000

# Operator's Manual



BIRTCHER MEDICAL SYSTEMS

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#### Dear Customer:

We are in the process of updating our Model 5000 Operator's Manual. We have included a temporary Operator's Manual for your immediate use. A copy of the updated manual will be forwarded to you as soon as it is available.

We regret any inconvenience this may cause you. If you have any questions, please call us.

Thank you.

#### **BIRTCHER MEDICAL SYSTEMS**

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## Foreword

#### General -

Electrosurgical safety is a combination of good equipment design and safe surgical practices. The Bard System 5000\*, as part of this combination, represents state-of-the-art designs using the most modern solid-state components. As a pioneer in solid-state electrosurgery. Bard continues to design automatic safety systems into it's equipment. The cord fault alarm, audible tones, discrete outputs and isolated output circuitry are examples of the safety circuitry built into the Bard System 5000 Electrosurgical Generator. The other, and equally important, part of this safety combination is an operating team trained and knowledgeable in the use of electrosurgical equipment.

#### **Operational Considerations**

An operating room is a complex electrical environment. Understanding each piece of equipment and following the recommended operating procedure is an absolute requirement. Interaction between different pieces of equipment is not always predictable. Unusual performance by any surgical equipment is a warning to check the entire set up and confirm that an unsafe condition does not exist. If the safety or performance of a piece of equipment is in doubt, remove it from service for evaluation by a trained specialist.

- Solid-state electrosurgical devices are not designed for continuous operation (activation of handcontrol or footswitch). Observe duty cycles. Allow as much "OFF" time as "ON" time.
- The System 5000 can be operated in any of three different modes. If the monopolar mode is selected, a patient plate is required and bipolar mode is inactive. If the bipolar mode is selected, a patient plate is not required and monopolar mode is inactive. If the dual mode is selected, a patient plate is required and either a monopolar or bipolar output may be selected on a "first come, first served" basis.
- design of the System 5000 enhances safety by allowing only one output to be activated at a given time. This feature assures that only the device you first activate will be an active device. Secondary commands will not override the first command. As an example: While the monopolar footcontrolled output is activated, all handswitching capability is inactive, as well as the bipolar footswitch capability.
- The monopolar cutting speed and degree of hemostasis is controlled by the monopolar blend control. When the control is full counterclockwise, the blend indicator bar is extinguished and a pure cutting output with no hemostasis will be obtained. As the control is

advanced in a clockwise direction, the blend indicator bar begins to illuminate. As the illumination advances from left to right, the degree of hemostasis will increase and cutting speed may decrease. The cutting power may have to be increased to maintain cutting speed as blend is increased.

Two types of monopolar coagulation are available, Pinpoint and Spray. Each type of coagulation has it's uses. These are discussed below.

Pinpoint: Use with forceps, blade or needle electrodes, and endoscopic devices. The technique employed is to activate the generator just prior to contact with the tissue. After desired effect is achieved, remove from tissue, then deactivate. Pinpoint coagulation is intended for use on a small defined area.

Spray: Use with all types of pencil electrodes, endoscopic devices and clamps. The technique employed is to activate the generator without contacting tissue. The area can then be repeatedly sprayed until desired hemostasis is established. Spray coagulation can be used on all types of tissue whenever it is desirable to coagulate a larger area.

Whenever greater depth of penetration is desired, the spray mode is the mode of choice. The technique employed is to activate the generator

just prior to contact with tissue. After desired effect is achieved, remove from tissue, then deactivate.

Whenever a clamp is employed, touch a non-crusted portion of the electrode to the clamp, then activate. When desired effect is achieved, deactivate before breaking contact with the clamp.

Exercise great care when using needle electrodes with any mode. Fine needle electrodes may overheat and fail at high wattage settings.

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# **General Safety Precautions**

General Safety Precautions When Using The Bard System 5000

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Do not use in the presence of flammable anesthesia agents, flammable disinfecting agents, or other combustable materials. Common items, such as dry sponges, lubricants, and endotracheal tubes, can become combustable in the presence of oxygen. Therefore, insure draping technique does not allow pockets of methane, hydrogen, oxygen or any gas to form around patients' body.

- During electrosurgical procedures utilizing insufflation, such as laparoscopic tubal ligation or polypectomy, take care to insufflate only with a gas that is not combustable. Carbon dioxide is recommended for this purpose.
- During electrosurgical procedures involving small bowel or colon, take care that the bowel/colon is properly protected to reduce the possibility of explosive methane gas being present within these structures.
- Avoid skin to skin contact by separating body extremities from body trunk with dry towels or drape material.
- Do not allow solutions to pool underneath or around patient.

Fluid pooling underneath patient can provide an "alternate pathway" for electrosurgical current to return to the

generator through the grounded1 operating table.

Iodine based prep solutions pooling under the patient can create severe chemical burns to the patients' tissues.

- Do not use the generator as a shelf or temporary storage point for liquids. While the Bard System 5000 is of "drip-proof" design to minimize fluid entry, any electrosurgical<sup>2</sup> generator can become a serious hazard to the patient and personnel if conductive or flammable liquid enters the generator.
- Utilize minimum power to provide the desired surgical effect. Excessive power delivered to the patient results in increased tissue destruction and can increase the risk of accidental patient burns.

The Bard System 5000 delivers consistent, repeatable power into varying load impedences, therefore greatly reducing the need for changing the power setting to obtain desired surgical effect.

 Do not loop active accessory/ instrument cables around towel clips or other instruments to attach or secure these cables to the surgical drapes.

Electrosurgical generators utilize radio frequency current similar to a radio transmitter. A certain amount of electrosurgical current leaks out through the insulated cables. If active

Ground = Earth Electrosurgical = Surgical Diathermy the insulated cables. If active cables are looped around a metal instrument, this leakage current can energize the instrument. If it touches the patient's skin on the patient side of the surgical drape a burn can occur to the patient at that point of contact.

# Automatic Safety Systems With The Bard System 5000

In regard to understanding why Automatic Safety Systems within the Bard System 5000 or any electrosurgical unit are necessary, it is important to understand that burns, either intentional or accidental, can occur to the operator or patient: as a result of Current Density or Current Concentration.

High frequency, electrosurgical current is applied to the patient's body by means of electrodes. If both electrodes have a relatively large surface area in contact with the patient, the current flow is evenly distributed throughout the tissue in contact with the electrodes. As a result, the heating effect is spread out. The patient will experience only sensation of warmth. However, when one of these two electrodes has a very small contact area with the patient, the current flow is very concentrated in the immediate vicinity of that electrode and a burn occurs at that site. As long as the

Dispersive Electrode<sup>3</sup> = Neutral Electrode Isolated<sup>4</sup> = Floating Output

dispersive electrode has a large. contact area with the patient, the heating effect at that site is minimal, this is the intended situation. When electrosurgical current is applied to the ... patient via an active electrode with small patient contact area. the current concentration, or current density is quite high in the immediate vicinity of contact, hence heating is maximized and localized and thus an intentional burn occurs producing the surgical effect at the operative site.

Operators should be aware that this principle of Current Density/Current Concentration applies to all electrosurgical burns - intentional (at the surgical site) or accidental, whether to the operator or to the patient.

# Isolated<sup>4</sup> Output vs Ground Referenced Output

The preferred pathway for electrosurgical current during electrosurgical procedures is from the generator through the active accessory and cable, through the patient and returning to the generator via the dispersive electrode<sup>3</sup> (neutral) and cable.

There are two types of electrosurgical systems, those that utilize ground referenced power output and those utilizing isolated power output.

The Bard System 5000 utilizes isolated (floating) output.

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Aspects of ground referenced power output electrosurgical systems:

Everything in a typical Operating Room<sup>5</sup> is grounded. This includes operators and equipment. The common ground point is the conductive operating room floor. Ground referenced electrosurgical generators have their power output circuits, the one producing electrosurgical current, referenced to the grounded operating room floor. Thus, in some cases, the floor itself can serve as an alternate pathway for the electrosurgical current to return to the generator. Consequently, anyone or anything in contact with the patient and the grounded operating room floor can become an alternate pathway for significant amounts of electrosurgical current to return to the generator.

When this situation occurs, the potential for an "alternate path burn" to the operator or patient greatly increases.

# Examples And Explanation Of Typical "Alternate Path Burns"

To The Doctor:

The surgeon can burn his hand while holding a hemostat or similar clamp if his glove has

Operating Room<sup>5</sup> - theatre

a pinhole or tear in it. The burn can occur when electrosurgical current is applied to the hemostat. What happens is the surgeon becomes an alternate pathway for the current to return to the generator via the pinhole or tear. The pinhole or tear has a small surface area and can allow sufficient current density or concentration to produce a serious burn, also a burn can occur to the hand or fingers while an urologist is holding an endoscopic instrument such as a resectoscope. Again, the surgeon becomes the pathway for the current to return to the generator. Urologists have also reported burns to the face and eye area. Non-conductive resectoscope eyepieces are a recommended device to be used with electrosurgical equipment.

#### To The Patient:

Burn at ECG monitoring electrode site - the electrode, via the cable and monitor unit can become an alternate pathway for the electrosurgery current to return to the generator. Eliminate the use of ECG monitoring needle electrodes in favor of those with larger surface areas, and place them as far away as possible from the operative and dispersive electrode site These precautions can help to minimize this potential hazard.

## Burns at temperature probe site

- such probes can also become alternate pathways for electrosurgical current. Battery operated temperature probes can help minimize the potential for this occurrance:

Burns caused by current taking an alternate path can be avoided by conducting preoperative inspections. Insure that the patient is sufficiently insulated from grounded points. These points could occur where the patient is in direct contact with the metal operating table or other grounded components like metal retractors, or neurosurgical headframes connected to the operating table.

# Aspects Of The Bard System 5000 Isolated Power Output

Unlike ground referenced electrosurgical generators, the power output circuit of the Bard System 5000 is not referenced to the grounded operating room floor. The Bard System 5000 is isolated from ground points.

This isolated output design helps to insure that the electrosurgical current travels only in the preferred pathway, and minimizes the risk of accidental burns to the operator and patient through electrosurgical current taking "alternate pathways" to return to the generator.

Unlike ground referenced electrosurgical generators, the

Bard System 5000 will not deliver usable surgical current if the patient is not in contact with the dispersive electrode. The one exception is if the dispersive electrode via the attached cable is plugged into the generator and not in contact with the patient, but in direct contact with a grounded object such as the operating room floor, a metal instrument table, or on top of the generator. In such a position the power output circuit of the generator would then be referenced to ground. Surgical current output would be reduced yet the generator would still operate. The system would then function as a ground referenced generator. Care should be taken to avoid this.

#### **Cord Fault Alarm Feature**

- The Bard System 5000 is equipped with an automatic alarm system to deactivate the generator and alert the staff if there is interruption in the continuity of the dispersive electrode (patient plate) cicuit.
- An audible alarm will sound and the generator will automatically become disabled when the following conditions occur:

Dispersive electrode cable not plugged securely into generator.

Dispersive electrode cable damaged or broken.

Cable/cord connection at dispersive electrode site is defective, damaged or not connected to dispersive electrode.

The cord fault alarm only measures the continuity of the dispersive electrode circuit and does not measure proper patient and dispersive electrode contact.

### Discrete Output (First Come-First Served)

The "first come, first served" design of the System 5000 enhances safety by allowing only one output to be activated at a given time.

This feature assures that only the device you first activate will be an active device.

Secondary commands will not override the first command. As an example: While the monopolar footcontrolled output is activated, all handswitching capability is inactive, as well as the bipolar footswitch capability and vise versa.

While this safety feature allows only one accessory to be active at a time, electrosurgical instruments, when not it use, should be kept away from the patient in an insulated safety cup holder.

# Dispersive Electrode Safety With The Bard System 5000

To maximize patient safety, it is very important to maintain uniform dispersive electrode and patient contact throughout surgical procedures utilizing monopolar electrosurgical current with the Bard System 5000 or any electrosurgical generator.

#### Warning

Inadequate/poor patient and dispersive electrode contact can create an accidental patient burn at the dispersive electrode site. Please read the discussion of "Current Density/Current Concentration" located in the operator's manual in the Safety Systems section.

Follow the manufacturer's instructions regarding application of dispersive electrodes.

# Guidelines For Proper Dispersive Electrode Location:

Dispersive electrode site should have good blood supply.

While a properly applied dispersive electrode results in minimal tissue heating beneath the electrode, a good blood supply helps carry heat away from the site.

 Dispersive electrode site chosen should be primarily <u>muscle</u> <u>tissue</u>. Buttocks, thighs and biceps are common sites, muscle tissue generally has a good blood supply and a relatively low resistance to electrosurgical current flow.

Dispersive electrode - patient application site should be as close as possible to operative site.

This will minimize the distance the electrosurgical current has to flow through the patient. The further the dispersive (neutral) electrode is from the operative site, the greater number of alternate paths that will be available before the current reaches the dispersive electrode. This is especially important with ground referenced electrosurgical systems. In addition, a dispersive electrode far from the surgical site can result in more power required to produce the desired surgical effect.

When reusuable, metal dispersive electrodes or rigid disposable cardboard and foil types are utilized, the only suitable patient application site is under the patient's buttocks.

An appropriate amount of conductive gel should be applied to the dispersive electrode.

The gel should be designed for use with electrosurgical equipment only.

Other gels, ECG paste or lubricants should not be used. Such gels or lubricants can dry

out during surgical procedures and become insulators rather than conductors, thus increasing the potential for an accidental burn to the patient.

### Utilization Of Flexible Type Disposable Dispersive Electrodes

Patient Application Sites To Avoid:

Avoid application under the patient's buttocks.

While this is a suitable application site for reusable type dispersive electrodes, disposable dispersive electrodes usually have a connector attaching the electrode to the cable. Depending upon the location of the connector on the dispersive electrode, the connector site could become a pressure point thus increasing the potential for the current to concentrate at that point and produce an accidental burn. This pressure point can also increase the potential for damage to the patient's tissue from a pressure lesion.

Avoid application over scar tissue:

Scar tissue generally has poor blood supply and higher resistance to electrosurgical current flow than normal tissue.

 Avoid application over metal implants (prostheses): The electrosurgical current may tend to concentrate at the metal implant site producing areas of high current density. The effects of such current concentration to the acrylic cement/bone interface are not known.

- Hairy areas should be shaved.
- Avoid application to areas of the patient affected by a tourniquet.

Due to compromised blood supply, the dispersive electrode should not be placed below a tourniquet.

Avoid application sites in close proximity to monitoring electrodes. Especially with ground referenced electrosurgical generators. The monitor via the electrode and cable can provide an "alternate path" for the electrosurgical current to return to the generator. Thus, the potential for an accidental patient burn at the electrode site is increased.

Leakage current from the dispersive electrode can also increase interference with monitoring equipment.

(For more information regarding interference to monitoring equipment, please read the chapter in this manual entitled "Minimizing Interference With Monitoring Equipment").

 When utilizing electrosurgical current in the presence of cardiac pacemakers, place the dispersive electrode at right angles (90°) to the pacemaker.
\*(For more information regarding pacemakers and electrosurgical current, see the chapter in this manual entitled "Precautions For Utilization Of System 5000 In The Presence Of Cardiac Pacemakers").

Avoid application to areas that are wet or likely to become wet.

Dispersive electrodes which have adhesive, to affix them to the patients skin can become loose or dislodged if they become wet.

 Avoid application over bony prominences (such as over the patient's spine or shoulder blade).

Application over bony prominences can create pressure points resulting high current concentration at that site, thus increasing the potential for an accidental patient burn.

# General Safety Precautions Regarding Dispersive (Neutral) Electrodes

- Do not alter the shape or size of the dispersive electrode.
- Metal, reusable dispersive electrodes which have become scratched, dented, bent or otherwise altered, should not be used. Electrosurgical current will tend to "concentrate" at these defects thus producing high current density at the defect location and increase the

potential for an accidental patient burn at that site.

When utilizing pre-gelled type disposable dispersive electrodes, inspect the gelled area on the electrode before application to the patient to insure:

The gel is not discolored

Has not dried out during storage

Is evenly distributed within the conductive area.

If there is a failure of any or all of the above items; do not use the disposable dispersive electrode.

During the surgical procedure, take care that tension is not applied to the dispersive electrode cable.

This can cause the electrode to become dislodged and thus not maintain proper patient contact and may result in an accidental burn to the patient.

During the surgical procedure, inspect the dispersive electrode application site:

If tension has been placed on the cable (as discussed above).

If the patient has been moved to another position, the dispersive electrode may have become dislodged.

If it is a long procedure (over 4 hours) - the gel could have

dried out in the disposable/ adhesive type. (A reusable electrode or disposable, nonadhesive type requiring gel should be inspected for dry-out after 2 1/2 hours).

If the surgeon requires more power than usual to produce the desired surgical effect one of the first signs of insufficient electrode and patient contact is a reduction of power delivered from the electrosurgical generator.

#### Utilization Of The Bard System 5000 For Bipolar Electrosurgical Procedures

Bipolar Current and Instrument Utilization

 A surgical procedure wherein only bipolar current will be utilized with the Bard System 5000 does not require a dispersive electrode be applied to the patient and connected to the generator. However, a dispersive electrode applied pre-operative to the patient but not connected to the generator may be of benefit, if during the procedure, the surgeon requires monopolar current (which does require a dispersive electrode) the electrode will already be applied to the patient and is easy to connect to the generator. This technique can be beneficial as it can prevent delay during the procedure. It also helps to insure that the drape material does not accidently become lodged

between the electrode and the patient.

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Bipolar forceps care and use:

If forceps are the insulated type, check insulation for chips, cracks or other defects before use, cables should also be inspected for damage and discarded if not free of defects.

Tips of bipolar forceps should be kept clean and free of coagulum build-up during bipolar procedures.

Tissue should always be contained between or within the forcep jaws before activation. If the forceps tips touch, without tissue between them, no usable surgical current will be delivered.

- Keep the bipolar cutting power control in the "O"/OFF position if cutting current is not desired.
- Utilizing bipolar current with the Bard System 5000 for coagulation during pediatric or neonate surgical procedures is most preferable. The Bard System 5000 has sufficient bipolar coagulation power to produce the desired surgical effect in such cases and provides the following benefits:

Helps eliminate hazards associated with dispersive electrodes and placement/application difficulties on small patients.

Helps eliminate potential hazards of current taking alternate pathways.

Allows for precise coagulation with minimal tissue destruction.

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#### Precautions Regarding The Use Of Electrosurgical Accessories/ Instruments With The Bard System 5000

- Only accessories and instruments which, by design, conform to the manufacturers specifications should be utilized with the Bard System 5000.
- Accessories/Instruments and all cables should be inspected for defects such as broken cable insulation, or chipped, nicked or cracked insulation on forceps before use. Defective accessories, instruments or cables should not be used.
- Do not try to temporarily repair defects in accessories, instruments or cables with tape.
   Defective or damaged items should be replaced or professionally repaired.
- Electrosurgical handcontrols, (finger controlled handles) which by design, offer no protection from the ingress of liquids should be avoided whenever possible.
- Electrosurgical accessories or instruments, when not in use, should be kept away from the patient in an insulated safety cup holder.

### Minimizing Electrosurgical Interference With Monitoring Equipment

All electrosurgical generators, when activated, create certain levels of monitor interference. Generator design, such as the isolated output design of the Bard System 5000, can help to reduce this by allowing the monitor to return to normal sooner than ground referenced generators generally allow.

The following actions can be taken to help reduce this interference:

Contact the manufacturer of the monitor for suggestions to reduce interference.

Utilize a monitoring electrode cable which incorporates a "RF CHOKE" (filter) connected between the monitoring electrode and the monitor.

Keep electrosurgical cables (active and dispersive) separated from and not in direct contact with monitor cables.

Place the dispersive electrode as far away as possible from the monitoring electrodes (this also helps to reduce the potential for "alternate path burns" at the monitoring electrode site).

<eep active and dispersive
electrodes from lying on the
pperating room floor. When
active or dispersive cables</pre>

contact the operating room floor, RF leakage and thus the potential for interference is increased.

### Precautions For Utilization Of The Bard System 5000 In The Presence Of Cardiac Pacemakers

Although cardiac pacemakers manufactured within the past several years do have shielding which helps to protect the pacemaker from electrosurgical interference - careful attention should be given to the following safety precautions:

Consult the manufacturer of the cardiac pacemaker per recommendations regarding the use of electrosurgical current in the presence of the pacemakers. Some manufacturers may feel the use of any electrosurgical equipment in the presence of a pacemaker is contraindicated.

If the Bard System 5000 is utilized, place the dispersive electrode at right angles (900) to the pacemaker to minimize the possibility of current traveling through the pacemaker.

Take care not to touch any leads connected to the pacemaker or the pacemaker unit with an active accessory/instrument.

Take care to insure the operator does not activate the generator at a rate that approximates the patients pulse rate as this can

create inhibition of the pacemaker.

To avoid most pacemaker interference utilize bipolar current for coagulation. The power Tevel of bipolar in the Bard System 5000 is sufficient to provide, in most instances, satisfactory coagulation effect. Utilization of bipolar electrosurgical current for coagulation also eliminates the need for a dispersive electrode and thus the potential hazards of accidental burns at the dispersive electrode site as well as "alternate path burns".

### **Pacemakers And Electrosurgery**

#### The Problem:

A patient with a pacemaker may be sensitive to such high frequency devices as electrosurgical generators. This is usually most prevalent in "demand" pacemakers where the pacemaker will activate only when the heart needs to be stimulated. A potential problem may exist when high frequency currents create interference with the pacemaker which might cause shutdown.

What Should Be Done?

## Surgeon's Considerations:

If possible, limit the ESU use

to Bipolar.;

- Always consult the pacemaker manufacturer before using the ESU - have the name of the pacemaker and ESU's frequency available for the manufacturer. Follow the manufacturer's suggestions.
- Use an isolated generator to minimize the potential problem of current division when some current may be seeking an alternate ground source through the pacemaker.
- If you must introduce electrosurgical current near the pacemaker leads, do so at right angles to reduce the chance of tissue destruction by the leads.
- Do NOT activate the ESU at such a rapid rate that it may mimic the pulse rate.
- Always have qualified personnel taking the pulse as a crosscheck when the ESU is being activated.

#### Nurse's Considerations:

- Place the dispersive electrode (patient plate) as close as possible to the surgery site.
- Carefully place the dispersive electrode (patient plate) distal to the pacemaker site, so that current will be less likely to go through the pacemaker.
- If the case is performed under local anesthesia, the circulating nurse should monitor

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the pulse, especially when the ESU is being activated.

Have a defibrillator and an external pacemaker available.

Keep in mind that the newer pacemakers have significant amounts of shielding to minimize the effects not high frequency interference. Following these precautions should optimize the safety for the patient with a pacemaker.

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## Specifications

## System 5000 Power Plus Specifications

Output characteristics (maximum control settings)

Frequency all modes 500KHz

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Mode	Power (Types)	oical)	P/P Voltage	(Maximum	open circuit)	
Cut	350 W		2000 V		The State of the S	
Cut Blend 1.5	320 W	500 ohm	3600 V		THE LAND TO SERVE .	
Coag Pinpoint	130 W		4000 V		and the second resource of the second of the second of	
Coag Spray	75 W		V 0008			
Cut Bipolar	50 W	125 ohm	550 V		क क्षत्री हैं।	
Coag Bipolar	50 W	120 01111	1280 V			
Operating Cycle In	ntermittent 10S/30S					
Operating Cycle In	ntermittent 10S/30S	8				

## Input Characteristics (Typical)

Maximum control setting into 500 ohm load The subdence of the same

Model 132030, 132036 Model's 132031, 132033, 132034, 132035

115 VAC~60 Hz 220/240 VAC~50 Hz

Idle: 0.6 A Idle: 0.3 A

Chade ... : 6 A Cut: 12 A Cut:

Coag: 6 A 3 A Coag:

Amps

3

0

0 0 0 Hz =Hertz

Volts

## System 5000 Power Plus Specifications

Risk Currents (Typical)

R.F. High Frequency (Per IEC 601-2-2, Sec. 19, 101) THE PARTY OF THE P

	Patient to Ground	Active	to Gr	cound	
Cut Pure to ham seemed	100 ma	100	) ma		
coag Finpoint	70 ma	70 A & A & A & A & A & A & A & A & A & A			
Coag Spray	125 ma	J.120	) ma		
Cut Bipolar	105 ma	95	o ma		
Coag Bipolar	95 ma	C (\$ 19)	) ma		
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General

Classification: Class I

CF Type:

Spillage Protection: Drip Proof

Internal Design: Solid State

NEWS THE RF Floating (Isolated) Output Configuration:

Cooling: Convention (No Fan)

Dimension: 8 H x 18 W x 19 D Inches

DEV MASSITE 20 x 4 x 46 W x 49 D centimeters

Weight: 43 lbs. (19 KG)

BS5724, SPRIMA, TNO (220/240V) Approvals:

UL544, CSA22.2 No. 125 (115V), AS. 3200,

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Cardiac Floating (See Glossary) CF

## System 5000 Power Plus Specifications

Company and the Company of the Compa
isk Currents (Typical)
ow Frequency (Per IEC 601-1 Sec 19)
orth Leakage (Ground) .042 ma (N.C.), 0.0003 ma (S.F.C.)
nclosure Leakage .042 ma (N.C.), 0.080 ma (S.F.C.)
o.0004 ma (N.C.), 0.0004 ma (S.F.C.)
ins Voltage on AP (Type CF) 0.001-ma
.0001 ma (N.C.), .0001 ma (S.F.C.)
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## Risk Currents (Typical)

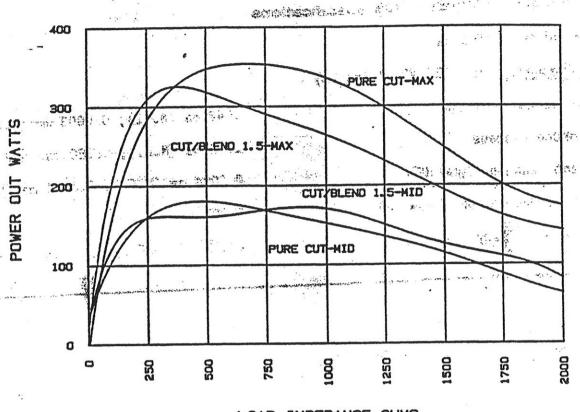
## Low Frequency (Per U.L. 544 Sec 27).

## Chassis to Neutral

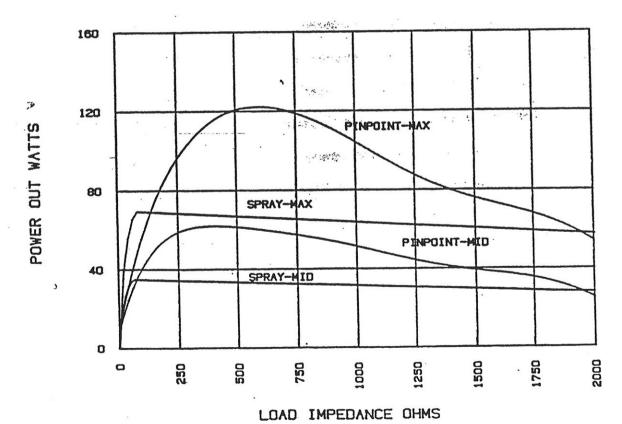
Line Polarity Normal (Ground Open)	18.0 uA
Line Polarity Reversed (Ground Open)	24.0 uA
Patient Lead (All - RF Active or Neutral)	•
Line Polarity Normal - Ground Closed	0.4 uA
Line Polarity Reversed - Ground Closed	0.5 uA
Line Polarity Normal - (Ground Open)	1.5 uA
Line Polarity Reversed - (Ground Open)	2.5 uA

AP Applied Part
CF Cardiac Floating
ma Milliamp
N.C. Normal Condition
S.F.C. = Single Fault Condition
uA Microamp

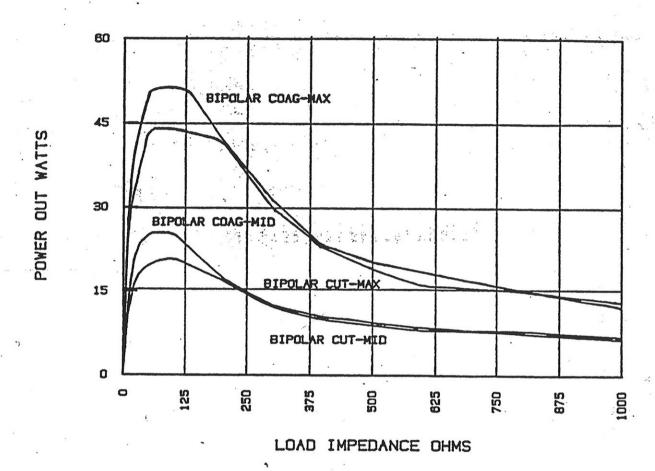
Typical Power Output vs Load Impedance
At Maximum And Mid Positions
Monopolor







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# **Operational Checkout**

The following checklist will guide you through a users operational check. Perform the pre-operational control settings in Section 2 first. Then perform the operational check steps in Section 3. Generator and accessory actions are listed in the left hand column. Generator expected outcomes are listed in the right hand column.

NOTE

The parentheses after the name of the control or connector contains the reference number. Refer to Page to use the reference number to locate the item.

Connect a serviceable footswitch to the FOOTSWITCH Connector (22) on the rear panel.

Connect a serviceable 3-Wire Handcontrol to the Monopolar Handcontrol receptable (16).

If the generator fails any of the following tests, DO NOT USE. Refer to qualified service personnel.

### PRE-OPERATIONAL CONTROL SETTINGS

CONTROL	SETTING
POWER (1)	OFF.
FOOTSWITCH (2)	BIPOLAR
MODE (4)	BIPOLAR
MONOPOLAR BLEND Control (3)	Full CCW
MONOPOLAR CUTTING POWER Control (6)	Zero (0) Full CCW
MONOPOLAR COAGULATION Type (13)	PINPOINT (P)
MONOPOLAR COAGULATION POWER Control (8)	Zero (0) Full CCW
BIPOLAR CUTTING POWER Control (12)	Zero (0) Full CCW
BIPOLAR COAGULATION POWER Control (11)	Zero (0) Full CCW
SOUND LEVEL (19)	Mid Range

After completion of pre-operation control settings, plug the generator into a directly grounded power outlet.

DO NOT use adapters or extension cords between the generators power cord and the directly grounded power outlet because said utilization may cause increased riscurrents.

## **Operational Checkout**

#### Action

1. Turn the POWER switch (1) ON.

- Depress the CUT treadle of the footswitch
- Depress the COAG treadle of the footswitch
- Depress both the CUT and COAG treadles of the footswitch
- 5. Set the FOOTSWITCH control (2) to MONOPOLAR.
- 6. Depress the CUT and then the COAG treadles of the footswitch
- Set the MODE control (4) to MONOPOLAR.

- 8. Connect a patient plate to the DISPERSIVE ELECTRODE receptacle (17).
- Depress the CUT treadle of the footswitch
- 10. Depress the COAG treadle of the footswitch
- 11. Set the footswitch control (2) to BIPOLAR.

#### **Expected Outcome**

- 1. BIPOLAR CUTTING and COAGULATION POWER displays are lit and read zero. The BIPOLAR FOOTCONTROL and HANDCONTROL green indicators are lit. All monopolar function indicators are OFF. CORD FAULT light and audible warning are OFF.
- 2. BIPOLAR CUTTING indicator light is lit. An audible tone is heard. (Tone volume is adjusted with a control on the rear panel.)
- 3. BIPOLAR COAGULATION light is lit.
  An audible tone is heard. (This tone is lower in pitch than the cut tone.)
- 4. BIPOLAR COAGULATION light is lit.
  An audible tone is heard.
- The BIPOLAR FOOTCONTROL light is out.
- No event occurs.
- 7. The CORD FAULT light is lit. An audible alarm is heard. Both MONOPOLAR HANDCONTROL and FOOTCONTROL indicators are lit. All bipolar function indicators are Off. The MONOPOLAR CUTTING and COAGULATION POWER displays are lit and read zero.
- 8. The CORD FAULT light is out. The audible alarm is OFF.
- MONOPOLAR CUTTING indicator is lit. An audible tone is heard.
- 10. MONOPOLAR COAGULATION indicator is lit. An audible tone is heard. (This tone is lower in pitch than the cut tone.)
- 11. The MONOPOLAR FOOTCONTROL light is out.

#### Action

- 12. Depress the CUT and then the COAG treadles of the footswitch
- 13. Activate the CUT control on the handcontrol.
- 14. Activate the COAG control on the
- 15. Set the MODE Control (4) to DUAL.
  - 16. Remove the patient plate from the DISPERSIVE ELECTRODE receptacle (17).

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- 17. Activate the handcontrol in CUT.
- 18. Reconnect the patient plate.
- 19. Depress the CUT treadle of the footswitch
- 20. Depress and hold the COAG control of the handcontrol. Then depress the CUT treadle of the footswitch.
- 21. Set MONOPOLAR COAGULATION POWER
  (8) to 65 watts. Then set the
  MONOPOLAR COAGULATION TYPE (13)
  to SPRAY.
  - 22. Set MONOPOLAR CUTTING POWER (6) to 260 watts. Then turn the MONOPOLAR BLEND Control (3) full clockwise so that the entire blend indicator bar is lit.
  - 23. This completes the operational check.

## **Expected Outcome**

- 12. No event occurs.
- 13. MONOPOLAR CUTTING indicator it lit. An audible tone is heard.
- 14. MONOPOLAR COAGULATION indicator is lit. An audible tone is heard.
- 15. Both MONOPOLAR CUTTING and COAGULATION and BIPOLAR CUTTING and COAGULATION POWER displays are lit and read zero.
- 16. The CORD FAULT light is lit. An audible alarm is heard.
- 17. No event occurs.
- 18. The CORD FAULT light is out. The audible alarm if OFF.
- 19. The BIPOLAR CUTTING light is lit.
  An audible tone is heard.
- 20. The MONOPOLAR COAGULATION light is lit. An audible tone is heard.
- 21. MONOPOLAR COAGULATION POWER now reads 35 ± 5 watts.
- 22. The MONOPOLAR CUTTING power display now reads 230 ± 5 watts.

## Service Support

#### Preventive Maintenance

The System 5000 Technical Manual spells out a recommended preventive maintenance program for your Engineering Department. Following this program will increase equipment life and help provide for the safe, consistent performance of your Bard equipment. For accessories, see packaged instructions.

#### Service

Should your System 5000 require service beyond the recommended preventive maintenance, contact the Bard Electro Medical Systems Field Service Department (1-303-790-1117) to arrange for prompt professional service.

International customers, please contact your local sales representative.

#### **Limited Warranty**

The Electrosurgical Generator is warranted to the original purchaser to be free from defects in material and workmanship for a period of two (2) years from the date of purchase. If the Electrosurgical Generator proves to be so defective, Purchaser may return same to Bard Electro Medical Systems, for repair, or replacement, as Bard deems appropriate. The liability of Bard under this limited warranty does not extend to any Electrosurgical Generator which has been abused misused or serviced by anyone other than an authorized Bard representative.

While the Electrosurgery Generator is within the stated warranty period, no unauthorized service repairs or modifications

on this equipment other than that described in the 'Mainten-ance' Section of the Technical Manual should be attempted. Any unauthorized repairs will immediately void the remainder of the warranty. If a local Bard representative is not available, service assistance is available by calling 1-303-790-1117.

This limited warranty is in lieu of all other warranties, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the Electrosurgical Generator or any other component, and the liability and remedy stated in this limited warranty will be the sole liability of Bard Electro Medical Systems, and remedy available to purchaser for said products, whether in contract tort (including negligence) or otherwise, and Bard will not be liable to purchaser for any incidental or consequential damages arising out of or incident to the handling, use, maintenance or servicing or disposition of same.

#### Inservice

Your sales representative is thoroughly trained to provide inservice Programs for your hospital's surgical personnel. Should you have any questions on the use of your System 5000, contact your local representative.

# Glossary of Terms

- ACTIVE CABLE The conductor between the electrosurgical generator and the active electrode, including any connectors and/or handle.
- AC CURRENT Abbreviated AC. A flow of electricity which reaches maximum in one direction, decreases to zero, then reverses itself and reaches maximum in the opposite direction. The cycle is repeated continously.
- ACTIVE ELECTRODE The electrode or electrode assembly at which the electrosurgical effect is intended. It usually has a small contact surface area and provides a high current density to achieve the desired surgical effect. A bipolar instrument is to be considered an active electrode.
- AMPS Abbreviation for ampere which is a unit of electrical current or rate of flow of electrons. One volt across 1 ohm of resistance causes a current flow of 1 ampere (unit of measured current).
- BIPOLAR INSTRUMENT A forceps or other electrosurgical accessory having two electrodes, both of which are intended to be applied to the tissue undergoing electrosurgical treatment and energized by the electrosurgical generator so that the current passes between the electrodes and by design produces a surgical effect at both electrodes. It is intended that the electrosurgical current is restricted to tissue between the electrodes.
- placed across the tissue to be treated. It is intended that the electrosurgical current is confined to the tissue between the electrodes. Because the current passes between the paired electrodes no patient electrode (dispersive electrode) is required.
- $\frac{\text{BLEND}}{\cdot}$  A cut waveform with intermittent bursts of coagulation to allow cutting with hemostasis.
- BREAKDOWN (Dielectric) The failure of insulation under the stress of a voltage characterized by marked increase in conductivity and/or disruptive discharge.
- CAPACITOR A devise consisting of two conducting surfaces separated by an insulating material or dielectric. Capacitors can store electrical energy in DC circuits and conduct radio frequency current.

- DISCRETE OUTPUT Only one output active at any time.
- DISPERSIVE ELECTRODE The electrode at which no electrosurgical effect is intended. It is usually large in area in order to provide a low current density so that no electrosurgical effect occurs at that site. It is also known as a patient plate, plate electrode, return electrode, neutral electrode, inactive electrode, etc. It is sometimes (inaccurately) referred to as a ground plate.
- and the dispersive electrode, together with any attached connector.
- <u>DISPOSABLE ACCESSORY</u> An electrosurgical accessory, such as active electrodes, handles, dispersive electrodes, etc., which is not intended to be used more than once.

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- DUTY CYCLE The proportion of time (expressed in percentage) that a current or device is "on" versus off. Duty cycle may be used when referring to current wave forms which are repetitive. Thus high frequency current would be "on" using a shorter period of time than a low frequency current. Duty cycle is also used in reference to electrical components or equipment. For example, some equipment is designed to be used continuously, that is, with a duty cycle rating of 100%, while other equipment may be rated for intermittent use, that is, less than 100% duty cycle. Most ESU's are designed to be used intermittently. Typically they are rated for 50% duty cycles from 25% to 50%. Use of any equipment beyond its duty cycle rating may result in premature failure.
- ELECTROCAUTERY The searing or destruction of tissue by heat delivered to the tissue from a conductor brought to a high temperature by the passage of an electric current through the conductor. Current does not pass through the patient.
- ELECTROSURGERY (Surgical Diathermy) the generation and delivery of a radio frequency current between an active electrode and a dispersive electrode or through a bipolar instrument for the purposes of dehydration of tissue. Electrosurgery also includes the cutting or vaporising (tissue explosion). In contrast to electrocautery, the electric current actually passes through the tissue.
- <u>ELECTROSURGICAL ACCESSORY</u> Equipment used in conjunction with the electrosurgical generator to accomplish electrosurgery. These include, but are not limited to footswitch, cable, dispersive electrode, and active electrode.

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- GROUNDED GENERATOR OUTPUT An electrosurgical generator output which has the patient electrode grounded to the metal chassis of the generator. This means that current will flow from the active electrode when it touches any grounded object in the room.
- HEMOSTASIS (electrosurgical) The desired therapeutic effects of electrosurgical current, which is used to stop bleeding of cut vessels. A relatively slow (compared to cutting) evaporation of fluid which results in the formation of a "plug" or coagulated tissue in the cut vessel. The property of stopping blood flow.

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- HEMOSTAT (artery forcep) A scissors-like clamp for occluding a blood vessel and stopping flow of blood.
- IMPEDANCE (Measured in Ohms) Total opposition, both resistive and reactive, a circuit offers to the flow of alternating current at a given frequency.
- ISOLATED POWER SYSTEM A large transformer assembly commonly found in operating rooms that converts conventional 120/220 volts A.C. ground-referenced power to isolated power with no voltage reference to ground.
- LEAKAGE CURRENT The non-functional currents (milliampere, microampere) that can "leak" or pass through the insulation of cables, cords, connectors and other electrical circuit components.
- Dower systems which monitors the supply leakage current flowing to ground through the power system ground wiring. The monitor sounds an alarm if the current exceeds preset limits.
- LOAD An impedance or resistance placed across a voltage source which draws current from that source. For example, the electrical resistance of the tissue grasped in the jaws of bipolar forceps is the load on the output of the electrosurgical generator.
- LOW FREQUENCY LEAKAGE CURRENT Any supply current (50 or 60 Hz), including capacitively-coupled currents, which may be conveyed from accessible parts of the electrosurgical generator or accessories to ground, or through the patient to ground.

- MEDICAL DIATHERMY The application of a high-frequency current, electromagnetic field or ultrasonic mechanical energy to attain diffuse heating of body tissues, usually at some distance from the energy coupling electrodes or other applicator. In contrast to electrosurgery, tissue temperature rises are maintained well below that which would cause tissue destruction. Sometimes also called therapeutic diathermy.
- MICRO Abbreviated u, prefix meaning one millionth (1000,000 or 10<sup>-6</sup>).
- MICROBIPOLAR A Bipolar mode with low power output designed to allow fine contact in critical areas.
- MILLI Abbreviated m, prefix meaning one-thousanth (1000 or 10-3).
- MODE (Operating) Each of the distinct ways in which the electrosurgical unit can be operated with electrosurgical output, e.g., monopolar cutting, monopolar coagulation, monopolar blended, monopolar spray (fulguration), bipolar coagulation, bipolar cutting.
- MODULE A combination of components which are contained in a package to preform a complete function. The several modules in an ESU facilitate fault isolation to a given functional module for quick replacement.
- MONOPOLAR The traditional form of electrosurgery which uses an active electrode to apply the therapeutic current to the surgical site, and a dispersive electrode (patient plate) to return the current to the ESU.
- MONOPOLAR TECHNIQUE The electrosurgical effect that takes place at the active electrode only. At the dispersive electrode, no electrosurgical effect is intended or desired.
- NECROSIS Localized tissue death that occurs in groups of cells.
- OHM Unit of resistance. One ohm is the value of resistance through which a potential difference of one volt will maintain a current of one ampere. In AC currents the resistance is called impedance.
- OPEN CIRCUIT No load or resistance connected to a voltage source. For example, if the generator is activated and the active electrode is not touching any tissue, the output of the generator is said to be open circuit.

- CIRCUIT PEAK VOLTAGE For the purpose of this standard, the maximum instantaneous output voltage of the electrosurgical waveform under the condition of no intentional load.
- RATING ROOM Hospital surgical area, also known as O.R., O.R. Suite, Operating theatre, etc.
- ERATIONAL CHECKOUT Any examination, such as visual or auditory, without the use of special laboratory test equipment.
- TPUT POWER The rate of delivery of electrosurgical energy as determined by the measurement of the RMS current in a non-reactive load resistance and/or the RMS voltage across the load resistance.
- TPUT TERMINALS (Electrosurgical) The terminals on the electrosurgical generator to which are connected the cables and electrodes through which electrosurgical current pass to accomplish electrosurgery.
- TIENT CIRCUIT SAFETY MONITOR Any circuit in an electrosurgical unit designed to detect an unsafe condition in the output circuit and give a warning or disable the generator.
- N POINT COAGULATION A procedure where in a small amount of tissue on the surface is dried out by placing the active electrode in contact with the tissue.
- WER The rate at which energy is produced or consumed. Power is equal to voltage times current or resistance times current squared. The unit of measure of power is the watt.
- SISTANCE (measured in OHMS) The opposition that a device or material presents to the flow of current independent of frequency. When current actually flows through a resistance, heat is produced.
- F. Radio Frequency. A high frequency alternating current usually greater than 100,000 Hz or that coherent electromagnetic radiation of energy is possible.
- F. CHOKE A small value inductor whose low frequency impedance is small but offers very high impedance to R.F.

- R.F. ISOLATED (Floating) The patient terminals have no intentional conductive path to ground (earth).
- SHORT CIRCUIT —A zero impedance load connected across a voltage source. For example, if the generator touches the metal active electrode directly to the patient plate, the resistance to current flow in the cables will be essentially zero and the generator is said to be operating short circuit.

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- solid state Electronic circuitry which is entirely transistorized and does not use vacuum tubes, spark gaps, or other such active circuit elements. The word "solid" refers to the structure of transistors which perform their electric function inside solid crystals, rather than in a vacuum, air gaps or rarified gases.
- SPARK An electric discharge across an air gap. In electrosurgery it is the discharge seen at the end of an electrode when cutting or fulgurating.
- spray coagulation Coagulating tissue by means of radio frequency sparks. In contrast to Pin Point, the active electrode is not in contact with the tissue and sparks are to the tissue. When the active electrode is touched using the spray mode, the depth of desiccation is deeper.
- STERILIZATION Destruction of micro-organisms using heat, water chemicals, or gases.
- SURGICAL DIATHERMY An alternative term for electrosurgery.
- TRANSFORMER A circuit device which couples the electrical energy from one circuit to another by electromagnetic induction on a common magnetic path (core).
- TRANSISTOR, BIPOLAR A three terminal, current controlled device made of semi-conducting material (like silicon or germanimum). The base current controls the amount of current in the collector emitter circuit, and is used in many applications. However, in power amplifiers, their speed and amplification capabilities can become limiting factors.
- TRANSISTOR, (POWER MOS) A three terminal voltage controlled device, made of semi-conducting material (generally silicon). The gate voltage controls the amount of current in the drain source circuit. Generally, used as a power amplifier due to its excellent speed and amplification capabilities.

- VOLT Abbreviation for voltage. It is equivalent to the force required to produce a current of 1 ampere through a resistance of 1 ohm. (The unit of measured voltage.)
- VOLTAGE The force, or pressure that drives electrons (electric current) through a circuit, wires, etc. In electrosurgery voltage is the force that drives electrons across an air gap to tissue to make an electric spark.
- Abbreviated W. A unit of the electric power required to do work at the rate of 1 joule per second. In an alternating current the true power in watts is effectively volt-amperes multiplied by the circuit power factor.
- RMS ampere meter in series with a large power resistor. The meter is calibrated in the watts of power dissipated in the resistor.

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# Addendum

Bard Electro Medical Systems, division of C.R. Bard Inc., is now wholly owned by Birtcher Medical Systems of 50 Technology Drive in Irvine, California. Please disregard the telephone numbers for service printed inside the manual and use the following numbers:

For Technical Service: 1-800-888-1771

For Customer Service: 1-800-888-1771

In California (714) 753-9400